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Management of Eating Disorders

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-Based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. The report topic was nominated by the American Psychiatric Association (APA) and the Laureate Psychiatric Clinic and Hospital. Funding for this report was provided by the Office of Research on Women's Health at the National Institutes of Health (NIH) and the Health Resources and Services Administration. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

To bring the broadest range of experts into the development of evidence reports and health technology assessments, AHRQ encourages the EPCs to form partnerships and enter into collaborations with other medical and research organizations. The EPCs work with these partner organizations to ensure that the evidence reports and technology assessments they produce will become building blocks for health care quality improvement projects throughout the Nation. The reports undergo peer review prior to their release.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality.

We welcome comments on this evidence report. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by e-mail to **epc@ahrq.gov.**

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Structured Abstract

Objectives. The RTI International—University of North Carolina at Chapel Hill Evidence-based Practice Center (RTI-UNC EPC) systematically reviewed evidence on efficacy of treatment for anorexia nervosa (AN), bulimia nervosa (BN), and binge eating disorder (BED), harms associated with treatments, factors associated with the treatment efficacy and with outcomes of these conditions, and whether treatment and outcomes for these conditions differ by sociodemographic characteristics.

Data Sources. We searched MEDLINE®, the Cumulative Index to Nursing and Applied Health (CINAHL), PSYCHINFO, the Educational Resources Information Center (ERIC), the National Agricultural Library (AGRICOLA), and Cochrane Collaboration libraries.

Review Methods. We reviewed each study against a priori inclusion/exclusion criteria. For included articles, a primary reviewer abstracted data directly into evidence tables; a second senior reviewer confirmed accuracy. We included studies published from 1980 to September, 2005, in all languages. Studies had to involve populations diagnosed primarily with AN, BN, or BED and report on eating, psychiatric or psychological, or biomarker outcomes.

Results. We report on 30 treatment studies for AN, 47 for BN, 25 for BED, and 34 outcome studies for AN, 13 for BN, 7 addressing both AN and BN, and 3 for BED.

The AN literature on medications was sparse and inconclusive. Some forms of family therapy are efficacious in treating adolescents. Cognitive behavioral therapy (CBT) may reduce relapse risk for adults after weight restoration.

For BN, fluoxetine (60 mg/day) reduces core bulimic symptoms (binge eating and purging) and associated psychological features in the short term. Individual or group CBT decreases core behavioral symptoms and psychological features in both the short and long term. How best to treat individuals who do not respond to CBT or fluoxetine remains unknown.

In BED, individual or group CBT reduces binge eating and improves abstinence rates for up to 4 months after treatment; however, CBT is not associated with weight loss. Medications may play a role in treating BED patients. Further research addressing how best to achieve both abstinence from binge eating and weight loss in overweight patients is needed.

Higher levels of depression and compulsivity were associated with poorer outcomes in AN; higher mortality was associated with concurrent alcohol and substance use disorders. Only depression was consistently associated with poorer outcomes in BN; BN was not associated with an increased risk of death. Because of sparse data, we could reach no conclusions concerning BED outcomes.

No or only weak evidence addresses treatment or outcomes difference for these disorders.

Conclusions. The literature regarding treatment efficacy and outcomes for AN, BN, and BED is of highly variable quality. In future studies, researchers must attend to issues of statistical power, research design, standardized outcome measures, and sophistication and appropriateness of statistical methodology.

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Appendixes and Evidence Tables for this report are provided electronically at http://www.ahrq.gov/downloads/pub/evidence/pdf/eatingdisorders/eatdis.pdf.

Executive Summary

Introduction

The RTI International–University of North Carolina at Chapel Hill Evidence-based Practice Center (RTI-UNC EPC) conducted a systematic review of the literature on key questions concerning anorexia nervosa (AN), bulimia nervosa (BN), and eating disorders not otherwise specified (EDNOS) (focusing on binge eating disorder [BED]) to address questions posed by the American Psychiatric Association and Laureate Psychiatric Hospital through the Agency for Healthcare Research and Quality (AHRQ). Funding was provided by AHRQ, the Office of Research on Women's Health at the National Institutes of Health, and the Health Resources and Services Administration. We received guidance and input from a Technical Expert Panel (TEP).

We systematically reviewed the evidence on two categories of issues—treatment and outcomes for AN, BN, and BED—in six key questions (KQs): (1) efficacy of treatment, (2) harms associated with treatment, (3) factors associated with the efficacy of treatment, (4) whether efficacy of treatment differs by sex, gender, age, race, ethnicity, or cultural group, (5) factors associated with outcomes, and (6) whether outcomes differ by sex, gender, age, race, ethnicity, or cultural group.

AN is marked by low body weight, fear of weight gain, disturbance in the way in which one's body size is perceived, denial of illness, or undue influence of weight on self-evaluation. Although amenorrhea is a diagnostic criterion, it is of questionable relevance.

BN is characterized by recurrent episodes of binge eating in combination with some form of compensatory behavior. Binge eating is the consumption of an uncharacteristically large amount of food by social comparison coupled with a feeling of being out of control. Compensatory behaviors include self-induced vomiting; misuse of laxatives, diuretics, or other agents; fasting; and excessive exercise.

BED is marked by binge eating in the absence of compensatory behaviors, a series of associated features of binge eating, and marked distress regarding binge eating. Overweight and obesity are commonly seen in individuals with BED.

Although rigorous epidemiologic data are lacking in the United States, the mean prevalence of AN is 0.3 percent, of subthreshold AN 0.37 percent to 1.3 percent, of BN 1.0 percent, and of BED 0.7 percent to 3.0 percent. Mortality from AN is about 5 percent per decade of followup. Treatment for severe AN can involve inpatient or partial hospitalization in costly specialized settings. Inadequate insurance coverage often truncates the recommended duration of treatment. Treatment costs for AN are higher than those for obsessive-compulsive disorder and comparable to those for schizophrenia. In contrast, treatment for BN in the United States is typically on an outpatient basis.

Methods

We searched MEDLINE®, the Cumulative Index to Nursing and Applied Health (CINAHL), PSYCHINFO, the Educational Resources Information Center (ERIC), the National Agricultural Library (AGRICOLA), and Cochrane Collaboration libraries. Based on key questions and discussion with our TEP, we generated a list of article inclusion and exclusion criteria. We reviewed studies of humans, ages 10 years and older, of both sexes, published in all languages and from all nations, from 1980 to September 2005. Studies had to include populations diagnosed primarily with AN, BN, or BED and to report on at least one of our outcomes

categories of interest: eating-related behaviors, psychiatric and psychological outcomes, and biomarker measures. We reviewed each abstract and article systematically against a priori criteria to determine whether to include it in the review. One reviewer initially evaluated abstracts for inclusion or exclusion. If that reviewer concluded that the article should be included in the review, it was retained. Articles that the reviewer determined did not meet our criteria were re-reviewed by a senior reviewer who could include the article if she disagreed with the initial determination. We assigned each excluded article a reason for exclusion.

The RTI-UNC EPC team abstracted data from included articles directly into evidence tables. For both the treatment and the outcomes literatures, a primary reviewer abstracted data directly into evidence tables; a second (senior) reviewer confirmed accuracy, completeness, and consistency. The two staff reconciled all disagreements about information in evidence tables.

Each abstractor independently evaluated study quality. Because of differences in the treatment and outcomes literature, we evaluated the two bodies of literature using separate criteria. For the treatment literature, our evaluation used 25 items in 11 categories: (1) research aim/study question, (2) study population, (3) randomization, (4) blinding, (5) interventions, (6) outcomes, (7) statistical analysis, (8) results, (9) discussion, (10) external validity, and (11) funding/sponsorship. For the outcomes literature, we evaluated the evidence against 17 items in 8 categories: (1) research aim/study question, (2) study population, (3) eating disorder diagnosis method, (4) study design, (5) statistical analysis, (6) results/outcome measurement, (7) external validity, and (8) discussion.

We focused our analysis on studies that received fair or good quality ratings. This included 19 studies discussed in 22 articles concerning treatment for AN: 38 studies discussed in 48 articles concerning treatment for BN: 20 studies discussed in 21 articles concerning treatment for BED: 26 studies discussed in 32 articles concerning outcomes for AN: 9 studies discussed in 13 articles concerning outcomes for BN: 7 studies discussed in 7 articles concerning outcomes for both AN and BN: and 3 studies discussed in 3 articles concerning outcomes for BED.

Results

Treatment Studies

Anorexia Nervosa. We divided the treatment literature into medication-only (generally in the context of clinical management or hospitalization), medication plus behavioral intervention, and behavioral intervention only for either adults or adolescents. The literature regarding medication treatments for AN is sparse and inconclusive. The vast majority of studies had small sample sizes and rarely had adequate statistical power to allow for definitive conclusions. Although studies did include medication administered during or after inpatient intervention, no AN studies that systematically combined medication with behavioral interventions met our inclusion criteria, revealing a substantial gap in the literature.

In the behavioral intervention literature, preliminary evidence suggests that cognitive behavioral therapy (CBT) may reduce relapse risk for adults with AN after weight restoration. Sufficient evidence does not exist to determine whether CBT has any effect during the acute phase of the illness, and one study, also requiring replication, showed that a manual-based treatment combining elements of sound clinical management and supportive psychotherapy by a specialist was more effective than CBT during the acute phase. Family therapy as currently conceptualized does not appear to be effective with adults with AN with longer duration of illness. Specific forms of family therapy initially focusing on parental control of renutrition is

efficacious in treating AN in adolescents and leads to clinically meaningful weight gain and psychological change. The lack of follow-up data compromises our ability to determine the extent to which treatment gains are maintained.

Bulimia Nervosa. In medication trials, fluoxetine (60 mg/day) administered for 6 weeks to 18 weeks reduced the core bulimia symptoms of binge eating and purging and associated psychological features in the short term. The 60 mg dose performs better than lower doses and is associated with prevention of relapse at 1 year. Evidence for the long-term effectiveness of relatively brief medication treatment does not exist. The optimal duration of treatment and the optimal strategy for maintenance of treatment gains are unknown.

Studies that combine drugs and behavioral interventions provide only preliminary evidence regarding the optimal combination of medication and psychotherapy or self-help. How best to treat individuals who do not respond to CBT or fluoxetine remains a major shortcoming of the literature. For behavioral interventions for BN, CBT administered individually or in group format is effective in reducing the core behavioral symptoms of binge eating and purging and psychological features in both the short and long term. Further evidence is required to establish the role for self-help in reducing bulimic behaviors.

Binge Eating Disorder. For BED, we addressed two critical outcomes—decrease in binge eating and decrease in weight in overweight individuals. Various medications were studied, including selective serotonin reuptake inhibitors (SSRIs); a combined serotonin, dopamine, and norepinephrine uptake inhibitor; tricyclic antidepressants; an anticonvulsant; and one appetite suppressant. In short-term trials, SSRIs led to greater rates of reduction in target eating, psychiatric and weight symptoms, and severity of illness than placebo controls. However, in the absence of clear endpoint data, and in the absence of data regarding abstinence from binge eating, we cannot judge the magnitude of the clinical impact of these interventions. Moreover, in the absence of follow-up data after drug discontinuation, we do not know whether observed changes in binge eating, depression, and weight persist.

The combination of CBT plus medication may improve both binge eating and weight loss, although sufficient trials have not been done to determine definitively which medications are best at producing and maintaining weight loss. Moreover, the optimal duration of medication treatment for sustained weight loss has not yet been addressed empirically.

Collectively, clinical trials incorporating CBT for BED indicated that CBT decreases either the number of binge days or the actual number of reported binge episodes. CBT leads to greater rates of abstinence than does a waiting list control approach when administered either individually or in group format, and this abstinence persists for up to 4 months posttreatment. CBT also improves the psychological aspects of BED, such as ratings of restraint, hunger, and disinhibition. Results are mixed as to whether CBT improves self-rated depression in this population. Finally, CBT does not appear to produce decreases in weight.

Various forms of self-help were efficacious in decreasing binge days, binge eating episodes, and psychological features associated with BED. Self-help also led to greater abstinence from binge eating than waiting list; short-term abstinence rates approximate those seen in face-to-face psychotherapy trials.

Strength of Evidence in Treatment Literature. We graded the strength of the body of evidence for each question separately. For efficacy of treatment (KQ 1), we graded evidence for AN treatment as weak, that for BN medication and behavioral interventions as strong, and that for BED therapies as moderate. For harms associated with treatment (KQ 2), we graded medication interventions for BN and BED as consistently strong; the literatures for all AN

interventions and all other BN and BED interventions were graded as weak to nonexistent because many studies failed to address harms associated with treatment. For factors associated with efficacy of treatment (KQ 3), with the exception of behavioral interventions for BN, which we graded as moderate, we graded the literature uniformly as weak. No published literature provided evidence on whether the efficacy of treatment for these conditions differs by sociodemographic factors (KQ 4). Overall, the literature on the treatment of AN in particular was deficient.

Outcomes Literature

Outcomes of Eating Disorders. One prospective cohort study, conducted in Sweden, followed individuals with AN in the community. Over a 10-year period, approximately half of the group had fully recovered; a small percentage continued to suffer from AN, and the remainder still had other eating disorders. Members of the AN group no longer differed from those in the comparison group in terms of weight, but they continued to be more depressed and to suffer from a variety of personality disorders, obsessive-compulsive disorder, Asperger syndrome, and autism spectrum disorders.

The remaining AN studies followed patient populations. Typically, at least one-half of the patients no longer suffered from AN at followup. However, many continued to have other eating disorders such as BN or EDNOS, and mortality was significantly higher than would be expected in the population matched by sex and age. Factors associated with recovery or good outcomes included lower levels of depression and compulsivity. Factors associated with increased mortality included concurrent alcohol and substance use disorders.

All of the BN outcomes studies followed patient populations. This literature emphasizes comparisons of various definitions of disease outcomes and diagnostic subtypes. Generally, more than one-half of the patients followed no longer had a BN diagnosis at the end of the study. A substantial percentage continued to suffer from other eating disorders, but BN was not associated with an increased mortality risk. A limited number of analyses uncovered factors significantly associated with outcomes of this disease, but only depression was consistently associated with worse outcomes.

Only sparse evidence addresses factors associated with BED outcomes. The three included studies have vastly different designs and research questions; more importantly, they do not converge on any systematic findings. Recalling that no studies of EDNOS outcomes exist, we conclude that the literature regarding outcomes of both EDNOS in general and BED in particular is seriously lacking; we believe that no conclusions can be drawn about factors influencing outcomes of these disorders.

Age of AN disease onset was examined in several AN outcomes studies. However, the relation between this variable and outcomes was mixed. No additional differences by participant sex, gender, age, race, ethnicity, or cultural group emerged from the AN, BN, or BED outcomes literature.

Strength of Evidence in Outcomes Literature. The strength of the evidence addressing factors associated with outcomes among individuals with AN and BN is moderate. In contrast, given the limited information about factors related to outcomes among individuals with BED (KQ 5), we rated BED evidence as weak. We used the body of literature concerning KQ 5 to examine differences in outcomes by sociodemographic factors (KQ 6). We graded the AN literature as weak and the BN and BED literature as nonexistent.

Discussion

In conclusion, the literature regarding treatment efficacy and outcome for AN, BN, and BED is of highly variable quality. In the treatment literature, the largest deficiency rests with treatment efficacy for AN where the literature was weakest. Future studies require large numbers of participants, multiple sites, appropriate biomarker outcomes, and clear delineation of the age of participants. For BN, future studies should address novel treatments for the disorder, optimal duration of intervention, and optimal approaches for those who do not respond to medication or CBT. For BED, future studies should identify interventions that are effective for both elimination of binge eating and reduction of weight (in overweight individuals), optimal duration of intervention, and effective strategies for prevention of relapse. For all three disorders, exploration of additional treatment approaches is warranted. In addition, for all three disorders, greater attention must be paid to factors influencing outcomes, harms associated with treatment, and differential efficacy by sex, gender, age, race, ethnicity, or cultural group.

For all three disorders, consensus definitions of remission, recovery, and relapse are essential. Greater attention to disease presentations currently grouped under the heading of EDNOS is required for both treatment and outcome literature. For outcome studies, especially for BN and BED, population-based cohort studies with comparison groups and adequate durations of followup are required. For both future treatment and outcome studies, researchers must carefully attend to issues of statistical power, research design including the use of similar outcome measures across studies, and sophistication and appropriateness of statistical analyses.

Evidence Report

Chapter 1. Introduction

Scope of the Problem

The eating disorders discussed in this report include anorexia nervosa (AN), bulimia nervosa (BN), and eating disorders not otherwise specified (EDNOS). Although rigorous epidemiologic data specific only to the United States are lacking, the mean prevalence of AN in young females in Western Europe and the United States is 0.3 percent and the mean prevalence of BN is 1.0 percent. Clinically concerning subthreshold conditions are more prevalent.[1] These eating disorders are associated with substantial morbidity and mortality.[2,3] The financial and social impact of these potentially fatal disorders on disability, productivity, and quality of life remains unknown.

Anorexia Nervosa

Clinical Characteristics

AN is a serious psychiatric illness marked by an inability to maintain a normal healthy body weight, often dropping well below 85 percent of ideal body weight. Patients who are still growing fail to make expected increases in weight (and often height) and bone density. Despite increasing weight loss, individuals with AN continue to obsess about weight, remain dissatisfied with the perceived size of their bodies, and engage in an array of unhealthy behaviors to perpetuate weight loss (e.g., purging, dieting, excessive exercise, fasting). Individuals with AN place central importance on their shape and weight as a marker of self-worth and self-esteem. Although amenorrhea is a diagnostic criterion, it is of questionable relevance. There do not appear to be meaningful differences between individuals with AN who do and do not menstruate.[4,5] Typical personality features of individuals with AN include perfectionism, obsessionality, anxiety, harm avoidance, and low self-esteem.[6]

The most common comorbid psychiatric conditions include major depression[7,8] and anxiety disorders.[9,10] Anxiety disorders often predate the onset of the eating disorder,[9,10] and depression often persists post-recovery.[11]

Diagnostic Criteria

Table 1 presents the diagnostic criteria that authors of articles reviewed in this report use. They include Russell criteria,[12] Feighner criteria,[13] Diagnostic and Statistical Manual for Mental Disorders III, III-R and IV (DSM III, III-R, and IV),[14-16] and the International Classification of Diseases-Versions 9 and 10 (ICD-9 and ICD-10).[17]

Epidemiology

The mean prevalence of AN in young females in Western Europe and the United States is 0.3 percent.[1] The prevalence of subthreshold AN, defined as one criterion short of threshold, is greater—ranging from 0.37 percent to 1.3 percent.[18,19]

Although awareness of the disorder has increased, the data on changing incidence are conflicting. Some studies suggest that the incidence is increasing,[20-26] and others report stable

Table 1. Diagnostic criteria: anorexia nervosa

Diagnostic Criteria	
Russell's Criteria for Anorexia Nervosa	1. Patient resorts to a variety of devices aimed at achieving weight loss (starvation, vomiting, laxatives, etc.) 2. Evidence of an endocrine disorder, amenorrhea in the female, and loss of sexual potency and interest in the male 3. Patient manifests the characteristic psychopathology of a morbid fear of becoming fat. This is accompanied by a distorted judgment by the patient of her body size
Feighner's Criteria for Anorexia Nervosa	1. Onset prior to age 25 2. Anorexia with accompanying weight loss of at least 25 percent of original body weight 3. A distorted implacable attitude toward eating food or weight that overrides hunger, admonitions, reassurances, and threats 4. No known medical illness accounts for the anorexia [nervosa] and weight loss 5. No other known psychiatric disorder, with particular reference to primary affective disorders, schizophrenia, obsessive, and compulsive and phobic neurosis 6. At least two of the following manifestations: amenorrhea, lanugo, bradycardia, periods of overactivity, episodes of bulimia, vomiting
DSM III Criteria for Anorexia Nervosa (307.10)	A. Intense fear of becoming obese, which does not diminish as weight loss progresses B. Disturbance of body image (e.g., claiming to "feel fat" even when emaciated) C. Weight loss of at least 25% of original body weight or, if under 18 years of age, weight loss from original body weight plus projected weight gain expected from growth charts may be combined to make the 25% D. Refusal to maintain body weight over a minimal normal weight for age and height E. No known physical illness that would account for the weight loss
DSM III-R Criteria for Anorexia Nervosa (307.10)	A. Refusal to maintain body weight over a minimal normal weight for age and height (e.g., weight loss leading to maintenance of body weight 15% below that expected or failure to make expected weight gain during period of growth, leading to body weight 15% below that expected) B. Intense fear of gaining weight or becoming fat, even though underweight C. Disturbance in the way in which one's body weight, size, or shape is experienced (e.g., the person claims to "feel fat" even when emaciated, believes that one area of the body is "too fat" even when obviously underweight) D. In females, absence of at least three consecutive menstrual cycles when otherwise expected to occur (primary and secondary amenorrhea). (A woman is considered to have amenorrhea if her periods occur only following hormone, e.g., estrogen, administration.)
DSM IV Criteria for Anorexia Nervosa (307.10)	A. Refusal to maintain body weight at or above a minimally normal weight for age and height (e.g., weight loss leading to maintenance of body weight less than 85% of that expected or failure to make expected weight gain during period of growth, leading to body weight less than 85% of that expected). B. Intense fear of gaining weight or becoming fat, even though underweight. C. Disturbance in the way in which one's body weight or shape is experienced, undue influence of body weight or shape on self-evaluation, or denial of the seriousness of the current low body weight. D. In postmenarchal females, amenorrhea i.e., the absence of at least three consecutive cycles. (A woman is considered to have amenorrhea if her periods occur only following hormone, e.g., estrogen administration.) *Specify type:* • **Restricting Type:** During the current episode of anorexia nervosa, the person has not regularly engaged in binge-eating or purging behavior (i.e., self-induced vomiting or the misuse of laxatives, diuretics, or enemas). • **Binge-Eating/Purging Type:** During the current episode of anorexia nervosa, the person has regularly engaged in binge-eating or purging behavior (i.e., self-induced vomiting or the misuse of laxatives, diuretics, or enemas).

DSM, Diagnostic and Statistical Manual; ICD, International Classification of Diseases.
For citations, see text.

Table 1. Diagnostic criteria: anorexia nervosa (continued)

Diagnostic Criteria	
ICD-9 Criteria for Anorexia Nervosa (307.1)	A disorder in which the main features are persistent active refusal to eat and marked loss of weight The level of activity and alertness is characteristically high in relation to the degree of emaciation Typically the disorder begins in teenage girls but it may sometimes begin before puberty and rarely occurs in males Amenorrhoea is usual and there may be a variety of other changes including slow pulse and respiration and low body temperature and dependent oedema Unusual eating habits and attitudes toward food are typical and sometimes starvation follows or alternates with periods of overeating The accompanying psychiatric symptoms are diverse
ICD-10 Criteria for Anorexia Nervosa (F50.0)	A. There is weight loss or, in children, a lack of weight gain, leading to a body weight at least 15% below the normal or expected weight for age and height B. The weight loss is self-induced by avoidance of "fattening foods" C. There is self-perception of being too fat, with an intrusive dread of fatness, which leads to a self-imposed low weight threshold D. A widespread endocrine disorder involving the hypothalamic-pituitary-gonadal axis is manifested in women as amenorrhoea and in men as a loss of sexual interest and potency. (An apparent exception is the persistence of vaginal bleeds in anorexic women who are on replacement hormonal therapy, most commonly taken as a contraceptive pill) E. The disorder does not meet criteria A or B for bulimia nervosa
ICD-10 Criteria for Atypical Anorexia Nervosa (F50.1)	Disorder that fulfills some of the features of anorexia nervosa but in which the overall clinical picture does not justify that diagnosis. For instance, one of the key symptoms, such as amenorrhoea or marked dread of being fat, may be absent in the presence of marked weight loss or weight-reducing behavior. This diagnosis should not be made in the presence of known physical disorders associated with weight loss

rates.[27-31] Epidemiological studies indicate that the peak age of onset is between 15 and 19 years.[32] Anecdotal reports suggest increasing presentations in prepubertal children[33] and new onset cases in mid- and late-life.[34,35] The gender ratio for AN is approximately 9:1, women to men.[16]

Etiology

The etiology of AN remains incompletely understood. Although numerous psychological, social, and biological factors have been implicated as potentially causal, few specific risk factors have been consistently replicated in studies of the etiology of the disorder.[36,37] Although not disorder-specific, common risk factors across eating disorders include sex, race or ethnicity, childhood eating and gastrointestinal problems, elevated shape and weight concerns, negative self-evaluation, sexual abuse and other adverse events, and general psychiatric comorbidity.[36] In addition, prematurity, smallness for gestational age, and cephalohematoma have been identified as risk factors for AN.[38]

The preponderance of reports from western cultures fueled early conceptualizations of AN as a culturally determined disorder, but the past decade of biological and genetic research has revealed that AN is familial[39] and that the observed familial aggregation is attributable primarily to genetic factors.[40-42] Moreover, molecular genetic studies have identified areas of the human

genome that may harbor susceptibility loci for AN[43,44] and specific genes that may influence risk.[45,46]

In addition, an array of pharmacologic, genetic, and neuroimaging studies have identified fundamental disturbances in serotonergic function in individuals with AN even after recovery.[47] Although serotonin has received considerable research attention, given the interrelatedness of neurotransmitter function, other neurotransmitter systems, most notably dopamine, are also implicated in these disorders.[48] The ultimate understanding of AN etiology will likely include main effects of both biological and environmental factors as well as their interactions and correlations.

Course of Illness

AN has serious medical and psychological consequences that can persist even after recovery. Features associated with the eating disorder including depression, anxiety, social withdrawal, heightened self-consciousness, fatigue, and multiple medical complications.[7,49-51] The social toll of AN interferes with normal adolescent development.[52] Across psychiatric disorders, the highest risks of premature death, from both natural and unnatural causes, are from substance abuse and eating disorders.[53]

A history of AN is associated with greater problems with reproduction,[54] osteoporosis,[55-57] continued low body mass index (BMI, a commonly used measure of normal weight, overweight, or obesity calculated as weight in kilograms divided by height in meters squared [kg/m^2]), and major depression.[11] Chapter 6 reviews eating-related, psychological, and biomarker-measured outcomes of AN in detail.

Treatment

Given the high morbidity and mortality associated with AN, developing effective treatments for AN is critical. Because of the frequent medical complications and nutritional compromise, clinical practice typically includes a comprehensive medical evaluation and nutritional counseling. Typically, less medically compromised cases of AN are treated on an outpatient basis by psychiatrists, psychologists, and other therapists with primary care providers managing medical care. Professional organizations have developed several English-language treatment guidelines or position papers for the treatment of AN; these include the American Psychiatric Association,[58] the National Institute for Clinical Excellence,[59] the Society for Adolescent Medicine,[60] the American Academy of Pediatrics,[61] and the Royal Australian and New Zealand College of Psychiatrists.[62]

Psychotherapeutic approaches include individual psychotherapy (cognitive-behavioral, interpersonal, behavioral, and psychodynamic), family therapy (especially for younger patients), and group therapy. The American Psychiatric Association Working Group on Eating Disorders concluded that hospitalization is appropriate for individuals below 75 percent of ideal body weight.[58] Weight is not the only parameter to be considered in level of care decisions. Other considerations include medical complications, suicide attempt or plan, failure of outpatient or partial hospitalization treatment, psychiatric comorbidity, role impairment, poor psychosocial support, compromised pregnancy, and lack of availability of less intensive treatment options.[58] Such treatment commonly involves highly specialized multidisciplinary teams including psychologists, psychiatrists, internists or pediatricians, nutritionists, social workers, and nurse specialists.

Striegel-Moore et al. reported the average length of stay to be 26 days using an insurance database of approximately 4 million individuals in the United States;[63] this is substantially shorter than the lengths of stay in other countries, including New Zealand (72 days)[64] and Europe, which ranges from 40.6 days (Finland) to 135.8 days (Switzerland).[65] They found that, per patient, AN treatment costs in the United States were higher than those for obsessive-compulsive disorder and comparable to those for schizophrenia, both of which have prevalences similar to those of AN.[63]

A workshop sponsored by the National Institute of Mental Health (NIMH) examined problems in conducting research on AN treatment.[66] It highlighted obstacles such as relatively low incidence and prevalence, lack of consensus on best treatments, variable presentation within the patient population based on age and illness factors, high costs of providing treatment, and the complex interaction of medical and psychiatric problems associated with the illness. This report also highlighted the importance of improving and expanding the workforce in the eating disorders research field.

Bulimia Nervosa

Clinical Characteristics

BN is characterized by recurrent episodes of binge eating in combination with some form of inappropriate compensatory behavior. Binge eating is the consumption of an abnormally large amount of food coupled with a feeling of being out of control. Compensatory behaviors (aimed at preventing weight gain) include self-induced vomiting; the misuse of laxatives, diuretics, or other agents; fasting; and excessive exercise.

The onset of BN usually occurs in adolescence or early adulthood and is most frequently seen in women who are of normal body weight.[16] Although the gender ratio is approximately 9:1, women to men, the diagnostic criteria themselves are gender-biased. In contrast to women, men tend to present with a greater reliance on nonpurging forms of compensatory behavior such as excessive exercise.[67,68] Considerations of differences in the clinical presentation of BN in men may lead to revised estimates.[67,69]

Approximately 80 percent of patients with BN are diagnosed with another psychiatric disorder at some time in their life.[70] Commonly comorbid psychiatric conditions include anxiety disorders, major depression, dysthymia, substance use, and personality disorders.[9,71-77] Personality features of individuals with BN include some features shared with AN such as high harm avoidance, perfectionism, and low self-esteem. Features more specific to BN include higher novelty seeking, higher impulsivity, lower self-directedness, and lower cooperativeness.[78-80]

Diagnostic Criteria

Table 2 presents DSM III, III-R, and IV and ICD-10 diagnostic criteria for BN. According to DSM IV criteria, a diagnosis of BN requires a minimum of 3 months of binge eating and compensatory behavior occurring twice a week or more. Similar to AN, individuals have to report the undue influence of weight and shape on their self-esteem. In addition, BN is diagnosed

Table 2. Diagnostic criteria: bulimia nervosa

Diagnostic Criteria	
DSM III Criteria for Bulimia Nervosa (307.51)	A. Recurrent episodes of binge eating (rapid consumption of a large amount of food in a discrete period of time, usually less than two hours) B. At least three of the following: (1) consumption of high-caloric, easily ingested food during a binge (2) inconspicuous eating during a binge (3) termination of such eating episodes by abdominal pain, sleep, social interruption, or self-induced vomiting (4) repeated attempts to lose weight by severely restrictive diets, self-induced vomiting, or use of cathartics or diuretics (5) frequent weight fluctuations greater than 10 pounds due to alternating binges and fasts C. Awareness that the eating pattern is abnormal and fear of not being able to stop eating voluntarily D. Depressed mood and self-deprecating thoughts following eating binges E. The bulimic episodes are not due to anorexia nervosa or any known physical disorder
DSM III-R Criteria for Bulimia Nervosa (307.51)	A. Recurrent episodes of binge eating (rapid consumption of a large amount of food in a discrete period of time) B. A feeling of lack of control over eating behavior during the eating binges C. The person regularly engages in either self-induced vomiting, use of laxatives or diuretics, strict dieting or fasting, or vigorous exercise in order to prevent weight gain D. A minimum average of two binge eating episodes a week for at least 3 months E. Persistent overconcern with body shape and weight
DSM IV Criteria for Bulimia Nervosa (307.51)	A. Recurrent episodes of binge eating. An episode of binge eating is characterized by both of the following: (1) Eating, in a discrete period of time (e.g., within any 2-hour period), an amount of food that is definitely larger than most people would eat during a similar period of time and under similar circumstances (2) A sense of lack of control over eating during the episode (e.g., a feeling that one cannot stop eating or control what or how much one is eating) B. Recurrent inappropriate compensatory behavior in order to prevent weight gain, such as self-induced vomiting; misuse of laxatives, diuretics, enemas, or other medications; fasting or excessive exercise C. The binge eating and inappropriate compensatory behaviors both occur, on average, at least twice a week for 3 months D. Self-evaluation is unduly influenced by body shape and weight E. The disturbance does not occur exclusively during episodes of anorexia nervosa *Specify type:* Purging type: During the current episode of bulimia nervosa, the person has regularly engaged in self-induced vomiting or the misuse of laxatives, diuretics, or enemas Nonpurging type: During the current episode of bulimia nervosa, the person has used inappropriate compensatory behaviors, such as fasting or excessive exercise, but has not regularly engaged in self-induced vomiting or the misuse of laxatives, diuretics, or enemas

DSM, Diagnostic and Statistical Manual; ICD, International Classification of Diseases.
For citations, see text.

Table 2. Diagnostic criteria: bulimia nervosa (continued)

Diagnostic Criteria	
ICD-10 Criteria for Bulimia Nervosa (F50.2)	A. There are recurrent episodes of overeating (at least twice a week over a period of 3 months) in which large amounts of food are consumed in short periods of time B. There is persistent preoccupation with eating, and a strong desire or sense of compulsion to eat (craving) C. The patient attempts to counteract the "fattening" effects of food by one or more of the following: (1) self-induced vomiting (2) self-induced purging (3) alternating periods of starvation (4) use of drugs such as appetite suppressants, thyroid preparations, or diuretics; when bulimia occurs in diabetic patients they may choose to neglect their insulin treatment D. There is self-perception of being too fat, with an intrusive dread of fatness (usually leading to underweight)
ICD-10 Criteria for Atypical Bulimia Nervosa (F50.3)	Disorder that fulfills some of the features of bulimia nervosa, but in which the overall clinical picture does not justify that diagnosis. For instance, there may be recurrent bouts of overeating or overuse of purgatives without significant weight change, or the typical overconcern about body shape and weight may be absent

secondary to AN (i.e., the illness is diagnosed as BN only if the criteria for AN are not met). Thus, to be diagnosed with BN, individuals should have a BMI greater than 17.5 or the equivalent in children and adolescents. The DSM distinguishes two subtypes of BN based on the individual's compensatory behavior: purging (including vomiting and misuse of laxatives, diuretics, or enemas) and nonpurging (restricted eating and exercise). The ICD-10[17]describes only the compensatory mechanisms of vomiting and use of purgatives for BN, because of societal pathologizing of vomiting and laxative misuse when compared with exercise or restrictive eating. ICD-10 does acknowledge alternate periods of starvation in BN.

Epidemiology

A recent review estimated the prevalence of BN to be 1 percent for women and 0.1 percent for men across Western Europe and the United States.[1] The prevalence of subthreshold BN was considerably higher: 1.5 percent for full syndrome and 5.4 percent for partial syndrome. Because of the late introduction of BN into psychiatric nomenclature, few studies have explored temporal changes in the incidence of the disorder. Moreover, few studies have estimated the prevalence of BN among children and adolescents.

Etiology

Historically, like AN, BN has been conceptualized as having sociocultural origins. Substantial familial aggregation of BN has been reported.[39] Twin studies reveal a moderate to substantial contribution of additive genetic factors (between 54 percent and 83 percent) and unique environmental factors to BN.[81,82] Linkage analyses have identified areas on chromosome 10p that may be implicated in BN.[83] Numerous candidate genes have been studied for their role in risk for the disorder.[46]

Ongoing biological studies suggest fundamental disturbances in serotonergic function in individuals with BN.[80,84] The ultimate understanding of the etiology of BN and of other disturbances that contribute to the development of inappropriate responses to satiety clues[85] will

most likely include main effects of both biological and environmental factors as well as their interactions and correlations.

Course of Illness

Although BN is not typically associated with the serious physical complications normally associated with AN, patients commonly report physical symptoms such as fatigue, lethargy, bloating, and gastrointestinal problems. Individuals with BN who engage in frequent vomiting may experience electrolyte abnormalities, metabolic alkalosis, erosion of dental enamel, swelling of the parotid glands, and scars and calluses on the backs of their hands.[86] Those who frequently misuse laxatives can have edema, fluid loss and subsequent dehydration, electrolyte abnormalities, metabolic acidosis, and potentially permanent loss of normal bowel function.[86] Chapter 6 reviews eating-related, psychological, and biomarker-measured outcomes of BN in detail.

Treatment

In the United States, most treatment for BN is conducted on an outpatient basis. Given the frequency of medical[87] and nutritional complications, a comprehensive medical evaluation is the typical first step in treatment. Thereafter, psychotherapy, delivered either individually or in group format, is usually the cornerstone of BN interventions. Common approaches include cognitive-behavioral therapy and interpersonal psychotherapy. In cases in which the individual is experiencing medical complications of BN, is pregnant, or is unable to bring an entrenched binge-purge cycle under control on an outpatient basis, partial hospitalization or inpatient treatment is often warranted.

In 1996, the Food and Drug Administration (FDA) approved fluoxetine for the treatment of BN. Currently, this is the only FDA-approved medication for the treatment of any eating disorder.

Eating Disorders Not Otherwise Specified (Binge Eating Disorder)

Clinical Characteristics

Eating disorders not otherwise specified (EDNOS) is a diagnostic category that captures those individuals with eating disorders who do not meet criteria for AN or BN. The DSM IV lists six different examples of presentations of EDNOS:

1. all features of AN except amenorrhea;
2. all features of AN except remaining in a normal weight range;
3. all criteria for BN except frequency of binge eating or purging or duration of 3 months;
4. regular inappropriate compensatory behavior after eating small amounts of food;
5. chewing and spitting out food; and
6. binge eating disorder (BED).

Clinical reports suggest that individuals with EDNOS constitute the majority of individuals seeking professional help for an eating disorder.[88,89] This suggests that the nomenclature for eating disorders is imperfect. Moreover, our attempts to address the key questions of this evidence report for the global category of EDNOS indicated a paucity of investigations on the nature of the highly heterogeneous category of EDNOS and on the treatment and outcome of specific presentations of EDNOS. We redirected the task to focus on BED, the one category of EDNOS that has a corpus of research.

Diagnostic Criteria

The symptom of binge eating was first recognized in a subset of obese individuals by Stunkard in 1959.[90] BED has had a slow and controversial evolution in the psychiatric nosology for eating disorders.[91-94] DSM IV currently includes BED as a disorder requiring further study.

The DSM IV criteria appear in Table 3. Individuals with BED engage in regular binge eating behavior. A binge eating episode is determined in the same manner as in BN; it requires consumption of an unusually large amount of food and a sense of being out of control. The frequency criterion of twice per week is the same as in BN, although this criterion is not well supported by the literature.[95,96] Unlike BN, individuals with BED do not regularly engage in compensatory behaviors. Several other criteria in the provisional BED diagnosis require further empirical support.

Table 3. Diagnostic criteria: binge eating disorder

Diagnostic Criteria	
DSM IV Criteria for Binge Eating Disorder (307.50)	A. Recurrent episodes of binge eating. An episode of binge eating is characterized by both of the following: (1) Eating, in a discrete period of time (e.g., within any 2-hour period), an amount of food that is definitely larger than most people would eat in a similar period of time under similar circumstances (2) The sense of lack of control over eating during the episode (e.g., a feeling that one cannot stop eating or control what or how much one is eating) B. Binge-eating episodes are associated with three (or more) of the following: (1) eating much more rapidly than normal (2) eating until feeling uncomfortably full (3) eating large amounts of food when not feeling physically hungry (4) eating along because of being embarrassed by how much one is eating (5) feeling disgusted with oneself, depressed, or very guilty after overeating C. Marked distress regarding binge eating is present D. The binge eating occurs, on average, at least 2 days a week for 6 months Note: The method of determining frequency differs from that used for bulimia nervosa; future research should address whether the preferred method of setting a frequency threshold is counting the number of days on which binges occur or counting the number of episodes of binge eating E. The binge eating is not associated with the regular use of inappropriate compensatory behavior (e.g., purging, fasting, excessive exercise, etc.) and does not occur exclusively during the course of anorexia nervosa or bulimia nervosa

DSM, Diagnostic and Statistical Manual.

Epidemiology

Population-based studies suggest that between 0.7 percent and 3 percent of individuals in community samples meet criteria for BED.[92,97-99] Community studies of obese individuals have found a prevalence of BED between 5 percent and 8 percent.[100,101] Population-based studies of

BED and the component behavior of binge eating report a relatively equal gender distribution,[92,99] few differences in prevalence across races or ethnic groups,[102] and possibly increased risk associated with lower socioeconomic status.[103,104] In a population-based study of female twins, 37 percent of obese women (BMI ≥ 30) endorsed the symptom of binge eating,[105] representing 2.7 percent of the female population studied.

Etiology

In a community-based case-control study, Fairburn et al.[106] found significant differences in exposure to risk factors between women with BED and healthy controls, but surprisingly few differences between women with BED and BN. In comparison to healthy controls, women with BED reported greater adverse childhood experiences, parental depression, personal vulnerability to depression, and exposure to negative comments about weight, shape, and eating.

BED has been shown to aggregate in families.[107] Although heritability estimates for frank BED are not yet available, the heritability of binge eating in the absence of compensatory behaviors has been estimated to be 41 percent.[108] In addition, binge eating has been explored as a potential intermediate behavioral phenotype in understanding the genetics of obesity. It has also been preliminarily identified in some studies as an important phenotypic characteristic of individuals with a mutation in the melanocortin 4 receptor (*MC4R*), a candidate gene that influences eating behavior,[109] although this finding has not been replicated.[110]

Course of Illness

Given that BED has only recently entered the psychiatric nomenclature, we have minimal population-based data on morbidity and mortality. The presence of binge eating or BED in obese individuals carries substantial risk. Obese individuals with binge eating or BED in clinical and community studies report earlier onsets of obesity and dieting,[92,111,112] greater weight fluctuations,[112] more cognitive features of disordered eating,[113] lower self-esteem and self-efficacy,[114] and higher scores on depression indices.[114-117] Chapter 6 reviews eating-related, psychological, and biomarker-measured outcomes of BED in detail.

Treatment

In the United States, treatment for BED is typically conducted on an outpatient basis. Psychological and dietary interventions aim to reduce binge eating and control weight.[118] Common psychotherapeutic approaches include cognitive-behavioral and interpersonal psychotherapy; nutritional approaches include very low calorie diets and behavioral self-management strategies.[118] Pharmacotherapy targeting both the core symptoms of binge eating and weight loss are also available as off-label interventions.[119]

Production of This Evidence Report

Organization

Given that eating disorders are an important public health problem, the Agency for Healthcare Research and Quality (AHRQ), the National Institutes of Health's Office of Research on Women's Health, together with the Health Resources and Services Administration (HRSA), and in consultation with National Institute of Mental Health (NIMH), commissioned an evidence

report through its Evidence Based Practice Program and assigned it to the RTI International-University of North Carolina Evidence-Based Practice Center (RTI-UNC EPC). The issue is also of particular concern to the American Psychiatric Association and the Laureate Psychiatric Clinic and Hospital, which nominated the topic.

Chapter 2 describes our methodological approach, including the development of key questions and their analytic framework, our search strategies, and inclusion/exclusion criteria. In Chapters 3 through 5, we separately present the results of our literature search and synthesis on the treatment of each disease (respectively, AN, BN, and BED). Chapter 6 documents our findings about outcomes associated with each disease. Chapter 7 further discusses our findings, grades the strength of the bodies of literature, highlights methodological shortcomings of the extant research, and offers recommendations for future research. Appendixes (available electronically at http://www.ahrq.gov) provide a detailed description of our search strings (Appendix A[*]), our quality rating forms (Appendix B), detailed evidence tables (Appendix C), list of excluded studies (Appendix D), and acknowledgments including our Technical Expert Panel and peer reviewers (Appendix E).

Technical Expert Panel

We identified experts in the field of eating disorders to provide assistance throughout the project. The Technical Expert Panel (TEP) (see Appendix E) contributes to AHRQ's broader goals of (1) creating and maintaining science partnerships as well as public-private partnerships and (2) meeting the needs of an array of potential customers and users of this product. The TEP served as both a resource and sounding board during the project. Our TEP comprised 10 individuals: three psychiatrists and two psychologists with eating disorder expertise; two nurses; one pediatric/adolescent medicine physician; one nutritionist; and one patient advocate.

To ensure accountability and scientifically relevant work, the TEP was called upon to provide guidance at all stages of the project. TEP members participated in conference calls and e-mail exchanges to

- refine the analytic framework and key questions at the beginning of the project;
- refine the scope of the project; and
- discuss inclusion and exclusion criteria.

Because of their extensive knowledge of the literature on eating disorders, including numerous articles authored by TEP members, and their active involvement in professional organizations and as practitioners in the field, we also asked TEP members to participate in external peer review of the draft report.

Uses of This Report

We anticipate this report will be of value to members of the various professional organizations who treat eating disorders. These include the Academy for Eating Disorders, American Academy of Pediatrics, American Academy of Family Practice, American College of Obstetricians and Gynecologists, American Dietetics Association, American Psychiatric Association, American Psychological Association, International Association of Eating Disorders Professionals, National Association of Social Workers, and Society for Adolescent Medicine.

[*] Appendixes cited in this report are provided electronically at http://www.ahrq.gov/downloads/pub/evidence/pdf/eatingdisorders/eatdis.pdf.

More generally, the report will assist these organizations in their mission to inform and educate practitioners. From this review, the National Institutes of Health can identify serious gaps in the research on eating disorders to guide funding policy. It can inform practitioners on the current evidence about outcomes associated with having these eating disorders and treating patients with them. Researchers will benefit from the concise analysis of the current status of the field, which will enable them to design future studies to address deficiencies in the field. Health educators can use this report to improve health communication. Finally, policymakers can use this report to allocate resources toward future research and initiatives that are likely to be successful.

Chapter 2. Methods

In this chapter, we document the procedures that the RTI International – University of North Carolina at Chapel Hill Evidence-based Practice Center (RTI-UNC EPC) used to develop this comprehensive evidence report on the management and outcomes related to eating disorders. To provide a framework for the review, we first present the key questions and their underlying analytic framework. We then describe our strategy for identifying articles relevant to our key questions, our inclusion/exclusion criteria, and the process we used to abstract relevant information from eligible articles and generate our evidence tables. We also discuss our criteria for grading the quality of individual articles and the strength of the evidence as a whole. Last, we explain the peer review process.

Key Questions and Analytic Framework

This report spans key questions (KQs) regarding both treatment and outcomes of three eating disorders: anorexia nervosa (AN), bulimia nervosa (BN), and eating disorders not otherwise specified (EDNOS), which we refined to focus exclusively on binge eating disorder (BED) because of the lack of availability of data on other EDNOS conditions. We examine issues concerning treatment efficacy and disease outcomes separately for each disorder. The American Psychiatric Association and Laureate Psychiatric Clinic and Hospital initially offered these questions, and we put them into final form with input from our Technical Expert Panel (TEP).

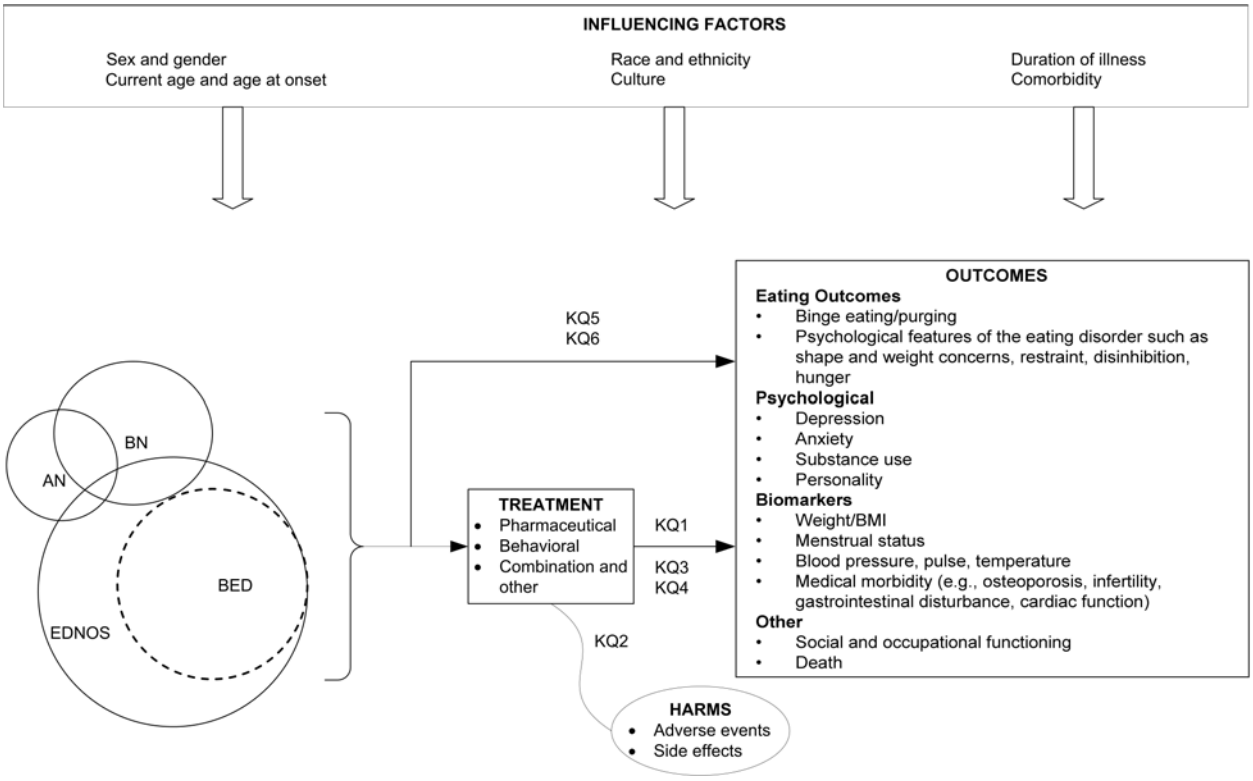
Key Questions

- 1. What is the evidence for the efficacy of treatments or combination of treatments for each of the following eating disorders: AN, BN, and BED?
- 2. What is the evidence of harms associated with the treatment or combination of treatments for each of the following eating disorders: AN, BN, and BED?
- 3. What factors are associated with the efficacy of treatment among patients with the following eating disorders: AN, BN, and BED?
- 4. Does the efficacy of treatment for AN, BN, and BED differ by sex, gender, age, race, ethnicity, or cultural group?
- 5. What factors are associated with outcomes among individuals with the following eating disorders: AN, BN, and BED?
- 6. Do outcomes for AN, BN, and BED differ by sex, gender, age, race, ethnicity, or cultural group?

In the analytic framework for these questions (Figure 1), we depict the partially overlapping syndromes of AN, BN and BED, the two types of studies included in this review (treatment and outcome analyses), and factors that influence both treatment response and disorder outcome. We do not include in our figure influencing factors, such as physical and sexual abuse, that are not discussed in the literature meeting our inclusion criteria.

Also depicted on the framework are the six KQs discussed in this report. KQ 1 addresses the efficacy of available treatments for the three disorders; we categorize outcomes as eating-related

Figure 1. Analytic framework



outcomes that deal with the core behavioral and psychological pathology of the disorders, psychiatric or psychological outcomes that focus on the presence of comorbid depression and anxiety, and biomarker outcomes that reflect weight, body mass index (BMI), and other biological indices of the disorders. Treatment may include relapse, diagnostic crossover, and symptomatic change. KQ 2 explores the harms associated with both medication and psychological treatments for these disorders. KQs 3 and 4 highlight the roles of illness-related factors (e.g., comorbid depression, subtype of the eating disorders, early onset of illness) and illness-independent factors (e.g., sex, gender, race or ethnicity, age) in influencing the outcomes of treating these conditions.

KQ 5 addresses short- and long-term outcomes of the disorders. We apply information from observational, cohort, and case series investigations and focus on eating-related, psychiatric or psychological, and biological indices. Finally, KQ 6 highlights whether these outcomes differ by sex, gender, age, race or ethnicity, or cultural groups.

Literature Review Methods

Inclusion and Exclusion Criteria

After discussions with our TEP, we generated a list of article inclusion and exclusion criteria (Table 4) for these KQs. We limited our review to human studies, including participants ages 10 years and older. Although interest is growing in developing appropriate nomenclature and interventions for young children with eating disorders,[120] we judged this literature to be beyond the scope of this review. We considered studies published in all languages from 1980 to September 2005. We included studies conducted with participants of both sexes, in all nations. The study population must be primarily diagnosed with AN, BN or BED.

Table 4. Eating disorders literature searches: inclusion and exclusion criteria

Category	Criteria
Study population	Humans All races, ethnicities, and cultural groups 10 years of age or older.
Study settings and geography	All nations
Time period	Published from 1980 to the present
Publication criteria	All languages Articles in print Articles in the "gray literature," published in nonpeer-reviewed journals, or unobtainable during the review period were excluded.
Admissible evidence (study design and other criteria)	Original research studies that provide sufficient detail regarding methods and results to enable use and adjustment of the data and results. Anorexia nervosa must be diagnosed according to DSM III, DSM III-R, DSM IV, ICD-10, Feighner, or Russell criteria. Bulimia nervosa must be diagnosed according to DSM III-R, DSM IV, or ICD-10 criteria. Eating disorders not otherwise specified (binge eating disorder) must be diagnosed according to DSM IV criteria. Relevant outcomes: eating related, psychiatric or psychological, and biomarker measures; must be able to be abstracted from data presented in the papers. Eligible study designs include: **Randomized controlled trials (RCTs):** Double-blinded, single-blinded, and cross-over designs (data from prior to the first cross-over). Anorexia nervosa studies: initiated with 10 or more participants and followed for any length of time. Eating disorders not otherwise specified (binge eating disorder) studies: initiated with 10 or more participants and followed for any length of time. Bulimia nervosa studies: initiated with 30 or more patients and followed for a minimum of 3 months. **Outcomes studies:** Observational studies including prospective and retrospective cohort studies and case series studies, with and without comparison populations. Disease population must be followed for a minimum of 1 year. Disease population must include 50 or more participants at the time of the analysis.

We excluded data that combined diseases because such mixed information would preclude us from separately examining evidence on any one of the three conditions. We also excluded editorials, letters, and commentaries; articles that did not report outcomes related to our key questions; and studies that did not provide sufficient information to be abstracted. Studies were required to report on at least one of our outcomes categories of interest: eating, psychiatric and psychological, or biomarker measures.

We defined individuals as having one of the three disorders of interest according to specific diagnostic criteria. We examined the impact of treatment through a review of the RCT efficacy of treatment literature.

To address a TEP concern that the size of the available AN and BED literature was too limited to permit us to constrain this review based on sample size or followup duration, we included very small AN and BED RCT treatment studies in our review (10 or more participants) and did not require specified followup durations for a study to be included. The BN literature, however, is much more voluminous, which allowed us to limit the treatment studies to larger ones (i.e., those with 30 or more participants).

To help ensure that we were not measuring short-term fluctuations in disease symptoms, we required BN efficacy of treatment studies to follow patients for a minimum of 3 months. The decision to place more stringent requirements on the BN literature was made in consultation with our TEP. Because of financial and time considerations, we used a recently completed EPC report entitled *Drug Class Review on Second Generation Antidepressants*[121] as a starting point for our discussion of harms or side effects related to *receiving treatment* for AN, BN, and BED; we then supplemented this information with harms reported in the RCT studies meeting our inclusion criteria.

We examined outcomes related to having one of the three eating disorders through a review of observational studies; outcomes included eating, psychiatric or psychological, and biomarker variables and death. Although many participants followed in these studies have received treatment, the outcomes of interest relate not to efficacy of treatments but rather to disease levels and other problems that persist over time. To avoid reporting short-term fluctuations among the disease populations and to have sufficient sample sizes to observe changes over time, we limited our review to studies of 50 or more individuals, followed for a minimum of 1year, with or without comparison groups. Our TEP concurred with this plan.

For both the RCT and outcome literatures, we were unable to perform pooled meta-analyses. Given the absence of consensus definitions of remission, recovery, and relapse for eating disorders, as well as the overabundance of outcome measures, we judged meta-analysis to be both inadvisable and infeasible.

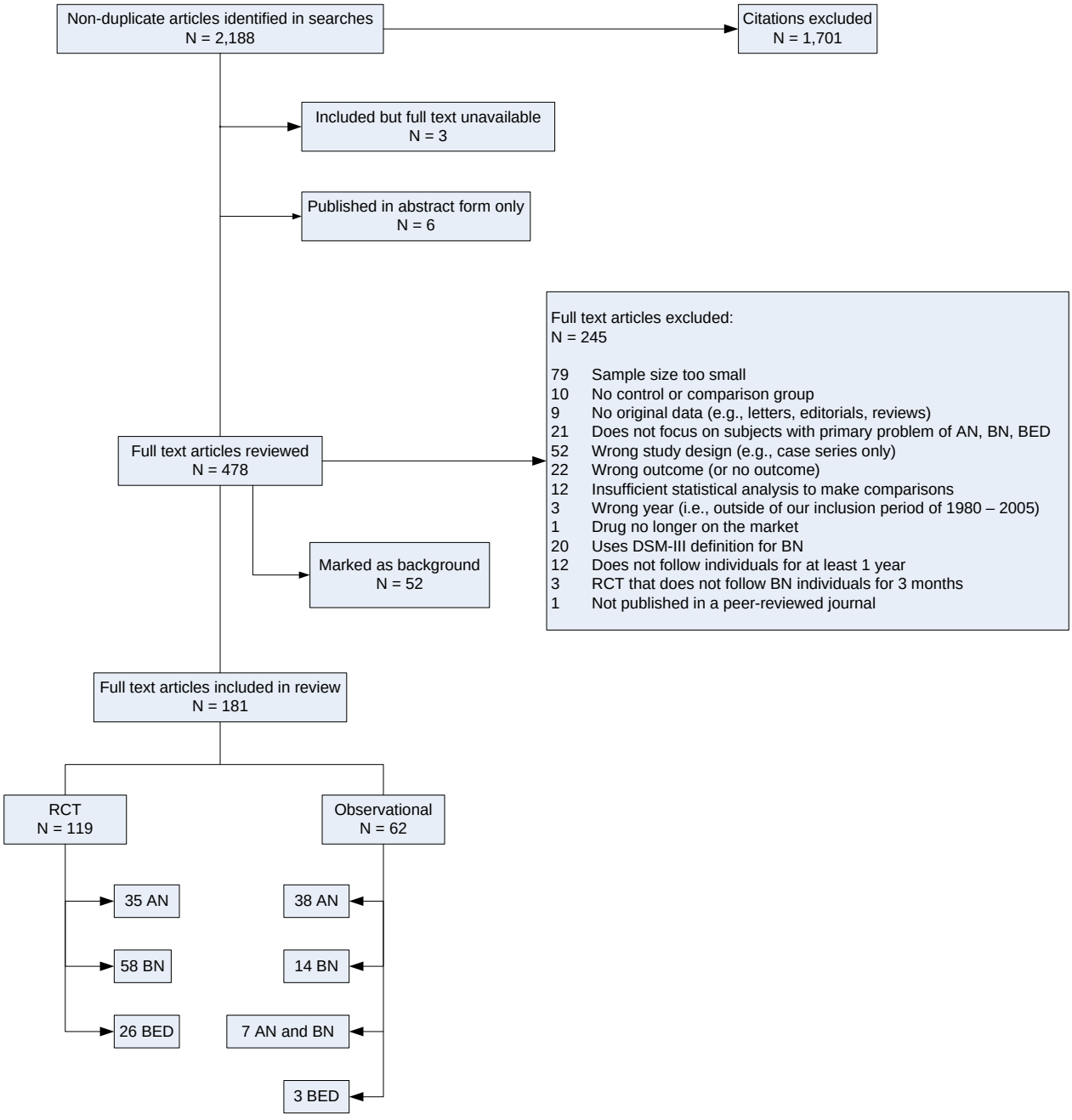
Literature Search and Retrieval Process

Databases and search terms. To identify the relevant literature for our review, we conducted systematic searches based on search terms, reviewed included studies by our TEP, and hand searched reference lists. We searched standard electronic databases such as MEDLINE®, the Cumulative Index to Nursing and Applied Health (CINAHL), PsycINFO, the Educational Resources Information Center (ERIC), the National AGRICultural OnLine Access (AGRICOLA), and Cochrane Collaboration libraries.

Based on inclusion/exclusion criteria specified above, we generated a list of Medical Subject Heading (MeSH) search terms, supplemented by key word searches of MEDLINE®. Comparable terms were used to search other databases. MeSH terms included anorexia, anorexia nervosa, and bulimia. Text terms included binge eating disorder. We limited our searches by type of study, including RCT, single-blind method, double-blind method, random allocation, longitudinal studies, and observational studies. For interventions, we used therapeutics or cognitive therapy or family therapy or drug therapy or therapy, computer-assisted. For outcomes of disease, we used outcome assessment (health care), treatment outcome, outcome and process assessment (health care), and recurrence. Finally, we asked our external peer reviewers for titles of articles that we may have missed.

Figure 2 presents the yield and results from our searches. We conducted our initial search in late 2004 and updated it in August 2005 (treatment studies) and September 2005 (outcome studies). Beginning with a yield of 2,188 titles and abstracts, we reviewed and further narrowed this pool to 478 articles.

Figure 2. Eating disorders article disposition



We retained the following for our review to answer KQs about treatment efficacy: 35 articles on AN, 58 articles on BN, and 26 articles on BED. To answer KQs about disease outcomes, we retained 38 articles on AN, 14 articles on BN, 7 articles on both AN and BN, and 3 articles on BED.

Article selection process. Once we had identified articles through the electronic database search, review articles, and bibliographies, we examined titles and abstracts to determine whether the studies met our inclusion criteria. One reviewer initially evaluated abstracts for inclusion or exclusion. If one reviewer concluded that the article should be included, it was retained. Abstracts initially excluded from the study by one reviewer received a second review by senior project staff—Nancy Berkman, PhD, MLIR (Project Director), Cynthia Bulik, PhD (Scientific Director), or Gerald Gartlehner, MD, MPH (UNC Project Manager).

In all, 478 articles appeared to meet our inclusion criteria through abstract review, so we obtained the full articles. For the full article review, one senior reviewer read each article and determined if it met our eligibility criteria. Those articles that the reviewer determined did not meet our criteria were re-reviewed by a second senior reviewer to ensure agreement that the article should be excluded. We assigned each of these articles one or more reasons for exclusion.

Literature Synthesis

Development of Evidence Tables and Data Abstraction Process

The senior staff members for this systematic review jointly developed the evidence tables. We created two designs for the evidence tables, one for KQs 1 to 4 (treatment studies) and one for KQs 5 and 6 (outcome studies). They are intended to provide sufficient information for readers to understand the study and determine its quality; we emphasized presenting information essential to answering the main questions. The formats of the two sets of evidence tables were based on successful designs used for prior systematic reviews.

Columns in the evidence tables for treatment studies report baseline and outcome measures for eating-related, psychological or psychiatric, and biomarker variables. For each outcome measured, the tables present data in a consistent format. Given the large number of outcomes that these studies typically report, our evidence table entries are relatively long. In contrast, the outcome studies evidence tables are shorter. However, because of the appreciable variety of study approaches and outcomes reported in this literature the presentation of outcome data is, by necessity, less consistent than that for the treatment studies.

For this work, the RTI-UNC EPC team decided to abstract data from included articles directly into evidence tables; this system has worked effectively in many of our past reviews. Because we bypassed the use of data abstraction forms, we had significant efficiencies in production.

We trained data abstractors intensively, thoroughly familiarizing them with table designs, required information and formats, and examples of abstracted articles. As the work progressed, we shared various reporting requirements with abstractors to ensure that information appeared in a consistent and easily understandable manner.

For both the treatment and the outcomes literatures, the first reviewer (UNC faculty, postdoctoral psychology fellow, or psychology graduate student) initially entered data from the article into the evidence table. The second reviewer (Drs. Berkman, Bulik, Brownley, Carey, or Gartlehner) read the article and edited the initial table entry for accuracy, completeness, and consistency. All disagreements concerning the information reported in the evidence tables were reconciled by the two abstractors.

The final evidence tables are presented in their entirety in Appendix C.* Separate tables are included for treatment studies by disease and type of treatment intervention:

- AN: Evidence Table 1, medication trials; Evidence Table 2, medication plus behavioral intervention trials; Evidence Table 3, behavioral intervention trials (adults); and Evidence Table 4, behavioral intervention trials (adolescents ages 10 and older);
- BN: Evidence Table 5, medication trials; Evidence Table 6, medication plus behavioral intervention trials; Evidence Table 7, behavior intervention with no medications trials; Evidence Table 8, self-help interventions trials; and Evidence Table 9, other interventions trials;
- BED: Evidence Table 10, medication trials; Evidence Table 11, medication plus behavioral interventions trials; Evidence Table 12, behavioral intervention with no medications trials; Evidence Table 13, self-help intervention trials; and Evidence Table 14, other interventions trials.

Appendix C also presents three evidence tables for outcome studies organized only by disease:

- AN outcome studies, Evidence Table 15;
- BN outcome studies, Evidence Table 16; and
- BED outcome studies, Evidence Table 17.

Within each evidence table, entries are listed alphabetically by the last name of the first author. Abbreviations and acronyms used in the tables appear in a glossary at the beginning of the appendix.

Finally, as noted earlier, the number of assessment instruments that investigators used for both diagnosis and outcome measurement in the studies reviewed here was extremely large. To help readers identify these, we created Table 5 (found at the end of this chapter) to briefly identify all measures, their acronyms or abbreviations, and their subscales, with a citation to a definitive source for the instrument.

Quality and Strength of Evidence Evaluation

Rating the quality of individual articles. For this systematic review, we developed our approach to assessing the quality of individual articles using domains and elements recommended in the evidence report by West and colleagues, *Systems to Rate the Strength of Scientific Evidence*.[122] We developed two quality-rating forms, one for the treatment literature and the other for the outcomes literature. Quality rating forms did not differ by disease. We tested several drafts of these forms, revising them as needed to ensure that they efficiently captured the desired information. The final grading forms can be found in Appendix B.

We assessed the treatment literature through 25 items in 11 categories: (1) research aim/study question, (2) study population, (3) randomization, (4) blinding, (5) interventions, (6) outcomes, (7) statistical analysis, (8) results, (9) discussion, (10) external validity, and (11) funding/sponsorship. We did not exclude any studies with so-called fatal flaws, such as the approach to randomization. Rather, we reduced the study's overall score if a category was flawed

* Appendixes cited in this report are provided electronically at http://www.ahrq.gov/downloads/pub/evidence/pdf/eatingdisorders/eatdis.pdf.

or inadequate. Because patients and those administering interventions in the psychological treatment studies could not be blinded, we did not evaluate these items when studies included these interventions. However, we always evaluated whether the outcome assessor was blinded. Studies that were reported in more than one article were given the same quality grade.

We weighted each item equally and calculated a score out of 100 percent. We then collapsed those scores into three categories: poor, 0 percent to 59 percent; fair, 60 percent to 74 percent; and good, 75 percent or better.

For the outcomes literature, we used 17 items in 8 categories: (1) research aim/study question, (2) study population, (3) eating disorder diagnosis method, (4) study design, (5) statistical analysis, (6) results/outcome measurement, (7) external validity, and (8) discussion. As with the RCTs, we weighted each item equally. Rather than calculating a score out of 100 percent, however, we converted ratings for each item into numeric values of 0, 1, or 2, in which 0 = poor, 1 = fair, and 2 = good. Studies without comparison groups were not evaluated by items addressing this aspect of design. However, studies that included comparison groups were scored as "good" on one item, whereas those without were scored as "poor" on that item. We calculated the mean score for all graded items and we concluded that, overall, an article should be graded as poor with a rating < 1, fair with a rating ≥ 1 and < 1.5, and good with a rating of ≥ 1.5.

Each quality grade was the composite (averaged) rating of two independent evaluators. The only items reconciled between the evaluators were those in which one rater provided a score for the item and the other said the item was not applicable. In assessing quality of the treatment studies, we asked the two evaluators to discuss their results if the difference in their total scores was 20 points or greater, but we did not require them to come to agreement.

Rating the strength of the available evidence. We rated the strength of the evidence base for both interventions and disease outcomes separately for the three diseases, using a single scheme for all bodies of evidence. Starting with the West et al. report that compared various schemes for grading bodies of evidence,[122] we based our evaluation on criteria developed by Greer et al.,[123] which we deemed most applicable to the study designs in this review. It includes three domains: quality of the research, quantity of studies (including number of studies and adequacy of the sample size), and consistency of findings.

We graded the body of literature applicable to each of the six KQs separately. For the treatment literature, we further divided studies by whether the intervention was pharmaceutical, behavioral, or a combination. Three senior staff defined by consensus four strength-of-evidence categories, as follows:

- I. Strong evidence base. The evidence is from studies of strong design; results are both clinically important and consistent with minor exceptions at most; results are free from serious doubts about generalizability, bias, or flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.
- II. Moderate evidence base. The evidence is from studies of strong design, but some uncertainty remains because of inconsistencies or concern about generalizability, bias, research design flaws, or adequate sample size. Alternatively, the evidence is consistent but derives from studies of weaker design.
- III. Weak evidence base. The evidence is from a limited number of studies of weaker design. Studies with strong design either have not been done or are inconclusive.
- IV. No evidence base. No published literature.

Peer Review Process

Among the more important activities involved in producing a credible evidence report is conducting an unbiased and broadly based review of the draft report. External reviewers for this report included clinicians, representatives of professional societies and advocacy groups, and potential users of the report, including TEP members (see Appendix D[†]). We charged peer reviewers with commenting on the content, structure, and format of the evidence report and asked them to complete a peer review checklist. We revised the report, as appropriate, based on their comments.

[†] Appendixes cited in this report are provided electronically at http://www.ahrq.gov/downloads/pub/evidence/pdf/eatingdisorders/eatdis.pdf.

Table 5. Diagnostic and outcome measures used in randomized controlled trials and outcome studies

Acronym and Full Name of Test	Description of Test and Subscales
ABOS: Anorectic Behaviour Scale for Inpatient Observation[124]	Proxy-report (relatives) questionnaire to obtain information about patient's behaviors and attitudes; 3 factors: eating behaviors, concerns with weight and food, denial of proteins; bulimic-like behaviors; hyperactivity.
ABS: Anorectic Behavior Scale[125]	Administrator-completed questionnaire about patient's behavior while in hospital; 8 items on resistance to eating, 8 items on methods of disposing of food, 6 items on overactivity.
ANSS: Anorexia Nervosa Symptom Score[126]	Clinical rating scale with psychological, social, and physical severity scores and subscales.
BAT: Body Attitudes Test[127,128]	Self-report questionnaire to measure subjective body experience and attitude towards one's body; 3 factors: negative attitudes about body size, lack of familiarity with one's own body, body dissatisfaction.
BDI: Beck Depression Inventory[129]	One of the most widely used self-report measures for depression. It is a 21-item test presented in multiple choice format that measures the presence and degree of depression in adolescents and adults.
BEDCI: Binge Eating Disorder Clinical Interview[130]	Structured clinical interview to establish the diagnosis of BED and both purging and nonpurging types of BN.
BES: Binge Eating Scale[131]	Self-report measure of binge eating severity as measured by loss of control over eating behavior; 8 items on behavioral manifestations, 8 items on feelings and cognitions.
BIAQ: Body Image Avoidance Questionnaire[132]	Self-report measure to assess avoidance of situations that provoke concern about physical appearance (including wearing tight fitting clothing, social outings, physical intimacy); 4 subscales: Eating Restraint, Clothing, Grooming/Weighing, Social Activities
BITE: Bulimic Investigation Test Edinburgh[133]	Brief self-report questionnaire with 2 subscales designed to assess the symptoms and severity of binge eating episodes.
BSI: Brief Symptom Inventory[134]	Brief self-report instrument to assess patients at intake for psychiatric problems; 9 Primary Symptom Dimensions: Somatization, Obsessive-Compulsive, Interpersonal Sensitivity, Depression, Anxiety, Hostility, Phobic Anxiety, Paranoid Ideation, Psychoticism; 3 Global Indices: Global Severity Index, Positive Symptom Distress Index, Positive Symptom Total.
BSQ: Body Shape Questionnaire[135]	Self-report inventory to measure worries about weight and body shape.
BSQ-short version: Body Shape Questionnaire – Short Version[136]	Self-report inventory to measure worries about weight and body shape.
BSS: Body Satisfaction Scale[137]	Self-report instrument to assess body image satisfaction; 3 subscales: general, body, head.
Bulimic Thoughts Questionnaire[138]	Self-report instrument of cognitive patterns and distortions associated with bulimic behavior.
CBCL: Child Behavior Checklist[139]	Parent-report standardized assessment of behavioral problems and social competencies of children ages 4 to 18; 3 scores: total, internalizing behaviors (fearful, shy, anxious, inhibited), externalizing behaviors (aggressive, antisocial, under controlled).
CCEI: Crown-Crisp Experimental Index[140]	Scale to measure neurotic symptomatology; 6 subscales: free-floating anxiety, phobic anxiety, obsessionality, somatic concomitants of anxiety, depression, hysterical personality.
CDI: Children's Depression Inventory[141]	Brief self-report test to measure cognitive, affective, and behavioral signs of depression in persons 6 to 17 years of age; 5 factors: negative mood, interpersonal problems, ineffectiveness, anhedonia, negative self-esteem.

Table 5. Diagnostic and outcome measures used in randomized controlled trials and outcome studies (continued)

Acronym and Full Name of Test	Description of Test and Subscales
CDRS: Contour Drawing Rating Scale[142]	Instrument to assess body size perception and dissatisfaction; 9 male and 9 female contour drawings shown to subjects who are asked to indicate which most closely resembles their current size and their ideal figure; the discrepancy is a measure of body dissatisfaction in 3 scores: real body, ideal body, body satisfaction index.
CGI or GIS: Clinical Global Impression[143]	Clinician-rated scale to assess treatment response in psychiatric patients; 3 subscales: severity of illness (CGI-S), global improvement (CSI-G), efficacy index (CGI-EI).
DICA-R: Diagnostic Interview for Children and Adolescents – Revised[144]	Semistructured clinical interview to determine Axis I psychiatric diagnoses in children and adolescents.
DIET: Dieter's Inventory of Eating Temptations[145]	Self-report inventory to assess behavioral competence in 6 weight control situations: overeating, negative emotions, exercise, resisting temptation, positive social, food choice.
DSED: Diagnostic Survey for Eating Disorders[146]	Self-report questionnaire to quantify frequency of disturbed behavior.
EAT: Eating Attitudes Test[147]	Standardized self-report measure of symptoms and concern characteristics of eating disorders; 2 versions: EAT-26, EAT-40.
EDE: Eating Disorder Examination[148]	Semistructured interview to measure specific psychopathology of anorexia nervosa and bulimia nervosa; 4 subscales: dietary restraint, eating concern, weight concern, shape concern.
EDE-Q4: Eating Disorders Evaluation Questionnaire – Version 4[149]	Self-report assessment of thoughts and behaviors commonly found in eating disorders; 4 subscales: dietary restraint, eating concern, weight concern, shape concern.
EDI-1: Eating Disorder Inventory-1[149]	Self-report questionnaire to measure psychiatric and behavioral traits commonly associated with eating disorders; 8 scales: drive for thinness, bulimia, body dissatisfaction, ineffectiveness, perfectionism, interpersonal distrust, interoceptive awareness, maturity fears.
EDI-2: Eating Disorder Inventory- 2[150]	Standardized self-report measure of psychiatric symptoms commonly associated with anorexia nervosa, bulimia nervosa, or other eating disorders; 8 subscales as for EDI-1, plus asceticism, impulse regulation, and social insecurity.
FACES III: Family Adaptability and Cohesion Evaluation Scales[151]	Instrument to assess family adaptation and cohesion. Family cohesion assesses degree of separation or connection of family members to the family; 4 levels of family cohesion range from extreme low cohesion to extreme high cohesion: disengaged, separated, connected, enmeshed; 4 levels of adaptability: rigid, structured, flexible, chaotic.
FAM III: Family Assessment Measure[152]	Self-report measure that assesses the strengths and weaknesses of functioning within a family; can be completed by pre-adolescents, adolescents, and adult family members (ages 10 years to adult); contains 7 subscales: Task Accomplishment, Role Performance, Communication, Affective Expression, Involvement, Control, Values and Norms.
FES: Family Environment Scale[153]	Instrument to assess actual, preferred, and expected social environment of all types of families; 10 subscales: cohesion, expressiveness, conflict, independence, achievement, intellectual-cultural, active-recreation, moral-religious, organization, control.
FMPS: Frost Multidimensional Perfectionism Scale[154]	Self-report measure of perfectionism; original measure had 6 subscales (Concern Over Mistakes, Personal Standards, Parental Expectations, Parental Criticism, Doubts About Actions, Organization).
FNE: Fear of Negative Evaluation[155,156]	Scale to measure social anxiety about receiving negative evaluations from others; 2 subscales: Negative Expectations, Negative Public Evaluation.
Brief-FNE: Brief Fear of Negative Evaluation[157]	Brief version of the original FNE.

Table 5. Diagnostic and outcome measures used in randomized controlled trials and outcome studies (continued)

Acronym and Full Name of Test	Description of Test and Subscales
FRS: Figure Rating Scale[158]	Silhouette drawings of male and female adult body figures ranging from very thin to very large used as measure of personal body perception; 3 subscales: Real Body, Ideal Body, Body Satisfaction Index.
GAAS: Goldberg Anorectic Attitude Scale[159]	Scale to measure short-term changes in anorectic cognitions across treatment including measures of hyperactivity, access, self-care, selective appetite, and denial of illness.
GAF: Global Assessment of Functioning[16]	Clinician-derived instrument to measure the highest level of social and occupational functioning in the previous week and year; sometimes broken down into the GAF-F function score (not including symptoms) and the GAF-S symptom score (not including function).
GIS: Global Improvement Scale[143]	See CGI (Clinical Global Improvement Scale).
HAM-A: Hamilton Anxiety Rating Scale[160]	Semistructured interview to assess severity of anxiety symptomatology.
HAM-D or HDRS: Hamilton Depression Rating Scale[161]	Semistructured interview to assess an array of behavioral, affective, and vegetative symptoms of depression.
HGSHS: Harvard Group Scale of Hypnotic Susceptibility, Form A[162]	Measure of susceptibility to a wide range of hypnotic experiences, designed for assessing groups of subjects.
HRQ: Helping Relationship Questionnaire[163]	Patient-rated instrument to measure therapeutic alliance.
HSCL: Hopkins Symptom Checklist[134]	Self-report screening instrument to identify common psychiatric symptoms; 9 subscales: somatization, obsessive–compulsive symptoms, interpersonal sensitivity, depression, anxiety, anger or hostility, phobic anxiety, paranoid ideation, psychotic symptoms.
IBC: Interactive Behavior Code[164]	A global interferential measure of communication, problem solving, and conflict, with 22 coded items rated by independent observers; summary scores are computed for negative and positive communication.
IIP: Inventory of Interpersonal Problems[165]	Instrument to measure interpersonal problems and level of distress arising from interpersonal sources.
LCB: Locus of Control of Behavior[166]	Instrument to measure the extent to which individuals believe they are responsible for personal problem behavior.
LIFE: Longitudinal Interval Continuation Evaluation[167]	Semistructured interview and rating system to assess longitudinal course of psychiatric disorders in several areas: psychopathology, nonpsychiatric mental illness, treatment, psychosocial functioning, overall severity, narrative account.
MCMI: Millon Clinical Multiaxial Inventory[168]	Lengthy test to diagnose 14 personality disorders and 10 clinical syndromes; scales: 14 Personality Pattern Scales, 10 Clinical Syndrome Scales, 3 Modifying Indices, 1 Validity Index.
MMPI: Minnesota Multiphasic Personality Inventory[169]	Test of adult psychopathology; 8 Validity Scales, 5 Superlative Self-Presentation Subscales, 10 Clinical Scales, 9 Restructured Clinical (RC) Scales, 15 Content Scales, 27 Content Component Scales, 20 Supplementary Scales, 31 Clinical Subscales (Harris-Lingoes and Social Introversion Subscales), and various special or setting-specific indices.
MOCI: Maudsley Obsessive Compulsive Index[170]	Self-report questionnaire to measure the presence of obsessional-compulsive behaviors; scores: total obsessional symptoms; checking; washing; doubting/conscientious; slowness/repetition.
MPS: Multidimensional Perfectionism Scale[154]	Self-report instrument to assess perfectionism; 6 subscales: concern over mistakes, personal standards, parental expectations, parental criticism, doubts about action, organization.

Table 5. Diagnostic and outcome measures used in randomized controlled trials and outcome studies (continued)

Acronym and Full Name of Test	Description of Test and Subscales
M-R Scales: Morgan and Russell Scales[171]	Structured interview to give a brief but thorough assessment of the central clinical features of anorexia nervosa; 5 subscales: eating behavior, menstrual state, mental state, relevant attitudes, socioeconomic state; sixth scale allows a self-progress rating.
M-R-H Scale; Morgan-Russell-Hayward Scale[172]	Guided interview concerned with clinical features of anorexia nervosa to evaluate eating behavior, body weight, mental state, and other attitudes relevant to anorexia nervosa; 5 scales: nutrition, menses, mental state, psycho-sexual state, socioeconomic state; additional subscales include: food intake, concern at body image, body weight, menstrual pattern, disturbance of mental state, attitudes toward sexual matters, overt sexual behavior, attitude to menstruation, relationship with family, emancipation from family, personal contacts, social activities, employment record.
MRT: Vandenberg and Kuse's Adaptation of Shepard and Metzler's Three-dimensional Mental Rotations Test[173]	Self-report test of visuospatial ability in which participants view a depiction of a 3-dimensional target figure and 4 test figures and determine which of the test figures are rotated versions of the target figure.
PARQ: Parent Adolescent Relationship Questionnaire[174]	Instrument completed by parents and adolescents 10 through 19 years of age to measure relationship between parents and adolescents; 3 scales: Overt Conflict/Skill Deficits, Extreme Beliefs, Family Structure.
PGWB: Dupuy's Psychological General Well-being Index[175]	Self-report inventory to measure self-representations of intrapersonal affective or emotional states reflecting a sense of subjective well-being or distress; 6 intrapersonal subscales: anxiety, depressed mood, positive well-being, self-control, general health, vitality.
PSE: Present State Examination[176]	Global index of mental state disturbance.
PSR: Psychiatric Status Rating[177]	Clinician-administered instrument to determine the severity of a range of psychiatric disorders that has been used to determine eating disorder outcomes.
QEWP-R: Questionnaire of Eating and Weight Patterns – Revised[178]	Self-report questionnaire to assess a range of features and problems associated with obesity and eating disorders.
RAS: Rathus Assertiveness Schedule[179]	Self-report instrument to measure assertiveness.
RSE: Rosenberg Self-Esteem Scale[180]	Self-report instrument to measure overall self-esteem.
SADS-C: Schedule for Affective Disorders and Schizophrenia-Change Version[181]	Structured interview to differentiate schizophrenia from mood disorders; 2 subscales: depression, mania.
SAMS (Situational Appetite Measures) Urge and SAMS Efficacy[182]	Complementary scales to measure the strength of the urge to binge in 40 different situations and the degree of confidence in one's ability to resist a binge in those same 40 situations.
SAS: Social Adjustment Scale[183]	Self-report questionnaire to assess social and work-related functions; 6 subscales: work, social and leisure, extended family, marital, prenatal, family unit.
SCFI: Standardized Clinical Family Interview[184]	Standardized clinical interview used with families in which the interviewer tries to get responses from all family members and adopts a neutral style. Questions concern numerous areas of family life, mainly what sort of family it is, who does what, who is like whom, life cycle, roles and responsibilities, conflicts, decisions, discipline, relation to the environment.
SCI: Shapiro Control Inventory[185]	Self-report measure of the psychological construct of control (comparable to Locus of Control scales) with 9 subscales.

Table 5. Diagnostic and outcome measures used in randomized controlled trials and outcome studies (continued)

Acronym and Full Name of Test	Description of Test and Subscales
SCID-I: Structured Clinical Interview I for the DSM IV[186]	Structured diagnostic interview to assess presence of current or past DSM IV Axis I major psychiatric disorders.
SCL-90 R Symptom Checklist 90-Revised[134]	General measure of psychopathology, including various forms of anxiety, depression, paranoia, psychotic features. Subscales: Global Severity Index (GSI) to measure overall psychological distress; Positive Symptom Distress Index to measure the intensity of symptoms; Positive Symptom Total of number of self-reported symptoms (Somatization, Obsessive-Compulsive, Interpersonal Sensitivity, Depression, Hostility, Phobic Anxiety, Paranoid Ideation, Psychoticism).
SDS: Zung Self-rating Depression Scale[187]	Self-report assessment to quantify depression, using criteria of pervasive depressed affect and its physiological and psychological concomitants.
SF-36: Medical Outcomes Study Short Form Health Survey[188]	Self-report questionnaire to assess health-related quality of life; 8 subscales: physical function, role physical, bodily pain, general health, mental health, role emotional, social function, vitality, 2 composite scores: physical health; mental health.
SIAB-P: Structured Interview for Anorexia and Bulimia Nervosa[189]	Interview to assess severity of current eating disorder symptoms; 6 subscales: body image and ideal of slimness, social integration and sexuality, depression, obsessive compulsive syndromes and anxiety, bulimic symptoms, laxative abuse.
SMFQ: Short Mood and Feeling Questionnaire[190]	Self-report measure of childhood and adolescent depression for children 8 to 16 years of age.
SOC: Stages of Change Scale[191]	Self-report inventory to describe how respondents feel as they initiate counseling; 4 subscales: Precontemplation, Contemplation, Action, Maintenance.
SPAQ: Seasonal Patterns Assessment Questionnaire[192]	Self-report instrument to rate the presence and severity of seasonal variation in mood, sleep, and eating-related variables; 2 added items monitor seasonal bingeing and purging patterns.
STAI: State Trait Anxiety Inventory[193]	Standardized self-report assessment of both state and trait anxiety (2 subscales).
STAXI: State Trait Anger Expression Inventory[194]	Self-report inventory to assess components of anger and anger expression of normal and abnormal personality.
STPI: State Trait Personality Inventory[193]	Self-report personality inventory.
SUDS: Subjective Units of Distress[195]	Self-report measure of intensity of subjective distress in response to a particular stimulus.
TAS-20: Toronto Alexithymia Scale[196]	Self-report inventory to assess the alexithymia construct (difficulty recognizing, identifying, and communicating emotions; reduced fantasy capacity; and an externally oriented cognitive style); 2 dimensions: identifying feelings (DIF), describing feelings (DDF).
TCI: Temperament and Character Inventory[197]	Self-report measure of temperament and character; 7 subscales: Novelty Seeking, Harm Avoidance, Reward Dependence, Persistence, Self-Directedness, Cooperativeness, Self-Transcendence.
TFEQ: Three-Factor Eating Questionnaire[198]	Self-report inventory; 3 subscales: Cognitive-Restraint, Hunger, Disinhibition. Also known as the Eating Inventory.
WAIS: Wechsler Adult Intelligence Scale[199]	Structured, clinician-administered general test of intelligence for persons 16 years of age and older; 6 Verbal tests: Information, Comprehension, Arithmetic, Digit Span, Similarities, Vocabulary; 5 Performance subtests: Picture Arrangement, Picture Completion, Block Design, Object Assembly, Digit Symbol.
WELSQ: Weight Efficacy Life Style Questionnaire[200]	Self-report measure of confidence about successfully resisting the desire to eat; 5 situational subscales: Negative Emotions, Availability, Social Pressure, Physical Discomfort, Positive Activities.

Table 5. Diagnostic and outcome measures used in randomized controlled trials and outcome studies (continued)

Acronym and Full Name of Test	Description of Test and Subscales
WLFL: Work, Leisure and Family Life Questionnaire[201]	Self-report instrument to measure social adjustment and functioning; 8 scales: work outside the home, housework, social and leisure activities, extended family, marital, parental-older children, parental-baby, family unit.
YBC-EDS and YBOCS-ED: Yale-Brown-Cornell Eating Disorder Scale[202]	Interview to assess preoccupations and rituals associated with eating disorders: symptom checklist produces 3 dimensions of preoccupations and rituals (severity, motivation, ego syntonicity) and covers 18 general categories of rituals and preoccupations.
Y-BOCS- BE: Yale-Brown Obsessive Compulsive Scale Modified for Binge Eating[203]	Clinician-rated inventory of obsessive-compulsive problems adapted for use with binge-eating disorder.
Y-BOCS Score: Yale-Brown Obsessive Compulsive Scale[204]	Clinician-rated scale with separate subtotals for severity of obsessions and compulsions; 2 subscales: obsessions, compulsions.
Youth Self-Report[139,205]	Self-report inventory on various behavior problems.

Chapter 3. Results: Anorexia Nervosa

This chapter presents results of our literature search and our findings for the key questions (KQs) regarding treatment for anorexia nervosa (AN). We examine evidence for the efficacy of various treatments or combinations of treatments for AN (KQ 1), harms associated with the treatment or combination of treatments for AN (KQ 2), factors associated with the efficacy of treatment for AN (KQ 3), and whether the efficacy of treatment for AN differs by sex, gender, age, race, ethnicity, or cultural groups (KQ 4).

We report first on specific details about the yields of the literature searches and characteristics of the studies, then on literature pertaining to treatment (KQs 1 to 4). For each included study, detailed evidence tables appear in Appendix C.* We report first on medication trials (Evidence Table 1), then combined medication and behavioral interventions (Evidence Table 2), then behavioral interventions separately for adults (Evidence Table 3), and adolescents (Evidence Table 4). We distinguish between behavioral interventions for adolescents and adults in order to address age differences (KQ 4) as clearly as possible, given the current state of the literature. Within each evidence table, studies are listed alphabetically by author.

Overview of Included Studies

We identified 32 studies published in 35 articles addressing treatment efficacy for AN; of these 15 were medication trials. We were unable to categorize medication studies into adolescent and adult trials given the paucity of medication trials focusing on adolescents.

We rated two medication trials as good,[206] six as fair,[207-213] and seven as poor (not discussed further).[124,214-219] Of the studies judged fair or good, the medications studied included second-generation antidepressants,[206,207] tricyclic antidepressants,[208,209] nutritional supplements,[213] and hormones.[210-212] Study designs included medication versus placebo (six trials), medication A versus medication B versus placebo (one), and medication versus waiting list or nonmedication control (one).

Eighteen of the 32 studies were behavioral intervention trials. In this report behavioral interventions refer to all forms of psychotherapy including cognitive, supportive, dynamic, family, individual, and group. One trial was of therapeutic warming.[220] We rated two of these trials as good,[221,222] nine as fair,[223-231] and six as poor (not discussed further).[220,232-236] Of the 11 trials reviewed here, six were conducted among adults and five among adolescents. Behavioral interventions studied include cognitive behavioral therapy (CBT),[223-225] cognitive analytic therapy (CAT),[226] focal psychoanalytic therapy,[228] and various forms of family therapy.[221,222,229-231,237] The behavioral intervention trials used two designs: psychotherapy A versus psychotherapy B, and psychotherapy A versus psychotherapy B versus control.

We do not discuss studies with a quality rating of "poor" further; reasons these studies received this rating are presented in Table 6. While studies were not lacking in all areas, the most frequent deficiencies across studies contributing to a poor rating include the following: a fatal flaw in the approach to randomization or the approach not being described; investigators and outcome assessors not being blinded to study arm or their blinding status not being described; adverse events not being reported; the statistical analysis not including or not reporting whether a power analysis was conducted; a lack of necessary controls for confounding

* Appendixes cited in this report are provided electronically at http://www.ahrq.gov/downloads/pub/evidence/pdf/eatingdisorders/eatdis.pdf.

Table 6. Reasons for poor quality ratings and number of trials with poor ratings: anorexia nervosa

Reasons Contributing to Poor Ratings	Types of Intervention, Number of Times Flaw Was Detected, and Citations
	Research Aim
Hypothesis not clearly described	Medication-only trials: 0 Behavioral intervention trials (adults): 0 Behavioral intervention trials (adolescents): 0
	Study Population
Characteristics not clearly described	Medication-only trials: 0 Behavioral intervention trials (adults): 0 Behavioral intervention trials (adolescents): 0
No specific inclusion or exclusion criteria	Medication-only trials: 1[214] Behavioral intervention trials (adults): 1[233] Behavioral intervention trials (adolescents): 0
	Randomization
Protections against influence not in place	Medication-only trials: 6[124,214-216,218,219] Behavioral intervention trials (adults): 1[233] Behavioral intervention trials (adolescents): 0
Approach not described	Medication-only trial: 6[124,214-216,218,219] Behavioral intervention trials (adults): 1[233] Behavioral intervention trials (adolescents): 1[236]
Whether randomization had a fatal flaw not known	Medication-only trials: 6[124,214-216,218,219] Behavioral intervention trials (adults): 1[233] Behavioral intervention trials (adolescents): 2[235,236]
Comparison group(s) not similar at baseline	Medication-only trials: 3[214,215,219] Behavioral intervention trials (adults): 0 Behavioral intervention trials (adolescents): 1[236]
	Blinding
Study subjects	Medication-only trials: 4[215-217,219] Behavioral intervention trials (adults): N/A Behavioral intervention trials (adolescents): N/A
Investigators	Medication-only trials: 6[124,215-219] Behavioral intervention trials (adults): 1[220] Behavioral intervention trials (adolescents): 0

N/A, not applicable.

Table 6. Reasons for poor quality ratings and number of trials with poor ratings: anorexia nervosa (continued)

Reasons Contributing to Poor Ratings	Types of Intervention, Number of Times Flaw Was Detected, and Citations
Outcomes assessors	Medication-only trials: 6[124,215-219] Behavioral intervention trials (adults): 3[220,233,234] Behavioral intervention trials (adolescents): 2[235,236]
Interventions	
Interventions not clearly described	Medication-only trials: 0 Behavioral intervention trials (adults): 0 Behavioral intervention trials (adolescents): 0
No reliable measurement of patient compliance	Medication-only trials: 5[214-217,219] Behavioral intervention trials (adults): 1[220] Behavioral intervention trials (adolescents): 1[235]
Outcomes	
Results not clearly described	Medication-only trials: 0 Behavioral intervention trials (adults): 2[220,233] Behavioral intervention trials (adolescents): 0
Adverse events not reported	Medication-only trials: 3[214,215,217] Behavioral intervention trials (adults): 2[233,234] Behavioral intervention trials (adolescents): 1[235]
Statistical Analysis	
Statistics inappropriate	Medication-only trials: 0 Behavioral intervention trials (adults): 3[220,232,233] Behavioral intervention trials (adolescents): 0
No controls for confounding (if needed)	Medication-only trials: 3[214,218,219] Behavioral intervention trials (adults): 2[232,233] Behavioral intervention trials (adolescents): 2[235,236]
Intention-to-treat analysis not used	Medication-only trials: 5[214,215,217-219] Behavioral intervention trials (adults): 2[220,233] Behavioral intervention trials (adolescents): 2[235,236]
Power analysis not done or not reported	Medication-only trials: 7[124,214-219] Behavioral intervention trials (adults): 4[220,232-234] Behavioral intervention trials (adolescents): 1[235]

Table 6. Reasons for poor quality ratings and number of trials with poor ratings: anorexia nervosa (continued)

Reasons Contributing to Poor Ratings	Types of Intervention, Number of Times Flaw Was Detected, and Citations
	Results
Loss to followup 26% or higher or not reported	Medication-only trials: 2[214,215] Behavioral intervention trials (adults): 1[233] Behavioral intervention trials (adolescents): 0
Differential loss to followup 15% or higher or not reported	Medication-only trials: 1[214,215] Behavioral intervention trials (adults): 3[220,233,234] Behavioral intervention trials (adolescents): 1[236]
Outcome measures not standard, reliable, or valid in all groups	Medication-only trials: 0 Behavioral intervention trials (adults): 1[220] Behavioral intervention trials (adolescents): 0
	Discussion
Results do not support conclusions, taking possible biases and limitations into account	Medication-only trials: 0 Behavioral intervention trials (adults): 0 Behavioral intervention trials (adolescents): 0
Results not discussed within context of prior research	Medication-only trials: 0 Behavioral intervention trials (adults): 0
External validity: population not representative of US population relevant to these treatments	Medication-only trials: 3[215,217,218] Behavioral intervention trials (adults): 1[220] Behavioral intervention trials (adolescents): 0
Funding/sponsorship not reported	Medication-only trials: 6[214-219] Behavioral intervention trials (adults): 3[220,232,234] Behavioral intervention trials (adolescents): 1[235]

or results not presented using an intention-to-treat approach; and sources of funding not being stated.

Dropouts are a significant element in the quality of all these trials. Table 7 documents the total sample size and attrition rates in the trials reviewed in this chapter.

Participants

Of the 19 studies rated fair or good, 10 were conducted in the United States, six in the United Kingdom, two in Canada, and one in New Zealand. A total of 891 individuals participated in fair or good clinical trials for AN. One study failed to report sex. From those studies that reported sex, 861 women and 23 men participated. Seventeen studies failed to report ethnicity for participants. Of those that did, 123 participants were identified as white, eight as Asian and three as other ethnicity.

Table 7. Dropout rates for randomized controlled trials: anorexia nervosa

Author	Total Enrollment	Total Dropouts	Group 1 Treatment (% dropout)	G2 Treatment (% dropout)	G3 Treatment (% dropout)	G4 Treatment (% dropout)
Medication Trials						
Attia et al., 1998[206]	33	1 (+1 unreliable self-reporter) (3%)	Fluoxetine (NR)	Placebo (NR)		
Kaye et al., 2001[207]	39	26 (66%)	Fluoxetine (16% at 30 days, 47% at 1 year)	Placebo (5% at 30 days, 85% at 1 year)		
Biederman et al.,1985[209]	25	0 (0%)	Amitriptyline (0%)	Placebo (0%)		
Halmi et al.,1986[208]	72	18 (25%)	Amitriptyline (30%)	Cyproheptadine (25%)	Placebo (20%)	
Hill, et al., 2000[212]	15	0 (0%)	Recombinant human growth hormone (0%)	Placebo (0%)		
Klibanski et al., 1995[210]	48	4 (8%)	Estrogen/ progestin (14%)	Control (4%)		
Miller, Grieco, and Klibanski 2005[211]	38	5 (13%)	Testosterone (NR)	Placebo (NR)		
Birmingham, Goldner, and Bakan1994[213]	54	19 (35%)	Zinc (39%)	Placebo (32%)		
Behavioral Intervention Trials (Adult)						
Channon et al., 1989[225]	24	3 (13%)	CBT (0%)	Behavioral treatment (13%)	Control (25%)	
McIntosh et al., 2005[224]	56	21 (38%)	CBT (37%)	Interpersonal psychotherapy (43%)	Nonspecific supportive clinical management (31%)	
Pike et al., 2003[223]	33	3 (9%)	CBT (0%)	Nutritional counseling (20%)		
Dare et al., 2001[228]	84	30 (36%)	Focal psychotherapy (43%)	Family therapy (27%)	Cognitive analytic therapy (41%)	Routine (32%)
Treasure et al., 1995[226]	30	10 (33%)	Educational behavioral therapy (38%)	Cognitive analytic therapy (29%)		
Crisp et al., 1991[227] and Gowers et al.,1994[238]	90	17 (19%)	Inpatient (40%)	Outpatient psychotherapy/ family therapy/ dietary counseling (10%)	Group therapy (15%)	No further treatment (0%)

CBT, cognitive behavioral therapy; NR, not reported.

Table 7. Dropout rates for randomized controlled trials: anorexia nervosa (continued)

Author	Total Enrollment	Total Dropouts	Group 1 Treatment (% dropout)	G2 Treatment (% dropout)	G3 Treatment (% dropout)	G4 Treatment (% dropout)
Behavioral Intervention Trials (Adolescent)						
Eisler et al., 2000[221]	40	4 (10%)	Conjoint family therapy (11%)	Separated family therapy (10%)		
Geist et al., 2000[229]	25	0 (0%)	Family therapy (0%)	Family group psychoeducation (0%)		
Russell et al., 1987[231] and Eisler et al., 1997[239]	80	28 (35%)	Family therapy (37%)	Individual therapy (33%)		
Robin et al., 1994[230] and Robin, Siegel, and Moye 1995[237]	24	2 (8%)	Behavioral family systems therapy (8%)	Ego-oriented individual therapy (8%)		
Lock et al., 2005[222]	86	17 (20%)	Long-term treatment (24%)	Short-term treatment (16%)		

Key Question 1: Treatment Efficacy

Medication Trials

Table 8 presents results from medication treatment trials for AN, including treatment aims, setting (inpatient or outpatient), and a summary of outcomes. Similar to text, it is organized by medication class. Of the identified AN trials, eight were randomized controlled double-blind medication trials. Medication trials for AN were most commonly conducted in the context of clinical management or during or following inpatient refeeding. Of these, none reported race or ethnicity of participants, while all but one reported sex of participants; six were conducted in the United States. One study explicitly reported intention-to-treat analyses.[212] The number of participants in the medication trials ranged from 15 to 72, with the total enrollment for all medication trials being 345. Thus, the average number of patients per study was 23. Based on those studies that reported sex, this includes 319 women and 1 man.

Weight gain is the primary outcome variable in the treatment of AN. Secondary outcomes in this population include reduction of the psychological features of AN (e.g., body dissatisfaction and drive for thinness), reduction of associated behaviors such as overexercising, resumption of menses, and, in the bingeing and purging subtype, decreased binge eating and purging behaviors. Additional psychiatric outcomes include reduction in depression and anxiety.

Second-generation antidepressants. The term "second-generation antidepressants" is commonly used in the psychiatric and pharmacological literature to distinguish newer antidepressants such as selective norepinephrine reuptake inhibitors (SNRIs), selective serotonin reuptake inhibitors (SSRIs), bupropion, nefazodone, and trazodone from traditional or first-generation antidepressants such as tricyclic antidepressants and monoamine oxidase inhibitors. We adopted this term to be consistent in terminology with other research conducted in the area of psychopharmacology.

Table 8. Results from medication trials: anorexia nervosa

Source, Treatment, Setting, and Quality Score	Major Outcome Measures	Significant Change Over Time Within Groups	Significant Differences Between Groups at Endpoint	Significant Differences Between Groups in Change Over Time
Attia et al., 1998[206] Fluoxetine vs. placebo Inpatient Good	Eating: AN behavior BSQ CGI EAT YBC-EDS Biomarker: IBW Psych: BDI CGI SCL-90	Both groups experienced decreased clinician-rated ED symptoms and illness severity, ED concerns, depressed mood, obsessive-compulsive symptoms, and food preoccupation and rituals. Both groups increased percent IBW.	No statistics reported.	No differences on any measures.
Kaye et al., 2001[207] Fluoxetine vs. placebo Inpatient and outpatient Fair	Eating: YBC-EDS Biomarker: ABW Psych: HAM-A HDRS YBOCS	Fluoxetine completers experienced decreased anxious and depressed mood and increased percent ABW	No differences on any measures.	No differences on any measures.
Biederman et al., 1985[209] Amitriptyline vs. placebo Inpatient and outpatient Fair	Eating: EAT Biomarker: Weight Psych: Global severity HSCL SADS-C	No statistics reported.	No differences on any measures.	No statistics reported.

ABW, average body weight; AN, anorexia nervosa; BDI, Beck Depression Inventory; BMI, body mass index; BN, bulimia nervosa; BSQ, Body Shape Questionnaire; CGI, Clinical Global Impressions; EAT, Eating Attitudes Test; ED, eating disorders; HAM-A, Hamilton Anxiety Inventory; HAM-D, Hamilton Depression Inventory; HDRS, Hamilton Depression Rating Scale; HSCL, Hopkins Symptom Checklist; IBW, ideal body weight; Psych, psychiatric and psychological; *rhGH*, recombinant human grown hormone; SADS-C, Schedule for Affective Disorders and Schizophrenia-Change Version; SCL-90, (Hopkins) Symptom Checklist; tx, treatment; vs., versus; YBC-EDS, Yale-Brown-Cornell Eating Disorders Scale; YBOCS, Yale-Brown Obsessive-Compulsive scale.

Table 8. Results from medication trials: anorexia nervosa (continued)

Source, Treatment, Setting, and Quality Score	Major Outcome Measures	Significant Change Over Time Within Groups	Significant Differences Between Groups at Endpoint	Significant Differences Between Groups in Change Over Time
Halmi et al., 1986[208] Amitriptyline vs. cyproheptadine vs. placebo Inpatient Fair	Eating: Caloric intake Biomarker: Weight Psych: HAM-D BDI SCL-90	No statistics reported.	Cyproheptadine associated with fewer days to target weight, higher caloric intake, and less depressed mood compared to placebo. BN subgroup: amitriptyline associated with improved tx efficacy compared to cyproheptadine; neither drug differed from placebo. For non-BN subgroup: cyproheptadine associated with improved tx efficacy compared to placebo. No other subgroup comparisons were significant.	No statistics reported.
Hill et al., 2000[212] *rhGH* vs. placebo Inpatient Good	Biomarker: Orthostasis Weight	No statistics reported.	*rhGH* associated with fewer days to restoration of normal orthostatic response compared to placebo.	No statistics reported.
Klibanski et al., 1995[210] Estrogen/ progestin vs. nonmedication control Outpatient Fair	Eating: Recovery Remission Biomarker: Bone density Percent Body fat Percent IBW Weight	No statistics reported.	No differences on any measures.	No differences on any measures.
Miller et al., 2005[211] Testosterone vs. placebo Setting unknown Fair	Biomarker: BMI IBW Psych: BDI	No statistics reported.	Testosterone associated with less depressed mood compared to placebo.	Depressed mood increased less in testosterone-treated group.
Birmingham et al., 1994[213] Zinc vs. placebo Inpatient Fair	Biomarker: BMI Percent body fat Weight	No statistics reported.	No differences on any measures.	Zinc superior to placebo in rate of BMI increase.

Fluoxetine. Two trials used fluoxetine at different stages of refeeding in AN patients. In an inpatient study, Attia et al.[206] randomized 31 females between 16 and 45 years who had achieved weight restoration of at least 65 percent of ideal body weight (IBW) to fluoxetine (60 mg/day) or placebo. The mean BMI at randomization was 15 kg/m^2. Patients continued to receive psychotherapy. No significant differences emerged between fluoxetine and placebo on weight gain (16 versus 13 pounds), psychological features of eating disorders, or depression or anxiety measures. Three percent of participants dropped out of fluoxetine treatment.

In the second study, patients were randomly assigned to either initiation on fluoxetine or placebo before inpatient discharge with a beginning dosage of 20 mg/day adjusted over 52 weeks to a maximum of 60 mg/day.[207] The range of weight for all participants at randomization was 76 percent to 100 percent average body weight (ABW) with the majority above 90 percent. Outpatient psychotherapy was permitted. Dropout was considerable. Of 39 individuals randomized, only 13 remained at the 52-week endpoint (47 percent of fluoxetine and 85 percent of placebo). In this small group of completers, fluoxetine was associated with significantly greater weight gain, reduced anxiety, depression, obsessive-compulsive features, and eating-disorder-related symptoms.

Tricyclic antidepressants. Two trials of fair or good quality investigated tricyclic antidepressant medication use. Neither provided strong data supporting the use of these medications in treating AN patients.

Amitriptyline in doses up to 175 mg/day in 25 youth ages 11 to 17 years led to no significant differences in eating, mood, or weight outcomes in comparison to placebo.[209] No patients dropped out in this trial. Halmi et al. compared amitriptyline (160 mg/day) versus cyproheptadine (32 mg/day) versus placebo in 72 females 13 to 36 years, determined to have AN according to the Diagnostic and Statistical Manual, third edition (DSM III).[208] Daily caloric intake was significantly higher in cyproheptadine than placebo and significantly fewer days were needed to achieve target weight (in those who did) in both the amitriptyline and cyproheptadine groups, compared with placebo. Drop out was thirty percent in the amitriptyline group, 25 percent in the cyproheptadine group, and 20 percent in the placebo group.

Hormones. Investigators have studied three hormones in the treatment of AN: growth hormone (rGH), testosterone, and estrogen. Three weeks of transdermal testosterone (150 mg or 330 mg) administered to 38 patients with AN ages 18 to 50 led to greater decreases in depression in patients who were depressed at baseline, but differences in weight were not interpretable.[211] Dropout was 13 percent overall.

Growth hormone (15 mg/kg/day) administered to 14 female and 1 male patient receiving inpatient care for AN led to fewer days to display normal orthostatic heart rate response to a standing challenge among the treatment group than among placebo group.[212] No patient dropped out of this study.

Klibanski et al. compared estrogen/progesterone (0.625 mg Premarin® or 5 mg Provera® per day) versus nonmedication control in 48 females 16 to 43 years and found no differences between groups on bone density at 6 months.[210] Dropout was 14 percent in hormone group and 4 percent in the nonmedication group.

Hormone treatment during the acute phase of AN illness does not appear to improve bone density.[210] Scant, preliminary evidence suggests that rGH leads to faster normalization of orthostatic changes seen in AN[212]and that testosterone improves depression in individuals with AN and depressed mood.[211]

Nutritional supplements. The one study of nutritional supplements was performed in 54 female inpatients older than 15 years with 14 mg/day zinc. It provides preliminary evidence that zinc may increase the rate of increase in BMI.[213] Dropout was 39 percent in zinc and 32 percent in placebo, suggesting that conclusions from this study must be viewed with great caution.

Summary of drug trials. All eight studies assessing the efficacy of medication interventions on AN examined weight gain; most reported on eating outcomes and some reported on additional symptom change.

Overall, none of the pharmacological interventions for AN had a significant impact on weight gain. Although tricyclic antidepressants may be associated with greater improvement in secondary mood outcomes, this outcome does not appear to be associated with improved weight gain. No trial has been adequately replicated.

Dropout rates for medication studies for AN are substantial, especially in outpatient trials. Conclusions drawn from studies with such high attrition must be reviewed with extreme caution.

Taken together, the literature regarding medication treatments for AN is sparse and inconclusive. The vast majority of studies had small sample sizes and rarely had adequate statistical power to allow for definitive conclusions. Many studies examined patients who were receiving additional treatments in conjunction with the study medication, including psychological interventions and concurrent pharmacological treatments. Some of these studies examined patients who were in inpatient settings, thus limiting generalizability to outpatient treatment. Only one conducted intention-to-treat analyses; the remaining studies reported completer analyses only. With one exception,[209] no medication trials have focused on adolescent patients. Because followup was limited, assessing longer-term impact of interventions on such outcomes as bone density was impossible. Finally, only one male participated in any of these studies, thereby making it impossible to draw any conclusions about the pharmacological treatment of AN in boys and men.

Behavioral Intervention Trials

Of the 11 behavior trials rated good or fair (Tables 9 and 10), four focused solely on adolescents (mean ages 14 to 15), six focused solely on adults (approximately 18 years and older), and one combined adolescent and adult patients. Of the 11 trials, four were conducted in the United States. We present behavioral interventions for adults with AN in Table 9.

Behavioral interventions for adults with anorexia nervosa. In the psychotherapy trials for adults only and the combined adult and adolescent trials, investigators tested CBT (three trials), various types of nonspecific therapy (three), family therapies (two), CAT (two), dietary counseling (one), interpersonal psychotherapy (IPT) (one), behavioral therapy (BT) (one), and focal analytic therapy (one).

Cognitive behavioral therapy. CBT studies generally used a form of therapy tailored to AN that focused on cognitive and behavioral features associated with the maintenance of eating pathology. Of the three CBT studies, one followed inpatient weight restoration[223] and two were done in the underweight state.[224,225] CBT significantly reduced relapse risk and increased the likelihood of good outcome compared to nutritional counseling based on nutritional education and food exchanges after inpatient weight restoration.[223] Of those receiving CBT, a greater number of individuals with good outcomes were also receiving antidepressant medication.

One study of underweight AN outpatients compared CBT with IPT and nonspecific supportive clinical management (NSCM).[224] IPT in the treatment of AN is based on IPT used for the treatment of depression[240] and BN;[241] it focuses on one of four interpersonal problem areas:

Table 9. Results from behavioral intervention trials in adults: anorexia nervosa

Source, Treatment, Setting, and Quality Score	Major Outcome Measures	Significant Change Over Time Within Groups	Significant Differences Between Groups at Endpoint	Significant Differences Between Groups in Change Over Time
Channon et al., 1989[225] CBT vs. BT vs. 'Usual care' control Outpatient Fair	Eating: EDI M-R scale Biomarker: BMI M-R scale Psych: BDI MOCI M-R scale	No statistics reported.	At 6-month FU, CBT associated with better psychosexual functioning than BT and BT was associated with greater improvement in menstrual functioning than CBT. At 1-year FU, the BT group scored better than the CBT group on preferred weight. CBT and BT combined were associated with greater improvements on nutritional functioning than the control group. The control group showed greater improvements on drive for thinness than the combined CBT and BT groups.	No statistics reported.
McIntosh et al., 2005[224] CBT vs. IPT vs. NSCM Outpatient Fair	Eating: EDE EDI Biomarker: BMI Percent body fat Weight Psych: GAF HDRS		Compared to IPT, NSCM associated with higher likelihood of 'good' global outcome.	NSCM superior to IPT in improving global functioning and eating restraint over 20 weeks. NSCM superior to CBT in improving global functioning over 20 weeks. CBT superior to IPT in improving eating restraint over 20 weeks.
Pike et al., 2003[223] CBT vs. nutritional counseling Outpatient Fair	Eating: Recovery Relapse Tx failure M-R scale	No statistics reported.	Compared to nutrition counseling, CBT associated with lower percentage tx failures, higher percentage 'good' outcome, and longer time (weeks) to relapse.	No statistics reported.

ABW, average body weight; BDI, Beck Depression Inventory; BMI, body mass index; BT, behavioral therapy; CAT, cognitive-analytic therapy; CBT, cognitive behavioral therapy; EBT, educational behavioral therapy; EDE, Eating Disorders Examination; EDI, Eating Disorders Inventory (EDI-2, Garner, 1991); FU, follow-up; GAF, Global Assessment of Functioning [DSM-IV]; HDRS, Hamilton Depression Rating Scale; IBW, ideal body weight; IPT, interpersonal therapy; MOCI, Maudsley Obsessional Compulsive Index; M-R, Morgan and Russell; NSCM, nonspecific supported clinical management, Psych, psychiatric and psychological; pt, patients; Tx, treatment, vs., versus.

Table 9. Results from behavioral intervention trials in adults: anorexia nervosa (continued)

Source, Treatment, Setting, and Quality Score	Major Outcome Measures	Significant Change Over Time Within Groups	Significant Differences Between Groups at Endpoint	Significant Differences Between Groups in Change Over Time
Dare et al., 2001[228] CAT vs. focal vs. family vs. 'routine' therapy Outpatient Fair	Eating: M-R scale Recovery Biomarker: BMI Percent ABW M-R scale Psych: M-R scale	No statistics reported.	At 1-year FU, compared to routine tx, focal and family tx associated with higher weight; also, higher percentage of patients in focal and family tx were recovered or significantly improved (i.e., > 85% IBW, no/few menstrual or BN symptoms).	No statistics reported.
Treasure et al., 1995[226] CAT vs. EBT Outpatient Fair	Eating: M-R scales Biomarker: BMI Weight Psych: M-R scales Self progress scale	No statistics reported.	Compared to EBT, CAT associated with higher self-rating of improvement.	No statistics reported.
Crisp et al., 1991[227] and Gowers et al., 1994[238] Inpatient tx vs. outpatient individual and family therapy and dietary counseling vs. group therapy vs. no formal tx Inpatient and outpatient Fair	Eating: M-R scale Remission Biomarker: BMI M-R scale Weight Psych: M-R scale	At 1-year FU, global score and menstruation improved in all 4 groups, nutrition score improved in 3 active tx groups, and mental state improved in outpatient family/diet counseling group. At 2-year FU, mental state improved in outpatient family/diet counseling; global score, menstruation, and nutrition improved in groups that received outpatient family/diet counseling and no formal tx.	Compared to 'no formal tx', outpatient family/diet counseling associated with higher weight and BMI at 1- and 2-year FU.	Compared to 'no formal tx,' weight increased more at 1-year FU in all 3 active groups. Weight increased more at 2-year FU in outpatient family/diet counseling compared to 'no formal tx' group.

Table 10. Results from behavioral intervention trials in adolescents only and adolescents and adults combined: anorexia nervosa

Source, Treatment, Setting, and Quality Score	Major Outcome Measures	Significant Change Over Time Within Groups	Significant Differences Between Groups at Endpoint	Significant Differences Between Groups in Change Over Time
Eisler et al., 2000[221] CFT vs. SFT Outpatient Good	Eating: Bulimic symptoms EAT EDI Biomarker: Percent ABW BMI Weight Psych: MOCI SMFQ Depression Obsessionality	No statistics reported.	No statistics reported.	CFT superior to SFT in reducing ED-related traits, depression, and obsessionality.
Geist et al., 2000[229] Family therapy vs. family group psycho-education Inpatient Fair	Eating: EDI Biomarker: Percent IBW Psych: BSI CDI FAM III	No statistics reported.	No differences on any measures.	No differences on any measures.
Russell et al., 1987[231] and Eisler et al., 1997[239] Family therapy vs. individual therapy Outpatient Fair	Eating: M-R scales Readmit rate Biomarker: Percent ABW M-R scales Weight Psych: M-R scales	No statistics reported.	No statistics reported.	Among early onset, less chronic AN patients, family therapy superior to individual therapy in improving nutritional status, menstrual and psychosexual function, and weight over 1 year tx; family therapy also more likely associated with a 'good' outcome over 1-year tx and 5-year FU.

ABW, average body weight; AN, anorexia nervosa; BDI, Beck Depression Inventory; BFST, behavioral family systems therapy; BMI, body mass index; BSI, Brief Symptom Inventory; BSQ, Body Shape Questionnaire; CDI, Children's Depression Inventory; CFT, conjoint family therapy; EAT, Eating Attitudes Test; ED, eating disorders; EDE, Eating Disorders Examination; EDI, Eating Disorders Inventory; EOIT, ego-oriented individual therapy; FAM-III, Family Assessment Measure; FU, follow-up; IBC, Interaction Behavior Code; IBW, ideal body weight; MOCI, Maudsley Obsessional Compulsive Index; M-R, Morgan and Russell; PARQ, Parent Adolescent Relationship Questionnaire; Psych, psychiatric and psychological; SFT, separated family therapy; SMFQ, Short Mood and Feeling Questionnaire; tx, treatment; vs., versus; YBC-EDS, Yale-Brown-Cornell Eating Disorders Scale.

Table 10. Results from behavioral intervention trials in adolescents only and adolescents and adults combined: anorexia nervosa (continued)

Source, Treatment, Setting, and Quality Score	Major Outcome Measures	Significant Change Over Time Within Groups	Significant Differences Between Groups at Endpoint	Significant Differences Between Groups in Change Over Time
Robin et al., 1994[230] and Robin et al., 1995[237] BFST vs. EOIT Outpatient and inpatient Fair	Eating: EAT EDI Eating conflict Biomarker: BMI Weight Menstruation Psych: BDI BSQ PARQ IBC	No statistics reported.	No differences on any measures.	BFST superior to EOIT in increasing BMI to post-tx and 1-year FU, and in improving mother's positive communication at FU.
Lock et al., 2005[222] Long-term vs. short-term family therapy Outpatient Good	Eating: EDE YBC-EDS Biomarker: BMI Weight	No differences on any measures.	No differences on any measures.	No differences on any measures among those with most severe YBC-EDS symptoms. Longer-term tx associated with better BMI outcome in those with most severe ED symptoms, and with better EDE global outcome in those with non-intact families.

interpersonal disputes, role transitions, grief, or interpersonal deficits. NSCM was designed for this study to mimic the type of treatment an individual could receive in the community from a provider familiar with the treatment of ED and incorporates elements of sound clinical management and supportive psychotherapy. In an intention-to-treat analysis, NSCM performed significantly better than IPT in producing global good outcome ratings; CBT outcomes fell in between and were not significantly different from the other two outcomes.[224] The second study compared CBT with BT and a control group for 6 months.[225] At 12-month followup, CBT showed no advantage over BT or control in eating, mood, or weight outcomes.

On the basis of one trial, preliminary evidence suggests that CBT delivered after weight restoration may help to decrease relapse. In contrast, when delivered during the acute phase of the illness, CBT does not appear to offer significant advantage over NSCM, which did offer advantage over IPT. No evidence suggests that nutritional counseling alone is efficacious in the treatment of AN.

Cognitive analytic therapy (CAT). The two studies that utilized CAT, a treatment which integrates psychodynamic with behavioral factors and focuses on interpersonal and transference issues, failed to find any advantage of CAT over educational behavioral therapy or focal family therapy in eating, mood, or weight outcomes.[226,228] Focal family therapy focused on eliminating

the eating disorder from its controlling role in determining the relationship between the patient and other family members.

Family therapy. Of the three studies in this category, Dare et al. found family therapy to be superior to routine treatment but equivalent to a focal time-limited psychodynamic psychotherapy in increasing percentage of adult body weight, restoring menstruation, and decreasing bulimic symptoms; overall clinical improvement was modest, however.[228]

Crisp et al.[227] found outpatient individual and family therapy with variable numbers of sessions to be superior to referral to a family physician for increased weight at 1- and 2-year followup.

The efficacy of family therapy in treating adults with AN has not yet been completely addressed. It may be more effective than medical management by a family physician and routine treatment; family therapy (including the family of origin) may be more effective in younger patients with shorter duration of illness. No studies have explored family therapy for adult patients that included the family of insertion (spouse and offspring of the patient) rather than the family of origin.

Behavioral interventions for adolescents with anorexia nervosa. We present behavioral interventions for adolescents with AN in Table 10.

Family therapy. Four family therapy studies focused exclusively on adolescents and one combined adolescent and adult patients.[231] Family therapy was more effective for younger patients with earlier onset than for older patients with a more chronic course in the United Kingdom trial performed by Russell et al.[231] and the followup by Eisler et al.[239] These studies did not yield evidence that the specific type of family therapy administered was helpful for the older more chronic group.[228,231] A form of family therapy focusing initially on parental control of re-nutrition delivered in two different manners revealed a significant advantage of conjoint therapy (family treated as a unit) over separated family therapy (parents and patient seen separately) on eating and mood outcomes but not on weight outcomes.[221]

In a second study, no differences emerged between family therapy and family psychoeducation on any outcomes at 16 weeks.[229] For a specific form of family therapy, when delivered in conjunction with a common medical and dietary regimen, behavioral family systems therapy (BFST), also characterized initially by parents taking control of renutrition, Robin et al. found BFST to be superior to ego-oriented individual therapy in increasing BMI and restoring menstruation, although neither therapy was superior on eating or mood outcomes.[230,237] Addressing the issue of optimal duration of family therapy, Lock et al. randomized adolescents to either short (10 sessions over 6 months) or long (20 sessions over 12 months) manualized family therapy based on the initial parental control of refeeding model[242] and found no differences on eating, psychiatric, or biomarker outcomes.[222] Longer-term family therapy suggested that those with more severe eating-related obsessions and nonintact families did better with longer treatment. Finally, in the one study that included both adolescents and adults, family therapy was superior to individual therapy for adolescent patients with shorter duration of illness. This difference did not emerge for adult patients with longer duration of illness.[231] Although few differences were observed across interventions, specific forms of family interventions did consistently show improvement over time with adolescent patients.

Summary of behavioral interventions for adults and adolescents with anorexia nervosa. Overall, one study of adults provides tentative evidence that CBT may reduce relapse risk for adults with AN after weight restoration has been accomplished.[223] Sufficient evidence does not exist to determine whether CBT is effective during the acute phase of the illness (i.e., in the

underweight state before weight restoration); one study found that a manualized nonspecific supportive treatment (NCSM) was more effective than CBT or IPT in terms of global outcome during the acute phase.[224] The three family therapy studies provide no support for the efficacy of the type of family therapy delivered in adults with AN with longer duration of illness; the superiority of this approach for younger patients with a shorter illness course is based on one study.[231] Two studies failed to find any benefit of CAT for eating, mood, or weight outcomes when compared to other treatments for this population.[226,228] No methodologically sound studies that systematically tested combinations of medication and psychotherapy were identified.

Serious methodological concerns arose with some of these trials. Two were very small (8 to 12 participants per group),[225,230] which does not provide adequate statistical power for the comparative analyses conducted. In addition, both had marked pretreatment differences between groups. Failure to control for contact time with a clinician while comparing multiple treatments, with some groups getting up to 80 percent more time in treatment than others, was another problem.[228] In addition, only one group of researchers conducted a follow-up study to determine the long-term impact of their interventions.[239]

Five studies evaluated family therapy in adolescents with AN. Overall, family therapy based on principles of parental control of initial refeeding leads to clinically meaningful weight gain and psychological change. However, the majority of family therapy studies compares one form of family therapy to another form and were underpowered to detect significant differences between active similar treatments. One study suggested that family therapy was superior to a non-family therapy comparison intervention for adolescent patients with relatively short duration of illness.[231] One additional study reported significantly greater weight gain at the end of treatment in family therapy than in ego-oriented individual therapy for adolescent AN patients.[230] The other three studies all involved some sort of family treatment – either comparing conjoint to separated family therapy or comparing family therapy to family psychoeducation.[221,229] Conjoint therapy was superior to separated family therapy for improving eating and mood but not weight outcomes.[221] Similarly, one study examining family therapy versus family psychoeducation found no differences between groups.[229]

Inadequate statistical power was a common problem among the behavioral interventions in AN, and power calculations were rarely reported. No studies had a pure no-treatment condition, which is appropriate given the gravity of the illness, although “usual” treatment took various forms. Many of these studies had adequate power to detect pre-post within-group differences or differences between no treatment and an active treatment, but few were adequately powered to detect differences across two or more treatment groups.

Key Question 2: Harms of Treatment for Anorexia Nervosa

Table 11 presents adverse events associated with treatments for AN reported in each of the 32 studies reviewed. Assuming that all relevant adverse events were reported, the most common was the need for inpatient treatment among participants in an outpatient trial. Eight studies reported that one or more participants dropped out because of the need for inpatient treatment. In one study, a participant died before commencing the intervention. In these cases, the events observed may be more ongoing features of the course of illness than an adverse event caused by the intervention per se. In behavioral interventions, physical and psychological harms of interventions are rarely reported.

For the trials using second-generation antidepressants, we refer to recent publications on the comparative effectiveness and tolerability of second-generation antidepressants.[243] Common side

Table 11. Adverse events reported: anorexia nervosa

Intervention	Adverse Events Reported*
Medication Trials	
Fluoxetine vs. placebo[206]	Fluoxetine group: insomnia and agitation; blurred vision
Fluoxetine vs. placebo[207]	No adverse events observed
Amitriptyline vs. cyproheptadine vs. placebo[208]	Amitriptyline: drowsiness, excitement, confusion, increased motor activity, tachycardia, dry mouth, constipation. Cyproheptadine: no consistent pattern observed Placebo: drowsiness, excitement, increased motor activity.
Amitriptyline vs. placebo[209]	Amitriptyline group: diaphoresis (2), drowsiness (6), dry mouth (4), blurred vision (1), urinary retention (1), hypotension (2), leucopenia (1) Placebo: dry mouth (2), palpitations (1), dizziness (2)
Estrogen vs. nonmedication control[210]	Estrogen group: depression (1), hyperlipidemia (1)
Growth hormone vs. placebo[212]	No adverse events observed
Testosterone vs. placebo[211]	Testosterone group: Mild skin irritation at patch site (3), increased depression (1), increased fatigue and vertigo (1), nausea (1) Placebo: Mild skin irritation at patch site (1)
Zinc vs. placebo[213]	NR
Behavioral Interventions Trials	
Behavioral family systems vs. ego-oriented individual[230,237]	NR
CBT vs. behavioral therapy vs. control[225]	NR
CBT vs. interpersonal psychotherapy vs. nonspecific supportive clinical management[224]	No adverse events observed
CBT vs. nutritional counseling[223]	CBT: Depression and suicidal ideation (1) Nutritional: Depression and suicidal ideation (3)
Cognitive analytical vs. educational behavioral[226]	NR
Conjoint family vs. separated family[221]	NR
Family therapy vs. family group psychoeducation[229]	NR
Family therapy vs. nonspecific individual[231,239]	NR
Focal psychotherapy vs. family therapy vs. cognitive analytical vs. routine treatment[228]	NR
Inpatient + 12 individual/family vs. outpatient individual/family variable vs. 10 outpatient group vs. family physician vs. dietary counseling[227,238]	NR
Short- vs. long-term family therapy[222]	NR: Dropout attributed to other psychological problems

CBT, cognitive behavioral therapy; NR, not reported; vs., versus.
* If no numbers appear in parentheses, authors had only listed adverse events but not reported the number of cases.

effects associated with the use of second-generation antidepressants in major depressive disorder are nausea, headache, diarrhea, constipation, dizziness, fatigue, sweating, and sexual side effects. Rare but severe adverse events include hyponatremia, suicidality, and seizures. Up to 90 percent of patients experienced at least one adverse event during treatment. Overall, discontinuation rates attributed to adverse events did not differ significantly among individual drugs and ranged from 6 percent to 14 percent. The authors report no substantial differences in adverse events with

respect to drugs that were also used in eating disorders trials (i.e., citalopram, fluoxetine, fluvoxamine, and sertraline).

Given the small sample sizes and completion rates of the two fluoxetine trials, we cannot draw definitive conclusions regarding whether harms associated with fluoxetine treatment in the underweight state differ in any way from treatment of normal-weight individuals with other psychiatric diagnoses. In these studies, Kaye et al. failed to report adverse events;[207] Attia et al. reported one case of insomnia and agitation and one case of blurred vision.[206]

For tricyclic antidepressants, Halmi et al. reported sporadic cases of drowsiness, excitement, confusion, increased motor activity, tachycardia, dry mouth, and constipation associated with amitriptyline;[208] however, the rate of adverse events did not differ from placebo.

The only specific adverse event associated with testosterone administration was skin irritation at the patch site. Estrogen administration yielded one case of depression and one of hyperlipidemia. No adverse effects were reported with either growth hormone or zinc administration.

Key Question 3: Factors Associated With Treatment Efficacy

We found no consistent factors associated with better or poorer treatment outcome across studies. In medication studies, individuals with the nonbulimic subtype of AN had better therapeutic outcomes on cyprohoptadine than amitriptyline and placebo.[208] Bone density increased more in women with AN who were less than 70 percent of ideal body weight on estrogen replacement therapy.[210] These subgroup analyses had very small samples, and conclusions should be regarded as tentative.

One observation that was an artifact of experimental design,[223] post-weight restoration trial of CBT and nutritional counseling is related to patients being permitted to be on antidepressant medication. In one trial, a significantly higher percentage of CBT successes occurred among patients on medication. Miller et al.[211] reported that 3 weeks of transdermal testosterone was superior in decreasing depression in individuals who were depressed at baseline.

In terms of family therapy, Lock et al. found that adolescents with severe eating-related obsessive-compulsive-related thinking and those who come from nonintact families benefitted from longer-term rather than shorter-term manual-based family therapy treatment.[222] Eisler et al. found that families that scored higher on maternal criticism did better in separated rather than conjoint family therapy.[221]

Finally, with reference to weight gain, family therapy was more effective for AN patients whose illness began at an early age and had not become chronic.[231,239]

Key Question 4: Treatment Efficacy by Subgroups

The total number of individuals enrolled in the eight medication trials that reported the sex of the participants was 320. Of those, one was male. No medication studies reported differential outcome by age. With the exception of the one rGH trial[212] and one amitriptyline trial,[209] no medication studies have explicitly focused on the treatment of adolescent AN. Not a single medication study reported race or ethnicity of participants. Of the eight trials, seven were conducted in the United States and one in Canada. Based on these results, we conclude that no information exists regarding differential efficacy of pharmacotherapy interventions for AN by sex, gender, age, race, ethnicity, or cultural group.

The total number of individuals enrolled in the 11 psychotherapy trials was 572; of these, 22 were men or boys. Only two trials reported race or ethnicity of participants; they included eight Asian Americans, 10 Hispanic Americans, no African Americans, and three individuals of "other" race or ethnicity. In no instance were results analyzed specifically by race or ethnic group. No data exist regarding differential efficacy of psychotherapeutic treatment for AN by sex, gender, race, ethnicity, or cultural group.

In terms of age, scant evidence shows that interventions involving the family have greater efficacy for individuals below the age of 15 than for patients above that age. This information is based solely on studies by just one team of investigators who found family therapy to be more effective for adolescent AN patients with a shorter duration of illness than for adults with a more chronic course.[231,239] However, no definitive replications have been done. Moreover, no studies have explored the role of family therapy in adults focusing on the family of insertion rather than family of origin, which may be the relevant comparison, or other adaptation of family therapy for adults or adolescents.

Chapter 4. Results: Bulimia Nervosa

This chapter presents results of our literature search and our findings for the four key questions (KQs) that pertain to bulimia nervosa (BN), including the efficacy of various treatments or combinations of treatments (KQ 1), harms associated with the treatment or combination of treatments (KQ 2), factors associated with the efficacy of treatment (KQ 3), and whether the efficacy of treatment differs by sex, gender, age, race, ethnicity, or cultural groups (KQ 4).

We report specific details about the yields of the literature searches and characteristics of the studies. For each included study, detailed evidence tables appear in Appendix C.[**] We report first on medication trials (Evidence Table 5), then combined medication and behavioral interventions (Evidence Table 6), behavioral interventions (Evidence Table 7), self-help interventions (Evidence Table 8), and other interventions (Evidence Table 9). Within each evidence table, studies are listed alphabetically by author. Summary tables in this chapter present selected outcomes by type of intervention.

Overview of Included Studies

We identified 47 studies reported in 58 publications addressing treatment efficacy for BN. Of these, 14 were medication-only trials.[244-257] We rated two of these trials as good,[246,248] 9 as fair,[244,247,249-255,257] and three as poor.[245,256,258] The drugs studied included second-generation antidepressants,[244,247-250,252,254,255] tricyclic antidepressants,[257] an anticonvulsant,[251,259] monoamine-oxidase inhibitors (MAOIs),[253] and a 5HT3 antagonist.[246]

Six trials combined medication with behavioral interventions.[260-265] Three used second-generation antidepressants,[261,262,265] one used a tricyclic antidepressant,[260] and two used both a second-generation antidepressant and a tricyclic antidepressant sequentially.[263,264] Of these, we rated two as good[264,265] and four as fair.[260-263]

We identified 19 behavioral intervention psychotherapy studies published in 24 articles.[266-289] We rated three psychotherapy intervention trials as good,[269,270,282] 10 as fair,[266,273,274,276,278,280,281,283,287,288] and six as poor.[275,279,284-286,289] Of the 13 fair- and good-rated studies, 11 used some form of cognitive-behavioral therapy (CBT) in comparison to other interventions,[266,269,270,273,274,276,278,280,283,287,288] one used dialectical behavior therapy (DBT),[282] and one used nutritional management and stress management.[281]

We also identified five trials of various self-help methods.[290-294] We rated four as fair[290-293] and one as poor.[294]

Finally, we identified three studies of "other" interventions including active light,[295] guided imagery,[296] and crisis prevention.[297] We rated all three studies as fair.

Of the 47 studies addressing treatment efficacy for BN, we rated 10 as poor. Studies with a quality rating of "poor" are not discussed below. Reasons that these studies received this rating are presented in Table 12. Although each study was not lacking in all areas, the most common concerns contributing to the low rating included a fatal flaw in the approach to randomization or the approach not being described, assessors not being blinded or their blinding status not being described, adverse events not being reported, outcomes not being reported using an intention-to-

[**] Appendixes cited in this report are provided electronically at http://www.ahrq.gov/downloads/pub/evidence/pdf/eatingdisorders/eatdis.pdf.

Table 12. Reasons for poor quality ratings and number of trials with poor ratings: bulimia nervosa

Reasons Contributing to Poor Ratings	Types of Intervention, Number of Times Flaw Was Detected, and Citations
	Research Aims
Hypothesis not clearly described	Medication-only trials: 0 Behavioral intervention and self-help trials: 0
	Study Population
Characteristics not clearly described	Medication-only trials: 0 Behavioral intervention and self-help trials: 1[289]
No specific inclusion or exclusion criteria	Medication-only trials: 0 Behavioral intervention and self-help trials: 0
	Randomization
Protections against influence not in place	Medication-only trials: 0 Behavioral intervention and self-help trials: 1[284]
Approach not described	Medication-only trials: 1[245] Behavioral intervention and self-help trials: 4[275,279,284,294,298]
Whether randomization had a fatal flaw not known	Medication-only trials: 2[245,256] Behavioral intervention and self-help trials: 6[275,279,284,286,289,294,298]
Comparison group(s) not similar at baseline	Medication-only trials: 2[245,256] Behavioral intervention and self-help trials: 1[289]
	Blinding
Study subjects	Medication-only trials: 0 Behavioral intervention and self-help trials: 1[289]
Investigators	Medication-only trials: 0 Behavioral intervention and self-help trials: 1[289]
Outcomes assessors	Medication-only trials: 2[245,256] Behavioral intervention and self-help trials: 7[275,279,284-286,289,294,298]
	Interventions
Interventions not clearly described	Medication-only trials: 0 Behavioral intervention and self-help trials: 0
No reliable measurement of patient compliance	Medication-only trials: 1[256] Behavioral intervention and self-help trials: 3[279,285,289]
	Outcomes
Results not clearly described	Medication-only trials: 0 Behavioral intervention and self-help trials: 0
Adverse events not reported	Medication-only trials: 0 Behavioral intervention and self-help trials: 6[275,279,284-286,289]

Table 12. Reasons for poor quality ratings and number of trials with poor ratings: bulimia nervosa (continued)

Reasons Contributing to Poor Ratings	Types of Intervention, Number of Times Flaw Was Detected, and Citations
	Statistical Analysis
Statistics inappropriate	Medication-only trials: 0 Behavioral intervention and self-help trials: 0
No controls for confounding (if needed)	Medication-only trials: 1[245] Behavioral intervention and self-help trials: 1[289]
Intention-to-treat analysis not used	Medication-only trials: 1[256] Behavioral intervention and self-help trials: 5[275,284-286,289]
Power analysis not done or not reported	Medication-only trials: 1[245] Behavioral intervention and self-help trials: 7[275,279,284-286,289,294,298]
	Results
Loss to followup 26% or higher or not reported	Medication-only trials: 0 Behavioral intervention and self-help trials: 2[289,294,298]
Differential loss to followup 15% or higher or not reported	Medication-only trials: 1[245] Behavioral intervention and self-help trials: 3[275,286,289]
Outcome measures not standard, reliable, or valid in all groups	Medication-only trials: 0 Behavioral intervention and self-help trials: 0
	Discussion
Results do not support conclusions, taking possible biases and limitations into account	Medication-only trials: 0 Behavioral intervention and self-help trials: 0
Results not discussed within context of prior research	Medication-only trials: 1[256] Behavioral intervention and self-help trials: 0
External validity: population not representative of US population relevant to these treatments	Medication-only trials: 1[256] Behavioral intervention and self-help trials: 6[279,284-286,289,294,298]
Funding/sponsorship not reported	Medication-only trials: 0 Behavioral intervention and self-help trials: 4[279,285,286,289]

treat approach, the statistical analysis not including a power analysis or not stating whether one was conducted, and concerns in relation to the external validity of the findings (the study population was not representative of the US population or the information of provided was insufficient to determine representativeness).

Participants

Of the 38 studies rated fair or good, 19 were conducted in the United States, five in Canada, four in Germany, three in the United Kingdom, two in Australia, and one each in Austria,

Finland, New Zealand, and Norway. In addition, one multinational trial had US and Canadian sites; another had German and Australian sites.

Of the fair and good studies, three failed to report the age of participants; of the remainder, the age range of participants was 16 to 61 years with the majority of participants being adults. A total of 3,403 individuals participated in fair or good clinical trials for BN. From those that reported sex, 2,985 women and 23 men participated.

Thirty-one studies failed to report the race or ethnicity of participants. Of those that did, 1,203 participants were identified as white, 79 as nonwhite, 27 as African American, 40 as Hispanic American, 30 as Asian or Pacific Islander, and one as Native American.

Similar to the AN studies, some BN trials also had high attrition. Table 13 documents the percentages of dropouts in total and in each arm of the study. Three studies had five study groups; those are combined with information relating to the fourth treatment group.

Key Question 1: Treatment Efficacy

Medication-only Trials

We report on 12 randomized controlled double-blind medication-only trials (Table 14). The total number of individuals enrolled was 1,430. Based on studies that reported sex, 1,364 women and 21 men participated in medication-only trials. The number of participants ranged from 26 to 398. The age of participants ranged from 16 to 55. Two trials reported the race of participants; in these, 521 individuals were reported as white and 27 as nonwhite. Seven trials were conducted in the United States, two in Canada, and one each in Australia, Germany, and Finland.

The medication-only trials used the following two designs: medication versus placebo (10) and medication (dose a) versus medication (dose b) versus placebo (1). The results of these studies are presented below by drug class.

Second-generation antidepressants. *Fluoxetine.* Six trials compared fluoxetine to placebo in outpatient and inpatient settings. The mean age of participants was mid-twenties; no studies of fluoxetine focused exclusively on adolescents.

Overall, fluoxetine (60 mg/day) administered for between 8 weeks and 16 weeks led to significant reductions in binge eating in most[244,249,250,254] but not all studies.[248,252] Fluoxetine (60 mg/day) also performed significantly better than fluoxetine (20 mg/day) in decreasing binge eating.[249] No effect of fluoxetine (60 mg/day) compared with placebo was observed in the one study in which patients were already receiving intensive inpatient psychotherapy.[248]

Fluoxetine (60 mg/day) was superior to placebo in decreasing purging behavior,[244,249,250,254] although not in the inpatient setting.[248]

All six fluoxetine trials either failed to report abstinence rates (absence of binge eating and purging behaviors) or did not report whether abstinence rates differed significantly between drug and placebo groups.

With reference to eating-related attitudes, fluoxetine (60 mg/day) was associated with significant improvements in measures of restraint, weight concern, and food preoccupation and with Eating Disorders Inventory (EDI) subscale scores of bulimia, drive for thinness, and body dissatisfaction.[244,249,250,254] Again, the exception was the inpatient study.[248]

Fluoxetine had mixed results on depression and anxiety scores. Some studies showed greater efficacy than placebo in decreasing depression scores,[249,252] but others showed no advantage of fluoxetine.[244,248,250,254]

Table 13. Dropout rates for randomized controlled trials: bulimia nervosa

Author	Total Enrollment, N	Total Dropouts N (% dropout)	G1 Treatment (% Dropout)	G2 Treatment (% Dropout)	G3 Treatment (% Dropout)	G4 Treatment (% Dropout) G5 Treatment (% Dropout)
Medication Trial						
Beumont et al., 1997[244]	67	27 (40%)	Fluoxetine (50%)	Placebo (30%)		
Fichter et al., 1991[248]	39	0 (0%)	Fluoxetine (0%)	Placebo (0%)		
Fluoxetine BN Collaborative Study Group, 1992[249]	387	117 (30%)	Placebo (37%)	Fluoxetine, 20 mg (23%)	Fluoxetine, 60 mg (30%)	
Goldstein et al.,1995[250]	398	173 (43%)	Fluoxetine (40%)	Placebo (52%)		
Kanerva et al., 1995[252]	50	4 (8%)	Fluoxetine (8%)	Placebo (8%)		
Romano et al., 2002[254]	150	131 (87%)	Fluoxetine (83%)	Placebo (92%)		
Fichter et al., 1996[247] and Fichter et al., 1997[299]	72	24 (33%)	Fluvoxamine (51%)	Placebo (14%)		
Pope et al., 1989[255]	46	4 (9%)	Trazodone (13%)	Placebo (4%)		
Hoopes et al., 2003[251] and Hedges et al., 2003[259]	68	28 (41%)	Topiramate (34%)	Placebo (47%)		
Kennedy et al., 1993[253]	36	8 (21%)	Brofaromine (21%)	Placebo (24%)		
Faris et al., 2000[246]	26	1 (4%)	Ondansetron (7%)	Placebo (0%)		
Walsh et al., 1991[257]	78	15 (19%)	Placebo (16%)	Desipramine (23%)		
Medication Plus Behavior Intervention Trials						
Goldbloom et al.,1997[261]	76	33 (43%)	Fluoxetine (39%)	CBT (35%)	Fluoxetine + CBT (55%)	
Mitchell et al., 2001[262]	91	2 (2%)	Placebo (5%)	Fluoxetine (0%)	Placebo + self-help manual (0%)	Fluoxetine + self-help manual (5%)
Walsh et al., 2004[265]	91	63 (69%)	Fluoxetine + guided self help (54%)	Placebo + guided self help (88%)	Fluoxetine (70%)	Placebo (64%)

B-ERP, exposure therapy with response prevention for bingeing; CBT, cognitive behavioral therapy; GP, general practitioner; IPT, interpersonal psychotherapy; N, number; NR, not reported; P-ERP, exposure therapy with response prevention for purging.

Table 13. Dropout rates for randomized controlled trials: bulimia nervosa (continued)

Author	Total Enrollment, N	Total Dropouts N (% dropout)	G1 Treatment (% Dropout)	G2 Treatment (% Dropout)	G3 Treatment (% Dropout)	G4 Treatment (% Dropout) G5 Treatment (% Dropout)
Agras et al., 1992[260] and Agras et al., 1994[300]	71	18 (25%)	Desipramine 16 weeks (NR)	Desipramine 24 weeks (NR)	Desipramine 16 weeks + CBT (NR)	Desipramine 24 weeks + CBT (NR) CBT (NR)
Mitchell et al., 2002[263]	62	25 (40%)	IPT (32%)	Antidepressant medication (48%)		
Walsh et al., 1997[264] and Wilson et al., 1999[301]	120	41 (34%)	CBT + medication (NR)	CBT + Placebo (NR)	Supportive therapy + medication (NR)	Supportive therapy + placebo (NR) Medication only (43%)
Behavioral Intervention Trials						
Agras et al., 2000[269]	220	57 (26%)	CBT (28%)	IPT (24%)		
Wolk and Devlin, 2001[268]	110	44 (40%)	CBT (NR)	IPT (NR)		
Cooper and Steere, 1995[274]	31	4 (13%)	CBT (13%)	Behavioral therapy (13%)		
Fairburn et al., 1991[276] and Fairburn et al., 1993[267]	75	15 (20%)	CBT (16%)	Behavioral therapy (24%)	IPT (12%)	
Wilfley et al., 1993[287]	56	8 (14%)	CBT (33%)	IPT (11%)	Waiting list (0%)	
Wilson et al., 2002[288]	220	Post treatment: 66 (30%), Follow up: 91 (41%)	CBT (NR)	IPT (NR)		
Garner et al., 1993[278]	60	10 (17%)	CBT (17%)	Supportive expressive (17%)		
Hsu et al., 2001[280]	100	27 (27%)	Nutritional therapy (39%)	Cognitive therapy (15%)	Cognitive and nutritional therapy (11%)	Sequential group (46%)
Sundgot-Borgen et al., 2002[283]	64	6 (9%)	Exercise (20%)	CBT (13%)	Nutrition (0%)	Waiting list (6%) Healthy control (0%)
Chen et al., 2003[273]	60	16 (27%)	Individual CBT (27%)	Group CBT (27%)		
Agras et al., 1989[266]	77	67 (13%)	Waiting list (5%)	Self monitoring (16%)	CBT (23%)	CBT + response prevention (6%)

Table 13. Dropout rates for randomized controlled trials: bulimia nervosa (continued)

Author	Total Enrollment	Total Dropouts N (% dropout)	G1 Treatment (% Dropout)	G2 Treatment (% Dropout)	G3 treatment (% Dropout)	G4 Treatment (% Dropout) G5 Treatment (% Dropout)
Bulik et al., 1998[270] and Bulik et al.,1998[271]	111	5 (5%)	Exposure to B-ERP (5%)	Exposure to P-ERP (6%)	Relaxation training (3%)	
Laessle et al., 1991[281]	55	7 (13%)	Nutritional management (19%)	Stress management (7%)		
Safer, Telch, and Agras, 2001[282]	31	2 (6%)	Dialectical behavior therapy (13%)	Waiting list (7%)		
Self-help Trials						
Bailer et al., 2004[290]	81	25 (31%)	Self help (25%)	CBT (37%)		
Carter et al., 2003[291]	85	20 (24%)	CBT (18%)	Nonspecific (25%)	Waiting list (28%)	
Durand and King, 2003[292]	68	14 (21%)	GP self-help (24%)	Specialist treatment (18%)		
Thiels et al., 1998[293]	62	13 (21%)	CBT (13%)	Guided self change (29%)		
Other Interventions						
Braun et al., 1999[295]	34	10 (29%)	Active light (31%)	Dim light (28%)		
Mitchell et al., 2004[297]	57	17 weeks: 9 (16%); 43 weeks: 16 (28%), 70 weeks: 23 (40%)	Crisis prevention 17 weeks: (10%), 43 weeks: (23%), 70 weeks: (37%)	Follow up 17 weeks: (22%), 43 weeks: (33%), 70 weeks: (44%)		
Esplen et al., 1998[296]	58	8 (14%)	Guided imagery (14%)	Control (13%)		

Table 14. Results from medication trials: bulimia nervosa

Source, Treatment, Setting, and Quality Score	Major Outcome Measures	Significant Change Over Time Within Groups	Significant Differences Between Groups at Endpoint	Significant Differences Between Groups in Change Over Time
Beumont, Russell et al., 1997[244] Fluoxetine vs. placebo Outpatient Fair	Eating: • BSQ • Bulimic episodes • EAT • EDE • Vomiting Biomarker: • Weight Psych: • HDRS	Both groups decreased bulimic and vomiting episodes, ED concerns and symptoms; and worries about body shape at week 4. Both groups decreased bulimic and vomiting episodes; ED concerns and symptoms; worries about body shape; restraint, overeating, and concerns about eating, shape, and weight at week 8. Both groups decreased bulimic and vomiting episodes, restraint, overeating, and concerns about eating and shape at 3-month FU. Fluoxetine group increased weight at 3 month FU.	Fluoxetine associated with lower restraint, weight concern, and shape concern at week 8	Significant difference on weight at 8 weeks with weight decreasing in fluoxetine group and increasing in placebo group. Fluoxetine group regained weight above baseline at FU while placebo group did not.
Fichter et al., 1991[248] Fluoxetine vs. placebo Inpatient Good	Eating: • Binge attacks • Binge urge • EDI • SIAB Biomarker: • Weight Psych: • CGI • HAM-D • SCL-90	No statistics reported.	No differences on any measures.	No differences on any measures.

BDI, Beck Depression Inventory; BITE, Bulimic Investigation Test Edinburgh; BMI, Body mass index; BSQ, Body Shape Questionnaire; CGI, Clinical Global Impression Scale; EAT, Eating Attitudes Test [EAT-26 items]; ED, Eating disorder; EDE, Eating Disorder Examination; EDI, Eating Disorders Inventory; FU, followup; HAM-A, Hamilton Anxiety Index; HAM-D (or HDRS), Hamilton Depression Rating Scale [HDRS-17 items, HDRS-21 items]; HRSD, Hamilton Rating Depression Scale; HSCL, Hopkins Symptom Check List (see SCL-90); kg, kilogram; PGI, Patient Global Impression; Psych, psychiatric and psychological; SCL, (Hopkins) Symptom Check List (SCL-90 items); SIAB, Structured Interview for Anorexia and Bulimia nervosa; STAI, Spielberger State-Trait Anxiety Inventory; tx, treatment; YBC-EDS, Yale-Brown-Cornell Eating Disorder Scale.

Table 14. Results from medication trials: bulimia nervosa (continued)

Source, Treatment, Setting, and Quality Score	Major Outcome Measures	Significant Change Over Time Within Groups	Significant Differences Between Groups at Endpoint	Significant Differences Between Groups in Change Over Time
Fluoxetine BN Collaborative Study Group, 1992[249] Fluoxetine (20 mg) vs. fluoxetine (60 mg) vs. placebo Outpatient Fair	Eating: • Bingeing • Vomiting • EAT • EDI • Carbohydrate craving Biomarker: • Weight Psych: • HDRS	No statistics reported.	Fluoxetine (60 mg) associated with greater reductions in binge eating and vomiting than fluoxetine (20 mg) or placebo. Fluoxetine (60 mg and 20 mg) associated with greater reductions in vomiting, weight, drive for thinness, bulimic intensity, carbohydrate craving, body dissatisfaction, and food and diet preoccupation than placebo. Fluoxetine (60 mg) associated with greater reductions in depressed mood, drive for thinness, oral control, and bulimia scores than placebo.	No statistics reported.
Goldstein, Wilson, Thompson et al., 1995[250] Fluoxetine vs. placebo Outpatient Fair	Eating: • Binge eating • Vomiting • EDI Biomarker: • Weight Psych: • CGI • HRSD • PGI	No statistics reported.	Fluoxetine associated with greater median percentage reduction in vomiting (at weeks 1-10, 13, 16, and endpoint) and binge eating (at weeks 1-9, 13, 16, and endpoint); greater reduction in total bulimia symptoms, drive for thinness, global symptoms scores, and weight; greater tx response (≥ 50% improvement in bulimic episodes)	No statistics reported.
Kanerva, Rissanen, and Sarna, 1994[252] Fluoxetine vs. placebo Outpatient Fair	Eating: • Bingeing • BITE • EAT • EDI Biomarker: • Weight Psych: • HDRS-17 • HDRS-21 • STAI	At 4 weeks, fluoxetine group decreased anxious mood and state anxiety.	No statistics reported.	Fluoxetine associated with greater reduction in depressed and anxious mood, bulimia and food preoccupation over 8 weeks. Difference in weight with decrease in fluoxetine group and increase in placebo group.

Table 14. Results from medication trials: bulimia nervosa (continued)

Source, Treatment, Setting, and Quality Score	Major Outcome Measures	Significant Change Over Time Within Groups	Significant Differences Between Groups at Endpoint	Significant Differences Between Groups in Change Over Time
Romano et al., 2002[254] Fluoxetine vs. placebo Outpatient Fair	Eating: • Bingeing • EDI • Relapse • Vomiting • YBC-EDS Biomarker: • BMI Psych: • CGI • HDRS	Both groups worsened over the 52-week extended tx period.	No statistics reported.	Fluoxetine group had smaller mean increases in vomiting, binge eating, total ED behavior, ritual, preoccupation and symptom severity. Relapse occurred less frequently in the first 3 months of 52-week extended tx period.
Fichter et al., 1996[247] Fichter et al., 1997[299] Fluvoxamine vs. placebo Inpatient and outpatient Fair	Eating: • Abstinence • Bingeing • EDI • Relapse • SIAB • Urge to binge Biomarker: • BMI Psych: • CGI • HDRS • HSCL	No statistics reported.	Fluvoxamine associated with higher binge abstinence rate, reduced clinical severity, and lower relapse rate.	Fluvoxamine superior in limiting increases in bulimic behavior (urge to binge, vomiting), global ED symptoms (SIAB total), EDI bulimia scores, fear of losing control, obsessive-compulsive symptoms, and, global severity during 12 week post-discharge relapse prevention phase.
Pope et al., 1989[255] Trazadone vs. placebo Outpatient Fair	Eating: • Binge frequency • EDI • Vomit frequency • Fear of eating Psych: • Self-control • Self-esteem • HAM-A • HAM-D	Trazadone group decreased binge and purge frequencies and fear of eating at 6 wks.	Trazadone associated greater percent decrease in binge and vomit frequencies and decrease in fear of eating and increase in self-esteem.	No statistics reported.

Table 14. Results from medication trials: bulimia nervosa (continued)

Source, Treatment, Setting, and Quality Score	Major Outcome Measures	Significant Change Over Time Within Groups	Significant Differences Between Groups at Endpoint	Significant Differences Between Groups in Change Over Time
Hoopes et al., 2003;[251] Hedges et al., 2003[259] Topiramate vs. placebo Outpatient Fair	Eating: • Binge days • Bulimic intensity scale • Carbohydrate craving • EAT • EDI • Purge days • Remission Biomarker: • Weight Psych: • CGI • HAM-A • HAM-D • PGI	No statistics reported.	Topiramate associated with greater percentage reduction in weekly number of binge and purge days, carbohydrate craving score, bulimic intensity, lower mean global symptoms and symptom intensity; and greater mean weight reduction. Larger percentage of topiramate group achieved moderate (> 50% reduction) or marked (> 75% reduction) improvement in weekly binge/purge days.	Topiramate superior to placebo in reducing uncontrolled eating, body dissatisfaction, dieting, food preoccupation,and anxious mood, and in increasing patient-rated percent improved.
Kennedy et al., 1993[253] Brofaromine vs. placebo Outpatient Fair	Eating: • Binge episodes • EAT-26 • EDI • Non-binge meals • Vomiting episodes Biomarker: • BMI • Weight Psych: • HAM-A • HAM-D	No statistics reported.	Brofaromine associated with greater reduction in vomiting episodes. A greater percentage of brofaromine group lost > 1 kg of weight. A greater percentage of placebo group gained > 1 kg of weight.	No statistics reported
Faris et al., 2000[246] Ondansetron vs. placebo Inpatient and outpatient Good	Eating: • Binge-purge episodes • Normal meals • Time spent in BN behaviors Biomarker: • Weight	Ondansetron group increased average number of normal meals, and decreased time spent engaging in BN behaviors at week 4.	Ondansetron associated with lower binge/purge frequency at week 4.	Ondansetron superior in reducing binge/vomit frequency and time spent engaging in BN behaviors and in increasing normal meals over 4 weeks.

Table 14. Results from medication trials: bulimia nervosa (continued)

Source, Treatment, Setting, and Quality Score	Major Outcome Measures	Significant Change Over Time Within Groups	Significant Differences Between Groups at Endpoint	Significant Differences Between Groups in Change Over Time
Walsh et al., 1991[257] Desipramine vs. placebo Outpatient Fair	Eating: • Binge episodes • BSQ • EAT • Remission • Vomiting episodes Biomarker: • BMI Psych: • BDI • HAM-D • SCL-90 • Social adjustment scale • STAI	No statistics reported.	Desipramine associated with fewer binge and vomiting episodes/week, fewer ED symptoms and body shape concerns, lower BMI, fewer symptoms of depression, global symptoms, and obsessive/compulsiveness, less hostility and trait anxiety.	No statistics reported.

One study explored the efficacy of fluoxetine (60 mg/day) versus placebo in preventing relapse of BN over 52 weeks.[254] Relapse rates were significantly lower for those receiving fluoxetine (33 percent) than for those receiving placebo (51 percent). However, dropout was substantial during the observation period (83 percent in the fluoxetine group and 92 percent in the placebo group).

Drop-out rates in fluoxetine arms of these trials ranged from zero (in an inpatient study) to 50 percent (three studies had greater than 40 percent dropout). In one study, dropout was greater in the fluoxetine than in the placebo group,[244] in three studies placebo had greater attrition,[249,250,254] and one inpatient study reported no dropout in either group.[248]

Fluvoxamine. To compare maintenance of therapeutic gains and prevention of relapse of BN after inpatient treatment, Fichter et al. compared fluvoxamine (average dose 182 mg/day) with placebo for 19 weeks.[247] Patients treated with fluvoxamine reported fewer urges to binge, lower frequency of vomiting, and lower depression scores than those receiving placebo. Both groups gained weight, with no differences between groups. Fluovoxamine was associated with a lower relapse rate. However, attrition was high (51 percent for those on fluovoxamine and 14 percent for those on placebo).

Trazodone. In a 6-week trial of trazodone (400 mg) versus placebo, trazodone led to significantly greater decreases in the frequency of binge eating and vomiting and decreased fear of eating.[255] No differences in depression or anxiety were observed, although baseline levels were not indicative of severe depression.

Tricyclic antidepressants. One 6-week trial of desipramine (200-300 mg/day) versus placebo found the active drug to be significantly more effective than placebo in decreasing binge eating, vomiting, and scores on the Eating Attitudes Test (EAT) and Body Shape Questionnaire (BSQ).[257] Abstinence rates from binge eating and purging did not differ between active drug and placebo. Both self-reported depression and anxiety were significantly decreased in the desipramine group compared with the placebo group; clinician-rated depression did not differ

significantly. Patients in the desipramine group lost significantly more weight than those in the placebo group, who tended to gain weight. Dropout was 23 percent in the desipramine group and 16 percent in the placebo group.

Anticonvulsants. The single 10-week trial of the anticonvulsant topiramate (mean dose 100 mg/day) led to significantly greater reductions than placebo in the number of binge/purge days reported and in body dissatisfaction, drive for thinness, and EAT scores.[251,259] Abstinence rates from binge eating and purging were 22.6 percent for topiramate and 6 percent for placebo (not significantly different). Topiramate was associated with significant reductions in anxiety but not depression, and the topiramate group lost significantly more weight than the placebo group, who tended to gain weight. Dropout from topiramate treatment was 34 percent and 47 percent for placebo.

MAOI. One 8-week trial of brofaromine (mean dose 175 mg/day) revealed no differences between the active drug and placebo on binge eating or psychological features of the eating disorder.[253] Brofaromine did lead to significant reductions in vomiting. Abstinence from binge eating and from vomiting were measured independently and did not differ between groups; no differences were observed on depression or anxiety scores, weight change, or drop-out rates (21 percent brofaromine and 24 percent placebo).

5HT3 antagonist. In a small 4-week trial of ondansetron versus placebo—self-administered when patients had an urge to binge or vomit—the active drug led to significantly greater decreases than placebo in binge and vomit frequencies and time spent in bulimic behavior, and to significant increases in normal meals.[246] The investigators did not measure depression or anxiety, and they found no differences in weight change. One patient dropped out from ondansetron, none from placebo.

Summary of medication-only trials. Fluoxetine (60 mg/day) administered for 6 to 18 weeks has been shown in several fair- to good-rated trials to reduce the core bulimia symptoms of binge eating and purging and associated psychological features of the eating disorder in the short term. The 60 mg dose performs better than the 20 mg dose;[249] it was also associated with prevention of relapse at 1 year in a study with considerable dropout.[254] Considerable evidence exists for the use of 60 mg/day of fluoxetine to treat BN in the short term. Evidence for the long-term effectiveness of relatively brief medication treatment does not exist. The optimal duration of treatment and the optimal strategy for maintenance of treatment gains are unknown.

Single studies provide preliminary evidence of the efficacy of two other second-generation antidepressants, namely trazodone[255] and fluvoxamine.[247] Likewise, evidence from single studies provides preliminary evidence of the efficacy of desipramine[257] and topiramate.[251] One preliminary trial of ondansetron, a 5HT3 antagonist and antiemetic, led to an intriguing decrease in binge eating and vomiting when patients could self-administer when they had urges to binge or purge.[246] This innovative study requires replication. One trial of brofaromine, an MAOI, showed a significantly greater effect on reducing vomiting than placebo.[253]

When reported, abstinence rates in medication-only trials suggest that medication treatment leads to abstinence in a minority of individuals. This finding indicates that although bulimia symptoms improved, they nonetheless persisted.

Drop-out rates in medication trials ranged from zero to 51 percent. No drug showed substantially greater attrition than others.

Medication Plus Behavioral Intervention Trials

We present the six trials of medications plus behavioral interventions in Table 15. These trials used a variety of designs to determine the extent to which a combination intervention is superior to either medication or behavioral intervention alone.

The total number of individuals enrolled in these combination trials was 1,895. The number of participants in the medication plus psychotherapy trials ranged from 71 to 120. No men participated in these trials. Participant ages ranged from 18 to 46. Three trials reported race or ethnicity of participants: 272 individuals were reported to be white, seven nonwhite, two Hispanic American, eight African American, and seven Asian. Five of these trials were conducted in the United States and one in Canada.

Second-generation antidepressants and CBT. Three trials used fluoxetine as the drug intervention. Comparing fluoxetine (60 mg/day) to CBT only to fluoxetine (60 mg/day) plus CBT in a 12-week trial, Goldbloom et al. used intention-to-treat analyses but found no difference across groups on eating related-measures.[261] In completers, all three interventions led to significant improvement in core bulimic symptoms; however, both combined treatment and CBT alone led to greater decreases than fluoxetine alone in objective and subjective binges and vomiting episodes. Abstinence rates, depression scores, and weight did not differ across groups. Dropout was highest in combined treatment (55 percent) compared to the fluoxetine (39 percent) and CBT only groups (35 percent). The investigators did not provide long-term followup data.

Walsh et al. compared fluoxetine (60 mg/day) with placebo, each with or without self-help in the form of a cognitive-behavioral self-help book[302] with instructions for use.[265] Physicians and nurses in primary care provided the treatments. Fluoxetine (either alone or with self-help) was associated with significantly decreased objective binge episodes, vomiting, restrained eating, and depression. The self-help book had no independent effect. No differences emerged on weight change. Dropout was high: 54 percent in fluoxetine plus guided self-help to 88 percent in placebo plus guided self-help.

Using the same design but a different self-help manual, also based on principles of CBT, and administering treatment from a specialized eating disorders program, Mitchell et al. found fluoxetine to be associated with a significantly greater decrease than placebo in vomiting episodes but not binge eating episodes.[262] No significant differences emerged in abstinence rates or depression. At the end of treatment, the investigators reported no independent effect of self-help. Dropout was low: none in fluoxetine only and fluoxetine plus self-help, 5 percent in placebo only and placebo plus self-help.

Tricyclic antidepressants and CBT. One complex trial compared desipramine treatment of different durations with or without CBT (16 versus 24 weeks) with CBT only.[260] The 16-week combined treatment was better than drug only for decreasing binge eating and purging. Longer combined treatment was significantly better than drug only on binge eating, vomiting, dieting preoccupation, and hunger. Abstinence rates did not differ across groups. The authors did not report results concerning depression. Weight change did not differ significantly across groups. At 1-year followup, the combined 24-week intervention and CBT alone were both better than the 16-week drug only treatment in decreasing binge eating and vomiting. The 24-week combined treatment was also superior to 16-week drug only in decreasing binge frequency, dietary preoccupation, disinhibition, and hunger.[300] In all but the medication-only group, between 78 percent and 100 percent of individuals who were abstinent at the end of treatment remained abstinent at followup. The overall drop-out rate was 25 percent.

Table 15. Results from medication plus behavioral intervention trials: bulimia nervosa

Source, Treatment, Setting, and Quality Score	Major Outcome Measures	Significant Change Over Time Within Groups	Significant Differences Between Groups at Endpoint	Significant Differences Between Groups in Change Over Time
Goldbloom et al., 1997[261] Fluoxetine vs. CBT vs. fluoxetine + CBT Outpatient Fair	Eating: • Binge episodes • EDE • EDI • Vomiting episodes Biomarker: • Weight Psych: • BDI • RSE	Decreased shape and weight concerns in the fluoxetine and the fluoxetine + CBT groups.	At tx completion, CBT alone and fluoxetine + CBT associated with greater percent reduction in vomiting frequency, compared to fluoxetine alone. At 4 weeks post-tx, fluoxetine + CBT associated with fewer objective binge and vomit weekly episodes compared to fluoxetine alone. CBT associated with fewer subjective binge episodes compared to fluoxetine alone. Note: no sig diff in ITT analyses.	No statistics reported.
Mitchell et al., 2001[262] Fluoxetine vs. placebo vs. self-help + placebo vs. fluoxetine + self-help Outpatient Fair	Eating: • Abstinence • Binge eating • EDI • Fasting days • Vomiting Psych: • CGI • HAM-D • PGI	No statistics reported.	Fluoxetine, alone and with self-help, associated with greater percentage reduction in vomiting and greater clinician-rated and patient-rated clinical improvement, compared to self help plus placebo or placebo alone, at endpoint (16 week tx period). Self-help manual plus placebo or fluoxetine associated with greater percentage reduction in vomiting compared to placebo or fluoxetine with no self-help manual, at 4-week time point (after 2 weeks active tx).	No statistics reported.

BDI, Beck Depression Inventory; BES, Binge Eating Scale; BMI, body mass index; BSQ, Body Shape Questionnaire; CBT, cognitive behavior therapy; CGI, clinical global impression; EAT, Eating Attitudes Test; ED, eating disorders; EDE, eating disorders examination; EDI, eating disorder inventory; FU, followup; HAM-D, Hamilton Rating Score for Depression; ITT, intention-to-treat; IPT, interpersonal psychotherapy; PGI, patient global impression; Psych, psychiatric and psychological; RSE, Rosenberg Self-Esteem Questionnaire; SCL, (Hopkins) Symptom Checklist (SCL-53 items, SCL-90 items); TFEQ, Three Factor Eating Questionnaire; tx, treatment; vs., versus; YBC-ED, Yale-Brown-Cornell Eating Disorder Scale.

Table 15. Results from medication plus behavioral intervention trials: bulimia nervosa (continued)

Source, Treatment, Setting, and Quality Score	Major Outcome Measures	Significant Change Over Time Within Groups	Significant Differences Between Groups at Endpoint	Significant Differences Between Groups in Change Over Time
Walsh et al., 2004[265] Fluoxetine vs. placebo vs. guided self-help vs. fluoxetine + guided self-help Outpatient Good	Eating: • EDE (episodes of bulimia, laxative use, vomiting) • Restraint Biomarker: • BMI Psych: • BDI • SCL-53	No statistics reported.	Fluoxetine associated with fewer objective bulimic and vomiting episodes and fewer vomiting days per month, less restraint, less depressed mood, and a lower general symptom index compared to placebo. Fluoxetine only and placebo groups greater decrease in bulimic episodes than self-help groups.	No statistics reported
Agras et al., 1992;[260] and Agras et al., 1994[300] Desipramine (16 weeks) vs. desipramine (24 weeks) vs. desipramine + CBT (16 weeks) vs. desipramine + CBT (24 weeks) vs. CBT alone (24 weeks) Outpatient Fair	Eating: • Abstinence • Bingeing • Dietary pre-occupation • Disinhibition • EDE • Hunger • Purging • Recovery Biomarker: • Weight Psych: • BDI • RSE	No statistics reported.	No statistics reported.	Desipramine + CBT superior to medication alone in reducing binge and purge frequency at 16 and 32 weeks, and in reducing diet preoccupation over 16 weeks. Desipramine + CBT superior to CBT alone in reducing hunger disinhibition over 24 weeks, and superior to medication alone in reducing diet preoccupation at 16 weeks. CBT alone superior to desipramine alone for 16 or 24 wks in reducing binge and purge frequency at 16 wks. CBT alone or in combination with desipramine for 24 weeks, superior to desipramine for 16 weeks in reducing binge frequency at 1 year FU. Desipramine + CBT for 24 weeks superior to desipramine for 16 weeks in reducing binge frequency, hunger, disinhibition, and diet preoccupation at 1 year FU.

Table 15. Results from medication plus behavioral intervention trials: bulimia nervosa (continued)

Source, Treatment, Setting, and Quality Score	Major Outcome Measures	Significant Change Over Time Within Groups	Significant Differences Between Groups at Endpoint	Significant Differences Between Groups in Change Over Time
Mitchell et al., 2002[263] IPT vs. fluoxetine (16 weeks) or vs. fluoxetine (8 weeks) followed by desipramine (8 weeks) Outpatient Fair	Eating: • Abstinence • BES • BSQ • EDE • Objective binges • Relapse • TFEQ Psych: • BDI	No statistics reported.	No differences on any measures.	No statistics reported.
Walsh et al., 1997[264] and Wilson et al., 1999[301] CBT + placebo vs. CBT + medication (desipramine only or desipramine followed by fluoxetine) vs. Supportive therapy + placebo vs. Supportive therapy + medication vs. Medication alone Outpatient Good	Eating: • Bingeing • BSQ • EAT • EDE • Remittance • Vomiting Biomarker: • BMI • Weight Psych: • BDI • SCL-90	All groups exhibited decreases in weekly bingeing and vomiting, EAT and BSQ scores, concerns about eating and eating restraint, global ED symptoms, and depressed mood. Weight and BMI decreased in 3 groups (CBT+ placebo, medication alone, and supportive therapy + medication). Anxiety decreased in each of the 3 groups receiving medication. Importance of shape and weight concerns decreased in two groups (CBT plus placebo and supportive therapy plus medication).	No statistics reported.	CBT groups combined superior to supportive therapy groups combined in reducing binge and vomit episode frequencies. Behavioral interventions plus medication superior to behavioral interventions alone in reducing binge frequency, EAT scores, depressed mood, weight, and in increasing remission rate. CBT plus medication superior to medication alone in reducing binge and vomit frequencies, EAT scores, body image, and increasing remission rate by self-report. Medication alone superior to CBT alone in reducing BMI and weight. Medication alone superior to supportive therapy plus medication in reducing binge and vomit frequency.

Multiple drugs and CBT. Walsh et al. examined supportive psychotherapy, CBT, both with or without placebo and with or without medication, and medication alone in a five-group 16-week comparison.[264,301] They started patients on desipramine (mean dose 188 mg/day) and switched nonresponders to fluoxetine (60 mg/day) after 8 weeks. Analyses combining all arms of the study that included CBT versus all arms of the study that included supportive therapy indicated that CBT was superior to supportive therapy in reducing binge and vomit episode frequencies. Behavioral interventions plus medication were superior to behavioral interventions alone in reducing binge frequency, EAT scores, depressed mood, weight, and in increasing remission rate.

CBT plus medication was superior to medication alone in reducing binge and vomit frequencies, EAT scores, body image, and increasing remission rate by self-report. Medication alone was superior to CBT alone in reducing BMI and weight. Medication alone was superior to supportive therapy plus medication in reducing binge and vomit frequency. Medication led to significantly greater decreases in depression scores. CBT was associated with greater likelihood of remission. The overall drop-out rate was 34 percent.

Mitchell et al. randomized patients who did not respond to CBT to either interpersonal psychotherapy or fluoxetine (60 mg/day), which could be switched to desipramine in those who did not achieve abstinence.[263] No difference in abstinence was observed between the two groups. Overall, the sequential second-level treatment was associated with high dropout.

Summary of medication plus psychotherapy trials. The combined medication plus behavioral intervention studies provide only preliminary evidence regarding the optimal combination of medication and psychotherapy or self-help. Given the variety of designs used and lack of replication, evidence remains weak. Combined CBT and fluoxetine and CBT alone led to greater decreases in binge eating and purging than fluoxetine alone in individuals who complete therapy.[261] When delivered in the context of a specialist eating disorders program, both self-help and fluoxetine were associated with decreased vomiting; however, the addition of self-help to fluoxetine was not associated with increased efficacy.[262] When these therapies were administered in a primary care setting, drop-out rates from fluoxetine (70 percent) and fluoxetine plus self-help (54 percent) were unacceptably high.[265]

The only study that looked at sequential treatment for individuals who did not respond to CBT revealed that the addition of interpersonal psychotherapy to fluoxetine (allowing the transition to desipramine) led to substantial attrition and minimal effects on subsequent abstinence rates. How best to treat individuals who do not respond to CBT or fluoxetine remains a major shortcoming of the literature.

Behavioral Intervention Trials

We report 13 psychotherapy-only trials, four self-help trials, one trial of light therapy, one of guided imagery, and one of crisis prevention. Summary outcomes data for the psychotherapy trials appear in Table 16. The total number of individuals enrolled in psychotherapy, self-help, and other trials was 1,462. From the studies that reported sex of participants, 1,064 women and two men participated. Across these 20 trials, participants ranged in age from 17 to 64 years. Six trials reported race and ethnicity of participants: in all, 410 patients were white; 22 nonwhite; 28 Hispanic American; 26 Asian, Maori, or Pacific Islander; 10 African American; and 1 Native American. In no instance were results analyzed specifically by race or ethnicity group. Of the 20 trials, seven were conducted in the United States, three each in Canada and the United Kingdom, one each in Australia, Austria, Germany, New Zealand, and Norway, and one two-site study in Germany and Australia, and one did not report location.

Psychotherapy trials for bulimia nervosa. *Cognitive Behavior Therapy.* CBT focusing on cognitive and behavioral factors that maintain bulimic behaviors is the most widely studied intervention for BN. Eleven trials of various designs delivered CBT either individually or in group format. CBT was compared with interpersonal psychotherapy (IPT),[269,276,287,288] with supportive expressive therapy,[278] with nutritional counseling,[280,283] and with exercise.[283] One study compared individually with group-administered CBT.[273] Several studies dismantled CBT by comparing complete CBT with behavioral therapy (BT) in the absence of a cognitive component,[276] by comparing cognitive therapy only with exposure with response prevention

Table 16. Results from behavioral intervention trials: bulimia nervosa

Source, Treatment, Setting, and Quality Score	Major Outcome Measures	Significant Change Over Time Within Groups	Significant Differences Between Groups at Endpoint	Significant Differences Between Groups in Change Over Time
Agras et al., 2000[269] and Wolk and Devlin, 2001[268] CBT vs. IPT Outpatient Good	Eating: • Bingeing • EDE • Purging • Remittance • Recovery Biomarker: • BMI Psych: • SCL-90R • Stage of change	No statistics reported.	CBT associated with higher percent remitted and percent recovered at end of tx (ITT analysis). In completers-only analysis, CBT associated with fewer objective binges and purges; less eating restraint; and less weight, shape, and eating concerns at the end of tx. Stage of change predicted improvement in IPT but not CBT.	No statistics reported.
Cooper and Steere, 1995[274] Cognitive therapy vs. exposure plus binge and purge response prevention Outpatient Fair	Eating: • Abstinence • Bulimic episodes • BSQ • EAT • EDE • Dietary restraint • Relapse • Vomiting episodes Biomarker: • Weight Psych: • BDI • PSE • MADRS • STAI	No statistics reported.	Relapse rate lower in cognitive therapy group among those who were abstinent from binge-eating at end of tx and at 12 month FU.	Cognitive therapy superior to exposure therapy in reducing vomiting and depression between baseline and 12 month FU.

B-ERP, exposure with response prevention to pre-binge cues; BDI, Beck Depression Inventory; BMI, Body mass index; BN, bulimia nervosa; BSQ, Body Shape Questionnaire; BT, Behavioral Therapy; CBT, Cognitive Behavioral Therapy; CNT, Cognitive nutritional therapy; CT, Cognitive Therapy; DBT, dialectical behavior therapy; EAT, Eating Attitudes Test; ED, Eating disorder; EDE, Eating Disorder Examination (EDE-12 items); EDI, Eating Disorders Inventory; FU, follow-up; GAFS, Global Assessment of Functioning Symptoms; HDRS, Hamilton Depression Rating Scale; IIP, Inventory of Interpersonal Problems; IPT, interpersonal psychotherapy; ITT, intention-to-treat; MADRS, Montgomery and Asberg Depression Rating Scale; NT, nutritional therapy; P-ERP, exposure with response prevention to pre-purge cues; PSE, Present State Examination; Psych, psychiatric and psychological; RSE, Rosenberg Self-Esteem Scale; SCL-90, (Hopkins) symptom checklist (SCL-90 items, SFL-90-R [SCL-90-revised]); STAI, Speilberger State-Trait Anxiety Inventory; SUDS, subjective units of distress; TFEQ, Three Factor Eating Questionnaire; tx, treatment.

Table 16. Results from behavioral intervention trials: bulimia nervosa (continued)

Source, Treatment, Setting, and Quality Score	Major Outcome Measures	Significant Change Over Time Within Groups	Significant Differences Between Groups at Endpoint	Significant Differences Between Groups in Change Over Time
Fairburn et al., 1991;[276] Fairburn, Jones et al., 1993[267] and Fairburn, Peveler et al., 1993[277] CBT vs. BT vs. IPT Outpatient Fair	Eating: • EAT • EDE • Laxative misuse • Objective bulimic episodes • Vomiting Biomarker: • BMI Psych: • BDI • SCL-90 • RSE	No statistics reported.	No statistics reported.	Over 18 week tx period, CBT superior to BT and IPT in reducing eating restraint, weight concerns, and overall ED psychopathology; CBT superior to IPT in reducing vomiting; and CBT superior to BT in reducing shape concerns. Over 12-month FU, CBT superior to BT in improving abstinence.
Wilfley et al., 1993[287] Group CBT vs. group IPT vs. waiting-list control Outpatient Fair	Eating: • Binge frequency • EDE • TFEQ Psych: • BDI • IIP • RSE	CBT and IPT decreased binge frequency at 1 year FU.	No statistics reported.	Group CBT and group IPT superior to waiting-list in reducing binge frequency, and disinhibition over 16 weeks. Group IPT superior to waiting-list in reducing restraint over 16 weeks.
Wilson et al., 2002[288] CBT vs. IPT Outpatient Fair	Eating: • Binge eating • EDE • Recovery • Vomiting Psych: • IIP • RSE • Self- efficacy	Both groups decreased shape and weight concerns at post-tx.	CBT showed greater mean reduction in eating restraint by tx week 6, greater improvements in self-efficacy by tx week 10, and a higher percentage reduction in binge eating at post-tx.	CBT superior in early (by week 6) improvement (reduction in frequency of vomit episodes)
Garner et al., 1993[278] CBT vs. supportive-expressive therapy Outpatient Fair	Eating: • Binge episodes • EAT • EDE • EDI • Vomiting Biomarker: • Weight Psych: • BDI • Millon Inventory • RSE • SCL-90-R	No statistics reported.	No statistics reported.	Over 18 week tx period, CBT superior in reducing dieting, food preoccupation, eating concerns, restraint, attitudes toward shape, bulimia behaviors, depressed mood, global symptoms, and symptoms of borderline personality disorder and dysthymia; and in improving self-esteem.

Table 16. Results from behavioral intervention trials: bulimia nervosa (continued)

Source, Treatment, Setting, and Quality Score	Major Outcome Measures	Significant Change Over Time Within Groups	Significant Differences Between Groups at Endpoint	Significant Differences Between Groups in Change Over Time
Hsu et al., 2001[280] CT vs. NT vs. CT+NT (CNT) vs. group support (control) Outpatient Fair	Eating: • Bingeing • EDI • Meals/ week • Purging Psych: • HDRS	No statistics reported.	No statistics reported.	CNT superior to NT alone and to group support in binge/purge abstinence and in reducing drive for thinness and BN symptoms. CT superior to NT in reducing BN symptoms and CT superior to group support in reducing drive for thinness.
Sundgot-Borgen et al., 2002[283] Exercise vs. CBT vs. nutrition counseling vs. waiting-list vs. healthy controls Outpatient Fair	Eating: • Binge frequency • EDI • Vomit frequency • Laxative abuse Biomarker: • Percent body fat	Exercise group decreased percent body fat at post-tx and fat mass at 18-month FU.	Body dissatisfaction lower in CBT compared to nutritional counseling group at post tx. Laxative use lower in exercise than CBT group at post tx. Vomit frequency, bulimia symptoms, and body dissatisfaction lower in CBT than nutritional counseling group at 6 month FU. Drive for thinness and laxative abuse lower in exercise than CBT group, at 6 month FU. Binge episodes lower in exercise than in CBT at 18 month FU.	No statistics reported.
Chen et al., 2003[273] Individual CBT vs. group CBT Outpatient Fair	Eating: • Abstinence • Binge episodes • EDE-12 • Laxative use • Over-exercising • Purge episodes Biomarker: • BMI Psych: • BDI • SCL-90 • STAI	No statistics reported.	Higher rate of abstinence in individual CBT than group CBT at end of tx.	Group CBT superior to individual CBT in reducing state anxiety.

Table 16. Results from behavioral intervention trials: bulimia nervosa (continued)

Source, Treatment, Setting, and Quality Score	Major Outcome Measures	Significant Change Over Time Within Groups	Significant Differences Between Groups at Endpoint	Significant Differences Between Groups in Change Over Time
Agras et al., 1989[266] Waiting-list vs. Self-monitoring vs. CBT vs. CBT+ response prevention Outpatient Fair	Eating: • Abstinence • Dieting urge • Food preoccupation • Purge/week Biomarker: • Weight Psych: • BDI	Decreased purges/week in self-monitoring, CBT, and CBT+ response groups at end of 4-month tx.	CBT associated with higher abstinence rate compared to waiting-list at end of tx, and compared to self-monitoring and response prevention at 6 month FU.	CBT alone superior to waiting-list in reducing purging frequency, increasing purging abstinence and decreasing depressed mood, by end of treatment. CBT alone and CBT+ response prevention superior to waiting-list in reducing depressed mood by end of treatment.
Bulik et al., 1998;[270] Bulik et al., 1998;[271] Carter, McIntosh et al., 2003[272] 8 weeks CBT followed by B-ERP tx vs. P-ERP tx vs. relaxation training Outpatient Good	Eating: • Abstinence • Bingeing • Clinician ratings (food restriction, body dissatisfaction • EDI • Laxative use • Purging • Vomiting Psych: • HDRS • GAFS • SUDS	P-ERP and relaxation groups improved body dissatisfaction at 3 yr FU	B-ERP associated with less drive for thinness, lower clinician-rated food restriction, body dissatisfaction, and depressed mood, lower subjective distress than relaxation training at 3 year FU. P-ERP associated with fewer ED psychological and behavioral measures.than relaxation training at 3 year FU. B-ERP associated with less food restriction, higher GAFS score than relax training at 12 month FU.	Relaxation superior to B-ERP in reducing depressed mood and clinician-rated body dissatisfaction from post-tx to 2 year FU. Relaxation superior to P-ERP in reducing ED psych and behavioral traits and depressed mood from post-tx to 3 year FU.
Laessle et al., 1991[281] Nutritional management vs. stress management Outpatient Fair	Eating: • Binge frequency • Calories/day • EAT • EDI • Vomit frequency Psych: • BDI • STAI	No statistics reported.	No difference on any measures.	Nutritional management superior to stress management in increasing calorie consumption and decreasing binge frequency over first 3 weeks of tx, and in increasing binge abstinence rate through 6 and 12 months. Stress management superior to nutrition management in reducing trait anxiety over 3 months of tx.

Table 16. Results from behavioral intervention trials: bulimia nervosa (continued)

Source, Treatment, Setting, and Quality Score	Major Outcome Measures	Significant Change Over Time Within Groups	Significant Differences Between Groups at Endpoint	Significant Differences Between Groups in Change Over Time
Safer et al., 2001[282] DBT vs. waiting-list Outpatient Good	Eating: Binge episodes EDE Emotional eating scale Purge episodes Psych: BDI Positive and Negative Affect Schedule	No statistics reported.	DBT superior in post-tx abstinence rate	DBT superior in reducing the number of binge and purge episodes measured in last 4 of 20 weeks of tx.

only,[274] and by exploring the additive efficacy of exposure with response prevention grafted onto a basis of cognitive therapy.[271] Exposure with response prevention is defined as exposing individuals to their high-risk cues (e.g., prebinge cues or prepurge cues) and then preventing the response (e.g., binge eating or purging) until the urge to engage in the behavior subsides.

In comparisons of individually administered CBT and IPT tailored for BN, CBT was associated with a significantly greater probability of remission than IPT[269] and with greater decreases in vomiting and restraint[269,276] and binge eating[269] at the end of treatment. In one study at 1-year followup, these differences were no longer apparent.[276] Neither CBT nor IPT led to greater improvements in mood or changes in weight. Changes in dietary restraint and in eating self-efficacy mediated change in binge and purge frequency.[288] Being in the precontemplation stage of change was associated with failure to achieve remission at the end of treatment.[268]

When administered in group format, differences between CBT and IPT were less clear. Both group-administered treatments led to significantly greater decreases than waiting list on days binged, psychological features of the eating disorder, disinhibition, and restraint, with no differences observed between the active therapies.[287]

When compared directly, few differences emerged between group and individual administration of CBT. Both showed decreases in objective and subjective binge episodes, vomiting, laxative use, overexercise and EDI bulimia, drive for thinness, and body dissatisfaction subscale scores.[273] Group CBT was associated with greater decreases in anxiety; individual CBT was associated with significantly higher rates of abstinence. From a cost-effectiveness perspective, the study concluded that group CBT was more economical, given the similarity of outcomes.

In the dismantling studies, which attempted to parse out the effects of various components of CBT, the cognitive component emerged as critical to therapeutic outcome. Complete CBT led to better eating-related outcomes than BT,[276] to lower relapse than exposure with response prevention only,[274] and to greater abstinence than a self-monitoring only intervention.[266]

Two studies examined the additive efficacy of exposure with response prevention. Agras and colleagues found no additive benefit of exposure to CBT.[266] Bulik et al. first treated all patients with a core of cognitive therapy and then explored the added efficacy of three augmentation strategies: exposure with response prevention to prebinge cues, exposure with response prevention to prepurge cues, and a relaxation therapy control.[270] They found no evidence that

either exposure treatment led to greater improvement in binge eating and vomiting than the relaxation control.

In other comparisons, cognitive therapy performed better than support only; adding a cognitive component to nutritional counseling led to a significantly greater decrease in drive for thinness than nutritional therapy alone.[280] CBT was superior to nutritional counseling alone in improving core binge eating, vomiting, laxative use, and body dissatisfaction. CBT also led to significantly greater decreases than supportive-expressive therapy (a nondirective psychodynamically oriented treatment) in EDI bulimia, EAT scores, food preoccupation, eating concerns, and depression.[278] Exercise therapy was superior to CBT at 18-month followup in improving drive for thinness, laxative abuse, and binge eating.[283]

Overall, dropout from CBT delivered individually or in group format ranged from 6 percent to 37 percent. Typical rates were about one-quarter of individuals randomized.

Other behavioral interventions. A single study compared nutritional management (focusing on decreasing restraint, detailed nutritional self-monitoring, and stimulus control) to stress management (focusing on decreasing stressors that may trigger binge eating). Both treatments led to significant decreases in binge eating and vomiting; abstinence from binge eating was greater in nutritional management than stress management, although abstinence from vomiting did not differ. Stress management was associated with greater reductions in trait anxiety.[281]

Dialectical behavioral therapy (DBT). DBT focuses on emotional dysregulation as the core problem in BN with symptoms viewed as attempts to manage unpleasant emotional states. A small study showed that patients receiving DBT had significantly greater decreases in binge eating and purging than did those on a waiting list and that abstinence was greater at the end of treatment in the DBT than in the waiting list group.[282]

Self-help trials. We present self-help trials for BN in Table 17. In a direct 18-week comparison of guided self-help (manual including visits with nonspecialists in eating disorders to check on progress) with group CBT, both treatments significantly decreased binge eating, vomiting, laxative use, EDI bulimia, drive for thinness and body dissatisfaction.[290] At 1-year followup, individuals in the self-help group showed greater reductions in vomiting and EDI bulimia. CBT was associated with greater reductions in drive for thinness over the treatment period and at followup. Both treatments significantly improved depression, with no differences between groups at the end of treatment; however, at followup, individuals in the self-help group had lower depression scores. Of those who completed treatment, a significantly greater number of individuals in the self-help group than in the CBT group were in remission for more than 2 weeks at the end of treatment (74 percent versus 44 percent). No significant change was seen in weight, although those in the self-help condition weighed significantly more at 1 year.

Carter et al. compared CBT-based self-help[302]with nonspecific self-help, focusing on self-assertion for women, with a waiting list control group in a 2-month trial.[291] Both self-help approaches led to significant decreases in objective binge episodes and purging; the waiting list did not. CBT-based self-help was associated with greater reductions in reducing intense exercise than nonspecific self-help or waiting list. No change in depression was observed. Abstinence and weight values were not reported.

To understand the feasibility and efficacy of self-help delivered in general practitioner (GP) offices, Durand and King compared GP-supported CBT-based self-help[303] with specialist outpatient treatment.[292] The duration of treatment was at the clinician's discretion. Patients in both groups reported significant decreases in scores on the Bulimic Investigation Test Edinburgh (BITE) and Eating Disorders Examination (EDE) total; however, binge eating and vomiting did

Table 17. Results from self-help trials, no medication: bulimia nervosa

Source, Treatment, Setting, and Quality Score	Major Outcome Measures	Significant Change Over Time Within Groups	Significant Differences Between Groups at Endpoint	Significant Differences Between Groups in Change Over Time
Bailer et al., 2004[290] Guided self-help vs. group CBT Outpatient Fair	Eating: • Binge frequency • EDI • Laxative use • Meal frequency • Recovery • Remittance • Vomit frequency Biomarker: • BMI Psych: • BDI	No statistics reported.	Higher meal frequency in self-help at post-tx. Lower vomit frequency, depressed mood, laxative use, and bulimia symptoms, and higher BMI in self-help, at 1-year FU.	Self-help superior to CBT in reducing bulimia symptoms over 18 weeks. CBT superior to self-help in reducing drive for thinness over tx and FU periods.
Carter et al., 2003[291] CBT-based self-help vs. non-specific self-help vs. waiting-list Outpatient Fair	Eating: • Binge frequency • EDE • Exercise frequency • Purge frequency Psych: • BAI • BDI • IIP	Both self-help groups decreased binge and purge frequencies. CBT-based self-help experienced a decrease in intense exercising.	No differences on any measures.	CBT-based self-help superior to non-specific self-help and to waiting-list in reducing intense exercising.
Durand and King, 2003[292] General practice physician- based self-help vs. specialist-based self-help Outpatient Fair	Eating: • BITE • Bulimic episodes • EDE • Vomit episodes Psych: • BDI • Patient-rated severity	No statistics reported.	No differences on any measures.	No differences on any measures.

BAI, Beck Anxiety Inventory; BDI, Beck Depression Inventory; BITE, Bulimic Investigation Text Edinborough; BMI, Body mass index; CBT, Cognitive Behavioral Therapy; EDE, Eating Disorder Examination; EDI, Eating Disorders Inventory; FU, followup; HDRS, Hamilton Depression Rating Scale [HDRS-17 items, HDRS-21 items]; IIP, Inventory of Interpersonal Problems; Psych, psychiatric and psychological; tx, treatment.

Table 17. Results from self-help trials, no medication: bulimia nervosa (continued)

Source, Treatment, Setting, and Quality Score	Major Outcome Measures	Significant Change Over Time Within Groups	Significant Differences Between Groups at Endpoint	Significant Differences Between Groups in Change Over Time
Thiels et al., 1998[293] CBT vs. guided self-change Outpatient Fair	Eating: • Binge abstinence • BITE • EDE • ED Awareness Test • Purge Abstinence Biomarker: • BMI Psych: • BDI • Self-esteem	No statistics reported.	Lower BITE scores in guided self-change group.	No differences on any measures.

not drop significantly. Both groups reported significant decreases in depression, but no treatment was superior. Weight change was not reported. Drop-out rates were similar across groups (24 percent in the GP group and 18 percent in specialist care).

A German study by Thiels et al. compared 16 weeks of CBT with guided self-change using a manual.[293] Guided self-change included 16 sessions with a therapist encouraging use of the manual and addressing motivation, obstacles, and emergent crises. Significant decreases occurred in overeating, vomiting, BITE scores, and EAT scores for both groups combined. Only on BITE scores did the CBT group perform significantly better than the guided self-change group. Depression dropped in both treatment groups with no significant differences between groups. Dropout was 13 percent in CBT and 29 percent in guided self-change.

Additional interventions for bulimia nervosa. We present other interventions for BN in Table 18. Three studies explored interventions that did not fit into our classification scheme: active light (such as that used to treat seasonal affective disorder), crisis prevention, and guided imagery.

Light therapy. In a small 8-week trial of 10,000 lux white light (active light) versus 50 lux red light (control), individuals in the active light group showed significantly greater decreases in binge eating than individuals in the control group.[295] Mood improved in both groups but no additional differences were observed for any other eating disorder, psychological, or biomarker outcome. The investigators did not provide long-term follow-up data. Given the size of this trial and the absence of followup, results should be viewed as preliminary.

Crisis prevention. Individuals who were abstinent after a trial of CBT were randomized to either a crisis prevention group in which they were able to contact their clinician to receive up to eight additional visits over 17 months if they felt their condition was deteriorating or a control follow-up-only group.[297] The percentage of individuals who resumed binge eating and purging did not differ over the 17-month interval; however, none of the individuals in the crisis prevention group used any of their available calls despite the reappearance of bulimic symptoms.

Table 18. Results from other trials: bulimia nervosa

Source, Treatment, Setting, and Quality Score	Major Outcome Measures	Significant Change Over Time Within Groups	Significant Differences Between Groups at Endpoint	Significant Differences Between Groups in Change Over Time
Braun et al., 1999[295] Bright light therapy vs. dim light/placebo Outpatient Fair	Eating: • Binge frequency • Meal frequency • Purge frequency • Seasonal patterns assessment questionnaire • YBC-EDS Psych: • BDI • HAM-D	No statistics reported.	No differences on any measures.	Bright light superior to dim light (placebo) in reducing binge frequency over 3 week tx.
Mitchell et al., 2004[297] Crisis prevention vs. usual follow-up Outpatient Fair	Eating: • Resumption of bingeing and/or purging after period of abstinence	No differences on any measures.	No differences on any measures.	No differences on any measures.
Esplen et al., 1998[296] Guided imagery vs. control (eating behavior journaling therapies) Outpatient Fair	Eating: • Abstinence • Binge frequency • EAT-26 • EDI • Purge frequency	No statistics reported.	Higher abstinence rate in guided imagery compared to control group.	Guided imagery superior to control in reducing binge and purge frequencies, drive for thinness, bulimia symptoms, and body dissatisfaction over 6 week tx period.

BDI, Beck Depression Inventory; EAT, Eating Attitudes Test (EAT-26 items); EDI, Eating Disorders Inventory; HAM-D, Hamilton Depression Rating Scale; Psych, psychiatric and psychological; tx, treatment; YBC-EDS, Yale-Brown-Cornell Eating Disorder Scale

Guided imagery. Esplen et al. conducted a 6-week trial of patients in a guided imagery group and a control journaling group.[296] Guided imagery was based on developing self-comforting in BN.[304] Guided imagery led to a significantly greater decrease in measures of binge eating, purging, EDI bulimia, drive for thinness, and body dissatisfaction. At the end of treatment, 21 percent of individuals in guided imagery and no individuals in the control condition were abstinent. Drop-out rates were comparable across groups.

Summary of behavioral interventions for bulimia nervosa. A large number of fair- to good-rated trials provide evidence that CBT administered individually or in group format is effective in reducing the core behavioral symptoms of binge eating and purging and psychological features of BN in both the short and the long term. One study suggests that CBT leads to more rapid reduction of symptoms than IPT.[276] Another suggests that individual CBT confers no advantage over the more economical group CBT approach;[273] although this finding is important for service delivery, it requires replication. The cognitive component of CBT appears

to be the active ingredient for change, as behavioral interventions alone are not as effective.[274,276] Exposure with response prevention, either alone or as an added component to a core of cognitive therapy, offers no additional therapeutic advantage to basic CBT.[270,272,274]

Adding a cognitive component to nutritional intervention led to greater effectiveness in one study,[280] and CBT led to better outcomes than a psychodynamically oriented supportive-expressive therapy.[278] Preliminary evidence suggests that DBT is effective and worth additional study for the treatment of BN.[282]

Four studies provided mixed evidence regarding the efficacy of self-help methods for BN. One German and one Austrian study provide support for guided self-help in comparison to group CBT[290] and individually administered CBT.[293] The nature of the self-help approach (CBT oriented versus nonspecific) did not lead to different outcomes.[291] Preliminary evidence from the United Kingdom indicates that GPs can successfully deliver self-help.[292] No self-help trials conducted in the United States met our inclusion criteria. Overall, especially in the absence of control conditions, few conclusions can be drawn regarding the efficacy of self-help approaches for BN. Moreover, the term self-help must be considered carefully as many of the interventions labeled self-help included considerable contact with providers.

One report yielded preliminary evidence for treating BN with light leading to some short-term decreases in binge eating.[295] One study provided some support for guided imagery compared to journaling, although long-term maintenance of treatment effects is unknown.[296] Crisis prevention approaches do not appear to be effective in the treatment of BN, based on one study, as patients do not avail themselves of the opportunity to contact their therapists when symptoms reemerge.[297]

Key Question 2: Harms of Treatment for Bulimia Nervosa

Table 19 presents adverse events associated with treatments for BN. As reported in Chapter 3, harms from second-generation antidepressants include the following: for fluoxetine, insomnia, nausea, asthenia, tremor, dizziness, rhinitis, sweating, urinary frequency, and sexual dysfunction; for fluvoxamine, nausea, dizziness and drowsiness.[243] Adverse events associated with second-generation antidepressants in BN appear to be consistent with those observed in other disorders.[253]

Side effects of MAOI administration were nausea, sleep disturbance, and dizziness. No hypertensive crises were reported, although this danger should always be considered in patients who experience uncontrollable eating episodes.[121]

Key Question 3: Factors Associated With Treatment Efficacy

Medication Trials

A few medication trials for BN explored factors associated with outcome. Walsh et al. reported that patients with greater concern for body shape and weight and longer duration of illness had more favorable treatment responses.[257] The Fluoxetine BN Collaborative Study group found that heavier patients had higher response rates in each treatment group.[249]

Table 19. Adverse events reported: bulimia nervosa trials

Intervention	Adverse Event *†
Medication Trials	
Fluoxetine vs. placebo[244]	Fluoxetine group: Insomnia, nausea, and shakiness significantly more common Placebo group: depression more common
Fluoxetine vs. placebo[248]	Fluoxetine: significantly more trembling than placebo
Fluoxetine 60mg (F60) vs. fluoxetine 20mg (F20) vs. placebo (PL)[249]	Side effects by treatment group: Insomnia: F60 (30); F20 (23); PL (10); (*P* < 0.001) Nausea: F60 (28); F20 (20); PL (14); (*P* = 0.021) Asthenia: F60 (23); F20 (16); PL (11); (*P* = 0.039) Tremor: F60 (12); F20 (4); PL (0); (*P* < 0.001) Sweating: F60(7); F20 (4); PL (1); (*P* = 0.036) Urinary frequency: F60 (5); F20 (0); PL (2); (*P* = 0.012) Palpitation: F60(5); F20(1); PL(1); (*P* = 0.017) Yawn: F60 (5); F20(1); PL(1); (*P* = 0.017) Mydriasis: F60 (3); F20 (0); PL(0); (*P* = 0.018) Vasodilation: F60(1); F20 (4); PL (0); (*P* = 0.029)
Fluoxetine (F) vs. placebo (PL)[250]	Side effects by treatment group: Insomnia: F (102); PL (19); (*P* < 0.05) Nausea: F (90); PL(13); (*P* < 0.001) Asthenia, F (63); PL (7); (*P* < 0.001) Anxiety: F (52); PL (9); (*P* < 0.05) Tremor: F (42); PL (2); (*P* < 0.001) Dizziness: F (37); PL (4); (*P* < 0.05) Yawning, F (36); PL (0); (*P* < 0.001) Sweating: F (28); PL (2); (*P* < 0.05) Decreased libido: F (19); PL (1); (*P* < 0.05) Depression: F (30); PL (19); (*P* < 0.05) Myalgia: F (14); PL (12); (*P* < 0.05) Emotional lability: F (8); PL (8); (*P* < 0.05) Conjunctivitis: F (1); PL (3); (*P* < 0.05)
Fluoxetine vs. placebo[252]	Fluoxetine: hand tremor (5) Placebo: Palpitations (1)
Fluoxetine vs. placebo[254]	Fluoxetine: rhinitis (24) Placebo: rhinitis (12); (*P* < 0.04)
Fluvoxamine vs. placebo[247,299]	Fluvoxamine: nausea, dizziness and drowsiness significantly more common in patients receiving fluvoxamine Fluvoxamine: Drop outs due to general side effects (8)
Trazodone vs placebo[255]	Trazodone significantly more dizziness and drowsiness than placebo
Topiramate vs. placebo[251,259]	Topiramate: Dropouts (1) facial rash and irritability Placebo: Dropouts (2)
Brofaromine vs. placebo[253]	Brofaromine: nausea (2); sleep disturbance, nausea, dizziness Placebo: headache (1); dry mouth, nausea
Ondansetron vs. placebo[246]	No adverse events observed
Desipramine vs. placebo[257]	NR

CBT, cognitive behavioral therapy; DBT, dialectical behavioral therapy; NR: not reported
* If no numbers appear in parentheses, authors had only listed adverse events but not reported the number of cases.
† *P* values indicate differences between groups; they are reported with they are provided by the author.

Table 19. Adverse events reported: bulimia nervosa trials (continued)

Intervention	Adverse Event *†
Medication plus Behavioral Intervention Trials	
Fluoxetine vs. individual CBT vs. fluoxetine and individual CBT[261]	Fluoxetine: Dropouts due to side effects (4) Fluoxetine plus CBT: Dropouts due to side effects (2) Nature of side effects NR
Fluoxetine vs. manual based self-help[262]	NR
Fluoxetine plus guided self-help vs. placebo plus guided self help vs. fluoxetine vs. placebo[265]	NR
Desipramine 16 wks vs. despipramine 24 wks vs. desipramine 16 wks plus CBT vs. CBT only[260,300]	NR
Interpersonal psychotherapy vs. antidepressant (fluoxetine replaced by desipramine if no effect) in CBT nonresponders[263]	NR
CBT plus medication vs. CBT plus placebo vs. Supportive therapy plus med vs. supportive therapy plus placebo[264,301]	NR
Behavioral Intervention Trials	
CBT vs. Interpersonal psychotherapy[269]	9 withdrawn from treatment: 7 severe depression, 1 acute onset of panic disorder
CBT vs. exposure response prevention[274]	NR
CBT vs. Behavior therapy vs. interpersonal psychotherapy[267,276,277]	Behavior therapy: Drop out (1) severe weight loss
Group CBT vs. group Interpersonal psychotherapy vs. waiting list control[287]	NR
CBT vs. interpersonal psychotherapy[288]	NR
CBT vs. supportive-expressive therapy[278]	NR
Cognitive therapy vs. nutritional therapy[280]	NR
CBT vs. physical exercise vs. nutritional counseling[283]	Exercise: injury (1)
Individual CBT vs. Group CBT[273]	Alcohol abuse (2), AN (1), visual hallucinations (1). No indication of which group these participants were in.
CBT vs. CBT plus response prevention vs. self-monitoring vs. waiting-list[266]	NR
CBT plus exposure with response prevention to pre-binge cues vs. CBT plus exposure to response prevention with pre-purge cues vs. CBT plus relaxation training[270-272]	NR
Nutritional management vs. stress management[281]	NR
DBT vs. waiting list[282]	NR
Self-help Trials	
Guided self-help vs. group CBT[290]	NR
Self-help manual vs. waiting list control[291]	NR
Self-help intervention vs. clinic intervention[292]	NR
CBT vs. guided self-change sessions[293]	NR
Other Trials	
Active light vs. placebo dim light[295]	No adverse events observed
Crisis prevention vs. follow up[297]	NR
Guided imagery vs. control[296]	NR

Behavioral Intervention Trials

Behavioral interventions in BN provided better and reasonably consistent information about factors associated with treatment response. Several investigators reported two factors as associated with poor outcome: high frequency of binge eating[270,272,274,298,301] and longer duration of illness.[274,298]

Evidence was mixed or contradictory for other factors. Higher body dissatisfaction was associated with both poorer[270] and better outcome.[277] With respect to weight, a history of obesity was reported as a positive prognostic indicator[270] and as a predictor of dropout.[278] Better outcomes or more rapid response were associated with higher baseline depression, lower severity of binge eating,[287] and greater attitudinal disturbance at baseline.[277] Positive response was reported to be associated with a history of obesity, a history of alcoholism, and high scores for self-directedness[270] and self-control.[280] Poorer outcomes were associated with greater food restriction, higher depression, higher drive for thinness and bulimia scores on the EDI, and greater cue reactivity,[270] low self-esteem,[277] and precontemplation stage of change.[268]

Self-help Trials

Factors associated with positive response to self help included higher EDI perfectionism scores, higher Dimensional Assessment of Personality Pathology (DAPP) compulsivity scores, higher DAPP intimacy problem scores, and lower cognitive behavior knowledge scores.[291]

Other Interventions Trials

Higher soothing receptivity and ability to tolerate aloneness were associated with more positive outcomes in guided imagery therapy.[296]

Key Question 4: Treatment Efficacy by Subgroups

The total number of individuals enrolled in the 18 trials of drugs or drug plus behavioral interventions was 1,941. Of those 67 were men. No studies reported differential outcome by age. Thirteen studies failed to report the race or ethnicity of participants. Of those that did, 793 participants were identified as white, 57 as nonwhite, 33 as Asian, 12 as Hispanic American, and eight as African American. Of the 18 trials, 12 were conducted in the United States. No study analyzed results separately by sex or by race or ethnicity. Based on these results, we conclude that no information exists regarding differential efficacy of medication only or combined medication plus behavioral interventions for BN by sex, gender, age, race, ethnicity, or cultural group.

The total number of individuals enrolled in behavioral intervention or other intervention trials was 1,462. Of those, two were men. Of the 18 trials, 14 failed to reported race or ethnicity of participants. From the remaining four trials, 410 subjects were identified as white; 22 as nonwhite; 28 Hispanic-American; 26 as Asian; Maori or Pacific Islander; 19 as African-American or Afro-Caribbean; and one as Native American. In no instance did the investigators analyze results separately by race or ethnic group. No data exist regarding differential efficacy of behavioral interventions for BN by sex, gender, age, race, ethnicity, or cultural group.

Chapter 5. Results: Binge Eating Disorder

This chapter presents results of our literature search and our findings for the four key questions (KQs) pertaining to binge eating disorder (BED). KQ 1 sought evidence for the efficacy of various treatments or combinations of treatments for BED. KQ 2 sought evidence of harms associated with the treatment or combination of treatments for BED. KQ 3 addressed factors associated with the efficacy of treatment for BED. KQ 4 addressed whether the efficacy of treatment for BED differs by sex, gender, age, race, ethnicity, or cultural groups. We report first on specific details about the yields of the literature searches and characteristics of the studies, then on literature pertaining to treatment (KQ 1, KQ 2, and KQ 3). Summary tables presenting findings grouped by selected outcomes appear at the end of this chapter.

Overview of Included Studies

For each included BED study, detailed evidence tables appear in Appendix C.[††] We report first on medication trials (Evidence Table 10), then combined medication and behavioral interventions (Evidence Table 11), behavioral interventions only (Evidence Table 12), self-help interventions (Evidence Table 13), and other interventions (Evidence Table 14). Within each table, studies are listed alphabetically by author. For each study we report eating disorder-related outcomes, psychiatric and psychological outcomes (such as comorbid depression and anxiety), and biomarker outcomes including weight loss.

We identified 26 studies addressing treatment efficacy for BED. Nine were medication-only trials.[305-313] We rated four of these trials as good,[305,307,309,312] and five as fair.[306,308,310,311,313] One study of a medication no longer available in the United States (d-fenfluramine) is not discussed here.[313] The medications studied included second-generation antidepressants,[305-309] tricyclic antidepressants,[310] an anticonvulsant,[311] sibutramine,[312] and d-fenfluramine.[313]

Four trials combined medication with behavioral interventions using second-generation antidepressants,[314,315] a tricyclic antidepressant,[316] and orlistat.[317] Of these, we rated two as good,[315,317] one as fair,[316] and one as poor.[314]

We identified eight behavioral-intervention-only studies. Of these, we rated one trial as good,[318] three as fair,[319-321] and four as poor.[322-325] Of the four fair or good studies, three used some form of cognitive behavioral therapy (CBT) in comparison to other interventions[318-320] and one used dialectical behavior therapy (DBT).[321]

Three trials investigated various self-help methods.[326-328] We rated one as good[326] and two, which report on the same sample at two points in time, as fair.[327,328] Finally, one trial involved exercise, rated as poor,[329] and another examined virtual reality therapy, rated as fair.[330]

Studies with a quality rating of "poor" are not discussed below. Reasons that these studies received this rating are presented in Table 20. Although each study was not deficient in all areas, the following are the most common concerns contributing to the low rating of studies: randomization (no description of protections against researchers' influence, a fatal flaw in approach or the approach not described), assessors not being blinded or their blinding status not described, adverse events not described, the statistical analysis not including or not reporting whether a power analysis was conducted, a lack of necessary controls for confounding, and results not reported using an intention-to-treat approach.

[††] Appendixes cited in this report are provided electronically at http://www.ahrq.gov/downloads/pub/evidence/pdf/eatingdisorders/eatdis.pdf.

Table 20. Reasons for poor quality ratings and number of trials with poor ratings: binge eating disorder

Reasons Contributing to Poor Ratings	Types of Intervention, Number of Times Flaw Was Detected, and Citations
	Research Aim
Hypothesis not clearly described	Medication-only trials: 0 Psychotherapy trials: 0
	Study Population
Characteristics not clearly described	Medication-only trials: 0 Psychotherapy trials: 0
No specific inclusion or exclusion criteria	Medication-only trials: 0 Psychotherapy trials: 0
	Randomization
Protections against influence not in place	Medication-only trial: 1[314] Psychotherapy trials: 3[322-324]
Approach not described	Medication-only trials: 0 Psychotherapy trials: 1[324]
Whether randomization had a fatal flaw not known	Medication-only trials: 0 Psychotherapy trials: 4[322-325]
Comparison group(s) not similar at baseline	Medication-only trials: 0 Psychotherapy trials: 0
	Blinding
Study subjects	Medication-only trials: 1[314] Psychotherapy trials: 0
Investigators	Medication-only trials: 1[314] Psychotherapy trials: 0
Outcomes assessors	Medication-only trial: 1[314] Psychotherapy trials: 4[322-325]
	Interventions
Interventions not clearly described	Medication-only trials: 0 Psychotherapy trials: 0
No reliable measurement of patient compliance	Medication-only trials: 0 Psychotherapy trials: 2[322,323]
	Outcomes
Results not clearly described	Medication-only trials: 0 Psychotherapy trials: 0
Adverse events not reported	Medication-only trials: 0 Psychotherapy trials: 3[322-324]

Table 20. Reasons for poor quality ratings and number of trials with poor ratings: binge eating disorder (continued)

Reasons Contributing to Poor Ratings	Types of Intervention, Number of Times Flaw Was Detected, and Citations
Statistical Analysis	
Statistics inappropriate	Medication-only trials: 0 Psychotherapy trials: 1[325]
No controls for confounding (if needed)	Medication-only trials: 0 Psychotherapy trials: 2[323,325]
Intention-to-treat analysis not used	Medication-only trials: 0 Psychotherapy trials: 3[323-325]
Power analysis not done or not reported	Medication-only trial: 1[314] Psychotherapy trials: 3[322-324]
Results	
Loss to followup 26% or higher or not reported	Medication-only trials: 0 Psychotherapy trials: 1[325]
Differential loss to followup 15% or higher or not reported	Medication-only trials: 0 Psychotherapy trials: 2[324,325]
Outcome measures not standard, reliable, or valid in all groups	Medication-only trials: 0 Psychotherapy trials: 0
Discussion	
Results do not support conclusions, taking possible biases and limitations into account	Medication-only trials: 0 Psychotherapy trials: 0
Results not discussed within context of prior research	Medication-only trials: 0 Psychotherapy trials: 0
External validity: population not representative of US population relevant to these treatments	Medication-only trials: 0 Psychotherapy trials: 0
Funding/sponsorship not reported	Medication-only trial: 1[314] Psychotherapy trials: 0

Participants

Of the 19 studies rated fair or good, 14 were conducted in the United States,[305-309,311,315-318,320,321,327,328] and one each in Brazil,[312] Germany,[319] Italy,[330] Switzerland,[310]and the United Kingdom.[326] Five studies failed to report the age of participants; of the remainder, all focused on individuals 18 years of age or older (range, 18 to 65 years). With respect to sex, 1,132 individuals participated in fair or good clinical trials (984 women and 87 men; for 61 subjects, sex was not reported).

Six studies failed to report the race or ethnicity of participants. Of those that did, 775 participants were identified as white, 48 as nonwhite, 20 as African American, 12 as Hispanic American, and one as Native American. Drop-out rates from treatment trials appear in Table 21.

Key Question 1: Treatment Efficacy

Medication-only Trials

We report eight randomized controlled double-blind trials of medications (Table 22).[305-312] A total of 413 individuals enrolled in medication-only trials. Based on studies that reported sex (all except one study),[311] 322 women and 25 men participated in medication-only BED trials. The number of participants in the medication trials ranged from 20 to 85. The age of participants ranged from 18 to 60 years. Five trials reported the race of participants: 234 individuals were reported to be white and 29 nonwhite. Six trials were conducted in the United States,[305-309,311] one in Brazil,[312] and one in Switzerland.[310]

Second-generation antidepressants. *Fluoxetine.* One trial compared fluoxetine (average dose 71.3 mg/day) with placebo in 60 individuals meeting the Diagnostic and Statistical Manual for Psychiatric Disorders-Version IV (DSM IV) criteria for BED with three or more binges per week for 6 months and higher than 85 percent ideal body weight (IBW) in a 6-week flexible dose trial.[305] Fluoxetine significantly decreased binges per week, severity of illness, and clinician-rated depression scores. It was associated with less weight gain than the placebo, although both groups gained weight during treatment. The investigators failed to report abstinence rates and long-term followup. Dropout was 57 percent in the fluoxetine group and 23 percent in the placebo group. Any inferences made from this study must be made with extreme caution because of the very high and differential attrition rate.

Other second-generation antidepressants. A 9-week trial compared fluvoxamine (50-300 mg/day) with placebo in 85 patients with BED, at least three binge eating episodes per week for 6 months, and higher than 85 percent of the midpoint of their ideal weight for height. Using intention-to-treat analyses, the investigators showed that patients on fluvoxamine had a significantly greater rate of reduction in binge frequency than those on placebo; however, the remission rate did not differ between groups.[306] The rate of improvement in severity of illness but not in depression was greater in the fluvoxamine group than in the placebo group. Fluvoxamine led to a greater rate of reduction of body mass index (BMI); however, BMI at endpoint was not reported so the clinical significance of the weight change could not be evaluated. The investigators failed to report long-term followup. Overall dropout was 21 percent.

In a 12-week trial of fluvoxamine (average dose 239 mg/day) versus placebo in 20 patients with DSM-IV BED, investigators observed no differences between fluvoxamine and placebo on binge eating frequency, although both groups combined showed decreases in binge frequency at the end of treatment.[307] Both groups combined had significant decreases in shape and weight concerns with no differences between them. Self-reported depression decreased similarly for both. Neither group showed significant weight change with treatment. The investigators failed to report long-term followup. Overall dropout was 20 percent.

McElroy et al. compared 6 weeks of sertraline (mean dose 187 mg/day) with placebo in 34 individuals with DSM-IV BED, at least three binge episodes per week for 6 months, and greater than 85 percent of IBW.[309] Sertraline led to greater reduction in binges per week but not with complete remission when rated categorically. It was also associated with increased reduction in

Table 21. Dropout rates for randomized controlled trials: binge eating disorder

Author	Total Enrollment, N	Total Dropouts, N (%)	G1 Treatment (% Dropout)	G2 Treatment (% Dropout)	G3 Treatment (% Dropout)	G4 Treatment (% Dropout)
Medication Trials						
Arnold et al., 2002[305]	60	24 (40%)	Fluoxetine (57%)	Placebo (23%)		
Hudson et al., 1998[306]	85	18 (21%)	Fluoxetine (NR)	Placebo (NR)		
Pearlstein et al., 2003[307]	25	5 (20%)	Fluvoxamine (NR)	Placebo (NR)		
McElroy et al., 2000[309]	34	8 (24%)	Sertaline (28%)	Placebo (19%)		
McElroy et al., 2003[308]	38	7 (18%)	Citalopram (16%)	Placebo (21%)		
Laederach-Hoffman et al., 1999[310]	31	2 (7%)	Imipramine (7%)	Placebo (6%)		
McElroy et al., 2003[311]	61	26 (43%)	Topiramate (47%)	Placebo (39%)		
Appolinario et al., 2003[312]	60	12 (20%)	Sibutramine (23%)	Placebo (17%)		
Medication plus Behavioral Intervention Trials						
Grilo, Masheb, and Wilson, 2005[315]	108	22 (20%)	Placebo (15%)	Fluoxetine (22%)	CBT + placebo (21%)	CBT + fluoxetine (23%)
Agras et al., 1994[316]	109	24 (22%)	Weight loss therapy (27%)	CBT + Weight loss (17%)	CBT + Weight loss + desipramine (23%)	
Grilo, Masheb, and Salant, 2005[317]	50	11 (22%)	Orlistat + CBT (24%)	Placebo + CBT (20%)		
Behavioral Interventions						
Gorin, Le Grange, and Stone, 2003[320]	94	32(34%)	Standard CBT (NR)	Standard CBT with spouse involvement (NR)	Waiting list control (NR)	
Hilbert and Tuschen-Caffier, 2004[319]	28	4 (14%)	CBT with a body exposure component (14%)	CBT with a cognitive restructuring component focused on body image (14%)		
Wilfley et al., 2002[318]	162	29 (18%)	CBT (20%)	Interpersonal psychotherapy (16%)		
Telch, Agras, and Linehan, 2001[321]	44	10 (23%)	Dialectical behavior therapy (18%)	Waiting list control (27%)		

CBT, cognitive behavioral therapy; G, group; N, number; NR, not reported.

Table 21. Dropout rates for randomized controlled trials: binge eating disorder (continued)

Author	Total Enrollment, N	Total Dropouts, N (%)	G1 Treatment (% Dropout)	G2 Treatment (% Dropout)	G3 Treatment (% Dropout)	G4 Treatment (% Dropout)
Self-help						
Carter and Fairburn, 1998[326]	72	9 (12%)	Guided self-help (24%)	Pure self-help (0%)	Waiting list control (4%)	
Peterson et al., 1998[328]	50 (to active treatment)	8 (16%)	Therapist-led (13%)	Partial self-help (11%)	Structured self-help (27%)	Waiting list control (0%)
Peterson et al., 2001[327]	51	7 (14%)	Therapist-led (NR)	Partial self-help (NR)	Structured self-help (NR)	
Riva et al., 2002[330]	20	0 (0%)	Virtual Reality (0%)	Psych-nutritional group (0%)		

Table 22. Results from medication trials: binge eating disorder

Source, Treatment, Setting, and Quality Score	Major Outcome Measures	Significant Change Over Time Within Groups	Significant Differences Between Groups at Endpoint	Significant Differences Between Groups in Change Over Time
Arnold et al., 2002[305] Fluoxetine vs. placebo Outpatient Good	Eating: • Abstinence • Binge eating Biomarker: • BMI • Weight Psych: • CGI • HAM-D	No statistics reported	Fluoxetine associated with lower illness severity and depressed mood, and less weight gain.	Fluoxetine superior in reducing binge frequency, illness severity, and depressed mood, and in controlling weight and BMI gain over 6 weeks.
Hudson et al., 1998[306] Fluvoxamine vs. placebo Outpatient Fair	Eating: • Binge eating • Remission Biomarker: • BMI Psych: • CGI • HDRS	No statistics reported	No statistics reported	Fluvoxamine superior in reducing binge frequency, clinical severity, and BMI over 9 weeks.
Pearlstein et al., 2003[307] Fluvoxamine vs. placebo Outpatient Good	Eating: • Binge eating • EDE Biomarker: • Weight Psych: • BDI • HAM-D • SCL-90	No statistics reported	No statistics reported	No differences on any measures
McElroy et al., 2003[311] Topiramate vs. placebo Outpatient Fair	Eating: • Binge eating • YBOCS-BE Biomarker: • BMI • Weight Psych: • CGI • HDRS	No statistics reported	No statistics reported.	Topiramate superior in reducing binge frequency, illness severity, eating-related obsessions, compulsions, BMI, and weight over 14 weeks.

BDI, Beck Depression Inventory; BES, Binge Eating Scale; BMI, body mass index; CGI, Clinical Global Impressions; EDE, Eating Disorders Examination; FU, followup; HAM-D, Hamilton Depression Inventory; HDRS, Hamilton Depression Rating Scale; Psych, psychiatric and psychological; SCL-90, (Hopkins) Symptom Check List; SDS, Self-rating Depression Scale; vs., versus; YBOCS-BE, Yale-Brown Obsessive Compulsive Scale (modified for binge eating).

Table 22. Results from medication trials: binge eating disorder (continued)

Source, Treatment, Setting, and Quality Score	Major Outcome Measures	Significant Change Over Time Within Groups	Significant Differences Between Groups at Endpoint	Significant Differences Between Groups in Change Over Time
McElroy et al., 2003[308] Citalopram vs. placebo Outpatient Fair	Eating: • Binge eating • YBOCS-BE Biomarker: • BMI • Weight Psych: • CGI • HAM-D	No statistics reported	Citalopram asscociated with greater reduction in frequency of binge days, BMI, and weight.	Citalopram superior to placebo in the rate of reduction in frequency of binges, illness severity, binge eating related obsessions and compulsions, and weight over 6 weeks.
Laederach-Hoffman et al., 1999[310] Imipramine vs. placebo (with dietary and psychological counseling Outpatient Fair	Eating: • Binge eating Biomarker: • BMI • Waist-hip ratio weight Psych: • HAM-D • SDS	Imipramine decreased binge frequency and depressed mood over 8 weeks, and decreased depressed mood and weight at 32 week FU.	No statistics reported	Imipramine superior to placebo in decreasing binge frequency, depressed mood, and body weight over 8 weeks of active tx, and 32-week FU.
McElroy, Casuto et al., 2000[309] Sertraline vs. placebo Outpatient Good	Eating: • Binge eating Biomarker: • BMI Psych: • CGI • HDRS	No statistics reported	No statistics reported	Sertraline superior to placebo in reducing binge frequency, illness severity, and BMI, and in increasing global improvement over 6 weeks.
Appolinario et al., 2003[312] Sibutramine hydrochloride vs. placebo Outpatient Good	Eating: • BES • Binge eating • Remission Biomarker: • Weight Psych: • BDI	No statistics reported	Sibutramine associated with less depressed mood.	Sibutramine superior to placebo in reducing binge frequency and severity. Difference in weight at end of treatment with weight decreasing over treatment period in the sibutramine group but increasing in the placebo group.

severity of illness but not with depression scores. The drug also led to greater reductions in weight; however, the investigators failed to report BMI at endpoint so the clinical significance of the weight change is unclear. The investigators failed to present long-term follow-up data. Dropout was 28 percent in the sertraline group and 19 percent in the placebo group.

In a 6-week trial of citalopram (40-60 mg/day) versus placebo in 38 individuals with BED, with three or more binge episodes per week for 6 months and more than 85 percent of IBW, the active drug led to a significantly greater rate of decrease of binge eating and binge eating days; however, the percentage of individuals remitted when measured categorically did not differ

significantly.[308] The citalopram group showed greater reductions in clinician-rated obsession and compulsion scores and in severity of illness and depression scores. The BMI rate of change was significantly greater in the citalopram group; patients lost on average 2.7 kg and those on placebo gained 5.2 kg during treatment. Although the rate of change data suggested more rapid response in the citalopram group, differences between the groups over time were not significant for the core outcome variables of binges per week or severity of illness. Dropout was 16 percent in the citalopram group and 21 percent in the placebo group.

Tricyclic antidepressants. Laederach-Hoffman et al. augmented standard bi-weekly diet counseling and psychological support with either impiramine (25 mg three times a day) or placebo in 31 individuals with DSM-IV BED and BMI greater than 27.5.[310] Significantly greater reductions in binge eating episodes and Hamilton Depression Rating Scale (HAM-D) scores occurred in the impiramine group at 8 and 32 weeks. Body weight was significantly reduced in the imipramine group at 8 and 32 weeks (mean reduction of 2.1 kg at 8 weeks and 5.0 kg at 32 weeks); the placebo group gained weight. Abstinence rates were not reported. Low doses of imipramine when delivered in the context of psychological support and diet counseling led to maintenance of decreased binge eating, depression, and weight. Dropout was between 6 percent and 7 percent in both groups.

Anticonvulsants. One 14-week trial compared topiramate (average dose 212 mg/day) with placebo in 61 individuals with BED, BMI greater than 30, and a score greater than 15 on the Yale-Brown Obsessive Compulsive Scale for Binge Eating (YBOCS-BE).[311] Patients receiving topiramate experienced a significantly greater rate of change and a significantly greater percentage reduction in binge episodes, binge days per week, and YBOC-BE. Severity of illness, but not depression scores, showed greater improvement in the topiramate group. Topiramate led to significantly greater and clinically meaningful weight loss (5.9 kg) than placebo (1.2 kg). No follow-up data were provided. The investigators failed to report abstinence rates or endpoint values, so estimating the magnitude of clinical significance of differences is difficult. Dropout was 47 percent in the topiramate group and 39 percent in the placebo group.

Sibutramine. A 12-week comparison of sibutramine (15 mg/day) with placebo in 60 individuals with DSM-IV BED and a Binge Eating Scale (BES) score of greater than or equal to 17 indicated that sibutramine produced significant decreases in binge days per week and BES scores than placebo.[312] Sibitramine was also associated with a significant decrease in self-reported depression scores over the course of treatment. At week 12, the sibutramine group had lost on average 7.4 kg whereas the placebo group gained weight (a significant difference). The authors did not report abstinence rates or provide long-term follow-up data. Dropout was 23 percent in the sibutramine group and 17 percent in the placebo group.

Summary of medication-only trials. Treating BED in overweight individuals has two critical outcomes—decrease in binge eating and decrease in weight. Although not all BED studies explicitly sampled on the basis of weight, all focused on overweight individuals. Four selective serotonin reuptake inhibitors (SSRIs)—one serotonin, dopamine, and norepinephrine uptake inhibitor; one tricyclic antidepressant; one anticonvulsant; and one appetite suppressant—have been studied in BED. In short-term trials, SSRIs appear to lead to greater rates of reduction in target eating, psychiatric and weight symptoms, and severity of illness. However, in the absence of clear endpoint data, and in the absence of data regarding abstinence from binge eating, we cannot judge the magnitude of the clinical impact of these interventions. Moreover, lacking follow-up data after drug discontinuation, we do not know whether observed changes in binge eating, depression, and weight persist.

Low-dose imipramine as an augmentation strategy to standard dietary counseling and psychological support is associated with decreases in binge eating and weight that persist after discontinuation of the medication. This finding suggests a potentially promising pairing worth further investigation.

Both sibutramine and topiramate yielded promising results in terms of weight reduction for patients with BED: clinically significant reductions in BMI over the short term. The authors of these reports did not supply remission rates. Additional research is required to track patients after drug discontinuation to determine whether observed changes in eating behavior and weight persist.

Several studies reported rate of change of symptoms rather than actual differences in groups in change over time including endpoint values. Although rate of change is of interest, endpoint measures, including consistently defined abstinence rates, are critical to evaluate the clinical status of participants at the end of treatment.

Overall, drop-out rates were between 16 percent and 57 percent in the medication trials for BED. The high placebo response in BED is noteworthy.

Medication Plus Behavioral Intervention Trials

We present three trials of medications plus psychotherapy in Table 23.[315-317] The total number of individuals enrolled in these combination trials was 267 (237 women and 30 men).

The number of participants in these combination trials ranged from 50 to 109. Age ranged from 21 to 65 years. Of these three trials, two reported the race or ethnicity of participants: 140 individuals were reported as white, 12 as African American, and six as Hispanic American.[315,317] The United States was the site of all three trials.

Second-generation antidepressants and CBT. Grilo et al. compared fluoxetine (60 mg/day) with placebo, both with and without CBT, in a 16-week trial.[315] Treatment groups receiving CBT reported greater reductions in binge episodes, eating and shape concerns, disinhibition, and depression and greater remission rates than did the medication-only or placebo groups. Weight loss did not differ across groups; the authors did not report within-group weight loss over time. Dropout between groups was comparable (between 15 percent and 23 percent).

Tricyclic antidepressants and CBT. Agras et al. compared the effects of weight-loss treatment, CBT, and desipramine in 109 individuals with DSM IV BED. They randomly allocated participants to 9 months of weight-loss-only therapy, 3 months of CBT followed by 6 months of weight-loss therapy, or 3 months of CBT followed by 6 months of weight-loss therapy and desipramine (300 mg/day).[316] Groups receiving CBT showed significant reduction in binge eating at 12 weeks but not at any later follow-up point. Likewise, any observed differences on self-report measures of eating pathology were no longer significantly different at 36 weeks. Changes in depression scores did not differ across groups. Initial weight loss was greater in the weight-loss therapy group. At 3-month followup, the greatest weight loss was seen in the group including CBT and desipramine (average reduction of 4.8 kg from baseline). Dropout from acute treatment was comparable across groups: from 27 percent in the weight-loss therapy group to 17 percent in the CBT plus weight-loss therapy group.

Orlistat and CBT. In a 12-week trial of orlistat (120 mg three times/day) with CBT and placebo with CBT in 50 individuals with DSM-IV BED and BMI > 30, the orlistat group had greater remission rates at the end of treatment but not at 2-month followup.[317] The authors reported no differences in any other eating-related or depression measures. Individuals in the orlistat group experienced greater initial weight loss (-3.5 kg) than those in the placebo group

Table 23. Results from medication plus behavioral intervention trials: binge eating disorder

Source, Treatment, Setting, and Quality Score	Major Outcome Measures	Significant Change Over Time Within Groups	Significant Differences Between Groups at Endpoint	Significant Differences Between Groups in Change Over Time
Grilo, Masheb, Salant, 2005[317] CBT + orlistat vs. CBT + placebo Outpatient Good	Eating: • EDE • Remission Biomarker: • Weight loss Psych: • BDI	No statistics reported	Greater percentage of CBT + orlistat group remitted and achieved at least 5 percent weight loss over 12 weeks. Group difference in weight loss maintained at 2-month FU	CBT + orlistat superior in total weight loss and in percent weight loss to post-tx over 12 weeks.
Agras et al., 1994[316] Weight loss therapy vs. CBT+weight loss therapy vs. CBT+weight loss therapy + desipramine Outpatient Fair	Eating: • Binge eating • TFEQ Biomarker: • Weight Psych: • BDI	No statistics reported	No statistics reported	CBT plus weight loss (with or without desipramine) superior to weight loss alone in reducing binge frequency over 12 weeks. Significant difference between groups at 12 wks in change in weight over time with weight decreasing in weight loss group and increasing in CBT groups. By 3 month FU, CBT plus desipramine superior to CBT without desipramine in reducing weight.
Grilo, Masheb, Wilson, 2005[315] Fluoxetine vs. placebo vs. CBT + placebo vs. CBT + fluoxetine Outpatient Good	Eating: • Binge eating • BSQ • EDE • Remission • TFEQ Biomarker: • BMI Psych: • BDI	No statistics reported	No statistics reported	CBT groups superior to placebo and fluoxetine alone in decreasing binge frequency, eating and shape concerns, global eating score, disinhibition, and rate of remission. CBT + fluoxetine superior to placebo alone and fluoxetine alone in decreasing weight concerns and hunger; superior to fluoxetine alone in reducing depressed mood and dietary restraint; superior to placebo in decreasing body dissatisfaction. CBT + placebo superior to placebo alone and fluoxetine alone in decreasing depressed mood; superior to fluoxetine alone in decreasing dietary restraint, weight concerns, and body dissatisfaction.

BDI, Beck Depression Inventory; BMI, Body mass index; BSQ, Body Shape Questionnaire; CBT, Cognitive Behavioral Therapy; EDE, Eating Disorders Examination; FU, followup; Psych, psychiatric and psychological; TFEQ, Three Factor Eating Questionnaire; Tx, treatment, vs., versus.

(-1.6 kg), but that loss was not maintained at followup; at followup, however, the orlistat group was more likely to have achieved a weight loss of 5 percent or more. Dropout (about 20 percent) was comparable between groups.

Summary of medication plus psychotherapy trials. Adding CBT conferred benefit on remission rate, but not weight loss, over fluoxetine alone or placebo alone in one trial.[315] Adding CBT to orlistat was associated with a greater decrease in weight during treatment, although this does not appear to be maintained at followup.[317] In one trial, adding desipramine to CBT and weight loss therapy led to greater maintenance of weight loss over time.[316] Combining medication and CBT may improve both binge eating and weight loss, although sufficient trialshave not been done to determine definitively which medications are best at producing and maintaining weight loss. Moreover, the optimal duration of medication treatment for sustained reductions in binge eating and maintenance of weight loss has not yet been addressed empirically.

Behavioral Intervention Trials

We identified eight behavioral intervention-only trials (Table 24),[318-325] three trials of self-help (Table 25),[326-328] and one trial each of exercise and virtual reality (Table 26).[329,330]

In behavioral intervention trials, CBT tailored for BED was the most commonly tested therapeutic approach; one study used DBT. The total number of individuals enrolled in psychotherapy, self-help, exercise, and virtual reality trials was 481 (449 women and 32 men). Of the eight trials identified, participants ranged in age from 18 to 65 years. Six trials reported the race and ethnicity of participants: in all, they involved 401 persons identified as white, 19 individuals as nonwhite, eight as African American or Afro-Caribbean, six as Hispanic American, one as Native American, and one as Asian. In no instance were results analyzed specifically by race or ethnic group. Of the eight trials, five were conducted in the United States and one each in Germany, the United Kingdom, and Italy.

Behavioral intervention trials for binge eating disorder. *CBT.* A 12-week trial of standard CBT tailored for BED compared with CBT and spousal involvement and with a waiting list control group in 94 individuals with a BMI of 25 or more showed that both active CBT groups had significant reductions in days binged, BMI, disinhibition, hunger, depression, and self-esteem than the controls and were more likely to be abstinent from binge eating at the end of treatment. Adding spousal involvement did not produce significantly greater improvements than standard CBT.[320] Both CBT groups had significantly lower depression scores and BMI, but they did not differ from each other. The average BMI decrease from baseline to followup was 0.11 for CBT and 0.77 for CBT with spousal involvement, suggesting that CBT alone, with or without a spouse participating, did not yield substantial weight change. Overall, dropout was 34 percent.

Hilbert et al. studied 5 months of group CBT with body exposure treatment and group CBT with cognitive restructuring of negative body cognitions in 28 women with BED, using a broad inclusion criterion of at least one binge per week.[319] Both groups showed decreases in binge eating, psychological aspects of binge eating, self-report binge eating scores, and decreases in self-report depression, but differences between groups were not statistically significant. Neither group experienced significant weight loss. Dropout was 14 percent in each group.

Looking at the efficacy of group psychotherapy, Wilfley et al. compared group CBT with group IPT in 20 sessions with 3 additional individual sessions in 162 individuals with BED and BMI levels between 27 and 48.[318] Both therapies led to significant decreases in the number of days binged at the end of treatment and at 4-month followup. CBT led to greater improvements in Eating Disorders Examination Restraint scores at all time points. At 12 months, the groups did not differ in abstinence (CBT, 72 percent; IPT, 70 percent), severity of illness, or depression; both treatments led to significant reductions in these parameters. No participants in either group

Table 24. Results from behavioral intervention trials, no medication: binge eating disorder

Source, Treatment, Setting, and Quality Score	Major Outcome Measures	Significant Change Over Time Within Groups	Significant Differences Between Groups at Endpoint	Significant Differences Between Groups in Change Over Time
Gorin et al., 2003[320] Group-based CBT vs. CBT with spouse involvement vs. waiting list Outpatient Fair	Eating: • Abstinence • Binge eating • TFEQ Biomarker: • BDI Psych: • BMI	No statistics reported	Higher percent abstinent in CBT groups compared to waiting list.	CBT (with and without spouse involvement) superior to waiting list in decreasing number of binge days, disinhibition, hunger, depressed mood, and BMI over 12 weeks.
Hilbert and Tuschen-Caffier, 2004[319] CBT+exposure vs. CBT+cognitive interventions for image disturbance Outpatient Fair	Eating: • Binge eating • Body Satisfaction • EDE • Negative automatic thoughts • Recovery Biomarker: • BMI Psych: • BDI	Binge frequency, depressed mood, shape and weight concerns, body dissatisfaction, and restraint decreased in both groups over time.	No differences in percent recovered.	No differences on any measures.
Wilfley et al., 2002[318] CBT vs. IPT Outpatient Good	Eating: • Abstinence • Binge eating • EDE Biomarker: • BMI Psych: • GSI • SCL-90	Both interventions associated with decreased number of binge days and eating restraint at post-tx, 4- and 8-month FU. Both tx associated with decreased GSI total scores; shape, weight, and eating concerns, restraint, and depressed mood at post-tx.	Less restraint in CBT at post-tx and 4-month FU.	CBT superior in decreasing eating restraint at post-tx and 4, 8, and 12 month FU.

BDI, Beck Depression Inventory; BES, Binge Eating Scale; BMI, body mass index; CBT, Cognitive Behavioral Therapy; DBT, Dialectical Behavior Therapy; EDE, Eating Disorders Examination; EES, Emotional Eating Scale; FU, followup; GSI, General Severity Index (derived from BSI); PANAS, Positive and Negative Affect Schedule; Psych, psychiatric and psychological; RSE, Rosenberg Self-Esteem Scale; SCL-90, (Hopkins) Symptom Check ListTFEQ, Three Factor Eating Questionnaire; Tx, treatment, vs. versus.

Table 24. Results from behavioral intervention trials, no medication: binge eating disorder

Source, Treatment, Setting, and Quality Score	Major Outcome Measures	Significant Change Over Time Within Groups	Significant Differences Between Groups at Endpoint	Significant Differences Between Groups in Change Over Time
Telch et al., 2001[321] DBT vs. waiting list Outpatient Fair	Eating: • BES • Binge eating • EDE • EES Biomarker: • Weight Psych: • BDI • PANAS • RSE	No statistics reported	No statistics reported	DBT superior to waiting list control in decreasing number of binge episodes and binge days, binge severity, and weight, shape, and eating concerns.

Table 25. Results from self-help trials, no medication: binge eating disorder

Source, Treatment, Setting, and Quality Score	Major Outcome Measures	Significant Change Over Time Within Groups	Significant Differences Between Groups at Endpoint	Significant Differences Between Groups in Change Over Time
Carter and Fairburn, 1998[326] Guided self-help vs. non-guided self-help vs. waiting list Outpatient Good	Eating: • Abstinence • Binge eating • EDE Biomarker: • BMI • Weight Psych: • BSI • GSI	Both self-help groups decreased binge eating, GSI, and EDE global at 12-week post-tx. Guided self-help only decreased eating restraint at post-tx.	Both self-help groups associated with higher abstinence rates, less binge eating, and lower GSI, EDE global and restraint scores, compared to waiting list at post-tx. Guided self-help associated with less restraint and binge eating at 3 month FU and with less binge eating at 6 month FU compared to non-guided self-help.	Guided self-help superior to non-guided self-help and waiting list in reducing eating restraint over 12 weeks.
Peterson et al., 1998[328] Therapist-led group CBT vs. partial self-help group CBT vs. structured self-help group CBT vs. waiting list Outpatient Fair	Eating: • Abstinence • BES • Binge eating • BSQ • Eating Behavior-IV • TFEQ Biomarker: • BMI Psych: • HDRS • RSE	No statistics reported	Abstinence rates for binge eating higher in each of the CBT groups compared to waiting list	CBT groups superior to waiting list in decreasing objective and total binge episodes/week, hours spent binge eating/week, binge severity, disinhibition, and hunger over 8 weeks.
Peterson et al., 2001[327] Therapist-led group CBT vs. partial self-help group CBT vs. structured self-help group CBT Outpatient Fair	Eating: • Abstinence • Binge eating • BSQ • TFEQ Biomarker: • BMI Psych: • BDI • HDRS	No statistics reported	Abstinence from total binge episodes higher in structured self-help group versus therapist-led self-help and partial self-help groups.	No differences on any measures

BDI, Beck Depression Inventory; BES, Binge Eating Scale; BMI, Body mass index; BSI, Brief Symptom Inventory; BSQ, Body Shape Questionnaire; CBT, Cognitive Behavioral Therapy; EDE, Eating Disorders Examination; FU, followup; GSI, General Severity Index (derived from BSI); HDRS, Hamilton Depression Rating Scale; Psych, psychiatric and psychological; RSE, Rosenberg Self-Esteem Scale; TFEQ, Three Factor Eating Questionnaire; Tx, treatment, vs., versus.

Table 26. Results from other trials: binge eating disorder

Source, Treatment, Setting, and Quality Score	Major Outcome Measures	Significant Change Over Time Within Groups	Significant Differences Between Groups at Endpoint	Significant Differences Between Groups in Change Over Time
Riva et al., 2002 Virtual reality-based tx for body image vs. CBT-based psycho-nutritional group therapy Inpatient Fair	Eating: • Abstinence • BIAQ • BSS • CDRS • DIET • FRS • WELSQ Psych: • STAI	Virtual reality tx associated with increased ideal body score and WELSQ total score, and decreased state anxiety.	No statistics reported	Virtual reality tx superior to psycho-nutritional tx in increasing WELSQ total score and in decreasing state anxiety and overeating.

BMI, Body mass index; BIAQ, Body Image Avoidance Questionnaire; BSS, Body Satisfaction Scale; CBT, cognitive behavioral therapy; CDRS, Contour Drawing Rating Scale; DIET, Dieter's Inventory of Eating Temptations; FRS, Figure Rating Scale; Psych, psychiatric and psychological; STAI, Spielberger State-Trait Anxiety Inventory; Tx, treatment; WELSQ, Weight Efficacy Life-style Questionnaire.

experienced reductions in BMI across treatment or follow-up periods. Dropout was 20 percent in CBT and 16 percent in IPT.

Dialectical behavioral therapy. Twenty weeks of DBT led to greater reduction in binge days, binge episodes, weight concern, shape concern, and eating concern than did being in a waiting list control group in 44 women with DSM-IV BED.[321] Depression and anxiety scores did not differ. The authors did not report whether DBT was associated with significant change in weight, although no differences in weight loss emerged between groups during treatment. Dropout was 18 percent in the DBT group and 55 percent in the waiting list group.

Self-help trials. Carter and Fairburn compared guided self-help using a book[302] combined with six to eight sessions with a facilitator with self-help-only using the same book in the absence of a facilitator and with waiting list controls in 72 women with BED with weekly binges.[326] Both self-help approaches were more efficacious than the control arm in reducing the mean number of binge days and improving abstinence and cessation rates and EDE scores. At the end of treatment, both self-help groups showed significantly greater reductions in clinical severity than the control group. No group reported significant weight loss at any point. Comparisons of the two self-help groups yielded no differences in eating, depression, or BMI measures at any follow-up point. Dropout was 24 percent from guided self-help and 4 percent from the control group; self-help-only had no dropouts.

In a four-group comparison, Peterson et al. compared therapist-led self-help, partial self-help, structured self-help, and waiting list controls in 61 individuals with DSM IV BED.[328] In therapist-led self-help, a doctoral-level therapist led both the psychoeducational component and group discussion; in the partial self-help group, participants viewed a 30-minute psychoeducational videotape and then participated in a therapist-led discussion; and in the structured self-help group, subjects viewed the 30-minute psychoeducational videotape and then led their own 30-minute discussion. All self-help groups performed better than controls on objective binges, total binges, hours spent bingeing, and self-reported eating attitudes. For abstinence rates, all self-help groups (68 percent to 87 percent) were better than controls (12.5 percent). The groups did not differ in depression scores or BMI changes. Dropout was higher in

the structured self-help group (27 percent) than in the therapist-led (13 percent) and partial (11 percent) self-help groups.

The second report on this sample compared therapist-led self-help, partial self-help, and structured self-help in 51 individuals with DSM-IV BED.[327] All three approaches led to significant decreases in objective binges, hours spent bingeing, and body dissatisfaction. Structured self-help led to significantly greater abstinence at the end of treatment but not at followup. Depression scores decreased over time but not differentially across groups. BMI changes did not differ across groups; the authors did not report whether significant decreases occurred within groups, but the numerical changes appeared to be minimal. Dropout was not reported.

Additional interventions for binge eating disorder. In an inpatient trial, Riva et al. compared virtual reality therapy to psychonutritional control in 20 women with DSM IV BED.[330] Virtual reality therapy uses interactive three-dimensional visualization, a head-mounted display, and data gloves to modify body image perceptions. In this very small study with a large number of outcome measures, the investigators compared seven sessions of virtual reality plus a low-calorie diet and physical training with psychonutritional CBT, a low-calorie diet, and physical training. Virtual reality showed significant improvements in weight efficacy and diet scores. Abstinence did not differ significantly between groups and was 100 percent in each, most likely secondary to intensive inpatient treatment. Dropout was not reported.

Summary of behavioral interventions for binge eating disorder. Investigators most frequently chose to study CBT. However, no basic trial comparing individually administered CBT with waiting list, treatment as usual, or a second therapy was rated as fair or good.

The three fair- or good-rated trials that incorporated CBT provided treatment for between 12 weeks and 5 months. Collectively, these trials indicated two main findings. First, CBT is effective in reducing either the number of binge days or the actual number of reported binge episodes. Second, in comparison to waiting list controls, it leads to greater rates of abstinence when administered either individually or in group format, and this abstinence persists for up to 4 months post treatment. CBT also improves the psychological aspects of BED such as ratings of restraint, hunger, and disinhibition. Results are mixed as to whether CBT improves self-rated depression in this population. In all three studies CBT did not lead to decreases in weight. Whether the successful treatment of BED with CBT is associated with less weight gain (as opposed to actual weight loss) over time in individuals with BED has not yet been adequately addressed. Similarly, DBT (one trial) is associated with decreases in binge eating and psychological aspects of the disorder but not with definitive change in depression or anxiety or apparent weight loss.

Although CBT and DBT decrease binge eating and related psychological features of the disorder, they have no observable impact on the important outcome variable of weight loss. This is a somewhat puzzling finding as one would expect decreases in binge eating to be associated with weight loss. The reason for no weight loss is unclear. It is possible that calories previously consumed as binges may be distributed over nonbinge meals; or, how patients label binges and nonbinge meals may change with treatment. In any case, despite reported changes in eating patterns, little demonstrable weight change is achieved.

Self-help (three trials) is efficacious in decreasing binge days, binge eating episodes, and psychological features associated with BED. It also leads to greater abstinence from binge eating when compared to individuals randomized to a waiting list control condition; short-term abstinence rates approximate those seen in face-to-face psychotherapy trials. No self-help trials

led to significant decreases in self-rated depression scores or weight in comparison to waiting list controls. Virtual reality therapy must be viewed as experimental; the intensive inpatient treatment associated with this trial invariably affects the perfect abstinence rates observed in both treatment groups. Observing any added efficacy of virtual reality therapy is difficult at best.

Overall dropout rates in behavioral interventions for BED were between 11 percent and 27 percent in active treatment groups.

Key Question 2: Harms of Treatment for Binge Eating Disorder

Table 27 presents adverse events associated with BED treatments. For the trials using second-generation antidepressants, we refer to a recently completed report on the comparative effectiveness and tolerability of second-generation antidepressants (see Chapter 3).[243] In the BED clinical trials, the commonly reported side effects in trials involving fluoxetine were sedation, dry mouth, headache, nausea, insomnia, diarrhea, fatigue, increased urinary frequency, and sexual dysfunction. With fluvoxamine adverse events that occurred significantly more frequently than with placebo included insomnia, nausea, and abnormal dreams. Additional commonly reported adverse events included headache, asthenia, depression, dizziness, somnolence, dry mouth, nervousness, and decreased libido. Patients treated with sertraline experienced insomnia at a significantly greater rate than those receiving placebo; citalopram was associated with more reports of sweating and fatigue than placebo. For tricyclic antidepressants, 24 percent of individuals treated with desipramine discontinued treatment because of side effects. For imipramine, only anticholinergic effects (constipation, dry mouth, blurred vision) were reported more frequently in active drug than placebo participants. In the topiramate trial, six of 30 patients dropped out because of adverse events including headache, parasthesias, and amenorrhea. Individuals treated with sibutramine experienced significantly more constipation than those treated with placebo. Gastrointestinal events were reported more often in individuals receiving orlistat than in those receiving placebo.

No direct adverse events were reported for any psychotherapy trials for BED. In the DBT trial, three individuals required treatment for depression during the follow-up period.

Key Question 3: Factors Associated With Treatment Efficacy

Few studies reported on factors associated with efficacy of treatment in BED. Early abstinence from binge eating was associated with significantly greater weight loss in one study.[316] In one self-help trial, higher initial self-esteem was associated with poorer outcome; however, the effect was small, accounting for 6 percent of the variance in outcome.[326]

Key Question 4: Treatment Efficacy by Subgroups

The total number of individuals enrolled in the 12 drug or medication plus behavioral intervention trials was 680; of those, 55 were men. The age range of participants was reported in eight of the 12 studies; no study reported differential outcome by age. Of the seven studies that did report race or ethnicity, 374 participants were identified as white, 29 as nonwhite, 12 as African American, and six as Hispanic-American. Ten trials were conducted in the United States. No study analyzed results separately by sex, gender, race, or ethnicity. Based on these results, we

Table 27. Adverse events reported: binge eating disorder trials

Intervention	Adverse Events Reported
Medication Trials* †	
Fluoxetine versus placebo[305]	Fluoxetine group: sedation (5), dry mouth (11), headache (9), nausea (7), insomnia (7), diarrhea (6), fatigue (6), increased urinary frequency (4), sexual dysfunction (4). Both groups: hand and foot swelling, palpitations, and apathy; (*P* = NS)
Fluvoxamine versus placebo[306]	Fluvoxamine group: insomnia, headache, nausea, asthenia, depression, dizziness, somnolence, abnormal dreams, dry mouth, nervousness, and decreased libido. Insomnia, nausea, and abnormal dreams significantly more common in fluvoxamine than placebo.
Fluvoxamine versus placebo[307]	Fluvoxamine group: sedation (8); nausea (4); dry mouth (4); decreased libido (3) Placebo group: sedation (3); nausea (1); dry mouth (3); decreased libido (0) (*P* = NR)
Sertraline versus placebo[309]	Sertraline group: insomnia (7) Placebo group: insomnia (1) (*P* = 0.04)
Citalopram versus placebo[308]	Citalopram group: sweating (9) (*P* = 0.008); fatigue (5) (*P* = 0.05) Placebo group: sweating (1); fatigue (0) Also reported: dry mouth, headache, diarrhea, nausea, sedation, insomnia, sexual dysfunction
Imipramine versus placebo[310]	Imipramine group: skin eruptions and an aversion to tablet intake (1) anticholinergic effects (7) Placebo group: hunger, sweating, palpitations, arrhythmia, and general malaise (1); anticholinergic effects (3); (*P* < 0.05)
Topiramate versus placebo[311]	Topiramate group: headache, paresthesias and amenorrhea Placebo: leg cramps, sedation and testicular soreness
Sibutramine hydrochloride versus placebo[312]	Sibutramine: dry mouth (22); headache (6); constipation (7) Placebo: dry mouth (3); headache (14); constipation (0) (*P* < 0.01) All other adverse events did not differ significantly (i.e., nausea, insomnia, sudoresis, lumbar pain, depressive mood, flu syndrome, malaise, others) (*P* = NS)
Medication Plus Behavioral Intervention	
Placebo versus fluoxetine versus CBT + placebo versus CBT + fluoxetine[315]	NR
Weight loss treatment versus CBT versus desipramine[316]	8 subjects discontinued desipramine because of side effects
Orlistat plus CBT versus Placebo plus CBT[317]	Orlistat + CBT: significantly more gastrointestinal events
Behavioral Interventions	
Standard CBT versus CBT with spouse involvement versus waiting list control[320]	NR
CBT + exposure versus CBT + cognitive interventions for body image disturbances[319]	NR
CBT versus IPT[318]	NR
Dialectical behavioral therapy versus waiting list control[321]	3 women in DBT group were treated with either psychotherapy or medication for a major depressive episode.

CBT, cognitive behavioral therapy; IPT, interpersonal psychotherapy; NR, not reported; NS, not significant, vs., versus.
* If no numbers appear in parentheses, authors had only listed adverse events but not reported the number of cases.
† *P* values indicate differences between groups, they are reported when provided by author.

Table 27. Adverse events reported: binge eating disorder trials (continued)

Intervention	Adverse Events Reported
Self-help	
Guided self-help versus pure self-help versus waiting list control[326]	NR
Therapist-led versus partial self-help versus structured self-help versus waiting list control[328]	NR
Therapist-led versus partial self-help versus structured self-help[327]	NR
Other Behavioral Interventions	
Virtual reality based treatment versus psychonutritional control[330]	No adverse events observed

conclude that no information exists about differential efficacy of pharmacotherapy interventions for BED by sex, age, gender, race, ethnicity, or cultural group.

The total number of individuals enrolled in psychotherapy, self-help, or other behavioral trials was 532; of those, 32 were men. Participants ranged in age from 18 to 64. No studies looked at BED treatment for children or adolescents. From the trials that reported race or ethnicity, participants included 450 whites, 19 nonwhites, eight African Americans or Afro-Caribbeans, six Hispanic-Americans, one Native American, and one Asian. In no instance did the investigators analyze results separately by race or ethnic group. No data exist regarding differential efficacy of psychotherapeutic treatment for BED by sex, age, gender, race, ethnicity, or cultural group.

Chapter 6. Outcomes of Eating Disorders

This chapter presents the results of our literature search and findings for key questions (KQs) 5 and 6. KQ 5 asks what factors are associated with outcomes among individuals with the following eating disorders: anorexia nervosa (AN), bulimia nervosa (BN), and binge eating disorder (BED). KQ 6 asks whether outcomes for each of these disorders differ by sex, gender, age, race, ethnicity, or cultural groups.

We report our results separately for each disease in three main sections of this chapter. Use of the term "significant" means that differences over time or between groups were statistically significant at least at the $P < 0.05$ level.

We include literature that discusses more than one disease if findings do not combine individuals with different eating disorders. The review focuses on four main outcomes categories of interest: those related to eating, those involving psychiatric or psychological variables, those measured by biomarkers (e.g., weight, menstruation), and death. Many studies were conducted outside the United States, including Germany, England, Scotland, Sweden, China, Japan, New Zealand, and Australia. For that reason, we note in many cases below the setting (city, country) of the studies to emphasize the extent to which this literature is not directly generalizable to US populations and reflects variations across locales.

We include summary tables containing information on outcomes for studies that we rated fair or good. Similar to text, tables group studies by design: cohort (following a group of individuals, with the disease, identified from the community) or case series (following a group of individuals, with the disease, who received treatment) and whether a nondisease comparison group is followed as well. Articles that discuss results from the same study (the same sample for the same amount of time) are grouped in the same row. Finally, within these categories, we list studies alphabetically by author.

Six of the 62 outcomes articles we identified presenting outcomes for individuals with AN, BN, or BED received a quality rating of "poor;" Table 28 documents the reasons why these studies received this rating. Although each study was not deficient in all areas, common concerns contributing to a low rating included the following: a study involved only participants from one eating disorder program in one location or lacked a description of the location; the study did not have a comparison group; the statistical analysis did not include a power analysis or the authors did not report that they conducted any power analyses; the statistical analysis did not have necessary controls for confounding; and outcome assessors were not blinded to study group or blinding status was not described. As in earlier chapters, we do not discuss these studies further in the text.

For each included study, detailed evidence tables appear in Appendix C.[‡‡] Evidence Table 15 contains the included articles for AN outcomes; Evidence Table 16, articles for BN outcomes; and Evidence Table 17, articles for BED outcomes. Within each table, studies are listed alphabetically. Studies with outcomes for individuals with both AN and BN are in evidence tables for both diseases. To answer KQ 6, we used the literature that met our inclusion criteria and was relevant to answer KQ 5.

[‡‡] Appendixes cited in this report are provided electronically at http://www.ahrq.gov/downloads/pub/evidence/pdf/eatingdisorders/eatdis.pdf.

Table 28. Outcome studies: reasons for poor quality ratings and number of poor ratings by disease type

Reasons Contributing to Poor Ratings	Types of Disease, Number of Times Flaw Was Detected, and Citations
	Research Aim
Hypothesis not clearly described	Anorexia Nervosa: 0 Bulimia Nervosa: 0 Binge Eating Disorder: 0
	Study Population
Characteristics not clearly described	Anorexia Nervosa: 1[331] Bulimia Nervosa: 0 Binge Eating Disorder: 0
No specific inclusion or exclusion criteria	Anorexia Nervosa: 2[331,332] Bulimia Nervosa: 1[333] Binge Eating Disorder: 0
Study groups not comparable to each other and/or to non-participants with regard to confounding factors or characteristics	Anorexia Nervosa: 0 Bulimia Nervosa: 0 Binge Eating Disorder: 0
	Eating Disorder Diagnosis Method
Used independent clinician diagnosis or method used not reported	Anorexia Nervosa: 2[331,334] Bulimia Nervosa: 0 Binge Eating Disorder: 0
None used to diagnose patients similar in treatment/disease and comparison groups	Anorexia Nervosa: 0 Bulimia Nervosa: 0 Binge Eating Disorder: 0
	Study Design
Participants drawn from a treatment program in one city or area not reported	Anorexia Nervosa: 5[332,334-337] Bulimia Nervosa: 1[333] Binge Eating Disorder: 0
No comparison group	Anorexia Nervosa: 6[332] [331,334-337] Bulimia Nervosa: 1[333] Binge Eating Disorder: 0

Table 28. Outcome studies: reasons for poor quality ratings and number of poor ratings by disease type (continued)

Reasons Contributing to Poor Ratings	Types of Disease, Number of Times Flaw Was Detected, and Citations
	Statistical Analysis
Statistics inappropriate	Anorexia Nervosa: 0 Bulimia Nervosa: 0 Binge Eating Disorder: 0
No controls for confounding (if needed)	Anorexia Nervosa: 4[331,332,335,336] Bulimia Nervosa: 0 Binge Eating Disorder: 0
Power analysis not done or not reported	Anorexia Nervosa: 5[331,332,334-336] Bulimia Nervosa: 1[333] Binge Eating Disorder: 0
	Results/Outcome Measurement
Outcome assessor not blinded or not reported	Anorexia Nervosa: 3[331,332,337] Bulimia Nervosa: 0 Binge Eating Disorder: 0
Outcome measures not standard, reliable, or valid in all groups	Anorexia Nervosa: 0 Bulimia Nervosa: 0 Binge Eating Disorder: 0
Interpretation of statistical tests inappropriate	Anorexia Nervosa: 0 Bulimia Nervosa: 0 Binge Eating Disorder: 0
	External Validity
Population not representative of US population relevant to these treatments	Anorexia Nervosa: 2[331,336] Bulimia Nervosa: 0 Binge Eating Disorder: 0
	Discussion
Results do not support conclusions, taking possible biases and limitations into account	Anorexia Nervosa: 0 Bulimia Nervosa: 0 Binge Eating Disorder: 0
Results not discussed within context of prior research	Anorexia Nervosa: 0 Bulimia Nervosa: 0 Binge Eating Disorder: 0

Anorexia Nervosa

Our discussion of AN outcomes includes 38 articles exclusively discussing individuals with AN[3,7,177,331,332,334-366] and seven articles discussing individuals with both AN and BN.[367-373] First we discuss results for KQ 5, then KQ 6.

Key Question 5: Factors Associated with Outcomes

Eating-related outcomes. Table 29 presents outcomes from studies rated fair or good; we discuss factors associated with outcomes in the text. Types of studies include prospective cohort with a nondisease comparison group and case series with and without a nondisease comparison group.

Many studies evaluate eating-related outcomes based on the general Morgan-Russell (M-R) scale or some modification of the scale, which evaluates weight (and menstruation in females), or the average M-R scale, which is a composite rating of subscales measuring nutritional status, mental status, sexual adjustment, menstrual functioning, and socioeconomic status. General scale categories are defined as good—normal body weight and regular menstruation—intermediate, amenorrhea *or* low body weight (i.e., weight less than 85 percent of average body weight [ABW]); and poor—amenorrhea *and* low body weight (i.e., less than 85% ABW).

Prospective cohort studies with comparison groups. We included one prospective cohort study with outcomes for individuals with AN in our review that reported results in several articles, after participants were followed for 5 years[345,356] and 10 years.[349,352,362] AN participants were 51 residents of Göteborg, Sweden (including three males), born in 1970, who had been diagnosed with AN as adolescents. Comparisons were Göteborg residents matched to the AN group by age, sex, and school attended. Data from all articles discussing this study did not match exactly; therefore, we caution readers about ostensible trends across time based on data from different studies.

At 5-year followup, approximately one-half of the individuals with AN were considered recovered: 59 percent had no eating disorder (ED) diagnosis and 41 percent had a good outcome according to M-R scale criteria. However, 6 percent still had AN and the remainder had other eating disorders including BN (22 percent) and EDNOS (14 percent). The AN group also remained significantly more symptomatic than the nondisease comparison group on several measures such as dietary restriction, concern about body weight, worry about appearance, and Eating Attitudes Test (EAT) scores.

By 10 years, the M-R scale outcomes had improved. One-half of the cohort who had AN at baseline had a good outcome (49 percent); the percentage of the group with a poor outcome had declined from 24 percent at 5 years to 10 percent at 10 years. Still, 27 percent had an ED diagnosis at followup.

Case series studies with comparison groups. One case series study with a nondisease comparison group discussed results in two articles, Bulik et al.[342] and Sullivan et al.[350] For this study, investigators recontacted 70 women 12 years after referral for treatment (inpatient, outpatient, or assessment) for AN at one facility in Christchurch, New Zealand. The AN group was not limited to those with adolescent onset of the disease. The comparison group (N = 98) resided in the same city and was matched by age. Although 30 percent of individuals with AN at baseline were fully recovered, 21 percent continued to have an eating disorder at followup, with 10 percent continuing to meet Diagnostic and Statistical Manual, version III, Revised

Table 29. Eating-related outcomes: anorexia nervosa

Authors, Year (Quality Score)	Country Sample Size	Outcomes
Prospective Cohort, Comparison Group		
Gillberg et al., 1994[345] (Good)	Sweden	Years followed (mean): 5
Råstam et al., 1995[356] (Good)	Cases: 51 Comparisons: 51	ED dx at FU: AN: 6%; BN: 22%; EDNOS: 14%; None: 59%
		Recovered (M-R scale): 47%
		M-R outcomes: Good: 41%; Intermediate: 35%; Poor: 24%
Nilsson et al., 1999[362] (Good)	Sweden	Years followed (mean): 10
Råstam et al., 2003[349] (Good)	Cases: 51 Comparisons: 51	ED dx at FU: AN: 6%; BN: 4%; EDNOS: 18%; Any ED: 27%
Wentz et al., 2001[352] (Good)		M-R outcomes: Good: 49%; Intermediate: 41%; Poor: 10%
Case Series, Comparison Groups		
Bulik et al., 2000[342] (Good)	New Zealand	Years followed (mean): 12
Sullivan et al., 1998[350] (Good)	Cases: 70 Comparisons: 98	Recovery outcomes: Fully: 30%, Partially: 49%, Chronically ill (current AN, BN or EDNOS): 21%, AN only: 10%
Halmi et al., 1991[7] (Fair)	USA	Years followed (mean): 10
	Cases: 62 Comparisons: 62	ED dx at FU: AN: 3%, BN: 3%, Normal weight bulimia: 23%, EDNOS: 39%, No ED: 27%, Unknown: 5%
Case Series, No Comparison Groups		
Ben-Tovim et al., 2001[367] (Good)	Australia	Years followed (mean): 5
	Cases: 92	ED dx at FU: AN: 21%, BN: 5%, EDNOS: 9%, No ED: 59%, Unknown: 2%, Deceased: 3%
		M-R-H Outcomes: Good: 34%, Intermediate: 54%, Poor: 13%
Dancyger et al., 1997[353] (Fair)	USA	Years followed (mean): 10
	Cases: 52	Recovered: 31%, Good: 13%, Intermediate: 21%, Poor: 35%
Deter et al., 1994[343] (Fair)	Germany	Years followed, mean (range): 11.8 (9-19)
	Cases: 75	Good: 54%; Intermediate: 25% Poor:11%, Deceased: 11%
		AN: 17%
Eckert et al., 1995[338] (Fair)	USA	Years followed, mean (range): 9.6 (8.5 – 10.5)
	Cases: 76	Recovered: 24%, Good: 26%, Intermediate: 32%, Poor: 12%, Deceased: 7%
		ED dx at FU: No ED: 24%, EDNOS: 36%, BN: 22%, AN: 9%, AN/BN: 3%

AN, anorexia nervosa; ANBP, anorexia nervosa binge eating and/or purging subtype; ANR, anorexia nervosa restricting subtype; BED, binge eating disorder; BN,bulimia nervosa; Dx, diagnosis; ED, eating disorder; EDE, Eating Disorder Examination; EDI, Eating Disorder Inventory; EDNOS, eating disorder-not otherwise specified; FU, followup; M-R scores: Morgan and Russell Scale; M-R-H Scale, Morgan-Russell-Hayward Scale; SIAB, Structured Interview for Anorexia and Bulimia Nervosa; Tx, treatment; USA, United States of America.

Table 29. Eating-related outcomes: anorexia nervosa (continued)

Authors, Year (Quality Score)	Country Sample Size	Outcomes
Eddy et al., 2002 (Fair)	USA	Years followed, median (range): 8 (8-12)
	Cases: 136	Full recovery (by subtype): Restricting pure: 46%, Restricting not pure: 22%, Binge/purge:39% Relapse from full recovery (by subtype): Restricting pure: 31%, Restricting not pure: 47%, Binge/purge: 68% Restricting subtype crossover to binge/purge subtype: 52%
Fichter et al., 1999[339] (Good)	Germany	Years followed (mean): 6.2
	Cases: 95	M-R outcomes: Good: 27%, Intermediate: 25%, Poor: 42% Deceased: 6% ED dx at FU: AN: 27%, BN: 17%, EDNOS: 2%, No ED: 55%
Halvorsen et al., 2004[366] (Fair)	Norway	Year followed, mean (range): 8.8 (3.5 – 14.5)
	Cases: 51	M-R outcomes: Good: 80%, Intermediate: 16%, Poor: 4% No ED: 82%, AN: 2%, BN: 2%, EDNOS: 14%
Herzog et al., 1996[370] (Good)	USA	Years followed (mean): 4
	Cases: 76	Full recovery (no symptoms for ≥ 8 wks): ANR: 8%; ANBP: 17% Partial recovery (symptom reduction): ANR: 54%; ANBP: 81%
Herzog, Schellberg et al., 1997[359] (Fair)	Germany	Years followed, mean: 11.7
	Cases:69	Average time to first recovery: 5.8 years
Herzog et al., 1999[369] (Good)	USA	Years followed: Up to 11 (median = 7.5)
	Cases: 136	Full recovery (no symptoms for ≥ 8 wks): ANR: 34%; ANBP: 32% Partial recovery (symptom reduction): ANR: 83%; ANBP: 82% No remission: ANR: 17%; ANBP: 18% Relapse after full recovery: 40%
Isager et al., 1985[340] (Fair)	Denmark	Years followed, mean (range): 12.5 (4 – 22)
	Cases: 142	Average annual hazard rate of relapse: 3%
Lee et al., 2003[347] (Fair) Lee et al., 2005[363] (Fair)	Hong Kong	Years followed: 9
	Cases: 74	M-R scale outcomes**:** Good: 62% (typical: 52.6%; atypical: 89.47%), Intermediate: 33% (typical: 42.11%; atypical: 5.26%), Poor: 5% (typical: 5.26%, atypical: 5.26%) ED dx at FU: No ED: 46% (typical: 40.68%; atypical: 57.14%), AN: 15%, BN: 20% (typical: 25.42%; atypical: 4.76%), EDNOS: 19% (typical: 15.25%; atypical: 28.57%)
Löwe et al., 2001[348] (Fair)	Germany	Years followed (mean): 21.3
	Cases: 63	Full recovery: 51%, Partial recovery: 21%, Poor (including death): 26%, Unknown: 2%
Morgan et al., 1983[355] (Fair)	United Kingdom	Years followed, mean (range): 5.8 (4 – 8.5)
	Cases: 78	M-R Outcomes: Good: 58%, Intermediate: 19%, Poor: 19%, Deceased: 1%, unknown: 3%

Table 29. Eating-related outcomes: anorexia nervosa (continued)

Authors, Year (Quality Score)	Country Sample Size	Outcomes
Strober et al., 1997[341] (Fair)	USA	Years followed (range): 10 – 15
	Cases: 93	Full recovery: 76%, Partial recovery: 86%
		Dx of chronically ill at FU: AN restricting: 3%, AN binge eating: 1%, BN: 10%
Tanaka et al., 2001[351] (Fair)	Japan	Years followed, mean (range): 8.3 (4.0 – 17.7)
	Cases: 61	M-R outcomes: Good: 51%, Intermediate: 13%, Poor: 25%, Deceased: 11%

(DSM III-R) criteria for AN. The AN group also continued to exhibit worse eating-related outcomes through other measures. Controlling for age and current AN status, individuals in the AN group reported higher scores on the Eating Disorder Inventory (EDI) drive for thinness and perfectionism subscales and the Three Factor Eating Questionnaire Scale (TFEQ) cognitive restraint and hunger subscales. Similarly, Halmi et al., in a separate US study, found that almost 30 percent of the AN group were recovered at followup.[7]

Case series studies with no comparison groups. Among case series studies with no comparison group, we reviewed three studies limited to patients with adolescent AN onset.[341,366,369,370] Among a mix of 51 former outpatients and inpatients who were followed from 3.5 to 14.5 years in Norway, Halvorsen et al. found that three-quarters of participants no longer had an ED and had a good M-R general scale outcome score.[366] Without controlling for the length of followup, patients who no longer had an ED were significantly less likely to be depressed or suffer from an anxiety disorder, with the exception of obsessive-compulsive disorder, which did not differ across groups.

Similarly, after following 95 patients for 10 to 15 years in the US who had all received inpatient treatment, Strober et al. found that three-quarters of participants had achieved full recovery (free of any symptoms of AN and BN for 8 consecutive weeks).[341] Significant predictors of chronic AN (intermediate or poor outcome) were an extreme compulsive drive to exercise and a history of poor social relating preceding onset of illness. Significant predictors of a longer time to recovery were a more hostile attitude towards one's family and extreme compulsivity in daily routines. In both models, early onset of disease was not a significant predictor.

Using survival analysis, D. Herzog et al. found that a shorter duration of the intake AN episode was a significant predictor of recovery after four years. Other variables in the model that were not significant predictors included age at ED onset, bulimic behaviors, impulse-control behaviors, current depression, and other Axis I disorders.[370] Again, at 7-year followup, the D. Herzog study found a shorter duration of intake episode and higher percentage of ABW at intake predicted both a shorter time to full recovery and a shorter time to partial recovery.[369]

D. Herzog and colleagues compared outcomes for restricting and for binge/purge subtypes of AN. Not all had received inpatient treatment. At up to 4-year followup, the authors found that the percentage of patients who were fully recovered (asymptomatic for at least 8 consecutive weeks) was greater in the AN-binge/purge subtype (17 percent) than in the AN-restricting subtype (8 percent).[370] Corresponding to these descriptive differences, the AN-binge/purge group was

significantly more likely to have recovered fully than the AN-restricting group (relative risk [RR], 4.6; 95% confidence interval [CI], 0.98-21.9). A much larger percentage achieved partial recovery (did not meet full criteria for AN but still experienced substantial symptomatology); 81 percent in the binge/purge subtype and 54 percent in the restricting group. At 7-year followup, differences between the groups in the percentage that had recovered had diminished; approximately one-third in both subgroups had fully recovered and more than 80 percent had partially recovered.[369] Forty percent of patients relapsed after first recovery. After following the group for 8 years, differences in duration of disease and ABW predicted being in the binge/purge subtype but measures of impulsivity including a history of alcohol abuse, drug abuse, kleptomania, suicidality, or borderline personality did not.[177]

Through 8-year followup, crossover between the restricting and binge/purge subtypes was high. Of those with the restricting subtype 52 percent changed to the binge/purge subtype, with most of the crossover occurring in the first 5 years of followup.[177] In contrast, Strober et al. found a lower rate of crossover (29 percent); the median time to onset of binge eating was 24 months.[341]

The remaining case series studies discussing eating-related outcomes are not limited to a sample of patients with adolescent onset of AN. First we report outcomes based on M-R scale criteria because they are the most common measures across studies.

A group of females who had all received inpatient treatment in Heidelberg, Germany, were followed up at several points in time. After 6 years, only 27 percent had a good M-R scale outcome, 25 percent had an intermediate outcome, and 42 percent had a poor outcome.[339] However, at later followup points, more than 40 percent of living patients had good outcomes.[338,339,353,354]

Among 74 women, 72 percent of whom had received inpatient treatment for AN, followed for an average of 9 years in Hong Kong, bivariate analyses comparing an M-R outcome of good and Shapiro Control Inventory measures found that a good M-R outcome was associated with a better overall general sense of control, a greater positive sense of control, and a lower negative sense of control.[347,363] A better M-R outcome was also associated with an initial diagnosis of atypical AN (no fat phobia). Using descriptive analyses, Tanaka et al. found, for patients who all had received inpatient treatment, that a good versus poor M-R outcome was associated with younger age at referral, younger age at admission, higher body mass index (BMI) at followup, higher minimum BMI, better menstrual functioning, and better mental state and psychosocial measures.[351]

Morgan and colleagues used bivariate analyses to report on UK patients followed from 4 to 8.5 years, one-half of whom had been hospitalized.[355] They reported that lower general M-R outcome scores were associated with longer duration of food difficulties and longer duration of amenorrhea. Poorer average M-R outcome scores were associated with a longer duration of food difficulties, a longer duration of amenorrhea, greater family hostility towards the patient, a disturbed relationship between the patient and family, and personality difficulties.

Ben-Tovim et al. examined the characteristics of the Morgan-Russell-Hayward Scale (M-R-H scale), a modification of the M-R scale, after adding items related to binge eating and vomiting to a subscale concerning dietary and eating patterns, body concern, and body weight.[367] Using multivariate analyses, the authors found that total M-R-H Scale outcomes were significantly related to the dietary and eating patterns, body concern, and body weight subscale mentioned above. Other subscales measuring menstrual pattern, mental state, psychosexual state, and work and family relations were not significant in the model. Significant predictors in a second model,

predicting the same outcome, included subscale 2 at baseline of the disability adjustment scale (measuring overall behavior and social role functioning), the Flinders Medical Centre Symptom Score at baseline (measuring ED symptoms), the Body Attitudes Questionnaire Subscales (measuring a range of body-related attitudes), attractiveness at 6 months, and lastly, change in the salience of weight and shape over the first 6 months of treatment.

Studies also examined diagnostic outcomes, including the persistence of eating disorders over time. Results varied greatly across studies and were not related to length of time to followup. The percentage of individuals who continued to have an AN diagnosis at followup ranged from 9 percent to 29 percent across studies, an EDNOS diagnosis from 2 percent to 36 percent, and no eating disorder from 24 percent to 59 percent of participants.[338,339,363,367,374]

W. Herzog and colleagues measured change over time in the likelihood of first recovery in the Heidelberg case series, after following patients for a mean of 11.7 years.[359] The average patient had a first recovery in 5.8 years, with a greater likelihood of recovering in the first 6 years than later. Significant predictors of first recovery in multivariate models were lower serum creatinine levels at baseline, less purging behavior, and the interaction of less purging and fewer social disturbances as measured by the Anorexia Nervosa Symptom Score (ANSS).

Löwe et al. followed this same group of patients for 21 years.[348] Among the 63 patients, 51 percent showed a good outcome and full recovery, 21 percent were partially recovered, and 26 percent had a poor outcome and 2 percent were unknown. Poor long-term outcome (at 21 years since inpatient admission) was related to low BMI, severe psychological symptoms and social problems, higher EDI perfectionism and interpersonal trust scores, and lower hemoglobin and alkaline phosphatase levels (at 12 years since inpatient admission).

After following this group of patients for 12 years, both Deter and W. Herzog[343] (N = 84, including deceased patients) and Deter et al.[365] (N = 70) found that the persistence of AN symptoms was predicted by older age at onset, more somatic symptoms, more laxative use, low albumin levels, and a high value on a global prognosis score developed from the ANSS.[343,365] Baseline factors associated with relapsing versus having a persistent disorder include being younger, having a shorter disease duration, and less vomiting.[343]

Eckert et al. found, in descriptive analyses in a group of patients who had received inpatient treatment, that recovered patients were less likely to have major affective disorder, anxiety disorders, and phobias.[338]

Isager and colleagues measured relapse rates (lost 15 percent or more of weight gained during course of treatment in a year's time) among 151 patients (93 percent female) who had received treatment (inpatient or outpatient) in Copenhagen, Denmark.[340] After following patients from 4 to 22 years, they found patients were experiencing a 3 percent average annual hazard rate of relapse. Relapse was greater among those whose duration of therapeutic contact was less than 1 year.

Other factors related to these types of outcomes include the following. Factors associated with poor Psychiatric Scale Ratings for AN outcomes in the Fichter and Quadflieg study included binge eating in the month before treatment, other mental illness diagnoses before treatment, and lower body weight at the end of treatment.[339] In research conducted by Lee and colleagues, a group of atypical AN patients scored better at followup on the Eating Attitudes Test – 26 and the Eating Disorders Evaluation Questionnaire.[347,363] Typical versus atypical AN patients at followup had a lower sense of control in the domain of body and a stronger desire for control.

Psychiatric/psychological outcomes. Table 30 documents outcomes from eight studies with psychiatric and psychological outcomes.

Prospective cohort studies with comparison groups. The one prospective cohort study that we reviewed followed individuals, at 5 and 10 years, with AN at baseline and compared them with a matched community comparison group in Göteborg, Sweden.[346] At 5 years, the AN group was significantly more likely to have various personality disorders including obsessive-compulsive personality disorder, any Cluster C personality disorder (avoidant, dependent, obsessive-compulsive, or passive aggressive), any personality disorder, or two or more personality disorders as measured by the Structured Clinical Interview II for the DSM-IV (SCID II). In addition, individuals in the AN group had significantly greater rates of Asperger syndrome, any autistic-like condition, and empathy disorder than the comparison group.

At 10 years,[349,352,361,362] the AN group continued to be significantly more likely than the comparison group to currently have a personality disorder, Asperger syndrome disorder or autism spectrum disorder, and lifetime and current obsessive-compulsive disorder. The AN group was not more likely, however, to have an anxiety disorder, excluding obsessive-compulsive disorder.

Ivarsson et al. examined depressive disorders in the AN and comparison groups in these cohorts at both 5- and 10-year followup.[360] The AN group had a higher lifetime prevalence of depression. Being in the AN group was the only significant predictor of depressive disorder at 5-year followup (odds ratio [OR], 7.7; 95% CI, 1.15-19.6). At 10 years, being in the AN group (OR, 4.03; 95% CI, 1.15-14.19) and having a depressive disorder at 5 years were significant predictors of current depressive disorder. The absence of a mood disorder was significantly associated with resolution of the eating disorder.

Case series studies with comparison groups. Two studies followed individuals with AN who had received treatment and a comparison group. Both found higher rates of lifetime major depression and OCD among the AN group.[7,342,350] The study in Christchurch, New Zealand, which followed women for 12 years, found, after controlling for age, significant differences in the lifetime prevalence of several psychological disorders including major depression, mood disorders, obsessive-compulsive disorder, anxiety disorders, and drug dependence.[342,350] The study conducted by Halmi and colleagues also identified that significant differences in the rates of diagnosis of major depression and OCD continued to be true at 10-year followup in their AN case series.[7]

Case series studies with no comparison groups. Descriptively, Eddy et al. found that a history of drug abuse differed among AN subgroups; it was more likely among the binge/purge subtype (16 percent).[177] Correspondingly, among patients who all had adolescent onset of AN, Strober et al., using stepwise regression, found that binge eating at treatment intake was the only significant predictor of the onset of a substance use disorder. Other variables included in the model, such as depression, anxiety, and weight, were not significant predictors.[358]

Also using stepwise regression, Dancyger et al. measured factors related to Minnesota Multiphasic Personality Inventory (MMPI) scores at 10-year followup on a population of women who had received inpatient treatment and were not limited to those with adolescent onset.[353] Poorer overall outcomes were related to higher scores on three MMPI subscales: hypochondriasis, paranoia, and psychopathic deviate.

Table 30. Psychological outcomes: anorexia nervosa

Authors, Year (Quality Score)	Country Sample Size	Outcomes
Prospective Cohort Studies, Comparison Groups		
Gillberg et al., 1995[346] (Good)	Sweden Cases: 51 Comparisons: 51	Years followed (mean): 5 Diagnoses in AN group*: OCD: 30%, Any cluster C: 37%, any SCID personality disorder: 41%, 2 or more SCID personality disorders: 24%, Asperger syndrome: 12%, any autistic-like condition: 20%; empathy disorder: 30%; OCPD/AS/Autistic-like condition at both age 16 and 21: 45%
Ivarsson et al., 2000[360] (Good) Nilsson et al., 1999[362] (Good) Råstam et al., 2003[349] (Good) Wentz et al., 2000[361] (Good) Wentz et al., 2001[352] (Good)	Sweden Cases: 51 Comparisons: 51	Years followed (mean): 10 Current diagnoses in AN group*: OCD:16%, axis I disorder (including ED): 53% autism spectrum disorder: 18%, cluster C: 22%, Lifetime diagnoses in AN group*: Any affective disorder: 96% OCD: 35%, OCPD:55%, any anxiety disorder: 57%, Any Axis I (including and excluding ED): 100%, depressive disorder: 84%, cluster C: 63%, autism spectrum disorder: 24%
Case Series, Comparisons Groups		
Bulik et al., 2000[342] (Good) Sullivan et al., 1998[350] (Good)	New Zealand Cases: 70 Comparisons: 98	Years followed (mean): 12 Lifetime diagnoses (controlling for age)*: Major depression: Cases: 51%; Comparisons: 36% Any mood disorder: Cases: 60%; Comparisons: 42%, Alcohol or any drug dependence: Cases: 30%; Comparisons: 12% OCD: Cases: 16%; Comparisons: 2% Separation anxiety disorder: Comparisons: 17%; Comparisons: 2% Overanxious disorder: Comparisons: 37%; Comparisons: 3% Any anxiety disorder: Comparisons: 60%; Comparisons: 33%
Halmi et al., 1991[7] (Fair)	USA Cases: 62 Comparisons: 62	Years followed: 10 Lifetime diagnoses*: Major depression: Cases: 68%; Comparisons: 21% Dysthymia: Cases: 32%; Comparisons: 3% Obsessive-compulsive disorder: Cases: 25%; Comparisons: 6% Agoraphobia: Cases: 14%; Comparisons: 3% Social phobia: Cases: 32%; Comparisons: 3% Current diagnoses*: Major depression: Cases: 29%; Comparisons: 6% OCD: Cases: 11%; Comparisons: 2%

*Difference between groups ($P < 0.05$)
AN, anorexia nervosa; AS, Asperger syndrome; CD, compulsive disorder; ED, eating disorder; OCD, obsessive-compulsive disorder; OCPD, obsessive-compulsive personality disorder; sig, significant or significantly; SCID, Structured Clinical Inventory for DSM-IV; USA, United States of America.

Table 30. Psychological outcomes: anorexia nervosa (continued)

Authors, Year (Quality Score)	Country Sample Size	Outcomes
Case Series, No Comparison Groups		
Eddy et al., 2002[177] (Fair)	USA Cases: 246	Years followed (median): 8 History of drug abuse at intake*: AN restricting pure: 0%; AN restricting not pure: 13%; AN binge purge: 16%
Halvorsen et al., 2004[366] (Fair)	Norway Cases: 51	Years followed (mean): 8.8 Diagnosis at followup: Depression: 22%; Anxiety (not OCD): 27%; OCD: 2% Diagnoses at followup*: Depression: No ED group: 13%; ED group: 56% Anxiety disorder (no OCD): No ED group: 20%; ED group: 56%
Löwe et al., 2001[348] (Fair)	Germany Cases: 63	Years followed (mean): 21 Mood disorders by Psychiatric Status Rating Scale outcomes*: Good: 8%; Intermediate: 31%; Poor: 38% Substance use disorders by Psychiatric Status Rating Scale outcomes*: Good: 5%; Intermediate: 6%; Poor: 50%
Strober, Freeman et al., 1996[358] (Good)	USA Cases: 95	Years followed: 10 Substance use disorder: Abuse: 12%; Dependence: 7%

Biomarker-measured outcomes. Table 31 contains study outcomes assessed with biomarkers. This category has very few studies primarily because many studies present measurement of weight and menstrual status through general M-R scale outcomes. These results are included among eating-related outcomes above.

Prospective cohort studies with comparison groups. At 5 years, the study of the Göteborg, Sweden, cohort found that the AN group still weighed significantly less than the non-ED comparison group; more of the AN group was appreciably underweight than the comparison, and while only half of the AN group were near average body weight, nearly all of the comparison group were at that weight.[344,345] Regular or cyclical menstruation was significantly less likely in the AN group, and a large percentage of the AN group had dysdiadochokinesis (an inability to execute rapidly alternating movements).

At 10 years, various measures of weight, including direct measures in kilograms, ABW, and mean BMI (body mass index), did not differ significantly between groups.[349,352,361] However, a significantly larger percentage of the AN group still did not have normal menstrual function and continued to demonstrate dysdiadochokinesis.

Case series studies with comparison groups. The AN cohort in the Christchurch, New Zealand, study had significantly lower BMI than comparison participants when controlling for age and current AN status.[344,345] Desired BMI was also lower in the chronically ill AN group than in recovered individuals or the comparison group.

Case series studies with no comparison groups. Hebebrand et al. examined factors associated with BMI at 0 to 33.6 years followup.[354] A BMI of less than 17.5 at followup (criterion cutoff for AN diagnosis) was related to lower BMI at referral, older age at referral, and younger age at

Table 31. Biomarker outcomes: anorexia nervosa

Authors, Year (Quality Score)	Country Sample Size	Outcomes
Prospective Cohorts, Comparison Groups		
Gillberg et al., 1994[344] (Good)	Sweden	Years followed (mean): 5
Gillberg et al., 1994[345] (Good)	Cases: 51 Comparisons: 51	Near average body weight at FU*: Cases: 53%; Comparisons: 96% Extremely underweight:* Cases: 8%; Comparisons: 0%
		Regular or cyclical menstruation*: Cases: 50%; Comparisons: 90%
		Dysdiadochokinesis*: Cases: 20%; Comparisons: 2%
Råstam et al., 2003[349] (Good)	Sweden	Years followed (mean): 10
Wentz et al., 2000[361] (Good)	Cases: 51 Comparisons: 51	Mean weight: Cases: 62.3 kg; Comparisons: 63.7 kg
		Regular or cyclical menstruation*: Cases: 65%; Comparisons: 85%
Wentz et al., 2001[352] (Good)		Dysdiadochokinesis*: Cases: 22%; Comparisons: 4%
Case Series, Comparison Group		
Bulik, et al. 2000[342] (Good)	New Zealand	Years followed (mean): 12
Sullivan et al., 1998[342] (Good)	Cases: 70 Comparisons: 98	BMI*: Cases: 20.1 kg/m^2; Comparisons: 25.6 kg/m^2
Case Series, No Comparison Group		
Eckert et al., 1995[338] (Fair)	USA	Years followed (range): 8.5 – 10.5
	Cases: 76	ABW at FU: <85%: 23%; 85%-115%: 73%; >115%: 3% Regular menses: 48%
Löwe et al., 2001[348] (Fair)	Germany	Years followed (mean): 21
	Cases: 63	BMI by Psychiatric Status Rating Scale outcomes*: Good: 21.6; Intermediate: 19.7; Poor: 15.3

*Difference between groups ($P < 0.05$).

ABW, percentage of average body weight; BMI: body mass index; diff, different; FU, Followup; IBW, ideal body weight; kg, kilograms; sig, significant or significantly; USA, United States of America.

followup; by contrast, age at disease onset was not a significant predictor. A higher BMI was also found to be significantly related to a better Psychiatric Status Rating Scale outcome at followup.[348]

Eckert et al. followed patients who had received inpatient treatment 10 years previously.[338] Lower weight was associated with greater food faddishness, laxative abuse, body image disturbance, fear of getting fat, disturbance in sexual adjustment, worse psychological adjustment, disturbed menses, and other weight loss behavior.

Mortality outcomes. Table 32 summarizes results from studies of mortality and risk of suicide in individuals with AN.

Prospective cohort studies with comparison groups. No deaths were reported in the Göteborg, Sweden, study through the 10-year followup.

Case series with no comparison groups. All mortality data were obtained from case series studies without a comparison group. Several studies calculated standardized mortality ratios

Table 32. Mortality outcomes: anorexia nervosa

Authors, Year Quality Score	Country Sample Size	Outcomes
Case Series*, No Comparison Groups		
Birmingham et al., 2005[3] (Fair)	Canada Cases: 326	Years followed (mean): 7 Deaths: N=17 (Suicide: N=7, Pneumonia: N=2, Hypoglycemia: N=2, Liver disease: N=2, Cancer: N=2, Alcohol poisoning: N=1, Subdural hemorrhage: N=1) SMR: 10.5
Crisp et al., 1992[357] (Fair)	England and Scotland Cases:168	Years followed (mean): 22 England: Deaths: N=4 (Anorexia: N=2; Suicide: N=1; Cancer: N=1) (SMR: 1.36 times more likely than women of same age, 1973 – 1989) Scotland: Deaths N=8 (Anorexia: N=3; Suicide: N=4; Cancer N=1) (SMR: 4.71 times more likely than women of same age, 1973 – 1979)
Deter et al., 1994[343] (Fair) and Herzog, Schellberg et al., 1997 (Fair)	Germany Cases: 75 at FU	Years followed, mean (range): 11.8 (9 – 19) Deaths: N=9 (AN complications: N=7; Suicide: N=2)
Eckert et al., 1995[338] (Fair)	USA Cases: 76	Years followed, mean (range): 9.6 (8.5 – 10.5) Deaths: N=5 (all complications of AN; no suicides); SMR: 12.8
Eddy et al., 2002[177] (Fair)	USA Cases: 136	Years followed, median (range): 8 (8-12) Deaths by subtype: Restricting pure: 8%; Restricting not pure: 8%, Binge/purge: 6% History of suicidality by subtype: Restricting pure: 4%; Restricting not pure: 29%; Binge/purge: 27%
Fichter et al., 1999[339] (Good)	Germany Cases: 95	Years followed (mean): 6.2 Deaths: N=6 (Traffic accident during exercise: N=1; Cardiac and renal failure: N=2; Hypocalcemia: N=2; Cardiac failure and cachexia: N=1)
Franko et al., 2004[368] (Good)	USA Cases: 136	Years followed (mean): 8.6 Suicide attempts during study period: 22%
Hebebrand et al., 1997[354] (Fair)	Germany Cases: 272	Years followed, mean (range): 9.5, 0 – 33.6 Deaths: N=12 (Emaciation: N=10, Suicide: N=2) Mortality rate by patient weight at referral: < 13 kg/m^2: 11%, ≥ 13 kg/m$^{2:}$ 0.6%; BMI < 13 at referral associated with higher likelihood of mortality
Herzog et al., 2000[371] (Fair)	USA Cases: 110	Years followed: 11 Deaths**:** N=7 (Suicide: N=3; Acute alcohol intoxication: N=1; Cardiorespiratory failure, heptic failure, and cirrhosis: N=1; Cardiac arrhythmia and seizure disorder: N=1; Fungal pneumonia: N=1) SMR (all deaths): 9.6; SMR (suicide): 58.1

AN, anorexia nervosa; FU, Followup; N, number; sig, significant; SMR, standardized mortality ratio; Tx, treatment; USA, United States of America.
*In case series studies, sample size is as of the date of the analysis and therefore does not include deceased cases.

Table 32. Mortality outcomes: anorexia nervosa (continued)

Authors, Year Quality Score	Country Sample Size	Outcomes
Isager et al., 1985[340] (Fair)	Denmark Cases: 142	Years followed, mean (range): 12.5 (4 – 22) Deaths N=9 (Suicide: N=6, Malnutrition: N= 2, Unknown: N=1)
Keel et al., 2003[372] (Fair)	USA Cases: 136	Years followed (mean): 8.6 Deaths: N=11; SMR: 11.6 Suicide: N=4; Suicide SMR: 56.9
Lee et al., 2003[347] (Fair)	Hong Kong Cases: 80	Years followed (mean): 9 Deaths: N=3 (Suicide: N=2, Emaciation: N=1); SMR: 10.5
Löwe et al., 2001[348] (Fair)	Germany Cases: 63 at FU	Years followed (mean): 21.3 Deaths: N=14 (12 directly due to AN)
Møller-Madsen et al., 1996[364] (Fair)	Denmark Cases: 853	Years followed, mean (range): 7.8 (< 1 – 17) Deaths: N=50 (AN complications: N=13, Natural causes: N=11, Suicide: N=18, Accidents: N=2, Unknown causes or could not be determined: N=4) SMR: Females: 9.2; SMR: Males: 8.2 Females only < 1 year following treatment admission, SMR=30.5
Patton, 1988[373] (Fair)	United Kingdom Cases: 332	Years followed (mean): 7.6 Deaths: N = 11 (Suicide: N = 6; low weight: N = 5) Overall SMR: 6.01; Higher than expected SMR at 4-year FU: 5.76, Higher than expected SMR at 8-year FU: 2.70, Normal level
Sullivan et al., 1998[350] (Good)	New Zealand Cases: 70	Years followed: 12 Deaths: N = 1 (suidice)
Tanaka et al., 2001[351] (Fair)	Japan Cases: 61 at FU	Years followed, mean (range): 8.3 (4.0 – 17.7) Deaths: N=7 (Emaciation: N=3; Suicide: N=2; Murder: N=1; Burn: N=1)

(SMR), allowing for comparison to the population based on age, sex, and time when the patient population was drawn.

The SMRs were elevated in the AN groups and ranged from 9 to 13 across studies.[3,338,347,364,371,372] In one study, SMRs were significantly elevated in a female patient population through 14 years of followup (ranging from 30.5 at less than 1 year followup to approximately 6 for the remainder of the period). The SMR was no longer significantly elevated after 14 years.[364]

Only in two studies conducted in the United Kingdom were the SMRs lower. Crisp et al. examined mortality among females more than 20 years after they had received treatment for AN in either London, England (1968 to1973), or Aberdeen, Scotland (1965 to 1973).[357] In England, women with AN were 1.36 times more likely to die than women of the same age in England and Wales between 1973 and 1979. In Scotland, women with AN were 4.71 times more likely to die than women of the same age in Scotland during the same period.

Patton and colleagues conducted a record review of 332 AN patients, mostly female (96 percent), who had received treatment at Royal Free Hospital in the United Kingdom between

1971 and 1981.[373] The SMR at 4-year followup was 5.76, which was a significant elevation; at 8-year followup, the SMR was 2.7 (not significant). Predictors of mortality included weight less than 35 kilograms at presentation and more than one inpatient admission.

In one study that followed patients for 8.6 years, significant predictors of death (controlling for age and duration of illness before intake) included greater severity of alcohol use disorders, greater severity of substance use disorders, worse social adjustment, and worse global assessment of functioning (GAF) scores. Predictors of shorter time to death included longer duration of illness at treatment intake, affective disorder hospitalization at intake, suicidality associated with mental illness other than an ED, substance abuse, and worse severity of alcohol use over the course of the illness.[372] Descriptively, Isager et al. found that deceased patients were significantly more likely to have been hospitalized.[340]

Suicide was a common cause of death. Among the group of females with adolescent AN onset who received ED treatment at the Massachusetts General Hospital or other Boston area clinics the SMR was 58.1, significantly higher than that for the population as a whole.[371]

Franko et al. reported predictors of suicide attempts among the women in the Boston cohort.[368] Thirty percent of their patients had a history of suicide attempts before they entered the study; during the study, 22 percent of AN patients attempted suicide. A history of a suicide attempt at intake significantly predicted time to a future attempt in individuals with AN. Using multiple regression techniques, the authors determined that a first suicide attempt was predicted by a history of suicide attempts at intake, greater drug use, participation in individual therapy, use of neuroleptic medications, and older age at disease onset.

A history of suicidality was significantly different among patient subtypes in one study – lower in the pure restricting group than other groups.[177] However, the groups did not differ in rates of death at 8-year (median) followup.

Several other case series studies that were discussed in relation to their eating, psychological, or biomarker outcomes reported deaths of patients during the followup period. These are summarized in Table 32.

Summary of studies addressing KQ 5. One prospective cohort study following individuals who had AN and a healthy comparison group has been conducted. Limited to individuals with adolescent onset of their illness and comparisons in Göteborg, Sweden, this study found that, over a 10-year period, approximately one-half of the group had fully recovered; a small percentage continued to suffer from AN, and the remainder still had other eating disorders. The AN group no longer differed from the comparison group in terms of weight but these individuals continued to be more depressed than comparisons and to suffer from a variety of personality and obsessive-compulsive disorders, Asperger syndrome, and autism spectrum disorders.

Two case series studies, which gathered followup measures from individuals who had received treatment for AN and a nondisease comparison group, were reviewed. They concluded that individuals with AN continued to be more likely to have eating and comorbid psychiatric diagnoses years after treatment. In one study, lower desired body weight and lower desired and actual BMI continued in the AN group, after controlling for current AN status. Individuals in the AN group were also more likely to be depressed and to suffer from mood and anxiety disorders. The second study, limited to psychiatric outcomes, found continued higher rates of major depression and obsessive-compulsive disorder.

The remaining studies had no comparison groups. Rates of recovery and good outcomes varied across studies. Only a relatively small percentage of patients continued to be diagnosed with AN or BN at long-term followup, but many continued to have eating disorders, and relapse

rates were high. We did not find evidence that age of disease onset was related to disease chronicity. A relatively large percentage of patients cross over from the restricting subtype to the binge/purge subtype of the disease, but results are mixed concerning which subtype has better eating outcomes.

Few studies examined psychiatric and psychological comorbidities independently of their relationship to eating disorder outcomes. Among those that did and had a comparison group, individuals with AN had a higher probability of having a depression and anxiety disorders diagnosis (including obsessive-compulsive disorder) than comparison individuals. Based on the results of one cohort study, individuals with AN may also be more likely to have Asperger syndrome or autism spectrum disorder. Among individuals with AN, substance abuse may be associated with binge eating.

Through at least 5 years of followup, individuals with AN are more likely to weigh less than comparisons and evidence suggests that their desired weight is lower. We did not find similar predictors of continued low weight in the AN case series studies and so are unable to draw conclusions concerning these relationships. However, some evidence exists that lower weight at treatment presentation is related to poorer outcomes.

The mortality risk is significantly greater among those diagnosed with AN than in the population as a whole. The risk of suicide is particularly pronounced, as is the risk of death early in the followup period. Increased risk is associated with alcohol and substance use disorders.

Key Question 6: Outcome Difference by Sex, Gender, Age, Race, Ethnicity, or Cultural Group

We examined whether AN outcomes differed by participants' sex, gender, age, race, ethnicity, or cultural groups. We found insufficient evidence to evaluate differences by sex or gender. Males were included in only 19 of 38 reviewed studies and were never more than 10 percent of the analysis sample in any one study. No study included any analyses examining differences controlling for sex or gender.

No study that we reviewed provided outcomes based on the age of the participant at followup. Some studies limited participants to those whose AN onset was during adolescence, but none compared outcomes of those with adolescent onset to those with older onset. However, six studies did include a measure of age at disease onset. Whether this is a significant factor in the course of AN is of particular interest in the field.

Results were mixed. Descriptively, Tanaka et al. found that a good M-R rating was related to younger age at referral;[351] Deter and Herzog found that earlier onset of disease was a significant predictor of AN symptoms at 12-year followup.[343] Suicide attempts were more likely among those whose disease began at an older age.[368] In contrast, Strober et al. did not find age at onset to be a significant factor in predicting chronic AN (intermediate or poor outcomes) at 10- to 15-year followup.[341] It was also not a predictor of time to recovery after 4 years in the Heidelberg case series.[370] Lastly, although Hebebrand et al. found age at onset not to be significantly related to lower BMI at followup,[354] they reported that older age at referral and younger age at followup predicted worse outcome.

Only two studies, both from the United States, reported the race or ethnicity of participants. Nonwhite subjects constituted 4 percent of the Boston, Massachusetts, case series[368] and 7 percent of the case series from the University of California at Los Angeles.[341,358]

Bulimia Nervosa

Our discussion of BN outcomes includes 14 articles exclusively discussing individuals with BN[70,333,375-385] and seven articles discussing individuals with both AN and BN.[367-373] As above for AN, we first discuss results for KQ 5, then results for KQ 6.

Key Question 5: Factors Associated with Outcomes

Eating-related outcomes. Table 33 summarizes results from studies that report eating-related outcomes. The BN literature that met our inclusion criteria included only case series studies (i.e., no cohort studies). One study had a nondisease comparison group; all other studies had no comparison group.

Case series studies with comparison groups. Female patients who had received inpatient treatment (N = 163), in Germany were followed for 12 years.[378] The comparison group (N = 202) included females ages 18 to 30 who had never received treatment for an eating disorder. The Structured Inventory for Anorexic and Bulimic Syndromes, Expert-Rating version (SIAB-EX) was used to compare eating disorder symptoms between cases and comparisons at 12 year followup. The BN group as a whole was significantly more symptomatic than the comparison group, as were individuals with BN who were considered to be recovered.

As shown in Table 33, the BN group improved over time. At 2 years, 53 percent were considered recovered and did not have any ED diagnosis. At 6 years, the same was true of 67 percent of the women and, at 12 years, of 66 percent of the women.[378] However, even though recovery rates improved over time, total EDI scores were worse at 2- and 6-year followup than at discharge.[70]

Lifetime psychiatric comorbidity predicted a significantly higher probability of having any eating disorder at 2- and 6-year followup. This variable was no longer significant at 12 years. In contrast, after 12 years, greater lifetime psychiatric comorbidity significantly predicted a higher probability of having a global eating disorder outcome as measured by the Psychiatric Status Rating Scale (PSR) (OR, 3.71; 95% CI, 1.16-11.91). A lifetime history of AN and older age at disease onset also predicted a worse PSR at 12 years.[378]

Case series studies with no comparison groups. Fairburn and colleagues conducted 5- and 6-year followup assessments of females recruited for two psychotherapy trials in the United Kingdom.[375-377,386] The investigators recruited 102 patients with BN through general practitioners and psychiatrists with no limitations on age at disease onset.

After 5 years, by a variety of measures, the group had improved since baseline and had experienced a significant reduction, in the previous 3 months, in mean objective bulimic episodes, self-induced vomiting episodes, and laxative misuse.[375] Eating Disorder Examination (EDE) interview measures that significantly improved included those measuring restraint, shape concern, weight concern, and eating concerns.

Fairburn et al. examined whether outcomes differed between persistent disease (at least two episodes of behavior at one or both of last two assessments) and remitted disease (not engaged in any relevant behavior over past 3 months); they focused solely on binge eating or compensatory behaviors.[377] The persistence of binge eating behavior was related to baseline duration of disturbed eating, overvaluation of shape and weight, and worse social adjustment. None of the tested baseline factors predicted compensatory behavior. However, binge eating and compensatory behaviors were significant predictors of each other.

Table 33. Eating-related outcomes: bulimia nervosa

Authors, Year (Quality Score)	Country Sample Size	Outcomes
Case Series, Comparison Groups		
Fichter and Quadflieg, 2004[378] (Fair)	Germany Cases: 163 Comparisons: 202	Years followed: 12 Case diagnosis at 6 year FU: Recovered/no ED: 67%; AN: 4%; BN purge: 21%; BN nonpurging: 1%; BED: 1%; EDNOS: 1%;Deceased: 1% Case diagnosis at 12 year FU: Recovered/no ED: 66%; AN: 2%; BN purge: 10%; BN nonpurging: 1%; BED: 2%; EDNOS: 14%; Deceased: 3%
Case Series, No Comparison Groups		
Ben-Tovim et al., 2001[367] (Good)	Australia Cases: 86	Years followed: 5 Diagnosis at FU: AN: 1%; BN: 8%; EDNOS: 13%; No ED:74%; Unknown: 5%; Deceased: 0 M-R-H Outcomes: Good: 76%; Intermediate: 19%; Poor: 2%; Unknown: 2%
Fairburn et al., 2000[375] (Good) Fairburn et al., 2003[377] (Good) Stice and Fairburn, 2003[386] (Fair)	United Kingdom Cases: 92	Years followed: 5 Diagnosis at FU: BN: 15%; BED: 7%; AN: 1%; EDNOS: 32% Any DSM-IV ED: 49%; Remission: 35%; Relapse: 26%
Fichter and Quadflieg, 1997[70] (Fair)	Germany Cases: 185	Years followed (mean): 6.2 Diagnosis at 2 years FU: AN: 2%; BN: 36%; EDNOS: 8%; No ED: 55% Diagnosis at 6 years FU: AN: 4%; BN: 21%; BED: 1%; EDNOS: 2%; No ED: 71%
Herzog et al., 1993[380] (Good)	USA Cases: 96	Years followed: 1 First shift to subclinical BN diagnosis (loss of full criteria without considering duration): 86% Partial recovery: 71%; Full recovery: 56%
Herzog et al., 1996[370] (Good)	USA Cases: 150	Years followed: 4 Partial recovery: 88%; Full recovery: 57%
Herzog et al., 1999[369] (Good)	USA Cases at baseline: 110	Years followed (Median): 7.5 Full recovery: 74%; Partial recovery: 98%; Relapse after full recovery: 35%
Jäger et al., 2004[381] (Fair)	Germany Cases: 80	Years followed: 8 Diagnosis at FU: BN: 29%; EDNOS (bulimic): 9%; EDNOS (anorexic): 1%; No ED diagnosis: 61% No binges per week at FU: 63%

AN, anorexia nervosa; BED, binge eating disorder; BN, bulimia nervosa; DSM-IV, Diagnostic and Statistical Manual for Mental Disorders, Fourth Edition; ED, eating disorder; EDNOS, eating disorder not otherwise specified; FU, followup; M-R-H Scale, Morgan-Russell-Hayward Scale; USA, United States of America.

Table 33. Eating related outcomes: bulimia nervosa (continued)

Authors, Year (Quality Score)	Country Sample Size	Outcomes
Keel et al., 1999[384] (Fair)	USA	Years followed (mean): 11.5
Keel, Mitchell, Davis et al., 2000[383] (Fair)	Cases: 173	Diagnosis at FU: BN: 11%; AN:1%; BED: 1%; EDNOS: 19%; lifetime history of AN: 36%; lifetime history of BED: 11%
Keel, Mitchell, Miller et al., 2000[385] (Fair)		Narrow definition of remission: Full: 42%, Partial: 28% Broad definition of remission: Full: 47%, Partial: 23%

At 6-year followup, using multivariate analysis, Fairburn, Norman et al. determined that significant predictors of current AN or BN status (adjusted for the type of treatment received and the duration of followup) included paternal obesity (OR, 5.73; 95% CI, 1.56-21.1) and premorbid obesity (OR, 4.31; 95% CI, 1.35-13.7).[376]

Stice and Fairburn categorized their BN patients into dietary and dietary-depressive subtypes using cluster analysis.[386] Compared with persons in the dietary subtype, those in the dietary-depressive subtype were significantly more likely to have lifetime psychiatric treatment for eating disorders at baseline and during followup, greater persistence of binge eating and compensatory behaviors, and diagnoses of major depression, panic disorder, obsessive-compulsive disorder, social phobia, generalized anxiety disorder, and agoraphobia.

D. Herzog and colleagues examined eating-related outcomes for a group of female patients who sought treatment at Massachusetts General Hospital and other Boston area ED programs.[369,370,380] The authors examined levels and predictors of full and partial recovery at 1, 4, and 7 years. Full recovery was defined as 8 consecutive weeks of being asymptomatic; partial recovery was defined as not meeting full criteria for AN or BN but still experiencing significant symptomatology.

The percentage of the group that fully recovered increased over time. At 1 year, 56 percent were fully recovered;[380] at 4 years, 57 percent were fully recovered;[370] and at 7 years, 73 percent had achieved a full recovery at some point during followup.[369] The trend was similar for partial recovery at some point during followup: 1 year, 71 percent;[380] 4 years, 91 percent;[370] and 7 years, 98 percent.[369] Recovery was not, however, necessarily persistent even if it covers 8 consecutive weeks. By 7 years, 35 percent had relapsed after achieving a full recovery.

The authors investigated predictors of recovery at each followup. At 1 year, ideal body weight (IBW) was not a significant predictor of time to partial recovery.[380] Variables included in their models at both 4- and 7- year followup included duration of the current disorder episode, age at onset of the current eating disorder, age at onset of the first eating disorder, weight, binge and purge frequency, and the co-occurrence of various other disorders including those involving a lack of impulse control, depression, personality and any Axis I disorder. At both points, no significant predictors of recovery emerged from among these variables.[369,370]

Ben-Tovim et al. analyzed results from 86 female BN patients who had been treated by an eating disorder specialist in Adelaide, South Australia, and followed for 5 years.[367] Not all had inpatient stays and age at onset was not reported. Using multivariate analyses, they reported that total M-R-H scale outcomes were significantly related to subscales for dietary and eating patterns, body concern, and body weight rather than other subscales concerning menstrual pattern, mental state, psychosexual state or work and family relations. In a second multivariate

model, M-R-H total scores were predicted by overall behavior and social functioning at baseline, feeling fat at study recruitment, attractiveness at 6 months, and change in depression over the first 6 months.

Jäger et al. compared outcomes of female patients who had received analytic inpatient and systemic outpatient treatment at a hospital in Germany.[381] Over time, binges, bulimia severity, the number of episodes of food restriction, and EAT measures of bulimia and dieting significantly decreased in both treatment groups; in addition, the number of normal meals increased. The group receiving analytic inpatient treatment had a greater decline in the severity index and the number of restrictions than the group receiving systemic outpatient therapy.

Keel and colleagues examined eating-related outcomes for 173 females with a mean of 11.5 years following evaluation at the University of Minnesota's Eating Disorders Clinic.[383-385] Members of the group had participated in one of two previous treatment studies. A particular interest in this study was comparing results based on different definitions of remission. Defining remission as freedom from disordered eating for at least 6 months and the absence of undue influence of shape and weight on self-evaluation, the authors reported that 42 percent were in full remission and 28 percent in partial remission. Using a broader definition of remission, including absence of disordered eating for at least 8 weeks with no restrictions based on the influence of weight and shape, they reported 47 percent were in full remission and 23 percent were in partial remission.[384]

The authors compared the relation between prognostic factors and two specifications of the outcome measure: categorical (full or partial remission vs. not in remission) and continuous (log of the number of months since last binge/purge episode).[384,385] The two models showed little difference in results. Significant factors in relation to both outcome specifications included lifetime substance use, baseline substance use, current mood, substance use, and impulse control disorders, and results on a multidimensional personality questionnaire. Prognostic factors that were not statistically significant in relation to either outcome specification included age at onset, duration of symptoms at baseline, baseline depression or anxiety disorder, and lifetime mood or anxiety disorder.

Keel et al. compared the association among six definitions of BN outcomes and a variety of other outcome measures and prognostic variables.[383] Definitions of BN outcomes varied based on the duration of abstinence required for full remission or recovery, the number of categories in which outcomes were placed, and how the categories were combined. Full recovery ranged from 47 percent to 38 percent based on the required duration of abstinence in the specification. Other outcomes that were significantly related to the eating disorder outcome in all specifications included depression, body image disturbance, impulse control, and social adjustment. The analysis did not identify any prognostic factors that were statistically significant in relation to all six eating disorder specifications. However, substance abuse was significant in four of six specifications, age of presentation in three specifications, and age of onset in two.

Including 101 of the females from the University of Minnesota study discussed above, Keel et al. also examined the independence and relative strength of depression compared with bulimic symptoms in predicting body dissatisfaction at followup.[382] Baseline depression was both independent of and superior to bulimic symptoms in predicting body dissatisfaction at followup, demonstrating a direct association between depression and body dissatisfaction that is independent of bulimic symptoms.

Psychiatric/psychological outcomes. Table 34 summarizes results from studies reporting psychiatric/psychological outcomes.

Table 34. Psychological outcomes: bulimia nervosa

Authors, Year (Quality Score)	Country Sample Size	Outcomes
Case Series, Comparison Groups		
Fichter and Quadflieg, 2004[378] (Fair)	Germany Cases: 163 at 12 year followup Comparisons: 202	Years followed: 12 Psychiatric comorbidity at followup: Lifetime 79.7%; current: 41.1% Mood disorders: Lifetime: 69.0%; current: 16.5% Major depression: Lifetime: 58.2%; current: 10.8% Anxiety: Lifetime: 36.1%; current: 22.2% Substance use: Lifetime 36.1%; current: 14.6% Borderline personality disorder: 9.5%
Case Series, No Comparison Groups		
Fichter and Quadflieg, 1997 (Fair)	Germany Cases: 185	Years followed (mean): 6 Psychiatric comorbidity at 2-year followup: Borderline personality disorder: 5%; Substance abuse: 24%; Mood disorders: 30%; Anxiety disorders: 13% Psychiatric comorbidity at 6-year followup: Borderline personality disorder: 4%; Substance abuse: 21%; Mood disorders: 46%; Anxiety disorders: 32%
Stice and Fairburn, 2003 (Fair)	United Kingdom Cases: 82	Years followed: 5 Psychiatric comorbidity at followup:* Major depression: Dietary: 61%; Dietary-depressive: 81% Panic disorder: Dietary: 15%; Dietary-depressive: 33% Obsessive-compulsive disorder: Dietary: 2%; Dietary-depressive: 25% Generalized anxiety disorder: Dietary: 11%; Dietary-depressive: 47% Agoraphobia: Dietary: 4%; Dietary-depressive: 36%

*Difference between groups ($P < 0.05$).

Prospective cohort studies with comparison groups. The Fichter and Quadflieg study that followed females with BN and a healthy comparison group recorded psychiatric comorbidities in the BN group only.[70,378] In the first 6 years after treatment, general psychopathology, as measured by the Symptom Checklist 90-Revised (SCL-90), found that symptoms were worse at 2-year followup but better at 6-year followup compared to the end of treatment.[70] At 12 years, 80 percent of patients had a lifetime psychiatric disorder, and 41 percent had a psychiatric disorder in the month before assessment. Half of the patients had suffered from a lifetime mood disorder or major depression and 36 percent had suffered from an anxiety or substance use disorder.[378]

Case series studies with no comparison groups. The Jäger et al. study that reported 8-year outcomes following either analytic inpatient or systemic outpatient treatment found that depression had declined in both groups[381] but that the decline was greater in those who received inpatient treatment.

Biomarker measured outcomes. Table 35 presents results from studies with outcomes assessed through various biomarkers.

Case series studies with no comparison groups: Gendall et al. followed 82 females for 1 year who had participated in outpatient treatment trials in New Zealand.[379] At followup, approximately 31 percent of the female participants had irregular menses. In multivariate analyses, irregular menses (irregular or absent menstrual cycles within the past 3 months) were significantly related to a greater maximum-minimum weight difference and current smoking.

Table 35. Biomarker outcomes: bulimia nervosa

Authors, Year (Quality Score)	Country Sample Size	Outcomes
Case Series, No Comparison Groups		
Fairburn et al., 2000[375] (Good)	England Cases: 92	Years followed: 5 Change over time: Weight: 69.8 kg, BMI: 25.5
Fichter and Quadflieg, 1997 (Fair)	Germany Cases: 185	Years followed (mean): 6 Weight at followup: Good (19<BMI<30): 74%; Intermediate (BMI 30-40 or 17.5-19): 17%; Poor (BMI<17.5 or >40): 9%
Gendall, Bulik et al., 2000[379] (Good)	New Zealand Cases: 82	Years followed: 1 Irregular menses: 30.5%
Keel et al., 1999[384] (Fair)	USA Cases: 173	Years followed (mean): 11.5 BMI: 22.1, Weight: 60.7 kg

BMI, Body mass index, measured in kg/m^2; USA, kg, kilograms; United States of America.

Several studies reported improvements over time in weight measures. After 5 years, Fairburn and colleagues found that participants' mean weight and BMI had increased.[375] At 6-year followup, Fichter and Quadflieg found that 74 percent of their participants were in the good weight range.[70] Similarly, Keel et al. measured differences in weight variables in 173 females followed for approximately 11 years.[384] BMI, actual weight, desired weight, and highest weight all significantly increased over time.

Mortality outcomes. Table 36 gives the results from studies that reported on either death or risk of suicide (or both) among individuals with BN.

Case series studies with comparison groups. In the Fichter and Quadflieg study, 2.5 percent of the BN group were deceased at 12-year followup.[378] The SMR was 2.36, not significantly different from the rate expected in the population matched by age and sex.

Case series studies with no comparison groups. Franko et al. reported predictors of suicide attempts in a group of 110 women with BN who had been recruited because they sought treatment for eating disorders at Massachusetts General Hospital and other Boston area clinics.[368] At baseline, 23 percent reported a history of suicide attempts before assessment, and 11 percent reported suicide attempts during the study. After approximately 9 years of followup, significant predictors of shorter time to first suicide attempt included receiving group therapy, receiving individual therapy, younger age at onset, a history of drug use disorder, paranoid personality disorder at intake, and greater severity of laxative use.

In a companion study, D. Herzog et al. followed this same group of women in Boston for 11 years to examine rates and causes of death.[371] At the end of that time, none of the women were deceased.

Keel et al. measured the mortality rates among 110 females, also recruited in Boston, in the same manner as Herzog et al., but the parameters of the recruitment dates differed somewhat. Participants were followed for a median of 9 years.[372] One individual died during the followup period. The SMR of 1.3 was not significantly different from what would be expected in the population as a whole.

Table 36. Mortality outcomes: bulimia nervosa

Authors, Year Quality Score	Country Sample Size	Outcomes
	Case Series Studies, Comparison Groups*	
Fichter and Quadflieg, 2004[378] (Fair)	Germany Cases: 163 at 12 year followup Comparisons: 202	Years followed: 12 BN Cases Deaths: 2 year followup: 0 6 year followup: 2 12 year followup: 4, SMR: 2.36
Franko et al., 2004[368] (Good)	USA Cases: 110	Years followed: 8.6 Suicide attempts: 11% Predictors of time to first suicide attempt (adjusted): Group therapy; Younger age at onset; History of drug use disorder; Individual therapy; Paranoid personality disorder; Greater severity of laxative use
Herzog, et al., 2000[371] (Fair)	USA Cases: 110	Years followed: 11 Loss to followup deaths: 0
Keel et al., 2003[372] (Fair)	USA Cases: 110	Years followed (Median): 9 Deaths: 1, SMR: 1.3
Patton et al. 1988[373] (Fair)	USA Cases: 96	Years followed: 4-15 Deaths: N=3 (2 car accidents, 1 low weight) Crude mortality rate: 3.3, SMR: 9.38

BN, bulimia nervosa; SMR, standardized mortality ratio; USA, United States of America.
*In case series studies, sample size is as of the date of the analysis and therefore does not include deceased cases.

Patton et al. measured mortality rates in patients in the United Kingdom who were followed for 4 to 15 years.[373] Three patients died during the observation period, one from low weight. Again, the SMR was not statistically significant from what would be expected in the healthy population.

Summary of findings. All of the BN literature is case series, that is, studies that follow individuals over time who have received treatment. One study included a nondisease comparison group. Much of the emphasis in the BN literature concerned comparing various definitions of disease outcomes and diagnostic subtypes. Generally in these studies, more than half of the patients followed no longer had a BN diagnosis at the end of the study period. A substantial percentage continued to suffer from other eating disorders, but BN was not associated with an increased mortality risk. A limited number of analyses uncovered factors significantly associated with outcomes of this disease. Only depression was associated with worse outcomes consistently across studies.

Key Question 6: Outcome Difference by Sex, Gender, Age, Race, Ethnicity, or Cultural Group

In each of the BN outcomes studies except for Patton et al., all participants we reviewed were female.[373] Four percent of the participants in the Patton et al. study were male; however, this study included both AN and BN populations, and the authors do not specify how many of the included males were in each disorder group.

Most studies did not report the race, ethnicity, or cultural group of the participants. Franko et al. reported that 4 percent of their sample was nonwhite, but they did not specify the distribution in the BN sample, relative to the AN sample.[368] Johnson and colleagues reported that the modal race was white;[333] Keel and colleagues reported that 1 percent of their sample was nonwhite.[384] These investigators did not, however, report outcome differences by race, ethnicity, or cultural group. No outcome studies of BN controlled for the age of participants at entry; no studies were limited to individuals with adolescent onset of the disorder. We conclude that no evidence exists to determine whether outcomes for BN differ by any of these categories.

Binge Eating Disorder

Given the recent addition of the provisional criteria for BED to the psychiatric nomenclature, three studies met our inclusion criteria for this section. All three studies were case series.[387-389] One study included a comparison group.[389] One study was conducted in the United States (rated as fair),[388] one in Germany (rated as fair),[387] and one in Italy (rated as fair).[389]

Key Question 5: Factors Associated with Outcomes

In KQ 5 we address outcomes of BED and factors associated with outcomes. We partitioned outcomes into eating-related outcomes, psychological outcomes, and biomarker outcomes (largely weight change).

Case series with comparison groups. The only case series with a comparison group explored a special population of individuals undergoing laparoscopic adjustable gastric banding.[389] This is an important research question intended to determine whether individuals with BED who are obese are appropriate for bariatric surgery. In this large study of 130 BED patients versus 249 obese comparison individuals without BED, those with BED experienced more band adjustments and more pouch and esophageal dilatations than those without BED. The authors did not report on psychological outcomes. At 5 years, the groups did not differ on measures of either weight loss or weight regain. The authors did not report on any variations in disordered eating behavior that may have persisted after bariatric surgery.

Case series without comparison groups. Fichter et al.[387] followed 62 cases with BED for 6 years; of these patients, 78 percent had no ED diagnosis, 6 percent continued to have a BED diagnosis, and a minority had developed BN or EDNOS over the followup interval. Over the 6-year interval, depression, anxiety, and obsessionality measures also improved. The authors did not report whether changes observed in BMI over time were significant. No additional factors associated with outcome were reported.

The second case series examined the impact of comorbid psychopathology and personality disorders on treatment outcome for BED.[388] Individuals with cluster B personality disorders reported a greater number of binge days at 1-year followup. Neither binge frequency nor EDE global scores were related to other comorbid conditions. The authors did not report additional psychological or biomarker outcomes.

Summary of studies addressing KQ 5. Only sparse evidence addresses factors associated with BED outcomes. The three included studies have vastly different designs and research questions; more importantly, their findings do not converge.

Key Question 6: Outcome Difference by Sex, Gender, Age, Race, Ethnicity, or Cultural Group

KQ 6 addresses whether outcomes differ for BED by sex, gender, age, race, ethnicity, or cultural groups In all, 405 women and 134 men participated in outcome studies of BED. No study compared differential factors associated with outcome by sex or gender.

Only one study reported ethnicity:[388] 151 whites, five blacks, four Hispanics, and two Native Americans. This study did not report any differential outcomes by ethnicity.

All three studies were of adults. No outcome studies of BED in children have been performed. Nothing is known about differential outcome by age group.

Chapter 7. Discussion

This chapter discusses our findings about anorexia nervosa (AN), bulimia nervosa (BN), and binge eating disorder (BED), which derive from our systematic review of literature for six key questions (KQs). Four KQs dealt with evidence about treatment issues (Chapters 3, 4, and 5):

1. Efficacy of treatments or combination of treatments
2. Harms associated with the treatment or combination of treatments
3. Factors associated with the efficacy of treatment
4. Differences in efficacy of treatment by sex, gender, age, race, ethnicity, or cultural group.

Two other KQs covered the course and outcomes of these conditions (Chapter 6):

5. Factors associated with outcomes among individuals with these conditions
6. Differences in outcomes by sex, gender, age, race, ethnicity, or cultural group.

Our report focused on randomized controlled trials (RCTs) for AN, BN, and BED and on outcomes studies that included sample sizes of 50 or greater and included at least 1 year of follow-up. All studies were published since 1980.

In this chapter, we first review the quality of the literature and the strength of the evidence based on the outcomes of and treatment of eating disorders. The confidence that readers can have in our findings, conclusions, inferences, and research recommendations rests heavily on the quality of the research reviewed and the overall robustness of the evidence. We then discuss the major issues resolved (or not resolved) in treating and managing patients with these conditions, drawing as appropriate from the findings for all six questions. Following that section, we present our research recommendations. The chapter ends with a brief recapitulation of our conclusions.

Critical Findings and Implications for Treatment of Eating Disorders

In this section we review our main findings on treatments for AN, BN, and BED, with specific attention to medications only, behavioral or psychotherapy interventions only, combination approaches, and novel interventions. We also comment on issues relating to outcomes from the disorders, including mortality. Before presenting the findings, we document our approach to assessing the strength of these bodies of evidence. Interpreting our findings accurately requires appreciation of the considerable drawbacks to much of this literature.

Quality of Literature and Strength of Evidence

As described in Chapter 2 and documented in both evidence and summary tables, we first applied rigorous selection criteria for articles and assessed the quality of each study. We then evaluated the strength of the bodies of evidence available to address each KQ for each disorder. The possible grades in our scheme are as follows:

I. Strong evidence. The evidence is from studies of strong design; results are both clinically important and consistent with minor exceptions at most; results are free from serious doubts about generalizability, bias, or flaws in research design. Studies

with negative results have sufficiently large samples to have adequate statistical power.

II. Moderately strong evidence. The evidence is from studies of strong design, but some uncertainty remains because of inconsistencies or concern about generalizability, bias, research design flaws, or adequate sample size. Alternatively, the evidence is consistent but derives from studies of weaker design.

III. Weak evidence. The evidence is from a limited number of studies of weaker design. Studies with strong design either have not been done or are inconclusive.

IV. No published literature (for those situations in which no study addressed the question).

For the four treatment KQs, we found the strength of the body of evidence to be of mixed quality that varied considerably across the three disorders (Table 37). For KQ 1, evidence for treatment efficacy, we judged the AN literature to be weak (III); the exception was for psychotherapy for adolescents with AN, for which more evidence was available yielding a moderate rating (II). The strongest treatment efficacy literature was for BN; we judged both medication and behavioral interventions as strong (I), although we gave self-help and other interventions only a weak rating (III). For BED, both medication and behavioral interventions were viewed as moderate (II) with self-help and other interventions as weak (III).

Table 37. Strength of evidence concerning four treatment key questions

Interventions	KQ 1	KQ 2	KQ 3	KQ 4
Anorexia Nervosa				
Medication and Medication plus Behavioral Interventions				
Adults	III	III	III	IV
Adolescents	III	III	III	IV
Behavioral Interventions				
Adults	III	IV	III	IV
Adolescents	II	IV	III	IV
Bulimia Nervosa				
Medication and Medication plus Behavioral Interventions				
All ages	I	I	III	IV
Behavioral Interventions				
All ages	I	IV	II	IV
Self-help				
All ages	III	IV	III	IV
Other				
All ages	III	IV	III	IV
Binge Eating Disorder				
Medication and Medication plus Behavioral Interventions				
Adult	II	I	III	IV
Behavioral Interventions				
Adult	II	IV	III	IV
Self-help				
Adult	III	IV	III	IV
Other				
Adult	III	IV	III	IV

Regarding harms of therapy (KQ 2), we gave strong ratings (I) to the literature on medication interventions for BN and BED. The evidence for harms of other interventions for all three disorders received ratings of either weak (III) or nonexistent (IV). Behavioral trials rarely reported harms associated with treatment.

KQ 3 dealt with factors associated with or influencing therapeutic outcome. With the exception of behavioral interventions for BN, which we rated moderate (II), we rated the literature for all three disorders as weak (III). Very few well-designed studies addressed those factors that lead to good or poor outcome in clinical trials.

Finally, KQ 4 addressed differences in treatment outcome by age, sex, gender, race, ethnicity, or cultural group. For all three disorders and all types of interventions, we rated the

literature as nonexistent (IV). The treatment literature for eating disorders has virtually ignored all these factors.

As reported in Table 38, we found considerable evidence to address factors related to outcomes among individuals with AN and BN (KQ 5) and rated the evidence for both of these disorders as moderate (II). In contrast, the evidence available to address factors related to BED outcomes (KQ 5) was much more limited and, thus, weak (III).

Table 38. Strength of evidence concerning two outcomes key questions

Eating Disorder	KQ 5	KQ 6
Anorexia nervosa	II	III
Bulimia nervosa	II	IV
Binge eating disorder	III	IV

The AN outcomes literature includes one prospective cohort study (following individuals identified in the community) with a comparison group design and one case series study (following a treatment population) with a comparison group design. The remaining literature follows case series of patients without comparisons. Some studies use strong methodological designs that control for length of followup and the effect of independent predictors. However, results were not consistent across studies.

The BN outcomes literature included no prospective cohort studies but did include several studies with strong methodological designs, including one case series study with a comparison group. However, partially because the literature is inconsistent in the methodology used to measure outcome, few factors were found to be consistently related to outcomes and so uncertainty remains.

The BED literature included only three studies. Much of the data provided in these studies was descriptive and offered very limited information concerning factors related to outcomes.

We used the body of literature that met our inclusion criteria for answering KQ 5 to address KQ 6 concerning differences in outcomes by sex, gender, age, race, ethnicity, or cultural group. We graded the AN literature as weak (III) and the BN and BED literature as nonexistent (IV). The AN literature had limited evidence discussing the effect of age of onset on outcomes, but results were not conclusive. The AN literature yielded no evidence to evaluate differences in outcomes by any other KQ 6 criteria. No study addressed any of these concerns for BN and BED.

Our review supports and extends previous systematic reviews on treatment of eating disorders, including several Cochrane reports. Broadly, Cochrane reviews of AN treatment concur that the literature is weak, made no specific recommendations regarding AN treatment, and encouraged larger well-designed trials.[390] For psychotherapy for BN and binge eating, a Cochrane review supported cognitive behavioral therapy (CBT) for BN, in individual or group format, and encouraged further study of self-help.[391] For antidepressant treatment, Cochrane reviewers concluded that single antidepressant agents were clinically effective for BN in comparison to placebo, with greater remission rate but also greater dropouts. No differential effect regarding efficacy and tolerability among the various classes of antidepressants was reported.[392] Examining combinations of psychotherapy and antidepressants for BN, another Cochrane review reported that combination treatments were superior to psychotherapy alone, that psychotherapy appeared to be more acceptable to participants, and that the addition of antidepressants to psychological treatments decreased the acceptability of the psychological intervention.[393]

In addition, guidelines from the National Institute of Clinical Effectiveness (NICE) in the United Kingdom (http://www.nice.org.uk/) concur that AN evidence is weak. The NICE authors

assigned high grades to CBT for BN and BED and to antidepressants for BN. For both BN and BED, NICE recommended self-help as an initial treatment step.

Managing Patients with Medication Alone

Managing individuals with AN with medication only is inappropriate, based on evidence reviewed here. No pharmacological intervention for AN has a significant impact on weight gain or the psychological features of AN. Although mood may improve with tricyclic antidepressants, this outcome is not associated with improved weight gain. Moreover, medication treatment for AN is associated with high dropout rates, suggesting that the currently available medications are not acceptable to individuals with AN.

For BN, good evidence indicates that fluoxetine (60 mg/day) reduces core bulimic symptoms of binge eating and purging and associated psychological features of the eating disorder in the short term. Based on two studies, the 60 mg dose performs better than lower doses and may contribute to decreased relapse at 1 year; however, patients do not tend to remain on the drug. Preliminary evidence exists for other second-generation antidepressants (trazodone and fluvoxamine), an anticonvulsant (topiramate), and a tricyclic antidepressant (desipramine). Preliminary evidence exists that monoamine oxidase inhibitors (MAOIs) are associated with decreased vomiting in the treatment of BN, although diet should be closely monitored.

Medication trials for BED have focused primarily on overweight individuals with BED. In these individuals, desired outcomes are twofold: weight loss and abstinence from binge eating. The majority of medication research for BED reflects short-term trials. Preliminary efficacy has been shown for selective serotonin reuptake inhibitors (SSRIs), one serotonin, dopamine, and norepinephrine uptake inhibitor, one tricyclic antidepressant, one anticonvulsant, and one appetite suppressant. In the absence of abstinence data and long-term followup, however, we do not know whether observed changes in binge eating, depression, and weight persist.

Managing Patients with Behavioral Interventions Alone

For adult AN, we have tentative evidence that CBT reduces relapse risk for adults with AN after weight restoration has been accomplished. By contrast, we do not know the extent to which CBT is helpful in the acutely underweight state, as one study found that a manual-based form of nonspecific supportive clinical management was more effective than CBT and interpersonal psychotherapy (IPT) in terms of global outcomes during the acute phase. No replications of these studies exist.

Family therapy as currently practiced has no supportive evidence for adults with AN and a comparatively long duration of illness. Overall, family therapy focusing on parental control of renutrition is efficacious in treating younger patients with AN; these approaches lead to clinically meaningful weight gain and psychological improvement. Although most studies of family therapy compared one variant of family therapy with another, two studies produced results suggesting that family therapy was superior to an individual therapy for adolescent patients with shorter duration of illness.

For BN, evidence for CBT is strong. Although IPT is also as effective, at 1-year followup, based on one study, symptomatic change appears to be more rapid with CBT. This factor decreases the time that patients are exposed to the symptoms of BN. Dialectical behavioral therapy (DBT) and guided imagery both show preliminary promise for BN patients.

For BED, CBT decreases the target symptom of binge eating. It does not, as currently delivered, promote weight loss in overweight patients. DBT may hold promise for BED patients as well.

Managing Patients with Combination Interventions

Although many of the medication trials for AN were conducted within the context of basic clinical management, no study that systematically studied medication plus psychotherapy for AN met our inclusion criteria.

For BN, the combined drug plus behavioral intervention studies provide only preliminary evidence regarding the optimal combination of medication and psychotherapy or self-help. Although some preliminary evidence exists for incremental efficacy with combined treatment, given the variety of designs used and lack of replication, evidence remains weak.

For BED, the combination of CBT plus medication may improve both binge eating and weight loss outcomes. Sufficient trials have not been done to determine definitively which medications are best at producing and maintaining weight loss in this population. Moreover, the optimal duration of medication treatment for abstinence from binge eating and sustained weight loss has not yet been addressed empirically, yet weight-loss effects of medication are generally known to cease when the medication is discontinued.[394]

Managing Patients with Novel Interventions

Across the three disorders, we found evidence of various innovative approaches that seem to hold promise, especially for conditions as complex as these eating disorders. Nonetheless, nothing can be said definitively because the trials were small and inconclusive.

Reducing Mortality

The AN outcomes literature clearly and consistently identified that the risk of death is significantly higher in the AN population than would be expected in the population in general. Life-threatening complications of the disease include not only those directly related to weight loss and other physical problems but also a significantly elevated risk of suicide.

Studies were inconsistent concerning whether deceased patients had been included in the analysis sample at followup. Therefore, factors related to poor outcomes did not always include mortality risk. Several studies identified factors related to death versus all other outcomes. Only by including death with other outcome categories can we determine if factors related to death differ from factors related to other poor outcomes.

Individuals with BN and BED were not identified as being at elevated risk of death.

Methods and Other Deficiencies in Reviewed Studies and Recommendations to Overcome Them

Sample Sizes, Attrition, and Statistical Power

Adequate sample sizes. Especially in AN clinical trials, sample size was often insufficient to draw conclusions regarding differential efficacy across groups. Even when investigators did power calculations, they often did not plan an adequate allowance for attrition. Given this limitation, researchers using designs that contrasted one approach with another most commonly

observed no differences across interventions. This result was especially true in trials of behavioral interventions and even more so in those that included a large number of comparison groups.

Accurate power analyses should be conducted before starting any study and presented in the methods section. Larger multisite studies should be conducted as a means of bolstering patient numbers.

Subgroup analyses. Even in the face of small sample sizes, many authors conducted subgroup analyses on outcome variables, often in the absence of *a priori* hypotheses. In these small studies, the ability to discern even large differences between groups is limited, and some findings might arise by chance. Investigators must avail themselves of adequate statistical assistance to ensure against inappropriate analyses of this sort.

Attrition. Loss to followup and dropout from clinical trials is especially problematic in AN studies.[395] Individuals with AN are often in denial, deeply fearful of weight gain (which is the key treatment outcome), and hesitant to take medication. High attrition compromises the integrity of outcome data; differential attrition between treatment intervention groups and comparison (e.g., usual-care or placebo) groups is even more damaging. In light of high attrition, researchers often reported completer analyses rather than intention-to-treat analyses, and the former practice can bias results.

Substantial attention needs to be paid to enhancing motivation for treatment in individuals with AN and to improving retention in clinical trials. Although dropout is somewhat lower in BN and BED studies than in AN studies, investigators should also address these factors in clinical trials for these disorders.

Study Design and Statistical Analysis Issues

In general, the eating disorders literature suffers from insufficient rigor with respect to statistical design and analysis in both the planning and conduct of trials. This leads to both gaps and inaccuracies in reporting and interpreting results. Minimally, these problems call into question the validity of the conclusions that can be drawn from individual studies. More broadly, it limits cross-study comparisons and the systematic accumulation of findings that stand the test of time and replication. Ultimately, these problems will hinder the advancement of effective treatments.

Unclear randomization and allocation concealment. Randomization procedures were not of uniformly high standards in the AN, BN, and BED literatures. Many studies failed to report how investigators achieved randomization (if indeed they did achieve it). In many instances, clinical decisions interfered with the integrity of the randomization procedures. No studies reported procedures for allocation concealment.

Trial design challenges. A common problem involves lack of attention to the within-subject repeated design inherent in intervention and treatment trials. For example, studies often indicate the use of repeated-measures analysis but then actually report analysis of posttreatment outcome data only using a paired *t*-test to identify treatment group differences. In some cases, investigators include baseline data as a covariate (which is not explicitly identical to using a repeated-measures model); in other cases, they do not take baseline data into account at all.

In addition, authors sometimes compute a change (delta) score (posttreatment minus baseline) representing within-subject change over time. This is a reasonable (indeed, often preferable) analytic approach to understand pre-post differences. However, they then fail to

account for baseline differences that could result in misinterpretation of mean within-group delta scores; an example is when higher baseline values are associated with smaller delta scores.

Overall, advances in this field demand more clarity in the description of analytical methods employed, including specifically the analytic models that have been determined *a priori*, and for the use of repeated measures models with appropriate inclusion of covariates. Attention to these recommendations should improve our ability to integrate information from disparate studies and to draw conclusions with higher yield with respect to the design and implementation of future interventions.

Duration of treatment and absence of followup. Only a very few studies included a dimension of differential duration of treatment in their designs. Assuming that a medication trial that lasts weeks is likely to have long-lasting effects on symptoms that have been present often for many years is unrealistic. Realistic duration of treatment and longer followup of patients in clinical trials for AN, BN, and BED are essential. In addition, strategies to develop continuation and maintenance treatments have not yet been addressed in this field. They are a critical next step in both medication and psychotherapy research.

Excessive diagnostic and outcome measures. The field of eating disorders has spawned an unusually large array of diagnostic and outcome assessment measures. The lack of consistency of measures renders comparisons across studies virtually impossible. This problem is an especially important barrier to standardizing measures of weight and weight change in outcome assessments and trials involving AN therapies, especially when age and sex corrections for body mass index (BMI) should be employed. Future efforts to refine and consolidate the number of measures would be a valuable contribution to the field.

Researchers should be careful not to include too many outcome measures in their designs. They need to avoid having many outcome variables at the expense of the most important behavioral indicators. Excessive numbers of outcome measures, especially those that may be closely related, lead to a higher likelihood of Type I errors and an inevitable focus on the minor significant findings that do emerge. This is especially detrimental to understanding the efficacy of therapeutic regimens when those findings are not the most clinically relevant dimensions or when their relevance to recovery is unknown.

Treatment of medical morbidities. Insufficient attention has been paid to addressing the optimal approach to treatment of serious long-term physical sequelae of AN and BN, most notably osteoporosis. We advise that measures of physical health issues be considered in the design of future trials.

Sociocultural context. Although the facilitating nature of sociocultural forces such as emphasis on thinness and unhealthy dieting have long been acknowledged, few treatment or outcome studies have attempted to measure the impact of these pernicious contextual factors. Although these variables are less tractable (for study design and conduct) than more readily measured factors such as eating-disordered behaviors, depression, anxiety, or biomarkers, greater attention to developing effective methods to measure these contextual factors may reveal important and often overlooked factors that influence recovery. This in turn may open new avenues for prevention, community education, policy, and strategies for maintenance of treatment gains.

Reporting Issues

Lack of definition of stage of illness, remission, recovery, and relapse. For AN, BN, and BED, investigators did not apply consensus definitions of stage of illness, remission, recovery,

and relapse. Developing standardized definitions of these terms for each disorder and the means to evaluate them are high priorities for future research. Accomplishing this will require a concerted and orchestrated effort to bring researchers together to develop such definitions and reporting guidelines.

Reporting change as reduction in behaviors rather than abstinence or remission. Especially in the BN and BED literature, researchers commonly reported outcomes such as percentage reduction in binge days, percentage reduction in binges, or amount of time spent binge eating. Although these are potential indicators of therapeutic change, when used alone they can be misleading because individuals with high weekly binge eating can reduce this behavior by even as much as 50 percent but still be highly symptomatic. Depending on the disorder and core behaviors being targeted, future studies should report either abstinence from binge eating, vomiting, and other compensatory behaviors or absence of binge days for a specified duration of time (at least 1 month but preferably longer).

Statistical reporting. Frequently, authors do not report degrees of freedom, making it impossible to decipher the exact nature of the model being tested. Incomplete reporting of results derived from multivariate models is problematic. Authors should take care to report clearly any interaction, between-group, and within-group effects when they employ repeated designs.

Statistically significant differences versus clinically meaningful differences. Across all three disorders attention to distinguishing between statistically significant and clinically meaningful differences is insufficient. For example, significant differences in weight gain in AN and in weight loss in BED may be observed; however, the extent to which group differences as small as 1 kg to 2 kg truly represent clinically meaningful differences is rarely addressed. Definitions of what constitutes clinically meaningful differences in eating disorders are required.

This issue is even more complex when dealing with psychological features of the eating disorder or associated anxiety or depression. Although significant group differences may emerge in a parameter such as hunger, the extent to which this type of finding reflects improvement in the disorder and is a harbinger for remission remains unknown.

Future Research Needs

Gaps in the Literature for Interventions

Gaps in the literature can be identified for the specific diseases and for broader issues of research across eating disorders. We first examine deficits in the evidence base for the main types of interventions (for one, two, or all three of the conditions), drawing on the points made above about the quality of articles or strength of evidence. We then turn to broader methods and related issues for the entire body of investigations in these conditions.

Medications. Discovering new medications that target the core biological and psychological features of AN, address adverse medical sequelae such as osteoporosis, and enhance motivation and retention in medication trials are critically needed steps. As noted, fluoxetine offers some benefits for BN patients. Additional studies are required to determine the long-term effectiveness of relatively brief medication trials, the optimal duration of medication treatment, and the optimal strategy for maintenance of treatment gains. In addition, work to identify and test novel medications that decrease the urge to purge (e.g., with antiemetics) or reduce the extent to which binge eating and purging are experienced as reinforcing is also warranted. Medication trials should focus on achieving abstinence from binge eating and purging, not merely reducing the

frequency with which these behaviors occur. Efforts to improve retention in medication trials for BN are also warranted, as are additional studies combining medications and behavioral interventions.

For BED medication questions, future investigations should take care to report specifically and separately on two outcomes – weight loss and abstinence from binge eating – because weight loss is less applicable to individuals with BED who are of normal weight. Future BED studies should clearly distinguish between normal weight and overweight participants and address whether treatment goals include both cessation of binge eating and weight loss. The impact of high placebo response should be considered in future trials and designs modified accordingly (e.g., sufficiently long placebo run-in phases).

Across all three disorders, no effort has been made to study drug augmentation effects. All trials were monotherapy trials; only a few allowed sequential medication in nonresponders. Investigators should consider augmentation strategies in their future studies.

Behavioral interventions. Strategies for enhancing CBT to change both binge eating and weight loss should be included in the next generation of behavioral studies. They should also focus on strategies for enhancing efficacy of CBT and how best to treat CBT nonresponders. On the basis of preliminary trials, DBT also deserves further study.

Combination interventions. The absence of trials combining medications and behavioral interventions (e.g., psychotherapy) is a serious deficit in the AN literature, and it is striking given that treatment delivered in the community for AN patients is often some form of combination treatment. Future studies must address the efficacy of various combinations of treatments for individuals with AN. Future studies should further explore optimal combinations and how best to combine treatments for BN patients who do not respond to CBT or fluoxetine alone. For BED patients, the needed research centers more on which medications have the greatest efficacy for producing desired outcomes and the optimal duration of medication use.

Novel and "borrowed" interventions. Research on innovative medications and behavioral treatments are warranted, especially given the state of treatment of AN. Medications studied to date have either focused on peripheral symptoms such as depression or anxiety or attempted to capitalize on medication side effects such as weight gain, with the aim of aiding weight restoration in AN. Of special importance will be trials of novel medications that target core biological and cognitive features of the disorders and that are also acceptable to patients.

Similarly, psychotherapies applied to eating disorders have been borrowed from other fields such as depression (CBT and IPT), anxiety disorders (exposure with response prevention), and personality disorders (DBT). We should actively seek to further adapt psychotherapeutic interventions that are tailored to the unique core pathology of eating disorders (e.g., drive for thinness, body dissatisfaction, appetite dysregulation) and that are both efficacious and acceptable to the patients. New behavioral interventions that target motivation to change and encourage retention in treatment are required. Further dismantling of complex therapies such as CBT to determine the active therapeutic components is also warranted.

Other fields are benefiting from the application of new information technologies to the treatment of illness. Adequately powered clinical trials that include the use of email, the Internet, personal digital assistants, text messaging, and other technological advances to enhance treatment will add to future treatment development. These approaches may be well suited to disorders marked by shame, denial, and interpersonal deficits and where availability of specialty care is limited.

Multidisciplinary interventions. Specialist inpatient and partial hospitalization treatment of AN often reflects a multidisciplinary approach: medicine, psychiatry, psychology, nutrition, family therapy, and sometimes additional disciplines such as recreational therapy and occupational therapy. The majority of treatment trials have been monotherapeutic. When they are multidisciplinary, the actual component of multidisciplinarity was rarely a variable on which patients were randomized. Studies that directly address the therapeutic benefits of and optimal approach to multidisciplinary treatment are required.

Maintenance of gains after drug discontinuation. For all three disorders, investigators typically failed to provide adequate follow-up time for medication trials. This means they cannot determine the extent to which positive behavior changes seen during medication administration are maintained over time. At minimum, such studies should have at least 1 year of followup. Especially with BN and BED, for which evidence for the short-term efficacy of medication interventions exists, additional information on maintenance of treatment gains, prevention of relapse, and optimal duration of medication treatment are critical next phases for clinical trials.

Gaps in the Literature for Certain Types of Patients

Patients with anorexia nervosa. AN is a serious psychiatric illness. Treatment research on AN is particularly challenging given the characteristic denial of illness, high drop-out rates from treatment, and the limited population prevalence in any single catchment area. Despite the fact that this is the most challenging eating disorder to treat, our evidence base is scant. Studies tend to be small, inadequately powered, and hence inconclusive. Medications studied to date have either focused on peripheral symptoms such as depression or anxiety or attempted to capitalize on medication side effects such as weight gain, with the aim of aiding weight restoration in AN. Both medication and behavioral intervention trials tend to be derivative—using medications or behavioral interventions that are borrowed from other areas of medicine without focusing on the core symptoms of AN.

We noted above some specific gaps related to medication and psychotherapy interventions. We reiterate here the urgency of more, and better, research on this disease. Trials of novel medications that target the core cognitive symptoms and biological processes of AN and medical sequelae are especially needed to move the field forward.

The literature on AN has failed to distinguish sufficiently between interventions targeted at individuals before or after weight restoration and has failed to address the optimal approach to renutrition. Indeed, whether medication and behavioral interventions have different outcomes depending on weight status remains murky. Given that low weight and malnutrition can interfere with the efficacy of medication and the ability to process information in psychotherapy, the optimal timing of the administration of medications and therapy vis-a-vis weight restoration is a critical question that remains unaddressed.

Patients with eating disorders not otherwise specified (EDNOS). Several treatment centers have reported that the majority of individuals who seek treatment for an eating disorder receive a diagnosis of EDNOS.[88,89] EDNOS is a compound category illustrated in the Diagnostic and Statistical Manual, Version IV (DSM IV), by six examples including BED. Despite the patient characteristics that lead to this diagnosis, investigators appear to have ignored systematically those with EDNOS diagnoses. Given the preponderance of individuals with EDNOS diagnoses in treatment settings, this is a serious shortcoming of the literature.

In part, this gap reflects the greater clarity and homogeneity that investigators can achieve in clinical trials when they recruit only individuals with clearly defined AN or BN. However, the

price of this clarity is generalizability and, ultimately, understanding the effectiveness of interventions tested. Although some trials have begun to expand inclusion criteria to reflect typical clinical practice, others have retained strict inclusion criteria. Only by further clarifying clinical syndromes within the current EDNOS category and investigating the optimal approach to treat these conditions will we be able to determine how best to treat the majority of treatment-seeking individuals.

Improved epidemiologic data are required to determine whether the frequency with which EDNOS is seen in the clinic reflects population prevalence rates of the various eating disorders. In addition, active strides should be taken to characterize the syndromes that are captured under the heading of EDNOS and to determine the best way to treat conditions that exist under that umbrella diagnostic category.

The need for additional attention to individuals with EDNOS was clearly shown through our review of the outcomes literature. EDNOS is a common outcome among individuals who formerly had AN or BN. However, virtually nothing is known about the persistence of these conditions.

Age and lifespan orientation. The treatment literatures on AN, BN, and BED differ in how they examine differential therapeutic outcomes by age group. For all three disorders, a more thoughtful lifespan approach is required to determine optimal approaches from childhood through older adulthood.

The AN literature is devoid of medication studies for adolescents; drug trials have focused exclusively on adults. Future medication trials should explore medication efficacy in adolescents and the differential efficacy of medications between adolescents and adults.

In contrast, behavioral interventions have focused more on adolescent patients, possibly because of the existence of various family therapy models that are well suited to the context within which adolescent AN arises. Nonetheless, behavioral interventions should pay greater attention to the appropriateness of various approaches across the lifespan (including duration of illness) and of adaptations that depend on age of the patient.

The extent to which CBT approaches to adolescent treatment of AN were adapted to match the developmental level of the patients is unknown. Likewise, approaches that are effective in adolescents may be inappropriate for adults, although developmentally appropriate adaptations may be worthy of study. For example, the relative efficacy of family therapy for adolescents with AN may signal the important role of the family. However, the family of relevance for an adult with AN may be her or his spouse and children rather than family of origin. Such permutations of the therapeutic approach have not yet been tested.

For BN, most commonly older adolescent and adult patients received the same treatment and researchers made no effort to explore differential outcome by age group. Future studies that delve more into mechanisms of treatment response should take care to explore differential age effects.

For BED, no medication or behavioral intervention trials exist for adolescents. No study enrolled patients younger than 18; many included individuals up to 65 without documenting age effects. The first step for BED research is to acquire epidemiologic data to determine the extent to which this disorder is a problem for adolescents. The second needed step is to explore differential outcomes by age.

Males and females. Although males suffer from eating disorders, they are underrepresented in clinical trials of AN and BN. When included, their numbers are usually too small to be

analyzed separately. Clinical trials of BED often include a greater number of men; however, no study has reported on differential efficacy by sex.

This situation can be remedied, first, by better studies comparing the phenomenology of AN, BN, and BED in males and females. Second, more extensive epidemiological data can provide more accurate estimates of the actual sex ratio in the population. Third, efforts should be expanded to explore differential treatment needs and outcomes in males and females across the age spectrum. Fourth, we have no data on whether treatment for eating disorders is best conducted in mixed-sex or single-sex environments. Fifth, multisite trials can be designed to increase sample size of male participants.

We note that much of the literature to date deals with males and females (a construct related to sex and biology). Very little research, apparently, tries to deal with gender (a construct related to socialization and social roles). We believe that more attention to the difference between these ideas, and some effort to understand the impact of gender, and not simply sex, may be valuable in understanding treatment approaches and efficacy.

Race and ethnicity. The majority of the literature on AN fails even to report the race and ethnicity of participants. All descriptions of participants should include this critical parameter. Although the more recent BN and BED literature has improved on this point, no studies of medication or behavioral interventions have addressed the issue of whether treatment efficacy differs by race or ethnic background. This is a serious omission in the literature.

To remedy this shortcoming, we must collect adequate epidemiologic data to provide critically needed information about the frequency with which eating disorders occur across racial and ethnic groups. Such data would provide guidance for planning targeted recruitment in clinical trials and enable researchers to set priorities for approaches to incorporating race and ethnicity into both treatment and outcomes studies. In addition, further exploration of sociocultural factors (e.g., stigma) may also assist with understanding both underdetection and underrepresentation of racial and ethnic minorities in research studies.

Underserved populations. The literature on AN, BN, and BED is devoid of any mention of specific issues of gay, lesbian, transsexual, or transgender individuals. These parameters should be systematically recorded in both treatment and outcome studies.

Gaps in the Overall Evidence Base

The United States' contribution to the literature. The literatures on AN, BN, and BED are geographically imbalanced. Although the United States has contributed considerably to the literature on BN and BED, it has done much less on both the treatment and outcome literature for AN. Although outcome studies of AN may be more difficult in the United States because of the mobility of the population, large-scale multisite treatment trials are perhaps more feasible in the United States given the number of academic treatment centers, the generally shared language, and the size of the population base. The United States should expand its contribution to the global literature for the next phase of treatment studies, especially for AN.

In addition, the unique racial and ethnic composition of the United States could assist with addressing the vacuum of information regarding differential treatment outcome by race and ethnicity across AN, BN, and BED. For the outcomes literature, the majority of literature for AN comes from outside of the United States. The extent to which data from outside the United States accurately reflect outcomes in the United States is unclear.

Replication. The hallmark of good science is replication. One major weakness of the existing literature and a critical need for the future is replication. Once efficacious interventions

are identified, adequately powered replication studies should be supported to confirm their effectiveness. Results of such studies would need to be careful to report findings using measures and statistical techniques that would allow for direct comparisons across trials.

Large multisite randomized controlled trials. The majority of eating disorders treatment studies are small, single-site trials. The average sample size of AN trials, 23, illustrates this point robustly. Future multisite trials will facilitate patient recruitment, enhance statistical power, enable meaningful subset analyses, buffer against high drop-out rates, and improve generalizability of results. Working in partnership with insurance companies to enable such trials in the current reimbursement milieu may be critical to success.

Generalizability and key treatment questions in the community. Clinical trials for AN in particular do not adequately reflect the type of treatment typically delivered in the community. Nor do clinical trials for AN address some of the key challenges facing clinicians who treat this disorder in inpatient and partial hospitalization or residential settings.

For low-weight patients with AN, the first treatment challenge is weight restoration. Guidelines from the American Psychiatric Association (APA) suggest that individuals at 75 percent of ideal body weight (IBW) or lower are candidates for inpatient weight restoration, although many other factors influence level of care decisions. When facilities are available, weight restoration occurs in hospital, followed by various levels of step-down marked by increasing autonomy and exposure to real-life eating and emotional situations.

No clinical trials for AN address the optimal approach to inpatient weight restoration that can achieve the most lasting gain. This also includes nutritional trials of optimal approaches to renutrition. No studies address the accuracy of the recommendation for hospitalization at 75 percent IBW. No studies address the optimal conditions under which a patient should be discharged from inpatient treatment and stepped down to less structured environments. Given the financial expense of prolonged inpatient hospitalizations and the toll on both patient and family, the conditions under which extended hospitalizations are superior to intensive outpatient management should be the focus of future studies.

Harms of treatment. Trials of medication or behavioral interventions for patients with AN, BN, and BED do not routinely describe the degree of medical compromise or strategies to monitor for potential harm in malnourished patients. Indeed, behavioral intervention trials often completely overlook the fact that their interventions may have adverse effects on patients. Especially given the high drop-out rates from AN trials, behavioral interventions should pay greater attention to both physical and psychological harms associated with interventions. All studies should report adverse events associated with interventions with these disorders. In addition, with AN, researchers should determine, especially within medication trials, whether adverse events differ between the underweight and the weight-restored state.

Issues in Outcomes Research

Outcomes research and treatment research. One serious gap in the evidence base about eating disorders is the absence of "cross talk" between the outcomes and the treatment literatures. Outcomes literature reveals intriguing problems that persist years after the onset of AN. One example is the presence of autism spectrum disorders reported in the Göteborg cohort.[344-346,349,356] Such observations could provide critical information to individuals designing new interventions for AN. Targeting social information processing deficits, for example, could be one way to enhance AN treatment delivery. Paying greater attention to premorbid traits and

traits that persist after recovery or through persistent illness may help to enhance treatment efficacy by identifying new treatment targets.

In addition, greater attention to demographic patterns in outcome studies such as typical age of recovery from AN may assist with better appraising where an individual entering treatment is in the course of her or his illness. This could assist with enhancing engagement in treatment and reducing the number of dropouts.

Prospective cohort studies and comparison groups. Virtually all the outcome results and relationships that we identified came from case series studies. This design limits generalizability beyond the specific treatment population being studied. Only one prospective cohort study has been conducted with individuals identified with AN; none has been done among persons with either BN or BED. Therefore, little evidence exists as to whether outcomes differ across treatment populations, individuals in the general population who suffer from these disorders, and those who may not meet threshold diagnostic criteria yet report symptoms or features of the disorders.

Of particular interest would be studies that address factors associated with successful outcomes in AN or BN; these should explore trajectories of recovery and how current diagnostic nosology captures those trajectories. For example, an individual with AN who is assessed 5 years after the onset of that illness may be given a diagnosis of EDNOS; this pattern fails to acknowledge that the patient is on a *recovery* trajectory from AN. The appropriateness of receiving a diagnostic label (EDNOS) different from the original diagnosis (AN), rather than a specific indicator such as AN in partial remission, has yet to be addressed adequately in the literature.

Tracing outcomes across diagnoses. Many individuals who at one time suffered from AN or BN continue to experience less severe eating disorders in later years. Use of dichotomous or simplistic measures of disease state is increasingly seen as uninformative. Additional research is needed that can sufficiently capture the factors associated with transitions in severity of eating disorder diagnoses.

Statistical methods for outcomes research. Outcomes studies vary in their statistical sophistication. At their best, studies used multivariate techniques to control for the influence of various independent variables on outcomes; they may also employ survival analyses techniques to control for differences in the length of time that patients were followed. At their more rudimentary state, many studies simply presented descriptive comparisons between a series of prognostic factors and outcomes of interest, or they employed techniques more appropriate for exploratory research (e.g., stepwise regression). We encourage investigators doing outcomes research (as contrasted with trials) to plan from the outset on using advanced statistical and analytic methodological approaches.

Impact of weight loss treatment on binge eating. Although not a focus of this review, with the ever-increasing obesity epidemic,[396,397] an important area of study will be the impact of various weight loss treatments on binge eating and on the development of eating disorders and eating-disordered behaviors. Programs developed for obesity prevention and treatment in both children and adults should be carefully monitored to ensure that no untoward effects emerge that increase eating-disordered behaviors.[398-401]

Cost-effectiveness analyses. Only rarely has the cost-effectiveness of interventions for AN, BN, and BED been addressed. At some point, however, some medications, behavioral approaches, or combination therapies will appear to be efficacious in trials or effective in broader trials or observational studies. Then, clinicians, insurers, health plan administrators, and others

will want information on the relative cost-effectiveness of different therapeutic options. To provide information to address these questions, future studies should include data collection of costs and cost-effectiveness analyses in their designs.

Conclusions

The literature regarding treatment efficacy and outcomes for AN, BN, and BED is of highly variable quality. For AN, the literature on medications was sparse and inconclusive. No studies combining medication with behavioral interventions met inclusion criteria. Evidence suggests that specific forms of family therapy are efficacious in treating adolescents, and preliminary evidence suggests that CBT may reduce relapse risk for adults after weight restoration and that a manual-based form of nonspecific supportive clinical management may be effective in underweight adults.

For BN, fluoxetine (60 mg/day) decreases the core bulimic symptoms of binge eating and purging and associated psychological features in the short term. CBT administered individually or in groups reduced core behavioral symptoms and psychological features in both the short and long term. How best to treat individuals who do not respond to CBT or fluoxetine remains unknown.

In BED, CBT reduced binge eating and leads to greater rates of abstinence when administered either individually or in group format, persisting for up to 4 months after treatment; however, CBT does not lead to weight loss in individuals with BED. Medications may also play a role in the treatment of BED although further research addressing how best to achieve both abstinence from binge eating and weight loss in overweight patients is required.

Higher levels of depression and compulsivity were associated with poorer outcomes in AN; increased mortality was associated with concurrent alcohol and substance use disorders. Only depression was consistently associated with poorer outcomes in BN; BN was not associated with an increased risk of mortality. Because of sparse data, we could reach no conclusions concerning BED outcomes. We uncovered weak to no evidence to address sociodemographic differences in either treatment or outcomes for any of these disorders.

The quality of the literature about treatment efficacy and outcome for AN, BN, and BED is highly variable. In the treatment literature, the largest deficiency rests with treatment efficacy for AN; we rated this literature as the weakest.

Future AN studies require large numbers of participants, multiple sites, clear delineation of the age of participants, and interventions that are tailored to the unique core pathology and medical sequelae of the illness. For BN, future studies should address novel treatments for the disorder, optimal duration of intervention, and optimal approaches for those who do not respond to medication or CBT. For BED, future studies require better explication of how best to target both binge eating and weight loss goals, optimal duration of intervention, and prevention of relapse.

For all three disorders, exploring additional treatment approaches is warranted. In addition, research teams should pay greater attention to factors influencing outcome, harms associated with treatment, and differential efficacy by age, sex, gender, race, ethnicity, and cultural group. Consensus definitions of remission, recovery, and relapse are essential. For both treatment and outcome literature, greater attention is required to the presentations currently grouped under the heading of EDNOS.

Outcome studies, especially for BN and BED, should emphasize population-based cohort studies with comparison groups and plan for adequate durations of follow-up. Ongoing

psychiatric epidemiology studies should routinely include assessments of eating disorders. Epidemiologic studies of BMI and obesity trends should include assessments of eating-disordered behavior. Population-based studies should include measures of disability and impairment associated with eating disorders. For both future treatment and outcome studies, researchers must carefully attend to issues of statistical power, research design, and sophistication and appropriateness of statistical analyses.

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Appendix A. Exact Search Strings

Search Strategy

#3	Search "Eating Disorders"[MeSH]	17336
#4	Search "Eating Disorders"[MeSH] Field: All Fields, Limits: Randomized Controlled Trial	467
#6	Search "Anorexia"[MeSH] OR "Anorexia Nervosa"[MeSH]	9631
#7	Search "Anorexia"[MeSH] OR "Anorexia Nervosa"[MeSH] Field: All Fields, Limits: Randomized Controlled Trial	195
#11	Search "Bulimia"[MeSH]	3624
#12	Search "Bulimia"[MeSH] Field: All Fields, Limits: Randomized Controlled Trial	210
#14	Search "Therapeutics"[MeSH]	1607160
#23	Search "Cognitive Therapy"[MeSH] OR "Family Therapy"[MeSH] OR "Drug Therapy"[MeSH] OR "Therapy, Computer-Assisted"[MeSH]	289583
#34	Search "Randomized Controlled Trials"[MeSH] OR "Single-Blind Method"[MeSH] OR "Double-Blind Method"[MeSH] OR "Random Allocation"[MeSH]	157518
#35	Search #3 AND #34	306
#36	Search #6 AND #34	146
#37	Search #11 AND #34	130
#39	Search #36 OR #7	272
#40	Search #38 OR #12	624
#41	Search #23 OR #14	1614410
#42	Search #41 AND #35	111
#43	Search #41 AND #36	45
#44	Search #41 AND #37	49
#45	Search relapse	130475
#48	Search "Recurrence"[MeSH] OR "Patient Readmission"[MeSH]	103204
#49	Search #48 AND #4	18
#50	Search #48 AND #6	95
#51	Search #48 AND #11	68
#54	Search "Outcome Assessment (Health Care)"[MeSH] OR "Treatment Outcome"[MeSH] OR "Outcome and Process Assessment (Health Care)"[MeSH]	236323
#55	Search #54 AND #4	139
#56	Search #54 AND #6	341
#57	Search #54 AND #11	304
#58	Search "binge eating"	1240
#59	Search #58 AND #34	50
#60	Search #58 AND #41	335

#61	Search #58 AND #48	22
#65	Search **#60 AND #59**	2
#69	Search #12 OR #37	274
#3	Search "Eating Disorders"[MeSH]	17336
#4	Search "Eating Disorders"[MeSH] Field: All Fields, Limits: Randomized Controlled Trial	467
#6	Search "Anorexia"[MeSH] OR "Anorexia Nervosa"[MeSH]	9631
#7	Search "Anorexia"[MeSH] OR "Anorexia Nervosa"[MeSH] Field: All Fields, Limits: Randomized Controlled Trial	195
#11	Search "Bulimia"[MeSH]	3624
#12	Search "Bulimia"[MeSH] Field: All Fields, Limits: Randomized Controlled Trial	210
#14	Search "Therapeutics"[MeSH]	1607160
#23	Search "Cognitive Therapy"[MeSH] OR "Family Therapy"[MeSH] OR "Drug Therapy"[MeSH] OR "Therapy, Computer-Assisted"[MeSH]	289583
#24	Search #3 AND #23	789
#25	Search #6 AND #23	463
#26	Search #11AND #23	0
#27	Search #11 AND #23	291
#34	Search "Randomized Controlled Trials"[MeSH] OR "Single-Blind Method"[MeSH] OR "Double-Blind Method"[MeSH] OR "Random Allocation"[MeSH]	157518
#35	Search #3 AND #34	306
#36	Search #6 AND #34	146
#37	Search #11 AND #34	130
#39	Search #36 OR #7	272
#40	Search #38 OR #12	624
#41	Search #23 OR #14	1614410
#42	Search #41 AND #35	111
#43	Search #41 AND #36	45
#44	Search #41 AND #37	49
#45	Search relapse	130475
#48	Search "Recurrence"[MeSH] OR "Patient Readmission"[MeSH]	103204
#49	Search #48 AND #4	18
#50	Search #48 AND #6	95
#51	Search #48 AND #11	68
#54	Search "Outcome Assessment (Health Care)"[MeSH] OR "Treatment Outcome"[MeSH] OR "Outcome and Process Assessment (Health Care)"[MeSH]	236323

#55	Search #54 AND #4	139
#56	Search #54 AND #6	341
#57	Search #54 AND #11	304
#58	Search "binge eating"	1240
#59	Search #58 AND #34	50
#60	Search #58 AND #41	335
#61	Search #58 AND #48	22
#65	Search #60 AND #59	25
#66	Search #48 AND #3	186
#67	Search #54 AND #3	680
#68	Search #54 AND #58	134

Extra Numbers

#1	Search outcomes	96219
#10	Search "Outcome Assessment (Health Care)"[MeSH] OR "Fatal Outcome"[MeSH] OR "Treatment Outcome"[MeSH] OR "Outcome and Process Assessment (Health Care)"[MeSH] OR "Weight Gain"[MeSH] OR "Osteoporosis"[MeSH] OR "Tooth Diseases"[MeSH] OR "Suicide"[MeSH] OR "Stomach Diseases"[MeSH]	511077
#17	Search "Randomized Controlled Trial"[Publication Type] OR "Randomized Controlled Trials"[MeSH] OR "Double-Blind Method"[MeSH] OR "Single-Blind Method"[MeSH] AND "Random Allocation"[MeSH] OR "Longitudinal Studies"[MeSH]OR Observational Study	492971

Harms Search

#1	Search anorexia [mh] OR anorexia nervosa [mh] or bulimia [mh] or "binge eating disorder" [tw] OR eating disorders [mh] OR "binge eating" [tw]	17671
#2	Search coprophagia [mh] OR hyperphagia [mh] OR pica [mh]	2392
#3	Search #1 NOT #2	15279
#4	Search adverse effects [subheading] OR harms [tw] OR "side effects" [tw] OR "adverse effects" [tw] OR death [mh] OR drug hypersensitivity [mh] OR drug toxicity [mh] OR seizures [mh]	1211380
#5	Search #3 AND #4	1675
#6	Search therapeutics [mh] OR therapy [subheading]	3923801
#7	Search #5 AND #6	1228

Other Terms Search

#4	Search "Eating Disorders"[MeSH]OR "binge eating" [tw]	17669
#8	Search ("Anorexia"[MeSH] OR "Anorexia Nervosa"[MeSH]) OR "Bulimia"[MeSH] OR "binge eating disorder" [tw]	11821
#9	Search #4 NOT #8	5848
#10	Search #4 NOT #8 Field: All Fields, Limits: Randomized Controlled Trial	99
#15	Search ("Randomized Controlled Trial"[Publication Type] OR "Randomized Controlled Trials"[MeSH]) OR "Single-Blind Method"[MeSH] OR "Double-Blind Method"[MeSH] OR "Random Allocation"[MeSH]	277468
#16	Search #9 AND #15	133
#17	Search #10 OR #16	133
#18	Search longitudinal studies [mh] OR observational study [mh]	472680
#20	Search #18 AND #9	291
#21	Search #20 OR #16	400
#27	Search "Cognitive Therapy"[MeSH] OR "Therapeutics"[MeSH] OR "Family Therapy"[MeSH] OR "Drug Therapy"[MeSH] OR "Therapy, Computer-Assisted"[MeSH]	1640745
#28	Search #27 AND #9	910
#29	Search #28 NOT #8	910
#30	Search #28 NOT #8 Field: All Fields, Limits: 5 Years	277
#31	Search #28 NOT #30	633
#32	Search #28 NOT #30 Field: All Fields, Limits: 10 Years	194

#33	Search #31 NOT #32	439
#37	Search "Recurrence"[MeSH] OR "Patient Readmission"[MeSH]	104066
#38	Search #9 AND #37	49
#45	Search ("Outcome Assessment (Health Care)"[MeSH] OR "Treatment Outcome"[MeSH] OR "Outcome and Process Assessment (Health Care)"[MeSH]) OR "Weight Gain"[MeSH] OR "Osteoporosis"[MeSH] OR "Tooth Diseases"[MeSH] OR "Suicide"[MeSH] OR "Stomach Diseases"[MeSH]	494808
#46	Search #9 AND #45	482
#50	Search "Coprophagia"[MeSH] OR "Hyperphagia"[MeSH] OR "Pica"[MeSH]	2392
#51	Search #9 NOT #50	3922
#52	Search #9 NOT #50 Field: All Fields, Limits: Randomized Controlled Trial	70
#53	Search #15 AND #51 Limits: Randomized Controlled Trial	70
#54	Search #52 OR #53 Limits: Randomized Controlled Trial	70
#55	Search #51 AND #18 Limits: Randomized Controlled Trial	15
#56	Search #51 AND #18 Field: All Fields	236

Appendix B. Sample Data Collection Forms

Eating Disorders Outcomes Quality Rating Form (__points)

Author/Year: _____ **Reviewer:** _____

Article: _____

1. Research Aim/Study Question

a. Hypothesis/objective of the study clearly described

2 Good ☐
1 Fair ☐
0 Poor ☐

2. Study Population

a. Study subjects' characteristics clearly described

2 Good ☐
1 Fair ☐
0 Poor ☐

b. Specific inclusion/exclusion criteria

2 Yes ☐
0 No ☐

c. Study groups comparable to each other and/or to non-participants with regard to confounding factors or characteristics

2 Good ☐
1 Fair ☐
0 Poor ☐
Exclude No comparisons ☐

3. Eating Disorder Diagnosis Method

a. Method used to diagnose individuals with an eating disorder

2 Structured diagnostic interview ☐
1 Expert consensus diagnosis ☐
0 Independent clinician diagnosis ☐
Other method_____ ☐
1 Method NR ☐

b. Method used to diagnose patients similar in treatment/disease and comparison groups

2 Yes ☐
0 No ☐
0 NR ☐
Exclude No comparisons ☐

4. Study Design

a. Area from which participants were drawn

2 Community or catchment area ☐
1 Treatment programs in several cities ☐
0 Treatment program in one city ☐
Other_____ ☐
0 NR ☐

b. Study includes comparison group

2 Yes ☐
1 No ☐

5. Statistical Analysis

a. Statistical tests appropriate

2 Yes ☐
1 Partially ☐
0 No ☐

b. Statistical approach includes *necessary* controls for confounding such as multivariate analysis or stratification

2 Yes ☐
0 No ☐
2 not necessary ☐
0 NR ☐

c. Power analysis conducted to determine the sample size needed to detect a sig difference in effect size for one or more outcomes

2 Yes ☐
0 No ☐
0 NR ☐

6. Results/Outcome measurement

a. Outcome assessor blind to exposure or intervention status

2 Yes ☐
0 No ☐
0 NR ☐
Exclude No comparisons ☐

b. Method of outcome assessment clearly defined, standard, valid, reliable, and applied equally to groups

2 Good ☐
1 Fair ☐
0 Poor ☐

c. Interpretation of statistical tests appropriate

2 Yes ☐
0 No ☐
1 Partially ☐

7. External Validity

a. Study subjects comparable to the US population who would suffer from the eating disorder

2 Yes ☐
0 No ☐
0 Cannot determine ☐

8. Discussion

a. Study conclusions supported by results with possible biases and limitations taken into account

2 Good ☐
1 Fair ☐
0 Poor ☐

b. Results discussed within the context of prior research

2 Good ☐
1 Fair ☐
0 Poor ☐

Quality Review Form for Eating Disorder RCTs

Author, Year: _____ Reviewer _____

Short title: _____

1.	**Research Aim/Study Question**	Yes	No
1a.	Is the hypothesis/aim/objective of the study clearly described?	☐4	☐0

2.	**Study Population**	Yes	Partially	No
2a.	Are study subjects' characteristics clearly described, including comparisons of important confounders between groups?	☐4	☐2	☐0
2b.	Are specific inclusion/exclusion criteria provided?	☐4	☐2	☐0

3.	**Randomization**	Yes	No	Unknown
3a.	Were protections put in place to prevent researchers from (unconsciously or otherwise) influencing which participants are assigned to a given intervention group?	☐4	☐0	☐0
3b.	Is there a description of the approach to randomization?	☐4	☐0	☐0
3c.	Is there a fatal flaw in the approach to randomization?	☐0	☐4	☐0

		Yes	Partially	No	Unknown
3d.	Are comparison groups similar at baseline?	☐4	☐2	☐0	☐0

4.	**Blinding**	Yes	No	Not Reported	Not Applicable*
4a.	Are study subjects blinded to the intervention they received?	☐4	☐0	☐0	☐n/a
4b.	Are those administering the intervention blinded to the intervention received by the subjects?	☐4	☐0	☐0	☐n/a

*(not able to blind participants to their study arm)

		Yes	No	NR
4c.	Are outcome assessors blinded to the subject's treatment arm?	☐4	☐0	☐0

5.	**Interventions**	Yes	No	NR
5a.	Are study interventions clearly described?	☐4	☐0	☐0

		Yes	Partially	No	Not Reported
5b.	Is measurement of subjects' compliance with the intervention(s) reliable?	☐4	☐2	☐0	☐0

6.	**Outcomes**	Yes	No	Partially
6a.	Are study results clearly described?	☐4	☐0	☐2
6b.	Are adverse events reported?	☐4	☐0	☐2

7.	**Statistical Analysis**	**Yes**	**No**
7a.	Is the statistical technique used to assess the main outcomes appropriate?	☐4	☐0

		Yes	**No**	**Not Necessary**	**Not Reported**
7b.	Does the statistical technique include any *necessary* controls for confounding?	☐4	☐0	☐4	☐0

		Yes	**Not Reported**	**No**
7c.	Are results evaluated using an intention to treat approach?	☐4	☐0	☐0
7d.	Did the researchers say they conducted a power analysis to determine the sample size needed to detect a significant difference in effect size for one or more outcomes?	☐4	☐0	☐0

8.	**Results**	**Low (10% or below)**	**Fair (11%-25%)**	**Poor (26% or above)**	**Not Reported**
8a.	Is loss to follow-up	☐4	☐2	☐0	☐0

		Low (0-3% point difference)	**Fair (>3 and less than 15% point difference)**	**Poor (15% point difference or greater)**	**Not Reported**
8b.	Is differential loss to follow-up	☐4	☐2	☐0	☐0

		Yes	**Partially**	**No**
8c.	Are the main outcomes measured using standard, valid and reliable methods which are applied equally to both groups?	☐4	☐2	☐0

9.	**Discussion**	**Yes**	**Partially**	**No**
9a.	Are study conclusions supported by the results with possible biases and limitations taken into account?	☐4	☐2	☐0

		Yes	**No**
9b.	Are the results discussed within the context of the prior research?	☐4	☐0

10.	**External Validity**	**Yes**	**No**	**Cannot Determine**
10a.	Are the subjects who participated in the study representative of the US population that would receive treatment for this condition?	☐4	☐0	☐0

11.	**Funding/Sponsorship**	**Yes**	**No**
11a.	Are the sources of funding for the study listed?	☐4	☐0

Appendix C. Evidence Tables

Acronyms, Abbreviations, and Definitions

AA: African American
ABW: percentage of avg body wt (matched for age, gender, and height)
ADDM: adjustment disorder with depressed mood
ads: advertisements
aka: also known as
am: morning
AN: anorexia nervosa
ANBP: anorexia nervosa with binge eating and/or purging
ANCOVA: analysis of covariance
ANSS: anorexia nervosa symptom score
ANOVA: analysis of variance
ANR: restricting anorexia nervosa
AN-RDC: anorexia nervosa with concomitant major depression according to RDC
ANSS: Anorexia Nervosa Symptom Score
ASD: Autism spectrum disorder
avg: average
B-ERP: exposure with response prevention to pre-binge cues
BAI: Beck Anxiety Inventory
BAT: Body Attitudes Test
BP: blood pressure
BCE: bone collagen equivalents
BD: body dissatisfaction
BDI: Beck Depression Inventory
BE: binge eating episode
BEAQ: Binge Eating Adjective Checklist
BED: binge eating disorder
BES: Binge Eating Scale
BF: body fat
BFST: Behavioral family systems therapy
BIAQ: Body Image Avoidance Questionnaire
b.i.d.: twice a day
BITE: Bulimic Investigation Test Edinburgh
BMI: body mass index, measured in kg/m^2
BN: bulimia nervosa
BPD: borderline personality disorder
BSI: Brief Symptom Inventory
BSQ: Body Shape Questionnaire
BSS: Body Satisfaction Scale
BT: Behavioral therapy
CA: California
CAT: cognitive analytical therapy
CFT: conjoint family therapy
CBCL: Child Behavior Checklist
CBT: Cognitive-behavioral therapy

CBT-E: Cognitive-behavioral therapy with exposure
CBT-C: Cognitive-behavioral therapy with cognitive interventions for treatment of body disturbance
CCEI: Crown Crisp Experimental Index
CDI: Children's Depression Inventory
CDRS: Contour Drawing Rating Scale
CFT: conjoint family therapy
CGI: Clinical Global Impression
CGI-S score: Clinical Global Impressions-Severity of Illness scores: 1 = normal, 2 = borderline, 3 = mildly ill, 4 = moderately ill, 5 = markedly ill, 6 = severely ill, 7 = among the most extremely ill.
Chi-square: χ^2
CI: confidence interval
cm: centimeter
CNT: cognitive nutritional therapy
Co: company
CR: clinician rating
CT: Connecticut
CT: cognitive therapy
CUE: physiological cue assessment
d: day
DBT: Dialectical Behavior Therapy
DIET: Dieter's Inventory of Eating Temptations Questionnaire
Diff: Diff/Different
DSM IV: Diagnostic and Statistical Manual for Mental Disorders, Fourth Edition
DSM III: Diagnostic and Statistical Manual for Mental Disorders, Third Edition
DSM III-R: Diagnostic and Statistical Manual for Mental Disorders, Third Edition, Revised
DT: drive for thinness
Dx: diagnosis
EAT: Eating Attitudes Test
EB-IV: Diagnostic and Statistical Manual for Mental Disorders, eating behavior IV
EBT: educational behavioral therapy
ECG: electrocardiogram
ECT: Experimental Cognitive Therapy
ED: eating disorder
EDE: Eating Disorders Examination
EDE-Q: Eating Disorders Examination-Questionnaire
EDI: Eating Disorder Inventory
EDNOS: Eating disorder-not otherwise specified
EE: expressed emotion
EOIT: ego oriented individual therapy
ERP: exposure with response prevention
ES: effect size
et al: et alia
EWL: excess weightt loss
EXRP: exposure with response prevention

F: F-statistic
FAM-III: Family Assessment Measure
FBNCSG: Fluoxetine bulima nervosa collaborative study group
FH: family history
FL: Florida
FNE: Fear of Negative Evaluation
FRS: Figure Rating Scale
FU: FU
fx: function
g: grams
G: group
GAF: Global Assessment of Functioning Scale
GAF-S: Global Assessment of Functioning-Symptoms
GAF-F: Global Assessment of Functioning-Functionging
GCBT: group cognitive behavioral therapy
GEE: Generalized estimating equation
GI: gastrointestinal
GP: general practitioner
GSI: General Severity Index
HAM-A: Hamilton Rating Score for Anxiety
HAM-D: Hamilton Rating Score for Depression
HBT: Hypnobehavioral therapy
HDRS: Hamilton Depression Rating Scale (also HRSD: Hamilton Rating Scale for Depression)
HM: hazard multiplier
HRQ: Helping Relationship Questionnaire
HS: High School
HSCL: Hopkins Symptom Checklist
hr: hours
ht: height
Hx: history
IBC: Interaction Behavior Code
IBW: ideal body weight
ICBT: individual cognitive behavioral therapy
ICD: International Classification of Diseases
IDDB: Insulin dependent diabetes mellitus
IGF-1:
IL: Illinois
Inc.: Incorporated
info: information
IPT: Interpersonal psychotherapy
ITT: intention to treat
K_2HPO_4/cm^3: measure of bone mineral density (BMD)
kcal: kilocalories
Kg: kilograms
KS: Kansas
l: liter

LAGB: laparoscopic adjustable gastric banding
lb: pounds
LIFE: Longitudinal Interval FU Evaluation
Ltd.: limited
m: minutes
MA: Massachusetts
MADRS: Montgomery-Asberg Depression Rating Scale
MANCOVA: multivariate analysis of covariance
MANOVA: multivariate analysis of variance
MAOI: monoamine-oxidase inhibitors
max: maximum
MD: Maryland
MDD: major depressive disorder
MDE: major depressive episode
meds: medication(s)
MET: Motivational Enhancement therapy
mg: milligram
Mg: micrograms
MI: Michigan
Min: minimum
MKAT: measurement of bone specific alkaline phosphatase
mm Hg: millimeters mercury
MMPI: Minnesota Multiphasic Personality Inventory
MMPW: mean matched population wt
mmol: millimole
MN: Minnesota
MOCI: Maudsley Obsessive Compulsive Inventory
mo: month(s)
M-R Scores: Morgan and Russell scale
M-R-H Scale: Morgan-Russell-Hayward Scale
N: number
NA: not applicable
NATO: North Atlantic Treaty Organization
NBPD: non-borderline personality disorder
neg: negative
NG: nutritional groups
NIH: National Institutes of health
NIMH: National Institute of Mental Health
NJ: New Jersey
nM: nanomole
N: number
NC: North Carolina
NICHD: National Institute for Child Health and Development
NM: New Mexico
nmol: nanomile
NR: not reported

NS: not significant
NSMT: Non-specific Self Monitoring
NT: nutritional therapy
NY: New York
NYC: New York City
OBE: objective binge episode
OC: obsessive-compulsive
OCD: obsessive-compulsive disorder
OCPD: obsessive-compulsive personality disorder
outpt: outpatient
OR: odds ratio
***P*:** p-value
P61: Patient's gloval impression
PA: Pennsylvania
PARQ: Parent Adolescent Relationship Questionnaire
P-ERP: exposure with response prevention to pre-purge cues
PE: psychoeducation
PGI: Patient Global Impression
PICP: C-terminal propeptide of type 1 collagen
pmol: picomole
po: per os (by mouth)
pos: positive
PSE: Present State Exam
PSR: Psychiatric Status Rating Scale
psych: psychological or psychiatric
PTSD: posttraumatic stress disorder
QEWPR: Questionnaire on Eating and Wt Patterns - Revised
RAN: restricting anorexia nervosa
RCT: randomized controlled trial
RDC: Research Diagnostic Criteria
RELAX: relaxation training
rhGh: recombinant human growth hormone
RI: Rhode Island
RP: response prevention
RM-ANOVA: repeated measures analysis of variance
RSE: Rosenberg Self Esteem Inventory
RSEQ: Rosenberg Self-Esteem Questionnaire
SADS-C: Schedule for Affective Disorders and Schizophrenia-Change Version
SAS: Social Adjustment Scale
SCI: Shapiro Control Inventory
SCID: Structured Clinical Interview for DSM IV
SCL-90: Hopkins Symptom Checklist-90
SD: standard deviation
SDS: Self-rating Depression Scale
SE: standard error
SEM: standara error of the mean

SES: socioeconomic status
SF-36: Short-Form 36-item quality of life questionnaire
- **RP:** role physical component score
- **SF:** social functioning component score
- **Vit:** vitality component score

SFT: Separated family therapy
SIAB: Structured Interview for Anorexia Nervosa and Bulimic Syndromes
Sig: significant
SMFQ: Short Mood and Feeling Questionnaire
SMR: Standardized Mortality Ratio
SOC: stages of change
SPAQ: Seasonal Patterns Assessment Questionnaire
SR: Self-report
SRQ: Three Factor Eating Questionnaire
SRS: Self-Rating Depression Scale
SSRI: selective serotonin reuptake inhibitor
St: Saint
STAI: State/Trait Anxiety Inventory
STAXI: State Trait Anger Expression Inventory
SUD: substance use disorder
SUDS: Subjective units of distress
sx: symptoms
T: time
t.i.d.: three times a day
TAS-20: Toronto Alexithymia Scale
TCA: tricyclic antidepressants
TFEQ: Three Factor Eating Questionnaire
TN: Tennessee
TT_3: total testosterone
tx: treatment
U: university
UK: United Kingdom
USA: United States
UT: Utah
UTB: Urge to binge
UTP: Urge to purge
VAS: visual analog scale
vs: versus
WAIS: Wechsler Adult Intelligence Scale
WELSQ: Weight Efficacy Life Style Questionnaire
WLFL: Work, Life and Family Leisure Questionnaire
WI: Wisconsin
wk: week
wkly: weekly
WPIC: Western Psychiatric Institute and Clinic
wt: weight

X^2: chi square
YBC-ED: Yale-Brown-Cornell Eating Disorders Scale
Y-BOCS: Yale-Brown Obsessive Compulsive Scale
Y-BOCS-BE: Yale-Brown Obsessive Compulsive Scale Modified for Binge Eating
Yr: year
Yrs: years

Evidence Table 1. Medication trials for anorexia nervosa

Study Description	Objective	Design	Patient Characteristics
Author, yr: Attia et al., 1998 **Setting:** Inpatient research unit, NY, USA **Enrollment period:** NR	**Research objective:** To determine whether fluoxetine was associated with greater wt gain and improved psychological functioning compared to placebo when combined with a structured inpatient program for AN.	**Groups:** **G1:** Fluoxetine (N = 15) **G2:** Placebo (N = 16) **Enrollment:** • 33 enrolled • 1 drop out • 1 undetectable levels of meds • 1 unreliable self-reporter • 31 included in analyses	**Age, mean (SD):** 26.2 (7.4) **G1:** 29.1 (7.2) **G2:** 23.4 (6.4) *(P* < 0.03) **Sex:** Female:100% **Race/ethnicity:** NR **Duration (yrs) of AN, mean (SD):** 8.0 (5.8) **G1:** NR **G2:** NR *(P* = NS) **Wt, lb, mean (SD):** 92.0 (9.8) **G1:** NR **G2:** NR *(P* = NS) **% of IBW, mean (SD):** 72.5 (5.3) **G1:** NR **G2:** NR *(P* = NS) **BMI, mean (SD):** 15.0 (4.2) **G1:** NR **G2:** NR *(P* = NS)

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Female, between 16-45 yrs old, receiving inpatient tx for AN. Met DSM IV criteria A-C for AN, wt < 80% of IBW. **Exclusion:** Medically unstable, allergy to fluoxetine, alcohol or drug dependence in past 6 mo, bipolar disorder or psychotic disorder (current or lifetime), OCD with onset before AN.	**Inpatient tx:** Seen 3-5 times/wk in individual therapy. Several group sessions. Random assignment occurred after patient was medically stable and after having reached 65% IBW. **G1:** initiated at 20 mg/day and increased to 60 mg /day over 1 wk and was maintained unless side effects occurred. Patients continued with study until reached 90% IBW and remained at or above for 1 wk or for a max of 7 wks. **Days of medical tx, mean (SD):** **G1:** 36.1 (14.1) **G2:** 37.4 (13.8) *(P* = NS) **Dose at termination mg/day, mean (SD):** **G1:** 56.0 (11.2) **G2:** 58.7 (5.0) *(P* = NS)	Paired t tests, ANCOVA, ANOVA	**Score:** Good **Intent to treat:** No **Blinding:** Double **Adverse events:** Meds related insomnia and agitation in 1 patient and blurred vision in a second. **Funding:** Eli Lilly and Co

Evidence Table 1. Medication trials for anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Attia et al., 1998 (continued)	**Anorexic Behavior Scale, mean (SD):** **G1:** 49.0 (14.3) **G2:** 43.2 (11.2)	**Anorexic Behavior Scale, mean (SD):** **G1:** 38.5 (11.6) *(P* < 0.05) **G2:** 39.7 (9.5) (*P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	EAT, mean (SD): **G1:** 53.8 (23.3) **G2:** 54.1 (19.5)	**EAT, mean (SD):** **G1:** 37.1 (20.1) *(P* < 0.05) **G2:** 30.8 (17.5) *(P* < 0.05) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	CGI, ED, mean (SD): **G1:** 5.7 (1.0) **G2:** 5.8 (1.0)	**CGI, ED, mean (SD):** **G1:**4.2 (1.4) *(P* < 0.05) **G2:** 4.1 (1.1) *(P* < 0.05) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
CGI, Illness, mean (SD): **G1:** 5.3 (1.0) **G2:** 5.3 (1.2)	**CGI, Illness, mean (SD):** **G1:** 4.1 (1.4) *(P* < 0.05) **G2:** 4.3 (1.5) *(P* < 0.05) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)	**Wt, % of IBW, mean (SD):** **G1:** 73.3 (5.8) **G2:** 71.8 (5.0)	**Wt, % of IBW, mean (SD):** **G1:** 86.6 (6.3) *(P* < 0.05) **G2:** 87.4 (4.7) *(P* < 0.05) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
			Change in % of IBW, mean (SD): **G1:** 0.35 (0.17) *(P* = NS) **G2:** 0.42 (0.11) *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
BDI mean (SD): **G1:** 24.3 (11.9) **G2:** 20.0 (7.2)	**BDI mean (SD):** **G1:** 15.9 (11.3) *(P* < 0.05) **G2:** 14.0 (8.9) *(P* < 0.05) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)		
	CGI, Global Improvement, mean (SD): **G1:** 2.5 (1.4) *(P* = NS) **G2:** 2.8 (1.5) *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)		
BSQ mean (SD): **G1:** 129.9 (48.8) **G2:** 138.6 (35.1)	**BSQ mean (SD):** **G1:** 109.3 (39.5) *(P* < 0.05) **G2:** 119.4 (31.5) (*P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)		
SCL-90, Depression, mean (SD): **G1:** 3.2 (0.9) **G2:** 2.8 (0.6)	**SCL-90, Depression, mean (SD):** **G1:** 2.3 (1.0) *(P* < 0.05) **G2:** 2.2 (0.8) (*P* < 0.05) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)		
SCL-90, OC scale, mean (SD): **G1:** 2.5 (1.0) **G2:** 2.3 (0.9)	**SCL-90, OC scale, mean (SD):** **G1:** 1.9 (1.0) *(P* < 0.05) **G2:** 1.7 (0.5) (*P* < 0.05) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)		

Evidence Table 1. Medication trials for anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Attia et al., 1998 (continued)	**Yale Brown Cornell ED Scale, Preoccupation, mean (SD):** **G1:** 11.1 (3.4) **G2:** 9.7 (2.3)	**Yale Brown Cornell ED Scale, Preoccupation, mean (SD):** **G1:** 8.1 (3.4) *(P* < 0.05) **G2:** 8.1 (2.3) *(P* < 0.05) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	Yale Brown Cornell ED Scale, Ritual, mean (SD): **G1:** 9.9 (2.6) **G2:** 9.0 (2.7)	**Yale Brown Cornell ED Scale, Ritual, mean (SD):** **G1:** 7.7 (2.9) *(P* < 0.05) **G2:** 6.7 (2.6) *(P* < 0.05) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	Yale Brown Cornell ED Scale, total, mean (SD): **G1:** 20.9 (5.7) **G2:** 18.7 (4.3)	**Yale Brown Cornell ED Scale, total, mean (SD):** **G1:** 15.7 (6.1) *(P* < 0.05) **G2:** 14.8 (4.2) *(P* < 0.05) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
SCL-90, Global symptom, mean (SD): **G1:** 2.4 (0.7) **G2:** 2.3 (0.6)	**SCL-90, Global symptom, mean (SD):** **G1:** 1.9 (0.8) *(P* < 0.05) **G2:** 1.8 (0.5) *(P* < 0.05) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)		

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Barbarich, McConaha et al. 2004 **Setting:** Eating Disorders programs at WPIC, Pittsburgh, PA and NY Hospital/Cornell Medical Center, NYC, USA. **Enrollment period:** NR	**Research objective:** To determine if the use of supplements containing tryptophan and essential fatty acids would increase the efficacy of flouxetine in underwt AN subjects.	**Groups:** **G1:** daily dietary supplements (N = 15) **G2:** Placebo (N = 11) **Enrollment:** • 26 enrolled and randomized • 9 completed full study	**Age, mean (SD):** Mean: 23.0 (6.3) yrs **G1:** NR **G2:** NR *(P* = NR) **Sex:** Female: NR **Race/ethnicity:** NR **Other characteristics:** AN restricting type (N = 10) AN restricting and purging only (N = 6) AN Binge eating/purging type (N = 10) **Characteristics for completers only:** No sig diff between completers and drop outs on any measures except mean laxative abuse onset age (SD): Noncompleters: 16.3 (1.6) Completers: 21.3 (1.2); Diff between groups *(P* < 0.01) **Measures, mean (SD):** • Dieting start age: 16.9 (5.2) • Age of onset: 17.3 (6.3) • Duration of ED: 8.4 (8.1) • Binge eating start: 17.8 (6.9) • Laxative abuse start: 21.3 (1.2) • Vomiting start age: 20.2 (6.9) • Age: 25.7 (7.4) • Low BMI: 14.4 (1.4) • High BMI: 20.8 (2.3) • Perfectionism score (Frost multidimensional perfectionism scale): 87.8 (28.4)

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: NR **Exclusion:** NR	Tx lasted 6 mos. All enrolled subjects started on a dose of 20 to 40 mg of fluoxetine. Individual doses titrated throughout study. Dose at study end ranged from 20 to 60 mg. Subjects wted at wkly intervals for the first 8 wks, at 2-wk intervals for 6 wks, and at 4 wk intervals for 12 wks. In addition, G1 received 2.3 g tryptophan taken in divided dosage in the am and pm, 1 multivitamin/mineral capsule per day in the am, and 4 fish oil capsules per day in the am (600 mg of docosahexanoic acid and 180 mg of arachadonic acid). G2 received equivalent number of inactive capsules	Independent sample t-tests for measuring changes between groups.	**Score:** Poor **Intent to treat:** No **Blinding:** Double **Adverse /events:** NR **Funding:** NR

Evidence Table 1. Medication trials for anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Barbarich, McConaha et al. 2003 (continued)	NR	NR

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Psychological/Psychiatric		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
	Estimate is change over time (SE)		Estimate is change over time (SE)
STAI-Y: **G1:** 43.5 (17.6) **G2:** 54.5 (3.5) *(P* = NS)	**STAI – Y:** **G1:** -7.8 (23.8) **G2:** -10.5 (0.7) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)	NR	**Mean wt gain per wk:** **G1:** 0.27 kg (0.3) **G2:** 0.10 kg (0.1) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
YBOCS: **G1:** 11.8 (14.2) **G2:** 12.0 (11.3) *(P* = NS)	**YBOCS:** **G1:** -9.2 (12.9) **G2:** -6.5 (3.5) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)		

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Biederman et al., 1985 **Setting:** Inpatient Eating Disorder Unit, Massachusetts General Hospital; Psychosomatic Unit, Children's Hospital Medical Center, Boston, USA **Enrollment period:** Dates NR (2 yrs)	**Research objective:** To investigate effect of amitriptyline on wt and psychiatric sx's in AN.	**Groups:** **G1:** Amitriptyline (N = 11) **G2:** Placebo (N = 14) **Enrollment:** • 25 patients enrolled • 5 outpatients and 11 inpatients	**Age, mean (SD):** **G1:** 18.4 (4.9) **G2:** 17.2 (4.3) Range: 11-27 *(P* = NS) **Sex:** Female: NR **Race/ethnicity:** NR **SES (range 1-5), mean (SD):** **G1:** 2.4 (1.2) **G2:** 2.0 (1.4) *(P* = NS) **Age onset (yrs) of AN, mean (SD):** **G1:** 15.7 (1.2) **G2:** 16.1 (2.7) *(P* = NS) **Duration (mos) of present episode, mean (SD):** **G1:** 20.2 (16.7) **G2:** 25.2 (29.4) *(P* = NS)

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Dx for AN per Feighner et al. (1972) and DSM III. All but 1 patient met full criteria. **Exclusion:** Evidence of other medical disorders	All received regular psychiatric and medical tx (supportive, nutritional rehab illitation, individual therapy, family intervention, and inpatients received behavior modification). Meds: dosage increased every other day by 50 mg up to 3 mg/kg/day and a max dose of 175 mg/day unless adverse effects developed. Mean dose at wk 5: 115 (31) mg/day; 2.8 (1.1 mg/kg/day). Plasma levels varied among patients on the same dose of meds.	T-tests to compare placebo and drug group Diffs. One-way ANOVA to determine whether diffs emerged in change scores across groups. Correlations between improvement and plasma levels of meds.	**Score:** Fair **Intent to treat:** No **Blinding:** Double **Adverse events:** Assessed wkly. **G1:** diaphoresis (N = 2; 18%), drowsiness (N = 6, 55%), dry mouth (N = 4; 36%), blurred vision (N = 1; 9%), urinary retention (N = 1; 9%), hypotension (N = 2; 18%), leucopenia (N = 1; 9%) **G2:** Dry mouth (N = 2; 14%), palpitations (N = 1; 7%), dizziness (N = 2; 14%). No *P*-values reported **Funding:** NIMH, Charlupski Foundation, Milton Fund, Jane Hilder Harris Foundation.

Evidence Table 1. Medication trials for anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Biederman et al., 1985 (continued)		**Antibulimic effect (EAT-Bulimic factor):** **< 30% response, N (%):** **G1:** 2 (22%) **G2:** 8 (57%) **30 to 50% response, N (%):** **G1:** 1 (11%) **G2:** 1 (7%) **>50% response, N (%):** **G1:** 6 (67%) **G2:** 5 (36%) *(P*-values NR; described as NS)

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
Family Hx (FH): Depression (1st degree), N (%): **G1:** 6 (54%) **G2:** 6 (43%) **AN-RDC (AN with concomitant depression), N (%):** **G1:** 4 (36%) **G2:** 10 (71%) *(P* = NS) **Generation-FH (depression or substance abuse in 2 or more consecutive generations) N (%):** **G1:** 1 (10%) **G2:** 3 (21%) *(P* = NS)	**Antidepressant effect (SADS-C):** **< 30% response, N (%):** **G1:** 8 (73%) **G2:** 6 (46%) **30 to 50% response, N (%):** **G1:** 3 (27%) **G2:** 5 (36%) **>50% response, N (%):** **G1:** 0 (0%) **G2:** 2 (14%) *(P*-values NR; described as NS)	**Wt kg, mean (SD):** **G1:** 38.2 (4.2) **G2:** 35.5 (5.8) *(P* = NS) **Percent below ideal (wt for ht at baseline), mean (SD):** **G1:** 25.0 (7.3) **G2:** 31.0 (6.2) *(P* = NS)	**Wt gain:** **< 10%, N (%):** **G1:** 8 (72%) **G2:** 8 (57%) **10 to 30%, N (%):** **G1:** 3 (27%) **G2:** 5 (36%) **> 50%, N (%):** **G1:** 0 (0%) **G2:** 1 (7%) *(P*-values NR; described as NS)
	Antianxiety effect (SADS-C): **< 30% response, N (%):** **G1:** 9 (82%) **G2:** 8 (61%) **30 to 50% response, N (%):** **G1:** 2 (18%) **G2:** 3 (25%) **>50% response, N (%):** **G1:** 0 (0%) **G2:** 2 (15%) *(P*-values NR; described as NS)		**Plasma levels:** No correlation between plasma levels and any outcome variable.
	Antiobsessional effect (HSCL): **< 30% response, N (%):** **G1:** 9 (100%) **G2:** 12 (86%) **30 to 50% response, N (%):** **G1:** 0 (0%) **G2:** 1 (7%) **>50% response, N (%):** **G1:** 0 (0%) **G2:** 1 (7%) *(P*-values NR; described as NS)		

Evidence Table 1. Medication trials for anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Biederman et al., 1985 (continued)		

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
	Global effect (Clinical Global; Global Severity Scale): **< 30% response, N (%):** **G1:** 6 (54%) **G2:** 9 (64%) **30 to 50% response, N (%):** **G1:** 4 (36%) **G2:** 4 (27%) **> 50% response, N (%):** **G1:** 1 (9%) **G2:** 1 (7%) *(P*-values NR; described as NS)		
Substance use disorder (1st degree), N (%): **G1:** 3 (27%) **G2:** 6 (43%) *(P* = NS)			
TCA used previous to study, N (%): **G1:** 1 (9%) **G2:** 2 (14%) *(P* = NS)			

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Birmingham, Goldner et al., 1994 **Setting:** Inpatient eating disorders programs; St. Paul's Hospital, Health Sciences Centre Hospital, and the University of British Columbia, Vancouver, British Columbia, Canada. **Enrollment period:** September 1988-June 1991	**Research objective:** To determine whether zinc supplementation of hospitalized AN patients would enhance their rate of recovery as measured by the rate of increase in their BMI.	**Groups:** **G1:** zinc (N = 26) **G2:** placebo (N = 28) **Enrollment:** • 54 randomized • 35 patients completed **G1:** N = 16 **G2:** N = 19	**Age, mean (SD):** **G1:** 20.6 (3.8) **G2:** 23.8 (6.1) *(P* = NS) **Sex:** Female: 100% **Race/ethnicity:** NR **Hospitalizations, mean (SD):** **G1:** 1.9 (1.6) **G2:** 2.1 (1.8) *(P* = NS) **Yrs since dx, mean (SD):** **G1:** 3.6 (2.0) **G2:** 3.8 (3.2) *(P* = NS)

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Female, ≥ 15 yrs old, inpatient for AN tx **Exclusion:** NR	Routine inpatient tx for AN including group and individual psychotherapy; psychiatric meds and enteral feeding was individualized. On day 7 of admission baseline measures collected. Patient began trial of 14 mg of elemental zinc or placebo on day 8. The study of each patient was terminated when a 10% wt gain above baseline was achieved on 2 consecutive biwkly wtings.	Two-tailed tests. Mann-Whitney U to compare zinc and placebo groups. Chi square with Yates correction used to compare number of patients in each group who received psychiatric meds	**Score:** Fair **Intent to treat:** No **Blinding:** Double **Adverse events:** No adverse events reported **Funding:** Vancouver Foundation

Evidence Table 1. Medication trials for anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Birmingham, Goldner et al., 1994 (continued)	NR	NR

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
NR	NR	**BMI, mean (SD):** **G1:** 15.6 (1.2) **G2:** 16.2 (1.8) *(P* = NS)	**Rate BMI gain/day, mean (SD):** **G1:** 0.079 (0.07) *(P* = NR) **G2:** 0.039 (0.06) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.03) G1 greater than G2
		% total body fat, mean (SD): **G1:** 15.0 (5.5) **G2:** 15.0 (4.0) *(P* = NS)	**Rate % body fat gain/day, mean (SD):** **G1:** 0.18 (0.18) *(P* = NR) **G2:** 0.02 (0.27) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
			Total wt gain (kg), mean (SD): **G1:** 3.6 (2.0) *(P* = NR) **G2:** 2.6 (2.7) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Brambilla et al., 1995 **Setting:** Outpatient, Center for Eating Disorders of the Dipartimento di Scienze Neuropsichiche Universita, Milan, Italy **Enrollment period:** NR	**Research objective:** To determine if a 4-mo course of combined cognitive-behavioral, nutritional, and antidepressant therapy (amineptine or fluoxetine) results in positive clinical effects in patients with AN-binge-eating/purging subtype.	**Groups:** **G1:** Fluoxetine (N = 6) **G2:** Amineptine (N = 7) **Enrollment:** N = 13 **Completed:** 100%; N = 13	**Age, mean (SD) (range):** 23.1 (6.8) (17-43) **G1:** NR **G2:** NR **Sex:** Female: 100% **Race/ethnicity:** NR **Length of illness, yrs, mean (SD) (range): 4.6 (3.9) (3 mos – 13 yrs)** **G1:** NR **G2:** NR **Amenorrheic, N:** 3

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Dx of AN per DSM III-R and IV criteria **Exclusion:** NR	CBT, nutritional counseling, and pharmacotherapy **G1:** 60 mg/day of fluoxtine orally (p.o.) **G2:** 300 mg/day of aminepine (p.o.) **Length of Treatment:** 4 mos	Student t test and MANCOVA for repeated measures with time by group.	**Score:** Poor **Intent to treat:** Yes **Blinding:** NR **Adverse events:** None **Funding:** NR

Evidence Table 1. Medication trials for anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Brambilla et al., 1995 (continued)	**EDI, Global Score, mean (SD):** **G1:** 99.6 (31.6) **G2:** 82.3 (42.7) *(P* = NR)	**EDI, Global Score at 4 mos, mean (SD):** **G1:** 74.0 (13.7) *(P* = NR) **G2:** 46.2 (16.4) *(P* = NR) Change over time *(P* = 0.02) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	BITE, symptoms mean (SD): **G1:** 19.7 (4.4) **G2:** 20.2 (6.4) *(P* = NR)	**BITE, symptoms at 4 mos, mean (SD):** **G1:** 23.8 (3.6) *(P* = NR) **G2:** 18.8 (7.7) *(P* = NR) Change over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)
	BITE, gravity mean (SD): **G1:** 10.7 (6.0) **G2:** 12.0 (7.7) *(P* = NR)	**BITE, gravity at 4 mos, mean (SD):** **G1:** 10.4 (4.8) *(P* = NR) **G2:** 12.0 (6.3) *(P* = NR) Change over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)
	Binge eating (not defined), mean (SD): **G1:** 3.5 (2) **G2:** 4.1 (1) *(P* = NR)	**Binge eating, mean (SD):** **G1:** 3.2 (1.8) *(P* = NS) **G2:** 4.4 (0.5) *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)
	Vomiting (not defined), mean (SD): **G1:** 3.2 (2.3) **G2:** 3.6 (2.3) *(P* = NR)	**Vomiting, mean (SD):** **G1:** 2.2 (1.8) *(P* = NS) **G2:** 1.8 (2.0) *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
HAM-D, mean (SD): **G1:** 19.7 (7.3) **G2:** 20.2 (5.6) *(P* = NR)	**HAM-D at 4 mos, mean (SD):** **G1:** 11.2 (6.9) *(P* = NR) **G2:** 11.2 (7.8) *(P* = NR) Change over time *(P* = 0.002) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)	**BMI, mean (SD):** **G1:** 16.7 (2.2) **G2:** 16.3 (2.8) *(P* = NR)	**BMI, mean (SD) at 4 mo:** **G1:** 21.1 (6.3) *(P* = NS) **G2:** 17.7 (2.6) *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
HAM-A, mean (SD): **G1:** 85.7 (20.9) **G2:** 89.4 (11.2) *(P* = NR)	**HAM-A at 4 mos, mean (SD):** **G1:** 50.4 (34.8) *(P* = NR) **G2:** 37.0 (31.0) *(P* = NR) Change over time *(P* = 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)		

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Fassino et al., 2002 **Setting:** Single center; outpatient; Centre for Eating Disorders, Turin University; Turin, Italy **Enrollment period:** September 1, 1998 through September 1, 2000	**Research objective:** To study the efficacy of citalopram (an SSRI) in the outpatient tx of AN restricting type	**Groups:** **G1:** citalopram (N = 26) **G2:** waitlist control (N = 26) **Enrollment:** • 98 screened who were consecutively admitted AN patients • 52 met criteria for AN restricting type and were randomized • 39 participants (G1 = 19, G2 = 20) remained by wk 12 Open label study, no masking of observers	**Age, mean (SD):** **G1:** 24.35 (5.38) **G2:** 25.23 (8.64) *(P* = NS) **Sex:** Female: 100% **Race/ethnicity:** NR **Age of onset, mean (SD):** **G1:** 18.42 (4.16) **G2:** 17.69 (3.92) *(P* = NS) **Duration of disease in yrs, mean (SD):** **G1:** 5.69 (4.90) **G2:** 7.54 (8.19) *(P* = NS) **Duration of amenorrhea in mos, mean (SD):** **G1:** 15.81 (14.83) **G2:** 20.11 (25.35) *(P* = NS)

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Dx of AN restricting type; age 16-35; no psychopharmacologic tx within the mo preceding the beginning of the study or 6 wks without tx with fluoxetine (an exception was made for 4 subjects who were permitted to continue tx with lorazepam for anxiety-related sxs); no estrogen-progesterone therapy for the last mo **Exclusion:** Psychiatric comorbidity; sensitivity to citalopram	All randomized subjects were part of a waitlist group for entering an integrated, usual practice tx for AN; half of subjects randomized to citalopram group and half to waitlist control group. Over 12 wk tx, subjects in citalopram group initiated on 10 mg/day of the drug and increased to 20 mg/day after 6 days of tx. Subjects in the control group also followed by periodic clinical assessment and the administration of questionnaires of interest.	MANOVAs to assess the efficacy of citalopram versus waitlist control (at baseline and 12 wks); univariate analyses to assess within group diffs on questionnaire measures (at baseline and 12 wks); multiple regression models to assess the effect of citalopram on the outcome variables while controlling for age, duration of disease, personality disorders, and BMI at baseline.	**Score:** Poor **Intent to treat:** NR **Blinding:** None **Adverse events:** NR **Funding:** NR

Evidence Table 1. Medication trials for anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Fassino et al., 2002 (continued)	**EDI-2, mean (SD):** **Bulimia** **G1:** 5.88 (6.71) **G2:** 3.31 (3.66) *(P* = NR)	**EDI-2, mean (SD):** **Bulimia** **G1:** 2.26 (4.07) **G2:** 3.30 (3.67) Diff between groups *(P* = NR) Change over time from baseline to wk 12: **G1:** 3.62 (*P* = 0.005) **G2:** 0.01 (*P* = NS) Diff between groups in change over time *(P* = NR)

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BDI, mean (SD): **G1:** 14.46 (7.73) **G2:** 12.65 (6.39) *(P* = NR)	**BDI, mean (SD):** **G1:** 7.31 (5.07) **G2:** 12.30 (9.02) Diff between groups *(P* = NR) Change over time from baseline to wk 12: **G1:** -7.15 (*P* = 0.001) **G2:** -0.35 (*P* = NS) Diff between groups in change over time *(P* = NR)	**BMI, kg/m^2, mean (SD):** **G1:** 16.19 (0.81) **G2:** 15.62 (1.42) *(P* = NR)	**BMI, kg/m^2, mean (SD):** **G1:** 17.47 (1.41) **G2:** 16.33 (1.68) Diff between groups *(P* = NR) Change over time from baseline to 12 wks: **G1:** 1.28 (*P* = 0.002) **G2:** 0.71 (*P* = 0.005) Diff between groups in change over time *(P* = NR)
SCL-90, mean (SD): **Depression:** **G1:** 26.73 (11.56) **G2:** 23.69 (12.49) *(P* = NR)	**SCL-90, mean (SD):** **Depression:** **G1:** 17.11 (9.39) **G2:** 22.55 (12.78) Diff between groups *(P* = NR) Change over time from baseline to wk 12: **G1:** - 9.62 (*P* = 0.001) **G2: -** 1.14 (*P* = NS) Diff between groups in change over time *(P* = NR)	**Wt, kg, mean (SD):** **G1:** 43.48 (3.93) **G2:** 42.48 (4.60) *(P* = NR)	**Wt, kg, mean (SD):** **G1:** 46.47 (5.33) **G2:** 43.92 (4.86) Diff between groups *(P* = NR) Change over time from baseline to 12 wks: **G1:** 2.99 (*P* = 0.003) **G2:** 1.44 (*P* = 0.007) Diff between groups in change over time *(P* = NR)
Anxiety: **G1:** 17.38 (8.16) **G2:** 15.65 (9.26) *(P* = NR)	**Anxiety:** **G1:** 12.74 (6.59) **G2:** 14.15 (8.78) Diff between groups *(P* = NR) Change over time from baseline to wk 12: **G1: -** 4.64 (*P* = 0.005) **G2: -** 1.50 (*P* = 0.054) Diff between groups in change over time *(P* = NR)		

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Halmi et al., 1986 **Setting:** Inpatient, University of Minnesota Hospitals, Minneapolis; New York Hospital – Cornell Medical Center, Westchester Division, White Plains, USA **Enrollment period:** NR	**Research objective:** To assess the effects of amitriptyline and cyproheptadine for the tx of AN in an inpatient setting.	**Groups:** **G1:** amitriptyline (N = 23) **G2:** cyproheptadine (N = 24) **G3:** placebo (N = 25) **Enrollment:** • 72 randomly assigned • 54 completed: • **G1:** 16 • **G2:** 18 • **G3:** 20	**Age, mean (SD) (range):** 20.56 (5.1) (13 to) **Sex:** Female: 100% **Race/ethnicity:** NR **Age of onset of AN, mean (SD):** 17.44 (4.6) (12 to 30) **Duration of illness, yrs, mean (SD) (range):** 2.9 (2.3) (4 mo to 10 yrs). **Marital status, N:** Never married: 65 Divorced/Separated: 3 Married: 4. Hollingshead social level score (SD): 2.0 (1.2) corresponding to hs grad and employment level between white-collar and administrative **No hx of binge eating, N:** 39

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: DSM III criteria for AN plus amenorrhea **Exclusion:** NR	Baseline assessment on days 2 and 5 of the 7 day pre-tx period, conducted wkly during tx until patient reached within 5% of a normal wt for age and height *(*Per Iowa Growth Chart and 1959 Metropolitan Height-Wt Chart). Drug dosage was increased per discretion of the investigator to obtain max drug dosage (cyproheptadine: 32 mg; amitriptyline: 160 mg) at the end of the 2nd wk of tx. Patients maintained on highest tolerated dosage. During the 7 day pre tx: patients could choose their own food. During drug tx, patients received nutritious liquid product (Sustacal) diluted to 1 kcal/mL given in 6 equal feedings which was the only source of nutrients for first 15 days of tx (allowed as much as they wanted). After 15 days, patients received 3 meals of a regular diet and evening snack (allowed as much as they wanted). Length of time in tx varied by speed of reaching target wt or withdrawal due to clinical deterioration. Max days: 90	Computed "tx efficiency" = reciprocal of days to target wt X 90 (max days of tx). Chi Square, hierarchical multiple regression controlling for hospital, pre-tx wt, drug intervention, and interactions, ANOVA	**Score:** Fair **Intent to treat:** No **Blinding:** Double **Adverse events: Physical symptoms during tx, mean:** **Day 7:** **Moderate:** **G1:** 1.80 **G2:** 1.83 **G3:** 2.48 **Severe:** **G1:** 0.29 **G2:** 0.13 **G3:** 0.36 **Day 21:** **Moderate:** **G1:** 1.95 **G2:** 0.91 **G3:** 1.80 **Severe:** **G1:** 0.14 **G2:** 0 **G3:** 0.28 *(P* = NR) **G1:** drowsiness, excitement, confusion, increased motor activity, tachycardia, dry mouth, constipation **G2:** no pattern **G3:** drowsiness, excitement, increased motor activity. **Funding:** NIMH

Evidence Table 1. Medication trials for anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Halmi et al., 1986 (continued)	**Caloric Intake, mean (SD):** **Pre-tx wk:** **G1: 1802 (746)** **G2:** 1934 (940) **G3:** 1746 (542) *(P* = NR)	**Caloric Intake, mean (SD): Treatment wk:** **G1:** 2450 (1094) **G2:** 3023 (1103) **G3:** 2390 (844) Diff between groups *(P* < 0.04) G2 greater than G3 Diff between groups *(P* < 0.06)G2 greater than G1

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BDI, mean (SD): **Day 2:** **G1:** 26.0 (9.2) **G2:** 21.7 (12.7) **G3:** 22.0 (10.8) *(P* = NR) **Day 7:** **G1:** 19.7 (11.9) **G2:** 15.7 (9.4) **G3:** 14.4 (8.6) *(P* = NR)	**BDI, mean (SD): Day 14:** **G1:** 17.9 (10.4) **G2:** 12.9 (9.5) **G3:** 14.5 (9.3) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) **Day 28:** **G1:** 13.1 (12.1) **G2:** 11.5 (9.4) **G3:** 13.6 (9.8) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)		**Treatment efficiency, mean (SD) (N = 72):** **G1:** 3.21 (2.85) **G2:** 3.07 (2.95) **G3:** 2.30 (3.45) Diff between groups *(P* = NS)
Composite Depression Scores created from BDI and HSCL-90), mean (SD): **Day 2:** **G1:** 5.1 (1.0) **G2:** 4.7 (1.5) **G3:** 4.3 (1.2) *(P* = NR) **Day 7:** **G1:** 4.3 (1.3) **G2:** 3.8 (1.2) **G3:** 3.6 (1.0) *(P* = NR)	**Composite Depression Scores created from BDI and HSCL-90, mean (SD):** **Day 14:** **G1:** 4.0 (1.1) **G2:** 3.6 (1.1) **G3:** 3.6 (1.0) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) **Day 28:** **G1:** 3.6 (1.1) **G2:** 3.5 (1.2) **G3:** 3.5 (1.0) Diff between groups (interaction of G2 and wt gain vs G3, *P* < 0.01). Cyproheptadine + wt gain associated with less depression compared to placebo.		**Days to Target Wt in patients achieving target wt, mean (SD):** **G1 (N =** 17) 32.24 (17.37) **G2 (N =** 20) 36.50 (19.53) **G3 (N =** 16) 45.00 (18.34) Diff between G1 and G3 *(P* = 0.05) G1 better than G3 Diff between G1 and G2 *(P* < 0.05) G2 better than G3
Hamilton Rating Scale, mean (SD): **Day 2:** **G1:** 17.3 (10.0) **G2:** 19.6 (9.5) **G3:** 20.4 (7.8) *(P* = NR) **Day 7:** **G1:** 15.7 (6.9) **G2:** 17.1 (6.8) **G3:** 17.8 (6.9) *(P* = NR) Diff between groups over time *(P* = NR)	**Hamilton Rating Scale, mean (SD):** **Day 14:** **G1:** 14.6 (6.8) **G2:** 13.4 (7.9) **G3:** 18.1 (7.8) Diff between groups *(P* < 0.005) Diff between G2 and G3 *(P* < 0.001) G2 better than G3 **Day 28:** **G1:** 14.1 (6.9) **G2:** 13.2 (6.5) **G3:** 17.7 (8.5)		**Wt gain/day, kg, mean (SD):** **G1:** 0.31 (0.17) **G2:** 0.30 (0.19) **G3:** 0.23 (0.12) Diff between groups (interaction of G2 and wt on day 7 of tx vs G3, *P* < 0.03). Greater day 7 wt gain on cyproheptadine associated with greater rate of wt gain over 28 days compared to placebo

Evidence Table 1. Medication trials for anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Halmi et al., 1986 (continued)		

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
			Treatment Efficiency in AN subgroups, mean (SD): Bulimic (N = 33) **G1:** 4.99 (3.55) **G2:** 2.37 (1.78) **G3:** 3.65 (5.45) Diff between groups *(P* < 0.01) G1 better than G2
			Nonbulimic (N = 39): G1: 2.06 **(**1.51) **G2:** 4.23 (4.12) **G3:** 1.54 (1.21) Diff between groups *(P* < 0.01) G2 better than G3
			Treatment Failures (did not gain 2 kg after 6 wks of tx), N: **G1:** 6 **G2:** 4 **G3:** 9 *(P* = NR)

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Hill et al., 2000 **Setting:** Inpatient at Children's Hospital Medical Center, Cincinnati, Ohio, USA **Enrollment period:** NR; 28 days	**Research objective:** To learn if rhGH improves the efficiency of tx protocols for malnourished AN patients who have medical/cardiovascular instability and require hospitalizations.	**Groups:** **G1:** rhGH (N = 8) **G2:** placebo (N = 7) **Enrollment:** • 15 enrolled and completed	**Age, mean (SD):** **G1:** 14.5 **G2:** 15 Range: 12-18 **Sex:** Female: **G1:** N = 7 **G2:** N = 7 **Race/ethnicity:** NR

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: DSM IV criteria for AN; sigly malnourished (< 80% of IBW according to Frisancho's standard criteria). **Exclusion:** Suicidal ideation; pre-existing medical conditions unrelated to AN which could complicate nutritional rehabilitation (e.g., inflammatory bowel disease, chronic lung disease, cardiac disease).	**G1:** rhGH (0.05 mg/kg subcutaneously) received daily until discharge for a max of 28 days. **G2:** Placebo All patients received standard clinical care for AN.	Comparison of mean responses between groups: two-sample t tests. Comparison of the median waiting time to achieve orthostasis between groups: log rank statistic.	**Score:** Good **Intent to treat:** Yes **Blinding:** Double **Adverse events:** Monitored and none were reported **Funding:** NIMH, the Genentech Foundation for Growth and Development, the NIH, and the Veterans Administration

Evidence Table 1. Medication trials for anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Hill et al., 2000 (continued)	NR	NR

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
NR	NR	**Wt (kg):** **G1:** 38.3 **G2:** 40.7 *(P* = NS)	**Cardiovascular stability (2 consecutive mornings that patient was no longer orthostatic by pulse; orthostasis: change in pulse from a supine to standing position of > 20 beats per minute):** **Estimate is diff in median time until patient no longer orthostatic** **G1:** 17 days **G2:** 37 days Diff between groups *(P* < 0.02)
			Median length of hospitalization: **G1:** 32 days **G2:** 39 days Diff between groups *(P* = NS)
			Rate of wt gain: **G1:** 0.235 (0.077) kg/day **G2:** 0.166 (0.127) kg/day Diff between groups *(P* = NS)

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Kaye et al., 2001 **Setting:** Single center; inpatient and outpatient; location: eating disorders tx program at Western Psychiatric Institute and Clinic, University of Pittsburgh Medical Center, Pittsburgh, PA, USA **Enrollment period:** NR	**Research objective:** To assess the efficacy and safety of fluoxetine (an SSRI) in the long-term relapse prevention (52 wks) among restricting-type AN patients following intensive cognitive-behavioral, and dietary inpatient intervention. Also examined effect of fluoxetine on core eating disorder symptoms, obsessionality, and depression.	**Groups:** **G1:** fluoxetine (N = 16) **G1A:** fluoxetine completers (N = 10) **G1B:** fluoxetine drop-outs (N = 6) **G2:** placebo (N = 19) **G2A:** placebo completers (N = 3) **G2B:** placebo drop-outs (N = 16) **Enrollment:** • 95 screened who were admitted to the eating disorder inpatient unit • 39 enrolled and randomized (**G1:** N = 19; **G2:** N = 20) • 35 took fluoxetine or placebo for at least 30 days (**G1:** N = 16; **G2:** N = 19) • 13 completers remained at 1 yr FU (**G1: N =** 10; **G2:** N = 3) *(P* = 0.006)	**Age, mean (SD):** **G1:** 23 (9) **G2:** 22 (6) *(P* = NS) G1A, G1B, G2A, G2B: NR *(P* = NS) **Sex:** Female: 100% **Race/ethnicity:** NR **Age of onset (SD):** **G1:** 16 (5) **G2:** 18 (5) *(P* = NS) G1A, G1B, G2A, G2B: NR *(P* = NS)

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Met DSM IV criteria for AN (restricting and restricting and purging types) when they were underwt **Exclusion:** Hx of binge-eating; concurrent severe medical or neurological conditions; concurrent or previous schizophrenia; concurrent or recent (within last 12 mos) alcohol or substance dependence; use of psychotropic meds within a mo before entry (exception was alprazolam)	Subjects were randomly assigned to either initiation on fluoxetine or placebo prior to discharge. They began at a dosage of 20 mg/day and were adjusted over the 52 wks up to a max of 60 mg/day. Subjects evaluated every 4 wks after discharge (if status deteriorated sigly, then assessed every wk). Allowed to receive outpatient psychotherapy if they desired.	Survival analysis; Repeated measures MANOVAs for tx completers and drop-outs by condition, paired t-tests	**Score:** Fair **Intent to treat:** No, data analyzed either on the sample of 35 who completed at least 30 days of tx or for those whom data available through the 1 yr FU (N = 13) **Blinding:** Double **Adverse events:** NR **Funding:** Eli Lilly Corporation, NIMH

Evidence Table 1. Medication trials for anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Kaye et al., 2001 (continued)	**YBOCS-ED (SD):** **G1:** 20.9 (11.2) **G2:** 20.5 (9.5) *(P* = NS) **G1A:** 21.2 (11.2) **G1B:** 20.3 (13.3) **G2A:** 25.7 (2.9) **G2B:** 19.5 (10.1) *(P* = NR)	**YBOCS-ED:** **Change from baseline to 1 yr:** **G1A:** -8.4 (*P* < 0.05) **G1B:** 4.2 (*P* = NS) **G2A:** -14.3 (*P* = NS) **G2B:** 0.8 (*P* = NS) Diff between G1 and G2 *(P* = NS) Diff between groups in change over time *(P* = NS) **Abstinence/remission rates:** NR

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
HDRS (SD): **G1:** 13.7 (10.7) **G2:** 13.9 (10.4) *(P* = NS) **G1A:** 13.4 (9.7) **G1B:** 14.3 (13.1) **G2A:** 4.0 (5.3) **G2B:** 15.8 (10.0) *(P* = NR)	**HDRS (SD):** **Change from baseline to 1 yr:** **G1A:** -8.2 (7.9) *(P* < 0.01) **G1B:** 0.3 (8.1) *(P* = NS) **G2A:** 1.7 (2.1) *(P* = NS) **G2B:** -3.5 (10.5*)* *(P* = NS) Diff between G1 and G2 *(P* = NS) Diff between groups in change over time *(P* = NS)	**%ABW at entry (SD):** **G1:** 89 (6) **G2:** 89 (7) *(P* = NS) **G1A:** 88 (7) **G1B:** 92 (5) **G2A:** 89 (12) **G2B:** 90 (6) *(P* = NS)	**%ABW (SD):** **Change from baseline to 1 yr:** **G1A:** 5.3 (5.3) *(P* < 0.01) **G1B:** -1.2 (3.3) *(P* = NS) **G2A:** 11.2 (11.9) *(P* = NS) **G2B:** -0.2 (6.7) *(P* = NS) Diff between G1 and G2 *(P* = NS) Diff between groups in change over time *(P* = NS)
HAM-A (SD): **G1:** 11.3 (7.5) **G2:** 11.2 (6.4) *(P* = NS) **G1A:** 10.6 (1.7) **G1B:** 12.5 (4.4) **G2A:** 5.3 (3.9) **G2B:** 12.3 (1.5) *(P* = NR)	**HAM-A:** **Change from baseline to 1 yr:** **G1A:** -5.1 (*P* < 0.01) **G1B:** -0.8 (*P* = NS) **G2A:** -2.0 (*P* = NS) **G2B:** -2.4 (*P* = NS) Diff between G1 and G2 *(P* = NS) Diff between groups in change over time *(P* = NS)	**Low lifetime %ABW (SD):** **G1:** 70 (8) **G2:** 73 (7) *(P* = NS) G1A, G1B, G2A, G2B: NR *(P* = NS)	
Y-BOCS (SD): **G1:** 15.0 (10.1) **G2:** 14.3 (7.7) *(P* = NS) **G1A:** 16.8 (9.6) **G1B:** 12.0 (11.2) **G2A:** 8.0 (8.5) **G2B:** 15.5 (7.2) *(P* = NR)	**Y-BOCS (SD):Change from baseline to 1 yr:** **G1A:** -8.6 (12.7) *(P* < 0.10) **G1B:** 8.6 (7.2) *(P* < 0.10) **G2A:** -1.0 (5.6) *(P* = NS) **G2B:** -1.6 (6.9) *(P* = NS) Diff between G1 and G2 *(P* = NS) Diff between groups in change over time *(P* = NS)	**High lifetime %ABW (SD):** **G1:** 110 (24) **G2:** 112 (16) *(P* = NS) G1A, G1B, G2A, G2B: NR *(P* = NS)	

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Klibanski et al., 1995 **Setting:** Single center; inpatient evaluation, otherwise outpatient location: General Clinical Research Center and Eating Disorders Unit, Massachusetts General Hospital; Boston, MA, USA **Enrollment period:** NR	**Research objective:** To assess the efficacy and safety of estrogen and progestin replacement therapy for reducing bone loss in patients with AN at 6-mo intervals over an avg of 1.5 yrs.	**Groups:** **G1:** estrogen/progestin (N = 22) **G2:** control (N = 26) **Enrollment:** • 48 women were enrolled and randomized who were recruited from the hospital's Eating Disorders Clinic and from psychiatrists in the community • 44 completers **G1:** N = 19 **G2:** N = 25 *(P* = NR)	**Age, mean (SD):** **G1:** 23.7 (7.2) **G2:** 25.8 (6.6) Range: 16.3-42.5 *(P* = NS) **Sex:** Female: 100% **Race/ethnicity:** NR

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Women who met DSM III-R criteria for AN **Exclusion:** Other illnesses; taking meds that could impact bone density (e.g., thyroid hormone, antiseizure meds, or glucocorticoids)	Enrolled subjects were randomized either to the estrogen or non-meds control group. Tx included Premarin (0.625 mg, days 1-25), Provera (5 mg, days 16-25) or oral contraceptive. Biochemical indicators including bone density and serum hormone levels assessed at 6-mo intervals for an avg of 1.5 yrs. No psychosocial measures assessed. All participants also took 1500 mg calcium.	Students t-tests and Fisher's Exact Test used to evaluate between group diffs on the primary variables of interest including log-transformed spinal bone density. ANCOVAs used to test for interactions between the clinical and biochemical variables in affecting bone density changes over time.	**Score:** Fair **Intent to treat:** NR **Blinding:** NR **Adverse events:** **Depression:** **G1:** N = 1 **G2:** N = 0 (*P* = NR) **Hyperlipidemia:** **G1:** N = 1 **G2:** N = 0 (*P* = NR) **Funding:** NIH and Rubenstein Foundation

Evidence Table 1. Medication trials for anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Klibanski et al., 1995 (continued)	NR	NR

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
NR		**Wt, kg mean (SD):** **G1:** 43.03 (7.3) **G2:** 41.0 (5.6) (*P* = NR)	**Wt, kg mean (SD):** **G1:** NR **G2:** NR (*P* = NR)
		% IBW, mean (SD): **G1:** 72 (9) **G2:** 72 (8) (*P* = NS)	**%IBW, mean (SD):** **G1:** NR **G2:** NR (*P* = NR)
		% Body fat, mean (SD): **G1:** 15 (5) **G2:** 14 (4) (*P* = NS)	**% Body fat, mean (SD):** **G1:** NR **G2:** NR (*P* = NR)
		Bone density, mg K_2HPO_4/cm^3 mean (SD): **G1:** 124 (25) **G2:** 134 (28)	**Bone density, mg K_2HPO_4/cm^3 mean (SD):** **G1:** 128 (26) **G2:** 132 (31) Diff between groups in change over time (*P* = NS)
		Serum hormone levels, mean (SD): **Ethinyl estradiol, pmol/L:** **G1:** 81 (29) **G2:** 77 (44) (*P* = NS)	**Serum hormone levels, mean (SD):** **G1:** NR **G2:** NR (*P* = NS)
		Testosterone, nmol/L: **G1:** 1.2 (0.7) **G2:** 1.5 (0.8) (*P* = NS)	
		Unbound Testosterone, pmol/L: **G1:** 14 (7) **G2:** 16 (10) (*P* = NS)	
		IGF-1, U/L: **G1:** 223 (102) **G2:** 229 (89) (*P* = NS)	
		TT_3, nmol/L: **G1:** 1.5 (0.3) **G2:** 1.6 (0.4) (*P* = NS)	
			Remission/Recovery = 85% IBW and spontaneous return of menses: **G1:** N = 2 **G2:** N = 6 (*P* = NS)

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Miller et al., 2005 **Setting:** MA General Hospital, Boston, USA **Enrollment period:** NR	**Research objective:** Investigate effectiveness of low-dose testosterone replacement in increasing bone formation, depression and spatial abilities of women with AN and relative androgen deficiency.	**Groups:** **G1:** Testosterone (N = 24) **G2:** Placebo (N = 9) **Enrollment:** • 38 women were enrolled in the study. • 5 dropped out, resulting in 33 participants. • 33 individuals randomized to receive testosterone or placebo.	**Age, mean (SD):** **G1:** 25 (1) **G2:** 22 (1) Range: 18-50 *(P* = NS) **Sex:** Female: 100% **Race/ethnicity:** NR **Mos since last menstrual period (SEM):** **G1:** 20 (5) **G2:** 14 (6) **Bone Mineral Density at L4, mg/cc of K2 HPO4 (SEM):** **G1:** 126 (5) **G2:** 135 (6)

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Women; aged 18-50 yrs; DSM IV criteria for AN; < 85%IBW; amenorrhea for at least 3 mos; all psychiatric manifestations of AN; serum free testosterone level < median of reference range for premenopausal women; no oral contraceptives, progesterone derivatives, glucocorticoids, anabolic agents or any meds known to affect bone metabolism within 3 mos before study enrollment; no fracture within one yr of participation. **Exclusion:** NR	Doses of 150 and 300 µg transdermal testosterone (Patches) administered to two groups on group given placebo for a period of 3 wks. Antidepressant use allowed, no sig diff in use between G1 and G2 at baseline.	ANOVA to compare baseline characteristics and Wilcoxon rank-sums test for non-normal distributions Repeated measures ANOVA for biomarkers and mood. Data from two meds groups combined for analysis on tx effects after determining that there was no statistically sig diff between groups. For analysis of cognitive abilities, ANCOVA was used.	**Score:** Fair **Intent to treat:** NR **Blinding:** Participants and investigators were blind to group assignment. **Adverse events:** Mild skin irritation at the patch site (G1 = 3, G2 = 1). 1 participant in G1 with a hx of affective disorder reported increased depression and anxiety after 10 days of tx. Other side effects included increased fatigue and vertigo (G2 = 1), nausea (G2 = 1) and life threatening wt loss (G2 = 1, G1 = 1) **Funding:** NIH

Evidence Table 1. Medication trials for anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Miller et al., 2005 (continued)	NR	NR

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BDI (SEM): **G1:** 12 (2) **G2:** 14 (3)	**BDI (SEM):** **G1:** 15.1 (2.6) **G2:** 19.3 (5.2) Diff between groups *(P* = 0.02) Diff between groups in change over time *(P* = 0.03)	**%IBW (SD):** **G1:** 76.9 (1.6) **G2:** 75.6 (2.5)	**BMI:** **G1:** NR **G2:** NR Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.02)
		Free testosterone, pmol/liter (SEM): **G1:** 8.9 (1.1) **G2:** 9.1 (1.2)	**Free testosterone, pmol/liter (SEM):** **G1:** 26.7 (3.0) **G2:** 8.9 (1.5) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.0001) G1 greater increase than G2
BDI in depressed subgroup (score > 10): **G1:** 20.4 (2.1) **G2:** 19.8 (3.8)	**BDI in depressed subgroup:** **G1:** 15.1 (2.6) **G2:** 19.3 (5.2) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.02) G1 better than G2	**Total testosterone, nmol/liter (SEM):** **G1:** 0.9 (0.4) **G2:** 0.9 (0.3)	**Total testosterone, nmol/liter (SEM):** **G1:** 2.4 (0.2) **G2:** 0.8 (0.1) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.0001) G1 greater increase than G2
		Estradiol, nmol/liter (SEM): **G1:** 0.07 (0.007) **G2:** 0.07 (0.01)	**Estradiol, nmol/liter (SEM):** **G1:** 0.07 (0.009) **G2:** 0.06 (0.01) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
		SHBG, nmol/liter (SEM): **G1:** 113.9 (14.1) **G2:** 103.6 (20.1)	**SHBG, nmol/liter (SEM):** **G1:** 114.1 (14.3) **G2:** 116.1 (16.0) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
		Dehydroepiandrosterone Sulphate, nmol/liter (SEM): **G1:** 341 (26) **G2:** 354 (37)	**Dehydroepiandrosterone Sulphate, nmol/liter (SEM):** **G1:** 338 (33) **G2:** 394 (53) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 1. Medication trials for anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Miller et al., 2005 (continued)	NR	NR

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
		IGF-I, nmol/liter (SEM): **G1:** 30 (3) **G2:** 26 (4)	**IGF-I, nmol/liter (SEM):** **G1:** 32 (4) **G2:** 28 (5) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
		PICP, µg/liter (SEM): **G1:** 132 (12) **G2:** 119 (19)	**PICP, µg/liter during drug administration (SEM):** **G1:** NR **G2:** NR Diff between groups *(P* = NR) diff between groups in change over time *(P* = 0.02)
		Osteocalcin, µg/liter (SEM): **G1:** 13.9 (1.7) **G2:** 11.1 (2.0)	**Osteocalcin, µg/liter (SEM):** **G1:** NR **G2:** NR Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
		Bone Specific Alkaline Phosphatase, µkat/liter (SEM): **G1:**.38 (.02) **G2:**.37 (.04)	**Bone Specific Alkaline Phosphatase, µkat/liter (SEM):** **G1:** NR **G2:** NR Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
		N-telopeptide, nM BCE (SEM): **G1:** 16 (1) **G2:** 18 (3)	**N-telopeptide, nM BCE (SEM):** **G1:** NR **G2:** NR Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Ruggiero et al., 2001 **Setting:** Inpatient Endocrinology Department, Istituto Auxologico, Milan University Hospital, Milan, Italy **Enrollment period:** March 1997 to November 1998	**Research objective:** Compare amisulpride, clomipramine, and fluoxetine in treating AN and improving attitudes toward wt gain, eating, body shape and fear of fatness.	**Groups:** **G1:** clomipramine (N = 13) **G2:** fluoxetine (N = 10) **G3:** amisulpride (N = 12) **Enrollment:** Participants selected from a larger population of 164 ED patients treated in the endocrinology department.	**Age, mean (SD):** **G1:** 23.69 (4.57) **G2:** 24.50 (5.06) **G3:** 24.33 (5.76) (*P* = NR) **Sex:** NR **Height: mean cm (SD):** **G1:** 160.00 (9.17) **G2:** 160.40 (6.59) **G3:** 163.42 (4.03) (*P* = NR) **Race/ethnicity:** NR

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Dx of restricting type AN according to DSM IV, severe underwt condition needing urgent wt restoration, capacity to cooperate according to current health. **Exclusion:** Being younger than 17 yrs, not consenting, not completing refeeding tx, not speaking Italian with sufficient fluency, showing clear psychiatric comorbidity such as, depression, anxiety or obsessive-compulsive disorder and delusional body image related thinking.	Meds management done within the context of the 3-mo refeeding tx offered on the unit. G1 treated with clomipramine at a mean dosage of 57.69 mg/d (SD = 25.79). G2 treated with fluoxetine at a mean dosage of 28 mg/d (SD = 10.32) and G3 treated with amisulpride at a mean dosage of 50 mg/d (SD = 0).	ANOVA and Tukey's honestly sig diff were used to compare percentage wt increases of the 3 groups. T-tests used for paired data to compare absolute wt values of each group. The McNemar test for present/absent dichotomous variables used for the variables of wt phobia, body image, amenorrhea, bingeing and purging.	**Score:** Poor **Intent to treat:** NR **Blinding:** NR **Adverse events:** NR **Funding:** NR

Evidence Table 1. Medication trials for anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Ruggiero et al., 2001 (continued)	**Bingeing** **G1:** 0 **G2:** 0 **G3:** 0	**Bingeing:** **G1:** 0 **G2:** 40% **G3:** 25% Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
	Purging: **G1:** 0 **G2:** 0 **G3:** 0	**Purging:** **G1:** 0 **G2:** 30% **G3:** 25% Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
		Abstinence/Remission: NR

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
Wt phobia: **G1:** 61.53% **G2:** 60% **G3:** 91.66% *(P* = NR)	**Wt Phobia:** **G1:** 30.76% **G2:** 50% **G3:** 75% Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)	**Wt in kgs (SD):** **G1:** 37.62 (9.80) **G2:** 40.90 (6.98) **G3:** 38.42 (8.33) *(P* = NR)	**Wt in kgs (SD):** **G1:** 38.84 (9.38) *(P* = NS) **G2:** 42.75 (7.54) *(P* = 0.04) **G3:** 42.66 (10.09) *(P* = 0.01) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
Body Image Disturbance: **G1:** 46.15% **G2:** 50% **G3:** 75% *(P* = NR)	**Body Image Disturbance:** **G1:** 30.76% **G2:** 30% **G3:** 66.66% Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)	**BMI:** **G1:** 14.69 **G2:** 15.97 **G3:** 14.44 *(P* = NR)	**BMI:** **G1:** 15.17 **G2:** 16.70 **G3:** 16.03 Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)
		Amenorrhea: **G1:** 84.61% **G2:** 70% **G3:** 91.66% *(P* = NR)	**Amenorrhea:** **G1:** 53.84% **G2:** 70% **G3:** 66.66% Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Szmukler et al., 1995 **Setting:** Two inpatient tx centers for AN Australia **Enrollment period:** NR	**Research objective:** Test effectiveness of cisapride in treating gastric and psychological features associated with AN	**Groups:** **G1:** Cisapride (N = 16) **G2:** Placebo (N = 13) **Enrollment:** • Consecutive inpatients at tx centers for AN • Patients recruited soon after admission; however, meds trial started on avg 9 days after admission • 50 patients invited to participate in the study and 34 agreed. • Of these, 5 did not progress beyond 2 wks. • Gastric emptying patterns in 10 normal female controls (university students and staff) also studied over 2 time periods	**Age, mean (SE):** **G1:** 21.5 (0.8) **G2:** 22.5 (2.0) Diff between groups *(P* = NS) **Sex:** NR **Race/ethnicity:** NR **Height, cms (SE):** **G1:** 163.5 (1.7) **G2:** 166.5 (1.4) Diff between groups *(P* = NS) **Duration of illness, mos (SE):** **G1:** 39.5 (11.4) **G2:** 23.5 (4.8) Diff between groups *(P* = NS)

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: DSM III-R criteria for current AN, aged 18-40 yrs. Eligible if they had bulimic symptoms as long as the criteria for current AN still met. **Exclusion:** Concurrent illness that would affect gastric emptying.	Cisapride, 10 mg orally, three times daily. Patients were all expected to consume between 2500 to 3500 kCal per day. At entry to the trial, patients were asked to fast overnight, given a meal and measures of gastric emptying, lag and subjective states were evaluated. A full blood examination was also done.	Slopes representing change over time for each patient using the least squares method. The slopes for change were correlated among the variables.	**Score:** Poor **Intent to treat:** NR **Blinding:** Yes **Adverse events:** One patient reported loose motions without abdominal pain. **Funding:** Janssen-Cilag patienty Ltd.

Evidence Table 1. Medication trials for anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Szmukler et al., 1995 (continued)	NR	NR

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BDI (SE): **G1:** 28.6 (2.6) **G2:** 26.5 (3.2)	**Change in BDI (SE):** **G1:** - 9.0 (2.6) **G2:** - 6.8 (3.6) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)	**Wt, kg (SE):** **G1:** 40.5 (1.7) **G2:** 41.6 (1.8)	**Change in Wt, kg (SE):** **G1:** 5.1 (0.5) **G2:** 5.7 (0.6) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
Visual Analog Scale (SE):	**Change in Visual Analog Scale (SE):**		
Miserable: **G1:** 56 (10) **G2:** 33 (8)	**Miserable:** **G1:** - 15 (12) **G2:** - 4 (12) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)		
Tense: **G1:** 54 (9) **G2:** 35 (8)	**Tense:** **G1:** - 17 (10) **G2:** - 6 (11) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)		
Bloated: **G1:** 57 (9) **G2:** 58 (9)	**Bloated:** **G1:** - 16 (11) **G2:** - 7 (7) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)		
Fat: **G1:** 59 (9) **G2:** 55 (8)	**Fat:** **G1:** - 20 (11) **G2:** 0 (7) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)		
Hot: **G1:** 23 (8) **G2:** 27 (8)	**Hot:** **G1:** - 7 (9) **G2:** 1 (8) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)		
Hungry: **G1:** 8 (3) **G2:** 32 (8) *(P* < 0.01)	**Change in Hunger:** **G1:** 27 (10) **G2:** - 9 (7) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.02)		

Evidence Table 1. Medication trials for anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Szmukler et al., 1995 (continued)		**Global Improvement in Eating Symptoms (SE):** **G1:** 2.50 (0.27) **G2:** 3.38 (0.18) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.02) G1 better than G2

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Vandereycken, 1984 **Setting:** Inpatient at the University Psychiatric Center St-Jozef in Kortenberg, Belgium **Enrollment period:** NR	**Research objective:** To investigate the use of sulpiride in AN	**Groups:** **G1:** sulpiride – placebo sequence (N = 9) **G2:** placebo – sulpiride sequence (N = 9) **Enrollment:** NR	**Age, yrs, mean (SD):** **G1:** 23.2 (6.5) **G2:** 23.7 (9.6) *(P* = NS) **Sex:** Female: **G1:** 100% **G2:** 100% **Race/ethnicity:** NR **Duration of illness (mos), mean (SD):** **G1:** 51.8 (49.2) **G2:** 74.9 (106.9) *(P* = NS)

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Female dx of AN (DSM III criteria), no additional drug tx (except hypnotics) **Exclusion:** NR	Double-blind cross-over design. After 1 wk baseline, patients began 2 meds periods of 3 wks each. 13 patients received daily dose of 300 mg (100 mg t.i.d.) and 5 received 400 mg (200 mg b.i.d.). Inpatient tx as usual.	Inter-group comparison (Mann-Whitney U-test) Evidence table only contains outcomes prior to cross-over.	**Score:** Poor **Intent to treat:** Yes **Blinding:** Double **Adverse events:** None reported **Funding:** Drug and placebo provided by Laboratoire Delagrange, Belgium

Evidence Table 1. Medication trials for anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Vandereycken, 1984 (continued)	**EAT, mean (SD):** **Preoccupation with eating/body wt:** **G1:** 50.9 (26.0) **G2:** 31.0 (17.2) *(P* = 0.05) G2 lower than G1 **AN Behavior, mean (SD):** **Nurse observation:** **G1:** 17.7 (6.7) **G2:** 18.7 (5.5) *(P* = NS) **Psychiatrist observation:** **G1:** 10.7 (6.9) **G2:** 9.5 (7.7) *(P* = NS)	**EAT, mean (SD):** **Preoccupation with eating/body wt:** **G1:** 39.0 (27.2) *(P* = NR) **G2:** 17.8 (8.9) *(P* = NR) Diff between groups *(P* = 0.03) G2 lower than G1 Diff between groups in change over time *(P* = NR) **AN Behavior, mean (SD):** **Nurse observation:** **G1:** 15.1 (5.6) *(P* = NR) **G2:** 14.1 (4.4) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **Psychiatrist observation:** **G1:** 12.2 (9.3) *(P* = NR) **G2:** 7.0 (6.2) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)

Evidence Table 1. Medication trials for anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BAT, mean (SD): **G1:** 42.6 (11.4) **G2:** 30.4 (12.8) *(P* = 0.05)	**BAT, mean (SD):** **G1:** 36.8 (12.9) *(P* = NR) **G2:** 27.7 (8.1) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)	**Wt (kg), mean (SD):** **G1:** 40.4 (4.6) **G2:** 38.3 (4.3) *(P* = NS) **Wt vs ideal wt (%) (SD):** **G1:** 71.6 (8.2) **G2:** 67.6 (7.2) *(P* = NS) **Wt vs premorbid wt (%) (SD):** **G1:** 70.7 (5.9) **G2:** 69.9 (6.4) *(P* = NS) **Wt change (g/day) during 1-wk pre-tx phase, mean (SD):** **G1:** 86.4 (126.8) **G2:** 141.0 (115.5) *(P* = NS)	**Wt change (g/day), mean (SD):** **G1:** 153.8 (91.0) *(P* = NR) **G2:** 92.6 (49.4) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 2. Medication plus behavioral intervention trials for anorexia nervosa

Study Description	Objective	Design	Patient Characteristics
Author, yr: Ricca et al., 1999 **Setting:** Outpatient ED clinic, Italy **Enrollment period:** June 1, 1997 – April 31, 1998	**Research objective:** To compare the efficacy of venlafaxine and fluoxetine in the tx of atypical AN when combined with CBT.	**Groups:** **G1:** Fluoxetine (N = 13) **G2:** Venlafaxine (N = 13) **Enrollment:** • 26 Enrolled • 24 completed (1 drop out in each group)	**Age, mean (SD):** 19.0 (3.7) **G1:** 19.1 (3.6) **G2:** 18.9 (3.8) *(P* = NS) **Sex:** **Female:** 100% **Race/ethnicity:** NR **Marital Status, N:** **Unmarried:** **G1:** 9 **G2:** 7 **Married:** **G1:** 2 **G2:** 3 **Separated/Divorced:** **G1:** 1 **G2:** 2 *(P* = NR) **Education, N:** **Junior HS:** **G1:** 4 **G2:** 3 **Senior HS:** **G1:** 8 **G2:** 9 **Employment Status, N:** **Unemployed:** **G1:** 0 **G2:** 1 **Employed:** **G1:** 4 **G2:** 5 **Student:** **G1:** 8 **G2:** 6 *(P* = NR) **Axis I Dx per SCID for DSM III-R:** **Dysthymia:** **G1:** 4 **G2:** 4

Evidence Table 2. Medication plus behavioral intervention trials for anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Atypical AN defined as all DSM IV criteria except one and criteria for other ED not fulfilled. Atypical AN = all criteria for AN except: 1) amenorrhea 2) wt loss (body wt above the dx threshold). **Exclusion:** Illiteracy, mental retardation, concurrent medical condition that would preclude use of antidepressants, psychotropic drugs in the previous 2 mo (except for low doses of anxiolytic or hypnotic compounds).	**G1:** 40 mg/day **G2:** 75 mg/day Both had CBT provided wkly on an outpt basis. Tx: 6 mo	Paired and unpaired student's t test, Wilcoxon, Mann-Whitney U	**Score:** Poor **Intent to treat:** No **Blinding:** No **Adverse events, 2 stopped tx N:** **G1:** 1 nausea **G2:** 1 constipation **Funding:** NR

Evidence Table 2. Medication plus behavioral intervention trials for anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Ricca et al., 1999 (continued)			**Adjustment disorder with depressed mood (ADDM)** **G1:** 2 **G2:** 3 **OCD:** **G1:** 1 **G2:** 1 Diff between groups *(P* = NR)

Evidence Table 2. Medication plus behavioral intervention trials for anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality

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Evidence Table 2. Medication plus behavioral intervention trials for anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Ricca et al., 1999 (continued)	**EDE, restraint, mean (SD):** **G1:** 3.17 (1.23) **G2:** 3.40 (1.26) *(P* = NR)	**EDE, restraint, mean (SD):** **G1:** 2.57 (1.15) Diff over time *(P* < 0.05) **G2:** 2.74 (0.85) Diff over time *(P* < 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	EDE, eating concerns, mean (SD): **G1:** 3.14 (1.47) **G2:** 3.12 (2.12) *(P* = NR)	**EDE, eating concerns, mean (SD):** **G1:** 2.66 (1.07) Diff over time *(P* = 0.05) **G2:** 2.65 (1.76) Diff over time *(P* < 0.05) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	EDE, wt concerns, mean (SD): **G1:** 2.85 (1.46) **G2:** 3.40 (1.73) *(P* = NR)	**EDE, wt concerns, mean (SD):** **G1:** 2.54 (1.25) Diff over time *(P* = 0.05) **G2:** 3.08 (1.41) Diff over time *(P* < 0.05) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	EDE, shape concerns, mean (SD): **G1:** 3.62 (1.04) **G2:** 3.88 (1.77) *(P* = NR)	**EDE, shape concerns, mean (SD):** **G1:** 3.16 (0.86) diff over time *(P* < 0.01) **G2:** 3.48 (0.89) diff over time *(P* < 0.01) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 2. Medication plus behavioral intervention trials for anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BDI, mean (SD): **G1:** 12.50 (8.75) **G2:** 16.25 (9.32): *(P* = NR)	**BDI, mean (SD):** **G1:** 7.25 (4.27) Diff over time *(P* < 0.01) **G2:** 7.67 (3.96) Diff over time *(P* < 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)	**BMI, mean (SD):** **G1:** 15.84 (0.46) **G2:** 15.67 (0.59) *(P* = NS)	**BMI, mean (SD):** **G1:** 18.7 (1.1) Diff over time *(P* < 0.001) **G2:** 18.3 (1.3) Diff over time *(P* < 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
STAI-State, mean (SD): **G1:** 41.00 (8.06) **G2:** 45.17 (9.02) *(P* = NR)	**STAI-State, mean (SD):** **G1:** 51.08 (9.94) Diff over time *(P* = 0.001) **G2:** 38.00 (4.88) Diff over time *(P* < 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.001) G1 increased in state anxiety while G2 decreased		
STAI-Trait, mean (SD): **G1:** 44.17 (9.16) **G2:** 50.25 (10.0) *(P* = NR)	**STAI-Trait, mean (SD):** **G1:** 45.50 (8.47) Diff over time *(P* = NS) **G2:** 39.67 (4.83) Diff over time *(P* < 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.001) G1 showed no change while G2 decreased in trait anxiety		

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa

Study Description	Objective	Design	Patient Characteristics
Author, year: Birmingham et al., 2004 **Setting:** Inpatient Vancouver, British Columbia, Canada **Enrollment period:** NR	**Research objective:** To determine if warming therapy increases the rate of weight gain in patients with AN.	**Groups:** **G1:** Warming treatment (N = 10) **G2**: Control (N = 11) **Enrollment:** **Assessed:** N = 32 **Enrolled:** N = 21 **Completed:** N = 18 **G1:** 10 **G2:** 8	**Age, mean (SD):** **Total Sample:** 28.4 (6.6) **G1:** 26.4 (4.8) **G2:** 30.2 (7.6) (*P* = NS) **Sex:** Female = 100% **Race/ethnicity:** NR **Length of AN, yrs, mean (SD):** **Total Sample:** 13.6 (6.7) **G1:** 11.7 (7.1) **G2:** 15.0 (6.3) (*P* = NS)

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Female, between the ages of 17 – 50, admitted to the eating disorders inpatient unit at St. Paul's Hospital. **Exclusion:** Gravid, male gender, age over 50, diabetes mellitus, untreated hypothyroidism, use of beta blockers.	All subjects wore a warming vest on their chest for 3 hr a day for 21 days. All vests were plugged in. Wearing the vest required the subject to remain within the radius of the power cord. **G1:** Vests were set permanently at medium heat. **G2:** Vests were set permanently in the off position.	Descriptive Statistics Statistical tests used = NR	**Score:** Poor **Intent to treat:** NR **Blinding:** Patient blinded. Researcher or Assessor Blinding = NR **Adverse events:** NR **Funding:** NR

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, year: Birmingham et al., 2004 (continued)	NA	NA

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
NA	NA	**BMI, mean (SD):** **Total sample:** 17.7 (2.8) **G1:** 17.5 (3.2) **G2:** 17.9 (2.4) (*P* = NS)	**BMI, mean (SD):** **Total sample:** 18.4 (2.9) **G1:** 18.0 (3.6) **G2:** 18.8 (2.1) Diff over time (*P* = NR) Diff between groups (*P* = NS) Diff between groups in change over time (*P* = NR) **Change in BMI, mean (SD):** **Total sample:** 0.59 (1.2) **G1:** 0.60 (1.2) **G2:** 0.58 (1.1) Diff over time (*P* = NR) Diff between groups (*P* = NS) Diff between groups in change over time (*P* = NR)

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Channon et al., 1989 **Setting:** Outpatient ED Clinic of the Maudsley Hospital, London, UK **Enrollment period:** NR	**Research objective:** To investigate the effectiveness of an outpt CBT tx for AN and compare it to BT alone, and control for "usual care."	**Groups:** **G1:** CBT (N = 8) **G2:** BT (N = 8) **G3:** Control (N = 8) **Enrollment:** • 34 referred • 24 met criteria and enrolled • Dropouts, N: **G1:** 0; **G2:** 1; **G3:** 2. 3 dropped out during FU and still provided assessment data (included in analysis)	**Age, mean (SD):** **G1:** 21.63 (5.88) **G2:** 24.13 (5.77) **G3:** 25.75 (7.19) (*P* = NS) **Sex:** Female: 100% **Race/ethnicity:** NR **Age of Onset, mean (SD):** **G1:** 16.50 (3.82) **G2:** 21.38 (6.21) **G3:** 17.88 (4.36) (*P* = NS) **Duration of illness, yrs: mean (SD):** **G1:** 5.13 (4.85) **G2:** 3.13 (1.73) **G3:** 7.75 (6.09) *(P* = NS) **Previous hospitalization, % yes:** **G1:** 50.0 **G2:** 12.5 **G3:** 37.5 *(P* = NS) **Binge eating % yes:** **G1:** 25.0 **G2:** 50.0 **G3:** 12.5 *(P* = NS) **Vomiting % yes:** **G1:** 37.5 **G2:** 75.0 **G3:** 37.5 *(P* = NS) **Laxative use, % yes:** **G1:** 0.0 **G2:** 37.5 **G3:** 25.0 *(P* = NS)

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Dx AN per Russell's (1983) classification; bulimic features accepted as long as also met Russell's dx **Exclusion:** NR	Four assessments: 1) PreTx, 2) after 6 mo of tx (18 sessions), 3) after 6 mo FU (6 booster sessions), 4) after 12 mo FU. **G1:** Self-monitoring and daily food planning; information, education. Identification of dysfunctional thoughts and challenging them. **G2:** Daily diary, self-monitoring, daily planning. Construction of graded hierarchies of feared foods and situations and graded exposure. Relaxation and distraction techniques. **G3:** 1/2 hour tx session, eclectic therapy	Repeated measures ANOVA with appropriate contrasts for parametric tests; nonparametric tests for diff scores for clinical ratings and self-reports. No means given, only F statistics and *P* values. **Comparisons:** G1 vs. G2 (G1 + G2) vs. G3	**Score:** Fair **Intent to treat:** Yes **Blinding:** NA **Adverse events:** 2 patients in G1, 1 patient in G2 and 4 patients in G3 hospitalized for severe and progressive wt loss **Funding:** Bethlem-Maudsley Research Fund

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Channon et al., 1989 (continued)	NR	**Post Treatment** **EDI, drive for thinness:** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) **G3:** NR *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
		EDI, body dissatisfaction: **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) **G3:** NR *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
		EDI, bulimia: **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) **G3:** NR *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
		M-R all scales: **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) **G3:** NR *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
		Preferred wt: **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) **G3:** NR *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
		6 Mo FU: **EDI, drive for thinness:** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) **G3:** NR *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
		EDI, body dissatisfaction: **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) **G3:** NR *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Psychological/Psychiatric Measure		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
	Post-tx: **BDI:** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) **G3:** NR *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)	**BMI, mean (SD):** **G1:** 14.85 (1.10) **G2:** 16.06 (1.42) **G3:** 14.90 (1.49) *(P* = NS)	**Post Treatment:** **BMI** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) **G3:** NR *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
	MOCI: **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) **G3:** NR *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)		**6 mo:** **M-R menstrual:** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) **G3:** NR *(P* = NR) Diff between G1 and G2 *(P* < 0.05) G2 > G1 Diff between G1+G2 and G3 *(P* = NS) Diff between groups in change over time *(P* = NR)
	6-mo FU: **M-R, Psychosexual functioning:** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) **G3:** NR *(P* = NR) Diff between groups G1 and G2 *(P* < 0.02) G1 > G2 Diff between groups G1+G2 and G3 *(P* = NS) Diff between groups in change over time *(P* = NR)		**1 yr FU:** **BMI** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) **G3:** NR *(P* = NR) Diff over time *(P* < 0.0001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
	M-R mental state: **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) **G3:** NR *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)		**M-R Menstual:** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) **G3:** NR *(P* = NR) Diff over time *(P* < 0.0002) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
	1 yr FU: **MOCI:** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) **G3:** NR *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)		

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Channon et al., 1989 (continued)		**1 Yr FU:** **EDI, drive for thinness:** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) **G3:** NR *(P* = NR) Diff over time *(P* < 0.05) Diff between G1 and G2 *(P* = NS) Diff between (G1+G2) vs G3 *(P* < 0.03) G3 better than G1 or G2 Diff between groups in change over time *(P* = NR)
		M-R Nutritional: **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) **G3:** NR *(P* = NR) Diff over time *(P* < 0.0001) Diff between G1 and G2 *(P* = NS) Diff between G1+G2 and G3 *(P* < 0.04) G1 + G2 > G3 Diff between groups in change over time *(P* = NR)
		Preferred wt: **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) **G3:** NR *(P* = NR) Diff over time *(P* < 0.03) Diff between groups G1 and G2 *(P* < 0.04) G2 > G1 Diff between groups in change over time *(P* = NR)

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Psychological/Psychiatric Measure		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
	M-R Psychosexual: **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) **G3:** NR *(P* = NR) Diff over time *(P* < 0.03) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)		
	M-R mental state: **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) **G3:** NR *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)		
	M-R social: **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) **G3:** NR *(P* = NR) Diff between G1 and G2 *(P* = NS) Diff between G1+G2, G3 *(P* < 0.04) G3> G1 + G2 Diff between groups in change over time *(P* = NR)		

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Crisp, Norton et al., 1991 **Companion article:** Gowers, Norton et al., 1994 **Setting:** Inpatient and outpatient; St. George's Hospital; London, England, UK **Enrollment period:** 1983-1987	**Research objective:** Compare three different forms of tx and "no tx" for individuals with AN at one-yr FU.	**Groups:** **G1:** Inpatients (N = 30) **G2:** Outpatient individual and family psychotherapy and dietary counseling (N = 20) **G3:** Group psychotherapy (N = 20) **G4:** No further tx by research team (N = 20) **Enrollment:** • Patients comprised of successive referrals who fulfilled criteria • 90 patients randomized • Those who refused tx were defined as non-compliers (they were considered for FU analyses within their respective groups) **Compliers:** **G1: (**N = 18) **G2: (**N = 18) **G3: (**N = 17) **G4: (**N = 20)	**Age, mean (SD):** **G1:** 23.2 (4.9) **G2:** 21.2 (5.1) **G3:** 19.7 (2.6) **G4:** 21.9 (4.5) (*P* = NR) **Sex:** Female: 100% **Race/ethnicity:** NR **Age at onset (SD):** **G1:** 19.8 (4.7) **G2:** 18.4 (3.9) **G3:** 17.4 (1.9) **G4:** 17.4 (3.2) (*P* = NR) **Duration of illness (SD):** **G1:** 41.0 (30.17) **G2:** 33.4 (25.9) **G3:** 27.5 (25.8) **G4:** 53.5 (52.9) (*P* = NR)

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Diagnosed with AN (according to DMS-III R criteria), females, had AN for less than ten yrs and lived within outpatient reach of services (≤ 40 miles). **Exclusion:** None reported	**G1:** Inpatient tx including wt restoration to the mean-matched popwt at age of AN onset, wkly individual family and group therapy, dietary counseling and occupational therapy. Inpatient tx followed by 12 sessions of outpatient tx involving patient and family. **G2:** 12 sessions (of 1-1.5 hours duration) of outpatient individual/family therapy over several mos. Decision about how much depended on needs of the patient. **G3:** 10 outpatient group therapy meetings with partient and 10 separate meetings for parents at mo intervals. Dietary counseling and advice part of inpatient tx and offered on 4 occasions to the two outpatient conditions. **G4:** referred back to family doctor or local consultant with details of assessment along with advice on further management. In G4, 6 patients had no tx, 6 had inpatient tx, 5 had outpatient hospital tx, 3 had at least wkly contact with doc No psychotropic drugs provided to any participants	ANOVAs and ANCOVAs for testing between group diffs at randomization; Paired t tests to test within and between group diffs at 1 and 2 yr FU. All values scores at one-yr FU. Morgan and Russell scales used to evaluate nutritional status, menstrual status, and mental state	**Score:** Fair **Intent to treat:** Yes **Blinding:** NR **Adverse events:** One patient in outpatient tx group died as a result of her AN prior to tx beginning. **Funding:** Marks and Spencer plc, St. George's Hospital Special Trustees and Worshipful Company of Grocers

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Crisp, Norton et al., 1991 (continued)	**Nutrition score (SE):** **G1:** 4.7 (0.4) **G2:** 5.3 (0.4) **G3:** 5.0 (0.5) **G4:** 5.0 (0.3)	**Nutrition score (SE):** **One yr FU:** **G1:** 7.3 (0.6) *(P* < 0.01) **G2:** 8.1 (0.6) *(P* < 0.01) **G3:** 8.3 (0.7) *(P* < 0.01) **G4:** 6.4 (0.7) *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
	Morgan-Russell Global score (SE): **G1:** 3.5 (0.2) **G2:** 3.9 (0.3) **G3:** 3.8 (0.4) **G4:** 3.5 (0.3)	**Global Score (SE):** **One-yr FU:** **G1:** 5.5 (0.6) *(P* < 0.01) **G2:** 6.4 (0.6) *(P* < 0.01) **G3:** 6.2 (0.7) *(P* < 0.05) **G4:** 5.6 (0.7) *(P* < 0.05) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
Mental state (SE): **G1:** 5.6 (0.4) **G2:** 5.4 (0.6) **G3:** 5.8 (0.5) **G4:** 4.2 (0.6) G1 vs G4 *(P* < 0.05) Diff between groups all other comparisons *(P* = NS)	**Mental State (SE):** **One yr FU:** **G1:** 6.1 (0.9) *(P* = NS) **G2:** 7.3 (0.8) *(P* < 0.05) **G3:** 6.5 (0.8) *(P* = NS) **G4:** 5.5 (0.8) *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)	**Menstruation (SE):** **G1:** 0.4 (0.2) **G2:** 0.2 (0.2) **G3:** 0.8 (0.6) **G4:** 0.6 (0.4)	**Menstruation (SE):** **One-yr FU:** **G1:** 4.5 (1.0) *(P* < 0.01) **G2:** 4.4 (1.1) *(P* < 0.01) **G3:** 5.7 (1.5) *(P* < 0.05) **G4:** 4.6 (0.3) *(P* < 0.05) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
Mental state (SE): **G1:** 5.6 (0.4) **G2:** 5.4 (0.6) **G3:** 5.8 (0.5) **G4:** 4.2 (0.6) G1 vs **G4:** *(P* ≤ 0.05) Diff between groups all other comparisons (*P* = NS)	**Mental state (SD):** **2-yr FU (SD)*:** **G2:** 7.2 (3.4) *(P* < 0.05) **G4:** 5.5 (4.1) *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)	**Wt, in kgs (SD):** **G1:** 40.8 (6.1) **G2:** 40.3 (3.8) **G3:** 40.2 (6.0) **G4:** 41.0 (6.1)	**Wt gain in kgs:** **G1:** 9.6 **G2:** 9.0 **G3:** 10.1 **G4:** 3.2 Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.01) G4 < G1, G2, G3
		Menstruation (SE): **G1:** 0.4 (0.2) **G2:** 0.2 (0.2) **G3:** 0.8 (0.6) **G4:** 0.6 (0.4)	**Menstruation (SD):** **2-yr FU (SD)*:** **G2:** 6.1 (4.7) *(P* < 0.001) **G4:** 5.2 (5.7) *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Dare et al., 2001 **Setting:** Outpatient eating disorder program in Maudsley Hospital, UK **Enrollment period:** NR	**Research objective:** Compare two forms of individual psychodynamic tx's for adult AN with family therapy and controlled "routine" tx.	**Groups:** **G1:** Focal psychotherapy (N = 21) **G2:** Family therapy (N = 22) **G3:** Cognitive-analytic therapy (N = 22) **G4:** 'Routine' tx (N = 19) **Enrollment:** • Sequential referrals to the outpatient service were recruited for the study. • Patients were assessed and given information about the four kinds of tx. • Patients were interviewed with partners or family members following this and randomly allocated to one tx (total = 84) • Of the original 84 patients, 4 failed to attend the first tx session, 6 dropped out within the first 2 mos of tx and another 19 dropped out during the rest of tx. • From the original sample, 61 came for FU interviews at one yr. Some information was obtained by phone for an additional 9 patients. • 82 female; 2 male	**Age, mean (SD):** **G1:** 26.7 (6.4) **G2:** 26.6 (7.6) **G3:** 27.2 (7.6) **G4:** 24.3 (4.5) *(P* = NS) **Sex: Females** **G1:** 100% **G2:** 91% **G3:** 100% **G4:** 100% *(P* = NS) **Race/ethnicity:** NR **Age at onset (SD):** **G1:** 18.8 (4.2) **G2:** 20.5 (7.5) **G3:** 19.9 (4.1) **G4:** 16.6 (4.1) *(P* = NS) **Duration of illness (SD):** **G1:** 6.7 (5.9) **G2:** 5.8 (4.9) **G3:** 6.7 (7.6) **G4:** 6.1 (5.0) *(P* = NS) **Bingeing daily:** **G1:** 10% **G2:** 9% **G3:** 23% **G4:** 11% *(P* = NS) **Bingeing > = wkly:** **G1:** 5% **G2:** 5% **G3:** 5% **G4:** 26% *(P* = NS) **Bingeing < wkly:** **G1:** 10% **G2:** 9% **G3:** 0% **G4:** 0% *(P* = NS)

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: DSM IV for AN, 18 or older at the time of entry into trial **Exclusion:** If mental or physical state at assessment was considered so dangerous as to require hospitalization e.g., serious suicidal risk, extremely low wt (usually BMI < 12), hypoglycaemia, syncope or severe electrolyte disturbance (Potassium < 2.5 mMol/l; sodium < 130 mMol/l).	**G1** Focal psychoanalytic therapy which is a standardized form of time-limited psychoanalytic therapy. A doctor, social worker, and psychologist conducted therapy. Sessions lasted 50 m and occurred wkly for 1 yr. **G2** Family therapy, focuses on ED as problem of family life. Sessions were 1 hour to 1 hour 15 mins in duration and scheduled by negotiation between once a wk and once every 3 wks. Therapists saw patients, partner or spouse or parents for most of the sessions but individual contact was allowed at a max of once every 3 attendances. Same therapists as for G1. **G3** Cognitive analytic therapy which combines elements of cognitive therapy and brief focused psychodynamic therapy. Sessions were 50 m and occurred wkly for the first 20 wks and then moly for 3 mos. Therapists were members of the ED team. **G4** 'Routine' tx which consisted of low-contact outpatient management with no specific psychotherapies used. Patients attended 30-minute sessions with a trainee psychiatrist.	Categorical data were analyzed using the Fisher exact probability test. ANCOVAs used to analyze continuous data, controlling for initial scores. T-tests used to compare pre and post scores.	**Score:** Fair **Intent to treat:** Yes **Blinding:** NA **Adverse events:** 12 patients required hospitalization during the course of tx and 1 patient in G4 died. **Funding:** Leverhulme Foundation and Mental Health Research Fund

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Dare et al., 2001 (continued)			**Bingeing never:** **G1:** 76% **G2:** 77% **G3:** 73% **G4:** 63% (*P* = NS) **Vomiting daily:** **G1:** 19% **G2:** 9% **G3:** 27% **G4:** 11% (*P* = NS) **Vomiting < wkly:** **G1:** 5% **G2:** 0% **G3:** 0% **G4:** 5% (*P* = NS) **Vomiting never:** **G1:** 62% **G2:** 68% **G3:** 55% **G4:** 63% (*P* = NS) **Living arrangements:** **Family of origin:** **G1:** 52% **G2:** 59% **G3:** 41% **G4:** 47% **Spouse/cohabiting:** **G1:** 14% **G2:** 27% **G3:** 32% **G4:** 21% **Alone:** **G1:** 33% **G2:** 14% **G3:** 27% **G4:** 32% **Previous tx:** **Outpatient:** **G1:** 48% **G2:** 27% **G3:** 41% **G4:** 26%

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality

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Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Dare et al., 2001 (continued)			**Single inpatient:** **G1:** 19% **G2:** 32% **G3:** 18% **G4:** 26% **Repeat inpatient:** **G1:** 5% **G2:** 23% **G3:** 18% **G4:** 32% **Any tx:** **G1:** 71% **G2:** 82% **G3:** 77% **G4:** 84%

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality

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Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Dare et al., 2001 (continued)	**Morgan-Russell Assessment Schedule-A (nutritional status) (SD):** Total: 2.4 (1.8)	**One-yr FU:** **Morgan-Russell Assessment Schedule-A (nutritional status) (SD):** Total: 4.3 (2.8) *(P* = 0.0001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
Morgan-Russell Assessment Schedule-C (Mental state) (SD): **Total:** 10.1 (2.5)	**One-yr FU:** **Morgan-Russell Assessment Schedule-C (Mental state) (SD):** Total: 9.8 (3.0) *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)	**Morgan-Russell Assessment Schedule-B (Menstrual scale) (SD):** Total: 1.1 (2.8)	**At one-yr FU:** **Morgan-Russell Assessment Schedule-B (Menstrual scale) (SD):** Total: 3.4 (4.7) *(P* = 0.0001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
		Baseline BMI (SD): **G1:** 15.0 (1.6) **G2:** 15.2 (1.5) **G3:** 16.0 (1.7) **G4:** 15.3 (1.6) Total: 15.4 (1.6)	**At one yr FU:** **BMI (SD):** Total: 16.5 (2.4) *(P* = 0.0001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.03) Diff between G1 and G4 *(P* = 0.02) Diff between G2 and G4 *(P* = 0.05) Diff between G3 and G4 *(P* = NS)
			One-yr FU no longer meeting criterion for AN (by DSM IV): **Recovered 1 yr (wt > 85% ABW, menstruation returned and no bulimic symptoms):** **G1:** 14% **G2:** 14% **G3:** 14% **G4:** 0%

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Dare et al., 2001 (continued)		

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
			Sig improved (wt > 85% ABW, no menstruation and/or occasional bulimic symptoms): **G1:** 19% **G2:** 23% **G3:** 14% **G4:** 5% Diff between groups; 3 specialty tx's vs. routine tx *(P* = 0.01) G2 vs G4 *(P* = 0.02) G1 vs G4 *(P* = 0.03) G3 vs G4 *(P* = NS) **Diff between groups in change over time** (*P* = NR)

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Gowers, Norton et al., 1994 **Companion article:** Crisp, Norton et al., 1991 **Setting:** Inpatient and outpatient; St. George's Hospital; London, England, UK **Enrollment period:** 1983-1987	**Research objective:** To compare long-term (i.e., 1 and 2-yr) outcomes of a combined individual-family therapy versus assessment-only control for treating symptoms of AN	**Groups:** **G2:** Outpatient individual and family psychotherapy and dietary counseling (N = 20) **G4:** No further tx by research team Assessment-only (N = 20) **Enrollment:** • Patients comprised of successive referrals who fulfilled criteria • 90 patients randomized • Those who refused tx were defined as non-compliers (they were considered for FU analyses within their respective groups)	**Age, mean (SD):** **G1:** 23.2 (4.9) **G2:** 21.2 (5.1) **G3:** 19.7 (2.6) **G4:** 21.9 (4.5) *(P* = NR) **Sex:** Female: 100% **Race/ethnicity:** NR **Age at onset (SD):** **G1:** 19.8 (4.7) **G2:** 18.4 (3.9) **G3:** 17.4 (1.9) **G4:** 17.4 (3.2) *(P* = NR) **Duration of illness (SD):** **G1:** 41.0 (30.17) **G2:** 33.4 (25.9) **G3:** 27.5 (25.8) **G4:** 53.5 (52.9) *(P* = NR)

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Diagnosed with AN (according to DMS-III R criteria), females, had AN for less than ten yrs, and lived within outpatient reach of services (≤ 40 miles). **Exclusion:** None reported	**G1:** Inpatient tx including wt restoration to the mean-matched popwt at tage of AN onset, wkly individual family and group therapy, dietary counseling and occupational therapy. Inpatient tx followed by 12 sessions of outpatient tx involving the patient and the family. **G2:** 12 sessions (of 1-1.5 hours duration) of outpatient individual/family therapy over several mos. Decision about how much depended on needs of patient. **G3:** 10 outpatient group therapy meetings with patient and 10 separate meetings for parents at monthly intervals. Dietary counseling and advice part of inpatient tx and offered on 4 occasions to the two outpatient conditions. **G4:** Referred back to family doctor or local consultant with details of assessment along with advice on further management. In G4, 6 patients had no tx, 6 had inpatient tx, 5 had outpatient hospital tx, 3 had at least wkly contact with physician No psychotropic drugs provided to any participants	ANOVAs and ANCOVAs for testing between group diffs at randomization; Paired t tests to test within and between group diffs at 1 and 2 yr FU. All values are scores at one-yr FU. Morgan and Russell scales used to evaluate nutritional status, menstrual status, and mental state	**Score:** Fair **Intent to treat:** Yes **Blinding:** NR **Adverse events:** One patient in outpatient tx group died as a result of her AN prior to tx beginning. **Funding:** Marks and Spencer plc, St. George's Hospital Special Trustees and Worshipful Company of Grocers

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Gowers, Norton et al., 1994 (continued)	**Nutrition (SE):** **G1:** 4.7 (0.4) **G2:** 5.3 (0.4) **G3:** 5.0 (0.5) **G4:** 5.0 (0.3)	**Nutrition (SE):** **2-yr FU (SD):** **G2:** 9.2 (2.7) *(P* < 0.001) **G4:** 7.1 (3.1) *(P* < 0.01) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **Abstinence/Remission by 2 yrs:** **G2:** 20% **G4:** 10% Diff between groups *(P* = NR)
	Morgan-Russell Global score (SE): **G1:** 3.5 (0.2) **G2:** 3.9 (0.3) **G3:** 3.8 (0.4) **G4:** 3.5 (0.3)	**Morgan-Russell Global score (SD):** **Two-yr FU:** **G2:** 7.5 (2.8) *(P* < 0.001) **G4:** 6.2 (3.2) *(P* < 0.01) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
		Wt, in kgs (SD): **G1:** 39.5 (5.9) **G2:** 41.0 (3.4) **G3:** 40.2 (6.4) **G4:** 41.0 (6.1)	**Wt, kg (SD):** **1-yr FU:** **G2:** 48.76 (6.2) *(P* = NR) **G4:** 43.92 (8.0) *(P* = NR) Diff between groups *(P* < 0.05) G2 > G4 Diff between groups in change over time *(P* = NR) **Wt, kg (SD):** **2-yr FU (SD):** **G2:** 52.51 (8.5) *(P* = NR); **G4:** 46.24 (8.6) *(P* = NR) Diff between groups *(P* < 0.05) G2 > G4 Diff between groups in change over time *(P* < 0.01) G2 > G4
		BMI (SD): **G2:** 15.52 (1.4) **G4:** 15.84 (1.7)	**BMI (SD):** **1-yr FU:** **G2:** 18.97 (2.0) *(P* = NR) **G4:** 16.93 (2.8) *(P* = NR) Diff between groups *(P* < 0.05) G2 > G4 Diff between groups in change over time *(P* = NR) **2-yr FU:** **G2:** 20.09 (2.8) *(P* = NR) **G4:** 17.83 (3.2) *(P* = NR) Diff between groups *(P* < 0.01) G2 > G4 Diff between groups in change over time *(P* = NR)

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Hall and Crisp, 1987 **Setting:** Outpatient, UK **Enrollment period:** NR	**Research objective:** Compare effect of outpatient brief individual and family psychotherapy or dietetic advice on wt and eating behavior among outpatients with AN at one yr FU.	**Groups:** **G1:** Psychotherapy group (N = 15) **G2:** Dietary advice group (N = 15) **Enrollment:** • 30 participants selected from consecutive referrals to one of the authors. • Referrals initially screened by postal questionnaire and those meeting criteria were interviewed along with their families.	**Age, mean:** **G1:** 19.55 **G2:** 19.57 *(P* = NS) **Social class:** **Group I and II:** **G1:** 12 **G2:** 13 **Group III:** **G1:** 3 **G2:** 2 *(P* = NS) **Sex:** Female: 100% **Race/ethnicity:** NR **Height, cms:** **G1:** 161.7 **G2:** 162.3 *(P* = NS) **Age at onset of illness, mean:** **G1:** 17.07 **G2:** 17.53 *(P* = NS) **Age at onset of amenorrhea:** **G1:** 17.77 **G2:** 17.90 *(P* = NS) **Duration of illness, mos:** **G1:** 29.7 **G2:** 24.5 *(P* = NS) **Duration of amenorrhea, mos:** **G1:** 27.5 **G2:** 20.1 *(P* = NS) **Number having previous tx:** **G1:** 10 **G2:** 8 *(P* = NS) **Mean wt at onset of dieting (kg):** **G1:** 52.50 **G2:** 55.42 *(P* = NS)

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Diagnostic criteria for primary AN, aged 13-27, from social classes I-III, unmarried, wting less than 85% of matched population mean wt, had amenorrhea, had been ill for 6 – 72 mos and willing to attend outpatient tx. **Exclusion:** None reported	**G1:** 12 one hour sessions at one to two wkly intervals. Proportion of individual psychodynamic therapy and family therapy depended on clinical judgment, practicability and the willingness of the family to be involved. Patients seen by a dietitian for 4 15-minute interviews. **G2:** 12 one-hour sessions at wkly or fortnightly intervals. Family was seen with the participant on some occasions. All participants were seen by psychotherapist for four 15-minute interviews.	No description provided	**Score:** Poor **Intent to treat:** Yes **Blinding:** No **Adverse events:** One patient in G1 deteriorated after tx ended and had to be hospitalized. 2 patients in G2 hospitalized. **Funding:** NR

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Hall and Crisp, 1987 (continued)	NR	NR

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
Global clinical score: **G1:** 5.7 **G2:** 6.3	**One-yr FU:** **Global clinical score:** **G1:** 8.8 *(P* < 0.001) **G2:** 7.8 *(P* < 0.01) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)	**Wt, kgs:** **G1:** 41.00 **G2:** 39.54	**One yr FU:** **Wt, kgs:** **G1:** 45.1 *(P* = NS) **G2:** 46.0 *(P* < 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: McIntosh et al., 2005 **Setting:** Outpatient setting in Christchurch, New Zealand **Enrollment period:** NR	**Research objective:** Examine effectiveness of CBT, interpersonal psychotherapy and control tx (nonspecific supportive clinical management) in treating AN on an outpatient basis.	**Groups:** **G1:** CBT (N = 19) **G2:** Interpersonal psychotherapy (N = 21) **G3:** Nonspecific supportive clinical management (N = 16) **Enrollment:** Recruitment included referrals from health professionals, self-referrals and family referrals. 400 individuals inquired about study. 135 interviewed and 78 deemed eligible. 56 consented to participate and were randomly assigned to one of three tx's. 35 completed therapy (attending 15 of 20 sessions).	**Age, mean (SD):** NR **Sex:** Female: 100% **Race/ethnicity:** NR **Comorbid dx of panic disorder:** **G1:** 26% **G2:** 0 **G3:** 19% Diff between groups *(P* < 0.05) G1 > G2 and G3 **Comorbid dx of BN:** **G1:** 63% **G2:** 31% **G3:** 19% Diff between groups *(P* < 0.05) G1 > G2 and G3

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Female; of age 17-40 yrs; current primary AN; included DSM IV wt criterion (BMI < 17.5) and more lenient wt criterion (BMI, 17.5-19.0); could be receiving stable dose of a psychotropic med with no change in AN symptoms **Exclusion:** BMI < 14.5; current severe major depression; psychoactive substance dependence; major medical or neurological illness; developmental learning disorder; cognitive impairment; bipolar I disorder; schizophrenia; chronic refractory course of AN	Therapy in all 3 groups consisted of 20 hour-long manual-based sessions conducted over a min of 20 wks. CBT: working on entrenched food restriction and avoidance patterns. Interpersonal psychotherapy: based on IPT for depression and BN. Nonspecific supportive clinical management: aimed at mimicking outpatient tx that could be offered in usual clinical practice and combined features of supportive psychotherapy and clinical management. Information provided about wt maintenance strategies, energy requirements and relearning to eat normally.	Pairwise comparisons among groups made using Mann-Whitney U test. Repeated measures ANOVA was used for secondary and tertiary outcome variables to measure change over time. Pairwise least significance tests used for FU comparisons. Logistic regression used to examine independence of tx effects. Non-parametric Kruskal-Wallis test used to compare global AN measure values. Created a 4 patient global AN rating scale: 4: meets full criteria for AN, min improved from baseline in wt, BMI, EDE but min improvement in EDI; 3: not full AN but having features of eating disorders, gained wt, min changes on EDE, considerable symptoms on EDI; 2: few features of eating disorders, “much improved”, 1: no sig features of ED, min symptoms on EDI and EDE	**Score:** Fair **Intent to treat:** Yes **Blinding:** NA **Adverse events:** Reported only for those who dropped out. Of these, 4 hospitalized (one died) for wt loss or medical complications of AN. **Funding:** Health Research Council of New Zealand

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: McIntosh et al., 2005 (continued)	**EDE-Restraint (SD):** Total sample: 3.9 (1.3)	**EDE-Restraint (SD):** **G1:** 2.8 (1.7) **G2:** 4.0 (1.5) **G3:** 2.1 (1.7) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.01) Diff between 2 groups in change over time *(P* < 0.05) G1 and G3 > G2
	EDE-Eating concerns (SD): Total sample: 2.8 (1.3)	**EDE-Eating concerns:** **G1:** 1.7 (1.7) **G2:** 2.5 (1.2) **G3:** 1.8 (1.6) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	EDE-wt concerns (SD): Total sample: 3.1 (1.7)	**EDE-wt concerns:** **G1:** 2.5 (1.2) **G2:** 1.8 (1.5) **G3:** 1.8 (1.5) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	EDE-shape concerns (SD): Total sample: 3.8 (1.3)	**EDE-shape concerns:** **G1:** 2.7 (1.5) **G2:** 3.1 (1.7) **G3:** 2.6 (2.0) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	EDI-Drive for thinness (SD): Total sample: 11.7 (5.4)	**EDI-Drive for thinness:** **G1:** 7.9 (6.5) **G2:** 9.5 (5.6) **G3:** 6.8 (7.5) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	EDI-Bulimia (SD): Total sample: 3.1 (4.0)	**EDI-Bulimia:** **G1:** 1.5 (4.0) **G2:** 2.6 (3.2): **G3:** 1.8 (2.5) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	EDI-Body dissatisfaction (SD): Total sample: 7.7 (7.0)	**EDI-Body dissatisfaction:** **G1:** 5.8 (6.9) **G2:** 7.3 (7.6) **G3:** 7.7 (9.5) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **Global outcome – rating of 1:** **G1:** 5% **G2:** 0 **G3:** 25%

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
Global assessment of functioning (SD): Total sample: 48.8 (5.6)	**Global assessment of functioning (SD):** **G1:** 53.2 (9.5) **G2:** 51.1 (7.2) **G3:** 60.7 (13.9) *(P* = NR) Change over time Diff between groups in change over time *(P* < 0.02) Diff between 2 groups in change over time *(P* < 0.05) G3 better than G1 or G2	**Wt, in kgs:** Total sample: 46.6 (3.9)	**Wt, in kgs:** **G1:** 48.6 (5.5) **G2:** 49.0 (8.5) **G3:** 50.4 (7.3) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
HDRS (SD): Total sample: 12.6 (6.9)	**HDRS (SD):** **G1:** 6.9 (7.8) **G2:** 9.9 (7.3) **G3:** 6.8 (7.1) *(P* = NR) Diff between groups in change over time *(P* = NS)	**BMI (SD):** Total sample: 17.3 (1.1)	**BMI (SD):** **G1:** 18.1 (1.9) **G2:** 18.1 (3.1) **G3:** 18.8 (2.1) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
		Body fat (SD): Total sample: 18.9% (3.4)	**Body fat (SD):** **G1:** 22.0% (5.3) **G2:** 20.7% (6.6) **G3:** 22.1% (5.9) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: McIntosh et al., 2005 (continued)		**Global outcome – rating of 2:** **G1:** 26% **G2:** 10% **G3:** 31% **Global outcome – rating of 3:** **G1:** 16% **G2:** 24% **G3:** 6% **Global outcome – rating of 4 *(P*oor):** **G1:** 53% **G2:** 67% **G3:** 38% *(P* = NR) Diff between groups in change over time G3 > G2 *(P* < 0.02) G3 vs G1 *(P* = NS) G2 vs G1 *(P* = NS)

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Pike et al., 2003 **Setting:** Outpatient, New York State Psychiatric Institute, USA **Enrollment period:** NR	**Research objective:** Assessed the efficacy of CBT vs. nutritional counseling in the posthospitalization tx of AN among outpatient adults.	**Groups:** **G1:** CBT (N = 18) **G2:** Nutritional counseling (N = 15) **Enrollment:** • 43 met initial eligibility criteria • 33 randomly assigned to tx immediately before their first session which was scheduled within 1 wk of hospital discharge • Random assignment based on an adaptive stratification procedure • Dropout before session 10: **G1:** 0; **G2:** 3	**Age, mean (SD):** **G1:** 26.1 (6.2) **G2:** 24.3 (6.9) *(P* = NS) Range: 18-45 **Sex:** Female: 100% **Race/ethnicity:** **G1:** NR% **G2:** NR% **Age at illness onset (SD):** **G1:** 17.4 (5.2) **G2:** 16.5 (3.1) *(P* = NS) **Duration of illness (SD):** **G1:** 7.6 (5.9) **G2:** 7.3 (5.8) *(P* = NS) **Previous hospitalizations (SD):** **G1:** 1.8 (2.6) **G2:** 1.1 (1.2) *(P* = NS) **Percent restricting type AN (N):** **G1:** 56% (10) **G2:** 40% (6) *(P* = NS)

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: DSM IV dx of AN, successfully completed inpatient tx (defined as achievement of at least 90% IBW based on 1959 Metropolitan Life Insurance Tables) for a min of two wks, normalization of eating, resolution of acute medical problems and living within commuting distance of the hospital. **Exclusion:** NR	Both tx's consisted of 50 individual therapy sessions delivered over one yr. CBT and nutritional counseling based on manuals created by K. Pike. CBT focused on cognitive and behavioral features associated with maintenance of eating pathology and used a schema-based approach. Nutritional counseling was psychoeducational and supportive and focused on dietary analyses and balanced meal planning. Both txs conducted by PhD licensed, experienced psychologists. Participation terminated if subject's wt fell below BMI of 17.5 for > 10 days or if medical status compromised by exacerbation of AN pathology to the extent that inpatient care required or exacerbation of non-eating disorder pathology requiring alternative care. Participants monitored wkly. Allowed to continue with psychopharmacological tx started before study.	T-tests conducted to compare baseline characteristics between of two groups. Kaplan Meier survival analyses done to compare time to relapse for the participants in the two tx groups. Relapsing not defined Full recovery defined using EDE as: good outcome, eating attitudes and wt concerns < 1 SD above mean of comprison group without ED, binge eating or purging had to be absent.	**Score:** Fair **Intent to treat:** No **Blinding:** NR **Adverse events:** Reasons for participants dropping out of tx or relapsing: wt loss, increased suicidality and in most cases, these were referred for inpatient tx or alternative tx. **Funding:** NIMH

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Pike et al., 2003 (continued)	NR	**Time to relapse (sessions/wks):** **G1:** 43.79 (2.9) **G2:** 27.21 (5.9) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.004)
		Number of participants relapsing: **G1:** 22% **G2:** 53% Diff between groups *(P* = NS)
		Overall tx failure (relapse + dropout): **G1:** 22% (4 of 18) **G2:** 73% (11 of 15) Diff between groups *(P* < 0.003) Diff between groups in change over time *(P* = NR)
		Morgan-Russell criteria for "good outcome": **G1:** 44% (8 of 18) **G2:** 7% (1 of 15) Diff between groups *(P* < 0.02) Diff between groups in change over time *(P* = NR)
		"Full Recovery" **G1:** 17% **G2:** 0% Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) Good vs fair/poor/other outcome **Psychotropic med vs not** **G1** *(P* < 0.04) On med superior to no med **G2** *(P* = 0.39) **AN subtype** **G1:** *(P* = NS) **G2:** *(P* = NS)

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
Treatment logic: **G1:** 11.8 (3.0) **G2:** 10.61 (3.3)	NR	**BMI (SD):** **G1:** 16.0 (2.1 **G2:** 15.2 (1.5) (*P* = NS)	NR
Treatment relevance: **G1:** 10.6 (3.6) **G2:** 10.0 (2.8)			
Expectation of success: **G1:** 10.2 (3.0) **G2:** 11.6 (2.5)			

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Pillay and Crisp, 1981 **Setting:** Inpatient unit, London, UK **Enrollment period:** NR	**Research objective:** To investigate impact of a social skills program within a longer tx approach to AN.	**Groups:** **G1:** Social skills/social anxiety reduction (N = 11) **G2:** placebo nonspecific therapy (N = 12) **Enrollment:** • 33 patients enrolled • 9 patients (8 from G2) dropped out and replaced by other patients. • 1 excluded **Completed** **G1:** 11 **G2:** 12 **1 yr FU** **G1:** 10 **G1:** 12	**Age, mean (SD):** **G1:** 23.6 (8.2) **G2:** 23.8 (7.8) *(P* = NS) **Sex:** Female: 100% **Race/ethnicity:** NR **Married (N = 5):** **G1:** 2 **G2:** 3 *(P* = NS) **Single (N = 18):** **G1:** 9 **G2:** 9 **Social class, 1 or 2 (N = 9):** **G1:** 4 **G2:** 5 *(P* = NS) **3/4/5 (N = 14):** **G1:** 7 **G2:** 7 *(P* = NS) **Ht, cm, mean (SD) (N = 162.6 [5.3]):** **G1:** 162.7 (5.6) **G2:** 162.5 (5.1) *(P* = NS) **Vomiters (N = 10):** **G1:** 6 **G2:** 4 *(P* = NS) **Wks as inpatient, mean (SD):** **G1:** 17.4 (4.8) **G2:** 16.3 (4.7) *(P* = NS) **WAIS equivalent score, mean (SD):** **G1:** 106.0 (9.8) **G2:** 106.6 (14.0) *(P* = NS)

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: NR **Exclusion:** NR	Initial bed rest, 3000 kcal/day, individual, milieu, and family therapy. **G1:** 12 sessions of social skills/social anxiety tx (approach behavior). **G2:** 12 sessions non-specific counseling Intervention provided during 4 mo inpatient tx Assessments: admission, post = target wt + 4 wks FU = 1 yr	Chi square 2 tailed group comparisons	**Score:** Poor **Intent to treat:** No **Blinding:** NA **Adverse events:** NR **Funding:** St George's Medical Research Committee

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Pillay and Crisp, 1981 (continued)	NR	NR

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
		Wt, kg, mean (SD): **G1:** 41.0 (5.7) **G2:** 40.2 (7.5) *(P* = NS)	**Post tx:** **Wt, kg, mean (SD)** **G1:** 54.4 (3.6) *(P* = NR) **G2:** 54.1 (5.2) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)
			% Wt increase, mean (SD) **G1:** 34.5 (15.5) *(P* = NR) **G2:** 37.1 (18.6) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)
(CCEI, mean (SD): **Anxiety** **G1:** 11.1 (3.5 **G2:** 10.8 (3.6) *(P* = NS)	**CCEI, mean (SD):** **Anxiety** **G1:** 8.9 (3.5) *(P* = 0.05) **G2:** 10.2 (4.6) *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)		**1 Yr FU:** **Wt, kg, mean (SD)** **G1:** 48.0 (7.1) *(P* = NR) **G2:** 47.4 (7.6) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)
Phobic Anxiety **G1:** 5.2 (4.3) **G2:** 4.3 (3.2) *(P* = NS)	**Phobic Anxiety** **G1:** 4.4 (3.2) *(P* = NS) **G2:** 5.3 (3.7) *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)		**FU Wt as % MMPW, mean (SD):** **G1:** 84.6 (11.7) *(P* = NR) **G2:** 83.1 (10.9) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)
Obsessionality **G1:** 11.6 (2.1) **G2:** 8.8 (3.4) *(P* = NS)	**Obsessionality** **G1:** 9.9 (1.5) *(P* = NS) **G2:** 7.9 (3.1) *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)		
Depression **G1: 1**0.3 (4.2) **G2:** 8.4 (3.9) *(P* = NS)	**Depression** **G1:** 7.1 (3.8) *(P* = 0.01) **G2:** 9.0 (4.0) *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)		
Total Score **G1:** 56.0 (15.8) **G2:** 49.3 (14.1) *(P* = NS)	**Total Score** **G1:** 43.4 (14.7) *(P* = 0.01) **G2:** 44.2 (16.4) *(P* = NS) *(P* = NR) Diff between groups in change over time *(P* = NR)		

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Pillay and Crisp, 1981 (continued)		

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
	1 yr FU: **CCEI, mean (SD)** **Anxiety** **G1:** 9.4 (4.3) *(P* = 0.05) **G2:** 8.8 (3.9) *(P* = 0.01) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)		
	Phobia **G1:** 3.7 (3.3) *(P* = NS) **G2:** 4.3 (3.2) *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)		
	Obsessionality **G1:** 10.3 (3.4) *(P* = NS) **G2:** 7.1 (2.8) *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)		
	Depression **G1:** 7.5 (5.3) *(P* < 0.05) **G2:** 7.0 (4.0) *(P* < 0.04) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)		
	Total Score: FU **G1:** 44.2 (18.4) *(P* < 0.05) **G2:** 39.6 (14.4) *(P* < 0.01) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)		

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Thien et al., 2000 **Setting:** St. Paul's Hospital EDs Outpatient clinic, Canada **Enrollment period:** July 1997	**Research objective:** To determine whether an AN patient's quality of life is improved by being placed on a graded exercise program while not reducing gain of percent body fat or BMI.	**Groups:** **G1:** Graded Exercise (N = 8) **G2:** Control (N = 8) **Enrollment:** • 16 enrolled • 12 completed • **G1:** 3/8 drop out • **G2:** 1/8 drop out	**Age, mean (SD):** **G1:** 29.0 (4.4) **G2:** 36.1 (7.9) Diff between groups *(P* = 0.05) **% female:** **G1:** 100% **G2:** 86% **Race/ethnicity:** NR

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Age 17-45, DSM IV criteria of AN. **Exclusion:** NR	Patients followed as usual, every 2-3 wks for 3 mo. **G1:** patients seen by occupational therapist who reviewed and adjusted level of exercise based on a graded protocol. Patients remained at each level of activity for at least 1 wk and progression to the next level determined by team. **G2:** patients encouraged to limit exercise.	Nonpaired two-tailed t-tests.	**Score:** Poor **Intent to treat:** No **Blinding:** NA **Adverse events:** NA **Funding:** NR

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Thien et al., 2000 (continued)	NR	NR

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
SF-36, mean (SD): **G1:** 58.8 (13.9) **G2:** 53.3 (14.5) *(P* = NS)	**Change in SF-36, mean (SD):** **G1:** 6.6 (7.0) *(P* = NR) **G2:** -12.0 (25.5) *(P* = NR) Diff between groups in change over time *(P* = NS)	**BMI, kg/m^2, mean (SD):** **G1:** 20.26 (1.8) **G2:** 17.2 (1.6) *(P* = 0.02)	**Change in BMI, mean (SD):** **G1:** 1.0 (1.3) *(P* = NR) **G2:** 0.8 (1.1) *(P* = NR) Diff between groups *(P* = NS)
SF-36, RP, mean (SD): **G1:** 55.0 (37.1) **G2:** 50.0 (47.9) *(P* = NS)	**Change in SF-36, RP, mean (SD):** **G1:** 25.0 (35.4) *(P* = NR) **G2:**-10.7 (53.7) *(P* = NR) Diff between groups *(P* = NS)	**%Body fat, mean (SD):** **G1:** 21.0 (2.9) **G2:** 16.7 (4.9) *(P* = 0.05)	**Change in %Body fat, mean (SD):** **G1:** 0.9 (2.1) *(P* = NR) **G2:** 0.5 (2.6) *(P* = NR) Diff between groups *(P* = NS)
SF-36, SF, mean (SD): **G1:** 72.5 (18.5) **G2:** 62.5 (14.4) *(P* = NS)	**Change SF-36, SF, mean (SD):** **G1:** 5.0 (18.9) *(P* = NR) **G2:** -19.6 (27.8) *(P* = NR) Diff between groups in change over time *(P* = 0.05)		
SF-36, Vit, mean (SD): **G1:** 37.0 (28.2) **G2:** 39.3 (24.4) *(P* = NS)	**Change in SF-36, Vit, mean (SD):** **G1:** 5.0 (25.7) *(P* = NR) **G2:** -2.8 (32.3) *(P* = NR) Diff between groups in change over time *(P* = NS)		
SF-36, sum of 3 scales, mean (SD): **G1:** 54.8 (20.1) **G2:** 50.6 (22.5) *(P* = NS)	**Change in SF-36, sum of 3 scales, mean (SD):** **G1:** 11.7 (19.5) *(P* = NR) **G2:** -11.0 (34.2) *(P* = NR) Diff between groups in change over time *(P* = NS)		

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Treasure et al., 1995 **Setting:** Outpatients from the Eating Disorder Clinic at the Maudsley Clinic, London, UK **Enrollment period:** NR	**Research objective:** To compare EBT and CAT for adult AN.	**Groups:** **G1:** EBT (N = 16) **G2:** CAT (N = 14) **Enrollment:** • 38 Assessed • 32 met criteria • 30 enrolled (1 refused, 1 lost more wt and was excluded) • completed 20 sessions: **G1:** N = 10 **G2:** N = 10	**Age, mean (SD) (range):** **G1:** 25.3 (7) (18-39) **G2:** 24.7 (5) (18-35) *(P* = NR) **Sex:** Female (N): 29 **Race/ethnicity:** NR **Age onset, yrs, mean (SD) (range):** **G1:** 20.8 (5) (12-34) **G2:** 20.4 (5) (17-30) *(P* = NR) **% wt loss, mean (SD) (range):** **G1:** 28.9 (8) (20-24) **G2:** 25.5 (7) (18-42) *(P* = NR) **Height, meters, mean (SD) (range):** **G1:** 1.67 (0.80) (1.55-1.3*) **G2:** 1.66 (0.09) (1.5-1.85) *error in paper* *(P* = NR) **Duration amenorrhea, mos, mean (SD) (range):** **G1:** 50.1 (60) (6-224) **G2:** 63.1 (77) (6-264) *(P* = NR) **Premorbid wt, kg, mean (SD) (range):** **G1:** 60.3 (10) (44-80) **G2:** 56.5 (8) (46-77) *(P* = NR) **Bulimic episodes, N:** **G1:** 4/16 **G2:** 5/14 *(P* = NR)

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: ICD-10 dx for AN, > 18 yrs old. **Exclusion:** Inpatient tx because of extreme, rapid wt loss with other severe sx.	20 wkly, 50 minutes sessions. **G1:** monitor intake, goals to increase amt and range of food, wt/shape discussed, information re: nutrition and ED. **G2:** manual of Ryle (1990). Integrates psychodynamic factors with behavioral factors, transference, reformulate and interpret problems. FU assessments at end of tx and 3 mo intervals up to 1 yr.	Mann-Whitney-U t-tests	**Score:** Fair **Intent to treat:** Yes **Blinding:** NA **Adverse events:** None reported **Funding:** Mental Health Foundation and the Society for Research into AN (aka: Eating Disorders Association)

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Treasure et al., 1995 (continued)			**Vomiting, N:** **G1:** 7/16 **G2:** 7/14 (*P* = NR) **Laxatives, N:** **G1:** 4/16 **G2:** 5/14 (*P* = NR) **Previous hospitalizations, N:** **G1:** 6/16 **G2:** 3/14 (*P* = NR)

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality

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Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Treasure et al., 1995 (continued)		**M-R, Nutrition, mean (SD) (range):** **G1:** 6.2 (4.0) (0-12) *(P* = NR) **G2:** 7.1 (2.8) (3-12) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
		M-R, avg score mean (SD) (range): **G1:** 6.4 (2.8) (1.8-11.7) **G2:** 7.3 (2.7) (3.3-11) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
		Bulimia Nervosa, N (%): **G1:** 3 (19) *(P* = NR) **G2:** 2 (14) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
		Good outcome (body wt maintained within 15% of ABW), N (%): **G1:** 5 (31) *(P* = NR) **G2:** 6 (42) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
		Intermediate outcome (body wt increased to within 15% of ABW with persistent amenorrhea), N (%): **G1:** 3 (19) *(P* = NR) **G2:** 5 (36) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
		Poor outcome (< 15% ABW), N (%): **G1:** 8 (50) *(P* = NR) **G2:** 3 (22) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)

Evidence Table 3. Behavioral intervention trials for adults with anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes – 1 yr**
	Self rated improvement, mean (SD) (range): **G1:** 1.7 (0.9) (0-3) Diff between groups (*P* = NR) **G2:** 2.4 (0.5) (2-3) *(P* = NR) Diff between groups *(P* = 0.045) Diff between groups in change over time *(P* = NR)	**Wt, kg, mean (SD) (range):** **G1:** 42.2 (4) (34-50) **G2:** 42.9 (5) (34-51)	**Wt, kg, mean (SD) (range):** **G1:** 47 (7) (33-58) *(P* = NR) **G2:** 50 (6) (34-59) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
		BMI, mean (SD) (range): **G1:** 15.0 (1.0) (12.5-17.3) **G2:** 15.6 (2.1) (13-17.5)	**BMI mean (SD) (range):** **G1:** 17.4 (3.0) (12.3-20.7) *(P* = NR) **G2:** 18.5 (2.1) (14.1-21.8) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
			Wt gain, kg, mean (SD) (range): **G1:** 6.7 (5.2) (-1 -14) *(P* = NR) **G2:** 6.9 (4.3) (-8-16) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa

Study Description	Objective	Design	Patient Characteristics
Author, yr: Eisler et al., 2000 **Setting:** Outpatient at a postgraduate psychiatric teaching hospital in London, UK. Some patients may be inpatient at the hospital's eating disorder unit for some portion of the study **Enrollment period:** NR	**Research objective:** To compare the efficacy of two forms of outpatient family intervention for AN; conjoint family therapy (CFT) and separated family therapy (SFT).	**Groups:** **G1:** CFT (N = 19) **G2:** SFT (N = 21) **Enrollment:** • 57 referrals to the hospital (14 did not meet dx criteria) • 40 enrolled • 36 completed at least 3 mos of tx	**Age, mean (SD):** 15.5 yrs (1.6) **Sex:** Female (N): 39 of 40 **Race/ethnicity:** NR **Social class based on father's occupation:** I-II: Professional (65%) III-IV: Skilled (22%) VI-VIII: Unskilled (13%) **Family structure:** Nuclear (70%) Adoptive (5%) Single (10%) Reconstituted (15%) **Age of AN onset (SD):** 14.5 yrs (1.6) **Duration of illness (mos):** 12.9 (9.4) **M-R Scales (SD):** A (Nutritional): 3.3 (1.8) B (Menstrual): 1.8 (3.0) C (Mental State): 7.1 (2.0) D *(P*sychosexual): 7.0 (3.7) E *(P*sychosocial): 8.0 (2.9) Avg: 5.5 (1.7)

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Adolescents, met DSM IV or ICD-10 criteria for AN **Exclusion:** None	One yr of CFT or SFT with assessments independent of the research team conducted at 3, 6, and 12 mos. Assessments included patient and family interviews and self-report questionnaires. Frequency of sessions dictated by clinical need and similar in both txs. Generally, families were seem wkly during the early stages of tx, gradually increasing to every 3 to 4 wks (mean number of sessions = 16.4 (8.9) for CFT and 15.5 (6.8) for SFT). CFT sessions lasted 1 hour; in SFT the individual and parental sessions each lasted 45 m.	ANCOVA, G1 vs. G2, taking duration of illness, previous tx, and wt and the T1 values of each measure as covariates.	**Score:** Good **Intent to treat:** Yes **Blinding:** NR **Adverse events:** NR **Funding:** Medical Research Council (UK)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Eisler et al., 2000 (continued)	**Bulimic symptoms:** > wkly (25%) < wkly (22.5%) Never (52.5%) **Bulimic symptoms (scale 0-12, 12 = normal with no symptoms) (SD):** 7.7 (5.1)	**Change in bulimic symptoms:** **G1:** - 2.2 (6.4) *(P* = NR) **G2:** - 2.9 (4.5) *(P* = NR) Change over time *(P* = 0.01) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	EDI (SD): 56.2 (33.9)	**Change in EDI:** **G1:** - 32.3 (25.9) *(P* = NR) **G2:** - 21.8 (27.2) *(P* = NR) Change over time *(P* = 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.02) G1 better than G2
	EAT (SD): 47.7 (25.7)	**Change in EAT:** **G1:** - 26.8 (20.8) *(P* = NR) **G2:** - 29.2 (24.9) *(P* = NR) Change over time *(P* = 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
Depression (SD): 2.9 (3.2)	**Change in Depression (SD):** **G1:** - 5.6 (4.5) *(P* = NR) **G2:** - 4.2 (5.7) *(P* = NR) Change over time *(P* = 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.02) G1 better than G2	**Lowest wt (kg):** 38.5 (6.2) **Current wt (kg):** 40.0 (6.4)	**Change in Wt (kg):** **G1:** + 6.4 (6.2) *(P* = NR) **G2:** + 9.8 (6.7) *(P* = NR) Change over time *(P* = 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
Obsessionality (SD): 8.3 (3.4)	**Change in Obsessionality (SD):** **G1:** - 2.7 (2.8) *(P* = NR) **G2:** - 1.2 (3.5) *(P* = NR) Change over time *(P* = 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.03) G1 better than G2	**%ABW:** 74.3 (9.8)	**Change in %ABW:** **G1:** + 10.2 (11.3) *(P* = NR) **G2:** + 15.0 (11.0) *(P* = NR) Change over time *(P* = 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
			Change in BMI: **G1:** + 2.4 (2.5) *(P* = NR) **G2:** + 3.6 (2.4) *(P* = NR) Change over time *(P* = 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
SMFQ (SD): 26.5 (13.3)	**Change in SMFQ (SD):** **G1:** 16.5 (16.5) *(P* = NR) **G2:** 8.0 (11.5) *(P* = NR) Change over time *(P* = 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.01) G1 better than G2		
MOCI (SD): 6.2 (3.6)	**Change in MOCI (SD):** **G1:** - 2.8 (3.8) *(P* = NR) **G2:** - 2.4 (4.0) *(P* = NR) Change over time *(P* = 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)		

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Eisler et al., 1997 **Companion article:** Russell et al., 1987 **Setting:** Output tx: Maudsley Hospital, London, UK **Enrollment period:** NR	**Research objective:** To determine the long term benefit of family versus individual therapy in AN after 5 yrs.	**Groups:** **G1:** Family Therapy (N = 41) **G2:** Individual Therapy (N = 39) **Enrollment:** Of 80 original participants • Followed at 3 yrs: N = 77 • Followed at 5 yrs: N = 73	**Age, mean (SD):** 17.9 (6.4) *(P* = NS) **Age at end of trial, mean (SD):** 21.8 (7.1) *(P* = NS) **Duration of illness, y, mean (SD):** 3.8 (3.1) Diff between groups *(P* = NS) **Wt on admission, % ABW, mean (SD):** 69.6 (13.0) *(P* = NS) **Wt on discharge, % ABW, mean (SD):** 89.5 (7.1) *(P* = NS) **Duration of index hospital stay, wk, mean:** 10.4 **G1:** 8.8 **G2:** 12.1* *(P* = NR) **Subgroup 1:** **G1:** 8.6 **G2:** 11.8 Diff between groups *(P* < 0.05) **Subgroup 2:** **G1:** 8.2 **G2:** 13.0 Diff between groups *(P* < 0.02) **Previous admissions, N, mean: 1.5** Diff between groups *(P* = NS) **Sex, N:** Male: 7 Female: 73 Diff between groups *(P* = NS) **Race/ethnicity:** NR **Marital status, N:** Single: 69 Married: 8 Separated/divorced: 3 *(P* = NS)

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: **AN:** DSM III criteria; self-induced wt loss through avoidance of fattening foods, excessive exercise, and self-induced vomiting or purging (but did not follow binge eating); idea that fatness is dreadful state; specific endocrine disorder (amenorrhea or in males sexual interest/potency lost). **BN:** DSM III-R preoccupation with food and episodes of gross overeating; counteract fattening effects of food by vomiting, purging, or starvation; psychopathology similar to AN; hx of previous overt or minor episode of AN. **Exclusion:** NR	Upon reaching a near-healthy body wt and being discharged from inpatient tx, patients randomly assigned to conditions which were delivered on outpatient basis for one yr. Tx lasted 1 hour at least fortnightly for first 3 mos, then once every three wks for a total of 1 yr from date of discharge. **G1:** Family therapy: Included all members of the household. Tasks: family cooperation, organization (communication, rules), interventions (management, cooperation, support, consistency) **G2:** Nonspecific form of individual therapy: supportive, educational, problem-centered Antidepressant drug use allowed for both groups. **Amount of sessions, mean (SD):** **G1:** 10.5 (8.9) **G2:** 15.9 (8.5) Diff between groups *(P* < 0.01)	For subjects missing 5-yr data, 3-yr data substituted in analyses Chi square, Fisher exact probability test, student t tests Eating outcome categories: Good: body wt maintained within 15% of the ABW and menstrual cycles regular. Intermediate: body wt risen to within 15% of ABW but amenorrhea persists. Poor: body wt < 15% below ABW or bulimic sx have developed	**Score:** Fair **Intent to treat:** Yes **Blinding:** NA **Adverse events:** **Deaths, N:** 3 **Funding:** Medical Research Council, UK

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Eisler et al., 1997 (continued)		**Category of outcome at 5 years, N:** **Subgroup 1:** **Total Subgroup:** Good: 13 Intermediate: 2 Poor: 6 **G1:** Good: 9 Intermediate: 0 Poor: 1 **G2:** Good: 4 Intermediate: 2 Poor: 5 Diff between groups Good vs Intermediate + Poor *(P* < 0.02) G1 > G2 Diff between groups in change over time *(P* = NR) **Subgroup 2:** Total Subgroup: Good: 4 Intermediate: 5 Poor: 10 **G1:** Good: 3 Intermediate: 1 Poor: 6 **G2:** Good: 1 Intermediate: 4 Poor: 4 Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **Subgroup 3:** Total subgroup: Good: 6 Intermediate: 4 Poor: 4 **G1:** Good: 2 Intermediate: 2 Poor: 3 **G2:** Good: 4 Intermediate: 2 Poor: 1 Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
	M-R scales: mental state at 5 years, mean (SD): **Subgroup 1:** **G1:** 12.0 (0.0) **G2:** 11.5 (1.4) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **Subgroup 2:** **G1:**9.1 (3.8) **G2:** 9.5 (2.1) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **Subgroup 3:** **G1:** 9.7 (2.1) **G2:** 12.0 (0.0) Diff between groups *(P* ≤ 0.05) G2 > G1 Diff between groups in change over time *(P* = NR) **Subgroup 4:** **G1:** 8.0 (3.0) **G2:** 10.2 (2.1) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)		**Wt, % ABW at 5 years, mean (SD):** **Subgroup 1:** **G1:** 103.4 (13.2) **G2:** 94.4 (16.8) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **Subgroup 2:** **G1:** 86.9 (11.9) **G2:** 95.7 (11.5) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **Subgroup 3:** **G1:** 93.7 (18.0) **G2:** 97.5 (9.0) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **Subgroup 4:** **G1:** 93.4 (8.9) **G2:** 98.9 (8.8) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
	M-R scales: Psychosexual adjustment at 5 years mean (SD): **Subgroup 1:** **G1:** 10.5 (2.1) **G2:** 9.2 (2.2) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **Subgroup 2:** **G1:** 8.5 (3.0) **G2:** 8.1 (3.0) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)		**M-R scales: menstrual functioning at 5 years, mean (SD):** Subgroup 1: **G1:** 12.0 (0.0) **G2:** 7.0 (5.1) Diff between groups *(P* ≤ 0.05) G1 > G2 Diff between groups in change over time *(P* = NR) **Subgroup 2:** **G1:** 3.4 (5.9) **G2:** 4.5 (5.0) diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Eisler et al., 1997 (continued)		**Subgroup 4:** Total subgroup: Good: 3 Intermediate: 6 Poor: 10 **G1:** Good: 0 Intermediate: 4 Poor: 5 **G2:** Good: 3 Intermediate: 2 Poor: 5 Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
		M-R scales: nutritional status at 5 years, mean (SD): **Subgroup 1:** **G1:** 9.4 (1.8) **G2:** 8.7 (2.8) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **Subgroup 2:** **G1:** 7.4 (4.4) **G2:** 7.2 (3.3) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **Subgroup 3:** **G1:** 7.6 (4.8) **G2:** 9.2 (2.0) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **Subgroup 4:** **G1:** 6.2 (2.5) **G2:** 7.4 (4.2) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
	Subgroup 3: **G1:** 6.0 (4.3) **G2:** 10.1 (1.4) Diff between groups *(P* ≤ 0.05) G2 better than G1. Diff between groups in change over time *(P* = NR) **Subgroup 4:** **G1:** 8.5 (4.1) **G2:** 9.0 (3.3) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)		**Subgroup 3:** **G1:** 7.4 (5.4) **G2:** 11.3 (1.6) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **Subgroup 4:** **G1:** 8.5 (5.4) **G2:** 7.5 (5.4) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
	M-R scales: social adjustment mean at 5 years (SD): **Subgroup 1:** **G1:** 11.1 (1.2) **G2:** 10.2 (1.6) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **Subgroup 2:** **G1:** 9.6 (2.1) **G2:** 8.7 (2.9) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **Subgroup 3:** **G1:** 8.8 (3.0) **G2:** 10.5 (1.6) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **Subgroup 4:** **G1:** 7.0 (2.5) **G2:** 9.5 (3.0) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)		

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Eisler et al., 1997 (continued)		

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
	M-R scales: avg outcome at 5 years, mean (SD): **Subgroup 1:** **G1:** 11.0 (0.4) **G2:** 9.3 (2.1) Diff between groups *(P* ≤ 0.05) G1 better than G2 Diff between groups in change over time *(P* = NR) **Subgroup 2:** **G1:**7.6 (3.0) **G2:** 7.6 (2.5) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **Subgroup 3:** **G1:** 7.8 (2.8) **G2:** 10.6 (1.0) Diff between groups *(P* ≤ 0.05) G2 better than G1 Diff between groups in change over time *(P* = NR) **Subgroup 4:** **G1:** 7.6 (2.7) **G2:** 8.5 (2.8) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)		

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Geist et al., 2000 **Setting:** Inpatient/Outpatient Adolescent Eating Disorders Unit, The Hospital for Sick Children, Toronto, Canada **Enrollment period:** 2.5 yrs (dates not reported)	**Research objective:** Comparison of family therapy and family group psychoeducation for adolescent inpatients (who later became outpatients) with AN	**Groups:** **G1:** Family Therapy (N = 12) **G2:** Family Group Psychoeducation (N = 13) **Enrollment:** • 120 assessed and admitted to inpatient program • 61 met study criteria • 36 refused to participate • 25 enrolled and completed	**Age, mean (SD):** **G1:** 14.3 (1.5) **G2:** 14.9 (1.7) *(P* = NS) **Sex:** Female: 100% **Race/ethnicity:** NR **Dx:** RAN (excluding amenorrhea criteria) (N = 19) EDNOS (restricting) (N = 3) Study criterion only (N = 3)

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Admitted for inpatient tx, current wt < 90% of IBW (modification of DSM IV AN dx requiring < 85%) and self-imposed food restriction indicating onset or maintenance of low wt. **Exclusion:** < 12 and > 17.4 yrs of age, male, chronic medical condition, immediate suicide risk, presented with psychotic features, unavailable over the study period, receiving individual or family therapy in the community or could not communicate in English.	**G1:** 8 sessions of family therapy (every two wks). Sessions were 45 m, attended by patients, parents, and siblings. Therapists were social workers and 1 psychiatrist. **G2:** 8 sessions of family psychoeducation every 2 wks. Classes were 90 m, led by a dietitian, occupational therapist and psychiatric nurse. First 45 m, patients and parents together. Second 45 minutes separate. Both txs lasted 4 mo. All participants received standard medical and psychosocial tx. Once patients medically stable and met target wts, discharged to outpatient unit. Remainder of sessions carried out on outpatient basis.	Two-way multivariate MANOVA and ANOVA repeated measures. Patients completed post tx assessment after 16 wks (T2) using same measures as beginning of tx (T1).	**Score:** Fair **Intent to treat:** Yes **Blinding:** NR **Adverse events:** 5 participants readmitted to inpatient program during the study and another 6 later readmitted after the study was completed. **Funding:** Physician Services Inc.

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Geist et al., 2000 (continued)	**EDI measures, mean (SD):** **Drive for thinness:** **G1:** 11.1 (5.8) **G2:** 13.7 (6.2) *(P* = NR) **Body Dissatisfaction:** **G1:** 9.1 (6.6) **G2:** 11.0 (5.0) *(P* = NR) **Bulimia:** **G1:** 1.2 (1.3) **G2:** 1.9 (1.6) *(P* = NR)	**EDI measures, mean (SD):** **Drive for thinness:** **G1:** 12.3 (7.5) *(P* = NR) **G2:** 13.3 (7.6) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **Body Dissatisfaction:** **G1:** 10.6 (9.2) *(P* = NR) **G2:** 12.2 (6.1) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **Bulimia:** **G1:** 1.2 (2.0) *(P* = NR) **G2:** 2.5 (2.6); *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
CDI, mean (SD): **G1:** 11.8 (6.6) **G2:** 14.0 (4.7) *(P* = NR)	**CDI, mean (SD):** **G1:** 12.2 (7.4) *(P* = NR) **G2:** 15.4 (4.9) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)	**Wt:** **G1:** 41.1 kg (7.0) **G2:** 41.1 kg (6.3) *(P* = NS)	
BSI, global severity, mean (SD): **Patient:** **G1:** 1.3 (0.6) **G2:** 1.4 (0.9) *(P* = NR) **Mother:** **G1:** 0.7 (0.8) **G2:** 0.6 (0.5) *(P* = NR) **Father:** **G1:** 0.7 (0.7) **G2:** 0.4 (0.3) *(P* = NR)	**BSI, global severity, mean (SD):** **Patient** **G1:** 1.2 (0.7) *(P* = NR) **G2:** 1.2 (0.6) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **Mother:** **G1:** 0.6 (0.5) *(P* = NR) **G2:** 0.6 (0.5) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **Father:** **G1:** 0.4 (0.4) *(P* = NR) **G2:** 0.3 (0.2) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)	**IBW, %:** **G1:** 77.7% **G2:** 77.2% *(P* = NR)	**IBW, %:** **G1:** 91.4% *(P* = NR) **G2:** 96.3% *(P* = NR) Change over time *(P* < 0.0001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
FAM III, mean (SD): **G1:** 48.3 (7.3) **G2:** 50.9 (10.8) *(P* = NR)	**FAM III, mean (SD):** **G1:** 52.2 (8.5) *(P* = NR) **G2:** 55.8 (7.7) *(P* = NR) Change over time *(P* = 0.02) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)		

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: le Grange et al., 1992 **Setting:** Outpatient ED clinic; UK **Enrollment period:** NR	**Research objective:** To assess, in adolescents with AN, the efficacy of conjoint family therapy in which the whole family is seen together versus separate session, family counseling in which parents and adolescents seen separately.	**Groups (N = 18):** **G1:** Family Therapy (conjoint) (N = NR) **G2:** Family Counseling (separate) (N = NR) **Enrollment:** 18 consecutively referred from Department of Children and Adolescents, Bethlem Royal and Maudsley Hospital, randomized and enrolled **Duration of Illness:** < 3 yrs	**Age, mean (SD):** 15.33 (1.81) Range: 12-17 **Sex (N):** Female: 16 Male: 2 **Race/ethnicity:** NR **Duration of Illness, mean mo (SD):** 13.7 (8.38) **DSM III-R for BN:** **G1:** 1 **G2:** 3

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Meet DSM III-R criteria for AN; < 18 yrs old; duration of illness < 3 yrs **Exclusion:** Medical risk or risk of suicide requiring hospitalization; comorbid major psychiatric disorder	Both txs included wkly sessions, gradually spread out as they progressed to 32 wks; both txs first address wt gain, then include family in tx of ED-related issues **G1:** whole family in all tx sessions; **G2:** separate sessions between parents and therapist, and patient and therapist. **Avg # of tx sessions, 6 mos, mean (SD):** **G1:** 8.6 (4.12) **G2:** 9.3 (4.37) (*P* = NR)	Comparisons made between group and within group; further methodological details: NR Assessments at baseline, 16 wks, and 32 wks, including patient's biological and psychological variables and family interaction variables.	**Score:** Poor **Intent to treat:** No **Blinding:** No **Adverse events:** NR **Funding:** NR

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: le Grange et al., 1992 (continued)	**EAT scores, mean (SD):** **G1:** 36.9 (27.6) **G2:** 35.3 (22.8) *(P* = NS)	**End-of-tx (32 wks):** **EAT scores, mean (SD):** **G1:** 16.6 (12.1) *(P* = 0.01) **G2:** 15.6 (9.5) *(P* = 0.01) Diff between groups *(P* = NR) Diff between group in change over time *(P* = NS)
	M-R scores, avg outcome score, mean (SD): **G1:** 3.9 (1.7) **G2:** 4.8 (1.5) *(P* = NS)	**M-R scores, mean (SD):** **G1:** 7.3 (2.0*) (P* = 0.01) **G2:** 8.8 (1.4) *(P* = 0.01) Diff between groups *(P* = NR) Diff between group in change over time *(P* = NS)

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
		Wt (% ABW), mean (SD): **G1:** 75.9% (8.8) **G2:** 80.5% (5.3) *(P* value is not reported because inconsistent between table and text)	**End-of-tx (32 wks):** **Wt (% ABW), mean (SD):** **G1:** 89.1% (13.5) *(P* = 0.006) **G2:** 100.4% (9.1) *(P* = 0.0001) *(P* = NR) Diff between group in change over time *(P* = NS)

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Lock et al., 2005 **Setting:** Outpatient clinic for child and adolescent eating disorders, Stanford University School of Medicine, Stanford, CA, USA. **Enrollment period:** September 1999 to April 2002	**Research objective:** To determine the optimal length of family tx for adolescents with AN.	**Groups:** **G1:** Long-term tx (N = 42) **G2:** Short-term tx (N = 44) **Enrollment:** • 241 assessed for eligibility • 155 excluded (100 not meeting study criteria; 55 refusing participation) • 86 (61%) randomized • **G1:** 3 lost to FU, 7 discontinued intervention; **G2:** 5 lost to FU, 2 discontinued intervention	**Age, mean (SD):** **G1:** 15.2 (1.7) **G2:** 15.2 (1.6) *(P* = NS) **Sex, N (%):** **Female** **G1:** 38 (91%) **G2:** 39 (89%) **Race/ethnicity, N (%):** **Asian** **G1:** 2 (5%) **G2:** 6 (14%) **White** **G1:** 32 (76%) **G2:** 32 (73%) **Hispanic** **G1:** 6 (14%) **G2:** 4 (9%) **Native American** **G1:** 0 (0%) **G2:** 1 (2%) **Other** **G1:** 2 (5%) **G2:** 1 (2%) *(P* = NS) **Duration of Eating Problem, mos (SD):** **G1:**12.0 (9.9) **G2:** 11.3 (10.4) *(P* = NS) **Hospitalization before tx, N (%):** **G1:** 14 (34%) **G2:**12 (27%) *(P* = NS) **Previous tx, N (%):** **G1:** 36 (90%) **G2:** 39 (89%) *(P* = NS) **Intact families, N (%)** **G1:** 31 (74%) **G2:** 36 (82%) *(P* = NS)

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: DSM IV criteria for AN, though some partially wt restored participants entered; for postmenarchal females, those who had missed a min of one menstrual period instead of the three required by DSM IV criteria. **Exclusion:** Severe physical health problems likely to affect wt or psychiatric illnesses that would interfere with tx (e.g., psychosis); those who had failed family tx using the model employed in the study; use of psychotherapy in addition to that offered in the study protocol; *(*Psychotropic meds used to treat common comorbid psychiatric illnesses allowed.)	Randomized to either a short-term (10 sessions over 6 mos) or long-term tx (20 sessions over 12 mos). ED variables were evaluated at 6 mos and 1 yr using the EDE and YBC-ED. Manual-based txs (Dare and Eisler, 1997) conducted on an outpatient basis. In G2, sessions held wkly for 7 wks, then moly for 2 mos, and a final session at the 6 mos. In G1, sessions first held wkly for 7 wks, then biwkly through session 13, and finally, seven sessions were moly until the 1yr mark. All questionnaires were completed by the participants at home.	Repeated measures for each subject; Effect sizes are reported using the mean diff between groups divided by the pooled within-group SD; In a post hoc analysis, linear regression model was employed (using 1 yr FU data as the dependent measure and controlling for baseline values.)	**Score:** Good **Intent to treat:** Yes **Blinding:** Yes **Adverse events:** Brief hospitalization for medical instability was needed for participants in both groups (22% overall; **G1:** 21%, **G2:** 10%); One participant dropped out due to need for other psychiatric tx. **Funding:** NIH Career Development Award

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Lock et al., 2005 (continued)			**Purgers, N (%):** **G1:** 9 (21%) **G2:** 7 (16%) *(P* = NS) **Restrictors, N (%):** **G1:** 33 (79%) **G2:** 37 (84%) *(P* = NS)

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality

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Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Lock et al., 2005 (continued)	All comparisons refer to intent-to-treat outcomes:	
	EDE-Eating Concerns, mean (SD): **G1:** 1.04 (1.33) **G2:** 1.35 (1.13) *(P* = NS)	**EDE-Eating Concerns, mean (SD)** **6mos:** **G1:** 0.75 (1.00) *(P* = NS) **G2:** 0.86 (1.01) *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **1 yr:** **G1:** 0.52 (0.83) *(P* = NS) **G2:** 0.71 (0.92) *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	EDE-Restraint, mean (SD): **G1:** 2.64 (1.96) **G2:** 2.76 (1.97) *(P* = NS)	**EDE-Restraint, mean (SD)** **6mos:** **G1:** 1.64 (1.70) *(P* = NS) **G2:** 1.84 (1.77) *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **1 yr:** **G1:** 1.42 (1.63*) (P* = NS) **G2:** 1.62 (1.80*) (P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	EDE-Shape Concerns, mean (SD): **G1:** 2.41 (1.67) **G2:** 2.61 (1.73) *(P* = NS)	**EDE-Shape Concerns, mean (SD)** **6mos:** **G1:** 1.96 (1.55) *(P* = NS) **G2:** 2.25 (1.63) *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **1 yr:** **G1:** 1.76 (1.69) *(P* = NS) **G2:** 2.08 (1.70) *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
		BMI, kg/m², mean (SD): **G1:** 17.3 (1.5) **G2:** 17.0 (1.3) *(P* = NS)	**BMI, kg/m², mean (SD):** **6 mos:** **G1:**19.0 (1.8) *(P* = NS) **G2:**19.0 (2.3) *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **1 yr:** **G1:** 19.5 (2.1) *(P* = NS) **G2:** 19.5 (2.2) *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
		Wt (kg), mean (SD): **G1:** 46.7 (7.2) **G2:** 44.6 (5.5) *(P* = NS)	**Wt (kg), mean (SD):** **6mos:** **G1:** 51.4 (7.5) *(P* = NS) **G2:** 50.6 (8.1) *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **1 yr:** **G1:** 53.2 (8.0) **G2:** 52.0 (7.6) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Lock et al., 2005 (continued)	**EDE- Wt Concerns, mean (SD):** **G1:** 1.96 (1.52) **G2:** 2.32 (1.51) *(P* = NS)	**EDE-Wt Concerns, mean (SD)** **6mos:** **G1:** 1.62 (1.48) *(P* = NS) **G2:** 2.01 (1.50) *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **1 yr:** **G1:** 1.39 (1.44) *(P* = NS) **G2:** 1.97 (1.60) *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	YBC-ED-Total score, mean (SD): **G1:** 12.2 (8.4) **G2:** 13.4 (7.9) *(P* = NS)	**YBC-ED-Total Score, mean (SD)** **6mos:** **G1:** 8.8 (6.6) *(P* = NS) **G2:** 10.9 (9.7) *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **1 yr:** **G1:** 6.4 (6.4) *(P* = NS) **G2:** 9.2 (9.6) *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
		A secondary analysis of moderators of outcome found: • For BMI, YBC-ED-total score moderated outcome in favor of longer tx (G1) for those with the most severe symptoms *(P* = 0.008). • For global EDE, those with non-intact families did better in longer tx *(P* = 0.004). **Sx Remission:** • Using DSM IV BMI criterion (BMI < 17.5) only, 96% of the sample remitted at the end of tx • Using criterion of BMI = 20 and a global EDE score within 2 SDs of normal, 67% would be considered remitted.

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Robin et al., 1999 **Setting:** Outpt tx, MI, USA **Enrollment period:** 1988-19947	**Research objective:** To compare the effectiveness of behavioral family systems therapy (BFST) with ego-oriented individual therapy (EOIT) in adolescents with AN.	**Groups:** **G1:** BFST (N = 19) **G2:** EOIT (N = 18) **Enrollment:** • 120 telephone screened • 60 intake interviews • 56 met criteria • 41 enrolled • 37 completed (**G1:** 19 **G2:** 18) **1 yr FU:** N = 30	**Age, mean (SD):** **G1:** 14.9 *(P* = NR) **G2:** 13.4 *(P* = NR) *(P* < 0.05) **Sex:** Female: 100% **Race/ethnicity, N:** White: 35 Middle Eastern: 2 **Hollingshead 4-factor index: SES, mean (SD):** **G1:** 45.7 (13.6) **G2:** 47.9 (12.0) *(P* = NS) **Developed AN within previous 12 mos:** 100% **Wt, lbs, mean:** **G1:** 86.5 **G2:** 86.8 *(P* = NS) **Height, inches, mean:** **G1:** 63 **G2:** 61 *(P* = NS) **Comorbidity assessed via DSM III Diagnostic Interview for Children and Adolescents:** Mood disorder: 54% Anxiety: 13%

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Female; age 11-20; DSM III-R criteria for AN, residing at home with 1 or both parents. **Exclusion:** NR	**G1:** Family seen conjointly, parents placed in control of eating, cognitive restructuring, behavioral interventions to change family interactions. Met wkly for mean of 72 m. **G2:** Adolescent seen individually, emphasis on building ego strength and uncovering dynamics blocking eating, parents seen collaterally. Adolescents met wkly for 45 m. Parents met bimonthly for mean of 54 m. **G1 + G2:** medical and dietary regimen. **Therapy length, mean mo (range):** 15.9 (12-18). Wkly for the first half, bimoly thereafter. Post-assessment at termination FU at 12 mos. **Diet:** Balanced based on diabetic exchange, starting with 1200 cal/day and adjusted upward to permit 1 lb st gain/wk. **Hospitalizations, N:** If < 75% of ideal wt and/or had cardiac problems, received refeeding program and assigned therapy. Discharged when exceeded 80% of target wt, no other medical distress, and gaining wt on regular basis. **G1:** 11 **G2:** 5 **Psychoactive meds prescribed, N:** **G1:** 2 **G2:** 2 Due to OCD, MDD after wt gain	Univariate and Multivariate repeated-measures ANOVAs. Chi squares.	**Score:** Poor **Intent to treat:** No **Blinding:** NA **Adverse events:** NR **Funding:** NIMH

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Robin et al., 1999 (continued)	**EAT, Teen, mean (SD):** **G1:** 32.6 (15.6) **G2:** 20.6 (15.6)	**EAT, Teen, mean (SD): post** **G1:** 11.2 (13.6) **G2:** 7.9 (9.6) Change over time *(P* < 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **EAT, Teen, mean (SD): FU** **G1:** 8.1 (10.0) **G2:** 4.7 (6.1) Change over time *(P* < 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BDI, mean (SD): **G1:** 19.4 (12.3) **G2:** 11.3 (10.5)	**BDI, mean (SD): Post** **G1:** 8.5 (8.4) **G2:** 5.4 (9.0) Change over time *(P* < 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **FU** **G1:** 10.5 (11.0) **G2:** 2.7 (4.7) Change over time *(P* < 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)	**BMI, mean (SD):** **G1:** 15.2 (1.8) **G2:** 16.6 (2.1)	**BMI, mean (SD): Post** **G1:** 19.9 (1.9) **G2:** 18.9 (1.9) Change over time *(P* < 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.001) G1 > than G2 **BMI, mean (SD): FU** **G1:** 20.7 (2.7) **G2:** 19.8 (3.1) Change over time *(P* < 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.02)
			Attained target wt, %: Post: **G1:** 66.7 **G2:** 68.8 Change over time *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **Attained target wt, %: FU:** **G1:** 80.0 **G2:** 68.8 Change over time *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
			Attained 25 percentile BMI for age, %: Post: **G1:** 84.2 **G2:** 82.4 Change over time *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **Attained 25 percentile BMI for age, %: FU:** **G1:** 86.7 **G2:** 93.3 Change over time *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Robin et al., 1999 (continued)		

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
			Attained 50th percentile BMI for age, %: Post: **G1:** 52.6 **G2:** 41.2 Change over time *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **Attained 50th percentile BMI for age, %: FU:** **G1:** 66.7 **G2:** 46.7 Change over time *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
			Resumed/Began menstruation, %, post: **G1:** 94 **G2:** 64.4 Change over time *(P* = NR) Diff between groups *(P* < 0.03) Diff between groups in change over time *(P* = NR) **Resumed/Began menstruation, %, FU:** **G1:** 92.9 **G2:** 80 Change over time *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Robin et al., 1994 **Companion article:** Robin, Siegel and Moye, 1995 **Setting:** One site: outpatient and inpatient hospital setting, USA **Enrollment period:** NR	**Research objective:** Compare the effectiveness of BFST to EOIT on wt gain, eating attitudes, family measures, ego functioning, depression, internalizing behavior and other psychometric measures in adolescents with AN, restricting sub-type.	**Groups:** **G1:** BFST (N = 12) **G2:** EOIT (N = 12) Analysis in article presented on 22 completers only **Enrollment:** • Referred by pediatricians, school personnel, psychologists, and social workers. • Phone screen with parent • Randomization to G1 or G2 • Comprehensive intake interview and pediatric medical exam • Enrolled (N = 24) after confirmation of dx • Completed (N = 22) **Drop-outs:** **G1** = 1 **G2** = 1	**Age, mean (SD):** **G1:** 14.7 (2.7) **G2:** 13.9 (2.1) (*P* = NS) **Sex:** Female: 100% **Race/ethnicity:** Caucasian: 100% **SES (Hollingshead), mean (SD):** **G1:** 44.5 (15.4) **G2:** 44.5 (15.4) (*P* = NS) **Target Wt (lbs), mean (SD):** **G1:** 116.7 (10.7) **G2:** 108.3 (20.5) (*P* = NS)

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Dx of AN (restricting type) by DSM III-R criteria; onset within last 12 mos; lives at home with one or both parents; adolescent aged 12-19 **Exclusion:** NR	6 hr pre-assessment Randomized to BFST (G1) or EOIT (G2) Therapists (5) dedicated to 1 tx modality- standardized 12-18 mos of tx determined by case with amount of therapy time equalized across modes 6-9 mos of tx wkly, then 6-9 mos of tx bimoly diet to gain 1 lb wt /wk Inpatient re-feeding if < 75% IBW until 80% or more of target wt., no other sig problems and gaining wt. Participants also hospitalized for sig cardiac or neurologic problems **G2:** collateral sessions for parents 6-hr post-assessment (includes physical) FU (Planned) at 12, 30 and 48 mo post-tx	2x2 group (BFST vs EOIT) x time (Pre vs post) repeated measures ANOVA with Bonferroni correction for multiple comparison	**Score:** Fair **Intent to treat:** No **Blinding:** No **Adverse events:** Patients hospitalized for an avg of 26.4 days: BFST: 5 EOIT: 3 **Funding:** NIMH

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Robin, Siegel and Moye, 1995 **Companion article:** Robin et al., 1994 **Setting:** One site: outpatient and inpatient hospital setting, USA **Enrollment period:** NR	**Research objective:** In an adolescent AN, restricting sub-type population, compare the impact of behavioral family systems therapy (BFST) vs. ego-oriented individual therapy (EOIT) on family interactions including communication, problem-solving, warmo/hostility using self-report and observational measures of conflict and negative communication concerning eating and non-eating issues at end of tx and 1-yr FU.	**Groups:** **G1:** BFST (N = 12) **G2:** EOIT (N = 12) **G3:** BFST at FU (N = 11) **G4:** EOIT at FU (N = 9) **Enrollment:** • Referred by pediatricians, school personnel, psychologists, and social workers. • Phone screen with parent • Randomization to G1 or G2 • Comprehensive intake interview and pediatric medical exam • Enrolled (N = 24) after confirmation of dx • Completed (N = 22)	**Age, mean (SD):** **G1:** 14.7 (2.7) **G2:** 13.9 (2.1) *(P* = NS) **Sex:** Female: 100% **Race/ethnicity:** White: 100%

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Dx of AN (restricting type) by DSM III-R criteria; onset within last 12 mos; lives at home with one or both parents; adolescent aged 12-19 **Exclusion:** NR	6 hr pre-assessment Randomized to BFST (G1) or EOIT (G2) Therapists (5) dedicated to 1 tx modality- standardized 12-18 mos of tx determined by case with amount of therapy time equalized across modes 6-9 mos of tx wkly, then 6-9 mos of tx bimoly diet to gain 1 lb wt /wk Inpatient re-feeding if < 75% IBW until 80% or more of target wt., no other sig problems and gaining wt. Participants also hospitalized for sig cardiac or neurologic problems **G2:** collateral sessions for parents 6-hr post-assessment (includes physical) FU (Planned) at 12, 30 and48 mo post-tx 6-hr post-assessment (includes physical) 12 mo FU assessment	t-tests to determine initial diffs between groups at pre-assessment 2x2 group (BFST vs EOIT) x time (Pre vs post) repeated measures ANOVA orthogonal, repeated measures linear contrasts with tx condition as the grouping factor: Contrast I = pre-assessment vs. FU; Contrast II = post-assessment vs. FU Bonferroni correction for multiple comparisons.	**Score:** Fair **Intent to treat:** No **Blinding:** No **Adverse events:** Patients hospitalized for an avg of 26.4 days: BFST: 5 EOIT: 3 **Funding:** NIMH

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Robin, Siegel and Moye 1995 (continued)	**EAT, mean (SD): Adolescent** **G1:** 33.3 (16.7) **G2:** 18.0 (14.7) *(P* = NR)	**EAT, mean (SD): Adolescent** **G1:** 7.2 (7.8) *(P* = NR) **G2:** 4.1 (7.9) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	EAT, mean (SD): Mother **G1:** 42.8 (10.9) **G2:** 36.3 (15.8) *(P* = NR)	**EAT, mean (SD): Mother** **G1:** 6.0 (6.8) *(P* = NR) **G2:** 12.6 (11.8) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	EAT, mean (SD): Father **G1:** 41.3 (12.6) **G2:** 36.6 (15.9) *(P* = NR)	**EAT, mean (SD): Father** **G1:** 12.6 (16.9) *(P* = NR) **G2:** 20.4 (14.4) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	Eating Conflict (T scores) from PARQ, mean (SD): Adolescent **G1:** 76.4 (21.7) **G2:** 74.0 (16.1) *(P* = NS)	**Eating Conflict (T scores) from PARQ, mean (SD):Adolescent** **G1:** 55.0 (16.6) *(P* = NR) **G2:** 59.5 (21.1) *(P* = NR) Diff over time *(P* < 0.01) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	Eating Conflict (T scores) from PARQ, mean (SD): Mother **G1:** 88.5 (17.6) **G2:** 96.3 (18.1) *(P* = NS)	**Eating Conflict (T scores) from PARQ, mean (SD): Mother** **G1:** 52.0 (13.9) *(P* = NR) **G2:** 58.8 (17.1) *(P* = NR) Diff over time *(P* < 0.001)*(P* = NR) Diff between groups in change over time *(P* = NS)
	Eating Conflict (T scores) from PARQ, mean (SD): Father **G1:** 76.7 (19.1) **G2:** 86.1 (20.1) *(P* = NS)	**Eating Conflict (T scores) from PARQ, mean (SD): Father** **G1:** 46.8 (11.5) *(P* = NR) **G2:** 52.3 (22.0) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BSQ, mean (SD): **G1:** 106.0 (40.3) **G2:** 69.3 (47.1) *(P* = NR)	**BSQ, mean (SD):** **G1:** 53.1 (42.8) *(P* = NR) **G2:** 43.4 (38.9) *(P* = NR) Diff over time *(P* < 0.001) *(P* = NR) Diff between groups in change over time *(P* = NS)	**Wt (lbs), mean (SD):** **G1:** 85.4 (12.7) **G2:** 91.0 (23.1) *(P* = NS)	
EDI, mean (SD): **Body dissatisfaction** **G1:** 10.4 (8.3) **G2:** 9.8 (7.8) *(P* = NR)	**EDI, mean (SD):** **Body dissatisfaction** **G1:** 6.5 (9.2) *(P* = NR) **G2:** 8.8 (9.9) *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)	**BMI (kg/m^2), mean (SD)** **G1:** 15.0 (1.4) **G2:** 16.3 (2.8) *(P* = NS) **%Underwt, mean (SD):** **G1:** 26.9 (8.3) **G2:** 16.4 (10.6) *(P* < 0.05)	**BMI (kg/m^2), mean (SD):** **G1:** 20.1 (1.1*) (P* = NR) **G2:** 19.0 (1.4*) (P* = NR) Diff over time *(P* < 0.001) *(P* = NR) Diff between groups in change over time *(P* < 0.01) G1 better than G2 **≥ 50thpercentile BMI for age** **G1:** 73% **G2:** 45% Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **Menstruating at post-assessment** **G1:** 89% **G2:** 60% Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
BDI, mean (SD): **G1:** 21.4 (11.3) **G2:** 12.1 (12.8) *(P* = NR)	**BDI, mean (SD):** **G1:** 6.7 (8.0) *(P* = NR) **G2:** 6.2 (10.9) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)		

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

	Eating Related Measures (continued)	
Study Description	**Baseline**	**Outcomes**
Author, yr: Robin, Siegel and Moye 1995 (continued)	**Interaction Behavior Code (IBC) of Conflict During Discussion of Adolescent's Eating/Wt Problem: Negative communication, mean (SD): Adolescent** **G1:** 6.1 (3.5) **G2:** 7.5 (4.5) *(P* = NS)	**IBC Of Conflict OverEating: Negative communication, mean (SD): Adolescent** **G1:** 2.2 (1.9) *(P* = NR) **G2:** 3.9 (2.4) *(P* = NR) Diff over time *(P* < 0.003) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	Negative communication, mean (SD): Mother **G1:** 5.5 (3.3) **G2:** 4.1 (2.5) *(P* = NS)	**Negative communication, mean (SD): Mother** **G1:** 1.4 (1.4) *(P* < 0.002) **G2:** 3.4 (4.3) *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.04) G1 better than G2
	Negative communication, mean (SD): Father **G1:** 6.1 (4.1) **G2:** 6.4 (3.7) *(P* = NS)	**Negative communication, mean (SD): Father** **G1:** 3.4 (3.5) **G2:** 3.5 (3.0) Diff over time *(P* < 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	Positive communication, mean (SD): Adolescent **G1:** 1.3 (1.0) **G2:** 0.9 (0.6) *(P* = NS)	**Positive communication, mean (SD): Adolescent** **G1:** 2.3 (1.2) **G2:** 1.7 (1.6) Diff over time *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	Positive communication, mean (SD): Mother **G1:** 1.6 (1.4) **G2:** 2.5 (1.3) *(P* = NS)	**Positive communication, mean (SD): Mother** **G1:** 3.1 (1.6) *(P* < 0.005) **G2:** 2.2 (1.3) *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.05) G1 better than G2
	Positive communication, mean (SD): Father **G1:** 1.2 (1.2) **G2:** 1.3 (0.8) *(P* = NS)	**Positive communication, mean (SD): Father** **G1:** 3.5 (1.4) **G2:** 2.6 (0.9) Diff over time *(P* < 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
			FU: **BMI (kg/m^2):** **G3:** 21.5 (2.7) *(P* = NR) **G4:** 19.3 (2.2) *(P* = NR) Diff over time • vs. pre-tx *(P* < 0.001) • vs. post-tx *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time (Pre-tx: *P* < 0.004) G3 better than G4
			Achieved target wt (post-assessment) **G1:** 64% **G2:** 64% Diff between groups *(P* = NS) **Achieved target wt (FU)** **G3:** 82% **G4:** 50% Diff between groups *(P* = NS)
			Menstruating (at post-assessment) **G1:** 89% **G2:** 60% **G3:** 90% **G4:** 73% Diff between groups *(P* = NS) **Menstruating (at FU)** **G3:** 100% **G4:** 100% Diff between groups *(P* = NS)

	Eating Related Measures (continued)	
Study Description	**Baseline**	**Outcomes**
Author, yr: Robin, Siegel and Moye 1995 (continued)		**1 yr FU:** **Eating Conflict (T scores) from PARQ, mean (SD):** **Adolescent:** **G3:** 56.0 (21.8) *(P* = NR) **G4:** 55.6 (14.2) *(P* = NR) Change over time • vs. pre-tx *(P* < 0.006) • vs. post-tx *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **Mother:** **G3:** 54.0 (16.3) *(P* = NR) **G4:** 65.9 (13.0) *(P* = NR) Change over time • vs. pre-tx *(P* < 0.001) • vs. post-tx *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **Father:** **G3:** 53.3 (16.8) *(P* = NR) **G4:** 59.9 (18.0) *(P* = NR) Change over time • vs. pre-tx *(P* < 0.001) • vs. post-tx *(P* < 0.02) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Russell et al., 1987 **Companion article:** Eisler et al., 1997 **Setting:** Outpt tx: Maudsley Hospital, London, UK **Enrollment period:** NR	**Research objective:** To compare family therapy with individual supportive therapy in AN and BN.	**Groups:** **G1:** Family Therapy (N = 41) **G2:** Individual Therapy (N = 39) **Enrollment:** Following inpatient stay, patients randomly assigned after determined to be in 1 of 4 subgroups: **1)** AN, age of onset $\leq$ 18 yrs and duration < 3 yrs (N = 21) **2)** AN, onset ≤ 18 yrs and duration > 3 yrs (N = 15) **3)** AN, onset ≥ 19 yrs (N = 21) **4)** BN (N = 23) • Randomized: N = 80 • Analyzed: N = 73 (did not begin tx: **G1:** 5, **G2:** 2) • Dropout/Tx Refusers, N: 28 **Subgroup 1:** **G1:** 1 **G2:** 7 (*P* < 0.02) **Subgroup 2:** **G1:** 3 **G2:** 4 (*P* = NR) **Subgroup 3:** **G1:** 4 **G2:** 0 (*P* < 0.05) **Subgroup 4:** **G1:** 7 **G2:** 2 (*P* = NR) Diff between subgroups (*P* = NS)	**Age at onset, mean (SD):** 17.9 (6.4) (*P* = NS) **Age at entry to trial, mean (SD):** 21.8 (7.1) (*P* = NS) **Duration of illness, y, mean (SD):** 3.8 (3.1) (*P* = NS) **Wt on admission, % ABW, mean (SD):** 69.6 (13.0) (*P* = NS) **Wt on discharge, % ABW, mean (SD):** 89.5 (7.1) (*P* = NS) **Duration of index hospital stay, wk, mean:** 10.4 **G1:** 8.8 **G2:** 12.1* (*P* = NR) **Subgroup 1:** **G1:** 8.6 **G2:** 11.8 (*P* < 0.05) **Subgroup 2:** **G1:** 8.2 **G2:** 13.0 (*P* < 0.02) **Previous admissions, N, mean: 1.5** (*P* = NS) **Sex, N** Male: 7 Female: 73 (*P* = NS) **Race/ethnicity:** NR **Marital status, N:** Single: 69 Married: 8 Separated/divorced: 3 (*P* = NS)

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: **AN:** DSM III criteria; self-induced wt loss through avoidance of fattening foods, excessive exercise, and self-induced vomiting or purging (not following binge eating); idea that fatness is a dreadful state; specific endocrine disorder (amenorrhea or in males sexual interest/potency lost). **BN:** DSM III-R preoccupation with food and episodes of gross overeating; counteract fattening effects of food by vomiting, purging, or starvation; psychopathology similar to AN; hx of previous overt or minor episode of AN. **Exclusion:** NR	Upon reaching near-healthy body wt and being discharged from inpatient tx, patients were randomly assigned to conditions which were delivered on an outpt basis for one yr. Tx lasted 1 hour at least fortnightly for first 3 mos, then once every three wks for a total of 1 yr from date of discharge. **G1:** Family therapy: Included all members of the household. Tasks: family cooperation, organization (communication, rules), interventions (management, cooperation, support, consistency) **G2:** Nonspecific form of individual therapy: supportive, educational, problem-centered Antidepressant drug use allowed for both groups. **Number of sessions, mean (SD):** **G1:** 10.5 (8.9) **G2:** 15.9 (8.5) (*P* < 0.01)	t-tests, Fisher's exact probability test. Mulitivariate analyses and ANCOVAs	**Score:** Fair **Intent to treat:** Yes **Blinding:** N/A **Adverse events:** NR **Funding:** Medical Research Council, UK

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Russell et al., 1987 (continued)			**Social Class, N:** I: 23 II: 28 III: 21 IV: 6 V: 2 Diff between groups *(P* = NS) **Living with:** Parents: 60 Spouse/cohabitant: 12 Alone: 8 Diff between groups *(P* = NS) **Distance from hospital, km, N:** < 24: 28 25 – 80: 28 81 – 240: 16 > 240: 8 Diff between groups *(P* = NS)

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: **AN:** DSM III criteria; self-induced wt loss through avoidance of fattening foods, excessive exercise, and self-induced vomiting or purging (not following binge eating); idea that fatness is a dreadful state; specific endocrine disorder (amenorrhea or in males sexual interest/potency lost). **BN:** DSM III-R preoccupation with food and episodes of gross overeating; counteract fattening effects of food by vomiting, purging, or starvation; psychopathology similar to AN; hx of previous overt or minor episode of AN. **Exclusion:** NR			

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Russell et al., 1987 (continued)	**M-R Scales, Nutritional Status, mean (SD): Subgroup 1:** **G1:** 0.7 (1.0) **G2:** 1.3 (1.4) *(P* = NS)	**M-R Scales, Nutritional Status at one year, mean (SD): Subgroup 1:** **G1:** 9.6 (1.7) **G2:** 5.2 (3.3) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.001) G1 better than G2
		Subgroups 2-4: Data not shown Diff between groups in change over time *(P* = NS)
		Readmission rate, N (%): 22 **G1:** 9 (25) **G2:** 13 (35) Diff between groups *(P* = NS)

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
M-R Scales, Mental State, mean (SD): **Subgroup 1:** **G1:** 10.0 (2.8) **G2:** 8.7 (3.0) Diff between groups *(P* = NS) **Subgroup 4:** **G1:** 9.8 (2.9) **G2:** 7.6 (3.0) Diff between groups *(P* = NS)	**M-R Scales, Mental State mean (SD):** **Subgroup 1:** **G1:** 12.0 (0.0) **G2:** 10.2 (2.1) Diff between groups *(P* = NR) Diff between groups over time *(P* = NS) **Subgroup 4:** **G1:** 9.3 (2.8) **G2:** 10.8 (2.7) Diff between groups *(P* = NR) Diff between groups over time *(P* < 0.001) G2 > G1 **Subgroups 2-3:** **G1:** NR **G2:** NR Diff between groups in change over time *(P* = NS)	**ABW at discharge, %, mean (SD):** **Subgroup 1:** **G1:** 89.4 (6.9) **G2:** 88.4 (8.1) Diff between groups *(P* = NR) **Subgroup 2:** **G1:** 91.3 (4.9) **G2:** 92.1 (6.4) Diff between groups *(P* = NR) **Subgroup 3:** **G1:** 84.9 (8.8) **G2:** 86.6 (6.7) Diff between groups *(P* = NR) **Subgroup 4:** **G1:** 91.2 (8.3) **G2:** 87.8 (4.9) Diff between groups *(P* = NR)	**ABW at one year, %, mean (SD):** **Subgroup 1:** **G1:** 92.8 (8.4) **G2:** 80.1 (15.1) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.01) G1 better than G2 **Subgroup 2:** **G1:** 81.7 (9.0) **G2:** 80.3 (15.3) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **Subgroup 3:** **G1:** 71.1 (8.3) **G2:** 79.9 (13.1) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.03) G2 better than G1. **Subgroup 4:** **G1:** 989.0 (13.1) **G2:** 86.2 (11.5) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Russell et al., 1987 (continued)		

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
M-R Scales, Psychosexual adjustment, mean (SD): **Subgroup 1:** **G1:** 6.3 (3.2) **G2:** 5.6 (2.4) Diff between groups *(P* = NS)	**M-R Scales, Psychosexual adjustment at one year, mean (SD):** **Subgroup 1:** **G1:** 9.4 (3.0) **G2:** 6.3 (1.8) Diff between groups *(P* = NR) Diff between groups over time *(P* < 0.05) G1 better than G2. **Subgroups 2-4:** **G1:** NR **G2:** NR Diff between groups in change over time *(P* = NS)		**Wt maintenance >85% ABW from discharge to post tx at one year, N:** **Subgroup 1:** **G1:** 5/10 **G2:** 1/11 Diff between groups *(P* < 0.05) **Subgroup 2:** **G1:** 4/10 **G2:** 3/9 Diff between groups *(P* = NS) Subgroup 3: **G1:** 1/7 **G2:** 2/7 Diff between groups *(P* = NS) **Subgroup 4:** **G1:** 6/9 **G2:** 5/10 Diff between groups *(P* = NS)
		M-R Scales, Menstrual function, mean (SD): **Subgroup 1:** **G1:** 0.0 (0) **G2:** 0.0 (0) Diff between groups *(P* = NS)	**M-R Scales, Menstrual function at one year, mean (SD): Subgroup 1:** **G1:** 5.5 (6.0) **G2:** 0.8 (2.5) Diff between groups *(P* = NR) Diff between groups over time *(P* < 0.02) G1 better than G2. **Subgroups 2-4:** **G1:** NR **G2:** NR Diff between groups in change over time *(P* = NS)

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Russell et al., 1987 (continued)		

Evidence Table 4. Behavioral intervention trials for adolescents with anorexia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
M-R Scales, Socioeconomic status, mean (SD): **Subgroup 1:** **G1:** 9.2 (2.1) **G2:** 8.1 (3.5) *(P* = NS)	**M-R Scales, Socioeconomic status at one year, mean (SD):** **Subgroup 1:** **G1:** 10.8 (1.9) **G2:** 7.4 (3.4) Diff between groups *(P* = NR) Diff between groups over time *(P* < 0.03) G1 better than G2 **Subgroups 2-4:** **G1:** NR **G2:** NR Diff between groups in change over time *(P* = NS)		**M-R scales outcome at one year, N:** **Subgroup 1:** **G1:** Good: 6 Intermediate: 3 Poor: 1 **G2:** Good: 1 Intermediate: 1 Poor: 9 Diff between good and combined intermediate and poor *(P* = 0.02) Diff between poor and combined intermediate and good *(P* < 0.002) **Subgroup 2:** **G1:** Good: 2 Intermediate 2: Poor: 6 **G2:** Good: 2 Intermediate 1: Poor: 6 Diff between groups *(P* = NS) **Subgroup 3:** **G1:** Good: 0 Intermediate: 1 Poor: 6 **G2:** Good: 2 Intermediate: 1 Poor: 4 Diff between groups *(P* = NS) **Subgroup 4:** **G1:** Good: 0 Intermediate: 1 Poor: 8 **G2:** Good: 1 Intermediate: 2 Poor: 7 Diff between groups *(P* = NS)
M-R Scales, Avg outcome. mean (SD): **Subgroup 1:** **G1:** 5.5 (1.3) **G2:** 4.8 (1.4) Diff between groups *(P* = NS)	**M-R Scales, Avg Outcome at one year, mean (SD):** **Subgroup 1:** **G1:** 9.7 (2.0) **G2:** 5.7 (2.0) Diff between groups *(P* = NR) Diff between groups over time *(P* < 0.01). G1 better than G2. **Subgroups 2-4:** **G1:** NR **G2:** NR Diff between groups in change over time *(P* = NS)		

Evidence Table 5. Medication trials for bulimia nervosa

Study Description	Objective	Design	Patient Characteristics
Author, yr: Beumont et al., 1997 **Setting:** University-based outpatient clinics, Australia **Enrollment period:** NR	**Research objective:** Efficacy of nutritional counseling in treating BN and whether improvement is maintained. Examine additional benefit of fluoxetine.	**Groups:** **G1:** Fluoxetine (N = 34) **G2:** Placebo (N = 33) **Enrollment:** Participants recruited from two university-affiliated tx centers and from tertiary referrals from other psychiatric units. • Consecutive patients who met criteria were offered participation and asked for consent. • Participants received defined nutritional counseling program each wk (for 8 wks) in a one-one setting and randomly allocated to fluoxetine or placebo. • After initial interview, placebo washout period for 7-10 days. • 49 participants completed tx • Of these, 40 took part in the final FU assessment (**G1:** 17; **G2:** 23)	**Age, mean (SD):** **G1:** 24.2 (4.5) **G2:** 25.1 (5.8) **Sex:** Female: 100% **Race/ethnicity:** NR

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Women; at least 18 yrs old; fulfilled DSM III-R criteria for BN; within normal, healthy wt range with BMI between 20 and 25. **Exclusion:** Use of appetite suppressant or monoamine oxidase inhibitor within 2 wks of starting study or other psychotropic meds within one wk; presence of medical illness, psychosis or suicidal ideation; hx of drug abuse, bipolar depression, mania or hypomania; pregnancy, lactation or being of child bearing age, not using medically accepted means of contraception; previous participation in any fluoxetine study or use of fluoxetine in last 5 wks; electrolyte levels outside normal range.	All participants received nutritional counseling for 8 wks from same dietitian, along with random allocation to fluoxetine or placebo. Fluoxetine group: 20 mg 3 times a day with initial placebo washout period for 7-10 days. After washout, participants began trial and seen wkly until active tx ceased. FU assessments were made 4 wks after meds was stopped and 8 wks after that. The participants were all seen by the same research nurse, general practitioner and dietitian.	Mann-Whitney U tests, t-tests, median tests and chi-squared tests used to test Diffs.	**Score:** Fair **Intent to treat:** Yes **Blinding:** Double **Adverse events:** Insomnia, nausea, and shakiness sig more common in **G1**. Depression more common in **G2.** Tiredness and headaches present equally in both groups. **Funding:** Eli Lilly of Australia

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Beumont et al., 1997 (continued)	**Total number of bulimic episodes, mean (SD):** **G1:** 10.1 (10.1) **G2:** 6.1 (5.6) *(P* = NS)	**Wk 4:** **Total number of bulimic episodes, mean (SD):** **G1:** 1.9 (3.4) *(P* < 0.0001) **G2:** 1.5 (2.4) *(P* < 0.0001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **Wk 8:** **Mean total number of bulimic episodes (SD):** **G1:** 1.6 (3.21) *(P* < 0.0001) **G2:** 1.2 (2.0) *(P* < 0.0001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **3 mo FU:** **Total number of bulimic episodes, mean (SD):** **G1:** 2.2 (3.8) *(P* < 0.003) **G2:** 1.0 (3.3) *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
	Vomiting episodes per wk, mean (SD): **G1:** 8.8 (7.4) **G2:** 7.3 (6.5) *(P* = NS)	**Wk 4:** **Vomiting episodes per wk, mean (SD):** **G1:** 3.2 (7.4) *(P* = 0.0001) **G2:** 2.8 (3.6) *(P* = 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **Wk 8:** **Vomiting episodes per wk, mean (SD):** **G1:** 1.2 (3.0) *(P* = 0.0001) **G2:** 2.3 (3.3) *(P* = 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **3 mo FU:** **Vomiting episodes per wk, mean (SD):** **G1:** 2.5 (4.6) *(P* = 0.009) **G2:** 2.3 (3.3) *(P* = 0.003) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
	BSQ, mean (SD): **G1:** 142 (288) **G2:** 137 (26) *(P* = NS)	**Wk 4:** **BSQ, mean (SD):** **G1:** NR *(P* < 0.0001) **G2:** NR *(P* < 0.0001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **Wk 8:** **BSQ:** **G1:** NR *(P* < 0.001) **G2:** NR *(P* < 0.0001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
		Wt, kgs, mean (SD): **G1:** 60.5 (6.2) **G2:** 60.9 (6.9)	**Wk 4:** **Wt, kgs:** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.03) G1 > wt loss than G2 **Wk 8:** **Wt, kgs:** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.03) G1 > wt loss than G2 **3 mo FU:** **Wt increase, kgs, above baseline mean:** **G1:** 2.4 *(P* < 0.01) **G2:** NR *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)
HDRS, mean (SD): **G1:** 11 (5) **G2:** 11.8 (4.4) *(P* = NS)	**HDRS, mean (SD):** **G1:** 5.3 (5.5) *(P* = NS) **G2:** 6.8 (6.4) *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)		

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Beumont et al., 1997 (continued)		**Wk 8:** **Abstinence from binge eating:** **G1:** 69.6% **G2:** 61.5% Diff between groups *(P* = NS) **3 mo FU:** **Abstinence from binge eating:** **G1:** 35.7% **G2:** 60.9%
	EAT score, mean (SD): **G1:** 49 (17) **G2:** 40 (15) *(P* = 0.04)	**Wk 4:** **EAT score:** **G1:** NR *(P* < 0.005) **G2:** NR *(P* < 0.005) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **Wk 8:** **EAT score:** **G1:** NR *(P* < 0.005) **G2:** NR *(P* < 0.005) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **3 mo FU:** **EAT score:** **G1:** NR **G2:** NR
	EDE – Restraint, mean (SD): **G1:** 3.5 (1.5) **G2:** 3.4 (1.4) *(P* = NS)	**Wk 8:** **EDE – Restraint, mean (SD):** **G1:** 1.0 (1.3) *(P* < 0.05) **G2:** 2.0 (1.4) *(P* < 0.05) Diff between groups *(P* < 0.03) G1 better than G2 Diff between groups in change over time *(P* = NR) **3 mo FU:** **EDE – Restraint, mean (SD):** **G1:** 1.7 (1.7) *(P* < 0.05) **G2:** 1.7 (1.8) *(P* < 0.05) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Beumont et al., 1997 (continued)	**EDE – Overeating, mean (SD):** **G1:** 2.4 (0.8) **G2:** 2.1 (1.0) *(P* = NS)	**Wk 8:** **EDE – Overeating, mean (SD):** **G1:** 0.9 (1.0) *(P* < 0.05) **G2:** 1.2 (1.0) *(P* < 0.05) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **3 mo FU:** **EDE – Overeating, mean (SD):** **G1:** 1.4 (1.3) *(P* < 0.05) **G2:** 1.0 (1.1) *(P* < 0.05) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
	EDE – Eating Concern, mean (SD): **G1:** 3.1 (1.4) **G2:** 2.7 (1.6) *(P* = NS)	**Wk 8:** **EDE – Eating Concern, mean (SD):** **G1:** 1.1 (1.2) *(P* < 0.05) **G2:** 1.4 (1.2) *(P* < 0.05) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **3 mo FU:** **EDE – Eating Concern, mean (SD):** **G1:** 1.6 (1.7) *(P* < 0.05) **G2:** 1.4 (1.5) *(P* < 0.05) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
	EDE – Shape Concern, mean (SD): **G1:** 3.7 (1.3) **G2:** 3.9 (1.2) *(P* = NS)	**Wk 8:** **EDE – Shape Concern, mean (SD):** **G1:** 2.0 (1.3) *(P* < 0.05) **G2:** 2.9 (1.5) *(P* < 0.05) Diff between groups *(P* < 0.03) G1 better than G2 Diff between groups in change over time *(P* = NR) **3 mo FU:** **EDE – Shape Concern, mean (SD):** **G1:** 3.0 (1.5) *(P* < 0.05) **G2:** 2.6 (1.6) *(P* < 0.05) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 5. Medication trials for bulimia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Beumont et al., 1997 (continued)	**EDE – Wt Concern, mean (SD):** **G1:** 3.0 (1.5) **G2:** 3.0 (1.5) *(P* = NS)	**Wk 8:** **EDE – Wt Concern, mean (SD):** **G1:** 1.2 (0.8) **G2:** 2.4 (1.6) Diff between groups *(P* < 0.03) G1 better than G2 Diff between groups in change over time *(P* = NR) **3 mo FU:** **EDE – Wt Concern, mean (SD):** **G1:** 2.0 (1.7) *(P* = NS) **G2:** 2.2 (1.6) *(P* < 0.05) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Carruba et al., 2001 **Setting:** 3 Eating Disorder Units, Italy **Enrollment period:** 6 consecutive mos	**Research objective:** To examine the efficacy and tolerability of the MAOI-A moclobemide versus placebo in the tx of BN.	**Groups:** **G1:** Moclobemide (N = 28) **G2:** Placebo (N = 24) **Enrollment:** • 78 (of 103 patients seen in 3 ED Units) recruited • 77 met criteria after placebo run-in phase • 52 completed trial **Drop outs:** **G1:** 10 (4 adverse events) **G2:** 15 (5 adverse events)	**Age, mean (SE) (range):** **G1:** 25.65 (0.78) (19-36) **G2:** 25.15 (0.9) (18-40) (*P* = NS) **Sex:** Female: 100% **Race/ethnicity:** NR

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Age 18 to 40; DSM IV criteria for BN **Exclusion:** Hypersensitivity to MAOIs; neurological disorders; hx of schizophrenia, bipolar (I or II), suicide attempts, recent substance abuse; current dx of major depressive episode, high suicidal risk, unstable or uncontrolled medical diseases, clinically sig ECG; BMI < 17 or > 27; received psychotropic meds in past 4 wks	Pre-screening with HAM-D, BITE, EDI, and TFEQ Initial 1-wk single-blind run in phase to identify and exclude placebo responders (i.e., 50% reduction of binge eating). Randomization: **G1:** 400mg for 1 wk, 600mg wk 2-6 **G2:** NR Daily diaries to record binge eating, purging, or non-purging compensatory behaviors. 6 wkly sessions to collect diaries, record blood pressure, evaluate change in sx, effects, compliance, and to complete questionnaires.	Between-group diffs in outcomes assessed using an unspecified parametric test for numerical variables and a non-parametric test for categorical variables. Efficacy and safety frequency data evaluated using a non-parametric test, and psychometric data compared using ANOVA.	**Score:** Fair **Intent to treat:** No **Blinding:** Double **Adverse events, N (%):** **G1:** respiratory infectious disease, 3 (7.9%); vertigo, 2 (5.3%); derealization crisis, 1 (2.6%); headache, 1 (2.6%); skin rash, 1 (2.6%); sleep disturbances, 1 (2.6%). **G2:** headache, 2 (5.2%); sleep disturbances, 3 (7.8%); abdominal pain, 1 (2.6%); attention difficulty, 1 (2.6%); chest pain, 1 (2.6%); constipation, 1 (2.6%); palpitations, 1 (2.6%); renal colic, 1 (2.6%) **Funding:** Roche

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Carruba, Cuzzolaro et al., 2001 (continued)	**Pre-Placebo Run-in (N = 78):** **Binge Episodes, wkly, mean (SE):** **G1:** 6.24 (1.04) **G2:** 6.46 (0.96) *(P* = NS)	**Post-Treatment:** **Binge Episodes, wkly, mean (SE):** **G1:** 4.84 (0.79) *(P* = NR) **G2:** 3.61 (0.97) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	Vomiting Episodes, wkly, mean (SE): **G1:** 4.80 (1.03) **G2:** 5.69 (1.29) *(P* = NS)	**Vomiting Episodes, wkly, mean (SE):** **G1:** 4.44 (1.06) *(P* = NR) **G2:** 4.15 (1.24) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	BITE-Sx, mean (SE) (range): **G1:** 24.19 (0.56) (15-28) **G2:** 24.08 (0.64) (15-28) *(P* = NS)	**BITE-Sx, mean (SE):** **G1:** 22.46 (0.93) *(P* = NR) **G2:** 21.86 (0.83) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	BITE-Severity, mean (SE) (range): **G1:** 11.69 (0.78) (3-20) **G2:** 12.43 (0.80) (3-31) *(P* = NS)	**BITE-Severity, mean (SE):** **G1:** 9.26 (0.56) *(P* = NR) **G2:** 9.43 (0.81) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	EDI mean (SE): **G1:** 98.4 (6.3) **G2:** 83.4 (6.3) *(P* = NR)	**EDI mean (SE):** **G1:** 87.6 (6.7) *(P* = NR) **G2:** 66.0 (6.1) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	TFEQ-1, restriction, mean (SE): **G1:** 13.32 (0.82) **G2:** 13.04 (0.81) *(P* = NR)	**TFEQ-1, restriction, mean (SE):** **G1:** 13.04 (0.86) *(P* = NR) **G2:** 13.72 (0.94) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	TFEQ-2, disinhibition, mean (SE): **G1:** 12.92 (0.37) **G2:** 11.95 (0.51) *(P* = NR)	**TFEQ-2, disinhibition, mean (SE):** **G1:** 12.56 (0.48) *(P* = NR) **G2:** 10.95 (0.56) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	TFEQ-3, hunger, mean (SE): **G1:** 10.28 (0.60) **G2:** 8.22 (0.79) *(P* = NR)	**TFEQ-3, hunger, mean (SE):** **G1:** 9.84 (0.71) *(P* = NR) **G2:** 8.22 (0.83) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
Pre-Placebo Run-In (N = 78): **HAM-D, mean (SE) (range):** **G1:** 8.14 (0.90) (2-22) **G2:** 9.43 (1.28) (1-22) *(P* = NS)	**HAM-D, mean (SE):** **G1:** 6.22 (0.99) *(P* = NR) **G2:** 6.26 (1.26) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)	**Pre-Placebo Run-in (N = 78):** **Ht, cm (SE) (range):** **G1:** 165.28 (1.04) (150-179) **G2:** 163.56 (0.87) (153-173) *(P* = NS) **Wt, kg, mean (SE) (range):** **G1:** 55.76 (1.36) (41-75) **G2:** 55.14 (1.3) (42-76) *(P* = NS) **BMI, kg/m² (SE) (range):** **G1:** 20.35 (0.43) (17-26) **G2:** 20.49 (0.41) (17-26) *(P* = NS)	**Post-tx (N = 52):** **Wt, kg, mean (SE):** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Diff between groups Diff between groups *(P* = NR) **BMI, kg/m² (SE):** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Diff between groups Diff between groups *(P* = NR)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Faris, et al., 2000 **Setting:** Outpatient setting, Dept of Psychiatry, U of Minnesota, Minneapolis, MN, USA **Enrollment period:** NR	**Research objective:** RCT investigating use of ondansetron for participants with severe BN	**Groups:** **G1:** Ondansetron (N = 14) **G2:** Placebo (N = 12) **Enrollment:** • 43 screened • 29 selected for initial assessment • 28 completed baseline study • 26 completed single blind placebo wk and randomized • 25 completed tx	**Age, mean (SD):** Total: 29.1 (6) **Sex:** Female: 100% **Race/ethnicity:** NR **Duration of BN (SD):** Total: 11.8 yrs (6.6)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Females, aged 18 or older not receiving any tx, bingeing followed by self-induced vomiting a min of 7 times a wk for at least 6 mos with a definite feeling of lack of control over the behavior, not engaged in other methods of purging, such as laxative or diuretic use, more than twice per wk in the past mo (more stringent than DSM IV BN criteria), BMI:17.5-23.5 kg/m^2, normal blood counts, electrolyte concentrations, liver function tests, electrocardiograms and physical examinations, not pregnant, no serious diagnosed medical condition, not suicidal or psychotic, no current or previous dx of schizophrenia or bipolar disorder, no problem with drug or alcohol abuse in the 6 mos prior to study initiation, had not taken any psychoactive meds in 6 wks before study began. **Exclusion:** Those who developed psychiatric or physical symptoms requiring medical tx	One capsule (4 mg of drug or placebo) whenever urge to binge-eat or vomit. Should first try to restrain themselves for 30 min. If urges constant or not clearly defined, take doses 30 minutes before eating. Up to 6 doses per day, could alter timing to max perceived effect for 4 wks. Maintains daily meal pattern record, research assistants contacted participants to create backup of same info, met once a wk with a psychiatrist to evaluate compliance and any side effects.	Repeated measures analysis of variance (RM-ANOVA) with Huynh-Feldt corrections for sig. levels. Between-group effects examined using contrast analyses. To control for diff in groups in baseline values, data subjected to an ANCOVA with values during the single-blind placebo wk entered as covariates.	**Score:** Good **Intent to treat:** Yes **Blinding:** Double **Adverse events:** Participants evaluated but none reported. One patient dropped out due to injury but no information about injury provided. **Funding:** Mark A Nugent Research Foundation

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Faris et al., 2000 (continued)	**Binge-purge episodes in baseline wk for total sample, mean (SD):** 16.5 (7) **During single-blind placebo wk, coupled binge-eating and vomiting episodes/a wk, mean (SD):** **G1:** 12.8 (5.0) **G2:** 13.4 (9.9) *(P* = NR)	**Binge/vomit frequency during 4th wk, mean (SD):** **G1:** 6.5 (3.9) *(P* = NR) **G2:** 13.2 (11.6) *(P* = NR) Diff between groups *(P* < 0.0001) Diff between groups in change over time *(P* < 0.001) G1 better than G2
	Number of "normal meals" consumed: **G1:** NR **G2:** NR *(P* = NR)	**Number of "normal meals" consumed:** **G1:** NR *(P* = 0.03) **G2:** NR *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.03) G1 better than G2
	Time spent engaging in bulimic behaviors: **G1:** NR **G2:** NR *(P* = NR)	**Time spent engaging in bulimic behaviors:** **G1:** NR *(P* = 0.04) **G2:** NR Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.05) G1 less than G2

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
NR	NR	**BMI, kg/m^2, mean (SD):** Total sample: 21.6 (2.5)	
		Wt, at single blind placebo wk, kg, mean: **G1:** 60.3 **G2:** 60.1 *(P* = NR)	**Wt after wk 4, kg, mean:** **G1:** 60.4 *(P* = NR) **G2:** 60.8 *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Fichter et al., 1996 **Companion article:** Fichter et al., 1997 **Setting:** Roseneck Hospital, Prien, Germany **Enrollment period:** December 1989 to March 1992	**Research objective:** Compare fluvoxamine with placebo in maintaining improvement and preventing relapse in bulimic symptoms after tx with psychotherapy.	**Groups:** **G1 =** Fluvoxamine group **G2** = Placebo group **Enrollment:** • 257 patients admitted to inpatient unit between December 1989 and March 1992 • 81 fulfilled inclusion criteria and randomly assigned to meds or placebo at admission to inpatient program. • 72 patients who had responded sufficiently to inpatient tx (9 were excluded as they were bingeing > 5 times/wk) began the tx. The study had three phases; inpatient tx phase, followed by a maintenance/outpatient tx phase and lastly, a 4-wk off-meds/placebo phase.	**Age, yrs, mean (SD):** **G1:** 25.2 (4.9) **G2:** 23.7 (5.1) (*P* = NS) **Sex:** Female: 100% **Race/ethnicity:** NR **Age at onset, yrs, mean (SD):** **G1:** 19 (3) **G2:** 19 (4) **Binge episodes in the mo prior to admission, mean (SD):** **G1:** 16 (15) **G2:** 15 (15) **Marital status, never married:** **G1:** 81% **G2:** 86% **Hx of depression:** **G1:** 43% **G2:** 49% **Hx of anxiety disorder:** **G1:** 41% **G2:** 31% **Hx of obesity:** **G1:** 14% **G2:** 11% **Hx of alcohol abuse:** **G1:** 19% **G2:** 17% **Hx of suicide attempts:** **G1:** 27% **G2:** 23%

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Between 18 and 50, DSM III-R BN of at least 6 mos duration prior to admission, body wt between 85% and 125% of IBW, inpatient improvements of 4 points on clinical global impression – severity of illness scale during inpatient admission; 5 or fewer binges in the last wk of inpatient tx. Meds very rarely or in very low doses (i.e., low doses of psychoactive substances on a herbal basis or homeopathic dosages; up to 1 gm per night of chloralhydrate for sleep; 50 mg or less of isopromethazine; 1 mg in injection form of fluspirilene for crisis; 50 mg or less of amitriptyline; normal dose of benzodiazepines for less than 5 days or when taken in low or avg dosage, i.e., about 5 mg of diazepam a day).	Identical capsules containing either 50 mg of fluvoxamine or a lactose filler as a replacement; started at one capsule in the morning about 3 wks before the end of inpatient tx; stepwise increases every 3-4 days; usual dosage increased by one capsule and if tolerated, dose increased to a max of 300 mg of fluvoxamine by end of tx. Participants in placebo group received an avg of 4.4 capsules a day. Avg dose 182 ± 4.1mg.	Participants who took meds in the off-meds phase included in the examination but excluded from analyses related to the off-meds phase. Repeated measures MANOVA's for diffs between placebo and meds groups. ANOVA's for main diffs across all three tx phases. Chi-square tests for nonparametric data.	**Score:** Fair **Intent to treat:** Yes **Blinding:** Double **Adverse events:** 1 patient in G2 had to be admitted to the hospital. 1 patient from G2 complained of side effects. 8 patients from G1 dropped out due to side effects. Common side effects included nausea, dizziness and drowsiness (more common in the patients receiving fluvoxamine). **Funding:** NR

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Fichter et al., 1996 (continued)			

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Exclusion: Pregnant or lactating, serious medial conditions, psychosis or acute suicidal ideation, seizures, insulin-dependent diabetes or if used other psychoactive meds, appetite suppressants or other relevant meds within 2 wks prior to entering meds part of study. Avg or high dose of concurrent psychoactive meds over more than 4 days during the study also excluded.			

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Fichter et al., 1996 (continued)	Values obtained immediately before discharge.	Values obtained 12 wks post-discharge.
	Urge to binge: binge frequency previous wk, mean: **G1:** 0.9 **G2:** 1.0 *(P* = NR)	**Urge to binge: binge frequency previous wk, mean:** **G1:** 1.9 *(P* = NR) **G2:** 3.7 *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	SIAB-Bulimia, mean: **G1:** 1.2 **G2:** 0.8 *(P* = NR)	**SIAB-Bulimia, mean:** **G1:** 1.8 *(P* = NR) **G2:** 2.2 *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	SIAB-total, mean: **G1:** 1.3 **G2:** 1.1 *(P* = NR)	**SIAB-total, mean:** **G1:** 1.6 *(P* = NR) **G2:** 1.7 *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* < 0.05) G1 better than G2
	EDI-total score, mean: **G1:** 0.73 **G2:** 0.60 *(P* = NR)	**EDI-total score, mean:** **G1:** 0.78 *(P* = NR) **G2:** 0.86 *(P* = NR) Diff over time *(P* < 0.01) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	EDI-Bulimia, mean: **G1:** 0.47 **G2:** 0.22 *(P* = NR)	**EDI-Bulimia, mean:** **G1:** 0.40 *(P* = NR) **G2:** 0.61 *(P* = NR) Diff over time *(P* < 0.05) Diff between groups *(P* = NS) Diff between groups in change over time *(P* < 0.01) G1 better than G2
	SIAB-expert rating: fasting, mean: **G1:** 0.9 **G2:** 1.0 *(P* = NR)	**SIAB-expert rating: fasting, mean:** **G1:** 0.7 *(P* = NR) **G2:** 1.4 *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* < 0.05) G1 better than G2
	SIAB-expert rating: qualitative food reduction, mean N: **G1:** 1.2 **G2:** 0.9 *(P* = NR)	**SIAB-expert rating: qualitative food reduction, mean:** **G1:** 0.8 *(P* = NR) **G2:** 1.0 *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
Global assessment, mean: **G1: 3.0** **G2:** 2.8 *(P* = NR)	**Global assessment, mean:** **G1:** 3.3 *(P* = NR) **G2:** 4.1 *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* < 0.01) G1 better than G2	**BMI, kg/m^2, mean:** **G1:** 20.7 **G2:** 20.2 *(P* = NS)	**BMI, kg/m^2, mean:** **G1:** 21.4 *(P* = NR) **G2:** 20.7 *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Fichter et al., 1996 (continued)	**SIAB-expert rating: vomiting, mean:** **G1:** 1.3 **G2:** 0.6 *(P* = NR)	**SIAB-expert rating: vomiting, mean:** **G1:** 1.8 *(P* = NR) **G2:** 2.0 *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* < 0.05) G1 better than G2
	Fear to lose control over eating behavior, mean: **G1:** 97 **G2:** 97 *(P* = NR)	**Fear to lose control over eating behavior, mean:** **G1:** 98 *(P* = NR) **G2:** 187 *(P* = NR) Diff over time *(P* < 0.01) Diff between groups *(P* = NS) Diff between groups in change over time *(P* < 0.01) G1 better than G2
	Urge to binge in last 7 days in VAS, mean: **G1:** 138 **G2:** 118 *(P* = NR)	**Urge to binge in last 7 days in VAS, mean:** **G1:** 147 *(P* = NR) **G2:** 195 *(P* = NR) Diff over time *(P* < 0.01) Diff between groups *(P* = NS) Diff between groups in change over time *(P* < 0.05) G1 better than G2
		Severity of Eating Disorder- patient rating: Diff between groups in change over time *(P* < 0.05) **Severity of Eating Disorder – expert rating:** Diff between groups in change over time *(P* < 0.05)
		Figure Consciousness and Body Image: Diff between groups in change over time *(P* = NS)
		"Deterioration" (increase) in severity of bulimic symptoms: **G1:** 10% *(P* = NR) **G2:** 46% *(P* = NR) **"Deterioration" (increase) in number of binges in previous wk:** **G1:** 111% *(P* = NR) **G2:** 270% *(P* = NR)
		Abstinence from bingeing: **G1:** NR **G2:** NR Diff between groups *(P* < 0.05) G1 better than G2 **Abstinence from vomiting:** **G1:** NR **G2:** NR Diff between groups *(P* = NS)
		"Deterioration" (increase) in SIAB-bulimia: **G1:** 50% *(P* = NR) **G2:** 175% *(P* = NR)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Fichter et al., 1996 (continued)		**Relapse (defined as score of 5 or more on CGI severity) before end of the relapse prevention phase:** **G1:** 8.1% *(P* = NR) **G2:** 31.4% *(P* = NR) Diff between groups *(P* < 0.05) G1 better than G2 Diff between groups in change over time *(P* = NR)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Fichter et al., 1997 **Companion article:** Fichter et al., 1996 **Setting:** Roseneck Hospital, Prien, Germany **Enrollment period:** December 1989 to March 1992	**Research objective:** Compare fluvoxamine with placebo on depression, anxiety and other areas of psychopathology among individuals with BN after inpatient tx with psychotherapy.	**Groups:** **G1 =** Fluvoxamine group **G2** = Placebo group **Enrollment:** • 257 patients admitted to inpatient unit between December 1989 and March 1992 • 81 fulfilled inclusion criteria and were randomly assigned to meds or placebo at admission to the inpatient program. • 72 patients who responded sufficiently to inpatient tx and began the tx. (9 were excluded as they were bingeing > 5 times/wk) • Out of 72 patients who began tx, 24 dropped out or excluded because of low fluvoxamine levels. The study had three phases; inpatient tx phase, followed by a maintenance/outpatient tx phase and lastly, a 4-wk off-meds/placebo phase.	**Age, yrs, mean (SD):** **G1:** 25.2 (4.9) **G2:** 23.7 (5.1) (*P* = NS) **Sex:** Female: 100% **Race/ethnicity:** NR **Age at onset, yrs, mean (SD):** **G1:** 19 (3) **G2:** 19 (4) **Binge episodes in the mo prior to admission, mean (SD):** **G1:** 16 (15) **G2:** 15 (15) **Marital status, never married:** **G1:** 81% **G2:** 86% **Hx of depression:** **G1:** 43% **G2:** 49% **Hx of anxiety disorder:** **G1:** 41% **G2:** 31% **Hx of obesity:** **G1:** 14% **G2:** 11% **Hx of alcohol abuse:** **G1:** 19% **G2:** 17% **Hx of suicide attempts:** **G1:** 27% **G2:** 23%

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Years of age between 18 and 50, DSM III-R BN of at least 6 mos duration prior to admission, body wt between 85% and 125% of IBW, inpatient improvements of 4 points on clinical global impression – severity of illness scale during inpatient admission; 5 or fewer binges in the last wk of inpatient tx. Meds very rarely or in very low doses (i.e., low doses of psychoactive substances on a herbal basis or homeopathic dosages; up to 1 gm per night of chloralhydrate for sleep; 50 mg or less of isopromethazine; 1 mg in injection form of fluspirilene for crisis; 50 mg or less of amitriptyline; normal dose of benzodiazepines for less than 5 days or when taken in low or avg dosage, i.e., about 5 mg of diazepam a day).	Patients dispensed identical capsules containing either 50 mg of fluvoxamine or a lactose filler as a replacement; started at one capsule in the morning about 3 wks before end of inpatient tx; stepwise increases every 3-4 days; usual dosage increased by one capsule and if tolerated, increased to a max of 300 mg of fluvoxamine by end of tx. Placebo group received an avg of 4.4 capsules a day. Avg dose 182 ± 4.1mg.	MANOVA's for the relapse prevention phase and two factorial ANOVA's for each of the 3 phases (only completer for last phase). Mann Whitney U tests for examining relapses. T-tests were used to look at diffs in side effect duration and severity and use of subsequent tx.	**Score:** Fair **Intent to treat:** Yes **Blinding:** Double **Adverse events:** 1 patient in G2 had to be admitted to the hospital. 1 patient from G2 complained of side effects. 8 patients from G1 dropped out due to side effects. Common side effects included nausea, dizziness and drowsiness (more common in fluvoxamine group). **Funding:** NR

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Fichter et al., 1997 (continued)			

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Exclusion: Pregnant or lactating, serious medial conditions, psychosis or acute suicidal ideation, hx of seizures, insulin-dependent diabetes or if used other psychoactive meds, appetite suppressants or other relevant meds within 2 wks prior to entering meds part of study. Avg or high dose of concurrent psychoactive meds over more than 4 days during the study also excluded.			

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Fichter et al., 1997 (continued)	Values obtained immediately before discharge.	Values obtained 12 wks post-discharge.
	Urge to binge: binge frequency previous wk, mean: **G1:** 0.9 **G2:** 1.0 *(P* = NR)	**Urge to binge: binge frequency previous wk, mean:** **G1:** 1.9 *(P* = NR) **G2:** 3.7 *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	SIAB-Bulimia, mean: **G1:** 1.2 **G2:** 0.8 *(P* = NR)	**SIAB-Bulimia, mean:** **G1:** 1.8 *(P* = NR) **G2:** 2.2 *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	SIAB-total, mean: **G1:** 1.3 **G2:** 1.1 *(P* = NR)	**SIAB-total, mean:** **G1:** 1.6 *(P* = NR) **G2:** 1.7 *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* < 0.05) G1 better than G2
	EDI-total score, mean: **G1:** 0.73 **G2:** 0.60 *(P* = NR)	**EDI-total score, mean:** **G1:** 0.78 *(P* = NR) **G2:** 0.86 *(P* = NR) Diff over time *(P* < 0.01) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	EDI-Bulimia, mean: **G1:** 0.47 **G2:** 0.22 *(P* = NR)	**EDI-Bulimia, mean:** **G1:** 0.40 *(P* = NR) **G2:** 0.61 *(P* = NR) Diff over time *(P* < 0.05) Diff between groups *(P* = NS) Diff between groups in change over time *(P* < 0.01) G1 better than G2
	SIAB-expert rating: fasting, mean: **G1:** 0.9 **G2:** 1.0 *(P* = NR)	**SIAB-expert rating: fasting, mean:** **G1:** 0.7 *(P* = NR) **G2:** 1.4 *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* < 0.05) G1 better than G2

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
CGI Severity, mean: **G1:** 3.1 **G2:** 3.0 *(P* = NS)	**CGI Severity, mean:** **G1:** 3.3 *(P* = NR) **G2:** 3.7 *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* < 0.05) G1 better than G2	**BMI, kg/m^2, mean:** **G1:** 20.7 **G2:** 20.2 *(P* = NS)	**BMI, kg/m^2, mean:** **G1:** 21.4 *(P* = NR) **G2:** 20.7 *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
HDRS, mean: **G1:** 12.3 **G2:** 10.1 *(P* = NS)	**HDRS, mean:** **G1:** 13.2 *(P* = NR) **G2:** 15.0 *(P* = NR) Diff over time *(P* < 0.05) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)		
Hopkins Symptom Checklist Depression, mean: **G1:** 1.9 **G2:** 1.7 *(P* = NS)	**Hopkins Symptom Checklist depression, mean:** **G1:** 1.9 *(P* = NR) **G2:** 2.0 *(P* = NR) Diff over time *(P* < 0.05) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)		
Hopkins Symptom Checklist Anxiety, mean: **G1:** 1.7 **G2:** 1.8 *(P* = NS)	**Hopkins Symptom Checklist Anxiety, mean:** **G1:** 1.7 *(P* = NR) **G2:** 1.9 *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)		
Hopkins Symptom Checklist Obsessions-Compulsions, mean: **G1:** 1.8 **G2:** 1.7 *(P* = NS)	**Hopkins Symptom Checklist Obsessions-Compulsions, mean:** **G1:** 1.8 *(P* = NR) **G2:** 2.1 *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* < 0.05) G1 better than G2		

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Fichter et al., 1997 (continued)	**SIAB-expert rating: qualitative food reduction, mean N:** **G1:** 1.2 **G2:** 0.9 *(P* = NR)	**SIAB-expert rating: qualitative food reduction, mean:** **G1:** 0.8 *(P* = NR) **G2:** 1.0 *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	SIAB-expert rating: vomiting, mean: **G1:** 1.3 **G2:** 0.6 *(P* = NR)	**SIAB-expert rating: vomiting, mean:** **G1:** 1.8 *(P* = NR) **G2:** 2.0 *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* < 0.05) G1 better than G2
	Fear to lose control over eating behavior, mean: **G1:** 97 **G2:** 97 *(P* = NR)	**Fear to lose control over eating behavior, mean:** **G1:** 98 *(P* = NR) **G2:** 187 *(P* = NR) Diff over time *(P* < 0.01) Diff between groups *(P* = NS) Diff between groups in change over time *(P* < 0.01) G1 better than G2
	Urge to binge in last 7 days in VAS, mean: **G1:** 138 **G2:** 118 *(P* = NR)	**Urge to binge in last 7 days in VAS, mean:** **G1:** 147 *(P* = NR) **G2:** 195 *(P* = NR) Diff over time *(P* < 0.01) Diff between groups *(P* = NS) Diff between groups in change over time *(P* < 0.05) G1 better than G2
		Severity of Eating Disorder- patient rating: Diff between groups in change over time *(P* < 0.05) **Severity of Eating Disorder – expert rating:** Diff between groups in change over time *(P* < 0.05)
		Figure Consciousness and Body Image: Diff between groups in change over time *(P* = NS)
		"Deterioration" (increase) in severity of bulimic symptoms: **G1:** 10% *(P* = NR) **G2:** 46% *(P* = NR) **"Deterioration" (increase) in number of binges in previous wk:** **G1:** 111% *(P* = NR) **G2:** 270% *(P* = NR)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 5. Medication trials for bulimia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Fichter et al., 1997 (continued)		**Abstinence from bingeing:** **G1:** NR **G2:** NR Diff between groups *(P* < 0.05) G1 better than G2 **Abstinence from vomiting:** **G1:** NR **G2:** NR Diff between groups *(P* = NS)
		"Deterioration" (increase) in SIAB-bulimia: **G1:** 50% *(P* = NR) **G2:** 175% *(P* = NR)
		Relapse (defined as score of 5 or more on CGI severity) before end of the relapse prevention phase: **G1:** 8.1% *(P* = NR) **G2:** 31.4% *(P* = NR) Diff between groups *(P* < 0.05) G1 better than G2 Diff between groups in change over time *(P* = NR)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Fichter et al., 1991 **Setting:** Inpatient clinic; Klinik Roseneck, Prien, Germany **Enrollment period:** NR	**Research objective:** To assess the efficacy of fluoxetine (60mg) versus placebo in the tx of individuals with BN already receiving intensive inpatient behavioral psychotherapy.	**Groups:** **G1:** Fluoxetine (N = 20) **G2:** Placebo (N = 20) **Enrollment:** • 40 randomized • 39 analyzed (**G1:** 19; **G2:** 20), with I exclusion • 0 drop outs	**Age, mean (SD):** **G1:** 26.5 (NR) **G2:** 24.6 (NR) *(P* = NS) **Sex, N:** Female: 39 Male: 1 **Race/ethnicity:** NR **Age of onset of eating disorder, yrs, mean (SD):** **G1:** 16.6 (NR) **G2:** 16.2 (NR) *(P* = NS) **Hx of AN, N (%):** **G1:** 10/20 (50%) **G2:** 10/20 (50%) *(P* = NS) **Laxative abuse, past wk, N (%):** **G1:** 4/20 (30%) **G2:** 1/20 (35%) *(P* = NR)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Dx of BN (DSM III-R); inpatient status **Exclusion:** Pregnancy; serious suicidal risks, medical risks or disorders; schizophrenia, hx of seizures or drug/alcohol addiction; PreTx with long-acting neuroleptics	In 10 balanced blocks of 4, 40 patients with BN randomly assigned to 60mg fluoxetine or placebo; in addition to meds, all participants continued in intensive inpatient care—a broad spectrum, behavioral tx program. After a 3-7 day washout period, received a 60 mg/day dose of fluoxetine or placebo for 35 days; no other psychotropic meds given, except for chloralhydrate and benzodiazepines, if necessary.	Repeated-measures ANOVA Self-report measures regarding and clinically administered ratings, and biometric measures made one wk before tx start, and on days, 7, 14, 21, 28, 35.	**Score:** Good **Intent to treat:** Yes **Blinding:** Double **Adverse events:** One patient excluded due to undetectable fluoxetine plasma levels at all measurement points; G1 reported sig more “trembling” than G2 *(P* = 0.02); No sig diffs observed for numbness, nausea, body tingling, “mind going blank, hot and cold spells, trouble getting breath, heart racing, pains in heart, nervousness or shaking, heartache or restlessness, trouble concentrating, anxiety, poor appetite, sweating, elevated systolic and diastolic blood pressure, elevated pulse rate, reduced white blood count, reduced hemoglobin, increased liver enzymes and creatinine, and changes in serum potassium. **Funding:** NR

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Fichter et al., 1991 (continued)	**EDI, Bulimia, mean (SD)** **G1:** 10.2 (5.3) **G2:** 9.9 (3.5) *(P* = NS)	**End of tx:** **EDI, Bulimia, mean (SD)** **G1:** 3.0 (4.8) *(P* = NR) **G2:** 4.0 (4.8) *(P* = NR) Diff over time *(P* = 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	EDI, Drive for thinness, mean,\ (SD) **G1:** 12.3 (5.4) **G2:** 11.0 (4.7) *(P* = NS)	**EDI, Drive for thinness, mean (SD)** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Diff over time *(P* = 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	EDI, Total score, mean (SD): **G1:** 82.7 (32.5) **G2:** 76.9 (28.9) *(P* = NS)	**EDI, Total score, mean (SD):** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Diff over time *(P* = 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **EDI, Body Dissatisfaction, mean (SD):** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Diff over time *(P* = 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
		SIAB-Global rating, mean (SD): **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Diff over time *(P* = 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	Urge to binge, past wk, mean (SD): **G1:** 2.51 (1.20) **G2:** 2.64 (0.83) *(P* = NS)	**Urge to binge, past wk, mean (SD):** **G1:** 1.37 (0.90) *(P* = NR) **G2:** 1.54 (0.95) *(P* = NR) Diff over time *(P* = 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	Binge attacks, past wk, mean (SD): **G1:** 5.63 (9.10) **G2:** 8.85 (7.99) *(P* = NS)	**Binge attacks, past wk, mean (SD):** **G1:** 3.00 (4.77) *(P* = NR) **G2:** 6.60 (6.94) *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	Anxiety, loss of control over eating (0-4), mean (SD): **G1:** 2.7 (1.4) **G2:** 1.9 (1.0) *(P* = 0.05)	**Anxiety, loss of control over eating (0-4), mean (SD):** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Diff over time *(P* = 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
HAM-D, total score, mean (SD): **G1:** 13.3 (5.6) **G2:** 14.1 (7.0) *(P* = NS)	**End of tx:** **HAM-D, total score, mean (SD):** **G1:** 8.3 (5.0) *(P* = NR) **G2:** 11.1 (7.4) *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)	**Wt, kg, mean (SD):** **G1:** 56.8 (12.3) **G2:** 54.7 (11.1) *(P* = NS)	**Wt, kg, mean (SD):** **G1:** 55.3 (9.1) *(P* = NR) **G2:** 55.0 (10.1) *(P* = NR) Diff over time *(P* = 0.05) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
SCL-90, depression, mean (SD): **G1:** 1.7 (0.9) **G2:** 1.8 (0.8) *(P* = NS)	**SCL-90, depression (SD):** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)		
SCL-90, anxiety, mean (SD): **G1:** 1.0 (0.8) **G2:** 1.3 (1.0) *(P* = NS)	**SCL-90, anxiety, mean (SD):** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)		

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Fichter et al., 1991 (continued)	NR	Abstinence NR The following selected SIAB items were reported over time within both groups (means: NR): • Compulsive eating behavior *(P* = NS) • Compulsive thoughts about eating*(P* = NS) • Ideal of slimness *(P* = 0.001) • Fasting *(P* = 0.001) • Body image disturbance *(P* = 0.05) • Induced vomiting *(P* = 0.01) • Laxative abuse *(P* = NS) No sig diff between groups, or sig diff between groups in change over time were reported for any of these items

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
	CGI-Severity of illness, mean (SD): **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Diff over time *(P* = 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)		
	CGI-Change over time, mean (SD): **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Diff over time *(P* = 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)		
	CGI-Therapy effectiveness, mean (SD): **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Diff over time *(P* = 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)		
	CGI-Risk index, mean (SD): **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Diff over time *(P* = 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)		

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Fluoxetine BN Collaborative Study Group, 1992 **Comparison articles:** Goldstein, 1995 and Goldstein, 1999 **Setting:** 13 Outpatient centers in the U.S. and Canada **Enrollment period:** NR	**Research objective:** To compare the efficacy and safety of two doses of fluoxetine in the tx of BN	**Groups:** **G1:** Placebo (N = 129) **G2:** Fluoxetine 20 mg (N = 129) **G3:** Fluoxetine 60 mg (N = 129) **Enrollment:** • 442 screened • 387 randomized (129 assigned to each group) • 270 after 8 wks	**Age, mean (SD):** **G1:** 27.7 (8.0) **G2:** 27.4 (7.2) **G3:** 26.4 (6.2) (*P* = NS) **Sex:** Female: 100% **Race/ethnicity:** White: **G1:** 98% **G2:** 95% **G3:** 97% (*P* = NS) **BMI, kg/m^2, mean (SD):** **G1:** 22.6 (3.3) **G2:** 22.7 (4.2) **G3:** 22.4 (3.2) (*P* = NS) **BN behaviors (self-report):** Vomiting (83%) Laxative abuse (60%) Diuretic abuse (22%) Fasting (13%) Strict dieting or exercising (27%)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Female, met DSM III-R criteria for BN; ≥ 3 binge eating episodes per wk for at least 6 mos; age 18+; between 85%-130% of midpoint of IBW for ht. **Exclusion:** Pregnant or lactating; serious medical illness; psychosis; acute suicidal ideation; initial serum potassium level < 3.0 mmol/L; used psychoactive meds 2 wks prior to enrollment; initiated some other form of tx for BN (e.g., psychotherapy or behavior therapy) 1 mo prior to enrollment; 1 wk placebo responders (i.e., 75% improvement or had < 3 bulimic episodes per wk).	1 wk of single-blind placebo admin, followed by random assignment to placebo, 20 mg fluoxetine, or 60 mg of fluoxetine for 8 wks. Participants seen wkly for recording of wt, blood pressure, resting pulse, and oral temperature. Administered HDRS, EDI, EAT, and 2 visual analog scales for measuring carbohydrate craving and bulimic intensity. Subjects recorded number of daily binge eating and purging episodes in diary, which were totaled at wkly visit. Clinicians subjectively rated subject's global improvement during each visit. Med compliance assessed by capsule count (# dispensed - # returned). Tx responders: at least 50% improvement in binge-eating and vomiting frequency. Med non-compliance: taking < 80% of recommended dosage by endpoint.	ANOVAs on rank transformed data for continuous efficacy and safety variables; Pairwise comparisons using Fisher's least sig diff; Cochran-Mantel-Haenszel mean score test for bulimic response data; Pearson's X^2 tests for subject dispositional and adverse event data; Spearman's rank correlation coefficients for efficacy versus drug plasma concentration correlations; multiple logistic regressions for predicting response to fluoxetine.	**Score:** Fair **Intent to treat:** Analyses not performed on initial randomized sample of 387 but on those who returned for at least 1 visit after randomization (N = 382). **Blinding:** Double **Adverse events:** Insomnia *(P* < 0.001) Nausea *(P* = 0.021) Asthenia *(P* = 0.039) Tremor *(P* < 0.001) Sweating *(P* = 0.036) Urinary frequency *(P* = 0.012) Palpitation *(P* = 0.017) Yawn *(P* = 0.017) Mydriasis *(P* = 0.018) Vasodilation *(P* = 0.029) All events greater in the active vs placebo groups. No sig diff among groups for adverse events being the reason why participants discontinued the study. **Funding:** Eli Lilly and Company

Evidence Table 5. Medication trials for bulimia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Fluoxetine BN Collaborative Study Group, 1992 (continued)	**Binge episodes/wk, mean (SD):** **G1:** 11.0 (8.0) **G2:** 8.0 (5.0) **G3:** 11.0 (10.0) *(P* = NR)	**Median % reduction in binges/wk:** **G1:** 33% *(P* = NR) **G2:** 45% *(P* = NR) **G3:** 67% *(P* = NR) Diff between groups *(P* ≤ 0.003) G3 better than G2 and G1 Diff between groups in change over time *(P* = NR) **Wkly median % change in binges/wk (wks 1-7):** G1, G2, G3 data shown in figure Diff between groups *(P* < 0.005) G3 better than G1 Diff between groups in change over time *(P* = NR) **% ≥ 50% improved in binges/wk at end of tx:** **G1:** 43% *(P* = NR) **G2:** 49% *(P* = NR) **G3:** 63% *(P* = NR) Diff between groups *(P* ≤ 0.003) G3 better than G1 and G2 Diff between group in change over time *(P* = NR) **Binge Abstinence (full remission):** G1, G2, G3 shown in figure Diff between groups *(P* = NR)
	Vomiting episodes/wk, mean (SD): **G1:** 11.0 (14.0) **G2:** 9.0 (10.0) **G3:** 11.0 (14.0) *(P* = NR)	**Median % reduction vomiting/wk:** **G1:** 5% *(P* = NR) **G2:** 29% *(P* = NR) **G3:** 56% *(P* = NR) Diff between groups *(P* ≤ 0.04) G3 and G2 better than G1 *(P* = 0.003) G3 better than G2 Diff between groups in change over time *(P* = NR) **Wkly median % change in vomiting/wk frequency (wks 1-7):** G1, G2, G3 shown in figure Diff between groups *(P* < 0.005) G3 better than G1 Diff between groups in change over time *(P* = NR) **% ≥ 50% improved in tx vomiting/wk at end of tx:** **G1:** 26% *(P* = NR) **G2:** 45% *(P* = NR) **G3:** 57% *(P* = NR) Diff between groups *(P* = 0.021) G3 and G2 better than G1 *(P* = 0.011) G3 better than G2 **Vomiting Abstinence (full remission):** G1, G2, G3 shown in figure Diff between groups *(P* = NR)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
HDRS total score, mean (SD): **G1:** 11.8 (7.7) **G2:** 11.9 (7.3) **G3:** 11.9 (7.3) *(P* = NS)	**Change HDRS total score, median:** **G1:** -3.0 *(P* = NR) **G2:** -4.0 *(P* = NR) **G3:** -5.0 *(P* = NR) Diff between groups *(P* = 0.033) G3 better than G1 Diff between groups in change over time *(P* = NR) **% med non-compliance at 8 wks:** **G1:** 16.3% **G2:** 13.2% **G3:** 20.2% *(P* = NS)	**Wt, kg, mean (SD):** **G1:** 61.1 (9.8) **G2:** 60.3 (10.9) **G3:** 60.4 (9.2) *(P* = NS)	**Change in wt, kg, median:** **G1:** 0.0 *(P* = NR) **G2:** -0.5 *(P* = NR) **G3:** -1.6 *(P* = NR) Diff between groups *(P* = 0.013) G3 and G2 better than G1 Diff between groups in change over time *(P* = NR)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Fluoxetine BN Collaborative Study Group, 1992 (continued)	**EAT total score, mean (SD):** **G1:** 35.0 (13.3) **G2:** 32.5 (12.4) **G3:** 31.5 (12.5) *(P* = NS)	**Change in EAT Total Scale, median:** **G1:** -4.0 *(P* = NR) **G2:** -8.5 *(P* = NR) **G3:** -8.5 *(P* = NR) Diff between groups *(P* = 0.006) G3 and G2 better than G1 Diff between groups in change over time *(P* = NR) **Change in EAT diet preoccupation, median:** **G1:** -2.0 *(P* = NR) **G2:** -5.0 *(P* = NR) **G3:** -4.0 *(P* = NR) Diff between groups *(P* = 0.011) G3 and G2 better than G1 Diff between groups in change over time *(P* = NR) **Change in EAT food preoccupation, median:** **G1:** -2.0 *(P* = NR) **G2:** -4.0 *(P* = NR) **G3:** -5.0 *(P* = NR) Diff between groups *(P* = 0.016) G3 and G2 better than G1 Diff between groups in change over time *(P* = NR) **Change in EAT oral control, median** **G1:** 0.0 *(P* = NR) **G2:** 0.0 *(P* = NR) **G3:** 0.0 *(P* = NR) Diff between groups *(P* = 0.005) G3 better than G1 Diff between groups in change over time *(P* = NS) **Change EDI drive for thinness, median:** **G1:** -1.5 *(P* = NR) **G2:** -2.0 *(P* = NR) **G3:** -3.0 *(P* = NR) Diff between groups *(P* = 0.008) G3 better than G1 Diff between groups in change over time *(P* = NS) **Change EDI Bulimia, median:** **G1:** -3.0 *(P* = NR) **G2:** -4.0 *(P* = NR) **G3:** -5.0 *(P* = NR) Diff between groups *(P* = 0.003) G3 better than G1 Diff between groups in change over time *(P* = NS) **Change EDI body dissatisfaction, median:** **G1:** 0.0 *(P* = NR) **G2:** -2.0 *(P* = NR) **G3:** -3.0 *(P* = NR) Diff between groups *(P* = 0.027) G3 and G2 better than G1 Diff between groups in change over time *(P* = NS)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 5. Medication trials for bulimia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Fluoxetine BN Collaborative Study Group, 1992 (continued)	**Bulimic intensity (SD):** **G1:** 7.2 (2.0) **G2:** 6.8 (1.8) **G3:** 6.6 (2.1) *(P* = NS)	**Change bulimic intensity, median:** **G1:** -1.0 *(P* = NR) **G2:** -2.0 *(P* = NR) **G3:** -2.0 *(P* = NR) Diff between groups *(P* = 0.035) G3 and G2 better than G1 Diff between groups in change over time *(P* = NR)
	Carbohydrate craving (SD): **G1:** 7.0 (2.3) **G2:** 6.8 (2.4) **G3:** 6.7 (2.4) *(P* = NS)	**Change carbohydrate craving, median:** **G1:** -1.0 *(P* = NR) **G2:** -2.0 *(P* = NR) **G3:** -2.0 *(P* = NR) Diff over time between *(P* = 0.017) G3 and G2 better than G1 Diff between groups in change over time *(P* = NR)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, year: Goldstein et al., 1999 **Companion article:** Goldstein et al., 1995 and Fluoxetine BN Collaborative Study Group, 1992 **Setting:** 15 outpatient psychiatry clinics in the US (See Goldstein, Wilson, Thompson et al., 1995) **Enrollment period:** NR See Goldstein et al., 1995 for specific details from original RCTs. Data from Fluoxetine Bulimia Nervosa Collaboration Study Group, 1992 unknown.	**Research objective:** Retrospective analyses of data obtained from two previous RCTs assessing the effectiveness and safety of fluoxetine in treating the primary and associated symptoms of BN. This study aimed to evaluate whether improvements in binge-eating and vomiting were independent of depression status at baseline.	**Groups:** **G1:** Fluoxetine 60 mg-Hi depressed-8-wk trial **G2:** Fluoxetine 20 mg-Hi depressed-8-wk trial **G3:** Placebo-Hi depressed-8-wk trial (N = 61) **G4:** Fluoxetine 60mg-Lo depressed-8-wk trial **G5:** Fluoxetine 20 mg-Lo depressed-8-wk trial **G6:** Placebo-Lo depressed-8-wk trial (N = 66) **G7:** Fluoxetine 60 mg-Hi depressed 16-wk trial **G8:** Placebo-Hi depressed-16-wk trial (N = 39) **G9:** Fluoxetine 60 mg-Lo depressed-16-wk trial **G10:** Placebo-Lo depressed-16-wk trial (N = 61) **G11:** Fluoxetine 60 mg-depressed-8-wk trial **G12:** Fluoxetine 20 mg-depressed-8-wk trial **G13:** Placebo-depressed-8-wk trial (N = 47) **G14:** Fluoxetine 60 mg-nondepressed-8 wk trial **G15:** Fluoxetine 20 mg-nondepressed-8 wk trial **G16:** Placebo-nondepressed-8-wk trial (N = 73) **G17:** Fluoxetine 60 mg-depressed-16-wk trial **G18:** Placebo-depressed-16-wk trial (N = 22) **G19:** Fluoxetine 60 mg-nondepressed-16-wk trial **G20:** Placebo-nondepressed-16-wk trial (N = 73) **Enrollment:** Participants were male and female outpatients at each of the 15 centers. Details regarding the recruiting methods were not reported	**Age, mean (SD):** NR **Sex:** NR **Race/ethnicity:** NR

Evidence Table ?. Goldstein, Wilson, Ascroft et al., 1999 (ID JB/) (BN) (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Males and Females who met DSM-IIIR criteria for BN; at least 3 vomiting episodes per week after binge eating for at least six months; age 18 and older. **Exclusion:** Previous participation in a fluoxetine study; had taken fluoxetine within 5 wks before enrollment or had a cumulative lifetime fluoxetine dose of more than 140 mg; pregnant or lactating; a medically unstable condition; psychosis; acute suicidal ideation; a history of seizures; a diagnosis of AN; a diagnosis of organic brain disease; an allergy to fluoxetine or a history of severe allergies or multiple adverse drug reactions; hypertension treated with guanethidine, reserpine, clinidine, or methyldopa; having used MAOI's within two wks of enrollment or who anticipated using an MAOI within 5 wks of study completion; use of lithium, tryptophan or any other psychoactive agent in the wk prior to enrollment; had initiated some other form of treatment for BN within 1 month prior to enrollment; 2 wk placebo responders (i.e. 75% reduction in the number of vomiting episodes or had < 3 vomiting episodes per wk).	1 wk drug-free pre-screen period followed by 2 wks of single-blind placebo run-in administration, followed by random assignment (1:3) to placebo or 60 mg of fluoxetine for 16 wks. Subjects were seen by a physician and/or study coordinator weekly during the initial placebo lead-in phase, were seen every other week for the first four wks of the double-blind phase, and then monthly. Subjects completed a bulimic activity diary (i.e. recording the number of weekly vomiting and binge-eating episodes) and were administered a HRSD, EDI, and Patient's Global Impression (PGI) scales at each visit. Clinicians subjectively rated the subject's global improvement during each visit. Tx responders were defined as those who met the criteria of at least 50% improvement in binge-eating and vomiting frequency.	For each RCT, subjects stratified by median depression scores on the HRSD (i.e.12). Baseline dx of current depression or hx of depression as assessed via patient history also used to stratify subjects for another set of analyses per RCT. Analyses included ANOVAs to assess sig between group diffs in change of median frequencies of binge eating and vomiting from baseline to endpoint.	**Score:** Poor **Intent to treat:** Yes **Blinding:** Double **Adverse events:** NR **Funding:** Eli Lilly

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, year: Goldstein et al., 1999 (continued)	Baseline data reported in companion articles	**For 8-wk trial stratified by median HRSD:** **Binge-eating (median % improvement):** **G1**: ~75% (*P* = NR) **G2**: ~28% (*P* = NS) **G3**: ~40% (*P* = NR) **G4**: ~61% (*P* = NR) **G5**: ~48% (*P* = NS) **G6**: ~19% (*P* = NR) Diff between groups in change over time **G1** > G3 (*P* = 0.03) **G1** > G2 (*P* = 0.00) **G4** > G6 (*P* = 0.02) **G4** = G5 (*P* = NS) **Vomiting (median % improvement):** **G1**: ~65% (*P* = NR) **G2**: ~21% (*P* = NS) **G3**: ~15% (*P* = NR) **G4**: ~48% (*P* = NR) **G5**: ~50% (*P* = 0.014) **G6:** ~13% (*P* = NR) Diff between groups in change over time **G1** > G2 (*P* = 0.01) **G1** > G3 (*P* = 0.002) **G4** = G5 (*P* = NS) **G4** > G6 (*P* = 0.003) **For 16-wk trial stratified by median HRSD:** **Binge-eating (median % improvement):** **G7**: ~42% (*P* = NR) **G8**: ~12% (*P* = NR) **G9**: ~50% (*P* = NR) **G10**: ~22% (*P* = NR) Diff between groups in change over time **G7** > G8 (*P* = 0.042) **G9** > G10 (*P* = 0.002) **Vomiting (median % improvement):** **G7**: ~50% (*P* = NR) **G8**: ~18% (*P* = NR) **G9**: ~51% (*P* = NR) **G10**: ~30% (*P* = NR) Diff between groups in change over time **G7** > G8 (*P* = 0.03) **G9** > G10 (*P* = 0.002)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
None reported		None reported	

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, year: Goldstein et al., 1999 (continued)		**For 8-wk trial stratified by current or hx of depression:** **Binge-eating (median % improvement):** **G11**: ~71% (*P* = NR) **G12**: ~30% (*P* = NR) **G13**: ~38% (*P* = NR) **G14**: ~67% (*P* = NR) **G15**: ~53% (*P* = NR) **G16**: ~32% (*P* = NR) Diff between groups in change over time **G11** > G13 (*P* = 0.04) **G14** > G16 (*P* = 0.005) **G12** = G13 (*P* = NS) **G15** = G16 (*P* = NS) **G11** > G12 (*P* = 0.02) **G14** > G15 (*P* = 0.03) **Vomiting (median % improvement):** **G11**: ~63% (*P* = NR) **G12**: ~29% (*P* = NR) **G13**: ~15% (*P* = NR) **G14**: ~55% (*P* = NR) **G15**: ~31% (*P* = NR) **G16**: ~12% (*P* = NR) Diff between groups in change over time **G11** > G13 (*P* = 0.005) **G14** > G16 (*P* = 0.0004) **G12** = G13 (*P* = NS) **G15** = G16 (*P* = NS) **G11** = G12 (*P* = NS) **G14** > G15 (*P* = 0.04) **For 16-wk trial stratified by current or hx of depression:** **Binge-eating (median % improvement):** **G17**: ~48% (*P* = NR) **G18**: ~5% (*P* = NR) **G19**: ~50% (*P* = NR) **G20**: ~20% (*P* = NR) Diff between groups in change over time **G17** > G18 (*P* = 0.005) **G19** > G20 (*P* = 0.01) **Vomiting (median % improvement):** **G17**: ~53% (*P* = NR) **G18**: ~8% (*P* = NR) **G19**: ~50% (*P* = NR) **G20**: ~29% (*P* = NR) Diff between groups in change over time **G17:** > G18 (*P* = 0.001) **G19:** > G20 (*P* = 0.005)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Goldstein et al., 1995 **Companion article:** Fluoxetine Bulimia Nervosa Collaborative Study Group, 1992 and Goldstein et al., 1999 **Setting:** 15 outpatient psychiatry clinics in the US **Enrollment period:** NR	**Research objective:** As an extension of a previous 8-wk RCT (see Fluoxetine Bulimia Nervosa Collaborative Study Group, 1992), the primary aim was to assess the efficacy and safety of fluoxetine versus placebo in improving principal symptoms of BN (i.e., binge eating and purging behavior) during a 16-wk, double blind RCT. Secondary aims: evaluating improvements in self-reported depression, eating dysregulation and both patient and clinician-rated global psychiatric impressions.	**Groups:** **G1:** Fluoxetine (N = 296) **G2:** Placebo (N = 102) **Enrollment:** Male and female outpatients at 15 centers. Details regarding the recruiting methods not reported • 483 enrolled • 398 randomized at a ratio of 3:1 (fluoxetine: placebo) • 225 completers **G1:** 59.5% **G2:** 48% (*P* = 0.045)	**Age, yrs, median (range):** **G1:** 27 (17 - 63) **G2:** 26 (17 - 61) (*P* = NS) **Sex:** % Female **G1:** 95.3 **G2:** 99.0 (*P* = NS) **Race/ethnicity:** % White **G1:** 96.6 **G2:** 97.1 (*P* = NS) **Fasting days/wk median (range):** **G1:** 0 (0 - 7) **G2:** 0 (0 - 7) (*P* = NS) **Diuretic abuse days/wk median (range):** **G1:** 0 (0 - 14) **G2:** 0 (0 - 8) (*P* = NS) **Laxative abuse days/wk median (range):** **G1:** 0 (0 - 14) **G2:** 0 (0 - 9) (*P* = NS) **BN Behavior:** **Bingeing** **G1:** 100 % **G2:** 99.0% (*P* = NS) **Vomiting** **G1:** 99.0% **G2:** 100% (*P* = NS) **Laxative use** **G1:** 11.8% **G2:** 16.6% (*P* = NS) **Diuretic use** **G1:** 6.9% **G2:** 7.4% (*P* = NS) **Fasting** **G1:** 14.7% **G2:** 17.9% (*P* = NS)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Met DSM III-R criteria for BN; 3 vomiting episodes per wk after binge eating for at least 6 mos; age 18 and older. **Exclusion:** Previous participation in a fluoxetine study; had taken fluoxetine within 5 wks before enrollment or had a cumulative lifetime fluoxetine dose of more than 140 mg; pregnant or lactating; medically unstable condition; psychosis; acute suicidal ideation; hx of seizures; dx of AN; a dx of organic brain disease; allergy to fluoxetine or hx of severe allergies or multiple adverse drug reactions; hypertension treated with guanethidine, reserpine, clinidine, or methyldopa; having used MAOI's within 2 wks of enrollment or who anticipated using an MAOI within 5 wks of study completion; use of lithium, tryptophan or any other psychoactive agent in the wk prior to enrollment; had initiated some other form of tx for BN within 1 mo prior to enrollment; 2 wk placebo responders (i.e., 75% reduction in the number of vomiting episodes or had < 3 vomiting episodes per wk).	1 wk drug-free pre-screen period followed by 2 wks of single-blind placebo run-in administration, followed by random assignment (1:3) to placebo or 60 mg of fluoxetine for 16 wks. Subjects were seen by a physician and/or study coordinator wkly during initial placebo lead-in phase, seen every other wk for first four wks of double-blind phase, and then moly. Subjects completed bulimic activity diary (i.e., recording number of wkly vomiting and binge-eating episodes) and administered HRSD, EDI, and PGI scales at each visit. Clinicians subjectively rated subject's global improvement during each visit. Tx responders defined as those who met criteria of at least 50% improvement in binge-eating and vomiting frequency.	ANOVAs on rank transformed data for continuous efficacy and safety variables using Bonferroni correction for controlling Type I error; Pearson's X^2 and Mantel-Haenszel X^2 tests for linear associations in conjunction with computing confidence intervals for odds ratios for comparing among bulimic responder and non-responder groups; Pearson's X^2 tests for subject dispositional and adverse event data.	**Score:** Fair **Intent to treat:** Yes **Blinding:** Double **Adverse events (% reporting):** **Insomnia:** **G1:** 34.5 **G2:** 18.6 (*P* ≤ 0.05) **Nausea:** **G1:** 30.4 **G2:** 12.7 (*P* ≤ 0.001) **Asthenia:** **G1:** 21.3 **G2:** 6.9 (*P* ≤ 0.001) **Anxiety:** **G1:** 17.6 **G2:** 8.8 (*P* ≤ 0.05) **Tremor:** **G1:** 14.2 **G2:** 2.0 (*P* ≤ 0.001) **Dizziness:** **G1:** 12.5 **G2:** 3.9 (*P* ≤ 0.05) **Yawning:** **G1:** 12.2 **G2:** 0.0 (*P* ≤ 0.001) **Sweating:** **G1:** 9.5 **G2:** 2.0 (*P* ≤ 0.05) **Decreased Libido:** **G1:** 6.4 **G2:** 1.0 (*P* ≤ 0.05) **Depression:** **G1:** 10.1 **G2:** 18.6 (*P* ≤ 0.05)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Goldstein et al., 1995 (continued)			**> 1 Purging Behavior:** **G1:** 27.5% **G2:** 32.8% (*P* = NS)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
			Myalgia: **G1:** 4.7 **G2:** 11.8 *(P* ≤ 0.05) **Emotional lability:** **G1:** 2.7 **G2:** 7.8 *(P* ≤ 0.05) **Conjunctivitis:** **G1:** 0.3 **G2:** 2.9 *(P* ≤ 0.05) **Funding:** Eli Lilly

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Goldstein et al., 1995 (continued)	**Vomiting episodes/wk, median (range):** **G1:** 9 (1 - 94) **G2:** 9 (0 - 225) *(P* = NS)	**% Change in vomiting episodes/wk, median:** **G1, G2:** data shown in figure Diff between groups *(P* < 0.017) G1 better than G2 through wk 10, and during wk 13 and 16 Diff between groups in change over time *(P* = NR)
	Vomiting days/wk, median (range): **G1:** 6 (0 - 15) **G2:** 5.5 (0 - 12) *(P* = NS)	**Change in vomiting episodes/wk at endpoint, median (range):** **G1:** -4 (-64 - 34) *(P* = NR) **G2:** -2 (-55 - 58) *(P* = NR) Diff between groups *(P* < 0.0005) G1 better than G2 Diff between groups in change over time *(P* = NR) **% Change in vomiting episodes/wk at endpoint, median:** **G1:** -50 *(P* = NR) **G2:** -21 *(P* = NR) Diff between groups *(P* < 0.0001) G1 better than G2 Diff between groups in change over time *(P* = NR) **Vomiting Remission:** **G1:** 19% **G2:** 12% *(P* = NR) **Vomiting Treatment Responders (≥ 50% improvement):** **G1:** 53.1% **G2:** 35.0% Diff between groups *(P* = 0.002) G1 better than G2
	Binge-eating episodes/wk, median (range) **G1:** 9 (0 - 68) **G2:** 9.5 (1 - 150) *(P* = NS)	**Change in binge-eating episodes/wk, median:** G1, G2: data shown in figure Diff between groups *(P* < 0.01) G1 better than G2 through wk 9, and during wk 13 and 16 Diff between groups in change over time *(P* = NR) **Change in binge-eating episodes/wk at endpoint, median (range):** **G1:** -4 (-59 - 30) **G2:** -2 (-143 - 40) Diff between groups *(P* < 0.0003) G1 better than G2 Diff between groups in change over time *(P* = NR)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
HRSD, median: **G1:** 10 **G2:** 8.5 *(P* = NS)	**Change in HRSD, median (Range):** **G1:** -4 (-20 - 20) *(P* = NR) **G2:** -3 (-27 - 9) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)	**Wt, kg, median (range):** **G1:** 58 (39 - 132) **G2:** 58 (43 - 96) *(P* = NS)	**Change in wt, kg, median:** **G1:** -0.45 *(P* = NR) **G2:** 0.16 *(P* = NR) Diff between groups *(P* = 0.001) G1 better than G2 Diff between groups in change over time *(P* = NR)
CGI, median (range): **G1:** 5 (3 - 7) **G2:** 5 (3 - 7) *(P* = NS)	**CGI, median (range):** **G1:** 2 (1 - 6) *(P* = NR) **G2:** 3 (1 - 6) *(P* = NR) Diff between groups *(P* < 0.0001) G1 better than G2 Diff between groups in change over time *(P* = NR)		
PGI: **G1:** NR **G2:** NR *(P* = NR)	**PGI, median (range):** **G1:** 2 (1 - 6) *(P* = NR) **G2:** 3 (1 - 5) *(P* = NR) Diff between groups *(P* < 0.0001) G1 better than G2 Diff between groups in change over time *(P* = NR)		

Evidence Table 5. Medication trials for bulimia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Goldstein et al., 1995 (continued)	**Binge-eating days/wk, median (range):** **G1:** 6 (0 - 15) **G2:** 6 (1 - 12) *(P* = NS)	**% Change in binge-eating episodes/wk at endpoint, median:** **G1:** -50 *(P* = NR) **G2:** -18 *(P* = NR) Diff between groups *(P* < 0.0002) G1 better than G2 Diff between groups in change over time *(P* = NR) **Binge-eating Remission (%):** **G1:** 18.3% **G2:** 12.0% Diff between groups *(P* = NR) **Binge-eating Treatment Responder (≥ 50% improvement):** **G1:** 51.4% **G2:** 36.0% Diff between groups *(P* = 0.008) G1 better than G2)
	EDI Total: **G1:** NR **G2:** NR	**Change in EDI Total, median:** **Total:** **G1:** -21 *(P* = NR) **G2:** -12 *(P* = NR) Diff between groups *(P* = 0.006) G1 better than G2 Diff between groups in change over time *(P* = NR)
	EDI Bulimia: **G1:** NR **G2:** NR	**Change in EDI Bulimia, median:** **G1:** -6 *(P* = NR) **G2:** -3 *(P* = NR) Diff between groups *(P* = 0.003) G1 better than G2 Diff between groups in change over time *(P* = NR)
	EDI Drive for Thinness: **G1:** NR **G2:** NR	**Change in EDI Drive for Thinness, median:** **G1:** -3 *(P* = NR) **G2:** -1 *(P* = NR) Diff between groups *(P* = 0.040) G1 better than G2 Diff between groups in change over time *(P* = NR)
	EDI Body Dissatisfaction: **G1:** NR **G2:** NR	**Change in EDI Body Dissatisfaction, median:** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Hedges et al., 2003 **Companion article:** Hoopes et al., 2003 **Setting:** Idaho and UT Outpatient **Enrollment period:** 4/1999 to 12/2000	**Research objective:** To investigate topiramete's effect on psychological symptoms associated with disordered eating.	**Groups:** **G1:** Topiramate (N = 34) **G2:** Placebo (N = 34) **Enrollment:** • Randomized (N = 69) • Discontinued after washout: Total Sample (N = 1) G1 (N = 1) G2 (N = 0) • Evaluable for safety and received at least 1 dose of study med: Total (N = 68) G1 (N = 34) G2 (N = 34) • Returned for at least 1 post-baseline assessment (included in ITT): Total (N = 64) G1 (N = 31) G2 (N = 33) • Discontinued tx: Total (N = 28) G1 (N = 12) G2 (N = 16) • Completed: Total (N = 40) G1 (N = 22) G2 (N = 18) *(P* = NR)	**Age, yrs, mean (SD):** **G1:** 29.0 (9.7) **G2:** 29.6 (8.1) *(P* = NS) **Sex:** **Female, N:** **G1:** 33 **G2:** 34 *(P* = NS) **Race/ethnicity:** NR **Wt, kg (mean):** **G1:** 61.5 **G2:** 67.4 *(P* = NR)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Age: 16 – 50; DSM IV criteria for BN for at least 6 mo. **Exclusion:** Recent hx of clinically sig suicidality, substance abuse, bipolar I or II, major depressive, anxiety, or personality disorder that could have interfered with assessments. Hx of nephrolithiasis. Currently pregnant or lactating. Use of psychoactive meds within 2 wks prior to the study other than occasional use of short-acting sedatives for sleep. Dx of AN, BMI of ≤ 17, serum potassioum level < 3.0 mmol/L. Patients were not permitted to initiate psychotherapy during the study, but were allowed to be randomized if psychotherapy had been started 3 mo prior to the study.	2 to 4 wk screening and washout period during which baseline values established. Study med: 25 mg or 100 mg tablets of topiramate or placebo. Topiramate started at 25 mg/day for the first wk and titrated by 25 to 50 mg/wk until max tolerated dose, complete or near-complete efficacy, or max daily dose of 400 mg achieved. Once this level was achieved, patients continued at that dose through wk 10. Patients allowed 1 reduction in dose during titration period if they experienced side effects. Patients seen wkly for 10 wks and then tapered from study meds and offered option to continue into a 40 wk open label extension. Topiramate dose, mean (range): 100 mg/day (25 – 400 mg/day).	% change from baseline compared by a Wilcoxon rank sum test; ANCOVA; Cochran-Mantel-Haenszel test stratified by site	**Score:** Fair **Intent to treat:** Yes **Blinding:** Double **Adverse events, N (%):** **Fatigue:** **G1:** 11 (32%) **G2:** 8 (24%) **Flulike symptoms:** **G1:** 10 (29%) **G2:** 6 (18%) **Paresthesia:** **G1:** 8 (24%) **G2:** 2 (6%) **Hypoesthesia:** **G1:** 7 (21%) **G2:** 1 (3%) **Nausea:** **G1:** 6 (18%) **G2:** 3 (9%) **Constipation:** **G1:** 5 (15%) **G2:** 2 (6%) **Difficulty with Concentration:** **G1:** 5 (15%) **G2:** 2 (6%) **Nervousness:** **G1:** 4 (12%) **G2:** 2 (6%) **Headache:** **G1:** 4 (12%) **G2:** 5 (15%) Diff between groups in all adverse effects *(P* = NR) **Funding:** Ortho-McNeil Pharmaceutical, Inc.

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Hedges et al., 2003 (continued)	**EDI: Bulimia/uncontrollable overeating, mean (SD):** **G1:** 10.4 (5.0) **G2:** 11.5 (5.1) *(P* = NS)	**EDI: Bulimia/uncontrollable overeating, mean (SD):** **G1:** 5.9 (5.5) **G2:** 10.3 (6.8) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.005) G1 better than G2
	EDI: Body dissatisfaction: mean (SD): **G1:** 16.7 (8.2) **G2:** 19.1 (8.7) *(P* = NS)	**EDI: Body dissatisfaction: mean (SD):** **G1:** 14.2 (8.5) **G2:** 19.9 (8.5) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.007) G1 better than G2
	EDI: Drive for thinness, mean (SD): **G1:** 14.1 (5.6) **G2:** 16.2 (4.0) *(P* = NS)	**EDI: Drive for thinness, mean (SD):** **G1:** 10.9 (5.7) **G2:** 15.3 (4.4) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.002) G1 better than G2
	EAT: Bulimia/food preoccupation, mean (SD): **G1:** 11.5 (4.3) **G2:** 12.4 (3.9) *(P* = NS)	**EAT: Bulimia/food preoccupation, mean (SD):** **G1: 7.9 (5.2)** **G2:** 10.9 (5.2) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.19) G1 better than G2
	EAT: Dieting, mean (SD): **G1:** 18.3 (8.3) **G2:** 22.5 (7.5) *(P* = NS)	**EAT: Dieting, mean (SD):** **G1:** 15.2 (9.0) **G2:** 20.6 (8.1) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.031) G1 better than G2
	EAT: Oral control, mean (SD): **G1:** 2.8 (3.4) **G2:** 3.3 (3.5) *(P* = NS)	**EAT: Oral control, mean (SD):** **G1:** 2.5 (3.1) **G2:** 2.8 (3.4) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	EAT: Total score, mean (SD): **G1:** 32.5 (12.8) **G2:** 37.8 (12.0) *(P* = NS)	**EAT: Total score, mean (SD):** **G1:** 25.6 (14.6) **G2:** 33.8 (13.6) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.022) G1 better than G2

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
	Change in HAM– A, mean: **G1:** -4.0 **G2:** -1.7 Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.046) G1 better than G2 **Change in HAM– D, mean:** **G1:** -2.9 **G2:** -1.3 Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **PGI, % improved:** **G1:** 61.3% **G2:** 36.4% Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.004) G1 better than G2 **Change in PGI, %, mean:** **G1:** No change: 38.7% Minimally improved: 25.8% Much improved: 22.6% Very much improved: 12.9% **G2:** No change: 63.6% Minimally improved: 30.3% Much improved: 6.1% Very much improved: 0%		

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Hoopes et al., 2003 **Companion article:** Hedges et al., 2003 **Setting:** Idaho and UT Outpatient, USA **Enrollment period:** 4/1999 to 12/2000	**Research objective:** To assess the efficacy and safety of topiramate in BN	**Groups:** **G1:** Topiramate (N = 34) **G2:** Placebo (N = 34) **Enrollment:** • Randomized (N = 69) • Discontinued after washout: Total (N = 1) G1 (N = 1) G2 (N = 0) • Evaluable for safety and received at least 1 dose of study med: Total (N = 68) G1 (N = 34) G2 (N = 34) • Returned for at least 1 post-baseline assessment (included in ITT): Total (N = 64) G1 (N = 31) G2 (N = 33) • Discontinued tx: Total (N = 28) G1 (N = 12) G2 (N = 16) • Completed: Total (N = 40) G1 (N = 22) G2 (N = 18)	**Age, yrs, mean (SD):** **G1:** 29.0 (9.7) **G2:** 29.6 (8.1) *(P* = NS) **Sex:** Female, N: **G1:** 33 **G2:** 34 *(P* = NS) **Race/ethnicity:** NR **Reported Self-induced vomiting, N (%):** 64 (100) *(P* = NS) **Reported Laxative use, N (%):** 13 (20.3%) *(P* = NS) **Reported diuretic use, N (%):** 5 (7.8%) *(P* = NS) **Reported fasting, N (%):** 11 (17.2%) *(P* = NS)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Age: 16 – 50; DSM IV criter for BN for at least 6 mo. **Exclusion:** Recent hx of clinically sig suicidality, substance abuse, bipolar I or II, major depressive, anxiety, or personality disorder that could interfere with assessments. Hx of nephrolithiasis. Currently pregnant or lactating. Use of psychoactive meds within 2 wks prior to the study other than occasional use of short-acting sedatives for sleep. Dx of AN, BMI of ≤ 17, serum potassioum level < 3.0 mmol/L. Patients not permitted to initiate psychotherapy during the study, but allowed to be randomized if psychotherapy had been started 3 mo prior to study.	Participants underwent 2 to 4 wk screening and washout period during which baseline values established. Study med provided as 25 mg or 100 mg tablets of topiramate or placebo. Topiramate started at 25 mg/day for first wk and was then titrated by 25 to 50 mg/wk until max tolerated dose, complete or near-complete efficacy, or max daily dose of 400 mg achieved. Once this level was achieved, patients continued at that dose through wk 10. Patients allowed 1 reduction in dose during the titration period if they experienced side effects. Patients seen wkly for 10 wks and then tapered from study meds and offered the option to continue into a 40 wk open label extension. Topiramate dose, mean (range): 100 mg/day (25 – 400 mg/day).	Wilcoxon rank sum test, ANCOVA, Cochran-Mantel-Haenszel test stratified by site	**Score:** Fair **Intent to treat:** Yes **Blinding:** Double **Adverse events:** **G1:** 1 drop out due to nausea **G2:** 2 drop outs due to facial rash and irritability. No serious adverse events, generally mild/moderate in nature, resolved with time or dose reduction. **N (%):** **Fatigue:** **G1:** 11 (32) **G2:** 8 (24) **Influenza-like symptoms:** **G1:** 10 (29) **G2:** 6 (18) **Paresthesia:** **G1:** 8 (24) **G2:** 2 (6) **Hypoesthesia:** **G1:** 7 (21) **G2:** 1 (3) **Nausea:** **G1:** 6 (18) **G2:** 3 (9) **Constipation:** **G1:** 5 (15) **G2:** 2 (6) **Difficulty with concentration/ attention:** **G1:** 5 (15) **G2:** 2 (6) **Headache:** **G1:** 4 (12) **G2:** 5 (15) **Nervousness:** **G1:** 4 (12) **G2:** 2 (6) (*P* = NR) **Funding:** Ortho-McNeil Pharmaceutical, Inc.

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Hoopes et al., 2003 (continued)	**Binge and/or Purge days per wk, mean (SD):** **G1:** 5.0 (1.6) **G2:** 5.1 (1.5) *(P* = NS)	**Change in binge/purge days per wk, %, mean:** **G1:** -44.8% **G2:** -10.7% Diff between groups *(P* = 0.004) G1 better than G2) Diff between groups in change over time *(P* = NR) **Achieved at least moderate improvement (≥ 50% reduction) in number of binge and/or purge days, N (%):** **G1:** 16/31 (51.6%) **G2:** 8/33 (24.2%) Diff between groups *(P* = 0.012) G1 better than G2 Diff between groups in change over time *(P* = NR) **Achieved marked improvement (≥ 75% reduction) or complete remission of binge and/or purge days, N (%):** **G1:** 9/31 (29.0%) **G2:** 2/33 (6.1%) Diff between groups *(P* = 0.021) G1 better than G2 Diff between groups in change over time *(P* = NR) **Remission of binge and/or purge days, N (%):** **G1:** 7/31 (22.6%) **G2:** 2/33 (6.1%) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
	Binge days per wk, mean (SD): **G1:** 4.8 (1.7) **G2:** 4.7 (1.7) *(P* = NS) **Binge episodes per wk, mean (SD):** **G1:** 10.8 (10.4) **G2:** 11.3 (10.7) *(P* = NS)	**Change in binge days per wk, %, mean:** **G1:** -48.2% **G2:** -17.7% Diff between groups *(P* = 0.015) G1 better than G2) Diff between groups in change over time *(P* = NR) **Achieved at least moderate improvement in number of binge days, N (%):** **G1:** 19/31 (61.3%) **G2:** 10/33 (30.3%) Diff between groups *(P* = 0.032) G1 better than G2 Diff between groups in change over time *(P* = NR) **Change in wkly binge frequency, %, mean:** **G1:** -49.2% **G2:** -28.0% Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NRS)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
CGI-S, mean (SD): **G1:** 4.9 (0.7) **G2:** 4.6 (0.7) *(P* = NS)	**CGI-S, mean (SD):** **G1:** 3.7 (1.4) **G2:** 4.3 (1.1) Diff between groups *(P* = 0.022) G1 better than G2 Diff between groups in change over time *(P* = NR)	**Wt, kg, mean (SD):** **G1:** 61.3 (10.3) **G2:** 65.9 (14.2) *(P* = NS)	**Change in wt, kg (lb), mean:** **G1:** -1.8 (-4.0) **G2:** 0.2 (0.4) Diff between groups *(P* = 0.004) G1 better than G2) Diff between groups in change over time *(P* = NR)
CGI–I, mean (SD): **G1:** NR **G2:** NR	**CGI–I, mean (SD):** **G1:** 2.8 (1.3) **G2:** 3.6 (1.0) Diff between groups *(P* = 0.004) G1 better than G2 Diff between groups in change over time *(P* = NR)		

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Hoopes et al., 2003 (continued)	**Purge days per wk, mean (SD):** **G1:** 4.8 (1.9) **G2:** 4.8 (1.6) *(P* = NS) **Purge episodes per wk, mean (SD):** **G1:** 13.3 (13.5) **G2:** 12.4 (13.0) *(P* = NS)	**Change in purge days per wk, %, mean:** **G1:** -43.4% **G2:** -16.6% Diff between groups *(P* = 0.016) G1 better than G2 Diff between groups in change over time *(P* = NR) **Achieved at least moderate improvement in number of purge days per wk, N (%):** **G1:** 16/31 (51.5%) **G2:** 8/33 (24.2%) Diff between groups *(P* = 0.021) G1 better than G2 Diff between groups in change over time *(P* = NR) **Change in wkly purge frequency, %, mean:** **G1:** -49.8% **G2:** -21.6% Diff between groups *(P* = 0.016) G1 better than G2 Diff between groups in change over time *(P* = NR)
	Bulimic Intensity Scale Score, mean (SD): **G1:** 7.1 (1.6) **G2:** 7.4 (1.8) *(P* = NS)	**Change in Bulimic Intensity Scale Score, %, mean:** **G1:** -37% **G2:**- 14% Diff between groups *(P* = 0.007) G1 better than G2 Diff between groups in change over time *(P* = NR)
	Carbohydrate Craving Scale score, mean (SD): **G1:** 7.0 (2.6) **G2:** 7.3 (2.4) *(P* = NS)	**Change in Carbohydrate Craving Scale score, %:** **G1:** -43% **G2:** -16% Diff between groups *(P* = 0.011) G1 better than G2 Diff between groups in change over time *(P* = NR)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Kanerva, Rissanen, and Sarna, 1995 **Setting:** Single center; outpatient; location: Department of Psychiatry and Adolescent Psychiatry of Helsinki University Central Hospital; Helsinki, Finland **Enrollment period:** NR	**Research objective:** To assess the efficacy and safety of fluoxetine (an SSRI) versus placebo in the tx of BN and its effect on associated eating-related attitudes, depression, and anxiety symptoms.	**Groups:** **G1:** fluoxetine (N = 24) **G2:** placebo (N = 26) **Enrollment:** • Potential subjects recruited through letters sent out to somatic and mental healthcare departments of hospital • 50 enrolled • 46 completers (**G1:** 22; **G2:** 24; *P* = NR)	**Age, yrs, mean:** Total Sample: 25.2 **Sex:** Female: 100% **Race/ethnicity:** NR

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Female; met DSM III-R criteria for BN; age 15+; BMI; ≥16 **Exclusion:** Pregnancy; lactation; inadequate contraception; major somatic or psychiatric illness (e.g., recent drug or alcohol abuse, severe depression or suicidal features, recent or concurrent use of other psychotropic drugs such as lithium or MAOIs); previous tx with fluoxetine; concurrent psychiatric tx	All subjects went through single-blind placebo run-in phase for first wk of study. Subjects then randomized to either 60 mg of fluoxetine or placebo for 8 wks.	Mann-Whitney U test to assess between group diffs on continuous variables of interest and Fisher's exact test to evaluate between group diffs on the categorical variables being studied at baseline, 4 wks and at 8 wks of tx. Repeated measures ANOVA for diffs between groups at mid-tx (4 wks) and post-tx (8 wks)	**Score:** Fair **Intent to treat:** No **Blinding:** Double **Adverse events:** Heart palpitations (**G2:** N = 1) Worsening hand tremor (**G1:** N = 5) **Funding:** Eli Lilly and Company grant Helsinki University Central Hospital

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Kanerva, Rissanen, and Sarna, 1995 (continued)	**Binges/wk, mean (SD):** **G1:** 9.2 (NR) **G2:** 10.5 (NR) *(P* = NR)	**End of Treatment (8 wks):** **Binges/wk, mean (SD):** **G1:** 5.3 *(P* = NR) **G2:** 5.7 *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
		Abstinence/Remission: NR
	BITE, mean (SD): **G1:** 24.3 (2.3) **G2:** 23.9 (3.5) *(P* = NR)	**BITE, mean (SD):** **G1:** 22.3 (4.3) *(P* = NR) **G2:** 22.1 (5.4) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	EAT Dieting mean (SD): **G1:** 14.6 (7.2) **G2:** 16.2 (7.6) *(P* = NR)	**EAT Dieting, mean (SD):** **G1:** 11.9 (7.0) *(P* = NR) **G2:** 14.1 (7.6) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	EAT Bulimia and Food Preoccupation, mean (SD): **G1:** 10.5 (4.0) **G2:** 10.5 (4.1) *(P* = NR)	**EAT Bulimia and Food Preoccupation, mean (SD):** **G1:** 6.3 (4.0) *(P* = NR) **G2:** 8.2 (4.5) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.033) G1 better than G2
	EAT Oral Control, mean (SD): **G1:** 3.4 (2.8) **G2:** 3.6 (3.1) *(P* = NR)	**EAT Oral Control, mean (SD):** **G1:** 2.9 (2.2) *(P* = NR) **G2:** 3.0 (2.6) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	EAT Total Score, mean (SD): **G1:** 40.3 (15.6) **G2:** 42.5 (16.4) *(P* = NR)	**EAT Total Score, mean (SD):** **G1:** 29.6 (13.3) *(P* = NR) **G2:** 35.9 (16.6) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	EDI Drive for Thinness, mean (SD): **G1:** 10.7 (5.2) **G2:** 13.6 (4.8) *(P* = NR)	**EDI Drive for Thinness, mean (SD):** **G1:** 9.2 (5.3) *(P* = NR) **G2:** 11.6 (5.5) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	EDI Bulimia, mean (SD): **G1:** 11.4 (2.6) **G2:** 12.9 (4.3) *(P* = NR)	**EDI Bulimia, mean (SD):** **G1:** 6.7 (4.8) *(P* = NR) **G2:** 7.4 (4.6) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
HDRS-21, mean (SD): **G1:** 12.2 (4.6) **G2:** 11.7 (5.8) *(P* = NR)	**At mid-tx (4 wks):** **HDRS-21, mean (SD):** **G1:** 7.4 (4.7) *(P* = NR) **G2:** 10.9 (5.6) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.0062) G1 better than G2 **End of Treatment (8 wks):** **HDRS-21, mean (SD):** **G1:** 7.1 (5.1) *(P* = NR) **G2:** 9.5 (5.5) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.05) G1 better than G2	**Wt, kg, mean (SD):** **G1:** 62.2 (15.4) **G2:** 63.0 (17.0) *(P* = NR)	**End of Treatment (8 wks):** **Wt, kg, mean (SD):** **G1:** 61.2 (12.9) *(P* = NR) **G2:** 65.7 (16.1) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.023) G1 better than G2
HDRS-17, mean (SD): **G1:** 9.3 (4.5) **G2:** 9.4 (4.9) *(P* = NR)	**At mid-tx (4 wks):** **HDRS-17, mean (SD):** **G1:** 5.9 (4.2) *(P* = NR) **G2:** 8.9 (4.6) *(P* = NR) Within group change from baseline *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.030) G1 better than G2 **End of Treatment (8 wks):** **HDRS-17, mean (SD):** **G1:** 5.5 (4.3) *(P* = NR) **G2:** 7.7 (4.8) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)		
HDRS-Depression mean (SD): **G1:** 5.3 (2.6) **G2:** 5.1 (2.4) *(P* = NR)	**At mid-tx (4 wks):** **HDRS-Depression, mean (SD):** **G1:** 2.2 (1.9) *(P* = NR) **G2:** 4.9 (2.8) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.0002) G1 better than G2 **End of Treatment (8 wks):** **HDRS-Depression, mean (SD):** **G1:** 2.0 (2.0) *(P* = NR) **G2:** 4.2 (2.8) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.0003) G1 better than G2		

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Kanerva, Rissanen, and Sarna, 1995 **(continued)**	**EDI Body Dissatisfaction, mean (SD):** **G1:** 12.8 (9.9) **G2:** 16.4 (7.9) *(P* = NR)	**EDI Body Dissatisfaction mean (SD):** **G1:** 10.3 (9.4) *(P* = NR) **G2:** 14.6 (8.1) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	EDI Total Score, mean (SD): **G1:** 69.4 (22.5) **G2:** 80.5 (26.1) *(P* = NR)	**EDI Total Score, mean (SD):** **G1:** 50.0 (23.7) *(P* = NR) **G2:** 61.9 (22.8) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
HDRS-Anxiety mean (SD): **G1:** 2.3 (1.1) **G2:** 1.8 (1.0) *(P* = NR)	**At mid-tx (4 wks):** **HDRS-Anxiety, mean (SD):** **G1:** 1.1 (1.0) *(P* = 0.0004) **G2:** 2.0 (1.4) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) **End of Treatment (8 wks):** **HDRS-Anxiety, mean (SD):** **G1:** 1.2 (1.2) *(P* = NR) **G2:** 1.8 (1.2) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.0013) G1 better than G2		
Spielberger State Anxiety mean (SD): **G1:** 50.3 (11.8) **G2:** 45.8 (11.4) *(P* = NR)	**At mid-tx (4 wks):** **Spielberger State Anxiety, mean (SD):** **G1:** 39.8 (8.3) *(P* = 0.0004) **G2:** 48.2 (10.7) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) **End of Treatment (8 wks):** **Spielberger State Anxiety, mean (SD):** **G1:** 42.5 (8.3) *(P* = NR) **G2:** 44.5 (11.2) *(P* = NR) Diff between groups (*P* = NR) Diff between groups in change over time *(P* = 0.0004) G1 better than G2		

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Kennedy et al., 1993 **Setting:** The Toronto Hospital, Outpatient, Canada **Enrollment period:** NR	**Research objective:** Evaluate efficacy of Brofaromine on eating behavior and attitude towards wt shape and psychopathology in women with BN.	**Groups:** **G1:** Brofaromine (N = 19) **G2:** Placebo (N = 17) **Enrollment:** • 110 women screened and 38 enrolled. • All participants completed single-blind placebo phase during which binge eating and vomiting episodes recorded. • Individuals who reported fewer than 3 binge episodes a wk or experienced a 50% reduction in binge frequency were removed from study. • 2 participants dropped during the single blind washout phase. • 4 dropped out of each tx group after 4 wks	**Age, yrs, mean (SD):** **G1:** 27.6 (6.7) **G2:** 25.9 (6.4) **Sex:** Female: 100% **Race/ethnicity:** NR **Duration of illness, yrs, mean (SD):** **G1:** 14.3 (15.3) **G2:** 13.8 (10.1) **Diagnostic comorbidity, %:** **Major Depression:** **Current:** **G1:** 26% **G2:** 24% **Past:** **G1:** 63% **G2:** 47% **Dysthymic Disorder:** **Current:** **G1:** 5% **G2:** 6% **Past:** **G1:** 5% **G2:** 12% **Substance abuse:** **Current:** **G1:** 0 **G2:** 0 **Past:** **G1:** 21% **G2:** 18% **Panic with Agoraphobia:** **Current:** **G1:** 0 **G2:** 0 **Past:** **G1:** 5% **G2:** 12% **Panic without Agoraphobia:** **Current:** **G1:** 0 **G2:** 12%

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Women, 18-40 yrs, met DSM III-R criteria for BN who engaged in vomiting as the primary method of purging. **Exclusion:** Wt < 85% or > 125% of statistical avg for age and height; use of any psychotropic meds in the preceding 4 wks; presence of suicidal ideation, substance abuse or medical instability (including aserum potassium of < 3 µmol/liter).	Both groups received identical looking capsules. Dosing started at 25 mg and increased on days 4, 7, 11, 15 and 19 to reach max permitted dose of 200 mg [mean = 175 mg, range 75 to 200 mg] given in a twice daily regimen. Clinicians could omit dose increment due to reported side effects. After randomization, participants assessed once every 2 wks for remainder of the 8-wk trial. Sessions lasted 10 to 20 m and included review of symptom changes, adverse events, and compliance.	Repeated measures ANCOVA for binge, purge and meal completion data. Binge and purge data log transformed prior to analysis. Only completers included in analyses. Baseline values included as covariates for eating and psychological measures.	**Score:** Fair **Intent to treat:** No **Blinding:** Double **Adverse events:** 2 individuals in G1 experienced intolerable side effects (nausea) and dropped out and 1 individual from G2 reported headaches and dropped out. Common side effects included sleep disturbance, nausea and dizziness among G1 participants. Headache, dry mouth, and nausea were common side effects for G2. **Funding:** Ciba-Geigy Canada and Ontario Mental Health Foundation

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Kennedy et al., 1993 (continued)			**Past:** **G1:** 0 **G2:** 12% **Generalized Anxiety:** **Current:** **G1:** 5% **G2:** 0 **Past:** **G1:** 0 **G2:** 0 **Social Anxiety:** **Current:** **G1:** 11% **G2:** 0 **Past:** **G1:** 11% **G2:** 0 **Simple phobia:** **Current:** **G1:** 16% **G2:** 0 **Past:** **G1:** 11% **G2:** 0 **Obsessive-compulsive disorder:** **Current:** **G1:** 0 **G2:** 6% **Past:** **G1:** 0 **G2:** 6% **Somatoform pain disorder:** **Current:** **G1:** 0 **G2:** 6% **Past:** **G1:** 0 **G2:** 0

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality

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Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Kennedy et al., 1993 (continued)	**Binge eating episodes/wk, mean (SD):** **G1:** 9.1 (5.7) **G2:** 8.8 (3.7) *(P* = NS)	**Binge eating episodes/wk, mean (SD):** **G1:** 3.5 (3.0) *(P* = NR) **G2:** 4.4 (3.9) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	Vomiting episodes/wk, mean (SD): **G1:** 10.2 (12.9) **G2:** 7.5 (6.5) *(P* = NS)	**Vomiting episodes/wk, mean (SD):** **G1:** 2.6 (3.0) *(P* = NR) **G2:** 5.7 (6.3) *(P* = NR) Diff between groups *(P* < 0.02) G1 better than G2 Diff between groups in change over time *(P* = NS)
	Non-binge meals/wk, mean (SD): **G1:** 8.8 (6.9) **G2:** 14.1 (5.5) *(P* < 0.02)	**Non-binge meals/wk, mean (SD):** **G1:** 11.6 (6.5) *(P* = NR) **G2:** 17.9 (2.7) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* < 0.04) G2 better than G1 at wk 8 only
	EAT-26, mean (SD): **G1:** 36.5 (12.4) **G2:** 34.6 (14.9) *(P* = NS)	**EAT-26, mean (SD):** **G1:** 24.4 (15.3) *(P* = NR) **G2:** 23.9 (15.0) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	EDI-Body Dissatisfaction, mean (SD): **G1:** 18.4 (9.2) **G2:** 19.4 (9.6) *(P* = NS)	**EDI-Body Dissatisfaction, mean (SD):** **G1:** 19.5 (9.9) *(P* = NR) **G2:** 18.3 (9.6) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	EDI-Bulimia, mean (SD): **G1:** 14.3 (4.8) **G2:** 13.6 (3.3) *(P* = NS)	**EDI-Bulimia, mean (SD):** **G1:** 5.9 (5.9) *(P* = NR) **G2:** 7.9 (5.3) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	EDI-Drive for thinness, mean (SD): **G1: 15.7 (4.6)** **G2:** 14.4 (6.2) *(P* = NS)	**EDI-Drive for thinness, mean (SD):** **G1: 13.5 (6.1) *(P* = NR)** **G2:** 12.4 (5.9) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
HAM-D, mean (SD): **G1:** 14.5 (8.7) **G2:** 12.4 (8.7) *(P* = NS)	**HAM-D, mean (SD):** **G1:** 7.5 (6.7) *(P* = NR) **G2:** 6.8 (7.9) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)	**Wt, kg, mean (SD):** **G1:** 70.2 (18.6) **G2:** 62.8 (10.9) *(P* = NS)	**Wt, kg, mean (SD):** **G1:** NR **G2:** NR Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **Change in Wt (%):** **> 1 kg wt loss:** **G1:** 53% **G2:** 12% Diff between groups *(P* = NR) G1 better than G2 **> 1 kg wt gain:** **G1:** 32% **G2:** 53% Diff between groups *(P* = NR) G1 better than G2 Chi-square *(P* < 0.05)
HAM-A, mean (SD): **G1:** 13.4 (7.9) **G2:** 11.3 (8.8) *(P* = NS)	**HAM-A, mean (SD):** **G1:** 7.6 (7.8) *(P* = NR) **G2:** 5.9 (6.7) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)	**BMI, kg/m^2, mean (SD):** **G1:** 26.2 (6.5) **G2:** 24.2 (4.8) *(P* = NS)	**BMI, kg/m^2, mean (SD):** **G1:** NR **G2:** NR

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Kennedy et al., 1993 (continued)		**Abstinence from vomiting, %:** **Wk 4:** **G1:** 56% **G2:** 27% **End of tx:** **G1:** 44% **G2:** 20% (*P* = NS)
		Abstinence from bingeing, %: **Wk 4:** **G1:** 31% **G2:** 7% **End of tx:** **G1:** 19% **G2:** 13% (*P* = NS)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Pope et al., 1989 **Setting:** Outpatients of a teaching hospital in the USA **Enrollment period:** NR	**Research objective:** To assess the efficacy of trazodone compared to placebo and its adverse effects in BN	**Groups:** **G1:** Trazodone (N = 23) **G2:** Placebo (N = 23) **Enrollment:** • 56 recruited and entered 2 wk placebo washout period • 10 eliminated during placebo period (5 drop outs, 1 reduced sx, 1 sickness, 3 lab abnormalities) • 46 randomized (N = 23 each condition) • 42 completed at least 4 wks of tx • **G1** (N = 20) (1 hospitalized for alcohol dependence, 2 did not return after baseline) • **G2** (N = 22) (1 developed medical condition and was withdrawn_ • 5 terminated on or after wk 4 and termination scores were based on 14-day period before termination day	**Age, yrs, mean (SD):** **Total sample:** 26.0 **G1:** 25.7 (N = 20) **G2:** 26.2 **(**N = 22) *(P* = NS) **Sex:** Female: 100% **Race/ethnicity:** NR **% IBW, mean:** **Total: 98.3** **G1:** 98.4 **G2:** 98.2 *(P* = NS) **Duration of bulimic symptoms, yrs, mean:** **Total: 7.4** **G1:** 6.8 **G2:** 7.9 *(P* = NS) **SCID Current major depression, N:** **Total: 10 (24%, 3 of which were bipolar)** **G1:** 6 **G2:** 4 **SCID Hx of AN, N:** **Total: 6**

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: DSM III-R criteria for BN (at least 3 binge episodes per wk and duration of 3 mos, as opposed to 2 per wk and for only 3 mos); age: 18-55; wt between 80% and 140% of IBW; use of vomiting as principal method of purging **Exclusion:** No sig medical disorder; pregnant, at risk for pregnancy, nursing; taking meds with psychotropic effects; psych med within 14 days of baseline; investigational meds within 28 days of baseline; active suicidal ideation, current drug/alcohol abuse, psychotic symptoms; hx of drug hypersensitivity; hx of failure to respond to an adequate trial of antidepressants or ECT; starting any other non-pharmacological therapy within 2 mo before or after baseline.	2 wk placebo wash out. Randomized to trazodone (50 mg) or placebo and instructed to raise the dose by 1 tablet every second day to a max of 8 tablets (trazodone 400 mg). Allowed to raise dose more slowly or take $\leq$ 8 if side effects. 6 wks of active drug phase and seen at wks 2, 4, 6. Assessment at baseline and wk 6	Wilcoxon rank sum, 2-tailed for frequency fx of binge eating between groups. Diff. in proportions between groups assessed by Fisher's exact test, 2-tailed.	**Score:** Fair **Intent to treat:** No **Blinding:** Double **Adverse events:** Sig more patients on trazodone than on placebo suffered dizziness, 29% vs. 4% (P = 0.042) and drowsiness, 52% vs. 17% (P = 0.025) **Funding:** Bristol-Myers Pharmaceuticals and NIMH

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Pope et al., 1989 (continued)	**Current frequency of binges/wk:** **G1:** 11.3 **G2:** 12.8 *(P* = NS)	**Current frequency of binges/wk:** **G1:** data in graph *(P* < 0.05) **G2:** data in graph *(P* = NS) **% change in Binge Eating:** **G1:** 31% reduction **G2:** 21% increase Diff between groups *(P* < 0.001) G1 better than G2 **Remission of Binge Eating, N (%):** **G1:** 2 (10%) **G2:** 0 *(P* = NR)
	Current frequency of vomiting/wk: **G1:** NR **G2:** NR *(P* = NR)	**Current frequency of vomiting/wk:** **G1:** data in graph *(P* < 0.05) **G2:** data in graph *(P* = NS) **% change in vomiting frequency:** **G1:** NR **G2:** NR Diff between groups *(P* < 0.001) G1 better than G2
		Self-Report measures: **Fear of Eating:** **G1:** NR *(P* < 0.05) **G2:** NR *(P* = NS) Diff between groups *(P* = 0.007) G1 better than G2 **Self -control:** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Diff between groups *(P* = NS) **Self-esteem:** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Diff between groups *(P* = 0.009) **Global Improvement:** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Diff between groups *(P* = NS) **Preoccupation with food:** Data NR G1 = G2 Diff between groups *(P* = NS) **Intensity of binges:** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Diff between groups *(P* = NS) **Self-control regarding food:** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Diff between groups *(P* = NS)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
			No relation between blood trazodone plasma levels and degree of clinical improvement. Data NR
HAM-D (mean): Total sample: 12.4 **G1:** NR **G2:** NR	**HAM-D:** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Diff between groups *(P* = NS)		
HAM-A (mean): Total sample: 9.8 **G1:** NR **G2:** NR	**HAM-A:** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Diff between groups *(P* = NS)		
	Patient-rating of effectiveness of tx (4 patient Likert scale): **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Diff between groups *(P* = 0.04) G1 better than G2		

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Romano et al., 2002 **Setting:** 16 sites in USA (NY, MA, CA, MD, IL, NM, UT, NC, TN, PA, FL, WI, KS); Outpatient, USA **Enrollment period:** NR	**Research objective:** Evaluate fluoxetine versus placebo in preventing relapse of BN over one yr	**Groups:** **G1:** Fluoxetine (N = 76) **G2:** Placebo (N = 74) **Enrollment:** • 265 in initial screening • 1 wk no-therapy screening phase • 232 received single-blind acute therapy (60 mg/day of fluoxetine) • After 8 wks of acute tx, 150 responders randomly assigned to 60 mg/day of fluoxetine or placebo (double-blind therapy) • Nonresponders and patients unable to tolerate 60 mg/day were discontinued	**Age, yrs, mean (SD):** **G1:** 29.5 (7.0) **G2:** 30.0 (9.3) *(P* = NS) **Sex:** Female: **G1:** 97% **G2:** 98.6% *(P* = NS) **Race/ethnicity:** Caucasian: **G1:** 93% **G2:** 88% *(P* = NS)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Male and female outpatients, at least 18 yrs old with a psychiatric dx of BN, purging type (as defined by DSM IV). Purging must included self-induced vomiting. **Exclusion:** Participated in a prior fluoxetine study or taken fluoxetine within 5 wks before enrollment or previously treated with 60 mg/day of fluoxetine for longer than 8 wks. Co-existing schizophrenia or bipolar disorder, mood-congruent or incongruent psychotic features, serious suicidal risk, organic brain disease, hx of seizures, medically unstable condition or hx of an alcohol and/or other substance abuse disorder within 3 mos before enrollment. Also, patients who had used a monoamine oxidase inhibitor within 2 wks before enrollment had used other investigational drugs or psychoactive meds within 4 wks before enrollment had received CBT within 4 wks of enrollment or who planned to begin a structured, focused therapy at any time during the study were excluded.	After one-wk of no-therapy screening, patients assigned to acute, single blind tx with 60 mg/day of fluoxetine. During screening and acute tx phase patients seen by the investigators each wk. Dosage adjustment allowed in first 2 wks at clinician's discretion if patient unable to tolerate 60 mg initially. To be considered a "tx responder" at the end of acute period, patients must have experienced a decrease of ≥ 50% in frequency of vomiting episodes during at least 1 of 2 preceding wks compared to baseline. After 8 wks of acute tx, tx responders randomly assigned to receive 60 mg of fluoxetine or placebo for up to 52 wks. Study meds packaged in blister packs that contained 20 mg of fluoxetine capsules or matching placebo capsules. At each visit, patients returned the blister pack so that remaining capsules could be counted. Patients who missed meds for 5 consecutive days or who failed to attend visits within stated periods were deemed noncompliant and withdrawn from study. During 52-wk double blind therapy phase, visits occurred at 2-wk intervals during first 8 wks and at 4-wk intervals after that. The primary efficacy measure was change in the number of vomiting episodes per wk.	Time to relapse curves estimated for each tx group and a two sided log rank test used to compare time to relapse distributions. Tx diffs assessed with Fisher's exact test for categorical variables and student's t test for continuous variables.	**Score:** Fair **Intent to treat:** Yes **Blinding:** Double **Adverse events:** Rhinitis: **G1:** 31.6% **G2:** 16.2% (*P* < 0.04) **Unwanted Pregnancy:** **G1:** 2.6% **G2:** 4.1% (*P* = NR) **Funding:** Eli Lilly and Co.

Evidence Table 5. Medication trials for bulimia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline and at Random Assignment**	**Outcomes**
Author, yr: Romano et al., 2002 (continued)	**Vomiting episodes/wk**, mean (SD)**:** **G1:** 12.1 (8.7) **G2:** 14.0 (11.7) *(P* = NS) **Vomiting episodes/wk at random assignment**, mean (SD**):** **G1:** 4.1 (5.5) **G2:** 4.5 (6.1) *(P* = NS)	**Change in vomiting episodes/wk, mean (SD):** **G1:** 2.92 (7.08) **G2:** 4.82 (8.43) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.001) G1 better than G2 (less increase after random assignment)
	Binge eating episodes/wk, mean (SD)**:** **G1:** 10.3 (7.7) **G2:** 12.5 (10.1) *(P* = NS) **Binge eating episodes/wk at random assignment**, mean (SD)**:** **G1:** 3.0 (4.8) **G2:** 3.9 (5.1) *(P* = NS)	**Change in Binge eating episodes/wk, mean (SD):** **G1:** 2.47 (6.58) **G2:** 4.11 (6.70) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.02) G1 better than G2 (less increase after random assignment)
	EDI total, mean (SD)**:** **G1:** 76.6 (26.9) **G2:** 78.4 (29.9) *(P* = NS) **EDI total at random assignment**, mean (SD)**:** **G1:** 37.0 (22.0) **G2:** 39.1 (27.2) *(P* = NS)	**Change in EDI total, mean (SD):** **G1:** 7.79 (25.49) **G2:** 17.41 (24.45) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
		Relapse rate, %: **3 mos:** **G1:** 19% **G2:** 37% Diff between groups *(P* < 0.04) G1 better than G2 **6 mos:** **G1:** 29% **G2:** 43% *(P* = NS) **12 mos:** **G1:** 33% **G2:** 51% *(P* = NS) Two sided log rank test applied to Kaplan-Meier survival function *(P* < 0.02) G1 better than G2 **Abstinence/Remission:** NR

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
CGI severity score: **G1:** 4.5 (0.6) **G2:** 4.5 (0.7) *(P* = NS) **CGI severity at random assignment:** **G1:** 2.9 (1.0) **G2:** 2.9 (0.9) *(P* = NS)	**CGI severity mean change score (SD):** **G1:** 0.45 (1.33) **G2:** 0.97 (1.21) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.004) G1 deteriorated less than G2 **CGI Improvement severity mean change score (SD):** **G1:** 0.77 (1.43) **G2:** 1.37 (1.39) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.009) G1 deteriorated less than G2	**BMI:** **G1:** 22.5 (3.9) **G2:** 23.0 (3.8) *(P* = NS) **BMI at random assignment:** **G1:** NR **G2:** NR *(P* = NR)	**BMI:** **G1:** NR **G2:** NR Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
HDRS: **G1:** 10.5 (6.1) **G2:** 10.5 (5.9) *(P* = NS) **HDRS at random assignment:** **G1:** 4.6 (3.9) **G2:** 6.1 (5.3) *(P* = NS)	**HDRS mean change score (SD):** **G1:** 2.03 (5.66) **G2:** 3.23 (6.60) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)		
	Patient's global impression mean change score (SD): **G1:** 0.72 (1.54) **G2:** 1.37 (1.49) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.03) G1 deteriorated less than G2		

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
Author, yr: Romano et al., 2002 (continued)	**Yale-Brown Cornell ED Scale (YBC-EDS) score, mean** (SD)**:** **G1:** 18.8 (4.1) **G2:** 18.3 (5.1) *(P* = NS) **YBC EDS at random assignment, mean** (SD)**:** **G1:** 9.4 (4.8) **G2:** 9.4 (5.4) *(P* = NS)	**Change in YBC EDS, mean (SD):** **G1:** 2.92 (7.91) **G2:** 7.38 (6.80) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.002) G1 better than G2 (less increase after random assignment) **Change in YBC EDS preoccupation, mean** (SD)**:** **G1:** 1.53 (3.82) **G2:** 3.63 (3.74) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.008) G1 better than G2 (less increase after random assignment) **Change in YBC EDS ritual, mean** (SD)**:** **G1:** 1.35 (4.51) **G2:** 3.75 (3.79) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.008) G1 better than G2 (less increase after random assignment)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Sundblad et al., 2005 **Setting:** Single center Outpatient, Sweden **Enrollment period:** NR	**Research objective:** Comparison of efficacy of four txs for BN: flutamide (androgen antagonist) vs citalopram (SSRI) vs combination of flutamide and citalopram, vs placebo.	**Groups:** **G1:** Flutamide (N = 9) **G2:** Citalopram (N = 15) **G3:** Flutamide + Citalopram (N = 10) **G4:** Placebo (N = 12) **Enrollment:** • Individuals recruited through advertisements • Patients randomized to one of 4 conditions once consent obtained • Dropouts during tx (G1 = 3; G2 = 3; G3 = 2; G4 = 2)	**Age, yrs, mean:** **G1:** 29 **G2:** 26 **G3:** 25 **G4:** 28 **Sex:** Female: 100% **Race/ethnicity:** NR **Wt, kgs, mean:** **G1:** 58 **G2:** 61 **G3:** 61 **G4:** 61

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: DSM IV criteria for for BN, purging type, irregular menstruation allowed **Exclusion:** Age ≤ 18 yrs; other mental disorders	Initial dose of flutamide (250 mg/day) and citalopram (20mg/day) titrated within 2 wks to final doses of 500 mg/day and 40 mg/day, respectively. Subjects received no formal psychotherapy; supportive and educative therapy kept to a min. Tx lasted for 12 wks.	T-tests were used to evaluate within-group changes in symptom severity from baseline to end of tx. 2-sided Mann-Whitney U tests used to compare global effect of tx vs placebo on change in BN symptoms.	**Score:** Poor **Intent to treat:** Yes **Blinding:** Double **Adverse events:** 2 cases of elevated serum aminotrans-ferase in flutamide-tx group; both normalized after tx withdrawal. Nausea most common side effect for citalopram; dry skin most common for flutamide participants. **Funding:** H Lundbeck AB, Sweden and Swedish Medical Research Council

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Sundblad et al., 2005 (continued)	**BN symptom VAS, mean (SD):** **G1:** 52.0 (16.0) **G2:** 54.1 (13.9) **G3:** 44.5 (10.4) **G4:** 52.3 (17.2) *(P* = NR)	**BN symptom VAS, mean (SD):** **G1:** 29.5 (27.2) *(P* = 0.04) **G2:** 31.6 (22.6) *(P* = 0.003) **G3:** 26.4 (16.3) *(P* = 0.005) **G4:** 46.9 (21.9) *(P* = NS) Diff between groups G1, G2, G3 vs. G4 *(P* = NR) G1+G3 < G4 *(P* = 0.03) G2+G3 < G4 *(P* = 0.03) Diff between groups in change over time *(P* = NR) **% reduction BN VAS, mean (SD):** **G1:** 46 (15) *(P* = NR) **G2:** 41 (12) *(P* = NR) **G3:** 41 (11) *(P* = NR) **G4:** 8 (10) *(P* = NR) Diff between groups G1, G3 > G4 *(P* = 0.04) G1+G3 < G4 *(P* = 0.02) G2+G3 < G4 *(P* = 0.03)
	Binge eating episodes per wk, mean (SD): **G1:** 6.1 (1.8) **G2:** 6.6 (3.4) **G3:** 6.4 (2.1) **G4:** 8.0 (3.8) *(P* = NR)	**Binge eating episodes per wk (SD):** **G1:** 3.0 (3.0) *(P* = 0.01) **G2:** 4.9 (3.9) *(P* = NS) **G3:** 2.9 (2.0) *(P* = 0.0007) **G4:** 6.7 (5.9) *(P* = NS) Diff between groups G1, G2, G3 vs. G4 *(P* = NR) G1+G3 < G4 *(P* = 0.02) G2+G3 < G4 *(P* = NS) Diff between groups in change over time *(P* = NR) **% reduction binge episodes, mean (SD):** **G1:** 54 (40) *(P* = NR) **G2:** 21 (88) *(P* = NR) **G3:** 54 (28) *(P* = NR) **G4:** 15 (47) *(P* = NR) Diff between groups G3 > G4 *(P* = 0.04) G1, G2 *(P* = NS) G1+G3 < G4 *(P* = 0.01) Diff between groups in change over time *(P* = NR)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
	Global Rating of Sadness: **G1:** NR **G2:** NR **G3:** NR **G4:** NR Diff between groups *(P* = NR) Diff between groups in change (reduction) over time *(P* < 0.05) G2 and G3 better than G4 G2 vs G4 *(P* = NS) **Global Rating of Anxiety:** **G1:** NR **G2:** NR **G3:** NR **G4:** NR Diff between groups *(P* = NR) Diff between groups in change (reduction) over time *(P* < 0.05) G2 and G3 better than> G4 G2 vs G4 *(P* = NS)		

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Sundblad et al., 2005 (continued)	**Vomiting episodes, per wk, mean (SD):** **G1:** 8 (4) **G2:** 9 (7) **G3:** 7 (3) **G4:** 9 (3) *(P* = NR)	**Vomiting episodes per wk, mean (SD):** **G1:** 4 (4) *(P* = 0.01) **G2:** 6 (6) *(P* = NS) **G3:** 3 (3) *(P* = 0.0007) **G4:** 7 (5) *(P* = NS) Diff between groups G1, G2, G3 vs. G4 *(P* = NR) G1+G3 < G4 *(P* = NS) G2+G3 < G4 *(P* = NS) Diff between groups in change over time *(P* = NR) **% reduction vomiting episodes, mean (SD):** **G1:** 45 (56) *(P* = NR) **G2:** 28 (46) *(P* = NR) **G3:** 52 (36) *(P* = NR) **G4:** 31 (37) *(P* = NR) Diff between groups *(P* = NS) **BN symptom improvement, %:** **G1:** Enormously (22%), Much (22%), Somewhat (33%), No change (11%), Deterioration (11%) **G2:** Enormously (20%), Much (20%), Somewhat (33%), No change (27%), Deterioration (0%) **G3:** Enormously (10%), Much (40%), Somewhat (20%), No change (20%), Deterioration (10%) **G4:** Enormously (0%), Much (8%), Somewhat (17%), No change (50%), Deterioration (25%) **Global BN symptom change vs. placebo, Mann-Whitney U:** **G1:** 23.5 *(P* = 0.03) **G2:** 35.5 *(P* = 0.008) **G3:** 28.5 *(P* = 0.04)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics

Author, yr:
Walsh et al., 1991
 	
Setting:
Outpatient, New York, USA
 	
Enrollment period:
NR
	Research objective:
	Compare antidepressant desipramine with placebo in treating BN and examine long-term efficacy of drug.
		Groups:
		G1: placebo (N = 38)
		G2: desipramine (N = 40)
		
		Enrollment:
		• 217 individuals had screening interviews
		• 98 entered study (56 did not meet entry criteria, 46 refused and 17 who did not FU after screening)
		• Patients first entered into a 2-wk single-blind placebo washout phase
		• 10 patients dropped after washout phase because they had reduced binge eating by 75% or more or were binge eating less than twice a wk.
		• 8 patients dropped out.
		• 80 patients entered the double-blind trial.
		• Completers:
		  • 2 patients did not return after assignment and are not included in analyses
		  • **G1:** 32/38
		  • **G2:** 31/40
			Age, yrs, mean (SD):
			G1: 25.7 (5.6)
			G2: 24.8 (4.5)
			(P = NS)
			
			Height, inches, mean (SD):
			G1: 65.0 (2.7)
			G2: 65.4 (2.1)
			(P = NS)
			
			Wt, lbs, mean (SD):
			G1: 132.4 (17.8)
			G2: 136.2 (16.1)
			(P = NS)
			
			Sex:
			Female:
			G1: 100%
			G2: 100%
			(P = NS)
			
			Race/ethnicity:
			NR
			
			BMI, kg/m^2, mean (SD):
			G1: 22.0 (2.3)
			G2: 22.4 (1.9)
			(P = NS)
			
			Duration of illness, yrs, mean (SD):
			G1: 6.6 (4.5)
			G2: 6.7 (3.6)
			(P = NS)
			
			Hx of AN:
			23.1%
			
			Current Depression:
			51.3%

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: DSM III-R criteria for BN for at least 1 yr, only women between the ages of 18 and 45 whose wt was 85%-120% of their IBW (according to Metropolitan Life Insurance Company tables) **Exclusion:** Acute or chronic medical conditions; judged to be acutely suicidal; currently being treated with psychotropic meds; had abused drugs or alcohol in the past yr or had previous adequate trial of antidepressant meds (min of 200 mg of desipramine for at least 3 wks or equivalent meds doses).	During the first wk of tx, dose of desipramine gradually raised to 200 mg/day (four 50 mg tablets) or the equivalent dose of placebo. If tolerated, this dose was continued for three wks. Four wks after randomization, patients who continued to binge eat had dose raised to 300 mg/day. Tx lasted for 6 wks. After the 6 wk tx, patients who had been randomly assigned to placebo and had not improved were offered open trial of desipramine. To enter the maintenance phase, patients required to have achieved reduction of 50% or more in binge frequency in the last two wks of the tx phase compared to baseline. Patients who met this criterion were continued on desipramine for another 16 wks. Patients who had not relapsed during maintenance phase, offered to participate in the discontinuation phase. Here patients randomly assigned to either continue taking the same dose of meds or switch to placebo. Meds tapered to placebo over two wks.	Student's t test was used to compare groups.	**Score:** Fair **Intent to treat:** Used termination data for those who completed initial 6 wks and those who discontinued before initial 6 wks. **Blinding:** Initially participants were in a single blind washout phase and the tx component was double blinded. **Adverse events:** NR **Funding:** NIMH

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Walsh et al. 1991 (continued)	**Binge episodes/wk, mean (SD):** **G1:** 8.3 (5.4) **G2:** 8.1 (4.6) *(P* = NS)	**Binge episodes/wk, mean (SD):** **G1:** 8.6 (7.2) *(P* = NR) **G2:** 4.3 (3.9) *(P* = NR) Diff between groups *(P* < 0.001) G2 better than G1 Diff between groups in change over time *(P* = NR)
	Vomiting episodes/wk, mean (SD): **G1:** 13.0 (16.7) **G2:** 10.8 (12.7) *(P* = NS)	**Vomiting episodes/wk, mean (SD):** **G1:** 13.3 (17.5) *(P* = NR) **G2:** 7.8 (14.4) *(P* = NR) Diff between groups *(P* = 0.02) G2 better than G1 Diff between groups in change over time *(P* = NR)
	Eating Attitudes Test, mean (SD): **G1:** 39.6 (15.2) **G2:** 39.8 (16.9) *(P* = NS)	**Eating Attitudes Test, mean (SD):** **G1:** 37.7 (15.1) *(P* = NR) **G2:** 29.9 (16.0) *(P* = NR) Diff between groups *(P* = 0.03) G2 better than G1 Diff between groups in change over time *(P* = NR)
	Body Shape Questionnaire, mean (SD): **G1:** 135.3 (28.3) **G2:** 148.7 (35.6) *(P* = NS)	**Body Shape Questionnaire, mean (SD):** **G1:** 120.5 (34.2) *(P* = NR) **G2:** 101.6 (36.6) *(P* = NR) Diff between groups *(P* = 0.02) G2 better than G1 Diff between groups in change over time *(P* = NR)
		Remission rate: **G1:** 7.9% **G2:** 12.5% Diff between groups *(P* = NS)

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
HAM-D, mean (SD): **G1:** 7.3 (4.6) **G2:** 8.3 (4.6) *(P* = NS)	**HAM-D, mean (SD):** **G1:** 6.5 (5.1) *(P* = NR) **G2:** 6.0 (4.7) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)	**BMI, mean (SD) kg/m^2:** **G1:** 22.0 (2.3) **G2:** 22.4 (1.9) *(P* = NS)	**BMI, mean (SD) kg/m^2:** **G1:** 22.3 (2.5) *(P* = NR) **G2:** 22.0 (1.9) *(P* = NR) Diff between groups (*P* = 0.001) G2 better than G1 Diff between groups in change over time *(P* = NR)
BDI, mean (SD): **G1:** 15.0 (11.1) **G2:** 10.4 (7.3) *(P* = 0.04)	**BDI, mean (SD):** **G1:** 13.0 (11.0) *(P* = NR) **G2:** 9.2 (7.7) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)		
SCL-90 Global Symptom index, mean (SD): **G1:** 2.1 (0.7) **G2:** 1.9 (0.5) *(P* = NS)	**SCL-90 Global Symptom index, mean (SD):** **G1:** 2.0 (0.7) *(P* = NR) **G2:** 1.6 (0.4) *(P* = NR) Diff between groups *(P* = 0.009) G2 better than G1 Diff between groups in change over time *(P* = NR)		
SCL-90 Anxiety scale, mean (SD): **G1:** 2.0 (0.8) **G2:** 1.9 (0.6) *(P* = NS)	**SCL-90 Anxiety scale, mean (SD):** **G1:** 1.9 (0.8) *(P* = NR) **G2:** 1.7 (0.6) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)		
SCL-90 Depression scale, mean (SD): **G1:** 2.5 (1.0) **G2:** 2.3 (0.8) *(P* = NS)	**SCL-90 Depression scale, mean (SD):** **G1:** 2.5 (0.9) *(P* = NR) **G2:** 1.9 (0.7) *(P* = NR) Diff between groups *(P* = 0.007) G2 better than G1 Diff between groups in change over time *(P* = NR)		
SCL-90 Obsessive/Compulsive scale, mean (SD): **G1:** 2.2 (1.0) **G2:** 2.0 (0.7) *(P* = NS)	**SCL-90 Obsessive/Compulsive scale, mean (SD):** **G1:** 2.1 (1.0) *(P* = NR) **G2:** 1.6 (0.6) *(P* = NR) Diff between groups *(P* = 0.003) G2 better than G1 Diff between groups in change over time *(P* = NR)		
SCL-90 Hostility scale, mean (SD): **G1:** 1.9 (0.9) **G2:** 1.7 (0.8) *(P* = NS)	**SCL-90 Hostility scale, mean (SD):** **G1:** 2.1 (1.0) *(P* = NR) **G2:** 1.6 (0.6) *(P* = NR) Diff between groups *(P* = 0.02) G2 better than G1 Diff between groups in change over time *(P* = NR)		

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	Outcomes
Author, yr: Walsh et al. 1991 (continued)		

Evidence Table 5. Medication trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
STAI – State, mean (SD): **G1:** 51.5 (14.3) **G2:** 48.1 (12.2) *(P* = NS)	**STAI – State, mean (SD):** **G1:** 49.3 (14.3) *(P* = NR) **G2:** 45.5 (12.4) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)		
STAI – Trait, mean (SD): **G1:** 54.3 (10.3) **G2:** 51.9 (10.5) *(P* = NS)	**STAI – Trait, mean (SD):** **G1:** 54.1 (11.6) *(P* = NR) **G2:** 46.5 (10.2) *(P* = NR) Diff between groups *(P* = 0.01) G2 better than G1 Diff between groups in change over time *(P* = NR)		

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa

Study Description	Objective	Design	Patient Characteristics
Author, yr: Agras et al., 1992 **Companion article:** Agras, Rossiter et al., 1994 **Setting:** Outpatient, ED Clinic; location: Stanford, CA, USA **Enrollment period:** NR	**Research objective:** To assess the efficacy of desipramine, CBT and their combination in the tx of women with BN.	**Groups (N = 71):** **G1:** desipramine, 16 wks (N = 12) **G2:** desipramine, 24 wks (N = 12) **G3:** desipramine, 16 wks, plus CBT (N = 12) **G4:** desipramine, 24 wks, plus CBT (N = 12) **G5:** CBT only (N = 23) **Enrollment:** • 100 recruited from university ED clinic and media, then interviewed • 11 met exclusion criteria; 18 withdrew • 71 met criteria and participated **Meds Drop-out rate:** • 6 wks (12.2%) • 16 wks (14.6%) • 24 wks (17%) **CBT Drop-out rate** (4.3%)	**Age, yrs, mean (SD):** 29.6 (8.9) **Sex:** Female: 100% **Race/ethnicity:** NR **Marital Status (%):** Married: 32% Single: 56.3% Divorced: 8.5% Separated: 2.8% **Education (%):** Graduated HS: 5.6% Completed some HS: 1.4% Graduated college: 56% Completed some college: 36.7% **Age of onset of BE, yrs, mean (SD):** 19.9 (5.7) **Age of onset of purging, yrs, mean (SD):** 20.7 (5.9) **Frequency of bingeing/wk, mean (SD):** 7.5 (5.7) **Frequency of purging/wk, mean (SD):** 9.2 (6.9) **Ideal wt, kg, mean (SD):** 53.7 (5.8) **Baseline wt, kg, mean (SD):** 59.9 (9.1) **Prior AN Dx:** 22%

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Age 18-65; met DSM III-R criteria for BN; no concurrent medical condition that would preclude use of antidepressants; no evidence of conduction disturbance on ECG **Exclusion:** Current AN, drug or alcohol abuse, psychosis, or depression with suicidal risk of sufficient severity to preclude use of antidepressants on an outpatient basis.	Participants randomized to one of 5 groups: desipramine continued for 16 or 24 wks; individual CBT; combined CBT with drug tx for 16 or 24 wks. For individuals randomized to drug tx, dose began at 25 mg/day for 3 days, increased by 50 mg increments every 3-5 days to a max of 300 mg, response-contingent. At 6 wks, serum levels assessed, drug increased to 350 mg/day, as needed. Participants seen wkly for first 4 wks, then at wks 6, 8, 12, 16 (for those withdrawn per tx), then 18, 20, 24, for those continuing, per tx group. CBT was administered in 15, individual, 50 min, wkly sessions, and FU included sessions at wks 20, 24 and 28. Assessments were collected at baseline, wks 16 and 24; bingeing and purging frequency also assessed at wk 32.	Two primary (binge and purge frequencies) and 5 secondary factors subjected to a repeated measures ANCOVA for three groups (med alone, CBT and combined) at 16 wks; similarly, an ANCOVA was used to assess diff between 5 groups at 32 wks for primary measures, and at 24 wks for secondary measures. Two-tailed test for sig was used throughout. When sig time X group effect found, post hoc tests carried out and Bonferroni correction applied, resulting in an adjusted sig level of $P < 0.005$.	**Score:** Fair **Intent to treat:** Yes, for analysis of primary outcomes; secondary analyses used “completers” only. **Blinding:** N/A **Adverse events:** “side effects” of meds reported; further detail: NR **Funding:** National Institute of Mental Health

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Agras et al., 1992 (continued)	**Binges, past 7 days, mean (SD):** **G1:** 5.5 (4.6) **G2:** 5.9 (5.1) **G3:** 7.5 (3.4) **G4:** 9.3 (5.8) **G5:** 8.7 (7.2) *(P* = NS)	**Binges, past 7 days, mean (SD):** **16 wks:** **G1:** 3.5 (6.1) *(P* = NR) **G2:** 3.4 (3.5) *(P* = NR) **G3:** 2.4 (3.1) *(P* = NR) **G4:** 1.7 (1.5) *(P* = NR) **G5:** 1.5 (2.6) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.005) G5 better than G1+G2 *(P* < 0.005) G3+G4 better than G1+G2 *(P* < 0.004) **24 wks:** **G1:** 3.7 (7.1) *(P* = NR) **G2:** 2.7 (2.8) *(P* = NR) **G3:** 2.1 (2.8) *(P* = NR) **G4:** 2.3 (4.7) *(P* = NR) **G5:** 2.8 (5.9) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) **32 wks:** **G1:** 6.2 (13.7) *(P* = NR) **G2:** 3.3 (3.9) *(P* = NR) **G3:** 3.2 (4.2) *(P* = NR) **G4:** 1.0 (3.0) *(P* = NR) **G5:** 2.5 (3.6) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.02) G4 better than G1 *(P* < 0.004) GG4 better than G2 *(P* < 0.005)

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
		Wt (kg): **G1:** NR **G2:** NR **G3:** NR **G4:** NR **G5:** NR *(P* = NR)	**Wt (kg):** **32 wks** **G1:** NR **G2:** NR **G3:** NR **G4:** NR **G5:** NR Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Agras et al., 1992 (continued)	**Purges, past 7 days, mean (SD):** **G1:** 9.7 (9.4) **G2:** 6.3 (4.9) **G3:** 8.3 (4.3) **G4:** 11.7 (5.9) **G5:** 10.1 (7.7) *(P* = NS)	**Purges, past 7 days, mean (SD):** **16 wks:** **G1:** 4.7 (8.6) *(P* = NR) **G2:** 3.9 (3.8) *(P* = NR) **G3:** 2.6 (3.2) *(P* = NR) **G4:** 1.2 (2.7) *(P* = NR) **G5:** 1.7 (2.7) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.004) G5 better than G1+G2 *(P* < 0.004) G3 better than G1+G2 *(P* < 0.003) **Purges, past 7 days, mean (SD*) (*continued):** **24 wks:** **G1:** 5.0 (10.8) *(P* = NR) **G2:** 2.9 (3.0) *(P* = NR) **G3:** 2.7 (4.2) *(P* = NR) **G4:** 1.7 (4.7) *(P* = NR) **G5:** 2.7 (5.9) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) **32 wks:** **G1:** 6.2 (13.7) *(P* = NR) **G2:** 3.4 (4.1) *(P* = NR) **G3:** 3.2 (4.3) *(P* = NR) **G4:** 1.1 (3.0) *(P* = NR) **G5:** 2.2 (3.6) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.02) G4 better than G1 *(P* < 0.005)

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Agras et al., 1992 (continued)	**Hunger/disinhibition, mean (SD):** **G1:** 10.0 **(**2.3) **G2:** 9.6 (2.3) **G3:** 11.1 (2.1) **G4:** 11.0 (2.1) **G5:** 10.1 (3.2) *(P* = NS)	**Hunger/disinhibition, mean (SD):** **16 wks:** **G1:** 7.4 (2.1) *(P* = NR) **G2:** 7.9 (2.7) *(P* = NR) **G3:** 9.1 (3.6) *(P* = NR) **G4:** 6.0 (3.4) *(P* = NR) **G5:** 8.6 (3.2) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) Diff between groups in change over time *(P* = NS) **24 wks:** **G1:** 8.7 (2.5) *(P* = NR) **G2:** 7.4 (1.7) *(P* = NR) **G3:** 11.1 (2.1) *(P* = NR) **G4:** 6.3 (3.2) *(P* = NR) **G5:** 8.3 (3.4) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.02) G4 better than G5 *(P* < 0.005)
	Dietary Preoccupation, mean (SD): **G1:** 14.0 **(**4.8) **G2:** 13.4 (5.4) **G3:** 15.3 (3.0) **G4:** 15.9 (3.0) **G5:** 14.1 (4.3) *(P* = NS)	**Dietary Preoccupation, mean (SD):** **16 wks:** **G1:** 9.7 (4.5) *(P* = NR) **G2:** 10.4 (6.7) *(P* = NR) **G3:** 10.5 (7.1) *(P* = NR) **G4:** 5.5 (2.9) *(P* = NR) **G5:** 9.3 (5.6) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.01) G3+G4 better than G1+G2 *(P* < 0.005) **24 wks:** **G1:** 8.9 (4.1) *(P* = NR) **G2:** 7.5 (5.6) *(P* = NR) **G3:** 10.7 (7.1) *(P* = NR) **G4:** 5.9 (6.2) *(P* = NR) **G5:** 9.5 (6.0) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)
	Abstinence from bingeing: NR	**Abstinence from bingeing %:** **16 wks:** **G1 + G2:** 35% **G3 + G4:** 65% **G5:** 50% Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) **24 wks:** NR **32 wks:** **G1 + G2:** 42% **G3 + G4:** 74% **G5:** 55% Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Agras et al., 1992 (continued)	**Abstinence from purging %:** NR	**Abstinence from purging:** **16 wks:** **G1 + G2:** 33% **G3 + G4:** 64% **G5:** 48% Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) **24 wks:** NR **32 wks:** NR

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Agras, Rossiter et al., 1994 **Companion article:** Agras et al., 1992 **Setting:** Outpatient, ED Clinic; location: USA **Enrollment period:** NR	**Research objective:** To assess the efficacy of desipramine, CBT and their combination in the tx of women with BN at 1 yr FU.	**Groups:** **G1:** desipramine, 16 wks **G2:** desipramine, 24 wks **G3:** desipramine, 16 wks, plus CBT **G4:** desipramine, 24 wks, plus CBT **G5:** CBT only **Enrollment:** • 100 recruited from university ED clinic and media, then interviewed • 71 met criteria and participated • 11 met exclusion criteria; 18 withdrew • 61 completed FU	**Age, mean (SD):** 29.6 (8.9) **Sex:** Female: 100% **Race/ethnicity:** NR **Marital Status (%):** Married: 32% Single: 56.3% Divorced: 8.5% Separated: 2.8% **Education (%):** Graduated HS: 5.6% Completed some HS: 1.4% Graduated college: 56% Completed some college: 36.7% **Age of onset of BE, yrs, mean (SD):** 19.9 (5.7) **Age of onset of purging, yrs, mean (SD):** 20.7 (5.9) **Frequency of bingeing/wk, mean (SD):** 7.5 (5.7) **Frequency of purging/wk, mean (SD):** 9.2 (6.9) **FU Ideal wt, kg, mean (SD):** 122.8 (55.3) **FU wt, kg, mean (SD):** 136.5 (61.4)

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Age 18-65; met DSM III-R criteria for BN; no concurrent medical condition that would preclude use of antidepressants; no evidence of conduction disturbance on ECG **Exclusion:** Current AN, drug or alcohol abuse, psychosis, or depression with suicidal risk of sufficient severity to preclude use of antidepressants on an outpatient basis.	Participants randomized to one of 5 groups: desipramine continued for 16 or 24 wks; individual CBT; CBT combined with drug tx for 16 or 24 wks. For individuals randomized to drug tx, dose began at 25 mg/day for 3 days, increased by 50 mg increments every 3-5 days to a max of 300 mg, response-contingent. At 6 wks, serum levels assessed, and drug was increased to 350 mg/day, as needed. Participants seen wkly for first 4 wks, then at wks 6, 8, 12, 16 (for those withdrawn per tx), then 18, 20, 24, for those continuing, per tx group. CBT administered in 15, individual, 50 min, wkly sessions, and FU included sessions at wks 20, 24 and 28. Assessments collected at baseline, wks 16 and 24; bingeing and purging frequency also assessed at wk 32.	Repeated ANCOVA for 5 groups to 1 yr FU using the baseline value as the covariate. Patients descriptively classified as recovered or not recovered, defined by abstinence from both bingeing and purging for a 3-mo period.	**Score:** Fair **Intent to treat:** Yes, for analysis of primary outcomes; secondary analyses used "completers" only. **Blinding:** NA **Adverse events:** "side effects" of meds; further detail: NR **Funding:** National Institute of Mental Health

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Agras, Rossiter et al., 1994 (continued)	**Binges/wk, mean (SD):** **G1:** 5.3 (6.2) **G2:** 7.4 (5.4) **G3:** 7.4 (3.6) **G4:** 7.9 (6.2) **G5:** 8.4 (6.8)	**Binges/wk, mean (SD):** **72 wks:** **G1:** 5.8 (10.2) *(P* = NR) **G2:** 2.4 (3.6) *(P* = NR) **G3:** 3.4 (4.6) *(P* = NR) **G4:** 3.1 (7.7) *(P* = NR) **G5:** 2.6 (3.8) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.03) G4 better than G1 *(P* < 0.02) G5 better than G1 *(P* < 0.02)
	Purges/wk, mean (SD): **G1:** 9.4 (10.9) **G2:** 7.8 (5.2) **G3:** 8.3 (4.5) **G4:** 10.0 (6.4) **G5:** 10.2 (7.5)	**Purges/wk, mean (SD):** **72 wks:** **G1:** 5.6 (14.3) *(P* = NR) **G2:** 2.6 (3.6) *(P* = NR) **G3:** 3.1 (4.6) *(P* = NR) **G4:** 2.9 (5.2) *(P* = NR) **G5:** 2.2 (3.5) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) Diff between groups in change over time *(P* = NS)
	Hunger/disinhibition, mean (SD): **G1:** 10.8 (2.6) **G2:** 10.0 (2.4) **G3:** 11.4 (2.0) **G4:** 10.0 (1.5) **G5:** 10.5 (3.2)	**Hunger/disinhibition, mean (SD):** **72 wks:** **G1:** 9.5 (2.5) *(P* = NR) **G2:** 6.3 (2.5) *(P* = NR) **G3:** 8.8 (3.7) *(P* = NR) **G4:** 6.1 (2.2) *(P* = NR) **G5:** 8.5 (3.5) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.01) G4 better than G1 *(P* < 0.01)
	Dietary Preoccupation, mean (SD): **G1:** 13.1 (4.4) **G2:** 11.2 (5.1) **G3:** 15.5 (4.2) **G4:** 15.3 (3.2) **G5:** 14.5 (4.2)	**Dietary Preoccupation, mean (SD):** **72 wks:** **G1:** 8.7 (3.7) *(P* = NR) **G2:** 5.1 (3.1) *(P* = NR) **G3:** 9.9 (6.8) *(P* = NR) **G4:** 3.2 (2.6) *(P* = NR) **G5:** 7.1 (5.3) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.03) G4 better than G1 *(P* < 0.001)
	Restraint, mean (SD): **G1:** 12.3 (5.1) **G2:** 11.4 (4.6) **G3:** 11.2 (4.2) **G4:** 13.7 (4.2) **G5:** 12.0 (4.4)	**Restraint, mean (SD):** **72 wks:** **G1:** 12.6 (3.2) *(P* = NR) **G2:** 11.3 (5.3) *(P* = NR) **G3:** 11.9 (5.2) *(P* = NR) **G4:** 12.6 (4.7) *(P* = NR) **G5:** 13.2 (4.5) *(P* = NR) *(P* = NR) Diff between groups in change over time *(P* = NR) Diff between groups in change over time *(P* = NR)

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BDI, mean (SD): **G1:** 15.0 (12.1) **G2:** 12.6 (10.5) **G3:** 14.0 (7.7) **G4:** 18.6 (4.1) **G5:** 14.3 (7.0) *(P* = NR)	**BDI, mean (SD):** **72 wks:** **G1:** 10.0 (7.5) *(P* = NR) **G2:** 5.1 (5.3) *(P* = NR) **G3:** 9.7 (8.9) *(P* = NR) **G4:** 4.4 (4.6) *(P* = NR) **G5:** 10.3 (13.1) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)	NR	NR
RSE, mean (SD): **G1:** 3.6 (1.7) **G2:** 3.3 (2.1) **G3:** 3.5 (1.7) **G4:** 3.3 (0.8) **G5:** 3.8 (1.4)	**RSE, mean (SD):** **G1:** 2.6 (1.7) *(P* = NR) **G2:** 1.8 (0.9) *(P* = NR) **G3:** 3.0 (1.8) *(P* = NR) **G4:** 2.0 (1.5) *(P* = NR) **G5:** 2.4 (1.9) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)		

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Agras, Rossiter et al., 1994 (continued)		**Post-tx:** **Recovered, abstinence from bingeing and purging for prior 3 mos, N (%):** **G1:** 5 (45%) *(P* = NR) **G2:** 5 (45%) *(P* = NR) **G3:** 5 (50%) *(P* = NR) **G4:** 5 (56%) *(P* = NR) **G5:** 9 (41%) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) **Not recovered, N (%)** **G1:** 6 (55%) *(P* = NR) **G2:** 4 (44%) *(P* = NR) **G3:** 5 (50%) *(P* = NR) **G4:** 4 (44%) *(P* = NR) **G5:** 13 (59%) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) **72-wk FU:** **Maintained Recovery, N (%):** **G1:** 1/5 (20%) *(P* = NR) **G2:** 5/5 (100%)) *(P* = NR) **G3:** 4/5 (80%) *(P* = NR) **G4:** 5/5 (100%) *(P* = NR) **G5:** 7/9 (78%) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) **Additional recovered, N (%)** **G1:** 1/6 (17%) *(P* = NR) **G2:** 1/4 (25%) *(P* = NR) **G3:** 0/5 (0%) *(P* = NR) **G4:** 2/4 (50%) *(P* = NR) **G5:** 5/13 (38%) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics N = 38 (completers)
Author, yr: Goldbloom et al., 1997 **Setting:** Eating Disorders Program – Toronto Hospital, Canada **Enrollment period:** 2 yrs	**Research objective:** To compare fluoxetine, individual CBT, and fluoxetine plus individual CBT in the tx of BN.	**Groups:** **G1:** Fluoxetine (N = 23) **G2:** CBT (N = 24) **G3:** Fluoxetine+CBT (N = 29) **Enrollment:** N = 76 (approximately 13% of all initial consultations for ED conducted during the recruitment period) **Completed at least 14 wks, N (%):** **G1:** 14 (60.9) **G2:** 16 (66.7) **G3:** 13 (43.8) *(P* = NS) **Completed and provided post assessment data, N:** **G1:** 12 **G2:** 14 **G3:** 12	**Age, yrs, mean (SD):** 25.8 (5.5) **Sex:** Female: 100% **Race/ethnicity:** NR **BMI, mean (SD):** 23.0 (2.5) **Past highest BMI, mean (SD):** 25.8 (3.6) **Past lowest BMI, mean (SD):** 19.8 (2.2) **Previous Dx of AN:** Total sample: 15.8% **G1:** N = 1 **G2:** N = 3 **G3:** N = 2 **Current mood disorders:** Total sample: 13.2% **G1:** N = 2 **G2:** N = 0 **G3:** N = 3 **Lifetime mood disorder, N:** **G1:** 8 **G2:** 8 **G3:** 6 **Anxiety disorders:** 10.5% **Substance use disorders:** 5.3% **Personality disorders:** Total sample: 18.4% Cluster A (G1 = 1; G2 = 0; G3 = 0) Cluster B (G1 = 1; G2 = 1; G3 = 1) Cluster 3 (G1 = 3; G2 = 0; G3 = 2) No diffs between groups on any characteristics.

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Female, age: 18-45; 85-125% matched population mean wt; DSM III-R dx of BN; binge and vomit at least twice per wk per EDE; min 6 mo duration of illness. **Exclusion:** Ongoing pharmacotherapy or psychotherapy or use of MAOIs within 2 wks prior to the onset of study tx; immediate suicide risk or psychosis; medical contraindications to drug tx; previous exposure to research txs.	**Assessment:** Baseline, 6 wks, end of tx, 4 wk FU **G1:** Met with psychiatrist individually once per wk for 4 wks and then biwkly for 12 wks (total = 10 sessions). Sessions < 10 m and focused on meds issues. Prescribed 60 mg per day, adjusted if side effects emerged. **G2:** Met with psychologist wkly for 16 wks. Sessions were 1 hr based on Fairburn's manual. **G3:** Met separately with pharmacotherapists and psychotherapists as described above; involved greater frequency of professional contacts than either tx alone.	Non-parametric chi square to compare sociodemographic variables. ANCOVA for 4-wk post tx symptom variables (controlling for pre-tx measures). Repeated measures MANOVA to compare change in primary and secondary psychological variables between groups.	**Score:** Fair **Intent to treat:** Yes **Blinding:** No **Adverse events:** **Dropped out because of side effects, N:** **G1:** 4 **G3:** 2 **Funding:** Eli Lilly Canada Inc.

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Goldbloom et al., 1997 (continued)		Note: ITT ANCOVA analyses (N = 76) found no sig diffs between groups on any measures.
		At Treatment Completion: **Reduction in objective binge frequency, %, mean:** **G1:** 70% **G2:** 80% **G3:** 87% Diff between groups *(P* = NS)
		Reduction in vomiting episodes, %, mean: **G1:** 37.4% **G2:** 79.2% **G3:** 82.4% Diff between groups *(P* < 0.05) G2 and G3 better than G1
	Objective binges, mean (SD): **G1:** 21.0 (12.2) **G2:** 33.6 (29.5) **G3:** 29.6 (16.5) *(P* = NS)	**4 Wks Post-tx:** **Objective binges, mean (SD):** **G1:** 10.0 (15.9) *(P* = NR) **G2:** 7.4 (16.6) *(P* = NR) **G3:** 1.8 (3.3) *(P* = NR) Diff between groups *(P* = NS) Diff between G3 and G1 *(P* < 0.03) G3 better than G1 Diff between groups in change over time *(P* = NR)
	Subjective binges, mean (SD): **G1:** 6.3 (9.6) **G2:** 3.2 (5.5) **G3:** 9.7 (14.3) *(P* = NS)	**Subjective binges, mean (SD):** **G1:** 10.7 (13.3) *(P* = NR) **G2:** 1.9 (3.8) *(P* = NR) **G3:** 4.7 (6.2) *(P* = NR) Diff between groups *(P* = 0.046) Diff between G2 and G1 *(P* < 0.02) G2 better than G1 Diff between groups in change over time *(P* = NR)
	Vomit episodes, mean (SD): **G1:** 24.6 (20.4) **G2:** 41.8 (34.4) **G3:** 30.9 (29.7) *(P* = NS)	**Vomit episodes, mean (SD):** **G1:** 17.3 (27.2) *(P* = NR) **G2:** 9.0 (16.8) *(P* = NR) **G3:** 3.3 (4.5) *(P* = NR) Diff between groups *(P* = NS) Diff between G3 and G1 *(P* < 0.03) G3 better than G1 Diff between groups in change over time *(P* = NR)
	EDE dietary restraint, mean (SD): **G1:** 3.8 (1.0) **G2:** 3.1 (1.5) **G3:** 3.7 (1.5) *(P* = NS)	**EDE dietary restraint, mean (SD):** **G1:** 2.3 (1.5) *(P* = NR) **G2:** 1.6 (1.6) *(P* = NR) **G3:** 1.6 (1.8) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BDI, mean (SD): **G1:** 16.3 (9.4) **G2:** 18.4 (11.5) **G3:** 14.8 (13.0) *(P* = NS)	**4 Wks Post-tx:** **BDI, mean (SD):** **G1:** 13.6 (15.3) *(P* = NS) **G2:** 13.8 (14.2) ***(P*** = NS) **G3:** 7.5 (9.0) *(P* = NS) Diff over time *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)	**Wt, lbs, mean (SD):** **G1:** NR **G2:** NR **G3:** NR *(P* = NR)	**4 Wks Post-tx:** **Change in wt, lbs, mean (SD):** **G1:** -2.0 (10.0) *(P* = NR) **G2:** 5.0 (7.7) *(P* = NR) **G3:** 3.2 (7.3) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
RSE, mean (SD): **G1:** NR **G2:** NR **G3:** NR *(P* = NR)	**RSE, mean (SD):** **G1:** 13.6 (15.3) *(P* = NR) **G2:** 13.8 (14.2) ***(P*** = NR) **G3:** 7.5 (9.0) *(P* = NR) Diff over time *(P* < 0.000) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)		

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Goldbloom et al., 1997 (continued)	**EDE shape concern, mean (SD):** **G1:** 4.1 (1.0) **G2:** 3.0 (1.8) **G3:** 3.7 (1.7) *(P* = NS)	**EDE shape concern, mean (SD):** **G1:** 2.8 (1.8) *(P* = NR) **G2:** 2.3 (2.0) *(P* = NS) **G3:** 2.3 (1.9) *(P* = NR) Diff over time *(P* < 0.0001), sig reductions in G1 and G3 Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
	EDE wt concern mean (SD): **G1:** 3.4 (1.4) **G2:** 2.6 (1.9) **G3:** 3.3 (1.8) *(P* = NS)	**EDE wt concern, mean (SD):** **G1:** 2.1 (1.4) *(P* = NR) **G2:** 1.8 (2.2) *(P* = NS) **G3:** 1.8 (1.7) *(P* = NR) Diff over time *(P* < 0.0001), sig reductions in G1 and G3 Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
	EDI Drive for thinness: **G1:** NR **G2:** NR **G3:** NR *(P* = 0.013) G2 diff than G1 and G3	**EDI Drive for thinness:** **G1** *(P* = NR) **G2** *(P* = NR) **G3** *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)
		Abstinent (no binges or vomit episodes in 4 wks post tx), %, mean: **G1:** 17% **G2:** 43% **G3:** 25% Diff between groups *(P* = NS)
		Subthreshold (< 2 binge or vomit episodes/wk in 4 wks posttx), %, mean: **G1:** 25% **G2:** 21% **G3:** 50% Diff between groups *(P* = NS)
		Threshold (2+ binge or vomit episodes per wk in the 4 wks post tx), %, mean: **G1:** 58% **G2:** 36% **G3:** 25% Diff between groups *(P* = NS)

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Mitchell et al., 2002 **Setting:** Outpatient, NY, NJ, Minnesota, USA **Enrollment period:** NR	**Research objective:** To investigate effect of meds management vs. IPT on abstinence rates in patients previously treated unsuccessfully with CBT (see Agras et al., 2000).	**Groups:** **G1:** IPT (N = 31) **G2:** Antidepressant meds (fluoxetine; replaced with desipramine in those who did not achieve abstinence) (N = 31) **Enrollment:** • 847 contacted clinics • 258 interviewed • 194 enrolled in initial CBT tx study (NY:77; Minnesota: 79; NJ: 38) • 62 of those who remained symptomatic after CBT tx enrolled in current study (NY: 22; Minnesota: 28; NJ: 12) **Completers (N = 37):** **G1:** 21 **G2:** 16 **Drop outs (N = 25):** **G1:** 10 **G2:** 15 Diff between sites (*P* = NS) Diff between groups (*P* = NS) **Completed FU (N = 33):** **G1:** 18 **G2:** 15 **Drop out FU (N = 4):** **G1:** 3 **G2:** 1	**Age, yrs, mean (SD):** **G1:** 28.0 (7.3) **G2:** 27.1 (6.3) (*P* = NS) **Sex:** Female: 100% **Race/ethnicity:** NR **BMI, kg/m^2, mean (SD):** **G1:** 23.2 (3.7) **G2:** 21.9 (2.5) (*P* = NS) **Duration of bingeing, yrs, mean (SD):** **G1:** 11.0 (6.7) **G2:** 10.4 (7.1) (*P* = NS) **Duration of purging, yrs, mean (SD):** **G1:** 10.7 (6.7) **G2:** 8.9 (6.3) (*P* = NS) **Hx of AN, %:** **G1:** 29 **G2:** 36 (*P* = NS) **Hx of depression, %: G1: 45** **G2:** 64 (*P* = NS) **Current depression, %:** **G1:** 26 **G2:** 26 (*P* = NS) **Personality Disorder, %:** **G1: 42** **G2:** 54 (*P* = NS) **Hx of substance abuse, %:** **G1:** 13 **G2:** 16 (*P* = NS)

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Adult women who met DSM III-R criteria for BN with purging by self-induced vomiting at least 2 times per wk for 3 mo. **Exclusion:** Substance dependence in last 6 mo, hx of psychosis	CBT (20 session, 16 wk) Those with active bulimic sx *(purging*) at the end of CBT tx randomized. **G1:** 20 sessions of IPT over 16 wks (developed by Klerman et al., 1984; modified by Fairburn, 1993), delivered by same therapist as previous CBT tx. **G2:** fluoxetine (60 mg/day; reduced if not well tolerated). For those who did not achieve abstinence at 60 mg over 8 wks, fluoxetine discontinued and desipramine initiated, beginning at a dose of 50 mg/day with subsequent increases to a max of 300 mg/day. **Timeline:** CBT: Wk 1-16; IPT/Meds: Wk 17 - 33. Post Assessment: wk 33 - 34; IPT discontinued at wk 33 and no further tx until FU. Med maintained at the same dosage until FU and was then discontinued. FU: wk 60	Two-way ANCOVA (Site x Tx) using baseline values as covariate. For binary outcomes, multiple logistic regression with site and tx as independent measures.	**Score:** Fair **Intent to treat:** Yes **Blinding:** NA **Adverse events:** NR **Funding:** McKnight Foundation

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Mitchell et al., 2002 (continued)	**Objective binges, median (SD):** **G1:** 4.0 **G2:** 5.0 *(P* = NR)	**Abstinence, 34 wks, N (%):** **G1:** 5/31 (16.1) **G2:** 3/31 (9.7) *(P* = NS) **Abstinence, 60 wks, N (%):** **Of those abstinent at 34 wks, N (%):** **G1:** 2/5 (40) **G2:** 3/3 (100) **Of those not abstinent at wk 34, N (%):** **G1:** 3/26 (11.5) **G2:** 0/28 (0.0) **Relapse, 60 wks, N (%):** **G1:** 3/5 (60) **G2:** 0/3 (0.0)
	EDE restraint, mean (SD): **G1:** 2.0 (1.3) **G2:** 2.6 (1.5) *(P* = NR)	**EDE restraint, mean (SD):** **G1:** NR **G2:** NR *(P* = NR)
	EDE Wt Concerns, mean (SD): **G1:** 2.5 (1.3) **G2:** 2.4 (1.5) *(P* = NR)	**EDE Wt Concerns, mean (SD):** **G1:** NR **G2:** NR *(P* = NR)
	EDE Shape Concerns, mean (SD): **G1:** 2.9 (1.4) **G2:** 2.8 (1.5) *(P* = NR)	**EDE Shape Concerns, mean (SD):** **G1:** NR **G2:** NR *(P* = NR)
	EDE Eating Concerns, mean (SD): **G1:** 1.3 (0.9) **G2:** 1.9 (1.4) *(P* = NR)	**EDE Eating Concerns, mean (SD):** **G1:** NR **G2:** NR *(P* = NR)
	BES, mean (SD): **G1:** 17.7 (9.9) **G2:** 20.8 (10.4) *(P* = NR)	**BES, mean (SD):** **G1:** NR **G2:** NR *(P* = NR)
	TFEQ – Restraint, mean (SD): **G1:** 12.5 (4.1) **G2:** 13.8 (4.4) *(P* = NR)	**TFEQ – Restraint, mean (SD):** **G1:** NR **G2:** NR *(P* = NR)
	TFEQ – Disinhibition, mean (SD): **G1:** 9.6 (3.2) **G2:** 9.9 (3.4) *(P* = NR)	**TFEQ – Disinhibition, mean (SD):** **G1:** NR **G2:** NR *(P* = NR)

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BDI, mean (SD): **G1:** 9.9 (8.4) **G2:** 11.8 (10.0) *(P* = NR)	**BDI, mean (SD):** **G1:** NR **G2:** NR *(P* = NR)		
RSE, mean (SD): **G1:** 23.6 (7.5) **G2:** 23.7 (6.0) *(P* = NR)	**RSE, mean (SD):** **G1:** NR **G2:** NR *(P* = NR)		

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Mitchell et al., 2002 (continued)	**TFEQ – Hunger, mean (SD):** **G1:** 6.8 (3.5) **G2:** 7.7 (3.3) *(P* = NR)	**TFEQ – Hunger, mean (SD):** **G1:** NR **G2:** NR *(P* = NR)
	Bulimic Thoughts Questionnaire, mean (SD): **G1:** 49.1 (16.8) **G2:** 50.0 (17.4) *(P* = NR)	**Bulimic Thoughts Questionnaire, mean (SD):** **G1:** NR **G2:** NR *(P* = NR)

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Mitchell et al., 2001 **Setting:** Outpatient University of Minnesota Hospital eating disorders program, USA **Enrollment period:** NR	**Research objective:** To examine the singular and combined effects of fluoxetine and a self-help manual on suppressing bulimic behaviors in BN.	**Groups:** **G1:** Placebo only (N = 22) **G2:** Fluoxetine Only (N = 26) **G3:** Placebo and Self-Help Manual (N = 22) **G4:** Fluoxetine and Self-Help Manual (N = 21) **Enrollment:** N = 91 **Endpoint (at least 1 post-randomization measurement), N:** **Total sample:** 89 **G1:** 21 **G2:** 26 **G3:** 22 **G4:** 20 **Wk 4 (evaluable data at wk 4), N:** **Total sample:** 83 **G1:** 18 **G2:** 25 **G3:** 21 **G4:** 19	**Age, yrs, mean (SD) (range):** **Total sample:** 26.6 (7.1) (18-46) **G1:** 23.8 (6.1) **G2:** 26.6 (7.1) **G3:** 26.8 (6.9) **G4:** 29.3 (7.8) *(P* = NS) **Sex:** Female: 100% **Race/ethnicity:** **White, N (%):** **G1:** 21 (95.5) **G2:** 25 (100) **G3:** 22 (100) **G4:** 20 (95.2) ***(P*** = NS) **Height, cm, mean (SD):** **G1:** 165.1 (6.9) **G2:** 162.6 (7.0) **G3:** 164.3 (5.7) **G4:** 162.7 (7.0) *(P* = NS) **Wt, kg, mean (SD):** **G1:** 60.7 (7.8) **G2:** 59.5 (13.9) **G3:** 61.2 (10.5) **G4:** 56.4 (6.8) *(P* = NS) **Smoking, Yes, N (%):** **G1:** 11 (50) **G2:** 8 (30.8) **G3:** 7 (31.8) **G4:** 3 (14.3) *(P* = NS) **Alcohol Use, Yes, N (%):** **G1:** 12 (54.5) **G2:** 15 (57.7) **G3:** 13 (59.1) **G4:** 10 (47.6) *(P* = NS)

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Female, at least 18 yrs old, at least 85% of IBW, DSM III-R criteria for BN and binge eating/vomiting 3 times per wk for last 6 mos, **Exclusion:** Currently receiving pharmacotherapy or psychotherapy; medical condition that would preclude safe outpt tx, hx of hypersensitivity to fluoxetine, prior exposure to fluoxetine in a total amt > 140 mg or within preceding 5 wks before entering study.	Baseline: interview, exam, assessment instruments. Instructed to self-monitored tx and return to the clinic in 2 wk to reassess admission criteria. Randomized into single blind for 2 wks. Participants who reported < 75% improvement in the number of vomiting episodes were then randomized. Patients seen wkly for 4 wks and then every other wk for 12 wks (by RA) and every other wk for 12 wks (by investigator). **Meds:** 60 mg/day fluoxetine for 16 wks. **Manual:** instructed to follow daily assignments. 14 readings/homework assignments equaling 1 hr each night: normalizing eating, behavioral strategies, cognitive restructuring, body image, relapse prevention.	Baseline comparisons – one way ANOVA Chi squares and Fisher exact test Two-way ANOVA Cochran-Mantel-Haenszel for response rates	**Score:** Fair **Intent to treat:** Yes **Blinding:** First 2 wks: Single Remainder: NR **Adverse events:** NR **Funding:** Dista Pharmaceuticals NIMH McKnight Foundation

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Mitchell et al., 2001 (continued)	**Episodes of vomiting, mean (SD):** **G1:** 11.77 (6.67) **G2:** 16.81 (27.72) **G3:** 13.86 (10.81) **G4:** 12.43 (6.92) *(P* = NS) **Days of vomiting, mean (SD):** **G1:** 5.59 (1.65) **G2:** 5.65 (1.60) **G3:** 6.09 (1.66) **G4:** 6.05 (1.36) *(P* = NS)	**At Wk 4 (after 2 wks of active tx):** **Vomiting, % decrease from baseline, mean (SD):** **G1:** 21.8 (48.1) *(P* = NR) **G2:** 46.1 (39.5) *(P* = NR) **G3:** 31.5 (66.4) *(P* = NR) **G4:** 66.7 (28.9) *(P* = NR) Diff between groups *(P* = 0.012) G2+G4 better than G1+G3 Diff between groups *(P* = 0.033) G3+G4 better than G1+G2 **At Endpoint:** **Vomiting, % decrease from baseline, mean (SD):** **G1:** 22.8 (56.1) *(P* = NR) **G2:** 52.8 (50.7) *(P* = NR) **G3:** 50.2 (55.0) *(P* = NR) **G4:** 66.7 (31.2) *(P* = NR) Diff between groups *(P* = 0.043) G2+G4 better than G1+G3
	Episodes of binge eating, mean (SD): **G1: 9.45 (5.34)** **G2:** 11.58 (6.74) **G3:** 11.91 (10.70) **G4:** 11.29 (5.87) *(P* = NS) **Days of binge eating, mean (SD):** **G1:** 5.45 (1.68) **G2:** 5.96 (1.40) **G3:** 5.73 (1.78) **G4:** 6.10 (1.37) *(P* = NS)	**At Wk 4 (after 2 wks of active tx):** **Binge eating, % decrease from baseline, mean (SD):** **G1:** 26.9 (62.1) *(P* = NR) **G2:** 43.4 (36.2) *(P* = NR) **G3:** 35.4 (66.0) *(P* = NR) **G4:** 61.6 (31.5) *(P* = NR) Diff between groups *(P* = NS) **At Endpoint:** **Binge eating, % decrease from baseline, mean (SD):** **G1:** 32.4 (66.7) *(P* = NR) **G2:** 50.3 (52.6) *(P* = NR) **G3:** 59.7 (39.6) *(P* = NR) **G4:** 66.8 (29.9) *(P* = NR) Diff between groups *(P* = NS)
	Days of fasting, mean (SD): **G1:** 1.18 (2.20) **G2:** 0.54 (1.07) **G3:** 0.59 (1.74) **G4:** 0.48 (1.03) *(P* = NS)	**At Endpoint:** **Days of fasting, mean (SD):** **G1:** NR **G2:** NR **G3:** NR **G4:** NR *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
HAM-D, mean (SD): **G1:** 10.91 (5.89) **G2:** 8.85 (6.83) **G3:** 10.14 (7.01) **G4:** 8.10 (6.56) *(P* = NS)	**At Endpoint:** **HAM-D:** **G1:** NR **G2:** NR **G3:** NR **G4:** NR Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)		
CGI Severity, mean (SD): **G1: 4.82 (0.59)** **G2:** 4.69 (0.62) **G3:** 4.82 (0.66) **G4:** 5.00 (0.77) *(P* = NS)	**CGI Improvement:** **G1:** NR **G2:** NR **G3:** NR **G4:** NR Diff between groups *(P* = 0.029) G2+G4 better than G1+G3		
	Patient's Global Improvement Scales *(PG*I): **G1:** NR **G2:** NR **G3:** NR **G4:** NR Diff between groups *(P* = 0.036) G2+G4 better than G1+G3		

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Mitchell et al., 2001 (continued)	**EDI total score, mean (SD):** **G1:** 72.11 (14.59) **G2:** 66.79 (16.21) **G3:** 68.74 (18.48) **G4:** 58.11 (15.14) *(P* = NS)	**At Endpoint:** **EDI total score, mean (SD):** **G1:** NR **G2:** NR **G3:** NR **G4:** NR Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **Abstinence rates:** **G1:** NR **G2:** 16% **G3:** 24% **G4:** 26% *(P* = NS)

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Walsh et al., 2004 **Setting:** Primary care clinics, Connecticut and Manhattan, NY, USA **Enrollment period:** March 1998 – October 2001	**Research objective:** To evaluate relative and combined benefits of fluoxetine and guided self-help for BN in a primary care setting.	**Groups:** **G1:** Fluoxetine and guided self-help (N = 24) **G2:** Placebo and guided self help (N = 25) **G3:** Fluoxetine only (N = 20) **G4:** (Placebo only; N = 22) **Enrollment:** • 227 contacted clinic and met phone screening • 101 chose to come for in person screening • 91 met criteria and were randomized • Completed tx, N (%): 28 (30.8%); G1: 11; G2: 3; G3: 6; G4: 8. • Diff in attrition • fluoxetine (G1 + G3) vs placebo (G2 + G4) *(P* = 0.02); G1/G3 had less attrition) • Guided self-help (G1 + G2) vs pills only (G3 + G4) *(P* = NS)	**Age, yrs, mean (SD):** 30.6 (7.8) **Duration of BN, yrs, mean (SD):** 12.0 (7.9) **Met full DSM IV criteria for BN, N (%):** 76 (83.5) **Received previous tx, N (%):** 28 (32.2) **Sex:** Female: 100% **Race/ethnicity, N (%):** Caucasian**:** 84 (92.3) Hispanic: 5 (5.5) Asian: 1 (1.1) African American: 1 (1.1) **Comorbidty, N (%):** MDD: 30 (33.3) Past MDD: 28 (31.1)

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Modified DSM IV criteria: included "moderately" large amounts of food during binges, and binge at least once per wk for 3 mos. Woman, age 18-60, BMI > 17.5 **Exclusion:** Pregnant, substantial medical illness, psychotropic drug use, meds known to influence shape or wt, previously received course of 60 mg/day of fluoxetine for at least 4 wks, received CBT, adverse reaction to fluoxetine, currently in other psychological /psychiatric tx, substantial alcohol or substance abuse or dependence in the last 6 mo, other serious psychiatric dx requiring immediate tx or actively suicidal.	Physicians were internists with limited experience in ED. Nurses had no specialized training in ED. Physicians and nurses received brief (< 2 hr) training in BN, guided self-help, and fluoxetine tx for BN. • Initial visit – met with physician for hx, exam, meds. patient returned 2 wks later for evaluation. All patients scheduled for 4 additional 15 minutes visit at moly intervals. • Med conditions –60 mg /day • Guided self help – received self-help book and instructions during initial visit. In addition to moly physician visits, met with nurse for 6 – 8 30 minutes sessions. First 4 were wkly during the first mo; 5th – 6th moly; 7 – 8th optional in the 3rd or 4th mo. Focused on encouraging patients to progress through self-help manual.	ANCOVA. Proportional odds polytomous logistic regression	**Score:** Good **Intent to treat:** Yes **Blinding:** NR **Adverse events:** NR **Funding:** NIDDK, Welcome Trust, Eli Lilly and Company

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures: Baseline	Eating Related Measures: Outcomes
Author, yr: Walsh et al., 2004 (continued)	**EDE interview, mean (SD):** **Objective bulimic episodes/mo:** **G1:** 27.42 (23.88) **G2:** 27.80 (25.64) **G3:** 24.20 (22.60) **G4:** 23.95 (15.57) *(P* = NS)	**EDE interview, mean (SD):** **Objective bulimic episodes/mo:** **G1:** 16.83 (24.65) *(P* = NR) **G2:** 26.92 (26.79) *(P* = NR) **G3:** 17.25 (23.93) *(P* = NR) **G4:** 20.09 (19.64) *(P* = NR) Diff between groups G1+G2 vs G3+G4 *(P* = NS) Diff between groups G1+G3 better than G2+G4 *(P* = 0.03) Diff between groups in change over time *(P* = NR)
	Subjective Bulimic Episodes/mo: **G1:** 17.58 (25.19) **G2:** 15.84 (22.37) **G3:** 16.25 (16.06) **G4:** 15.09 (18.85) *(P* = NS)	**Subjective Bulimic Episodes/mo:** **G1:** 14.25 (23.54) *(P* = NR) **G2:** 13.88 (20.79) *(P* = NR) **G3:** 3.70 (7.80) *(P* = NR) **G4:** 6.68 (12.73) *(P* = NR) Diff between groups G1+G2 worse than G3+G4 *(P* = 0.01) Diff between groups G1+G3 vs G2+G4 *(P* = NS) Diff between groups in change over time *(P* = NR)
	Days of vomiting/mo: **G1:** 20.29 (9.62) **G2:** 20.12 (9.18) **G3:** 18.80 (9.36) **G4:** 17.55 (9.01) *(P* = NS)	**Days of vomiting/mo:** **G1:** 11.83 (11.86) *(P* = NR) **G2:** 20.00 (9.63) *(P* = NR) **G3:** 11.55 (10.60) *(P* = NR) **G4:** 13.68 (10.63) *(P* = NR) Diff between groups G1+G2 vs G3+G4 *(P* = NS) Diff between groups G1+G3 better than G2+G4 *(P* = 0.004) Diff between groups in change over time *(P* = NR)
	Episodes of vomiting/mo: **G1:** 38.04 (25.08) **G2:** 44.16 (56.14) **G3:** 34.30 (29.34) **G4:** 26.32 (18.09) *(P* = NS)	**Episodes of vomiting/mo:** **G1:** 21.04 (27.08) *(P* = NR) **G2:** 46.12 (56.75) *(P* = NR) **G3:** 19.85 (25.80) *(P* = NR) **G4:** 21.32 (20.89) *(P* = NR) Diff between groups G1+G2 vs G3+G4 *(P* = NS) Diff between groups G1+G3 better than G2+G4 *(P* = 0.002) Diff between groups in change over time *(P* = NR)
	Episodes of laxative use/mo: **G1:** 2.54 (6.67) **G2:** 3.64 (8.15) **G3 (**4.70 (10.20) **G4:** 3.45 (7.66) *(P* = NS)	**Episodes of laxative use/mo:** **G1:** 2.25 (6.60) *(P* = NR) **G2:** 2.36 (6.42) *(P* = NR) **G3:** 3.90 (9.48) *(P* = NR) **G4:** 3.05 (6.55) *(P* = NR) Diff between groups G1+G2 vs G3+G4 *(P* = NS) Diff between groups G1+G3 vs G2+G4 *(P* = NS) Diff between groups in change over time *(P* = NR)
	Restraint rating for past mo: **G1:** 5.00 (2.00) **G2:** 5.16 (1.99) **G3:** 5.20 (1.67) **G4:** 5.24 (1.58) *(P* = NS)	**Restraint rating for past mo:** **G1:** 3.67 (2.62) *(P* = NR) **G2:** 4.92 (2.08) *(P* = NR) **G3:** 3.90 (2.65) *(P* = NR) **G4:** 4.19 (2.75) *(P* = NR) Diff between groups G1+G2 vs G3+G4 *(P* = NS) Diff between groups G1+G3 better than G2+G4 *(P* = 0.03) Diff between groups in change over time *(P* = NR)

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BDI, mean (SD): **G1:** 19.74 (11.85) **G2:** 19.56 (11.64) **G3:** 18.40 (9.65) **G4:** 18.41 (9.15) *(P* = NS)	**BDI, mean (SD):** **G1:** 12.52 (11.77) *(P* = NR) **G2:** 17.24 (11.74) *(P* = NR) **G3:** 12.25 (10.38) *(P* = NR) **G4:** 15.95 (11.23) *(P* = NR) Diff between groups G1+G2 vs G3+G4 *(P* = NS) Diff between groups G1+G3 better than G2+G4 *(P* = 0.01) Diff between groups in change over time *(P* = NR)	**BMI, kg/m^2, mean (SD):** **G1:** 21.79 (3.40) **G2:** 22.78 (4.33) **G3:** 24.29 (5.49) **G4:** 24.00 (3.72) *(P* = NS)	**BMI, kg/m^2, mean (SD):** **G1:** 21.68 (3.47) *(P* = NR) **G2:** 22.61 (4.49) *(P* = NR) **G3:** 24.58 (6.46) *(P* = NR) **G4:** 23.89 (4.08) *(P* = NR) Diff between groups G1+ G2 vs G3+G4 *(P* = NS) Diff between groups G1+ G3 vs G2+G4 *(P* = NS) Diff between groups in change over time *(P* = NR)
SCL-53, mean (SD): **G1:** 1.36 (0.80) **G2:** 1.49 (0.93) **G3:** 1.26 (0.77) **G4:** 1.20 (0.69) *(P* = NS)	**SCL-53, mean (SD):** **G1:** 1.03 (0.88) *(P* = NR) **G2:** 1.36 (0.88) *(P* = NR) **G3:** 0.95 (0.77) *(P* = NR) **G4:** 1.22 (0.85) *(P* = NR) Diff between groups G1+G2 vs G3+G4 *(P* = NS) Diff between groups G1+G3 better than G2+G4 *(P* = 0.02) Diff between groups in change over time *(P* = NR)		

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	Outcomes
Author, yr: Walsh et al., 2004 (continued)	**EDE questionnaire, mean (SD):** **Objective bulimic episodes /mo:** **G1:** 20.70 (15.46) **G2:** 17.92 (16.19) **G3:** 16.65 (12.82) **G4:** 15.48 (10.78) *(P* = NS)	**EDE questionnaire, mean (SD)** **Objective bulimic episodes /mo:** **G1:** 10.13 (13.14) *(P* = NR) **G2:** 13.88 (15.97) *(P* = NR) **G3:** 8.10 (9.09) *(P* = NR) **G4:** 9.91 (10.03) *(P* = NR) Diff between groups G1+G2 vs G3+G4 *(P* = NS) Diff between groups G1+G3 vs G2+G4 *(P* = NS) Diff between groups in change over time *(P* = NR)
	Subjective Bulimic Episodes/mo: **G1:** 10.19 (8.84) **G2:** 10.45 (10.32) **G3:** 8.95 (9.23) **G4:** 7.45 (8.61) *(P* = NS)	**Subjective Bulimic Episodes/mo:** **G1:** 9.00 (20.85) ***(P*** = NR) **G2:** 7.91 (9.29) *(P* = NR) **G3:** 3.11 (5.92) *(P* = NR) **G4:** 4.14 (5.38) *(P* = NR) Diff between groups G1+G2 vs G3+ G4 *(P* = NS) Diff between groups G1+G3 vs G2+ G4 *(P* = NS) Diff between groups in change over time *(P* = NR)
	Days of vomiting/mo: **G1:** 20.74 (9.12) **G2:** 19.32 (9.42) **G3:** 18.30 (10.19) **G4:** 17.32 (8.95) *(P* = NS)	**Days of vomiting/mo:** **G1:** 10.33 (10.93) *(P* = NR) **G2:** 17.20 (10.98) *(P* = NR) **G3:** 11.15 (10.63) *(P* = NR) **G4:** 12.45 (10.00) *(P* = NR) Diff between groups G1+G2 vs G3+G4 *(P* = NS) Diff between groups G1+G3 better than G2+G4 *(P* = 0.04) Diff between groups in change over time *(P* = NR)
	Days of laxative use/mo: **G1:** 2.70 (6.55) **G2:** 4.32 (8.78) **G3:** 4.89 (10.11) **G4:** 3.77 (8.12) *(P* = NS)	**Days of laxative use/mo:** **G1:** 2.21 (6.47) *(P* = NR) **G2:** 2.88 (7.32) *(P* = NR) **G3:** 2.70 (7.60) *(P* = NR) **G4:** 2.95 (6.60) *(P* = NR) Diff between groups G1+G2 vs G3+G4 *(P* = NS) Diff between groups G1+G3 vs G2+G4 *(P* = NS) Diff between groups in change over time *(P* = NR)
		Remission (absence of bingeing, vomiting, or laxative use for 1 mo) (N, %): Diff between groups G1+ G2 (6, 12.2%) vs G3+G4 (4, 9.5%) *(P* = NS) Diff between groups G1+G3 (7, 15.9%) vs G2+G4 (3, 6.4%) *(P* = NS)

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Wilson et al., 1999 **Companion article:** Walsh et al., 1997 **Setting:** Outpatient New York State Psychiatric Unit, Columbia University, USA **Enrollment period:** NR	**Research objective:** Examine effect of therapeutic alliance, predictive factors and time course of change on psychological and pharmacological tx of BN.	**Groups:** **G1:** CBT + Meds (N = 23) **G2:** CBT + Placebo (N = 25) **G3:** Supportive therapy + Meds (N = 22) **G4:** Supportive therapy + placebo (N = 22) **G5:** Meds only (N = 28) **Enrollment:** • Recruitment through advertisements in media • Individuals screened on telephone using EDE and SCID (DSM III-R) • 209 met with psychiatrist who confirmed dx and did physical • Eligible participants entered single-blind washout phase for 7-10 days • 120 who continued to meet criteria randomly assigned to one of the groups	**Age, yrs, mean (SD):** **G1:** 26.1 (5.7) **G2:** 25.8 (4.4) **G3:** 28.0 (5.3) **G4:** 26.9 (4.3) **G5:** 24.3 (4.5) *(P* = NS) **Sex:** Female: 100% **Race/ethnicity, %:** White: 83% African American: 6% Hispanic: 6% Asian: 5% *(P* = NS) **Duration of BN, yrs, mean (SD):** **G1:** 7.26 (5.8) **G2:** 8.0 (4.0) **G3:** 9.55 (5.3) **G4:** 7.55 (3.7) **G5:** 7.36 (4.3) *(P* = NS) **Current major depression, %:** **G1:** 17% **G2:** 24% **G3:** 23% **G4:** 9% **G5:** 29% *(P* = NS) **Past AN, %:** **G1:** 17% **G2:** 36% **G3:** 32% **G4:** 27% **G5:** 32% *(P* = NS)

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Meet DSM III-R criteria for BN for at least 1 yr; had to use self-induced vomiting as compensatory mechanism; Female between ages 18-45; wt between 80-120% of IBW **Exclusion:** Medically ill; possible cardiac conduction disease; pregnant; abused alcohol or drugs in past yr; appeared acutely suicidal; prior adverse reaction to desipramine or fluoxetine	Combination of therapy and meds or placebo, except for the 'Meds only' group. Both CBT and supportive therapy designed to include 20 sessions over 16 wks. 'Meds only' group expected to attend 16 sessions over 16 wks. CBT: based on manual (Wilson, 1989) derived from Fairburn et al. CBT included: self-monitoring, triggers, cognitive restructuring, coping strategies, problem solving, and dysfunctional cognitions. Supportive therapy: modified version of a manual-based approach (Fairburn et al.); aspects of tx that were similar to CBT eliminated. Meds: desipramine (up to 300 mg/day avg dose 188 mg/day) first for 8 wks. If binge frequency not reduced by at least 75% or if intolerable side effects occurred, desipramine tapered and discontinued over next 2 wks and given fluoxetine (up to 60 mg/day avg dose 55 mg/day). Placebo: same rules followed (8 wks of tx and if no 75% reduction in binge freq or side effects, tapering and discontinuation and switch to fluoxetine placebo). In the first wk of tx, dose of desipramine increased to 200 mg/day and if tolerated, continued for 3 wks. If needed, dose increased to 300 mg/day. Fluoxetine started at 60 mg/day with the option to lower the dose to minimize side effects.	Logistic regression analyses for outcomes of remission and completion of tx and regression for termination frequency. Survival analyses comparing variables among the tx's. Repeated measures ANOVA's.	**Score:** Good **Intent to treat:** Yes **Blinding:** Double, within groups receiving psychological tx **Adverse events:** NR **Funding:** NIMH; Eli Lilly; Marion Merrell Dow

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Wilson et al., 1999 (continued)		**Logistic Regression Analyses:** **Likelihood of remission, predictor variable, odds ratio [95% CI]:** CBT (G1+G3), OR = 4.81 [1.32-17.53] *(P* = 0.02), CBT increased likelihood of remission HRQ, OR = NR *(P* = NR), higher therapeutic alliance increased likelihood of remission **Predictors of Worse Outcome (end of tx binge and vomit frequencies):** Higher baseline binge and vomit frequencies *(P* = 0.0001) CBT assignment *(P* = 0.02) Positive hx of AN *(P* = 0.05) Positive hx of substance abuse *(P* = 0.04)
	Binges/wk, mean (SD): **G1:** 7.29 (4.8) **G2:** 7.22 (4.0) **G3:** 7.92 (5.6) **G4:** 6.18 (3.6) **G5:** 8.32 (7.5) *(P* = NS)	**Survival Analyses, hazard ratio [95% CI]:** **Binge eating:** G1+G2 better than G3+G4, HR = 1.88 [1.08-3.26], especially if baseline BSQ or eating restraint were low • If BSQ < 140, HR = 3.54 [1.57-8.00] • If BSQ > 140, HR = 1.04 [0.52-2.10] • Low EDE restraint, HR = 3.37 [1.45-7.81] • High EDE restraint, HR = 1.12 [0.55-2.28] **Repeated Measures ANOVA:** **Binge eating, overall:** Diff between groups G1+G2 better than G3+G4 *(P* = 0.003) Diff between groups in change over time, quadratic effect: G1+G2 better than G3+G4 in initial binge reduction *(P* = 0.05); G1+G3 vs. G2+G4 *(P* = NS) **Binge eating (wks 1-3):** Diff between groups *(P* = NS) Diff between groups in change over time, linear effects: G1+G2 better than G3+G4 *(P* = 0.001) G1+G3 vs. G2+G4 *(P* = NS) **Binge eating (wks 4-16):** Diff between groups *(P* = NR) Diff between groups in change over time, cubic effect: G1+G3 better than G2+G4 *(P* = 0.03)

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
NR	**Helping Relationship Questionnaire (Therapeutic Alliance), mean (SD):** *error in paper **G1:** 23.58 (4.56) **G2:** 19.74 (8.60) **G3:** 18.76 (7.81) **G4:** 20.55 (7.94) **G5:** 15.09 (7.79) Diff between groups *(P* = NS) Diff between groups in change over time G1 vs. G2 *(P* = NR) G3 vs. G4 *(P* = 0.03) *text states higher therapeutic alliance (higher HRQ) with meds vs. placebo within supportive tx and higher alliance with placebo vs. meds within CBT.	NR	NR

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Wilson et al., 1999 (continued)	**Vomiting episodes/wk, mean (SD):** **G1:** 10.8 (13) **G2:** 10.8 (12) **G3:** 10.6 (9) **G4:** 11.9 (13) **G5:** 10.5 (11) *(P* = NS)	**Survival Analyses, hazard ratio [95% CI]:** **Vomiting:** G1+G2 better than G3+G4, HR = 4.73 [2.21-10.10], especially if baseline BDI was high • If BDI < 20, HR = 2.91 [1.25-6.79] • If BDI > 20, HR = 29.34 [4.72-182.15] G1+G3 better than G2+G4, HR = 2.01 [1.04-3.89], especially if baseline BDI was high • BDI < 20 subgroup, HR = 1.22 [0.55-2.70] • BDI > 20 subgroup, HR = 6.79 [2.90-15.88] **Repeated Measures ANOVA:** **Vomiting, overall:** Diff between groups: G1+G2 better than G3+G4 *(P* = 0.002) G1+G3 better than G2+G4 *(P* = 0.04) **Vomiting (wks 1-3):** Diff between groups G1+G3 better than G2+G4 Diff between groups *(P* = 0.04) **Vomiting (wks 4-16):** Diff between groups *(P* = NR) Diff between groups in change over time, quadratic effect: G1+G3 better than G2+G4 *(P* = 0.03) For CBT, early responders remained superior to others over the course of tx. For supportive therapy, improvement in early responders deteriorated. **Time to remission:** G1+G3 vs. G2+G4 *(P* = NS)

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Walsh et al., 1997 **Companion article:** Wilson et al., 1999 **Setting:** Outpatient New York State Psychiatric Unit, Columbia University, USA **Enrollment period:** NR	**Research objective:** Compare supportive therapy with CBT and see if meds tx (desipramine, or desipramine followed by fluoxetine in meds non-responders) adds to tx efficacy for BN.	**Groups:** **G1:** CBT + Meds (N = 23) **G2:** CBT + Placebo (N = 25) **G3:** Supportive therapy + Meds (N = 22) **G4:** Supportive therapy + placebo (N = 22) **G5:** Meds only (N = 28) **Enrollment:** • Recruitment through advertisements in media • Individuals screened on telephone using EDE and SCID (DSM III-R) • 209 individuals met with psychiatrist who confirmed dx and did physical • Eligible participants entered single-blind washout phase for 7-10 days • 120 who continued to meet criteria were randomly assigned to one of the groups **Drop outs:** Overall: 34% Meds only group: 43% Psychotherapy groups: 32% *(P* = NS)	**Age, yrs, mean (SD):** **G1:** 26.1 (5.7) **G2:** 25.8 (4.4) **G3:** 28.0 (5.3) **G4:** 26.9 (4.3) **G5:** 24.3 (4.5) *(P* = NS) **Sex:** Female: 100% **Race/ethnicity, %:** White: 83% African American: 6% Hispanic: 6% Asian: 5% *(P* = NS) **Duration of BN, yrs, mean (SD):** **G1:** 7.26 (5.8) **G2:** 8.0 (4.0) **G3:** 9.55 (5.3) **G4:** 7.55 (3.7) **G5:** 7.36 (4.3) *(P* = NS) **Current major depression, %:** **G1:** 17% **G2:** 24% **G3:** 23% **G4:** 9% **G5:** 29% *(P* = NS) **Past AN, %:** **G1:** 17% **G2:** 36% **G3:** 32% **G4:** 27% **G5:** 32% *(P* = NS)

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: DSM III-R criteria for BN for at least 1 yr; had to use self-induced vomiting as compensatory mechanism; Female: between ages 18-45; wt between 80-120% of IBW **Exclusion:** Medically ill; possible cardiac conduction disease; pregnant; abused alcohol or drugs in past yr; appeared acutely suicidal; prior adverse reaction to desipramine or fluoxetine	Combination of therapy and meds or placebo, except for the 'Meds only' group. Both CBT and supportive therapy designed to include 20 sessions over 16 wks. Those receiving 'meds only' expected to attend 16 sessions over 16 wks. CBT based on a manual (Wilson, 1989) derived from Fairburn et al., Components of CBT included: self-monitoring, triggers, cognitive restructuring, coping strategies, problem solving, and dysfunctional cognitions. Supportive therapy: modified version of a manual-based approach (Fairburn et al.); aspects of the tx that were similar to CBT eliminated. Participants receiving meds received desipramine (up to 300 mg/day avg dose 188 mg/day) first for 8 wks. If binge frequency not reduced by ≥ 75% or if intolerable side effects occurred, the desipramine was tapered and discontinued over the next 2 wks and patients were then given fluoxetine (up to 60 mg/day avg dose 55 mg/day). The same rules were followed for those receiving placebo (8 wks of tx and if no 75% reduction in binge freq or side effects, tapering and discontinuation and switch to fluoxetine placebo). In the first wk of tx, the dose of desipramine was increased to 200 mg/day and if tolerated, this was continued for 3 wks. If needed, the dose was increased to 300 mg/day. Fluoxetine was started at 60 mg/day with the option to lower the dose to minimize side effects.	ANOVA for continuous variables and logistic regressions for categorical variables to examine diffs between pre and post tx levels. Odds ratio values were tested with chi square tests.	**Score:** Good **Intent to treat:** Yes **Blinding:** Double, within groups receiving psychological tx **Adverse events:** NR **Funding:** NIMH; Eli Lilly; Marion Merrell Dow

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Walsh et al., 1997 (continued)	**Binges/wk, mean (SD):** **G1:** 7.29 (4.8) **G2:** 7.22 (4.0) **G3:** 7.92 (5.6) **G4:** 6.18 (3.6) **G5:** 8.32 (7.5) *(P* = NS)	**Binges/ wk, mean (SD):** **G1:** 0.95 (1.6) *(P* < 0.05) **G2:** 2.56 (3.3) *(P* < 0.05) **G3:** 3.57 (3.1) *(P* < 0.05) **G4:** 3.32 (4.0) *(P* < 0.05) **G5:** 2.59 (3.5) *(P* < 0.05) Diff between groups *(P* = NR) Diff between groups in change over time G1+G2 better than G3+G4 *(P* = 0.0005) G1+G3 better than G2+G4 *(P* = 0.05) G1 better than G5 *(P* = 0.04) G3 vs. G5 *(P* = NS)
	Vomiting episodes/wk, mean (SD): **G1:** 10.8 (13) **G2:** 10.8 (12) **G3:** 10.6 (9) **G4:** 11.9 (13) **G5:** 10.5 (11) *(P* = NS)	**Vomiting episodes/wk, mean (SD):** **G1:** 1.1 (2) *(P* < 0.05) **G2:** 5.6 (15) *(P* < 0.05) **G3:** 5.5 (5) *(P* < 0.05) **G4:** 7.5 (10) *(P* < 0.05) **G5:** 3.7 (5) *(P* < 0.05) Diff between groups *(P* = NR) Diff between groups in change over time G1+G2 better than G3+G4 *(P* = 0.0002) G1+G3 vs. G2+G4 *(P* = NS) G1 better than G5 *(P* = 0.01) G3 vs. G5 *(P* = NS)
	EAT, mean (SD): **G1:** 45.0 (13) **G2:** 42.3 (16) **G3:** 45.8 (16) **G4:** 39.9 (16) **G5:** 40.9 (20) *(P* = NS)	**EAT, mean (SD):** **G1:** 19.1 (12) *(P* < 0.05) **G2:** 24.5 (17) *(P* < 0.05) **G3:** 28.1 (13) *(P* < 0.05) **G4:** 28.7 (23) *(P* < 0.05) **G5:** 27.8 (21) *(P* < 0.05) Diff between groups *(P* = NR) Diff between groups in change over time G1+G2 better than G3+G4 *(P* = 0.005) G1+G3 better than G2+G4 *(P* = 0.01) G1 better than G5 *(P* = 0.01) G3 vs. G5 *(P* = NS)
	BSQ, mean (SD): **G1:** 137 (29) **G2:** 132 (32) **G3:** 132 (30) **G4:** 127 (31) **G5:** 135 (38) *(P* = NS)	**BSQ, mean (SD):** **G1:** 87 (36) *(P* < 0.05) **G2:** 94 (36) *(P* < 0.05) **G3:** 94 (35) *(P* < 0.05) **G4:** 104 (39) *(P* < 0.05) **G5:** 106 (47) *(P* < 0.05) Diff between groups *(P* = NR) Diff between groups in change over time G1+G2 vs. G3+G4 *(P* = NS) G1+G3 vs. G2+G4 *(P* = NS) G1 better than G5 *(P* = 0.05) G3 vs. G5 *(P* = NS)

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BDI, mean (SD): **G1:** 10.9 (6) **G2:** 11.7 (10) **G3:** 15.9 (12) **G4:** 14.3 (9) **G5:** 14.5 (8) *(P* = NS)	**BDI, mean (SD):** **G1:** 4.4 (5) *(P* < 0.05) **G2:** 6.8 (7) *(P* < 0.05) **G3:** 6.7 (7) *(P* < 0.05) **G4:** 10.2 (11) *(P* < 0.05) **G5:** 8.2 (9) *(P* < 0.05) Diff between groups *(P* = NR) Diff between groups in change over time G1+G2 vs. G3+G4 *(P* = NS) G1+G3 better than G2+G4 *(P* = 0.04) G1 vs. G5 *(P* = NS) G3 vs. G5 *(P* = NS)	**BMI, kg/m^2, mean (SD):** **G1:** 21.6 (2.2) **G2:** 22.1 (2.1) **G3:** 21.7 (2.3) **G4:** 21.7 (2.2) **G5:** 22.3 (2.1) *(P* = NS)	**BMI, kg/m^2, mean (SD):** **G1:** 21.5 (2.1) *(P* = NR) **G2:** 22.6 (2.3) *(P* < 0.05) **G3:** 21.2 (2.5) *(P* < 0.05) **G4:** 22.1 (2.2) *(P* = NR) **G5:** 21.7 (2.3) *(P* < 0.05) Diff between groups *(P* = NR) Diff between groups in change over time G1+G2 worse than G3+G4 *(P* = 0.02) G1+G3 better than G2+G4 *(P* = 0.005) G1 worse than G5 *(P* = 0.01) G3 vs. G5 *(P* = NS)
SCL-90 Global Symptom index, mean (SD): **G1:** 1.83 (0.6) **G2:** 1.69 (0.5) **G3:** 1.88 (0.6) **G4:** 1.66 (0.3) **G5:** 1.73 (0.4) *(P* = NS)	**SCL-90 Global Symptom index, mean (SD):** **G1:** 1.39 (0.4) *(P* < 0.05) **G2:** 1.47 (0.5) *(P* < 0.05) **G3:** 1.51 (0.5) *(P* < 0.05) **G4:** 1.51 (0.5) *(P* = NR) **G5:** 1.41 (0.4) *(P* < 0.05) Diff between groups *(P* = NR) Diff between groups in change over time G1+G2 vs. G3+G4 *(P* = NS) G1+G3 vs. G2+G4 *(P* = NS) G1 vs. G5 *(P* = NS) G3 vs. G5 *(P* = NS)	**Wt (lb), mean (SD):** **G1:** 126 (15) **G2:** 130 (11) **G3:** 133 (17) **G4:** 130 (15) **G5:** 131 (17) *(P* = NS)	**Wt (lb), mean (SD):** **G1:** 125 (15) *(P* = NR) **G2:** 133 (11) *(P* < 0.05) **G3:** 131 (18) *(P* < 0.05) **G4:** 133 (13) *(P* = NR) **G5:** 128 (16) *(P* < 0.05) G1+G2 (+1.13 lb) worse than G3+G4 (-1.29 lb) *(P* = 0.03) G1+G3 (-1.54 lb) better than G2+G4 (+1.49 lb) *(P* = 0.007) G1 worse than G5 *(P* = 0.02) G3 vs. G5 *(P* = NS)
SCL-90 Depression Index, mean (SD): **G1:** 2.16 (0.8) **G2:** 20.01 (0.8) **G3:** 2.38 (0.9) **G4:** 20.07 (0.6) **G5:** 2.25 (0.7) *(P* = NS)	**SCL-90 Depression Index, mean (SD):** **G1:** 1.47 (0.5) *(P* < 0.05) **G2:** 1.74 (0.7) *(P* = NR) **G3:** 1.75 (0.7) *(P* < 0.05) **G4:** 1.83 (0.8) *(P* = NR) **G5:** 1.73 (0.8) *(P* < 0.05) Diff between groups *(P* = NR) Diff between groups in change over time G1+G2 vs. G3+G4 *(P* = NS) G1+G3 better than G2+G4 *(P* = 0.05) G1 vs. G5 *(P* = NS) G3 vs. G5 *(P* = NS)		

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Walsh et al., 1997 (continued)	**EDE binges/mo, mean (SD):** **G1:** 28.8 (23) **G2:** 28.1 (22) **G3:** 33.4 (21) **G4:** 21.8 (12) **G5:** 36.8 (35) *(P* = NS)	**EDE binges/mo, mean (SD):** **G1:** 2.5 (5) *(P* < 0.05) **G2:** 6.6 (14) *(P* < 0.05) **G3:** 13.2 (15) *(P* < 0.05) **G4:** 10.6 (18) *(P* < 0.05) **G5:** 6.1 (14) *(P* < 0.05) Diff between groups *(P* = NR) Diff between groups in change over time G1+G2 better than G3+G4 *(P* = 0.001) G1+G3 vs. G2+G4 *(P* = NS) G1 vs. G5 *(P* = NS) G5 better than G3 *(P* = 0.03)
	EDE vomiting episodes/mo, mean (SD): **G1:** 38.7 (27) **G2:** 45.9 (69) **G3:** 39.3 (29) **G4:** 41.6 (48) **G5:** 45.4 (38) *(P* = NS)	**EDE vomit episodes/mo, mean (SD):** **G1:** 3.4 (6) *(P* < 0.05) **G2:** 7.6 (17) *(P* < 0.05) **G3:** 16.8 (16) *(P* < 0.05) **G4:** 25.4 (43) *(P* < 0.05) **G5:** 8.9 (13) *(P* < 0.05) Diff between groups *(P* = NR) Diff between groups in change over time G1+G2 better than G3+G4 *(P* = 0.0001) G1+G3 vs. G2+G4 *(P* = NS) G1 better than G5 *(P* = 0.04) G5 better G3 *(P* = 0.03)
	EDE importance of shape and wt, mean (SD): **G1:** 8.43 (2.4) **G2:** 8.56 (2.9) **G3:** 9.45 (2.5) **G4:** 8.95 (2.5) **G5:** 9.55 (2.2) *(P* = NS)	**EDE importance of shape and wt, mean (SD):** **G1:** 7.11 (3.2) *(P* = NR) **G2:** 6.81 (3.6) *(P* < 0.05) **G3:** 6.25 (3.3) *(P* < 0.05) **G4:** 7.71 (3.2) *(P* = NR) **G5:** 8.45 (2.7) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time G1+G2 vs. G3+G4 *(P* = NS) G1+G3 vs. G2+G4 *(P* = NS) G1 vs. G5 *(P* = NS) G5 better than G3 *(P* = 0.01)
	EDE shape concern, mean (SD): **G1:** 3.74 (1.2) **G2:** 3.59 (1.3) **G3:** 3.78 (1.4) **G4:** 3.52 (1.2) **G5:** 3.99 (1.3) *(P* = NS)	**EDE shape concern, mean (SD):** **G1:** 2.18 (1.4) *(P* = NR) **G2:** 2.27 (1.3) *(P* = NR) **G3:** 2.47 (1.5) *(P* = NR) **G4:** 2.52 (1.5) *(P* = NR) **G5:** 2.80 (1.4) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time G1+G2 vs. G3+G4 *(P* = NS) G1+G3 vs. G2+G4 *(P* = NS) G1 vs. G5 *(P* = NS) G3 vs. G5 *(P* = NS)

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
SCL-90 Anxiety Index, mean (SD): **G1:** 1.83 (0.7) **G2:** 1.57 (0.6) **G3:** 1.66 (0.6) **G4:** 1.56 (0.5) **G5:** 1.55 (0.5) *(P* = NS)	**SCL-90 Anxiety Index, mean (SD):** **G1:** 1.31 (0.4) *(P* < 0.05) **G2:** 1.37 (0.5) *(P* = NR) **G3:** 1.37 (0.5) *(P* < 0.05) **G4:** 1.41 (0.5) *(P* = NR) **G5:** 1.29 (0.4) *(P* < 0.05) Diff between groups *(P* = NR) Diff between groups in change over time G1+G2 vs. G3+G4 *(P* = NS) G1+G3 vs. G2+G4 *(P* = NS) G1 vs. G5 *(P* = NS) G3 vs. G5 *(P* = NS)		

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Walsh et al., 1997 (continued)	**EDE wt concern, mean (SD):** **G1:** 3.53 (1.1) **G2:** 3.47 (1.4) **G3:** 3.69 (1.5) **G4:** 3.36 (1.2) **G5:** 3.37 (1.4) *(P* = NS)	**EDE wt concern, mean (SD):** **G1:** 2.06 (1.4) *(P* = NR) **G2:** 1.99 (1.4) *(P* = NR) **G3:** 1.98 (1.5) *(P* = NR) **G4:** 2.38 (1.7) *(P* = NR) **G5:** 2.44 (1.4) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time G1+G2 vs. G3+G4 *(P* = NS) G1+G3 vs. G2+G4 *(P* = NS) G1 vs. G5 *(P* = NS) G3 vs. G5 *(P* = NS)
	EDE restraint, mean (SD): **G1:** 3.21 (1.2) **G2:** 3.13 (1.2) **G3:** 3.28 (1.3) **G4:** 2.93 (1.5) **G5:** 3.59 (1.4) *(P* = NS)	**EDE restraint, mean (SD):** **G1:** 1.15 (1.2) *(P* < 0.05) **G2:** 1.43 (1.4) *(P* < 0.05) **G3:** 2.06 (1.6) *(P* < 0.05) **G4:** 1.68 (1.6) *(P* < 0.05) **G5:** 2.15 (1.5) *(P* < 0.05) Diff between groups *(P* = NR) Diff between groups in change over time G1 + G2 vs. G3 + G4 *(P* = NS) G1 + G3 vs. G2 + G4 *(P* = NS) G1 vs. G5 *(P* = NS) G3 vs. G5 *(P* = NS)
	EDE overeating, mean (SD): **G1:** 3.26 (0.5) **G2:** 3.18 (0.6) **G3:** 3.32 (0.7) **G4:** 2.99 (0.6) **G5:** 3.18 (0.6) *(P* = NS)	**EDE overeating, mean (SD):** **G1:** 1.37 (1.1) *(P* = NR) **G2:** 1.73 (1.3) *(P* = NR) **G3:** 2.17 (1.3) *(P* = NR) **G4:** 1.91 (1.2) *(P* = NR) **G5:** 1.49 (10.0) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time G1 + G2 vs. G3 + G4 *(P* = NS) G1 + G3 vs. G2 + G4 *(P* = NS) G1 vs. G5 *(P* = NS) G3 vs. G5 *(P* = NS)
	EDE eating concern, mean (SD): **G1:** 2.45 (1.6) **G2:** 2.36 (1.4) **G3:** 2.49 (1.3) **G4:** 2.31 (1.3) **G5:** 2.58 (1.2) *(P* = NS)	**EDE eating concern, mean (SD):** **G1:** 0.84 (1.0) *(P* < 0.05) **G2:** 0.77 (0.9) *(P* < 0.05) **G3:** 1.36 (1.6) *(P* < 0.05) **G4:** 1.32 (1.4) *(P* < 0.05) **G5:** 1.17 (0.8) *(P* < 0.05) Diff between groups *(P* = NR) Diff between groups in change over time G1 + G2 vs. G3 + G4 *(P* = NS) G1 + G3 vs. G2 + G4 *(P* = NS) G1 vs. G5 *(P* = NS) G3 vs. G5 *(P* = NS)

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Walsh et al., 1997 (continued)	**EDE global score, mean (SD):** **G1:** 3.23 (0.7) **G2:** 3.15 (0.7) **G3:** 3.31 (0.9) **G4:** 3.02 (1.3) **G5:** 3.34 (0.7) *(P* = NS)	**EDE global score, mean (SD):** **G1:** 1.52 (0.9) *(P* < 0.05) **G2:** 1.65 (0.9) *(P* < 0.05) **G3:** 2.01 (1.1) *(P* < 0.05) **G4:** 1.96 (1.2) *(P* < 0.05) **G5:** 2.01 (0.9) *(P* < 0.05) Diff between groups *(P* = NR) Diff between groups in change over time G1 + G2 vs. G3 + G4 *(P* = NS) G1 + G3 vs. G2 + G4 *(P* = NS) G1 vs. G5 *(P* = NS) G3 vs. G5 *(P* = NS)
		Remission of self-report binge eating and vomiting, N (%): **G1:** 11/23 (48) *(P* = NR) **G2:** 5/25 (20) *(P* = NR) **G3:** 2/22 (9) *(P* = NR) **G4:** 3/22 (14) *(P* = NR) **G5:** 6/28 (21) *(P* = NR) Diff between groups G1+G2 vs. G3+G4, OR = 4.3 [1.4-13.3] *(P* = 0.01) G1+G3 vs. G2+G4 *(P* = NR) G1 vs. G5, OR = 3.7 [1.1-12.5] *(P* = 0.04) G3 vs. G5 *(P* = NR)
		Remission of EDE binge eating and vomiting, N (%): **G1:** 9/18 (50) *(P* = NR) **G2:** 3/16 (19) *(P* = NR) **G3:** 3/17 (18) *(P* = NR) **G4:** 2/17 (12) *(P* = NR) **G5:** 5/20 (25) *(P* = NR) Diff between groups G1+G2 vs. G3+G4, OR = 3.3 [1.0-10.9] *(P* = 0.06) G1+G3 vs. G2+G4, OR = 2.7 [1.0-7.5] *(P* = 0.07) G1 vs. G5 *(P* = NR) G3 vs. G5 *(P* = NR)

Evidence Table 6. Medication plus behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa

Study Description	Objective	Design	Patient Characteristics
Author, yr: Agras et al., 1989 **Setting:** Single center; outpatient; location: Department of Psychiatry and Behavioral Sciences and the Behavioral Medicine Program, Stanford University School of Medicine; Stanford, CA, USA **Enrollment period:** NR	**Research objective:** To compare the efficacy of three, 4-mo long psychological txs (self-monitoring of binge-eating and purging only, CBT, CBT + response prevention of purging behavior) versus a waitlist control for reducing BN symptoms. Another primary objective was to assess whether the addition of a purging-related response prevention component to the CBT tx would yield additional reductions in purging frequency.	**Groups:** **G1:** waitlist (N = 19) **G2:** self-monitoring (N = 19) **G3:** CBT (N = 22) **G4:** CBT + response prevention (N = 17) **Enrollment:** • 119 recruited through media advertisements and through referrals from health care workers were screened • 77 were enrolled and randomized. • 67 remained at 4 mo post-tx (G1 = 18, G2 = 16, G3 = 17, G4 = 16) *(P* = NS)	**Age, yrs, mean (SD):** **Total Sample:** 29.2 (8.6) (range: 18-61 yrs) **Sex:** Female: 100% **Race/ethnicity:** NR

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: DSM III-R criteria for BN; Female; ages 18-65 **Exclusion:** Concurrent psychological or pharmacological tx for BN; concurrent DSM III-R dx of AN, schizophrenia, unipolar or bipolar affective disorder, drug abuse, or alcoholism; pregnancy; abnormal serum potassium; major medical disorders such as hepatic disease, renal disease, or major cardiac disease.	77 enrolled subjects randomized to one of four conditions which were administered over a 4-mo period (i.e., 1-hour long per session, up to 14 sessions). In each of the three tx conditions, subjects met individually with Ph.D. level psychologists. Assessments conducted at baseline, 6 wks, 4 mos for all groups and 6 mo FU for the three tx conditions only.	Repeated measures ANOVAs to evaluate between group diffs in changes in primary (e.g., purging frequency) and secondary (e.g., depression, dieting attitudes, maturity attitudes, and food preoccupation) continuous outcome measures over the course of tx at three different time points (i.e., baseline, 6 wks, 4 mos). Scheffe post-hoc analyses used to interpret sig interaction effects. Chi-square analyses used to assess between group diffs on categorical measures or percentage diffs in variables of interest. The secondary measures were created through principal components analysis of standard depression, anxiety, and eating-related self-report measures.	**Score:** Fair **Intent to treat:** No **Blinding:** NA **Adverse events:** NR **Funding:** NIMH

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Agras et al., 1989 (continued)	**Purges/wk, mean (SD):** **G1:** 13.8 (8.4) **G2:** 12.3 (8.3) **G3:** 11.1 (6.0) **G4:** 12.2 (8.3) *(P* = NS)	**Purges/wk, mean (SD):** **At 4 mos** **G1:** 13.6 (10.7) *(P* = NS) **G2:** 4.6 (6.2) *(P* < 0.01) **G3:** 2.8 (6.3) *(P* < 0.001) **G4:** 5.8 (10.3) *(P* < 0.04) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.02) G3 better than G1 *(P* < 0.05) G2, G4 vs. G1 *(P* = NS) **At 6-mo FU (% purge reduction):** **G1:** NA **G2:** 50% **G3:** 80% **G4:** 50% Diff between groups *(P* = NR) **Abstinence of Purging:** **At 4 mos** **G1:** 5.8% **G2:** 23.5% **G3:** 56.3% **G4:** 31.2% Diff between groups *(P* < 0.05) G3 greater than G1 *(P* < 0.01) G2, G4 vs. G1 *(P* = NS) **At 6-mo FU** **G1:** NA **G2:** 18% **G3:** 59% **G4:** 20% Diff between groups *(P* < 0.005) G3 greater than G2 and G4
	Food Preoccupation, mean (SD): **G1:** 11.4 (4.4) **G2:** 11.8 (3.6) **G3:** 10.4 (3.4) **G4:** 10.9 (4.3) *(P* = NS)	**Food Preoccupation, mean (SD):** **At 4 mos** **G1:** 9.2 (4.7) *(P* = NR) **G2:** 8.0 (5.7) *(P* = NR) **G3:** 2.5 (4.5) *(P* = NR) **G4:** 4.0 (4.0) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) **At 6-mo FU** *(P* = NR)
	Dieting urges, mean (SD): **G1:** 14.4 (6.3) **G2:** 17.7 (6.8) **G3:** 16.8 (4.3) **G4:** 15.5 (6.3) *(P* = NS)	**Dieting urges, mean (SD):** **At 4 mos** **G1:** 13.1 (5.4) *(P* = NR) **G2:** 14.0 (8.0) *(P* = NR) **G3:** 8.5 (7.1) *(P* = NR) **G4:** 10.2 (6.6) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **At 6-mo FU** (*P* = NR)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BDI, mean (SD): **G1:** 19.5 (7.6) **G2:** 19.6 (10.2) **G3:** 18.2 (6.7) **G4:** 19.1 (9.4) *(P* = NS)	**BDI, mean (SD):** **At 4 mos** **G1:** 18.8 (8.3) *(P* = NR) **G2:** 13.5 (10.2) *(P* = NR) **G3:** 7.1 (7.7) *(P* = NR) **G4:** 9.2 (7.2) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) G3, G4 better than G1 *(P* < 0.05) G2 vs. G1 *(P* = NS)	**Wt, kg, mean (SD):** **G1:** NR **G2:** NR **G3:** NR **G4:** NR *(P* = NS)	**Change in Wt, kg, mean (SD):** **At 4 mos** **G1:** -2.01 *(P* = NR) **G2:** +1.64 *(P* = NR) **G3:** +0.48 *(P* = NR) **G4:** +3.49 *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	Outcomes
Author, yr: Agras, et al., 1989 (continued)	**Maturity, mean (SD):** **G1:** 7.1 (4.2) **G2:** 6.3 (5.4) **G3:** 5.8 (4.2) **G4:** 6.9 (5.4) *(P* = NS)	

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Wilson et al., 2002 **Setting:** 2 tx sites: Stanford University, Palo Alto, CA; Columbia University, NY, NY, USA Outpatient Quality-control center: Oxford University, USA **Enrollment period:** NR	**Research objective:** To investigate the mechanism by which CBT vs. IPT improves BN symptomatology by examining three potential mediating factors and their time course of action: • reduction in dietary restraint • change in self-efficacy • modification of dysfunctional attitudes about body wt and shape	**Groups enrolled:** **G1:** CBT (N = 110) **G2:** IPT (N = 110) **Enrollment:** Potential subjects referred to outpatient tx facilities **Randomized (N = 220)** **G1:** 110 (NY = 54; CA = 56) **G2:** 110 (NY = 56; CA = 54) **Drop-outs:** **G1:** 31 **G2:** 25 **Analyses based on 'complete' data set:** Post-tx: N = 154 FU: N = 129	**Age, yrs, mean (SD):** **G1:** 28.3 (7.0) **G2:** 27.9 (7.5) *(P* = NS) **Sex:** Female: NR **Race/ethnicity N (%):** **White:** **G1:** 87 (79) **G2:** 81 (74) *(P* = NR) **Hispanic:** **G1:** 11 (10) **G2:** 14 (13) *(P* = NR) **African American:** **G1:** 7 (6) **G2:** 7 (6) *(P* = NR) **Asian:** **G1:** 4 (4) **G2:** 7 (6) *(P* = NR) **American Indian:** **G1:** 1 (1) **G2:** 0 (0) *(P* = NR) **Duration of Binge Eating, mean (SD):** **G1:** 11.5 (7.5) **G2:** 11.4 (7.6) *(P* = NS) **Duration of Purging, mean (SD):** **G1:** 10.0 (7.2) **G2:** 9.7 (6.4) *(P* = NS) **Hx of AN, N (%):** **G1:** 26 (24) **G2:** 26 (24) *(P* = NR) **Lifetime major depression, N (%):** **G1:** 54 (49) **G2:** 63 (57) *(P* = NR)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: DSM III-R criteria for BN **Exclusion:** Severe medical or psychiatric condition (e.g., psychosis), current AN, current psych tx of any type, use of any meds known to affect eating or wt, pregnancy, previous exposure to adequate trial of CBT or IPT for BN.	CBT and IPT: 19 individual 50-minutes therapy sessions conducted over 20 wks as 2x/wk for 2 wks, wkly for 12 wks, at 2-wk intervals for 6 wks. **G1:** manualized CBT (Fiarburn, Marcus, and Wilson, 1993) **G2:** manualized IPT (Fairburn, in Garner and Garfinkel, 1997) Questionnaires to evaluate dietary restraint, body and wt concerns (EDE-Q (Fairburn and Beglin, 1994), self-efficacy (Rosenberg, 1979, and study-defined SE), interpersonal problems (IIP), and therapeutic alliance (Helping Relationship Questionniare (Laborsky, 1984) were administered at pre-tx, wk 4 (HRQ only) and mid-tx (wk 10). Every 2 wks, subjects reported vomiting frequency and rated wt and shape dissatisfaction, and conscious food restriction over past 7 days. FU (at least 8 mos post-tx)	Stratification of sample on hx of AN Randomization by Efron's biased coin method at Stanford Data Center Multiple linear or logistic regression to test the model: Effect = B1 (main tx effect) + B2 (main mediator effect) + B3 (interactive effect) Tx outcomes included: proportion of subjects recovered (no bingeing or purging in previous 28 days), proportion of subjects remitted (bingeing or purging < 2x/wk in 28 days), frequency of bingeing/purging episodes post-tx and at FU co-varying for pre-tx base rates.	**Score:** Fair **Intent to treat:** No **Blinding:** No **Adverse events:** 9 withdrawn from tx, 8 of which received meds: 7 for severe depression, 1 for an acute onset of panic disorder. **Funding:** NR

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Wilson et al., 2002 (continued)		**Post-tx** **Reduction in Vomiting, %:** **G1:** 80% **G2:** 52% *(P* = 0.00) **Reduction in Binge Eating, %:** **G1:** 80% **G2:** 44% *(P* = 0.017) **Improvement in EDE Shape Concerns:** **G1:** *(P* < 0.01) **G2:** *(P* < 0.01) *(P* = NS) **Improvement in EDE Wt Concerns:** **G1:** *(P* ≤ 0.01) **G2:** *(P* = 0.001) *(P* = NS) **Change in EDE Restraint, wk 4, mean (SD):** **G1:** -1.9 (1.9) *(P* = NR) **G2:** -1.3 (1.9) *(P* = NR) *(P* = 0.04) G1 better than G2 **Change in EDE Restraint, wk 6, mean (SD):** **G1:** -2.2 (2.1) *(P* = NR) **G2:** -1.2 (1.7) *(P* = NR) *(P* < 0.01) G1 better than G2 **Recovered, N:** **G1:** 29 **G2:** 5 *(P* = NR) **Mediator Analyses:** **Binge Eating Frequency:** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Tx Main Effect *(P* < 0.05) Tx Effect on Wk 4 Dietary Restraint *(P* < 0.01) Tx Effect on Wk 6 Dietary Restraint *(P* < 0.01) Tx Effect on Wk 10 Self-Efficacy in Response to Food Cues *(P* < 0.05) Tx X Dietary Restraint Effect *(P* = NS) Tx X Self-Efficacy Effect *(P* = NS)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
	Post-tx: **Rosenberg Self-Esteem:** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) *(P* = NS) **Inventory of Interpersonal Problems:** **G1:** NR ***(****P* = NR) **G2:** NR *(P* = NR) *(P* = NS) **Change in Self-efficacy over eating behavior, wk 10, mean (SD):** **G1:** 2.1 (1.8) *(P* = NR) **G2:** 0.9 (1.8) *(P* = NR) *(P* < 0.01) G1 better than G2 **Change in Self-efficacy over negative affect, wk 10, mean (SD):** **G1:** 2.8 (2.5) *(P* = NR) **G2:** 1.9 (2.7) *(P* = NR) *(P* = 0.04) G1 better than G2 **Change in Self-efficacy over shape and wt, wk 10, mean (SD):** **G1:** 1.3 (1.6) *(P* = NR) **G2:** 0.6 (1.6) *(P* = NR) *(P* = 0.03) G1 better than G2 **Suitability of tx, mean (SD):** **G1:** 12.2 (2.9) *(P* = NR) **G2:** 13.1 (2.3) *(P* = NR) *(P* = 0.03) G2 better than G1		

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Wilson et al., 2002 (continued)		**Purge Frequency:** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Tx Main Effect *(P* < 0.01) Tx Effect on Wk 4 Dietary Restraint *(P* < 0.05) Tx Effect on Wk 6 Dietary Restraint *(P* < 0.01) Tx Effect on Wk 10 Self-Efficacy in Response to Food Cues *(P* < 0.01) Tx Effect on Wk 10 Self-Efficacy in Response to Shape/Wt Cues *(P* < 0.05) Tx Effect on Wk 10 Self-Efficacy in Response to Negative Affect *(P* < 0.05) Tx X Dietary Restraint Effect *(P* = NS) Tx X Self-Efficacy Effect *(P* = NS) **AT FU:** **Reduction in Vomiting, %:** **G1:** 61% **G2:** 62% *(P* = NS) **Reduction in Binge Eating, %:** **G1:** 72% **G2:** 70% *(P* = NS) **Remained Recovered, N (%):** **G1:** 19 of 29 (66%) **G2:** 4 of 5 (80%) *(P* = NR) **Previously Remitted, Recovered, N (%):** **G1:** 5 of 15 (33%) **G2:** 7 of 19 remitted (34%) *(P* = NR) **Newly Recovered, N (%):** **G1:** 2 **G2:** 6 *(P* = NR) **Mediator Analyses:** **Binge Eating Frequency:** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Tx Main Effect *(P* = NS) Tx Effect on Wk 4 Dietary Restraint *(P* < 0.05) Tx X Dietary Restraint Effect *(P* = NS)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Agras et al., 2000 **Companion article:** Wolk and Devlin, 2001 **Setting:** Two outpatient tx sites: Stanford University, Stanford, California; Columbia University, NY.; USA; Oxford University, UK served as an independent quality control center **Enrollment period:** NR	**Research objective:** To test whether IPT might be as efficacious as CBT in the tx of women with BN.	**Groups:** **G1:** CBT (N = 110) **G2:** IPT (N = 110) **Enrollment:** • Participants recruited via advertisement and physician referral • 923 contacted by phone; 584 screened out primarily due to not meeting BN dx criteria, meds use, and/or disinterest • 220 enrolled and randomized (110 at each tx site) • 9 withdrawn (6 CBT) • 27% (of 211) did not complete tx (N = 57): **G1:** 31 (28%) and **G2:** 26 (24%) • 154 completed tx • 129 completed tx and FU **G1:** (N = 65) **G2:** (N = 64)	**Age, yrs, mean (SD):** **G1:** 28.3 (7.0) **G2:** 27.9 (7.5) *(P* = NS) **Sex:** Female: NR **Race/ethnicity N (%):** **White:** **G1:** 87 (79) **G2:** 81 (74) *(P* = NR) **Hispanic:** **G1:** 11 (10) **G2:** 14 (13) *(P* = NR) **African American:** **G1:** 7 (6) **G2:** 7 (6) *(P* = NR) **Asian:** **G1:** 4 (4) **G2:** 7 (6) *(P* = NR) **American Indian:** **G1:** 1 (1) **G2:** 0 (0) *(P* = NR) **Duration of binge eating, mean (SD):** **G1:** 11.5 (7.5) **G2:** 11.4 (7.6) *(P* = NS) **Duration of purging, mean (SD):** **G1:** 10.0 (7.2) **G2:** 9.7 (6.4) *(P* = NS) **Hx of AN, N (%):** **G1:** 26 (24) **G2:** 26 (24) *(P* = NR) **Lifetime major depression, N (%):** **G1:** 54 (49) **G2:** 63 (57) *(P* = NR)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Met DSM III-R criteria for BN, dx using SCID **Exclusion:** Severe physical or psychiatric condition that would interfere with tx; current AN; current psychotherapeutic tx of any type; all psychotropic meds; pregnancy; having received adequate trial of CBT or IBT for BN prior to study	19, 50 minutes sessions of CBT or IPT over 20 wks; Tx occurred 2x/wk in first 2 wks, wkly for next 12 wks, at 2 wk intervals for remaining 6 wks; sessions audiotaped, and 20% randomly selected and monitored by the quality control site. CBT focused on shape, wt, and eating behaviors; IPT focused on non-eating/wt-related personal issues; tx conducted by doctoral level psychologist or psychiatrist. Assessments were taken at baseline, end-of-tx, 4-, 8-and 12-mos FU.	A power analysis was calculated for the primary outcome variables. For the primary analysis, logistic regression analyses performed at end of tx and at 1yr FU, using site and tx as independent variables. A secondary ANCOVA (with baseline value as the covariate) used to test for tx diffs in "completers only". Not normally-distributed data (bingeing, purging) were square root transformed prior to analysis.	**Score:** Good **Intent to treat:** Yes **Blinding:** NA **Adverse events:** 9 withdrawn from tx, 8 of which received meds: 7 for severe depression, 1 for an acute onset of panic disorder. **Funding:** NIMH and Wellcome Trust Principal Fellowshi*P* grant

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Agras et al., 2000 (continued)			**Current major depression, N (%):** **G1:** 22 (20) **G2:** 25 (23) (*P* = NR) **Lifetime substance abuse/dependence, N (%):** **G1:** 29 (26) **G2:** 22 (20) (*P* = NR)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Agras et al., 2000 (continued)	**Values for total sample (N = 220):** **EDI measures:** **Objective binges/28days, median:** **G1:** 24.5 **G2:** 25.5 *(P* = NS) **Purges/28days, median:** **G1:** 33.0 **G2:** 49.0 *(P* = 0.003) **Restraint, mean (SD):** **G1:** 3.4 (1.3) **G2:** 3.5 (1.2) *(P* = NS) **Shape Concerns, mean (SD):** **G1:** 3.7 (1.3) **G2:** 3.8 (1.2) *(P* = NS) **Wt. Concerns, mean (SD):** **G1:** 3.4 (1.4) **G2:** 3.4 (1.5) *(P* = NS) **Eating Concerns, mean (SD):** **G1:** 2.4 (1.4) **G2:** 2.9 (1.4) *(P* = 0.02) **Global Score, mean (SD):** **G1:** 3.2 (1.0) **G2:** 3.3 (0.9) *(P* = NS)	**Intent-to-treat analysis:** **End-of-tx:** **Recovered (no binge or purge in past 28 days), N (%):** **G1:** 32 (29%) **G2:** 7 (6%) Diff between groups *(P* < 0.001) G1 better than G2 **Remitted (binge or purge < 2/wk in past 28 days), N (%):** **G1:** 53 (48%) **G2:** 31 (28%) Diff between groups *(P* = 0.003) G1 better than G2 **Of participants recovered at end-of-tx:** **Recovered at FU, N (%):** **G1:** 21/32 (66%) **G2:** 4/7 (57%) Diff between groups *(P* = NS) **Of participants remitted (but not recovered) at end-or-tx:** **Remitted at FU, N (%):** **G1:** 6/21 (29%) **G2:** 8/24 (33%) Diff between groups *(P* = NS) **Of remaining participants at end of tx:** **Recovered at FU, N (%):** **G1:** 4/57 (7%) **G2:** 7/79 (9%) Diff between groups *(P* = NR)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
Completer Analyses: **SCL-90-R, mean (SD):** **G1:** 1.1 (0.6) **G2:** 1.1 (0.7) *(P* = NS)	**Completer Analyses:** **SCL-90-R, mean (SD):** **End-of-tx:** **G1:** 0.5 **(**0.5) *(P* = NR) **G2:** 0.5 (0.5*) (P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **4-mo FU:** **G1:** 0.5 (0.4) *(P* = NR) **G2:** 0.6 (0.6) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NRS) **8-and 12-mo FU:** **G1:** 0.5 (0.6) *(P* = NR) **G2:** 0.5 (0.6) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)	**Completer Analyses:** **BMI, kg/m², mean (SD):** **G1:** 23.0 **(**5.0) **G2:** 23.0 (4.8) *(P* = NS)	**Completer Analyses:** **BMI, kg/m², mean (SD):** **End-of-tx:** **G1:** 23.3 **(**4.9) *(P* = NR) **G2:** 23.0 (4.9) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **4-mo FU:** **G1:** 23.3 **(**5.1) *(P* = NR) **G2:** 23.2 (4.9) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **8-and 12-mo FU:** **G1:** 23.3 **(**4.9) *(P* = NR) **G2:** 22.9 (4.1) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Agras et al., 2000 (continued)	**Completer Analyses:** **EDE – Objective binges/28days, median (interquartile range):** **G1:** 20.0 (32) **G2:** 23.5 (27) *(P* = NS)	**Completer Analyses:** **EDE – Objective binges/28days, median (interquartile range):** **End of tx:** **G1:** 0 (5) *(P* = NR) **G2:** 5 (23.5) *(P* = NR) Diff between groups *(P* = 0.001) G1 better than G2 Diff between groups in change over time *(P* = NR) **4-mo FU:** **G1:** 0 (5) *(P* = NR) **G2:** 6 (20) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **8- or 12-mo FU:** **G1:** 0 (10) *(P* = NR) **G2:** 2 (17.5) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
	EDE – Purges/28days, median: **G1:** 30.0 (32) **G2:** 42.0 (54) *(P* = 0.001)	**EDE – Purges/28days, median:** **End of tx:** **G1:** 1.0 (8) *(P* = NR) **G2:** 13.5 (32.35) *(P* = NR) Diff between groups *(P* = 0.001) G1 better than G2 Diff between groups in change over time *(P* = NR) **4-mo FU:** **G1:** 1.0 (8.5) *(P* = NR) **G2:** 9.5 (35) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **8- and 12-mo FU:** **G1:** 3.0 (14.5) *(P* = NR) **G2:** 7.0 (27.5) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Agras et al., 2000 (continued)	**EDE – Restraint, mean (SD):** **G1:** 3.4 (1.3) **G2:** 3.3 (1.3) *(P* = NS)	**EDE – Restraint, mean (SD):** **End of tx:** **G1:** 1.4 (1.3) *(P* = NR) **G2:** 2.1 (1.4) *(P* = NR) Diff between group *(P* = 0.001) G1 better than G2 Diff between groups in change over time *(P* = NR) **4-mo FU:** **G1:** 1.3 (1.3) *(P* = NR) **G2:** 2.1 (1.5) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **8- and 12-mo FU:** **G1:** 1.4 (1.5) *(P* = NR) **G2:** 1.8 (1.4) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
	EDE – Wt Concerns, mean (SD): **G1:** 3.2 (1.4) **G2:** 3.2 (1.5) *(P* = NS)	**EDE – Wt Concerns, mean (SD):** **End of tx:** **G1:** 1.8 (1.2) *(P* = NR) **G2:** 1.9 (1.4) *(P* = NR) Diff between group *(P* = 0.001) G1 better than G2 Diff between groups in change over time *(P* = NR) **4-mo FU:** **G1:** 1.7 (1.2) *(P* = NR) **G2:** 2.0 (1.6) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **8- and 12-mo FU:** **G1:** 1.8 (1.3) *(P* = NR) **G2:** 1.9 (1.3) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
	EDE – Shape Concerns, mean (SD): **G1:** 3.5 (1.2) **G2:** 3.5 (1.4) *(P* = NS)	**EDE – Shape Concerns, mean (SD):** **End of tx:** **G1:** 2.1 (1.3) *(P* = NR) **G2:** 2.1 (1.4) *(P* = NR) Diff between group *(P* = 0.001) G1 better than G2 Diff between groups in change over time *(P* = NR) **4-mo FU:** **G1:** 1.8 (1.2) *(P* = NR) **G2:** 2.1 (1.6) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **8- and 12-mo FU:** **G1:** 1.9 (1.4) *(P* = NR) **G2:** 2.0 (1.4) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Agras et al., 2000 (continued)	**EDE – Eating Concerns, mean (SD):** **G1:** 2.2 (1.3) **G2:** 2.6 (1.3) *(P* = NS)	**EDE – Eating Concerns, mean (SD):** **End of tx:** **G1:** 0.7 (0.8) *(P* = NR) **G2:** 1.1 (1.1) *(P* = NR) Diff between group *(P* = 0.001) G1 better than G2 Diff between groups in change over time *(P* = NR) **4-mo FU:** **G1:** 0.6 (0.9) *(P* = NR) **G2:** 1.0 (1.0) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **8- and 12-mo FU:** **G1:** 0.8 (1.2) *(P* = NR) **G2:** 0.9 (1.0) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
	EDE – Global Score, mean (SD): **G1:** 3.0 (0.9) **G2:** 3.1 (0.9) *(P* = NS)	**EDE – Global Score, mean (SD):** **End of tx:** **G1:** 1.4 (0.9) *(P* = NR) **G2:** 1.8 (1.0) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **4-mo FU:** **G1:** 1.3 (0.9) *(P* = NR) **G2:** 1.8 (1.1) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **8- and 12-mo FU:** **G1:** 1.4 (1.1) *(P* = NR) **G2:** 1.6 (1.0) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
		Reduction of Binge Eating by end-of-tx: **G1:** 86% **G2:** 51% Diff between groups *(P* = 0.01) G1 better than G2 **Reduction of Purging by end-of-tx:** **G1:** 84% **G2:** 50% Diff between groups *(P* = 0.001) G1 better than G2

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Bulik, Sullivan, Carter et al., 1998 **Companion article:** Carter et al., 2003 and Bulik, Sullivan, Joyce et al., 1998 **Setting:** Outpatient, Christchurch, New Zealand **Enrollment period:** NR	**Research objective:** • To determine whether addition of ERP to a core of CBT leads to greater clinical improvement and lower risk of relapse. • To compare efficacy of 2 forms of ERP (ERP to pre-binge cues and ERP to pre-purge cures). • To determine whether ERP assists with preventing relapse.	**Groups:** **G1:** exposure to pre-binge cues (B-ERP) (N = 37) **G2:** exposure to pre-purge cues (P-ERP) (N = 35) **G3:** relaxation training (RELAX) (N = 39) **Enrollment:** • 135 began CBT tx • 116 completed CBT • 111 randomized to one of the study arms • 106 completed • 95 completed 6 mo FU (86% of those randomized) • 105 completed 12 mo FU (95% of those randomized) **Drop-outs:** **G1:** 2 **G2:** 2 **G3:** 1	**Age, yrs, mean (SD):** 26.1 (6.1) **Sex:** Female: 100% **BMI, kg/m^2, mean (SD):** 22.4 (2.5) **Race/ethnicity:** White: 91% Maori, Pacific Island, and Asian: 6% **Duration of BN, yrs (SD):** 6.7 (5.8) **Prior BN or Psych Treatment:** 73.6% **Lifetime comorbidity:** Mood: 70.4% Anxiety: 61.5% Alcohol use disorders: 48.1% AN: 25.0% **Marital Status:** Never married or “de facto relationship”: 62.2% **Currently employed:** 59.3% **Education, yrs, mean (SD):** 13.1 (2.6)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Female; age 17-45; current primary DSM III-R dx of BN **Exclusion:** Current AN, current obesity (BMI>30 kg/m^2), current severe major depression with severe suicidal ideation or requiring immediate tx with antidepressants, current severe medical illness or severe medical complications of BN, or the current use of psychoactive meds and unwillingness to undergo a supervised drug wash-out period.	All individuals received 8 sessions of CBT (2 first wk, then wkly) based on manuals. **Randomized groups:** 2 wks of sessions twice per wk, then 4 wkly sessions; at least 2 performed outside office; min of 50 minutes but lasted until arousal approached baseline (50 m – 3 h). **G1:** B-ERP **G2:** P-ERP **G3:** (RELAX)	Binge and purge outcomes: logistic regression controlling for mid-tx measure (end of CBT). Clinician rated food restriction and body dissatisfaction outcomes: ordinal logistic regression. Continuous outcomes: ANCOVA with main effects of experimental tx, relevant measures at end of CBT as covariates. All analyses compare B-ERP and P-ERP to RELAX (reference category).	**Score:** Good **Intent to treat:** Yes **Blinding:** Post-tx assessor was blinded to tx **Adverse events:** NR **Funding:** New Zealand Health Research Council and New Zealand Lottery Grants Board

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Bulik, Sullivan, Carter et al., 1998 (continued)	**Abstinence, prior 2 wks:** **Baseline:** All groups 0% **Mid-tx:** **G1:** 38% **G2:** 23% **G3:** 21% *(P* = NS)	**Abstinence, prior 2 wks:** **Post-tx:** **G1:** 66% *(P* = NR) **G2:** 45% *(P* = NR) **G3:** 47% *(P* = NR) **6 mo FU:** **G1:** 53% *(P* = NR) **G2:** 43% *(P* = NR) **G3:** 51% *P* = NR) **12 mo FU:** **G1:** 65% *(P* = NR) **G2:** 44% *(P* = NR) **G3:** 43% *(P* = NR) **Abstinence (Clinician Rated), Odds ratio [95% CI] vs. G3:** **Post-tx:** **G1:** OR = 2.15 [0.65, 7.08] *(P* = NS) **G2:** OR = 0.89 [0.28, 2.80] *(P* = NS) **6 mo FU:** **G1:** OR = 0.95 [0.34, 2.67] *(P* = NS) **G2:** OR = 0.67 [0.23, 1.98] *(P* = NS) **12 mo FU:** **G1:** OR = 2.59 [0.85, 7.92] *(P* = NS) **G2:** OR = 1.11 [0.38, 3.25] *(P* = NS)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
HDRS, mean (SD): **Baseline:** **G1:** 7.9 (5.5) **G2:** 7.7 (5.4) **G3:** 10.1 (5.3) **Mid-tx:** **G1:** 4.4 (4.3) *(P* = NR) **G2:** 5.7 (5.7) *(P* = NR) **G3:** 7.5 (5.6) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS)	**HDRS, mean (SD):** **Post-tx:** **G1:** 2.6 (3.1) *(P* = NR) **G2:** 4.9 (6.0) *(P* = NR) **G3:** 6.7 (6.0) *(P* = NR) **6 mo FU:** **G1:** 3.1 (3.1) *(P* = NR) **G2:** 6.4 (6.5) *(P* = NR) **G3:** 5.8 (5.1) *(P* = NR) **12 mo FU:** **G1:** 3.2 (3.0) *(P* = NR) **G2:** 5.2 (5.5) *(P* = NR) **G3:** 6.8 (7.6) *(P* = NR) **HDRS (Clinician Rated), Regression coefficient [95% CI] vs. G3:** **Post tx:** **G1:** -1.35 [-2.46, -0.25] *(P* = 0.02) G1 better than G3 **G2:** -0.55 [-1.66, 0.56] *(P* = NS) **6 mo FU:** **G1:** -1.41 [-3.51, 0.69] *(P* = NS) **G2:** 1.36 [-1.04, 3.75] *(P* = NS) **12 mo FU:** **G1:** -2.10 [-4.81, 0.62] *(P* = NS) **G2:** -1.09 [-3.70, 1.51] *(P* = NS)		

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Bulik, Sullivan, Carter et al., 1998 (continued)	**Bingeing absent prior 2 wks:** **Baseline:** All groups 0% **Mid-tx:** **G1:** 51% **G2:** 34% **G3:** 36% *(P* = NS)	**Bingeing absent prior 2 wks:** **Post-tx:** **G1:** 66% *(P* = NR) **G2:** 61% *(P* = NR) **G3:** 58% *(P* = NR) **6 mo FU:** **G1:** 6253% *(P* = NR) **G2:** 61% *(P* = NR) **G3:** 69% *P* = NR) **12 mo FU:** **G1:** 68% *(P* = NR) **G2:** 56% *(P* = NR) **G3:** 57% *(P* = NR) **Bingeing absent (Clinician Rated), Odds ratio [95% CI] vs. G3: Post-tx:** **G1:** OR = 1.36 [0.44, 4.22] *(P* = NS) **G2:** OR = 1.50 [0.49, 4.64] *(P* = NS) **6 mo FU:** **G1:** OR = 0.72 [0.24, 2.19] *(P* = NS) **G2:** OR = 0.80 [0.25, 2.53] *(P* = NS) **12 mo FU:** **G1:** OR = 1.64 [0.56, 4.76] *(P* = NS) **G2:** OR = 1.09 [0.39, 3.03] *(P* = NS)
	Binges/2 wks, mean (SD): **Baseline:** **G1:** 11.7 (10.5) **G2:** 9.3 (11.4) **G3:** 8.6 (9.1) **Mid-tx:** **G1:** 2.6 (4.3) *(P* = NR) **G2:** 2.7 (3.5) *(P* = NR) **G3:** 2.3 (3.2) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS)	**Binges/2 wks, mean (SD):** **Post-tx:** **G1:** 1.3 (2.4) *(P* = NR) **G2:** 1.8 (4.1) *(P* = NR) **G3:** 1.8 (3.1) *(P* = NR) **6 mo FU:** **G1:** 1.1 (2.6) *(P* = NR) **G2:** 3.0 (6.4) *(P* = NR) **G3:** 1.2 (2.7) *(P* = NR) **12 mo FU:** **G1:** 1.7 (3.5) *(P* = NR) **G2:** 2.1 (4.4) *(P* = NR) **G3:** 1.6 (2.4) *(P* = NR)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
GAFS, mean (SD): **Baseline:** **G1:** 56.2 (6.4) **G2:** 55.8 (6.7) **G3:** 55.3 (6.8) **Mid-tx:** **G1:** 65.4 (8.4) *(P* = NR) **G2:** 65.0 (8.2) *(P* = NR) **G3:** 62.2 (9.9) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS)	**GAFS, mean (SD):** **Post-tx:** **G1:** 72.6 (9.7) *(P* = NR) **G2:** 69.0 (10.0) *(P* = NR) **G3:** 67.8 (10.1) *(P* = NR) **6 mo FU:** **G1:** 72.0 (9.2) *(P* = NR) **G2:** 67.3 (10.6) *(P* = NR) **G3:** 67.0 (11.2) *(P* = NR) **12 mo FU:** **G1:** 73.6 (11.1) *(P* = NR) **G2:** 67.6 (12.1) *(P* = NR) **G3:** 65.3 (12.7) *(P* = NR) **GAFS (Clinician Rated), Regression coefficient [95% CI] vs. G3:** **Post tx:** **G1:** 1.54 [-0.41, 3.50] *(P* = NS) **G2:** -0.12; CI: [-2.10, 1.87] *(P* = NS) **6 mo FU:** **G1:** 3.49 [-1.05, 8.02] *(P* = NS) **G2:** 0.02 [-4.66, 4.70] *(P* = NS) **12 mo FU:** **G1:** 5.34 [0.16, 10.5] *(P* = 0.05) G1 better than G3 **G2:** 1.17 [-3.83, 6.17] *(P* = NS)		

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Bulik, Sullivan, Carter et al., 1998 (continued)	**Purging absent prior 2 wks:** **Baseline:** All groups 0% **Mid-tx:** **G1:** 46% *(P* = NR) **G2:** 31% *(P* = NR) **G3:** 28% *(P* = NR) Diff between groups *(P* = NS)	**Purging absent prior 2 wks:** **Post-tx:** **G1:** 69% *(P* = NR) **G2:** 55% *(P* = NR) **G3:** 50% *(P* = NR) **6 mo FU:** **G1:** 56% *(P* = NR) **G2:** 50% *(P* = NR) **G3:** 57% *(P* = NR) **12 mo FU:** **G1:** 68% *(P* = NR) **G2:** 47% *(P* = NR) **G3:** 46% *(P* = NR) **Purging absent (Clinician Rated), Odds ratio [95% CI] vs. G3:** **Post-tx:** **G1:** OR = 2.11 [0.64, 6.94] *(P* = NS) **G2:** OR = 1.10; [0.35, 3.42] *(P* = NS) **6 mo FU:** **G1:** OR = 0.73 [0.25, 2.09] *(P* = NS) **G2:** OR = 0.61 [0.21, 1.83] *(P* = NS) **12 mo FU:** **G1:** OR = 2.13 [0.72, 6.27] *(P* = NS) **G2:** OR = 0.94 [0.33, 2.61] *(P* = NS)
	Total purges per 2 wks, mean (SD): **Baseline:** **G1:** 14.4 (11.3) **G2:** 11.0 (13.3) **G3:** 12.4 (11.8) **Mid-tx:** **G1:** 3.9 (6.0) *(P* = NR) **G2:** 3.5 (4.6) *(P* = NR) **G3:** 7.0 (13.3) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS)	**Total purges per 2 wks, mean (SD):** **Post-tx:** **G1:** 2.0 (4.5) *(P* = NR) **G2:** 2.8 (5.2) *(P* = NR) **G3:** 5.6 (10.9) *(P* = NR) **6 mo FU:** **G1:** 1.5 (2.8) *(P* = NR) **G2:** 3.8 (6.2) *(P* = NR) **G3:** 5.3 (10.5) *(P* = NR) **12 mo FU:** **G1:** 3.2 (8.2) *(P* = NR) **G2:** 3.2 (5.0) *(P* = NR) **G3:** 5.6 (12.1) *(P* = NR)
	Vomiting episodes/2 wks, mean (SD): **Baseline:** **G1:** 12.3 (10.9) **G2:** 10.0 (13.4) **G3:** 10.3 (10.8) **Mid-tx:** **G1:** 3.4 (5.3) *(P* = NR) **G2:** 3.4 (4.7) *(P* = NR) **G3:** 5.5 (11.8) *(P* = NR) Diff over time *(P* = NR)	**Vomiting episodes/2 wks, mean (SD):** **Post-tx:** **G1:** 1.9 (4.5) *(P* = NR) **G2:** 2.4 (4.6) *(P* = NR) **G3:** 4.4 (9.8) *(P* = NR) **6 mo FU:** **G1:** 1.5 (2.8) *(P* = NR) **G2:** 3.7 (6.2) *(P* = NR) **G3:** 3.7 (8.6) *(P* = NR) **12 mo FU:** **G1:** 3.1 (8.2) *(P* = NR) **G2:** 3.0 (4.9) *(P* = NR) **G3:** 4.5 (11.7) *(P* = NR)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Bulik, Sullivan, Carter et al., 1998 (continued)	**Laxative use episodes/2 wks, mean (SD):** **Baseline:** **G1:** 2.1 (5.3) **G2:** 1.0 (2.9) **G3:** 2.1 (4.4) **Mid-tx:** **G1:** 0.5 (1.5) *(P* = NR) **G2:** 0.1 (0.4) *(P* = NR) **G3:** 1.5 (5.1) *(P* = NR) Diff between groups *(P* = NS)	**Laxative use episodes/2 wks, mean (SD):** **Post-tx:** **G1:** 0.1 (0.5) *(P* = NR) **G2:** 0.5 (2.4) *(P* = NR) **G3:** 1.2 (3.7) *(P* = NR) **6 mo FU:** **G1:** 0.0 (0.0) *(P* = NR) **G2:** 0.1 (0.3) *(P* = NR) **G3:** 1.7 (5.4) *(P* = NR) **12 mo FU:** **G1:** 0.2 (0.6) *(P* = NR) **G2:** 0.3 (1.0) *(P* = NR) **G3:** 1.1 (3.4) *(P* = NR)
		Peak Subjective Units of Distress (CUE), regression coefficient [95% CI] vs. G3: **Post-tx:** **G1:** -0.30 [-0.47, -0.12] *(P* = 0.001) G1 better than G3 **G2:** -0.11 [-0.29, 0.07] *(P* = NS)
		Peak Urge To Binge (CUE), regression coefficient [95% CI] vs. G3: **Post-tx:** **G1:** -0.20 [-0.40, 0.005] *(P* = NS) **G2:** -0.17 [-0.38, 0.00] *(P* = NS)
		Peak Urge To Purge (CUE), regression coefficient [95% CI] vs. G3: **Post-tx:** **G1:** -0.18 [-0.39, 0.04] *(P* = NS) **G2:** 0.05 [-0.17, 0.27] *(P* = NS)
		Food restriction (Clinician Rated), Odd ratio [95% CI] vs. G3: **Post-tx:** **G1:** OR = 0.39 [0.16, 1.01] *(P* = 0.05) G1 better than G3 **G2:** OR = 1.00 [0.41, 2.47] *(P* = NS) **6 mo FU:** **G1:** OR = 1.11 [0.44, 2.83] *(P* = NS) **G2:** OR = 1.54 [0.58, 4.10] *(P* = NS) **12 mo FU:** **G1:** OR = 0.30 [0.12, 0.80] *(P* = 0.02) G1 better than G3 **G2:** OR = 0.44 [0.17, 1.10] *(P* = NS)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Bulik, Sullivan, Carter et al., 1998 (continued)	**EDI drive for thinness, mean (SD):** **Baseline:** **G1:** 14.4 (4.7) **G2:** 14.3 (5.0) **G3:** 13.4 (4.7) **Mid-tx:** **G1:** 9.3 (6.0) *(P* = NR) **G2:** 8.5 (5.2) *(P* = NR) **G3:** 9.4 (6.0) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NS)	**EDI drive for thinness, mean (SD):** **Post-tx:** **G1:** 5.6 (5.7) *(P* = NR) **G2:** 6.6 (5.6) *(P* = NR) **G3:** 7.8 (6.6) *(P* = NR) **6 mo FU:** **G1:** 4.4 (5.1) *(P* = NR) **G2:** 6.8 (5.4) *(P* = NR) **G3:** 5.3 (6.2) *(P* = NR) **12 mo FU:** **G1:** 7.1 (6.1) *(P* = NR) **G2:** 5.5 (5.9) *(P* = NR) **G3:** 6.6 (5.9) *(P* = NR) **EDI drive thinness, regression coefficient [95% CI] vs. G3:** **Post-tx:** **G1:** -1.40 [-2.52, -0.28] *(P* = 0.01) G1 better than G3 **G2:** -0.38 [-1.49, 0.73] *(P* = NS) **6 mo FU:** **G1:** -0.86 [-3.37, 1.64] *(P* = NS) **G2:** 1.89 [-0.73, 4.51] *(P* = NS) **12 mo FU** **G1:** -0.43 [-3.68, 2.82] *(P* = NS) **G2:** 0.04 [-3.06, 3.15] *(P* = NS)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Bulik, Sullivan, Carter et al., 1998 (continued)	**EDI bulimia, mean (SD):** **Baseline:** **G1:** 9.5 (4.1) **G2:** 8.7 (5.5) **G3:** 10.1 (4.3) **Mid-tx:** **G1:** 3.2 (4.3) *(P* = NR) **G2:** 3.8 (3.8) *(P* = NR) **G3:** 4.4 (4.5) *(P* = NR) Diff over time *(P* = NR)	**EDI bulimia, mean (SD):** **Post-tx:** **G1:** 1.5 (3.0) *(P* = NR) **G2:** 1.6 (2.9) *(P* = NR) **G3:** 3.3 (3.5) *(P* = NR) **6 mo FU:** **G1:** 1.0 (1.8) *(P* = NR) **G2:** 1.8 (3.6) *(P* = NR) **G3:** 1.7 (3.0) *(P* = NR) **12 mo FU:** **G1:** 2.6 (4.6) *(P* = NR) **G2:** 3.1 (4.9) *(P* = NR) **G3:** 3.1 (4.9) *(P* = NR) **EDI bulimia, regression coefficient [95% CI] vs. G3:** **Post-tx:** **G1:** -0.60 [-1.23, 0.02] *(P* = 0.06) G1 better than G3 **G2:** -0.77 [-1.38, -0.16] *(P* = 0.01) G2 better than G3 **6 mo FU:** **G1:** -0.32 [-1.69, 1.06] *(P* = NS) **G2:** -0.07 [-1.50, 1.36] *(P* = NS) **12 mo FU:** **G1:** -0.71 [-3.54, 2.11] *(P* = NS) **G2:** 0.44 [-2.25, 3.13] *(P* = NS)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Bulik, Sullivan, Carter et al., 1998 (continued)	**EDI body dissatisfaction, mean (SD):** **Baseline:** **G1:** 18.9 (7.3) **G2:** 18.0 (7.4) **G3:** 18.0 (8.0) **Mid-tx:** **G1:** 13.3 (8.1) *(P* = NR) **G2:** 13.4 (7.7) *(P* = NR) **G3:** 15.0 (8.0) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NS)	**EDI body dissatisfaction, mean (SD):** **Post-tx:** **G1:** 10.8 (8.9) *(P* = NR) **G2:** 12.1 (8.2) *(P* = NR) **G3:** 12.3 (7.8) *(P* = NR) **6 mo FU:** **G1:** 8.0 (8.3) *(P* = NR) **G2:** 13.4 (8.8) *(P* = NR) **G3:** 10.6 (7.6) *(P* = NR) **12 mo FU:** **G1:** 12.2 (8.4) *(P* = NR) **G2:** 11.3 (9.3) *(P* = NR) **G3:** 13.3 (9.2) *(P* = NR) **EDI body dissatisfaction, regression coefficient [95% CI] vs. G3:** **Post-tx:** **G1:** -0.44 [-1.70, 0.82] *(P* = NS) **G2:** 0.71 [-0.54, 1.96] *(P* = NS) **6 mo FU:** **G1:** -0.29 [-3.58, 3.00] *(P* = NS) **G2:** 3.96 [0.54, 7.37] *(P* = 0.03) G1 better than G3 **12 mo FU:** **G1:** 0.93 [-2.93, 4.79] *(P* = NS) **G2:** 0.79 [CI: -2.89, 4.46] *(P* = NS) **Body dissatisfaction (Clinician Rated), Odd ratio [95% CI] vs. G3:** **Post-tx:** **G1:** OR = 0.32 [0.13, 0.83] *(P* = 0.02) G1 better than G3 **G2:** OR = 1.46 [0.58, 3.72] *(P* = NS) **6 mo FU:** **G1:** OR = 1.04 [0.42, 2.54] *(P* = NS) **G2:** OR = 1.16 [0.44, 3.01] *(P* = NS) **12 mo FU:** **G1:** 0.74 [0.30, 1.84] *(P* = NS) **G2:** 0.45 [0.18, 1.13] *(P* = NS)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Bulik, Sullivan, Joyce et al., 1998 **Companion article:** Bulik, Sullivan, Carter et al.,1998 and Carter et al., 2003 **Setting:** University of Canterbury, New Zealand **Enrollment period:** NR	To examine predictors of outcome from BN 1 yr after completion of CBT by partitioning predictors temporally into lifetime (including personality), PreTx, and posttx categories.	**Groups:** **G1:** exposure to pre-binge cues (B-ERP) (N = 37) **G2:** exposure to pre-purge cues *(*P-ERP) (N = 35) **G3:** relaxation training (RELAX) (N = 39) **Enrollment:** Enrolled (N = 135) Randomized (N = 111) Completed tx (N = 106) Completed 12-mo FU (N = 101)	**Age, yrs, mean (SD):** 26.5 (6.13) **Sex:** Female: 100% **Race/ethnicity:** White: 91% Maori, Pacific Island, and Asian: 6% **Duration of BN, yrs, mean (SD):** 6.7 (5.8) **Lifetime comorbidity:** Mood: 70.4% Anxiety: 61.5% Alcohol use disorders: 48.1% AN: 25.0% **Marital Status:** Never married or “de facto relationship”: 62.2% **Currently employed:** 59.3% **Education, yrs, mean (SD):** 13.1 (2.6)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Female, age: 17 to 45 yrs, primary DSM III-R dx of BN **Exclusion:** Current AN; current obesity (BMI > 30); current severe major depression, medical illness, or medical complications of BN; current use of psychoactive meds; unwilling to undergo a supervised drug wash-out period.	8 sessions of CBT (2 first wk, then wkly) based on manuals. **Randomized groups:** 2 wks of sessions twice per wk, then 4 wkly sessions; at least 2 performed outside office; sessions lasted until arousal approached baseline (min, 50 min, max, 3 hours). **G1:** B-ERP **G2:** P-ERP **G3:** RELAX FU interview inquired about 2 wk episodes throughout the 6 mos. The mean frequency of bingeing and purging per episode in the 3 mos before the 1 yr FU was calculated.	Univariate logistic regression, stepwise logistic regression	**Score:** Fair **Intent to treat:** No **Blinding:** Post-tx assessor was blinded, however FU assessor blinding is NR. **Adverse events:** NR **Funding:** Original study: New Zealand Health Research Council and New Zealand Lottery Grants Board

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures: Baseline	Eating Related Measures: Outcomes
Author, yr: Bulik, Sullivan, Joyce et al., 1998 (continued)		**Met DSM III-R criteria for BN in the mo before 1 yr FU:** 17% **Bingeing and Purging Episodes, past 3 mos:** Category 1 (none): 38% Category 2 (not more than 2/wk on avg): 45% Category 3 (2 or more/wk on avg): 16% **Reported additional tx between end of tx and 1 yr FU:** Category 1: 2.6% Category 2: 6.7% Category 3: 37.5% Diff between groups *(P* = 0.002) **Poor outcome at 1 yr FU (Predicted by lifetime hx and personality), odds ratio [95% CI]:** **G1:** 0.32 [0.12 – 0.91] **G2:** NR **G3:** NR **Predicting 1 Yr Outcome with demographics, lifetime hx, and personality:** **Univariate Model, predictor, mean (SD) or %, odds ratio [95% CI]:** **Self-directedness: 24.6 (8.20), 0.94 [0.89 – 0.98] *(P* < 0.05), higher self-directedness predicts better outcome.** Age, yrs: 26.5 (6.13), 0.97 [0.91 – 1.03] *(P* = NS) BMI min: 18.6 (2.46), 0.95 [0.81 – 1.10] *(P* = NS) Hx of obesity: 8.8%, 2.60 [0.71 – 9.56] *(P* = NS) Prior inpatient tx: 9.9%, 0.04 [0.80 – 3.57] *(P* = NS) Duration of BN, yrs: 6.82 (6.07), 0.96 [0.91 – 1.03] *(P* = NS) Lifetime AN: 24.3%, 1.09 [0.46 – 2.60] *(P* = NS) Lifetime major depression: 52.5%, 1.15 [0.55 – 2.41] *(P* = NS) Lifetime alcohol dependence: 42.6%, 0.81 [0.38 – 1.72] *(P* = NS) Lifetime anxiety disorder: 43.6%, 1.21 [0.57 – 2.56] *(P* = NS) Novelty seeking: 21.6 (6.33), 1.00 [0.94 – 1.06] *(P* = NS) Harm avoidance: 20.7 (6.89), 1.03 [0.98 – 1.09] *(P* = NS) Reward dependence: 15.8 (4.36), 1.03 [0.95 – 1.12] *(P* = NS) Persistence: 4.82 (1.98), 1.06 [0.88 – 1.29] *(P* = NS) Cooperativeness: 34.1 (5.77), 1.01 [0.95 – 1.06] *(P* = NS) Self-transcendence: 11.1 (5.66), 1.00 [0.94 – 1.07] *(P* = NS) Total cluster A personality symptoms: 4.12 (3.45), 1.02 [0.91 – 1.14] *(P* = NS) Total cluster B symptoms: 7.35 (4.96), 1.07 [0.99 – 1.16] *(P* = NS) Total cluster C symptoms: 6.36 (4.64), 1.02 [0.94 – 1.10] *(P* = NS) Borderline personality disorder: NR, 1.29 [0.55 – 3.04] *(P* = NS) **Stepwise Model, predictor, odds ratio [95% CI]:** Hx of Obesity: 7.88 [1.42 – 43.64] *(P* < 0.05), hx of obesity increased odds of poor outcome Lifetime hx of alcohol dependence: 0.26 [0.12 – 0.68] *(P* < 0.05), hx of alcohol dependence decreased odds of poor outcome Self-directedness: 0.92 [0.87 – 0.98] *(P* < 0.05), increased self-directedness decreased the odds of poor outcome

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Bulik, Sullivan, Joyce et al., 1998 (continued)		**Predicting 1 Yr Outcome with Pre-tx Status:** **Univariate model, predictor, mean (SD) or %, odds ratio [95% CI]:** GAFS: 55.6 (6.66), 0.91[0.86 – 0.97] *(P* < 0.05), lower GAFS predicted poorer outcome EDI, bulimia: 9.61 (4.78), 1.15 [1.05 – 1.25] *(P* < 0.05), higher EDI bulimia scores predicted poorer outcome Major depression, past mo: 23%, 3.54 [1.39 – 9.01] *(P* < 0.05) Greater current major depression predicted poorer outcome Binges past 2 wks: 10.6 (11.5), 1.03 [0.99 – 1.06] *(P* = NS) Total purges per 2-wk period: 14.7 (20.8), 1.03 [1.00 – 1.06] *(P* = NS) Food restriction (quartiles: 3 = 24%; 2 = 29%; 1 = 33%; 0 = 14%): 1.29 [0.88 – 1.88] *(P* = NS) Body dissatisfaction (quartiles: 3 = 37%; 2 = 35%; 1 = 24%; 0 = 4%): 0.97 [0.64 – 1.49] *(P* = NS) HDRS: 8.75 (5.39), 1.07 [0.99 – 1.15] *(P* = NS) EDI drive for thinness: 14.3 (4.64), 1.09 [1.00 – 1.19] *(P* = NS) EDI body dissatisfaction: 18.9 (7.50), 1.03 [0.98 – 1.08] *(P* = NS) Peak SUDS: 1.67 (0.83), 1.45 [0.68 – 3.12] *(P* = NS) Peak urge to binge: 2.44 (0.50), 1.68 [1.05 – 2.69] *(P* = NS) Peak urge to purge: 2.04 (0.95), 1.34 [0.89 – 1.98] *(P* = NS) Alcohol dependence, past mo: 16%, 1.16 [0.42 – 3.18] *(P* = NS) **Stepwise model, predictor, odds ratio [95% CI]:** GAFS: 0.93 [0.86 – 0.99] *(P* < 0.05), increased GAFS increased odds of a good outcome EDI bulimia: 1.16 [1.06 – 1.27] *(P* < 0.05), increased EDI bulimia scale increased the odds of poor outcome Major depression, past mo: 2.80 [1.04 – 7.52] *(P* < 0.05), presence of major depression at PreTx increased the odds of poor outcome Body dissatisfaction (quartiles): 0.67 [0.41 – 1.08] *(P* = NS)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures: Baseline	Eating Related Measures: Outcomes
Author, yr: Bulik, Sullivan, Joyce et al., 1998 (continued)		**Predicting 1 Yr Outcome with Post-tx Status:** **Univariate model, predictor, mean (SD) or %, odds ratio [95% CI]:** Binges past 2 wks: 1.58 (3.24), 1.30 [1.11 – 1.51] *(P* < 0.05), higher binge frequency predicted poorer outcome. Food restriction (quartiles: 3 = 5%; 2 = 15%; 1 = 34%; 0 = 46%): 2.45 [1.51 – 3.96] *(P* < 0.05) Greater food restriction predicted poorer outcome Body dissatisfaction (quartiles: 3 = 11%; 2 = 24%; 1 = 52%; 0 = 13%): 3.25 [1.89 – 5.58] *(P* < 0.05) Greater body dissatisfaction predicted poorer outcome GAFS: 69.6 (9.85), 0.90 [0.86 – 0.95] *(P* < 0.05), lower GAFS predicted poorer outcome HDRS: 5.15 (5.64), 1.11 [1.04 – 1.20] *(P* < 0.05), higher HDRS predicted poorer outcome EDI drive for thinness: 6.69 (6.08), 1.15 [1.07 – 1.24] *(P* < 0.05), higher EDI drive for thinness predicted poorer outcome EDI bulimia: 2.23 (3.26), 1.23[1.09 – 1.40] *(P* < 0.05), higher EDI bulimia scores predicted poorer outcome Peak SUDS: 1.68 (0.83), 1.79 [1.09 – 2.94] *(P* < 0.05), higher peak SUDS predicted poorer outcome Peak urge to binge: 0.79 (0.92), 2.11 [1.34– 3.34] *(P* < 0.05), higher peak urge to binge predicted poorer outcome Peak urge to purge: 0.80 (0.98), 2.81 [1.76 – 4.47] *(P* < 0.05), higher peak urge to purge predicted poorer outcome EDI body dissatisfaction: 11.9 (8.22), 1.05 [1.00 – 1.10] *(P* = NS) Total purges per 2-wk period: 3.67 (8.03), 1.10 [1.03 – 1.18] *(P* = NS) **Stepwise model, odds ratio [95% CI]:** Binges past 2 wks: 1.23 [1.06 – 1.42] *(P* < 0.05), higher binge frequency predicted poorer outcome Food restriction (quartiles): 2.35 [1.38 – 4.01] *(P* < 0.05) Greater food restriction predicted poorer outcome Peak urge to binge: 2.06 [1.24 – 3.43] *(P* < 0.05) Greater urge to binge predicted poorer outcome

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Carter et al., 2003 **Companion article:** Bulik, Sullivan, Carter et al., 1998 and Bulik, Sullivan, Joyce et al., 1998 **Setting:** Outpatient, Christchurch, New Zealand **Enrollment period:** NR	To evaluate 3-yr outcome of an RCT that compared the additive efficacy of exposure based behavioral txs versus non-exposure based behavioral txs with a core of CBT.	**Groups:** **G1:** exposure to pre-binge cues (B-ERP) (N = 37) **G2:** exposure to pre-purge cues *(*P-ERP) (N = 35) **G3:** relaxation training (RELAX) (N = 39) **Enrollment:** Completed 3 yr FU (N = 113) • **G1:** Completed B-ERP and 3 yr FU (N = 23) • **G2:** Completed P-ERP and 3 yr FU (N = 27) • **G3:** Completed RELAX and 3 yr FU (N = 30) • **G4:** Completed CBT and BT interventions and 3 yr FU (N = 92) • **G5:** Completed CBT and 3 yr FU but not BT (N = 15) • **G6:** Completed 3 yr FU but not CBT or BT (N = 6)	**Age, yrs, mean (SD):** 26.1 (6.1) **Sex:** Female: 100% **Race/ethnicity:** White: 91% Maori, Pacific Island Asian: 6%

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Female; age 17-45; current primary DSM III-R dx of BN **Exclusion:** Current AN, current obesity (BMI>30 kg/m^2), current severe major depression with severe suicidal ideation or requiring immediate tx with antidepressants, current severe medical illness or severe medical complications of BN, or the current use of psychoactive meds and unwillingness to undergo a supervised drug wash-out period.	8 sessions of CBT (2 first wk, then wkly) based on manuals. **Randomized groups:** 2 wks of sessions twice per wk, then 4 wkly sessions; at least 2 performed outside office; min of 50 minutes but lasted until arousal approached baseline (50 minutes– 3 h). **G1:** B-ERP **G2:** P-ERP **G3:** (RELAX)	Non-parametric (Kruskal-Wallis) ANOVA to evaluate outcomes in groups defined by tx completion (G4, G5, G6). Chi-square tests to compare eating-related dx at FU in G4 vs. G5 vs. G6. Separate series of repeated measures ANOVAs to evaluate outcomes in groups that completed CBT and BT (series 1: G1 vs. G3; series 2: G2 vs. G3).	**Score:** Good **Intent to treat:** Yes **Blinding:** Assessor, at post-tx only. **Adverse events:** NA **Funding:** Health Research Council of New Zealand and the New Zealand Lottery Grants Board

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, Yr: Carter et al., 2003 (continued)	**Binge frequency, past 2 wks, median (range):** NR	**Binge frequency, past 2 wks, median (range):** **Post-tx:** **G1:** 0.0 (0.0 – 10.0) *(P* = NR) **G2:** 0.0 (0.0 – 20.0) *(P* = NR) **G3:** 0.0 (0.0 – 12.0) *(P* = NR) **3 Yr FU:** **G1:** 0.0 (0.0 – 20.0) *(P* = NR) **G2:** 0.0 (0.0 – 12.0) *(P* = NR) **G3:** 0.0 (0.0 – 28.0) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **G4:** 0.0 (0.0 – 28.0) *(P* = NR) **G5:** 0.0 (0.0 – 4.0) *(P* = NR) **G6:** 5.5 (1.0 – 30.0) *(P* = NR) Diff between groups *(P* < 0.05) G1 and G2 better than G6
	Vomiting frequency, past 2 wks, median (range): NR	**Vomit frequency, past 2 wks, median (range):** **Post-tx:** **G1:** 0.0 (0.0 – 10.0) *(P* = NR) **G2:** 0.0 (0.0 – 20.0) *(P* = NR) **G3:** 0.0 (0.0 – 12.0) *(P* = NR) **3 Yr FU:** **G1:** 0.0 (0.0 – 20.0) *(P* = NR) **G2:** 0.0 (0.0 – 12.0) *(P* = NR) **G3:** 0.0 (0.0 – 42.0) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **G4:** 0.0 (0.0 – 42.0) *(P* = NR) **G5:** 0.0 (0.0 – 6.0) *(P* = NR) **G6:** 5.5 (1.0 – 30.0) *(P* = NR) Diff between groups *(P* < 0.05) G4 and G5 better than G6
	Purge frequency, past 2 wks, median (range): NR	**Purge frequency, past 2 wks, median (range):** **Post-tx:** **G1:** 0.0 (0.0 – 10.0) *(P* = NR) **G2:** 0.0 (0.0 – 20.0) *(P* = NR) **G3:** 0.0 (0.0 – 25.0) *(P* = NR) **3 Yr FU:** **G1:** 0.0 (0.0 – 20.0) *(P* = NR) **G2:** 0.0 (0.0 – 12.0) *(P* = NR) **G3:** 0.0 (0.0 – 42.0) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **G4:** 0.0 (0.0 – 42.0) *(P* = NR) **G5:** 0.0 (0.0 – 6.0) *(P* = NR) **G6:** 5.5 (1.0 – 35.0) *(P* = NR) Diff between groups *(P* < 0.05) G4 and G5 better than G6

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
HRDS, median (range): NR	**HDRS, median (range):** **Post-tx:** **G1:** 2.0 (0.0 –14.0) *(P* = NR) **G2:** 3.0 (0.0 – 24.0) *(P* = NR) **G3:** 7.0 (0.0 – 19.0) *(P* = NR) **3 Yr FU:** **G1:** 2.0 (0.0 – 19.0) *(P* = NR) **G2:** 6.0 (0.0 – 23.0) *(P* = NR) **G3:** 4.0 (0.0 – 18.0) *(P* = NR) Diff between groups *(P* = 0.008) G1 better than G3 Diff between groups in change over time *(P* = 0.02) G3 better than G1 (G1 benefit at post-tx not maintained at FU) Diff between groups in change over time *(P* = 0.03), G3 better than G2 (G2 NS advantage at post-tx and G3 NS advantage at FU) **G4:** 3.5 (0.0 – 23.0) *(P* = NR) **G5:** 4.0 (0.0 – 31.0) *(P* = NR) **G6:** 7.0 (0.0 – 20.0) *(P* = NR) Diff between groups *(P* = NS)		
GAF, median (range): NR	**GAF median (range):** **Post-tx:** **G1:** 75.0 (51.0-88.0) *(P* = NR) **G2:** 70.0 (52.0 – 85.0) *(P* = NR) **G3:** 70.0 (50.0 – 82.0) *P* = NR) **3 Yr FU:** **G1:** 70.0 (45.0 – 90.0) *(P* = NR) **G2:** 68.0 (40.0 – 90.0) *(P* = NR) **G3:** 64.0 (50.0 – 90.0) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **G4:** 68.5 (40.0 – 49.0) *(P* = NR) **G5:** 74.0 (55.0 – 89.0) *(P* = NR) **G6:** 51.0 (35.0 – 65.0) *(P* = NR) Diff between groups *(P* < 0.05) G4 and G5 better t han G6		

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, Yr: Carter et al., 2003 (continued)	**Dieting, median (range):** NR	**Dieting, median (range):** **Post-tx:** **G1:** 0.0 (0.0 – 28.0) *(P* = NR) **G2:** 1.0 (0.0 – 28.0) *(P* = NR) **G3:** 2.0 (0.0 – 42.0) *(P* = NR) **3 Yr FU:** **G1:** 3.0 (0.0 – 42.0) *(P* = NR) **G2:** 0.0 (0.0 – 42.0) *(P* = NR) **G3:** 5.5 (0.0 – 42.0) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **G4:** 3.5 (0.0 – 42.0) *(P* = NR) **G5:** 0.0 (0.0 – 28.0) *(P* = NR) **G6:** 28.0 (0.0 – 42.0) *(P* = NR) Diff between groups *(P* < 0.05) G4 and G5 better than G6
	Body dissatisfaction, median (range): NR	**Body dissatisfaction, median (range):** **Post-tx:** **G1:** 5.0 (0.0 – 28.0) *(P* = NR) **G2:** 14.0 (0.0 – 42.0) *(P* = NR) **G3:** 12.0 (0.0 – 42.0) *(P* = NR) **3 Yr FU:** **G1:** 8.0 (0.0 – 42.0) *(P* = NR) **G2:** 3.0 (0.0 – 42.0) *(P* = NR) **G3:** 3.5 (0.0 – 42.0) *(P* = NR) Diff over time *(P* = 0.005) G2 and G3 better at FU Diff between groups *(P* = NS) Diff between groups in change over time *(P* = 0.02) G3 better than G1 (benefit of G1 at post-tx not maintained at FU) **G4:** 4.0 (0.0 – 42.0) *(P* = NR) **G5:** 2.0 (0.0 – 28.0) *(P* = NR) **G6:** 17.0 (10.0 – 42.0) *(P* = NR) Diff between groups *(P* = NS)
	EDI Drive for thinness, median (range): NR	**EDI Drive for thinness, median (range):** **Post-tx:** **G1:** 4.0 (0.0 – 17.0) *(P* = NR) **G2:** 6.0 (0.0 – 17.0) *(P* = NR) **G3:** 4.0 (0.0 – 19.0) *(P* = NR) **3 Yr FU:** **G1:** 1.0 (0.0 – 23.0) *(P* = NR) **G2:** 2.0 (0.0 – 19.0) *(P* = NR) **G3:** 2.0 (0.0 – 15.0) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **G4: 2**.0 (0.0 – 23.0) *(P* = NR) **G5:** 2.0 (0.0 – 15.0) *(P* = NR) **G6:** 16.0 (0.0 – 12.0) *(P* = NR) Diff between groups *(P* = NS)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, Yr: Carter et al., 2003 (continued)	**EDI Bulimia, median (range):** NR	**EDI Bulimia, median (range):** **Post-tx:** **G1:** 0.0 (0.0 – 12.0) *(P* = NR) **G2:** 0.0 (0.0 – 10.0) *(P* = NR) **G3:** 2.0 (0.0 – 12.0) *(P* = NR) **3 Yr FU:** **G1:** 0.0 (0.0 – 34.0) *(P* = NR) **G2:** 0.0 (0.0 – 14.0) *(P* = NR) **G3:** 0.0 (0.0 – 17.0) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.04) G3 better than G2 (G2 benefit at post-tx not maintained at FU) **G4:** 0.0 (0.0 – 34.0) *(P* = NR) **G5:** 0.0 (0.0 – 15.0) *(P* = NR) **G6:** 7.0 (0.0 – 15.0) *(P* = NR) Diff between groups *(P* < 0.05) G4 better than G6
	EDI Body dissatisfaction, median (range): NR	**EDI Body dissatisfaction, median (range): Post-tx:** **G1:** 5.0 (0.0 –23.0) *(P* = NR) **G2:** 10.0 (0.0 – 27.0) *(P* = NR) **G3:** 12.50 (0.0 – 27.0) *(P* = NR) **3 Yr FU:** **G1:** 8.0 (0.0 – 34.0*) (P* = NR) **G2:** 5.0 (0.0 – 27.0*) (P* = NR) **G3:** 7.0 (0.0 – 27.0) *(P* = NR) Diff over time *(P* = 0.004) G2 and G3 better vs. post-tx Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **G4:** 7.0 (0.0 – 34.0) *(P* = NR) **G5:** 3.0 (0.0 – 25.0) *(P* = NR) **G6:** 15.0 (6.0 – 24.0) *(P* = NR) Diff between groups *(P* = NS)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, Yr: Carter et al., 2003 (continued)		**Eating-related dx** **BN Current (%):** **G4:** 12 **G5:** 7 **G6:** 83 Diff between groups *(P* < 0.05) G4 and G5 better than G6 **BN Last Yr (%):** **G4:** 16 **G5:** 27 **G6:** 83 Diff between groups *(P* < 0.05) G4 and G5 better than G6 **AN Current (%):** **G4:** 1 **G5:** 0 **G6:** 0 Diff between groups *(P* = NS) **AN Last Yr (%):** **G4:** 1 **G5:** 13 **G6:** 0 Diff between groups *(P* = NS) **EDNOS Current (%):** **G4:** 15 **G5:** 13 **G6:** 17 Diff between groups *(P* = NS) **EDNOS Last Yr (%):** **G4:** 20 **G5:** 27 **G6:** 17 Diff between groups *(P* = NS) **Any ED Current (%):** **G4:** 28 **G5:** 20 **G6:** 100 Diff between groups *(P* < 0.05) G4 and G5 better than G6 **Any ED Last Yr (%):** **G4:** 35 **G5:** 53 **G6:** 100 Diff between groups *(P* < 0.05) G4 and G5 better than G6

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Chen et al., 2003 **Setting:** Outpatient Sydney, Australia **Enrollment period:** NR	To develop the Oxford University individual CBT (ICBT) manual into a group format (GCBT) and compare them on measures of binge eating, purging, dietary restraint, wt and shape attitudes, eating disorder attitudes, and general pathology at post-tx, and at 3- and 6-mo FU	**Groups** **G1:** ICBT (N = 30) **G2:** GCBT (N = 30) **Enrollment:** Subjects recruited from University-affiliated hospital ED programs and general practitioners in the local area Referred: N = 153 Presented for general psych assessment: N = 125 Eligible: N = 94 Presented for BN symptom assessment: and randomized: N = 71 Enrolled: N = 60 **Dropouts:** During tx: N = 16 **G1:** 27% **G2:** 27% By 3 mo FU: N = 21 By 6 mo FU: N = 23	**Age, yrs, mean (SD):** 25.80 (7.24) **Sex:** 100% female **Race/ethnicity:** NR **BN Duration, yrs, mean (SD):** 9.6 (7.26) **BN Behaviors, N (%):** Purging, 55 (92%) Vomiting, 55 (92%) Laxative abuse, 19 (32%) Diuretic abuse, 3 (5%) Overexercise, 27 (45%) > one form, 32 (53%) **Treatment Hx, N (%):** ED tx, 32 (53%) Psych tx, 28 (47%) **Psychiatric Hx, N (%):** Past depression, 39 (65%) Past self-harm, 16 (30%) Past substance abuse, 19 (32%) Current substance abuse, 9 (15%)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Female, 18 yrs or older, BN via DSM IV, BMI = 19 to 27 kg/m2 **Exclusion:** Current BN tx, current suicide risk, medically unstable, other psychiatric comorbid dx, lived more than 1.5 hr away from test site	Pre-tx, post-tx, and FU assessments **G1 (ICBT):** 19, 50-minutes sessions based on Oxford semi-structured, 3 stage CBT program (Fairburn et al., 1993), over 4.5 mos, with optional self-help book (Fairburn, 1995) and information session with friends and family **G2 (GCBT):** 19, 90-minutes closed-group sessions adapted from ICBT program with identical handouts, content, and optional material over 4.5 mos; min 6 subjects per group Both txs conducted by same investigator; all sessions audiotaped. 3- and 6-mo FU	Randomized block design with 6 consecutive subjects per unit randomized to either ICBT or GCBT using random digits *(*Pocock, 1983). A priori power calculation estimated 30 subjects per group 2 group x 4 time-points repeated measures MANOVA with correction for multiple comparisons and post-hoc contrasts to assess change over time. Chi square test for categorical variables. Tx suitability ratings by patients and random, independent rater validations of 16.6% of EDE and 10% of therapy sessions	**Score:** Fair **Intent to treat:** Yes **Blinding:** No **Adverse events:** Alcohol abuse (N = 2) AN (N = 1) Visual hallucinations (N = 1) **Funding:** Australian Research Council, Australian Postgraduate Award, Welcome Trust Principal Research Fellowshi*P* Award

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Chen et al., 2003 (continued)	**Objective Binge Episodes, past 28 days, mean (SD):** **G1:** 32.07 (23.85) **G2:** 28.17 (25.47) *(P* = NS)	**Objective Binge Episodes, past 28 days, mean (SD):** **Post-tx:** **G1:** 7.77 (12.88) *(P* = NR) **G2:** 10.57 (17.84) *(P* = NR) **3 Mo FU:** **G1:** 8.80 (14.22) *(P* = NR) **G2:** 7.33 10.62) *(P* = NR) **6 Mo FU:** **G1:** 10.47 (14.24) *(P* = NR) **G2:** 9.60 (14.60) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	Subjective, mean (SD): **G1:** 14.97 (41.31) **G2:** 10.57 (15.72) *(P* = NS)	**Subjective, mean (SD):** **Post-tx:** **G1:** 5.57 (15.49) *(P* = NR) **G2:** 9.83 (18.57) *(P* = NR) **3 Mo FU:** **G1:** 2.37 (4.94) *(P* = NR) **G2:** 9.00 (16.87) *(P* = NR) **6 Mo FU:** **G1:** 4.30 (11.17) *(P* = NR) **G2:** 8.79 (17.21) *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	Objective and Subjective, mean (SD): **G1:** 47.03 (45.87) **G2:** 38.73 (31.99) *(P* = NS)	**Objective and Subjective, mean (SD):** **Post-tx:** **G1:** 13.33 (19.24) *(P* = NR) **G2:** 20.40 (29.82) *(P* = NR) **3 Mo FU:** **G1:** 11.17 (14.34) *(P* = NR) **G2:** 16.33 (17.91) *(P* = NR) **6 Mo FU:** **G1:** 14.77 (16.64) *(P* = NR) **G2:** 20.03 (25.23) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
State Anxiety, mean (SD): **G1:** 50.8 (10.38) **G2:** 48.70 (11.22) *(P* = NS)	**State Anxiety, mean (SD):** **Post-tx:** **G1:** 45.23 (11.60) *(P* = NR) **G2:** 43.87 (9.87) *(P* = NR) **3 Mo FU:** **G1:** 45.77 (11.21) *(P* = NR) **G2:** 45.70 (9.30) *(P* = NR) **6 Mo FU:** **G1:** 48.46 (10.67) *(P* = NR) **G2:** 42.43 (11.37) *(P* = NR) Diff over time *(P* = 0.02) Diff between group *(P* = NS) Diff between groups in change over time *(P* = 0.04) G2 better than G1	**BMI, mean (SD):** **G1:** 22.0 (2.1) **G2:** 22.4 (3.4) Diff between groups *(P* = NS)	**BMI, mean (SD):** **Post-tx:** **G1:** 22.2 (2.3) *(P* = NR) **G2:** 22.4 (3.3) *(P* = NR) **3 Mo FU:** **G1:** 22.0 (2.1) *(P* = NR) **G2:** 22.6 (3.0) *(P* = NR) **6 Mo FU:** **G1:** 22.3 (2.5) *(P* = NR) **G2:** 22.3 (2.9) *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
Trait Anxiety, mean (SD): **G1:** 55.33 (9.11) **G2:** 55.33 (8.15) *(P* = NS)	**Trait Anxiety, mean (SD):** **Post-tx:** **G1:** 51.87 (9.09) *(P* = NR) **G2:** 50.97 (8.90) *(P* = NR) **3 Mo FU:** **G1:** 52.60 (8.50) *(P* = NR) **G2:** 52.33 (9.48) *(P* = NR) **6 Mo FU:** **G1:** 52.53 (8.24) *(P* = NR) **G2:** 49.93 (10.02) *(P* = NR) Diff over time *(P* = 0.03) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)		
BDI, mean (SD): **G1:** 22.00 (9.69) **G2:** 22.70 (10.57) (*P* = NS)	**BDI, mean (SD):** **Post-tx:** **G1:** 15.37 (11.91) *(P* = NR) **G2:** 14.33 (10.36) *(P* = NR) **3 Mo FU:** **G1:** 16.73 (11.93) *(P* = NR) **G2:** 14.17 (10.18) *(P* = NR) **6 Mo FU:** **G1:** 16.70 (12.74) *(P* = NR) **G2:** 13.37 (10.68) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)		

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Chen et al., 2003 (continued)	**Purging episodes, past 28 days:** **Vomiting, mean (SD):** **G1:** 41.70 (48.79) **G2:** 31.20 (34.08) *(P* = NS)	**Purging episodes, past 28 days:** **Vomiting, mean (SD):** **Post-tx:** **G1:** 8.73 (16.39) *(P* = NR) **G2:** 18.83 (53.49) *(P* = NR) **3 Mo FU:** **G1:** 10.57 (16.89) *(P* = NR) **G2:** 10.77 (15.66) *(P* = NR) **6 Mo FU:** **G1:** 12.80 (17.86) *(P* = NR) **G2:** 11.20 (20.74) *(P* = NR) Diff over time *(P* < 0.001*)* Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	Laxatives, mean (SD): **G1:** 2.10 (4.32) **G2:** 2.33 (5.16) *(P* = NS)	**Laxatives, mean (SD):** **Post-tx:** **G1:** 0.06 (0.25) *(P* = NR) **G2:** 0.10 (0.40) *(P* = NR) **3 Mo FU:** **G1:** 0.93 (3.31) *(P* = NR) **G2:** 0.23 (1.10) *(P* = NR) **6 Mo FU:** **G1:** 1.23 (4.53) *(P* = NR) **G2:** 0.43 (2.19) *(P* = NR) Diff over time *(P* = 0.01) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	Overexercise, mean (SD): **G1:** 7.90 (10.98) **G2:** 8.07 (9.70) *(P* = NS)	**Overexercise, mean (SD):** **Post-tx:** **G1:** 2.53 (6.31) *(P* = NR) **G2:** 5.10 (8.97) *(P* = NR) **3 Mo FU:** **G1:** 2.37 (7.15) *(P* = NR) **G2:** 3.73 (7.87) *(P* = NR) **6 Mo:** **G1:** 2.47 (9.52) *(P* = NR) **G2:** 3.20 (7.17) *(P* = NR) Diff over time *(P* = 0.002) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
SCL-90R (Global), mean (SD): **G1:** 1.28 (0.55) **G2:** 1.45 (0.63) *(P* = NS)	**SCL-90R (Global), mean (SD):** **Post-tx:** **G1:** 1.03 (0.67) *(P* = NR) **G2:** 1.08 (0.75) *(P* = NR) **3 Mo FU:** **G1:** 1.05 (0.68) *(P* = NR) **G2:** 1.12 (0.72) *(P* = NR) **6 Mo FU:** **G1:** 1.11 (0.71) *(P* = NR) **G2:** 1.01 (0.75) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)		

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Chen et al., 2003 (continued)	**EDE-12 Restraint, mean (SD):** **G1:** 3.97 (1.10) **G2:** 3.96 (0.88) *(P* = NS)	**EDE-12 Restraint, mean (SD):** **Post-tx:** **G1:** 2.36 (1.78) *(P* = NR) **G2:** 2.65 (1.59) *(P* = NR) **3 Mo FU:** **G1:** 2.37 (1.80) *(P* = NR) **G2:** 2.51 (1.62) *(P* = NR) **6 Mo FU:** **G1:** 2.68 (1.78) *(P* = NR) **G2:** 2.56 (1.66) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	EDE-12 Wt Concern, mean (SD): **G1:** 6.97 (3.65) **G2:** 7.60 (3.64) *(P* = NS)	**EDE-12 Wt Concern, mean (SD):** **Post-tx:** **G1:** 5.71 (4.38) *(P* = NR) **G2:** 6.13 (4.50) *(P* = NR) **3 Mo FU:** **G1:** 5.44 (4.50) *(P* = NR) **G2:** 6.18 (4.63) *(P* = NR) **6 Mo FU:** **G1:** 5.67 (4.49) *(P* = NR) **G2:** 6.02 (4.66) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	EDE-12 Shape Concern, mean (SD): **G1:** 6.78 (2.45) **G2:** 6.50 (2.65) *(P* = NS)	**EDE-12 Shape Concern, mean (SD):** **Post –tx:** **G1:** 5.08 (2.36) *(P* = NR) **G2:** 5.16 (1.93) *(P* = NR) **3 Mo FU:** **G1:** 4.50 (2.54) *(P* = NR) **G2:** 4.00 (1.97) *(P* = NR) **6 Mo FU:** **G1:** 4.86 (2.87) *(P* = NR) **G2:** 4.50 (1.97) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Chen et al., 2003 (continued)	**EDE-12 total score, mean (SD):** **G1:** 5.19 (1.36) **G2:** 5.23 (1.26) *(P* = NS)	**EDE-12 Total score, mean (SD):** **Post-tx:** **G1:** 3.73 (2.05) *(P* = NR) **G2:** 3.97 (1.68) *(P* = NR) **3 Mo FU:** **G1:** 3.52 (2.17) *(P* = NR) **G2:** 3.87 (2.34) *(P* = NR) **6 Mo FU:** **G1:** 3.81 (2.21) *(P* = NR) **G2:** 3.74 (1.94) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
		Abstinence (Post): **G1:** 20% **G2:** 0% *(P* = 0.02) **Abstinence (3 mo):** **G1:** 16.7**%**% **G2:** 3.3% *(P* = NS) **Abstinence (6 mo):** **G1:** 13.3% **G2:** 10% *(P* = NS)
	EDE-12 Drive for Thinness, mean (SD): **G1:** 14.37 (4.06) **G2:** 14.93 (5.16) *(P* = NS)	**EDE-12 Drive for Thinness, mean (SD):** **Post-tx:** **G1:** 10.63 (5.58) *(P* = NR) **G2:** 11.20 (6.00) *(P* = NR) **3 Mo FU:** **G1:** 9.90 (6.13) *(P* = NR) **G2:** 10.70 (5.86) *(P* = NR) **6 Mo FU:** **G1:** 9.67 (6.77) *(P* = NR) **G2:** 9.53 (6.54) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Chen et al., 2003 (continued)	**EDE-12 Bulimia, mean (SD):** **G1:** 13.77 (4.11) **G2:** 12.87 (4.49) *(P* = NS)	**EDE-12 Bulimia, mean (SD):** **Post-tx:** **G1:** 8.07 (6.23) *(P* = NR) **G2:** 8.70 (6.45) *(P* = NR) **3 Mo FU:** **G1:** 8.33 (6.15) *(P* = NR) **G2:** 8.30 (6.60) *(P* = NR) **6 Mo FU:** **G1:** 6.26 (4.45) *(P* = NR) **G2:** 5.33 (4.73) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	EDE-12 Body Dissatisfaction, mean (SD): **G1:** 18.57 (7.75) **G2:** 16.57 (8.42) *(P* = NS)	**EDE-12 Body Dissatisfaction, mean (SD):** **Post-tx:** **G1:** 15.87 (8.25) *(P* = NR) **G2:** 14.70 (8.12) *(P* = NR) Diff over time *(P* = 0.001) **3 Mo Fu:** **G1:** 15.90 (8.89) *(P* = NR) **G2:** 14.23 (8.03) *(P* = NR) **6 Mo FU:** **G1:** 14.97 (8.99) *(P* = NR) **G2:** 12.43 (7.85) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Cooper and Steere, 1995 **Setting:** Outpatient, UK **Enrollment period:** 18 mos, dates not provided	**Research objective:** To compare CBT without exposure instructions versus with BT (EXRP) without cognitive restructuring to evaluate the validity of the CBT model of the maintenance of BN.	**Groups:** **G1:** CBT (cog therapy only; N = 15) **G2:** BT (EXR*P* only; N = 16) **Enrollment:** • Randomized (N = 31) • Completed (N = 27) **G1:** 13 **G2:** 14 **Drop Outs:** **G1:** N = 1 **G2:** N = 1 **Withdrawn (due to severe depression):** **G1:** N = 1 **G2:** N = 1 **FU:** **G1:** 12 **G2:** 13 1 in each group required tx for depression and was not assessed. Both responded poorly to tx.	**Age, yrs, mean (SD):** 23.8 (18-33) **Sex:** Female: 100% **Race/ethnicity:** NR **Wt, % of matched population mean (range):** 98.9% (82.7-122.2%) **Frequency of bulimic episodes during 4 wks before tx, mean (range):** 26.3 (6-72) **Frequency of self-induced vomiting during 4 wks before tx, mean (range):** 58.8 (0-580) **Onset of both bulimic episodes and purging, yrs, mean:** 19.6 **Duration of BN symptoms, mos, mean (range):** 56 (5-180) **Duration of purging, mos, mean (range):** 55.5 (4-168)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: DSM III-R criteria for BN, however only patients who were 'bout purgers' *(P*urged right after bingeing) were included. **Exclusion:** NR	18 wks of tx with 19 tx sessions; individual sessions lasting 50 minutes each. **Phase 1:** identical in each group *(*8 sessions on a twice wkly basis; education, exploring the problem; instituting bx techniques to gain control of eating). **Phase 2: G1:** 8 wkly sessions followed Fairburn's CBT *(P*roblem solving, cog restructuring; without behavioral instruction or hw for reducing dietary restraint). **G2:** 8 sessions (first 4 twice per wk for EXR*P* in session (eating and prevented vomiting; second 4 – wkly sessions and prevented bingeing rather than vomiting). Based on Rosen and Leitenberg (but modified to exclude cog factors). **Phase 3:** focused on maintenance as described by Fairburn (3 fortnightly sessions).	ANCOVA (controlling for pre tx diffs) but they did not report any significance levels for diffs pre-tx between the 2 groups and they did not state which variables they controlled for.	**Score:** Fair **Intent to treat:** No **Blinding:** N/A **Adverse events:** NR **Funding:** East Anglia Regional Health Authority

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Cooper and Steere, 1995 (continued)	**Bulimic episodes/mo, mean (SD):** **G1:** 21.9 (12.3) **G2:** 30.4 (19.4) *(P* = NR)	**Bulimic episodes/ mo, mean (SD):** **Post Treatment (after 18 wks):** **G1:** 4.5 (7.6) *(P* = NR) **G2:** 7.4 (13.9) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **FU (12 mos):** **G1:** 3.5 (6.3) *(P* = NR) **G2:** 16.5 (18.4) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **Abstinence rates, N (%):** **G1:** 6 (46%) **G2:** 7 (50%) *(P* = NS) **Reduction in freq of bulimic episodes, %:** **G1:** 78.0% **G2:** 78.7% *(P* = NS) **Relapse Rate (Bingeing):** **G1:** 0/6 who were abstinent **G2:** 5/7 who were abstinent Diff between groups *(P* < 0.04)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
Present State Examination (PSE) Global mental state, mean (SD): **G1:** 17.2 (9.8) **G2:** 17.9 (6.6) *(P* = NR)	**PSE Global mental state, mean (SD):** **Post tx (after 18 wks):** **G1:** 10.3 (7.7) *(P* = NR) **G2:** 9.3 (8.3) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **FU (12 mos):** **G1:** 8.3 (8.5) *(P* = NR) **G2:** 12.4 (8.9) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)	**Wt, % matched population mean (SD):** **G1:** 98.5 (11.5) **G2:** 99.3 (11.0) *(P* = NR)	**Wt, % of matched population mean (SD):** **Post-tx (after 18 wks):** **G1:** 98.8 (8.8) *(P* = NR) **G2:** 99.2 (10.5) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **FU (12 mos):** **G1:** 97.7 (10.4) *(P* = NR) **G2:** 99.5 (13.9) *(P* = NR) Diff over time *(P* = NR) *(P* = NR) Diff between groups in change over time *(P* = NR)
MADRS Depression, mean (SD): **G1:** 21.5 (7.4) **G2:** 21.1 (7.7) *(P* = NR)	**MADRS Depression, mean (SD):** **Post tx (after 18 wks):** **G1:** 14.0 (9.8) *(P* = NR) **G2:** 11.8 (11.5) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **FU (12 mos):** **G1:** 8.8 (7.5) *(P* = NR) **G2:** 14.9 (10.0) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.03) G1 better than G2		
BDI, mean (SD): **G1:** 21.8 (8.3) **G2:** 17.9 (11.5) *(P* = NR)	**BDI, mean (SD):** **Post tx (after 18 wks):** **G1:** 10.2 (9.4) *(P* = NR) **G2:** 10.4 (12.6) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **FU (12 mos):** **G1:** 8.0 (9.4) *(P* = NR) **G2:** 13.0 (10.8) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.04) G1 better than G2		

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures: Baseline	Eating Related Measures: Outcomes
Author, yr: Cooper and Steere, 1995 (continued)	**Self-induced vomiting/mo (SD):** **G1:** 36.1 (37.8) **G2:** 79.9 (149.1) *(P* = NR)	**Self-induced vomiting/mo, mean (SD):** **Post Treatment (after 18 wks):** **G1:** 4.5 (7.9) *(P* = NR) **G2:** 7.6 (13.2) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **FU (12 mos):** **G1:** 4.3 (7.1) *(P* = NR) **G2:** 23.4 (25.8) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.007) G1 better than G2 **Abstinence rates, N (%):** **G1:** 7 (54%) **G2:** 6 (43%) *(P* = NS) **Reduction in freq of vomiting, %:** **G1:** 82.8% **G2:** 91.1% *(P* = NS) **Relapse rate (Purging):** **G1:** 1/7 **G2:** 5/6 *(P* = NS)
	EDE – Dietary restraint, mean (SD): **G1:** 3.4 (1.6) **G2:** 3.2 (1.3) *(P* = NR)	**EDE – Dietary restraint, mean (SD):** **Post Treatment (after 18 wks):** **G1:** 1.2 (1.4) *(P* = NR) **G2:** 0.8 (1.2) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **FU (12 mos):** **G1:** 1.0 (1.1) *(P* = NR) **G2:** 1.6 (1.5) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
STAI – State Anxiety, mean (SD): **G1:** 54.2 (8.4) **G2:** 43.1 (13.0) *(P* = NR)	**STAI – State Anxiety, mean (SD):** **Post tx (after 18 wks):** **G1:** 38.8 (10.3) *(P* = NR) **G2:** 42.3 (15.3) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **FU (12 mos):** **G1:** 41.8 (11.0) *(P* = NR) **G2:** 42.0 (12.7) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)		
STAI – Trait Anxiety, mean (SD): **G1:** 55.8 (11.0) **G2:** 52.0 (10.6) *(P* = NR)	**STAI – Trait Anxiety, mean (SD):** **Post tx (after 18 wks):** **G1:** 44.8 (13.9) *(P* = NR) **G2:** 44.5 (14.6) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **FU (12 mos):** **G1:** 44.3 (12.5) *(P* = NR) **G2:** 49.3 (13.6) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)		

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Cooper and Steere, 1995 (continued)	**SRQ Dietary restraint, mean (SD):** **G1:** 13.6 (4.1) **G2:** 12.8 (4.5) *(P* = NR)	**SRQ Dietary restraint, mean (SD):** **Post Treatment (after 18 wks):** **G1:** 11.2 (5.1) *(P* = NR) **G2:** 8.5 (5.4) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **FU (12 mos):** **G1:** 11.2 (5.5) *(P* = NR) **G2:** 10.7 (4.2) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)
	EDE Shape concern, mean (SD): **G1:** 4.4 (1.2) **G2:** 4.3 (1.3) *(P* = NR)	**EDE Shape concern, mean (SD):** **Post Treatment (after 18 wks):** **G1:** 2.7 (1.8) *(P* = NR) **G2:** 2.2 (1.7) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **FU (12 mos):** **G1:** 2.6 (1.4) *(P* = NR) **G2:** 3.1 (1.4) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)
	EDE Wt concern, mean (SD): **G1:** 4.4 (1.3) **G2:** 3.8 (1.8) *(P* = NR)	**EDE Wt concern, mean (SD):** **Post Treatment (after 18 wks):** **G1:** 2.6 (1.9) ***(P*** = NR) **G2:** 1.6 (1.4) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **FU (12 mos):** **G1:** 2.3 (1.3) *(P* = NR) **G2:** 2.4 (1.6) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures: Baseline	Eating Related Measures: Outcomes
Author, yr: Cooper and Steere, 1995 (continued)	**Importance of shape and wt (geometric mean of 2 EDE items) (SD):** **G1:** 3.4 (1.8) **G2:** 3.4 (2.3) *(P* = NR)	**Importance of shape and wt (geometric mean of 2 EDE items) (SD):** **Post Treatment (after 18 wks):** **G1:** 2.7 (1.8) ***(P*** = NR) **G2:** 1.7 (2.1) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **FU (12 mos):** **G1:** 2.5 (1.2) *(P* = NR) **G2:** 2.4 (2.0) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)
	EAT, mean (SD): **G1:** 49.7 (16.9) **G2:** 44.3 (16.6) *(P* = NR)	**EAT, mean (SD):** **Post Treatment (after 18 wks):** **G1:** 20.0 (14.2) *(P* = NR) **G2:** 17.5 (15.6) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **FU (12 mos):** **G1:** 18.8 (14.7) *(P* = NR) **G2:** 24.3 (17.1) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	BSQ Body shape dissatisfaction, mean (SD): **G1:** 124.5 (30.9) **G2:** 120.6 (36.4) *(P* = NR)	**BSQ Body shape dissatisfaction, mean (SD):** **Post Treatment (after 18 wks):** **G1:** 84.3 (32.8) ***(P*** = NR) **G2:** 77.9 (36.5) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **FU (12 mos:** **G1:** 78.5 (26.3) *(P* = NR) **G2:** 89.3 (31.6) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Cooper and Steere, 1995 (continued)	**Desired wt, mean (SD):** **G1:** 87.6 (6.3) **G2:** 87.1 (4.5) *(P* = NR)	**Desired wt, mean (SD):** **Post Treatment (after 18 wks):** **G1:** 92.3 (6.9) *(P* = NR) **G2:** 91.7 (6.6) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **FU (12 mos):** **G1:** 91.1 (5.8) *(P* = NR) **G2:** 88.8 (8.3) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, year: Crosby, Mitchell et al., 1993 **Setting:** NR **Enrollment period:** NR	**Research objective:** To reanalyze treatment response and relapse using survival analyses in a 12-wk RCT of group CBT for the tx of BN.	**Groups (N = 143):** High Abstinence: HA High Intensity: HI Low Abstinence: LA Low Intensity: LI **G1**: HA/HI (N = 33) **G2**: HA/ LI (N = 41) **G3**: LA/HI (N = 35) **G4**: LA/LI (N = 34) **Enrollment:** • 143 enrolled and randomized	**Age, range:** 18 to 50 **Sex:** 100% female **Race/ethnicity:** NR

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Aged 18 to 50; meeting DSM-IIIR criteria for BN, with additional criteria for frequency at 3/wk for 6 mos prior to evaluation **Exclusion:** Concomitant alcohol or drug abuse, bipolar disorder or schizophrenia	12 wk study with 4 tx groups, differing on 2 factors: early abstinence and tx intensity; 2 groups were "high abstinence", with visits clustered early in tx, 2 were "low abstinence", where participants were instructed to improve at their own rate.; 2 groups were high intensity (45 program hours), 2 were low intensity (22.5 hrs); factors were crossed to create 4 tx conditions. All participants self-monitored daily eating behavior using the Eating Behaviors III.	Time to tx response: performed separately for 4 tx response definitions using survival analyses; drop-outs and completers who failed to meet tx response criteria were treated as censored observations. Time to relapse after initial response: analyzed in a sub-sample of participants using survival analyses; participants abstinent at tx end were treated as censored observations. In both analyses, relationships between groups and outcome variables were assessed by parametric accelerated failure time models, fitted using a log logistic distribution.	**Score:** Poor **Intent to treat:** NR **Blinding:** NR **Adverse events:** NR **Funding:** NR

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, year: Crosby, Mitchell et al., 1993 (continued)	**Initial Response:** **Total abstinence, no binging, vomiting, or laxative abuse per 2 wks (%):** **G1:** 27 (82%) **G2:** 27 (66%) **G3:** 20 (57%) **G4:** 8 (24%) **Overall:** 82 (57%) (P < 0.001) G1 sig higher overall G4 sig lower overall	**Maintained response, by last tx visit:** **Total abstinence (%):** **G1:** 22 (67%) (*P* =NR) **G2:** 28 (68%) (*P* =NR) **G3:** 22 (63%) (*P* =NR) **G4:** 7 (21%) (*P* =NR) **Overall:** 79 (55%) (*P* =NR) Diff between groups (*P* = NR) Diff between groups in change over time (*P* <0.0001) • 74 participants (90% initial; 93% maintained) met total criteria for both response times
	Near abstinence, 1 or fewer episodes per 2 wks (%): **G1:** 28 (85%) **G2:** 34 (83%) **G3:** 24 (69%) **G4:** 16 (47%) **Overall:** 102 (71%) (P < 0.001)	**Near abstinence (%):** **G1:** 25 (76%)(*P* =NR) **G2:** 30 (73%) (*P* =NR) **G3:** 23 (66%)(*P* =NR) **G4:** 9 (27%) (*P* =NR) **Overall:** 87 (61%) (*P* =NR) Diff between groups (*P* = NR) Diff between groups in change over time (*P* < 0.0001) • 86 participants (84% initial; 99% maintained) met near criteria for both response times

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, year: Crosby, Mitchell et al., 1993 (continued)		**Survival Analyses:** **Time to initial response, total abstinence:** Diff between groups in change over time: χ^2 = 46.9 (*P* < 0.001) Diff between G1 and G2 (*P* = 0.005) G1 sig shorter than G2 G2/G3 combined sig shorter than G4 Diff between G2 and G3 (*P* = NS) **Time to initial response, near abstinence:** Diff between groups in change over time:χ^2 = 34.7 (*P* < 0.001) Diff between G1 and G2 (*P* = 0.064) G2/G3 combined sig shorter than G4; Diff between G2 and G3 (*P* = NS) **Relapse after initial response, total abstinence:** In first week, 48% G1 and 25% G3 relapsed; Diff between groups in change over time (*P* = NS) **Relapse after initial response, near abstinence:** Diff between groups (*P* <0.001) Diff between G4 and G1/G2/G3 combined (*P* < 0.001) G4 sig higher than combined. G1 and G3 sig lower than others (*P* = NR) Diff between G1 and G3 (*P* = NS) **Relapse after maintained, total abstinence:** Diff between groups (*P* < 0001) **Relapse after maintained, near abstinence:** Diff between groups (*P* < 0001) Diff between G1 and G2/G3 combined in change over time (*P* = NS)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued))

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Davis et al., 1999 **Setting:** Eating Disorder Outpatient Clinic of Toronto Hospital, Toronto, Canada **Enrollment period:** 16 mos	**Research objective:** To investigate the efficacy of stepped care involving brief group PE followed by CBT to treat BN.To study the co-variation between clinical outcome and nonspecific psychopathology. To determine predictors of best response to stepped care strategy.	**Groups:** **G1:** PE only (N = 32) **G2:** PE + CBT (N = 39) Analysis presented on 56 completers only **G2R**: CBT remitters (N = 16) **G2N**: CBT non-remitters (N = 21) **Enrollment:** Referred by physician (71%) Recruited via newspaper ad (29%) Enrolled (N = 71) Completed initial 6 wk group PE and randomized (N = 58) **G1:** 19 **G2:** 39 **Dropouts, pre-tx:** **G1:** 13 **G2:** 2 Diff between groups in hx, demographics, bingeing, purging, and psychometric measures *(P* = NS) **Dropouts, during tx:** **G1:** 0 **G2:** 2	**Age, yrs, mean (SD):** 27.1 (5.3) **Sex:** Female: 100% **Race/ethnicity:** Caucasian: 100% **Duration of illness, yrs, mean (SD):** 7.6 (5.4) **Education:** College: 58% **Employment:** Full-time52% **Marital status:** Single: 78% **Hx of past AN:** 34% **Purge type:** Vomit: 87% Laxatives: 34%

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: DSM III-R criteria for BN by clinician or EDE, 85-125% of matched population mean wt, min 6-mo duration of illness **Exclusion:** Current psychological tx (therapy or meds); suicide risk; psychosis; medical instability; previous exposure to one of txs being studied	**Pre-tx Assessment:** EDE, BDI, BSI, RSE, semistructured interview, Binge Eating Adjective Checklist (BEAQ) Brief group PE (6, 90-minutes wkly sessions), manualized, focusing on self-care strategies (i.e., self-monitoring, meal planning, cognitive restructuring, stimulus control, and problem-solving) as well as normalizing eating behavior. Initially, 5-8 BN study participants plus 6-16 non-BN clinic patients (EDNOS or AN) per group. Followed by interim assessments. **Randomization (2:1)** **G1:** 16 wks individual CBT (12 sessions if < 4 binge/purge episodes in last 4 wks of mope; 20 session if ≥ 4 episodes) **G2:** 16 wk no-tx Post-tx and FU assessments **Post-assessment** (as above)	To test tx effects on psychopathology: ANCOVAs at post-tx and FU with pre-tx score as covariate (parametric data) or Mann-Whitney or Fischer's exact test for non-parametric data. To examine covariation between remission in eating sx and psychopathology: univariate and multivariate ANOVA and paired t-tests. To predict outcome: discriminant function analysis between nonremitted and remitted PE + CBT.	**Score:** Poor **Intent to treat:** No **Blinding:** No **Adverse events:** None reported **Funding:** Ontario Ministry of Health

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Davis et al., 1999 (continued)	**Binge frequency, past 28 days, mean (SD):** **G1:** 21.2 (12.8) **G2:** 24.2 (19.7)	**Binge frequency, past 28 days, mean (SD):** **Post-tx:** **G1:** 11.5 (19.0) *(P* < 0.001) **G2:** 3.9 (7.4) *(P* < 0.001) Diff between groups *(P* < 0.03) Diff between groups in change over time *(P* = NR) **16 wk FU:** **G1:** 8.4 (9.5), vs. post-tx *(P* = NS) **G2:** 3.6 (8.2), vs. post-tx *(P* = NS) Diff between groups *(P* < 0.02) Diff between groups in change over time *(P* = NR)
	Purge frequency, past 28 days, mean (SD): **G1:** 30.1 (16.6) **G2:** 38.3 (43.1)	**Purge frequency, past 28 days, mean (SD):** **Post-tx:** **G1:** 16.7 (21.7) *(P* < 0.001) **G2:** 4.8 (9.0) *(P* < 0.001) Diff between groups *(P* < 0.002) Diff between groups in change over time *(P* = NR) **16 wk FU:** **G1:** 12.3 (13.2), vs. post-tx *(P* = NS) **G2:** 4.8 (9.6), vs. post-tx *(P* = NS) Diff between groups *(P* < 0.012) Diff between groups in change over time *(P* = NR)
	EDE-Global, mean (SD): **G1:** 3.5 (1.0) **G2:** 3.6 (1.1)	**EDE Global, mean (SD):** **Post-tx:** **G1:** 1.9 (1.1) *(P* < 0.001) **G2:** 2.1 (1.3) *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **16 wk FU:** **G1:** 2.2 (1.2), vs. post-tx *(P* = NS) **G2:** 2.0 (1.3), vs. post-tx *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
		Binge remittance: **Post-tx:** **G1:** 26.3% **G2:** 51.4% Diff between groups *(P* = NS) **16 wk FU:** **G1:** 26.3% **G2:** 54.1% Diff between groups *(P* < 0.04)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BDI, mean (SD): **G1:** 21.3 (9.3) **G2R:** 18.9 (10.5) **G2N:** 22.1 (9.6)	**BDI, mean (SD):** **Post-tx:** **G1:** 11.8 (7.3) *(P* < 0.05) **G2R:** 4.2 (4.5) *(P* < 0.05) **G2N:** 16.5 (12.1) *(P* = NS) Diff between groups *(P* < 0.05) G2R better than G1 and G2N Diff between groups in change over time *(P* = NR) **16 wk FU:** **G1:** 12.9 (7.2), vs. post-tx *(P* = NS) **G2R:** 7.1 (7.7), vs. post-tx *(P* = NS) **G2N:** 15.6 (12.4), vs. post-tx *(P* = NS) Diff between groups *(P* < 0.05) G2R better than G2N Diff between groups in change over time *(P* = NR)		
Brief Symptom Inventory (Global), mean (SD): **G1:** 1.3 (0.6) **G2R:** 1.3 (0.8) **G2N:** 1.5 (0.7)	**Brief Symptom Inventory (Global), mean (SD):** **Post-tx:** **G1:** 1.0 (0.5) *(P* < 0.05) **G2R:** 0.4 (0.4) *(P* < 0.05) **G2N:** 1.2 (0.7) *(P* = NS) Diff between groups *(P* < 0.05) G2R better than G1 and G2N Diff between groups in change over time *(P* = NR) **16 wk FU:** **G1:** 1.0 (0.7), vs. post-tx *(P* = NS) **G2R:** 0.6 (0.6), vs. post-tx *(P* = NS) **G2N:** 1.2 (0.8), vs. post-tx *(P* = NS) Diff between groups *(P* < 0.05) G2R better than G2N Diff between groups in change over time *(P* = NR)		
Rosenberg Self-esteem (RSE), mean (SD): **G1:** 24.3 (5.4) **G2R:** 26.2 (4.8) **G2N:** 22.4 (4.3)	**Rosenberg Self-esteem (RSE), mean (SD):** **Post-tx:** **G1:** 26.5 (5.7) *(P* < 0.05) **G2R:** 34.6 (3.3) *(P* < 0.05) **G2N:** 24.1 (6.5) *(P* = NS) Diff between groups *(P* < 0.05) G2R better than G1 and G2N Diff between groups in change over time *(P* = NR) **16 wk FU:** **G1:** 26.9 (6.54), vs. post-tx *(P* = NS) **G2R:** 32.5 (4.8), vs. post-tx *(P* = NS) **G2N:** 24.6 (5.7), vs. post-tx *(P* = NS) Diff between groups *(P* < 0.05) G2R better than G2N Diff between groups in change over time *(P* = NR)		

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Davis et al., 1999 (continued)		**Purge remittance:** **Post-tx:** **G1:** 15.8% **G2:** 54.1% *(P* < 0.006) **16 wk FU:** **G1:** 21.1% **G2:** 51.4% *(P* < 0.03)
		Full remittance: **Post-tx:** **G1:** 10.5% **G2:** 43.2% *(P* < 0.02) **16 wk FU:** **G1:** 15.8% **G2:** 37.8% *(P* = NS)
	Binge frequency, past 28 days, mean (SD): **G2R:** 21.5 (16.5) **G2N:** 26.1 (22.0)	**Binge frequency, past 28 days, mean (SD):** **Post-tx:** **G2R:** 0.0 (NA) *(P* = NR) **G2N:** 6.8 (8.8) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **16 wk FU:** **G2R:** 0.3 (1.3), vs. post-tx *(P* = NR) **G2N:** 6.2 (10.2), vs. post-tx *(P* = NR) Diff between groups *(P* < 0.05) Diff between groups in change over time *(P* = NR)
	Purge frequency, past 28 days, mean (SD): **G2R:** 26.1 (25.7) **G2N:** 42.1 (51.5)	**Purge frequency, past 28 days, mean (SD):** **Post-tx:** **G2R:** 0.0 (NA) *(P* = NR) **G2N:** 7.7 (10.4) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **16 wk FU:** **G2R:** 0.6 (1.5) *(P* = NR) **G2N:** 7.3 (11.6) *(P* = NR) Diff between groups *(P* < 0.05) Diff between groups in change over time *(P* = NR)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
	Outcome, predictor (Wilks's lambda), mean: **RSE** (0.805) **G2R:** 28.0 **G2N:** 22.8 **Binge frequency** (0.691) **G2R:** 11.1 **G2N:** 18.6 **Binge Eating Adjective Checklist** (0.583) **G2R:** 2.0 **G2N:** 12.1 Lower self-esteem, more frequent bingeing, and more dramatic shifts away from negative psychological and physical states during an episode of bingeing were sigly more characteristic of non-remitted than remitted, chi-square = 18.0 *(P* < 0.001)		

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Davis et al., 1999 (continued)	**EDE Global, mean (SD):** **G2R:** 3.6 (1.1) **G2N:** 3.6 (1.1)	**EDE Global, mean (SD):** **Post-tx:** **G2R:** 1.3 (0.8) *(P* = NR) **G2N:** 2.8 (1.2) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) **16 wk FU:** **G2R:** 1.3 (0.9) *(P* = NR) **G2N:** 2.6 (1.3) *(P* = NR) Diff between groups *(P* < 0.05) Diff between groups in change over time *(P* = NR)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Fairburn et al., 1991 **Companion articles:** Fairburn, Jones et al., 1993 Fairburn, Peveler et al., 1993 **Setting:** Outpatient Clinic; Recruited from county of Oxfordshire, UK **Enrollment period:** NR	**Research objective:** To assess the efficacy of CBT versus a simplified behavioral version of CBT in the tx of 75 women with BN To assess the efficacy of CBT versus IPT in the tx of women with BN.	**Groups:** **G1:** CBT (N = 25) **G2:** BT (N = 25) **G3:** IPT (N = 25) **Enrollment:** • 126 individuals referred from physicians for a study on tx of BN offered screening appts • 117 (85%) screened • 83 met study criteria • 3 excluded due to major psychiatric condition; 2 excluded due to unavailability; 3 failed attendance to entry • 75 enrolled and randomized • 66 (88%) met full DSM III-R criteria for BN; 9 met all criteria save severity of attitudinal disturbance • 13 (17%) discontinued tx: 4 from G1 (16%); 6 from G2 (24%); 3 from G3 (12%); 2 others withdrew (1 from G2; 1 from G3) • 60 completed	**For entire sample (N = 75), unless otherwise indicated:** **Age, yrs, mean (95% CI):** 24.2 (22.8-25.6) **Sex:** Female: 100% **Race/ethnicity:** NR **Vomiting frequency, days/mo, mean (CI) (N = 56):** 28.9 (23.2-34.7) Practiced by 72% of sample **Laxative frequency, days/mo, mean (CI) (N = 26):** 14.7 (8.9-20.4) **Duration of BN, yrs, mean (CI):** 4.4 (3.4-5.3) **Current BMI, kg/m², mean (CI):** 22.2 (21.5-23.0) **Current BMI classification, N (%):** Underwt: 11 (18%) Normal wt: 42 (70%) Overwt: 4 (7%) Obese: 3 (5%) **Highest BMI since menarche, kg/m², mean (CI):** 25.3 (24.4-26.3) **Lowest BMI since menarche, kg/m², mean (CI):** 18.3 (17.6-18.9) **EAT score, mean (CI):** 48.2 (44.3-52.0) **SCL-90 Global Severity Index (GSI) score, mean (CI):** 1.4 (1.2-1.5) **BDI, mean (CI):** 24.0 (21.4-26.6) Of entire sample, 56% practiced vomiting, 35% used laxatives; 12% used neither

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: For prior 6 mos, met criteria for BN (DSM IIII-R); aged 17 yrs or older; BMI > 17 **Exclusion:** Patients with concurrent AN	Each tx group involved 19, 40-50 minutes outpatient sessions over 18 wks; for mo 1, sessions conducted 2x/wk, then fortnightly for duration of study. CBT occurred in 3 stages: wks 1-4 focused on behaviorally enhancing control over eating, including self-monitoring; wks 5-12 cognitively focused; wks 13-18 maintenance of progress following end of tx. BT tx focused exclusively on the normalization of eating habits, including self-monitoring. IPT used manual developed by Klerman et al. (1984), diverging from protocol only in the first phase of tx--focusing on the ED (rather than depression.) At baseline at end-of tx, eating-specific issues, global fx, and depression were assessed using the EDE, EAT, SCL-90, and BDI.	Two planned comparisons: CBT versus BT, and CBT versus IBT; Power analyses performed (assessing 20 persons per tx group); data inspected to assess whether transformation required for parametric testing; variables with skewed distribution were subject to log transformations; one-way ANOVA assessed pre-tx diffs; Tx effects assessed using 3 x 2, repeated measures ANOVA; diff effects between groups were assessed by ANCOVA with pre-tx values as the covariate; alpha was set at < 0.05, t-tests used for planned comparisons between groups.	**Score:** Fair **Intent to treat:** No **Blinding:** NA **Adverse events:** “Limited motivation to change” was the most common reason for attrition; 1 participant (G2) dropped out due to severe wt loss **Funding:** Welcome Trust, London, Eng; personal support for authors from lectureships/fellowships

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures: Baseline	Eating Related Measures: Outcomes
Author, yr: Fairburn et al., 1991 (continued)	Unless otherwise specified, N = 60 *Geometric means (N = 43 and N = 19 for vomiting and laxative use, respectively).	
	Objective Bulimic Episodes, per 28 days*, mean (95% CI): **G1:** 18.1 (12.2-26.5) **G2:** 14.9 (9.6-22.7) **G3:** 16.4 (12.1-22.2) *(P* = NS)	**End-of-tx:** **Objective Bulimic Episodes, per 28 days*, mean (95% CI):** **G1:** 0.6 (0.1-1.4) *(P* = NR) **G2:** 1.3 (0.3-3.4) *(P* = NR) **G3:** 1.8 (0.4-4.3) *(P* = NR) Diff over time *(P* < 0.05) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) • Mean overall geometric frequency changed from 16.5 to 1.2 at end-of-tx: a 95% reduction • Similarly for subjective BE, no diff between groups *(P* = NS) or for both types combined *(P* = NS) **Abstinence (no bulimic episodes), N (%):** **G1:** 15/21 (71%) *(P* = NR) **G2:** 11/18 (62%) *(P* = NR) **G3:** 13/21 (62%) *(P* = NR) Diff between group *(P* = NS)
	EDE-Dietary Restraint, mean (95% CI): **G1:** 3.7 (3.1-4.3) **G2:** 3.3 (2.6-4.0) **G3:** 3.3 (2.9-3.7) *(P* = NS)	**EDE-Dietary Restraint, mean (95% CI):** **G1:** 1.3 (0.7-1.9) *(P* = NR) **G2:** 2.3 (1.6-3.0) *(P* = NR) **G3:** 2.1 (1.5-2.7) *(P* = NR) Diff over time *(P* < 0.05) Diff between groups *(P* = 0.05) Diff between groups in change over time G1 better than G2 *(P* = 0.05) G1 better than G3 *(P* = 0.02)
	Self-induced vomiting, per 28 days, mean (95% CI): **G1:** 28.5 (18.1-44.6) **G2:** 18.5 (10.1-33.3) **G3:** 16.4 (9.9-26.6) *(P* = NS)	**Self-induced vomiting, per 28 days, mean (95% CI):** **G1:** 1.5 (0.5-3.1) *(P* = NR) **G2:** 0.9 (0-2.9) *(P* = NR) **G3:** 5.5 (1.6-14.9) *(P* = NR) Diff over time *(P* < 0.05) Diff between groups *(P* = 0.03) Diff between groups in change over time G1 vs. G2 *(P* = NS) G1 better than G3 *(P* = 0.03)
	Laxative misuse, per 28 days, mean (95% CI): **G1:** 4.7 (1.4-12.6) **G2:** 13.1 (3.9-39.4) **G3:** 13.7 (6.4-28.2) *(P* = NS)	**Laxative misuse, per 28 days, mean (95% CI) (N = 19):** **G1:** 0.3 (0-1.6) *(P* = NR) **G2:** 1.4 (0-8.1) *(P* = NR) **G3:** 2.3 (0-15.5) *(P* = NR) Diff over time *(P* < 0.05) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
SCL-90 Global severity index (GSI), mean (95% CI): **G1:** 1.35 (1.04-1.65) **G2:** 1.26 (0.90-1.62) **G3:** 1.33 (1.08-1.59) *(P* = NS)	**End-of-tx:** **SCL-90 GSI, mean (95% CI):** **G1:** 0.59 (0.33-0.85) *(P* = NR) **G2:** 0.76 (0.41-1.12) *(P* = NR) **G3:** 0.70 (0.46-0.94) *(P* = NR) Diff over time *(P* < 0.05) *(P* = NR) Diff between groups in change over time *(P* = NS)	**BMI, kg/m² mean (95% CI):** **G1:** 22.4 (20.8-23.9) **G2:** 22.6 (21.0-24.2) **G3:** 22.2 (21.1-23.3) *(P* = NS)	**End-of-tx:** **BMI, kg/m² mean (95% CI):** **G1:** 23.3 (21.3-25.2) *(P* = NR) **G2:** 23.0 (21.3-24.7) *(P* = NR) **G3:** 22.2 (20.7-23.7) *(P* = NR) Diff over time *(P* = 0.02) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
BDI, mean (95% CI): **G1:** 24.1 (20.1-28.1) **G2:** 22.3 (16.5-28.1) **G3:** 24.3 (18.6-30.0) *(P* = NS)	**BDI, mean (95% CI):** **G1:** 10.1 (5.3-15.0) *(P* = NR) **G2:** 13.6 (7.6-19.5) *(P* = NR) **G3:** 12.5 (7.6-17.4) *(P* = NR) Diff over time *(P* < 0.05) *(P* = NR) Diff between groups in change over time *(P* = NS)		

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Fairburn et al., 1991 (continued)	Unless otherwise specified, N = 60 *Geometric means (N = 43 and N = 19 for vomiting and laxative use, respectively).	
	EDE-Attitudes to shape, mean (95% CI): **G1:** 4.1 (3.6-4.7) **G2:** 4.0 (3.4-4.7) **G3:** 3.6 (3.0-4.2) *(P* = NS)	**End-of-tx:** **EDE-Attitudes to shape, mean (95% CI):** **G1:** 2.1 (1.5-2.6) *(P* = NR) **G2:** 3.3 (2.5-4.0) *(P* = NR) **G3:** 2.6 (2.1-3.2) *(P* = NR) Diff over time *(P* < 0.05) Diff between groups *(P* = 0.01) Diff between groups in change over time G1 better than G2 *(P* = 0.003) G1 vs. G3 *(P* = NS)
	EDE-Attitudes to wt, mean (95% CI): **G1:** 4.3 (3.7-4.8) **G2:** 3.8 (3.2-4.5) **G3:** 3.7 (2.9-4.4) *(P* = NS)	**EDE-Attitudes to wt, mean (95% CI):** **G1:** 1.7 (1.1-2.2) *(P* = NR) **G2:** 2.9 (2.2-3.6) *(P* = NR) **G3:** 2.4 (1.9-2.9) *(P* = NR) Diff over time *(P* < 0.05) Diff between groups *(P* = 0.01) Diff between groups in change over time G1 better than G2 *(P* = 0.002) G1 better than G3 *(P* = 0.04)
	EAT scores, mean (95% CI): **G1:** 45.4 (38.9-51.9) **G2:** 50.2 (43.7-56.7) **G3:** 46.1 (38.8-53.5) *(P* = NS)	**EAT scores, mean (95% CI):** **G1:** 15.5 (9.2-21.8) *(P* = NR) **G2:** 27.8 (19.4-36.3) *(P* = NR) **G3:** 29.0 (19.8-38.2) *(P* = NR) Diff over time *(P* < 0.05) Diff between groups *(P* = 0.02) Diff between groups in change over time G1 better than G2 *(P* = 0.05) G1 better than G3 *(P* = 0.01)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Fairburn, Jones et al., 1993 **Companion articles:** Fairburn et al., 1991 Fairburn, Peveler et al., 1993 **Setting:** Outpatient Clinic; Recruited from county of Oxfordshire, UK **Enrollment period:** NR	**Research objective:** To assess the efficacy of CBT versus IPT in the tx of women with BN at 4, 8, and 12-mo FU.	**Groups:** **G1:** CBT (N = 20) **G3:** IPT (N = 17) **Enrollment:** • During FU, 7/60 patients who completed tx were withdrawn (**G1:**1; **G2:** 3; **G3:** 3); 3 dropped out (**G2:** 2; **G3:** 1) • 25 (33%) of original 75 participants either dropped out or were withdrawn; **G1:** 8 (32%); **G2:** 12 (48%); **G3:** 8 (32%) • Diff between G1 and G2 *(P* = 0.04); diff between G1 and G3 *(P* = 0.33)	**Age, yrs, mean (95% CI):** 24.2 (22.8-25.6) **Sex:** Female: 100% **Race/ethnicity:** NR

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: For prior 6 mos, met criteria for BN (DSM IIII-R); aged 17 yrs or older; BMI > 17 **Exclusion:** Patients with concurrent AN	Assessments reported in Fairburn, Jones et al., 1991 were further measured at 4-, 8- and 12-mo FU.	Proportion of participants who had ceased overeating and self-induced vomiting or laxative use were compared across tx; a 2 x 4 ANCOVA was completed for each outcome variable	**Score:** Fair **Intent to treat:** No **Blinding:** No **Adverse events:** 7 participants were withdrawn during FU due to coexisting severe depressive features (N = 3), or BN sx too severe to withhold tx. **Funding:** Project grant from the Welcome Trust, London, Eng; personal support for authors from lectureships/ fellowships

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures: Baseline	Eating Related Measures: Outcomes
Author, yr: Fairburn, Jones et al., 1993		*Geometric means (N = 37 for objective BE; N = 25 and N = 10 for vomiting and laxative misuse, respectively)
(continued)	**Objective Bulimic Episodes, per 28 days, mean (95% CI):** **G1:** 18.5 (12.2-27.8) **G3:** 17.2 (12.5-23.5) *(P* = NS)	**Objective Bulimic Episodes, per 28 days, mean (95% CI):** **4-mo FU:** **G1:** 0.4 (-0.05-1.2) *(P* = NR) **G3:** 0.9 (-0.05-2.8) *(P* = NR)
	End of tx: **G1:** 0.5 (0.02-1.1) *(P* = NR) **G3:** 1.5 (0.1-4.5) *(P* = NR)	**8-mo FU:** **G1:** 0.4 (-.03-1.7) *(P* = NR) **G3:** 1.1 (0.1-3.2) *(P* = NR)
		12-mo FU: **G1:** 0.8 (.02-1.6) *(P* = NR) **G3:** 1.1 (0.01-3.2) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
		Mean overall geometric frequency was 0.9 at 12-mo FU: a 95% reduction from baseline
		Similarly for subjective BE, no diff between groups *(P* = NS) or for both types combined *(P* = NS)
	EDE-Dietary Restraint, mean (95% CI): **G1:** 3.7 (3.1-4.3) **G3:** 3.2 (2.8-3.7) *(P* = NS)	**EDE-Dietary Restraint, mean (95% CI):** **4-mo FU:** **G1:** 1.3 (0.5-2.0) *(P* = NR) **G3:** 1.4 (0.8-2.1) *(P* = NR)
	End of tx: **G1:** 1.3 (0.7-1.9) *(P* = NR) **G3:** 1.9 (1.2-2.6) *(P* = NR)	**8-mo FU:** **G1:** 1.1 (0.5-1.8) *(P* = NR) **G3:** 1.8 (1.1-2.5) *(P* = NR)
		12-mo FU: **G1:** 1.3 (0.7-2.0) *(P* = NR) **G3:** 1.7 (1.0-2.5) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	Self-induced vomiting, per 28 days, mean (95% CI): **G1:** 30.6 (19.5-48.2) **G3:** 18.1 (9.9-32.1) *(P* = 0.03)	**Self-induced vomiting, per 28 days, mean (95% CI):** **4-mo FU:** **G1:** 1.0 (0.02-2.9) *(P* = NR) **G3:** 3.4 (0.3-13.5) *(P* = NR)
	End of tx: **G1:** 1.3 (0.4-2.9) *(P* = NR) **G3:** 3.6 (0.5-12.8) *(P* = NR)	**8-mo FU:** **G1:** 1.2 (0.3-3.0) *(P* = NR) **G3:** 2.9 (0.2-11.3) *(P* = NR)
		12-mo FU: **G1:** 2.0 (0.6-4.5) *(P* = NR) **G3:** 2.4 (-0.04-11.0) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) Mean overall geometric frequency was 2.14 at 12-mo FU: a 90.9% reduction from baseline

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
SCL-90 GSI, mean (95% CI): **G1:** 1.38 (1.06-1.70) **G3:** 1.31 (0.99-1.63) **End of tx:** **G1:** 0.61 (0.34-0.88) **G3:** 0.60 (0.34-0.86)	**SCL-90 GSI, mean (95% CI):** **4-mo FU:** **G1:** 0.52 (0.29-0.75) *(P* = NR) **G3:** 0.49 (0.22-0.76) *(P* = NR) **8-mo FU:** **G1:** 0.45 (0.22-0.68) *(P* = NR) **G3:** 0.45 (0.22-0.68) *(P* = NR) **12-mo FU:** **G1:** 0.46 (0.16-0.76) *(P* = NR) **G3:** 0.46 (0.21-0.69) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)	**BMI, kg/m² mean (95% CI):** **G1:** 22.5 (20.8-24.1) *(P* = NR) **G3:** 22.5 (21.3-23.8) *(P* = NR) **End of tx:** **G1:** 23.4 (21.4-25.5) *(P* = NR) **G3:** 22.6 (21.0-24.2) *(P* = NR)	**BMI, kg/m² mean (95% CI):** **4-mo FU:** **G1:** 23.3 (20.9-25.7*) (P* = NR) **G3:** 22.4 21.2-23.6*) (P* = NR) **8-mo FU:** **G1:** 23.1 (21.1-25.1*) (P* = NR) **G3:** 22.1 (20.6-23.5*) (P* = NR) **12-mo FU:** **G1:** 22.2 (20.9-23.5*) (P* = NR) **G3:** 21.6 (20.4-22.8*) (P* = NR) Diff over time *(P* < 0.0005) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
BDI, mean (95% CI): **G1:** 24.1 (19.8-28.3) **G3:** 24.7 (17.8-31.6) **End of tx:** **G1:** 10.3 (5.1-15.4) **G3:** 11.7 (6.5-17.0)	**BDI, mean (95% CI):** **4-mo FU:** **G1:** 7.5 (3.1-11.9) *(P* = NR) **G3:** 8.8 (2.6-15.1) *(P* = NR) **8-mo FU:** **G1:** 6.0 (2.6-9.4) *(P* = NR) **G3:** 9.7 (3.5-15.9) *(P* = NR) **12-mo FU:** **G1:** 8.3 (2.3-14.2) *(P* = NR) **G3:** 7.7 (2.9-12.5) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)		
RSE, mean (95% CI): **G1:** 20.8 (19.0-22.5) **G3:** 21.3 (19.3-23.3) **End of tx:** **G1:** 27.1 (23.6-30.5) **G3:** 25.2 (22.8-27.7)	**RSE, mean (95% CI):** **4-mo FU:** **G1:** 27.4 (23.9-30.8) *(P* = NR) **G3:** 28.0 (24.3-31.7) *(P* = NR) **8-mo FU:** **G1:** 29.2 (26.2-32.2) *(P* = NR) **G3:** 28.0 (23.9-32.1) *(P* = NR) **12-mo FU:** **G1:** 28.9 (25.6-32.1) *(P* = NR) **G3:** 27.0 (22.6-31.4) *(P* = NR) Diff over time *(P* < 0.0005) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)		

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Fairburn, Jones et al., 1993 (continued)		*Geometric means (N = 37 for objective BE; N = 25 and N = 10 for vomiting and laxative misuse, respectively)
	Laxative misuse, per 28 days, mean (95% CI): **G1:** 4.6 (1.4-12.2) **G3:** 16.8 (5.3-49.1) *(P* = NS)	**Laxative misuse, per 28 days, mean (95% CI) (N = 19):** **End of tx:** **G1:** 0.3 (-0.3-1.5) *(P* = NR) **G3:** 1.6 (-0.8-30.1) *(P* = NR) **4-mo FU:** **G1:** 0.3 (-0.1-1.8) *(P* = NR) **G3:** 1.5 (-0.8-32.1) *(P* = NR) **8-mo FU:** **G1:** 0.4 (-0.4-2.3) *(P* = NR) **G3:** 1.0 (-0.7-12.8) *(P* = NR) **12-mo FU:** **G1:** 0.9 (-0.4-4.3) *(P* = NR) **G3:** 0.8 (-0.7-7.9) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) Sample too small to assess
	EDE-Attitudes to shape, mean (95% CI): **G1:** 4.2 (3.6-4.8) **G3:** 3.7 (3.0-4.4) *(P* = NS)	**EDE-Attitudes to shape, mean (95% CI):** **End of tx:** **G1:** 2.1 (1.5-2.7) *(P* = NR) **G3:** 2.5 (1.9-3.1) *(P* = NR) **4-mo FU:** **G1:** 2.1 (1.5-2.6) *(P* = NR) **G3:** 2.1 (1.3-2.8) *(P* = NR) **8-mo FU:** **G1:** 1.9 (1.2-2.6) *(P* = NR) **G3:** 1.9 (1.3-2.6) *(P* = NR) **12-mo FU:** **G1:** 1.9 (1.3-2.4) *(P* = NR) **G3:** 1.7 (1.0-2.4) *(P* = NR) Diff over time *(P* = 0.007) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Fairburn, Jones et al., 1993 (continued)	**EDE-Attitudes to wt, mean (95% CI):** **G1:** 4.3 (3.7-4.9) **G3:** 3.8 (3.0-4.6) *(P* = NS)	**EDE-Attitudes to wt, mean (95% CI):** **End of tx:** **G1:** 1.7 (1.1-2.3) *(P* = NR) **G3:** 2.3 (1.7-2.9) *(P* = NR) **4-mo FU:** **G1:** 1.7 (1.1-2.4) *(P* = NR) **G3:** 2.0 (1.3-2.7) *(P* = NR) **8-mo FU:** **G1:** 1.8 (1.2-2.4) *(P* = NR) **G3:** 2.1 (1.4-2.7) *(P* = NR) **12-mo FU:** **G1:** 1.8 (1.2-2.4) *(P* = NR) **G3:** 1.8 (1.1-2.5) *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	EAT scores, mean (95% CI): **G1:** 45.7 (38.8-52.5) **G3:** 45.2 (36.5-53.9) *(P* = NS)	**EAT scores (N = 37), mean (95% CI):** **End of tx:** **G1:** 15.4 (8.7-22.1) *(P* = NR) **G3:** 27.6 (17.0-38.2) *(P* = NR) **4-mo FU:** **G1:** 16.5 (9.2-23.8) *(P* = NR) **G3:** 18.7 (10.4-26.9) *(P* = NR) **8-mo FU:** **G1:** 14.5 (9.1-19.8) *(P* = NR) **G3:** 20.3 (11.3-29.3) *(P* = NR) **12-mo FU:** **G1:** 16.3 (7.9-24.7) *(P* = NR) **G3:** 20.4 (9.9-30.8) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
		Abstinence, ceasing to have episodes of uncontrolled overeating (both objective and subjective), and ceasing to take laxatives and vomit: **12-mo FU:** **G1:** 36% (N = 9/25) **G2:** 20% (N = 5/20) **G3:** 44% (N = 11/25) Diff between groups *(P* < 0.05) G1 better than G2, odds ratio (CI): 2.49 (1.34-4.62) *(P* = 0.05) G1 vs. G3 *(P* = NS)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, year: Fairburn, Peveler et al., 1993 **Companion articles:** Fairburn et al., 1991 Fairburn, Jones et al., 1993 **Setting:** Outpatient Clinic; Recruited from county of Oxfordshire, England **Enrollment period:** NR	**Research objective:** To assess predictors of 12-month outcome in patients who received short-term psychological tx for BN; also to test the specific hypothesis that high attitudinal disturbance predicts poorer outcome in patients who initially respond to short-term tx.	**Groups:** **G1:** CBT (N = 25) **G2:** BT (N = 25) **G3:** IPT (N = 25) **Enrollment:** • 126 individuals referred from physicians for a study on tx of BN offered screening appointments • 117 (85%) screened • 83 met study criteria • 3 excluded due to major psychiatric condition; 2 excluded due to unavailability; 3 failed attendance to entry • 75 enrolled and randomized • 66 (88%) met full DSM III-R criteria for BN; 9 met all criteria except severity of attitudinal disturbance • 60 (80%) completed tx: **G1:** N = 21 (84%) **G2:** N = 18 (72%) **G3:** N = 21 (84%) • 50 (67%) completed FU • On the Personality Diagnostic Questionnaire, non-completers had higher score (56.6 ±15.6) compared to completers (46.1 ± 17.1) (P = 0.02)	N = 75 unless otherwise indicated. **Age, yrs, mean (95% CI):** 24.2 (22.8-25.6) **Sex:** Female: 100% **Race/ethnicity:** NR **Vomiting frequency, days/mo, mean (CI) (N = 56):** 28.9 (23.2-34.7) **Laxative frequency, days/mo, mean (CI) (N = 26):** 14.7 (8.9-20.4) **Duration of BN, yrs, mean (CI):** 4.4 (3.4-5.3) **Current BMI, kg/m², mean (CI):** 22.2 (21.5-23.0) **Highest BMI since menarche, kg/m², mean (CI):** 25.3 (24.4-26.3) **Lowest BMI since menarche, kg/m², mean (CI):** 18.3 (17.6-18.9) **EAT score, mean (CI):** 48.2 (44.3-52.0) **SCL-90 GSI, mean (CI):** 1.4 (1.2-1.5) **BDI, mean (CI):** 24.0 (21.4-26.6) **Practiced vomiting:** 56% **Used laxatives:** 35% **Did neither:** 12%

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: For prior 6 mos, met criteria for BN (DSM IIII-R); aged 17 yrs or older; BMI > 17 **Exclusion:** Patients with concurrent AN	Each tx group involved 19, 40-50 minutes outpatient sessions over 18 wks; For mo 1, sessions conducted 2x/wk, then fortnightly for duration of study. CBT occurred in 3 stages: wks 1-4, focused on behaviorally enhancing control over eating, including self-monitoring; wks 5-12, cognitively focused; wks 13-18, maintenance of progress following end of tx. BT tx focused exclusively on the normalization of eating habits, including self-monitoring. IPT used manual developed by Klerman et al. (1984), diverging from protocol only in the first phase of tx, focusing on ED (rather than depression.) At baseline at end-of tx, eating-specific issues, global fx, and depression were assessed using EDE, EAT, SCL-90, and BDI. Patients judged not to need immediate further tx entered into closed 1-yr FU.	Based on prior research, pre-tx predictor variables selected for use in regression modeling. They included: ED duration, ED age of onset, hx of AN, objective binge frequency, dietary restraint severity, attitude disturbance (sum of EDE shape and wt concerns), ED psychopathology severity (sum of 5 EDE scales), SCL-90 GSI severity, self-esteem, personality disturbance. Linear regression to predict the continuous Outcome Index (overall severity of ED psychopathology); logistic regression to predict 2 categorical outcome indexes (1: decline in ED psychopathology within 1 SD of mean of comparison sample, yes/no; 2: cessation of objective and subjective bingeing, vomiting, and laxative use, yes/no).	**Score:** Fair **Intent to treat:** No **Blinding:** NA **Adverse events:** NA **Funding:** Welcome Trust

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, year: Fairburn, Peveler et al., 1993	No sig group diffs in objective binge episodes, dietary restraint, vomiting frequency, laxative misuse.	All analyses based on data from 50 patients who remained in the study to the end of FU. **Relation between degree of pre-tx attitudinal disturbance and three indexes of outcome:** **Outcome 1: Global EDE, mean (SD):** 1.40 (1.03) **Degree of Attitudinal disturbance at pretreatment:** **Low 0 – 7 (N = 12):** 1.55 (1.15) **Moderate 8 – 10 (N = 20):** 1.76 (1.10) **Severe 11 – 12 (N = 18):** 0.93 (0.70) Diff between groups ($P < 0.05$) Moderate did worst, most severe did best. **Outcome 2: Eating disorder psychopathology within 1 SD of mean for same age women, N (%): 32 (64%):** **Degree of Attitudinal disturbance at pretreatment:** **Low (0 – 7) (N = 12):** 8 (67%) **Moderate (8 – 10) (N = 20):** 9 (45%) **Severe (11 – 12) (N = 18):** 15 (83%) Diff between groups ($P < 0.05$) Intermediate did worst, most severe did best. **Relative Risk (95% CI) for Outcome 2:** **Degree of Attitudinal disturbance:** **Moderate (8 – 10):** 1.22 (0.22 – 6.82) **Severe (11 – 12):** 0.10 (0.01 – 1.11) **Outcome 3: Met strict criteria for good behavioral outcome (ceased episodes of uncontrolled eating, vomiting, laxative use), N (%): 22 (44%):** **Degree of Attitudinal disturbance at pretreatment:** **Low (0 – 7) (N = 12):** 5 (42%) **Moderate (8 – 10) (N = 20):** 5 (25%) **Severe (11 – 12) (N = 18):** 12 (67%) Diff between groups ($P < 0.05$) Intermediate did worst, most severe did best. **RR (95% CI) for Outcome 3:** **Degree of Attitudinal disturbance:** **Moderate (8 – 10):** 1.32 (0.25 – 7.17) **Severe (11 – 12):** 0.15 (0.02 – 1.25) **Relapse at FU (no longer meeting Outcome 3), N (%):** **Degree of Attitudinal disturbance:** **Low (0 – 7):** 1/11 (9%) **Moderate (8 – 10):** 2/7 (29%) **Severe (11 – 12):** 3/4 (75%) **RR (95% CI) relapse after adjusting for tx type:** **Degree of attitudinal disturbance:** **Moderate (8 – 10):** 3.4 (0.2 – 54.1) **Severe (11 – 12):** 45.2 (0.9 – 1,339.0)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
No sig group diffs global severity index or BDI.			

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Garner et al., 1993 **Setting:** Outpatient Toronto, Canada **Enrollment period:** NR	**Research objective:** To compare CBT and brief psychodynamic ("supportive-expressive") therapy, both delivered in an individual format, according to specific guidelines, and by experienced therapists.	**Groups:** **G1:** CBT (N = 30) **G2:** Supportive-Expressive (N = 30) **Enrollment:** Referred to study and screened (N = 92) Met inclusion criteria and enrolled (N = 60) Stratified by: • Duration of illness (< 3 yrs, ≥ 3 yrs). • Current wt (86 – 110% and > 111% of MPMW) • Probably hx of AN (adult wt < 85% of MPMW) **Completers (N: 50)** **G1:** 25 **G2:** 25 In a few cases a patient who should have been assigned to 1 tx was assigned to the other because therapists in the assigned condition were unavailable to accept a referral at the time. Also, any patient who dropped out was replaced by the next suitable patient, who was assigned to the same tx cell, in order to obtain 25 patients who completed each tx.	**Age, mean (SD):** **G1:** 23.7 (4.4) **G2:** 24.6 (4.0) *(P* = NS) **Sex:** Female: 100% **Race/ethnicity:** NR **Height, in, mean (SD):** **G1:** 65.6 (3.0) **G2:** 66.1 (2.5) *(P* = NS) **Wt, lbs, mean (SD):** **G1:** 126.4 (16.4) **G2:** 126.6 (13.1) *(P* = NS) **Current wt, % of matched population mean (MPMW), mean (SD):** **G1:** 95.3 (9.8) **G2:** 94.9 (7.9) *(P* = NS) **Maximum wt, % MPMW, mean (SD):** **G1:** 108.6 (9.9) **G2:** 111.8 (12.7) *(P* = NS) **Min wt. % MPMW, mean (SD):** **G1:** 84.3 (10.0) **G2:** 82.9 (8.7) *(P* = NS) **Duration of illness, mo, mean (SD):** **G1:** 71.8 (47.6) **G2:** 71.2 (40.2) *(P* = NS) **Binge episodes, past 28 days, mean (SD) (range):** 27.5 (25.1) (0-140) **Vomiting episodes, past 28 days, mean (SD) (range):** 42.2 (32.6) (8-154)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Russell criteria for BN and DSM III-R criteria with the exception that a min avg of 2 binges a wk involving "large" amounts of food was not required; min of 2 episodes of vomiting a wk for the past mo, min duration of illness of 1 yr; present body wt of 85% to 120% MPMW; 18 to 35 yrs old **Exclusion:** Current tx for BN	19, 45 to 60 minutes individual sessions delivered over 18 wks. Sessions occurred twice a wk during first mo, once a wk for the next 2 mo, and once every other wk for the final 6 wks. **G1:** followed Fairburn's (1985) CBT manual **G2:** Followed Luborsky's (1984) manual, supplemented by psychodynamic writings on ED. Nondirective and emphasized listening to patient and helping identify problems and solutions.	Repeated measures ANOVA. ANCOVA (Pre-tx scores as covariates).	**Score:** Fair **Intent to treat:** No **Blinding:** NA **Adverse events:** NA **Funding:** Health and Welfare Canada project grant, NATO Grants for Collaborative Research, Research Associate Award, Research Fellowshi*P* from the Ontario Mental Health Foundation

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Garner et al., 1993 (continued)		**For all outcome variables diff over time reported to be sig in text.
	Binge episodes, past 28 days, mean (SD): **G1:** 26.3 (30.2) **G2:** 31.1 (20.3) *(P* = NS)	**Binge episodes, past 28 days, mean (SD):** **G1:** 7.1 (14.1) **G2:** 9.6 (11.0) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	Vomiting episodes, past 28 days, mean (SD): **G1:** 41.4 (38.7) **G2:** 44.1 (30.5) *(P* = NS)	**Vomiting episodes, past 28 days, mean (SD):** **G1:** 7.5 (13.5) *(P* = NR) **G2:** 16.7 (18.5) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **Reduction in vomiting frequency, %:** **G1:** 81.9 **G2:** 62.1 Diff between groups *(P* = NS) **Improvement in vomiting frequency of at least 50%:** **G1:** 92% **G2:** 68.0% Diff between groups *(P* = NR) **Vomiting abstinence, past 28 days, N (%):** **G1:** 9 (36.0%) **G2:** 3 (12.0%) Diff between groups *(P* = NR)
	EAT Dieting, mean (SD): **G1:** 20.6 (8.6) **G2:** 19.7 (7.7) *(P* = NS)	**EAT Dieting, mean (SD):** **G1:** 6.8 (5.9) *(P* = NR) **G2:** 12.5 (9.5) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.008) G1 better than G2
	EAT Bulimia and food preoccupation, mean (SD): **G1:** 11.2 (4.3) **G2:** 10.9 (4.0) *(P* = NS)	**EAT Bulimia and food preoccupation, mean (SD):** **G1:** 2.0 (3.7) *(P* = NR) **G2:** 4.9 (4.5) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.01) G1 better than G2
	EAT Oral control, mean (SD): **G1:** 2.9 (2.9) **G2:** 2.8 (3.6) *(P* = NS)	**EAT Oral control, mean (SD):** **G1:** 1.6 (1.4) *(P* = NR) **G2:** 1.3 (1.9) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	EAT Total, mean (SD): **G1:** 34.7 (12.7) **G2:** 33.2 (11.6) *(P* = NS)	**EAT Total, mean (SD):** **G1:** 10.4 (9.1) *(P* = NR) **G2:** 18.7 (14.1) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.01) G1 better than G2

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological Measures		Biomarkers	
Baseline	**Outcome**	**Baseline**	**Outcome**
BDI, mean (SD): **G1:** 16.8 (9.9) **G2:** 18.7 (9.4) *(P* = NS)	**BDI, mean (SD):** **G1:** 7.5 (10.6) *(P* = NR) **G2:** 13.4 (9.5) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.05) G1 better than G2	**Wt (% matched population mean wt), mean (SD):** **G1:** 95.3 (9.8) **G2:** 94.9 (7.9) *(P* = NS)	**Wt gain, lb, mean:** **G1:** 6.6 (100.4% MPMW, *P* = NR) **G2:** 3.0 (97.6% MPMW, *P* = NR) Diff over time *(P* < 0.0001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
SCL-90-R, mean (SD): **G1:** 1.1 (0.7) **G2:** 1.3 (0.6) *(P* = NS)	**SCL-90-R, mean (SD):** **G1:** 0.6 (0.7) *(P* = NR) **G2:** 1.0 (0.6) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.03) G1 better than G2		
RSE, mean (SD): **G1:** 25.0 (5.7) **G2:** 23.7 (5.3) *(P* = NS)	**RSE, mean (SD):** **G1:** 29.4 (6.2) *(P* = NR) **G2:** 25.6 (5.2) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.03) G1 better than G2		
Millon Borderline subscale, mean (SD): **G1:** 73.4 (17.9) **G2:** 75.0 (13.3) *(P* = NS)	**Millon Borderline subscale, mean (SD):** **G1:** 56.8 (17.4) *(P* = NR) **G2:** 73.7 (20.6) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.005) G1 better than G2		
Millon Dysthymia subscale, mean (SD): **G1:** 85.1 (17.4) **G2:** 89.2 (15.4) *(P* = NS)	**Millon Dysthymia subscale, mean (SD):** **G1:** 65.6 (18.3) *(P* = NR) **G2:** 88.1 (16.8) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.0001) G1 better than G2		

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Garner et al., 1993 (continued)	**EDE Dietary restraint, mean (SD):** **G1:** 3.7 (1.3) **G2:** 3.2 (1.5) *(P* = NS)	**EDE Dietary restraint, mean (SD):** **G1:** 1.5 (1.7) *(P* = NR) **G2:** 2.5 (1.6) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.009) G1 better than G2
	EDE Attitudes toward shape, mean (SD): G1: 3.3 (1.4) **G2:** 3.6 (1.0) *(P* = NS)	**EDE Attitudes toward shape, mean (SD):** **G1:** 2.0 (1.3) *(P* = NR) **G2:** 2.9 (1.1) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.02) G1 better than G2
	EDE Attitudes toward wt, mean (SD): **G1:** 2.4 (1.4) **G2:** 2.9 (1.1) *(P* = NS)	**EDE Attitudes toward wt, mean (SD):** **G1:** 1.6 (1.2) *(P* = NR) **G2:** 2.4 (1.1) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	EDE Bulimia: **G1:** NR **G2:** NR	**EDE Bulimia:** **G1:** NR **G2:** NR Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
	EDE Eating concerns: **G1:** NR **G2:** NR	**EDE Eating concerns:** **G1:** NR **G2:** NR Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.02) G1 better than G2
	EDI Drive for thinness: mean (SD) **G1:** 14.3 (4.4) **G2:** 14.1 (5.2) *(P* = NS)	**EDI Drive for thinness, mean (SD):** **G1:** 5.9 (6.3) *(P* = NR) **G2:** 9.4 (6.8) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	EDI Bulimia, mean (SD): **G1:** 11.6 (4.9) **G2:** 10.2 (6.2) *(P* = NS)	**EDI Bulimia, mean (SD):** **G1:** 2.2 (3.9) *(P* = NR) **G2:** 4.8 (4.5) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.002) G1 better than G2
	EDI Body dissatisfaction, mean (SD): **G1:** 15.5 (8.4) **G2:** 16.7 (8.0) *(P* = NS)	**EDI Body dissatisfaction, mean (SD):** **G1:** 11.7 (9.0) *(P* = NR) **G2:** 13.7 (7.5) ***(P*** = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
		Treatment Satisfaction: Tx X Outcome Interaction *(P* = 0.02). G1 with good outcome were more satisfied with tx than G1 with poor outcomes or G2 with either good or poor outcomes. Good outcome = vomiting $\leq$ 4 episodes/mo)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological Measures		Biomarkers	
Baseline	**Outcome**	**Baseline**	**Outcome**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Griffiths et al., 1994 **Setting:** Teaching hospital, Sydney, Australia Outpatient **Enrollment period:** NR	**Research objective:** Compare immediate post-tx effects of CBT, HBT and a wait list control group in treating BN.	**Groups:** **G1:** Wait list control (N = 28) **G2:** CBT (N = 23) **G3:** Hypnobehavioral therapy (HBT) (N = 27) **Enrollment:** • Participants were recruited via media as well as referrals from the Eating Disorders Clinic within test site. • 130 participants presented with symptoms of BN • 85 completed the assessments and met criteria • 78 participants entered tx and were randomized to one of the 3 tx groups • 63 participants completed tx.	**Total Sample (**N = 78) **Age, yrs, mean (SD):** **Total sample:** 25.91 (5.73) **G1:** 27.1 (1.24) **G2+G3:** 24.4 (1.2) *(P* < 0.05) **Sex:** Female: 100% **Race/ethnicity:** NR **BMI, kg/m^2, mean (SD):** 21.89 (2.01) **Height, cms, mean (SD):** **G1:** NR **G2:** 165.60 (7.04) **G3:** 162.45 (5.35) *(P* < 0.05) **Duration of bulimic symptoms, yrs, mean (SD):** **Total:** 6.19 (5.08) **G1:** NR **G2:** 5.40 (2.31) **G3:** 3.31 (2.99) *(P* < 0.05) **Duration of objective bulimic episodes, yrs, mean (SD):** **Total:** 4.54 (5.15) **G1:** NR **G2:** 3.42 (3.14) **G3:** 1.96 (3.04) *(P* < 0.05) **Frequency (days/mo) of objective bulimic episodes, mean (SD):** 14.18 (7.78) **Frequency (days/mo) of self-induced vomiting,mean (SD):** 15.76 (10.40) **Frequency (days/mo) of laxative abuse, mean (SD):** 4.69 (8.67) **Hx of AN:** 25.6%

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Female; age 17 to 50 yrs; BMI 18 to 26; no more than 2 prior inpatient admissions for an ED; willing to participate in research and FU; willing to not seek additional tx during research study. **Exclusion:** Concurrent psychological or pharmacological tx; Coexisting major psychiatric disorder other than depressive or anxiety state or personality disorder; Physical dependence on drugs or alcohol; Suicide risk or poor physical health indicating need for hospitalization.	Both forms of manualized tx were and conducted for 8 wks and included 7 individual, 50 to 60 minute long sessions (6 with therapist, 1 with dietitian). CBT manual based on Fairburn (1985); HBT manual based on Griffiths (1989). HBT: used hypnosis to reinforce what was taught within the CBT component. CBT: cognitive explanation of BN and used cognitive techniques. Waitlist: did not complete the full assessment at baseline. They were asked to keep a baseline eating diary for 1 wk after their intake interview and another 1-wk diary before attending their appointment 8 wks later. They were not contacted during the tx.	T-tests and chi-square analyses done to examine baseline Diffs. MANOVA used to explore group Diffs. The variables of 'episodes of bingeing' and 'episodes of purging' underwent log transformations. Post tx for G1 refers to the last wk of waiting for tx (wk 9).	**Score:** Poor **Intent to treat:** Yes; however only completer results are presented in tables. **Blinding:** NA **Adverse events:** NR **Funding:** NR

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Griffiths et al., 1994 (continued)			**Serious psychological condition:** 20.5% **Suicide attempts:** 24.4% **Abused alcohol/drugs or both substances:** 21.8% **Previous tx for AN, BN or obesity:** 28.2% **Marital status:** Single: 78.2% Married: 12.8% Separated: 2.6% Divorced: 5.1% Widowed: 1.3% **Employment status:** Employed: 64.1% Students: 14.1% Unemployed: 11.5% Food-related employment: 6.5% Home duties: 3.8%

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Griffiths et al., 1994 (continued)	**EAT-40, mean (SD):** **G1:** 53 (16.06) **G2:** 46.63 (16.04) **G3:** 47.62 (19.91) *(P* = NR)	**EAT-40, mean (SD):** **G1:** 45.73 (17.99) *(P* = NR) **G2:** 18.79 (11.65) *(P* = NR) **G3:** 25.91 (20.56) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time G2+G3 better than G1 *(P* < 0.001) G2 vs. G3 *(P* = NS)
	EAT-26 – Dieting, mean (SD): **G1:** 21.41 (7.86) **G2:** 19.53 (9.62) **G3:** 20.67 (9.19) *(P* = NR)	**EAT-26 – Dieting, mean (SD):** **G1:** 18.96 (9.36) *(P* = NR) **G2:** 7.53 (6.48) *(P* = NR) **G3:** 11.19 (10.54) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time G2+G3 better than G1 *(P* < 0.001) G2 vs. G3 *(P* = NS)
	EAT-26 – Bulimia and Food Preoccupation, mean (SD): **G1:** 12.73 (3.72) **G2:** 11.53 (3.85) **G3:** 10.86 (4.77) *(P* = NR)	**EAT-26 – Bulimia and Food Preoccupation, mean (SD):** **G1:** 10.55 (5.18) *(P* = NR) **G2:** 1.95 (2.55) *(P* = NR) **G3:** 3.33 (3.93) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time G2+G3 better than G1 *(P* < 0.001) G2 vs. G3 *(P* = NS)
	EAT-26 – Oral Control, mean (SD): **G1:** 3.41 (1.27) **G2:** 2.16 (0.74) **G3:** 3.67 (1.97) G2 lower than G3 *(P* < 0.05)	**EAT-26 – Oral Control, mean (SD):** **G1:** 10.55 (5.18) *(P* = NR) **G2:** 1.95 (2.55) *(P* = NR) **G3:** 3.33 (3.93) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time G2+G3 better than G1 *(P* < 0.001) G2 vs. G3 *(P* = NS)
	EDI-DT, mean (SD): **G1:** 15.46 (4.22) **G2:** 14.32 (5.39) **G3:** 14.95 (5.38) *(P* = NR)	**EDI-DT, mean (SD):** **G1:** 13.55 (5.33) *(P* = NR) **G2:** 7.58 (6.17) *(P* = NR) **G3:** 8.62 (7.07) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Griffiths et al., 1994 (continued)	**EDI-B, mean (SD):** **G1:** 12.18 (4.24) **G2:** 11.58 (4.07) **G3:** 10.76 (4.97) *(P* = NR)	**EDI-B, mean (SD):** **G1:** 11.14 (5.14) *(P* = NR) **G2:** 3.32 (5.24) *(P* = NR) **G3:** 3.76 (4.63) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time G2+G3 better than G1 *(P* < 0.001) G2 vs. G3 *(P* = NS)
	EDI-BD, mean D (SD): **G1:** 18.32 (8.69) **G2:** 19.47 (7.94) **G3:** 18.09 (7.27) *(P* = NR)	**EDI-BD, mean (SD):** **G1:** 17.41 (8.17) *(P* = NR) **G2:** 14.21 (8.65) *(P* = NR) **G3:** 12.62 (7.95) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	Number of days bingeing, mean (SD): **G1:** 4.77 (1.83) **G2:** 3.18 (1.49) **G3:** 3.95 (1.67) *(P* = NR)	**Number of days bingeing, mean (SD):** **G1:** 4.14 (2.21) *(P* = NR) **G2:** 1.25 (1.45) *(P* = NR) **G3:** 1.62 (2.09) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time G2+G3 better than G1 *(P* < 0.01) G2 vs. G3 *(P* = NS)
	Number of days purging, mean (SD): **G1:** 5.27 (2.00) **G2:** 3.38 (2.29) **G3:** 3.86 (2.46) *(P* = NR)	**Number of days purging, mean (SD):** **G1:** 4.95 (2.38) *(P* = NR) **G2:** 0.95 (1.23) *(P* = NR) **G3:** 1.67 (1.98) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time G2+G3 better than G1 *(P* < 0.001) G2 vs. G3 *(P* = NS)
	Episodes bingeing, mean (SD): **G1:** 9.82 (9.49) **G2:** 4.73 (2.79) **G3:** 6.38 (6.12) *(P* = NR)	**Episodes bingeing, mean (SD):** **G1:** 8.77 (11.05) *(P* = NR) **G2:** 1.50 (2.01) *(P* = NR) **G3:** 2.00 (2.62) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time G2+G3 better than G1 *(P* < 0.001) G2 vs. G3 *(P* = NS)
	Episodes purging, mean (SD): **G1:** 11.27 (9.87) **G2:** 6.48 (7.43) **G3:** 8.55 (9.94) *(P* = NR)	**Episodes purging, mean (SD):** **G1:** 11.27 **(**12.09) *(P* = NR) **G2:** 1.25 (1.77) *(P* = NR) **G3:** 2.19 (3.52) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time G2+G3 better than G1 *(P* < 0.001) G2 vs. G3 *(P* = NS)
		Abstinence from bingeing: **G1:** 4.5% **G2:** 50% **G3:** 43% *(P* = NR)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Hsu et al., 2001 **Setting:** Outpatient Boston, MA, USA **Enrollment period:** NR	**Research objective:** To compare the efficacy of CT, NT, the combination (CNT), against a control support group in the tx of BN.	**Groups:** **G1:** Nutritional (NT) (N = 23) **G2:** Cognitive Therapy (CT) (N = 26) **G3:** Combined cognitive-nutritional (CNT) (N = 27) **G4:** Support (SG) (N = 24) **Enrollment:** 100 randomized (stratified according to presence of concurrent major depression) **Completion, N (%):** **Total sample:** 73 (73%) **G1:** 14 (61%) **G2:** 22 (85%) **G3:** 24 (89%) **G4:** 13 (54%). G3 vs. G4 *(P* = 0.006) G2 vs. G4 *(P* = 0.02) G3 vs. G1 *(P* = 0.02) **Wks in tx, mean (SD):** **G1:** 10.91 (4.42) **G2:** 12.92 (2.91) **G3:** 12.78 (3.56) **G4:** 9.21 (5.61) G3 vs. G4 *(P* = 0.007) G2 vs. G4 *(P* = 0.01) G3 vs. G1 *(P* = 0.039)	**Age, yrs, mean (SD):** **Total sample:** 24.5 (6.4) **G1:** 24.2 (5.6) **G2:** 23.3 (5.0) **G3:** 24.1 (5.3) **G4:** 26.5 (9.1) *(P* = NS) **Sex:** Female: 100% **Race/ethnicity:** NR **Duration of BN, yrs, mean (SD):** **Total sample:** 5.7 (4.5) **G1:** 5.0 (4.4) **G2:** 5.5 (3.2) **G3:** 5.9 (3.7) **G4:** 6.4 (6.3) *(P* = NS) **Hx of AN, N (%):** **Total sample:** 41 (41%) **G1:** 9 (39%) **G2:** 10 (38%) **G3:** 11 (4%1) **G4:** 11 (46%) *(P* = NS) **Previous tx for BN, N (%):** **Total sample:** 46 (46%) **G1:** 11 (48%) **G2:** 11 (42%) **G3:** 11 (41%) **G4:** 13 (54%) *(P* = NS) **% ABW, mean (SD):** **Total sample:** 112.2 (9.5) **G1:** 114.5 (9.4) **G2:** 112.5 (9.6) **G3:** 110.2 (8.7) **G4:** 111.9 (10.4) *(P* = NS)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Female, DSM III-R criteria for BN, within 85 – 125% of IBW, between 17 – 45 yrs old, BE and vomiting at least 3 times per wk in previous 6 mo, absence of: alcohol or substance abuse in previous 12 mo, psychotic features, suicide attempt within last 6 mo, psychotropic meds. **Exclusion:** None	**Length:** 14 wks (2 sessions for the first wk and then wkly) **CNT:** 16 2-hr sessions (1 hr of each) **NT:** 16 1-hr sessions aimed at helping patient to understand good nutrition, nutritional needs, relationship between nutrition and BE, meal planning, buying meals. **CT:** 16 1-hr sessions aimed at helping identify antecedents of bulimic episodes, thoughts/feelings/function/beliefs of episodes. Help develop alternative coping bx, cognitive restructuring, problem solving. 6 sessions of EXRP **SG:** 14, 90-minute sessions led by 2 recovered patients and a mother of a recovered patient. Open support groups of 6-8 patients.	**Baseline characteristics:** ANOVA and chi-square **Outcomes:** chi-squared contingency tests, Kruskal-Wallis non-parametric ANOVA, Mann-Whitney tests, ANCOVA followed by specific paired comparisons using least sig Diff. **Completion rates and abstinence relative to type of tx:** Multiple linear and logistic regression with covariates	**Score:** Fair **Intent to treat:** Yes **Blinding:** NA **Adverse events:** NR **Funding:** NICHD General Clinical Research Center at New England Medical Center funded by the National Center for Research Resources of the NIH

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Hsu et al., 2001 (continued)	**Binge episodes/wk, mean (SD):** Total sample: **10.9 (9.5)** **G1:** 12.3 (10.8) **G2:** 7.2 (4.3) **G3:** 12.1 (7.0) **G4:** 12.2 (13.4) *(P* = NS)	**Change in binge episodes/wk, mean (SD):** **G1:** -8.39 (10.43) *(P* = NR) **G2:** -4.92 (4.97) *(P* = NR) **G3:** -9.41 (7.59) *(P* = NR) **G4:** -5.79 (11.44) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups in change over time *(P* = NS)
	Vomiting episodes/wk, mean (SD): Total sample: **12.2 (10.3)** **G1:** 13.3 (11.2) **G2:** 7.7 (5.0) **G3** 13.4 (9.2) **G4:** 14.5 (13.6) *(P* = NS)	**Change in vomit episodes/wk, mean (SD):** **G1:** -9.43 (11.42) *(P* = NR) **G2:** -5.73 (5.02) *(P* = NR) **G3:** -10.56 (8.42) *(P* = NR) **G4:** -4.58 (13.28) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups in change over time *(P* = NS)
	Meals eaten/wk, mean (SD): Total sample: **10.8 (6.7)** **G1:** 11.4 (6.8) **G2:** 10.0 (7.1) **G3:** 10.9 (5.8) **G4:** 11.0 (7.3) *(P* = NS)	**Change in meals eaten/wk, mean (SD):** **G1:** 4.87 (6.97) *(P* = NR) **G2:** 5.42 (6.50) *(P* = NR) **G3:** 7.07 (5.86) *(P* = NR) **G4:** 3.79 (7.83) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups in change over time (*P* = NS)
		Abstinence (no binge/purge in wk prior to post tx, N (%): **G1:** 4/23 (17%) **G2:** 9/26 (35%) **G3:** 14/27 (52%) **G4:** 5/24 (24%) G1 vs. G4 *(P* = NS) G2 vs. G4 *(P* = NS) G3 vs. G4 *(P* = 0.022) G3 vs. G1 *(P* = 0.011)
		EDI-Drive for Thinness: **G1:** NR **G2:** NR **G3:** NR **G4:** NR Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) G1 vs. G4 *(P* = NS) G2 vs. G4 *(P* = 0.011) G2 vs. G1 *(P* = NS) G3 vs. G4 *(P* < 0.001) G3 vs. G1 *(P* = 0.006)
		EDI-Bulimia: Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) G1 vs. G4 *(P* = NS) G2 vs. G4 *(P* = NS) G2 vs. G1 *(P* = 0.029) G3 vs. G4 *(P* < 0.0045) G3 vs. G1 *(P* = 0.006)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
HDRS, mean (SD): Total sample: 17.64 (8.01) **G1:** 18.04 (7.54) **G2:** 14.92 (8.04) **G3:** 18.89 (8.28) **G4:** 18.79 (7.86) *(P* = NS)	**Change HDRS, mean (SD):** **G1:** -5.96 (11.11) *(P* = NR) **G2:** -4.46 (7.98) *(P* = NR) **G3:** -8.33 (7.35) *(P* = NR) **G4:** -4.33 (8.08) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)		

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Laessle et al., 1991 **Setting:** Munich, Germany; Sydney, Australia; outpatient **Enrollment period:** NR	**Research objective:** To evaluate the efficacy of a nutritional-management program which was aimed at modifying restrained eating vs. stress management in BN	**Groups:** **G1:** Nutritional management (N = 27) **G2:** Stress management (N = 28) **Enrollment:** Screened: N = 85 Randomized: N = 55 **Drop out, N:** **G1:** 5 **G2:** 2 *(P* = NS)	**Age, yrs, mean (SD):** 23.8 (3.8) **Sex:** Female: 100% **Race/ethnicity:** NR **Duration of Bulimic symptoms, yrs, mean (SD):** 7.5 (3.8) **Bulimic episodes per wk, mean (SD):** 13.3 (10.8) **Reported vomiting, N (%):** 50 (90.9) **Reported laxative use, N (%):** 19 (34.5) **Vomiting frequency, episodes per wk, mean (SD):** 14.8 (12.4) **Current BMI, mean (SD):** 21.0 (1.8) **Max adult BMI, mean (SD):** 24.4 (4.2) **Min adult BMI, mean (SD):** **G1:** 18.2 (1.8) **G2:** 16.8 (2.1) *(P* < 0.01) **Previously met criteria for AN, N (%):** 22 (40) **Current substance abuse problems, N (%):** 7 (12.7) **Previous psychiatric/ psychological tx, N:** 29 AN = 7 BN = 19 Depression = 3

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: DSM III-R criteria for BN, female age 18 to 35 yrs, BMI between 18 to 24, not more than 2 previous inpatient tx for psychiatric conditions, no co-existing major psychiatric disorder other than affective or anxiety, no indications for inpatient tx because of either a serious suicide risk or poor physical health. **Exclusion:** None	Groups (co-led by 2 therapists) of 5-8 participants in 15 two-hour sessions over a 3-mo period. The first 7 sessions were the intensive phase within the first 3 wks. The remaining 8 sessions were conducted on a wkly basis. Manuals were followed. **G1:** Discussed metabolic processes, energy requirements, body wt, biological and psychological effects of dieting; analysis of nutritional diaries and modification of inadequate patterns; advice on eating patterns, stimulus control, meal preparation was offered. **G2:** functional analysis of stressful situations relevant to BE; short term strategies to alter coping behavior in stressful situations, progressive muscle relaxation, problem solving, communication skills. No specific intervention to alter restrained eating, no individualized meal plan or homework.	Repeated measures MANOVA with 1 within factor (time) and 2 between factors (tx and center). Tested linear and quadratic trends over time. Tested separate models for the pre-tx to post-tx effects vs. the post-tx to 12 mo FU. Binge and vomiting behavior data were log-transformed. Fisher's exact tests used to evaluate diffs in abstinence rates.	**Score:** Fair **Intent to treat:** Yes **Blinding:** NA **Adverse events:** 1 patient hospitalized during FU **Funding:** NR

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Laessle et al., 1991 (continued)			**Previous hospital admission, N:** 9 AN = 6 BN = 3 **Marital status, married or regular partner in heterosexual relationship, N (%):** 27 (49.1) **Employment status, N (%):** HS student: 6 (11.0) Tertiary student: 19 (34.5) Employed: 24 (42.6) Unemployed: 6 (11.0)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Laessle et al., 1991 (continued)	**Binge frequency, per wk, mean (SD):** **G1:** 11.8 (10.6) **G2:** 14.0 (12.0) *(P* = NS)	**Binge frequency/wk, mean (SD):** **3 wks:** **G1:** 4.0 (6.5) *(P* = NR) **G2:** 9.2 (13.0) *(P* = NR) **Post-tx:** **G1:** 3.5 (6.1*) (P* = NR) **G2:** 4.2 (7.2) *(P* = NR) Diff over time *(P* < 0.0001) Diff between groups *(P* = NR) Diff between groups in change over time (linear trend, *P* = NS) (quadratic trend, *P* < 0.05). After 3 wks, G1 better than G2 **6 mo:** **G1:** 1.7 (3.4) *(P* = NR) **G2:** 3.0 (4.5) *(P* = NR) **12 mo:** **G1:** 1.0 (1.9) *(P* = NR) **G2:** 2.6 (4.8) *(P* = NR) Diff over time *(P* < 0.01) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **Binge Abstinence rates, %:** **3 wks:** **G1:** 29.6 **G2:** 14.3 *(P* = NS) **Post-tx:** **G1:** 40.7 **G2:** 25.0 *(P* = NS) **6 mo:** **G1:** 60 **G2:** 25 *(P* = 0.01) G1 better than G2 **12 mo:** **G1:** 56 **G2:** 25 *(P* = 0.04) G1 better than G2

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BDI, mean (SD): **G1:** 19.5 (12.6) **G2:** 23.0 (9.5) *(P* = NS)	**BDI, mean (SD):** **3 wks:** **G1:** 13.8 (11.8) *(P* = NR) **G2:** 12.2 (9.9) *(P* = NR) **Post-tx:** **G1:** 9.3 (9.2) *(P* = NR) **G2:** 11.8 (12.5) *(P* = NR) Diff over time *(P* < 0.0001) Diff between groups *(P* = NR) Diff between group in change over time *(P* = NS) **6 mo:** **G1:** 8.3 (7.2) *(P* = NR) **G2:** 7.8 (9.5) *(P* = NR) **12 mo:** **G1:** 5.1 (8.0) *(P* = NR) **G2:** 8.3 (9.7) *(P* = NR) Diff between groups *(P* = NR) Diff between group in change over time *(P* = NS)	**BMI, kg/m^2, mean (SD):** **G1:** 21.2 (1.8) **G2:** 20.6 (1.9) *(P* = NS)	**BMI, kg/m^2, mean (SD):** **3 wks:** **G1:** 21.8 (1.7) *(P* = NR) **G2:** 20.7 (2.5) *(P* = NR) **Post-tx:** **G1:** 22.0 (1.9) *(P* = NR) **G2:** 20.7 (2.0) *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **6 mo:** **G1:**NR **G2:** NR **12 mo:** **G1:** NR **G2:** NR Diff over time *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
STAI-State, mean (SD): **G1:** 49.6 (12.9) **G2:** 52.0 (13.2) *(P* = NS)	**STAI-State, mean (SD):** **3 wks:** **G1:** 46.2 (14.4) *(P* = NR) **G2:** 45.8 (13.5) *(P* = NR) **Post-tx:** **G1:** 41.8 (13.8) *(P* = NR) **G2:** 43.4 (13.2) *(P* = NR) Diff over time *(P* < 0.0001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **6 mo:** **G1:** 13.5 (12.2) *(P* = NR) **G2:** 42.0 (14.5) *(P* = NR) **12 mo:** **G1:** 38.9 (12.8) *(P* = NR) **G2:** 44.2 (16.2) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)		

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Laessle et al., 1991 (continued)	**Vomiting frequency, episodes per wk, mean (SD):** **G1:** 11.3 (8.5) **G2:** 16.9 (13.9) *(P* = NS)	**Vomiting frequency/ wk, mean (SD):** **3 wks:** **G1:** 4.5 (7.3) *(P* = NR) **G2:** 10.0 (13.6) *(P* = NR) **Post-tx:** **G1:** 3.7 (7.0) *(P* = NR) **G2:** 5.5 (8.8) *(P* = NR) Diff over time *(P* < 0.0001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **6 mo:** **G1:** 2.2 (4.2) *(P* = NR) **G2:** 3.3 (4.5) *(P* = NR) **12 mo:** **G1:** 2.5 (5.2) *(P* = NR) **G2:** 3.1 (5.1) *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **Vomiting Abstinence rates (%):** **3 wks:** **G1:** 40.7 **G2:** 21.4 *(P* = NS) **Post-tx:** **G1:** 48.1 **G2:** 32.1 *(P* = NS) **6 mo:** **G1:** 50 **G2:** 29 *(P* = NS) **12 mo:** **G1:** 56 **G2:** 33 *(P* = NS)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
STAI-Trait, mean (SD): **G1:** 55.2 (10.5) **G2:** 59.8 (7.4) *(P* = NS)	**STAI-Trait, mean (SD):** **3 wks:** **G1:** 50.7 (13.2) *(P* = NR) **G2:** 52.2 (9.8) *(P* = NR) **Post-tx:** **G1:** 47.2 (12.3) *(P* = NR) **G2:** 45.4 (11.6) *(P* = NR) Diff over time *(P* < 0.0001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.05) G2 better then G1 **6 mo:** **G1:** 46.4 (11.9) *(P* = NR) **G2:** 44.5 (11.5) *(P* = NR) **12 mo:** **G1:** 44.6 (11.6) *(P* = NR) **G2:** 45.8 (12.8) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)		

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Laessle et al., 1991 (continued)	**EAT, mean (SD):** **G1:** 51.0 (19.1) **G2:** 51.4 (17.2) *(P* = NS)	**EAT, mean (SD):** **3 wks:** **G1:** 29.9 (20.9) *(P* = NR) **G2:** 39.7 (15.4) *(P* = NR) **Post-tx:** **G1:** 27.3 (19.3) *(P* = NR) **G2:** 28.9 (21.6) *(P* = NR) Diff over time (linear trend (*P* < 0.0001) (quadratic trend, *P* < 0.05) Most improvements during the first three wks Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **6 mo:** **G1:** 24.9 (14.4) *(P* = NR) **G2:** 21.1 (14.9) *(P* = NR) **12 mo:** **G1:** 20.6 (18.0) *(P* = NR) **G2:** 19.2 (16.5) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	Calories per day, mean (SD): **G1:** 1228 (493) **G2:** 1071 (588) *(P* = NS)	**Calories per day, mean (SD):** **3 wk:** **G1:** 1821 (664) *(P* = NR) **G2:** 1299 (545) *(P* = NR) **Post-tx:** **G1:** 1697 (547) *(P* = NR) **G2:** 1584 (530) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups in change over time (quadratic trend, *P* < 0.05) G1 better than G2 after 3 wks **6 mo:** **G1:** 1621 (509) *(P* = NR) **G2:** 1623 (556) *(P* = NR) **12 mo:** **G1:** 1703 (589) *(P* = NR) **G2:** 1639 (649) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Laessle et al., 1991 (continued)	**EDI Drive for thinness, mean (SD):** **G1:** 13.8 (4.2) **G2:** 12.9 (5.3) *(P* = NS)	**EDI, Drive for thinness mean (SD):** **3 wks:** **G1:** 8.6 (5.2) *(P* = NR) **G2:** 9.1 (3.9) *(P* = NR) **Post-tx:** **G1:** 7.4 (5.6) *(P* = NR) **G2:** 6.4 (4.7) *(P* = NR) Diff over time (linear trend, *P* < 0.0001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **6 mo:** **G1:** 7.1 (5.7) *(P* = NR) **G2:** 5.8 (4.9) *(P* = NR) **12 mo:** **G1:** 5.3 (4.6) *(P* = NR) **G2:** 6.2 (6.3) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	EDI Bulimia, mean (SD): **G1:** 12.1 (4.6) **G2:** 12.2 (4.5) *(P* = NS)	**EDI Bulimia, mean (SD):** **3 wks:** **G1:** 5.8 (4.7) *(P* = NR) **G2:** 7.6 (4.9) *(P* = NR) **Post-tx:** **G1:** 3.6 (4.9) *(P* = NR) **G2:** 4.7 (5.3) *(P* = NR) Diff over time (linear trend, *P* < 0.0001) (quadratic trend, *P* < 0.05) Most improvements during the first three wks Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **6 mo:** **G1:** 3.2 (4.1) *(P* = NR) **G2:** 5.1 (5.3) *(P* = NR) **12 mo:** **G1:** 3.0 (3.7) *(P* = NR) **G2:** 5.2 (5.6) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Laessle et al., 1991 (continued)	**EDI Body dissatisfaction, mean (SD): G1: 16.1 (6.9)** **G2:** 15.1 (6.9) *(P* = NS)	**EDI Body dissatisfaction, mean (SD):** **3 wks:** **G1:** 13.4 (7.0) *(P* = NR) **G2:** 11.3 (5.6) *(P* = NR) **Post-tx:** **G1:** 13.0 (7.3) *(P* = NR) **G2:** 10.5 (6.6) Diff over time (linear trend, $P < 0.0001$) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **6 mo:** **G1:** 12.5 (8.6) *(P* = NR) **G2:** 10.6 (6.8) *(P* = NR) **12 mo:** **G1:** 12.3 (7.6) *(P* = NR) **G2:** 11.4 (6.6) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Safer, Telch, and Agras, 2001 **Setting:** Stanford, CA, USA **Enrollment period:** NR	**Research objective:** To examine the effects of DBT adapted for the tx of binge/purge behaviors.	**Groups:** **G1:** DBT (N = 16) **G2:** Wait list control (N = 15) **Enrollment:** • N = 31 **G1:** N = 16 **G2:** N = 15 • Completed: N = 29 **G1** = 14 **G2:** 14	**Age, yrs, mean (SD):** 34 (11) (range: 18-54) **Sex:** Female: **G1:** 100% **Race/ethnicity:** White: 87.1% **BMI, kg/m^2, mean (SD):** 23.7 (5.6) kg/m2 **Employed:** 51.6% **Full-time student:** 22.6% **At least some college:** 77.4% **Age at start of bulimic behavior, yrs, mean (SD):** 22.3 (7.0) **Duration of bulimic behaviors, yrs, mean (SD):** 12.2 (8.6) Does not include 2 patients withdrawn from tx; No diff between groups on any baseline measures except the Negative Mood Regulation Scale score (*P* = 0.02)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: At least 1 binge/purge per wk over the previous 3 mos (25 [80.6%] met full DSM criteria; 6 met modified criteria) **Exclusion:** BMI < 17.5; psychosis or severe depression with suicidal ideation; active drug/alcohol abuse; concurrent participation in psychotherapy or use of antidepressants/ mood stabilizers.	20 sessions of wkly 50-minute individual psychotherapy specifically aimed at teaching emotional regulation skills to reduce rates of bingeing and purging. Tx manual was adapted for BN from Linehan's skills training manual for txing BPD.	Binge eating and purging: square root transformation and ANCOVA (baseline measures as covariates). Bonferroni corrections.	**Score:** Good **Intent to treat:** Yes (for all participants with missing post tx data, but participants who were withdrawn for contraindications are not included in ITT). **Blinding:** N/A **Adverse events:** NR **Funding:** NIH

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Safer, Telch, and Agras, 2001 (continued)		After Bonferroni correction for multiple comparisons, diffs sig at *P* = 0.0045
	EDE – Binge Episodes, past 4 wks, median: **G1:** 27.0 **G2:** 22.0 *(P* = NS)	**EDE – Binge Episodes, past 4 wks, median:** **G1:** 1.5 ***(P*** = NR) **G2:** 20.0 *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.001)
	EDE – Purge Episodes, past 4 wks, median: **G1:** 40.0 **G2:** 28.0 *(P* = NS)	**EDE – Purge Episodes, past 4 wks, median:** **G1:** 1.0 *(P* = NR) *(P* = NR) **G2:** 28.0 *(P* = NR) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.002)
	Emotional Eating Scale subscale: Anger/frustration, mean (SD): **G1:** 2.7 (0.8) **G2:** 2.7 (0.6) *(P* = NS)	**Mean Emotional Eating Scale subscale: Anger/frustration, mean (SD):** **G1:** 1.8 (0.8) *(P* = NR) **G2:** 2.6 (0.9) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.006)
	Emotional Eating Scale subscale: Anxiety, mean (SD): **G1:** 2.1 (0.8) **G2:** 2.1 (0.9) *(P* = NS)	**Emotional Eating Scale subscale: Anxiety, mean (SD)** **G1:** 1.3 (0.9) *(P* = NR) **G2:** 2.0 (0.8) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.006)
	Emotional Eating Scale subscale: Depression, mean (SD): **G1:** 2.9 (0.7) **G2:** 2.7 (0.9) *(P* = NS)	**Emotional Eating Scale subscale: Depression, mean (SD):** **G1:** 2.1 (1.0) *(P* = NR) **G2:** 2.6 (0.7) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.008)
		Abstinence rates: **G1:** N = 4 (28.6%) **G2:** N = 0 (0%) Diff between groups *(P* < 0.05)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
	After Bonferroni correction for multiple comparisons, diffs sig at *P* = 0.0045		NR
Negative Mood Regulation Scale, mean (SD): **G1:** 81.3 (15.1) **G2:** 98.1 (16.8) *(P* = 0.02)	**Mean Negative Mood Regulation Scale, mean (SD):** **G1:** 96.1 (24.0) *(P* = NR) **G2:** 97.7 (15.0) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.03)		
BDI, mean (SD): **G1:** 22.9 (8.9) **G2:** 19.2 (11.9) *(P* = NS)	**BDI, mean (SD):** **G1:** 13.4 (11.6) *(P* = NR) **G2:** 17.4 (11.8) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.04)		
Positive and Negative Affect schedule subscale: Positive Affect, mean (SD): **G1:** 24.8 (8.3) **G2:** 26.1 (6.5) *(P* = NS)	**Positive and Negative Affect schedule subscale: Positive Affect, mean (SD):** **G1:** 27.6 (8.2) *(P* = NR) **G2:** 28.3 (7.9) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)		
Negative Affect, mean (SD): **G1:** 31.5 (9.9) **G2:** 28.6 (6.9) *(P* = NS)	**Negative Affect, mean (SD):** **G1:** 23.4 (8.4) *(P* = NR) **G2:** 30.0 (9.7) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.02)		

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Sundgot-Borgen, et al., 2002 **Setting:** Outpatient Oslo, Norway **Enrollment period:** NR	**Research objective:** To examine the effect of CBT vs physical exercise and vs nutritional counseling as tx for BN	**Groups:** **G1:** Exercise (N = 15) **G2:** CBT (N = 16) **G3:** Nutrition (N = 17) **G4:** Waitlist (N = 16) **G5:** Healthy Control (N = 13) **Enrollment:** 77 ED patients recruited by letter from private practice, ED clinics • 10 ineligible • 3 declined • 64 randomized 24 healthy participants recruited via college newspaper ads; 8 excluded • ED symptoms (3) • menstrual irregularity (2) • vegetarian diet (2) • competitive running (1) **Drop Outs** **G1: (**3) **G2: (**2) **G4: (**1)	**Age, mean (SD):** **G1:** 23 (2.3) **G2:** 22 (2.7) **G3:** 22 (2.9) **G4:** 23 (3.2) **G5:** 22 (4.1) *(P* = NS) **Sex:** Female: 100% **Race/ethnicity:** NR **BN Duration, yrs, mean (SD):** **G1:** 7 (3.7) **G2:** 5 (1.6) **G3:** 5 (2.3) **G4:** 6 (3.8) **G5:** NA *(P* = NS) **Wkly Exercise, hrs, mean (SD):** **G1:** 2.5 (3.8) **G2:** 2.1 (2.4) **G3:** 2.5 (2.2) **G4:** 3.1 (1.7) **G5:** 1.8 (1.3) *(P* = NS)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Patients: Age 18 to 29; meeting DSM IV criteria for BN Healthy controls: not meeting BN inclusion criteria; eumenorrhea; regular participation in wt. bearing exercise (1-2 hrs/wk); no use of meds; willingness to complete fitness test, dietary registration, med exam, and 4 interviews **Exclusion:** Hx of AN or other psychiatric or somatic disorders; tx of EDs in previous 6 mos; current use of meds.	16 wk outpatient tx for all groups Exercise: 2 hr introduction meeting, followed by 1-hr wkly session (45 minute aerobic, 15 minutes cool down) with fitness instructor; participants advised to exercise independently 2/wk at least 35 minutes CBT: wkly 2-hr group sessions, following modified Hsu et al. (1991) protocol (Martinsen et al., 1990). Nutrition Counseling: 2-hr group sessions, 2/wk in the first 2 wks, wkly thereafter, and held by a RD; tx modified from Hsu et al. (1992) protocol to include food log discussions and wt monitoring bi-wkly. For G2 and G3, wt change >2kg was addressed by additional meal planning; participants were assigned 90 m/wk of homework and food logs. BN sx (using EDI-II), physical activity, peak oxygen uptake, nutritional habits, and % body fat assessed at baseline, post-tx, 6- and 18-mos FU.	Group diffs were assessed by ANOVA for repeated measures and by paired-sample t-tests and nonparametric tests. *P* values < 0.05 were considered sig.	**Score:** Fair **Intent to treat:** No **Blinding:** NR **Adverse events:** 1 injury in G1 **Funding:** NR

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Sundgot-Borgen et al., 2002 (continued)	**EDI Drive for Thinness, mean (SD):** **G1:** NR **G2:** NR **G3:** NR **G4:** NR G2 vs G1 *(P* = NS) All other comparisons *(P* = NR)	**EDI Drive for Thinness, mean (SD):** **Post-Treatment:** **G1:** NR **G2:** NR **G3:** NR Diff over time *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **6-mo FU:** **G1:** 11.86 (4.33) *(P* = NR) **G2:** 7.15 (2.41) *(P* = NR) **G3:** NR Diff over time *(P* = NR) Diff between groups *(P* = 0.02) G1 better than G2 Diff between groups in change over time *(P* = NR) **18-mo FU:** **G1:** 13.43 (4.83) *(P* = NR) **G2:** 6.08 (4.65) *(P* = NR) **G3:** NR Diff over time *(P* = NR) Diff between groups *(P* = 0.000) G1 better than G2 Diff between groups in change over time *(P* = NR)
	EDI Bulimia, mean (SD): **G1:** NR **G2:** NR **G3:** NR **G4:** NR *(P* = NR)	**EDI Bulimia, mean (SD):** **Post-Treatment:** **G1:** NR **G2:** NR **G3:** NR Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) **6-mo FU** **G1:** NR **G2:** 2.64 (1.6) *(P* = NR) **G3:** 5.00 (3.1) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = 0.02) G2 better than G3 Diff between groups in change over time *(P* = NR) **18-mo FU** **G1:** NR **G2:** 2.14 (1.83) *(P* = NR) **G3:** 8.47 (2.15) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* < 0.000) G2 better than G3 Diff between groups in change over time *(P* = NR)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
		BMI, kg/m², mean (SD): **G1:** 21.0 (2.0) **G2:** 20.0 (1.9) **G3:** 21.0 (2.1) **G4:** 22.0 (2.5) **G5:** 21.0 (1.9) *(P* = NS)	**Post-tx:** **BMI, kg/m², mean (SD):** **G1:** NR **G2:** NR **G3:** NR **G4:** NR **G5:** NR *(P* = NS)
		% Body fat, mean (SD): **G1:** 24.1 (8.3) **G2:** 23.4 (8.1) **G3:** 23.7 (8.9) **G4:** 21.6 (5.1) **G5:** 25.5 (7.0) *(P* = NS)	**% Body fat, mean (SD):** **G1:** 21.5 (6.4) *(P* < 0.001) **G2:** NR **G3:** NR **G4:** NR **G5:** NR Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)
		Fat mass, mean (SD): **G1:** 21.5 (6.4) **G2:** NR **G3:** NR **G4:** NR **G5:** NR *(P* = NS)	**18-mo FU:** **Fat mass, mean (SD):** **G1:** 19.8 (4.89) Diff between groups *(P* = 0.034) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)
		Peak O2 uptake, mL/kg/min, mean (SD): **G1:** 43.5 (7.3) **G2:** 42.0 (6.0) **G3:** 44.1 (6.2) **G4:** 41.3 (12.2) **G5:** 43.1 (7.2) *(P* = NS)	**Peak O2 uptake, mL/kg/min, mean (SD):** NR

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Sundgot-Borgen et al., 2002 (continued)	**EDI Body Dissatisfaction, mean (SD):** NR *(P* = NR)	**EDI Body Dissatisfaction, mean (SD):** **Post-Treatment:** **G1:** NR **G2:** 9.64 (4.86) *(P* = NR) **G3:** 14.24 (5.53) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* < 0.02) G2 better than G3 Diff between groups in change over time *(P* = NS) **6-mo FU** **G1:** NR **G2:** 9.21 (3.02) *(P* = NR) **G3:** 14.00 (5.32) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* < 0.006) G2 better than G3 Diff between groups in change over time *(P* = NS) **18-mo FU:** **G1:** NR **G2:** 10.71 (3.45) *(P* = NR) **G3:** 12.71 (5.58) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Sundgot-Borgen et al., 2002 (continued)	**Binge Episodes/wk, mean (SD):** **G1:** 7.3 (2.72) **G2:** 7.9 (2.95) **G3:** 7.7 (3.76) **G4:** 5.4 (2.63) *(P* = NS)	**Binge Episodes/wk, mean (SD):** **Post-Treatment:** **G1:** NR **G2:** NR **G3:** NR **G4:** NR Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) **6-mo FU:** **G1:** NR **G2:** NR **G3:** NR **G4:** NR Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) **18-mo FU:** **G1:** 1.7 (2.87) *(P* = 0.002) **G2:** 4.4 (3.37) *(P* = 0.009) **G3:** 6.8 (3.67) *(P* = NS) **G4:** 4.5 (2.33) *(P* = NS) Diff over time *(P* = NR) Diff between groups *(P* = 0.04) G1 better than G2 Diff between groups in change over time *(P* = NR)
	Vomiting Episodes/wk, mean (SD): **G1:** 7.8 (3.39) **G2:** 8.6 (4.68) **G3:** 8.2 (4.34) **G4:** 5.6 (3.15) *(P* = NS)	**Vomiting Episodes/wk, mean (SD):** Post-tx: **G1:** NR **G2:** NR **G3:** NR **G4:** NR Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) **6-mo FU:** **G1:** NR **G2:** 3.50 (2.93) *(P* = NR) **G3:** 7.06 (4.16) *(P* = NR) **G4:** NR Diff over time *(P* = NR) Diff between groups *(P* < 0.01) G2 better than G3 Diff between groups in change over time *(P* = NR) **18-mo FU:** **G1:** 2.4 (2.39) *(P* = 0.001) **G2:** 2.7 (1.94) *(P* = 0.003) **G3:** 7.2 (4.05) *(P* = NS) **G4:** 5.1 (2.47) *(P* = NS) Diff over time *(P* = NR) Diff between G2 and G3 *(P* < 0.001) G2 better than G3 Diff between groups in change over time *(P* = NR)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Sundgot-Borgen et al., 2002 (continued)	**Laxative Use, episodes/wk, mean (SD):** NR *(P* = NR)	**Laxative Use, episodes/wk, mean (SD):** **Post-tx:** **G1:** 0.85 (0.99) *(P* = NR) **G2:** 2.1 (1.7) *(P* = NR) **G3:** NR **G4:** NR Diff over time *(P* = NR) Diff between groups *(P* < 0.02) G1 better than G2 Diff between groups in change over time *(P* = NR) **6-mo FU:** **G1:** 0.00 (0.00) *(P* = NR) **G2:** 2.57 (2.10) *(P* = NR) **G3:** NR **G4:** NR Diff over time *(P* = NR) Diff between groups *(P* = 0.000) G1 better than G2 Diff between groups in change over time *(P* = NR) **18-mo FU:** **G1:** 0.08 (0.28) *(P* = NR) **G2:** 3.10 (2.40) *(P* = NR) **G3:** NR **G4:** NR Diff over time *(P* = NR) Diff between groups *(P* < 0.000) G1 better than G2 Diff between groups in change over time *(P* = NR) **18-mo FU:** 62% G1 (N = 8) had recovered from BN, and one subject met EDNOS criteria 36% G2 (N = 5) had recovered from BN, 2 met EDNOS criteria 24% G3 (N = 4) met EDNOS criteria

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Thackwray et al., 1993 **Setting:** Outpatient, USA **Enrollment period:** NR	**Research objective:** Comparison of BT, CBT, and NSMT for BN	**Groups:** **G1:** CBT (N = NR) **G2:** BT (N = NR) **G3:** NSMT (N = NR) **Enrollment:** • Respondents to ads were screened on the phone • 65 applicants were seen for a screening interview • 47 met criteria for BN and were eligible for the study • 47 were randomly assigned to one of three groups • 39 completed tx and the 6-mo FU assessment	**Age, yrs, mean (SD):** 31.3 yrs (10.41) **Sex:** Female:100% **Race/ethnicity:** NR **Duration of BN, yrs, mean (SD):** 6.7 (7.28) **Employed full-time** 75% **Full or part-time students:** 19% **Homemakers:** 16% **Mothers:** 56% **Lives with spouse:** 62% **Lives with parents:** 18% **Lives with roommate:** 15% **Lives alone:** 5%

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Female, BN criteria from DSM III-R. **Exclusion:** Prior dx or current involvement in tx for BN and medical conditions, such as pregnancy or severe renal or cardiac problems	8 consecutive wkly 60-minutes individual sessions by one of two master's level therapists. BT participants: a behavioral eating habit control program that was modified to focus on reducing binge eating and purging. Participants were given self-monitoring forms to monitor daily caloric intake, binge eating and purging but not instructed to self-monitor cognitions. CBT, abbreviated version of Fairburn's (1985) manual used. Self-monitoring included daily caloric intake, binge purge behavior and cognitions. Within therapy, dysfunctional beliefs and distorted cognitions were addressed and assertiveness, problem solving skill building and relaxation taught. Nonspecific self-monitoring group: provided with rationale on the value of insight development and resolution of intrapsychic conflicts through self-knowledge, given self-monitoring forms and asked to numerically indicate total binge-purge episodes on a daily basis and estimate daily caloric intake. At all subsequent sessions, self-monitoring forms collected and reviewed by the therapist and the therapist presented didactic information about early childhood experiences and participants discussed the material relative to themselves. The main diff between the BT, CBT and the NSMT group was the emphasis on self-control of the participants via active participation in BT and CBT.	ANOVAs to look at pre-tx diff among groups, expectancy ratings and therapist ratings. For the dependent variables of binge purge frequency, a 3 (time) x 3 (group) ANOVA was done. A Chi-square analysis to examine percentage of abstinence between groups. MANOVA's: to measure EDI.	**Score:** Poor **Intent to treat:** NR **Blinding:** NA **Adverse events:** NR **Funding:** NR

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Thackwray et al., 1993 (continued)	**Binge-purge episodes/wk, mean (SD):** **G1:** 5.4 (3.0) **G2:** 5.6 (4.0) **G3:** 5.6 (3.0) *(P* = NS)	**Binge-purge episodes/wk, mean (SD):** **Post-tx:** **G1:** 0.6 (1.0) *(P* < 0.01) **G2:** 0.0 (0.0) *(P* < 0.01) **G3:** 1.0 (3.0) *(P* < 0.01) **6-mo FU:** **G1:** 0.4 (0.5) change from post-tx *(P* = NS) **G2:** 0.6 (0.5) change from post-tx *(P* = NS) **G3:** 2.7 (2.0) change from post-tx *(P* < 0.01) Diff over time *(P* < 0.0001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	EDI drive for thinness, mean (SD): **G1:** 15.3 (5.0) **G2:** 13.1 (5.0) **G3:** 13.8 (5.0) *(P* = NS)	**EDI drive for thinness, mean (SD):** **Post-tx:** **G1:** 10.1 (6.0) *(P* = NR) **G2:** 4.3 (4.0) *(P* = NR) **G3:** 11.7 (5.0) *(P* = NR) **6-mo FU:** **G1:** 8.3 (7.0) *(P* = NR) **G2:** 4.9 (4.0) *(P* = NR) **G3:** 10.9 (6.0) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.05) G2 better than G1 and G3 at post-tx G2 better than G3 at FU
	EDI Bulimia, mean (SD): **G1:** 14.5 (5.0) **G2:** 12.3 (6.0) **G3:** 11.0 (5.0) *(P* = NS)	**EDI Bulimia, mean (SD):** **Post-tx:** **G1:** 5.5 (6.0) *(P* = NR) **G2:** 2.5 (2.0) *(P* = NR) **G3:** 8.8 (7.0) *(P* = NS) **6-mo FU:** **G1:** 2.9 (4.0) *(P* = NR) **G2:** 3.3 (3.0) *(P* = NR) **G3:** 7.8 (6.0) *(P* = NS) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.005) G2 better than G3 at post-tx G1 and G2 better than G3 at FU

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BDI, mean (SD): **G1:** 25.5 (7.0) **G2:** 22.8 (14.0) **G3:** 28.1 (10.0) *(P* = NS)	**BDI, mean (SD):** **Post-tx:** **G1:** 10.8 (12.0) *(P* = NR) **G2:** 6.5 (9.0) *(P* = NR) **G3:** 16.1 (11.0) *(P* = NR) **6-mo FU:** **G1:** 7.2 (7.0) *(P* = NR) **G2:** 9.6 (8.0) *(P* = NR) **G3:** 19.3 (12.0) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.02) G1 better than G3 at 6-mo FU		**% IBW:** **Post-tx:** **G1:** NR **G2:** NR **G3:** NR **6-mo FU:** **G1:** NR **G2:** NR **G3:** NR Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Thackwray et al., 1993 (continued)		**Abstinence, %:** **Post-tx:** **G1:** 92% **G2:** 100% **G3:** 69% Diff over time *(P* = NR) Diff between groups *(P* < 0.05) G1 and G2 better than G3 **Maintained Abstinence at 6-mo FU:** **G1:** 69% **G2:** 38% **G3:** 15% Diff over time *(P* = NR) Diff between groups *(P* < 0.05) G1 better than G2 and G3

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Treasure et al., 1999 **Setting:** Eating Disorders Unit, Bethlem and Maudsley Hospital, UK **Enrollment period:** NR	**Research objective:** Explore relationship between patient's initial stage of change and symptom reduction, drop-out rate, and development of therapeutic alliance within context of CBT tx vs. MET tx.	**Groups:** **G1:** MET followed by Group CBT + MET followed by individual CBT (N = 48 + 39) **G2:** Individual CBT followed by Group CBT (N = 38) **Enrollment:** • 142 consecutive female attenders at unit assessed • 130 diagnosed with BN • 5 excluded because of complicating features • 12 were mixed cases AN (BP type) or EDNOS • 125 BN participants randomized	**Age, yrs, mean (SD):** **G1:** 28.8 (7.8) **G2:** 28.5 (7.2) **Sex:** Female 100% **Race/ethnicity:** NR **BMI, kg/m^2, mean (SD):** **G1:** 24.0 (6.5) **G2:** 26.3 (9.3) (*P* = NS) **Duration of illness, yrs, mean (SD):** **G1:** 10.8 (8.4) **G2:** 11.4 (6.4) **Previous tx, %:** **G1:** 62% **G2:** 62%

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Dx of BN according to DSM IV **Exclusion:** Complicating features like diabetes mellitus; mixed cases of AN of binge purge subtype or EDNOS.	All interventions were manual based. MET was based on the manual, "Clinician's guide to getting better bit (e) by bit (e) (Schmidt and Treasure, 1997) while patients followed the workbook for this guide. For CBT, therapists followed the first four chapters of "Bulimia Nervosa: A guide to recovery" (Cooper, 1993) and patients were given monitoring sheets, meal planning, activity lists and problem solving activities. Tx in 3 phases –initial 4-wk phase of individual tx followed by 8 wks of either group or individual care and the last phase of moly FUs. The three forms of tx: 1) 4 wks of MET followed by 8 wks of group CBT 2) 4 wks of individual CBT followed by group CBT for 8 wks 3) 4 wks of MET followed by 8 wks of individual MET The two groups in which MET was first were combined to form G1.	Continuous data analyzed using t-tests, ANOVA or stepwise regression analyses. Dichotomous data were cross-tabulated. Repeated measures ANOVA's used to examine symptom diffs between wk 0 and wk 4 with tx group and pre-tx stage as between-group factors.	**Score:** Poor **Intent to treat:** NR **Blinding:** Participants blinded to stage of change that they fell into. **Adverse events:** NR **Funding:** NR

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Treasure et al., 1999 (continued)	**Binge frequency, mean (SD):** **G1:** 5.0 (1.2) **G2:** 4.9 (1.1) *(P* = NS)	**Binge frequency, mean (SD):** **G1:** NR **G2:** NR Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
	Vomiting frequency, mean (SD): **G1:** 4.2 (1.9) **G2:** 4.4 (1.9) *(P* = NS)	**Vomiting frequency, mean (SD):** **G1:** NR **G2:** NR Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
	Laxative use, mean (SD): **G1:** 2.3 (1.9) **G2:** 1.9 (1.7) *(P* = NS)	**Laxative abuse, mean (SD):** **G1:** NR **G2:** NR Diff between groups *(P* = NS) Diff over time *(P* < 0.005) Diff between groups in change over time *(P* = NR) **Clinically sig improvement at 4 wks:** **Binge eating:** **G1:** 53% **G2:** 68% Diff between groups *(P* = NS)
	Symptoms by initial stage at wk 1: **Binge frequency, mean (SD):** **Contemplation:** **G1:** 4.7 (1.3) **G2:** 4.8 (1.2) *(P* = NR) **Action:** **G1:** 5.0 (1.4) **G2:** 5.6 (0.9) *(P* = NR)	**Symptoms by initial stage:** **Binge frequency, mean (SD):** **Contemplation:** **G1:** 3.8 (1.2) *(P* = NR) **G2:** 3.2 (1.3) *(P* = NR) **Action:** **G1:** 5.0 (1.4) *(P* = NR) **G2:** 5.6 (0.9) *(P* = NR) Diff between groups *(P* = NS) Diff between stages *(P* < 0.05) Diff between groups in change over time *(P* = NS) Diff between stages in change over time *(P* = NR)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
NR	NR	NR	NR

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Treasure et al., 1999 (continued)	**Vomiting frequency, mean (SD):** **Contemplation:** **G1:** 3.9 (1.8) **G2:** 4.6 (2.0) *(P* = NR)	**Clinically sig improvement at 4 wks:** **Vomiting:** **G1:** 58% **G2:** 46% Diff between groups *(P* = NS)
	Action: **G1:** 3.5 (3.5) **G2:** 5.0 (2.2) *(P* = NR)	**Vomiting frequency, mean (SD):** **Contemplation:** **G1:** 2.8 (1.6) *(P* = NR) **G2:** 3.1 (1.5) *(P* = NR)
		Action: **G1:** 2.0 (1.4) *(P* = NR) **G2:** 3.6 (1.7) *(P* = NR) Diff between groups *(P* = NS) Diff between stages *(P* = NS) Diff between groups in change over time *(P* = NR) Diff between stages in change over time *(P* = NR)
	Laxative abuse, mean (SD): **Contemplation:** **G1:** 2.3 (1.7) **G2:** 2.0 (1.8) *(P* = NR)	**Clinically sig improvement at 4 wks:** **Laxative use:** **G1:** 27% **G2:** 13% Diff between groups *(P* = NS)
	Action: **G1:** 2.5 (2.1) **G2:** 1.6 (1.3) *(P* = NR)	**Laxative abuse, mean (SD):** **Contemplation:** **G1:** 1.4 (1.1) *(P* = NR) **G2:** 1.7 (1.7) *(P* = NR)
		Action: **G1:** 0.0 (0.0) *(P* = NR) **G2:** 0.0 (0.0) *(P* = NR) Diff between groups *(P* = NS) Diff between stages *(P* = NS) Diff between groups in change over time *(P* = NS) Diff between stages in change over time *(P* = NR)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Ventura and Bauer, 1999 **Setting:** Private practice outpatient unit, Verona, Italy **Enrollment period:** February to July, 1996	**Research objective:** To examine nutritional rehabilitation-enhanced CBT focused on psychobiological reorganization of eating behaviors as compared to traditional CBT tx focused on the prescription of regular eating patterns in individuals with BN.	**Groups:** **G1:** PNR (N = 20) **G2:** TNR (N = 20) **Enrollment (**N = 24): **Completed:** • 6-mo tx (N = 20) • 9-mo FU **G1** = 19 **G2** = 15 • 12-mo FU **G1** = 17 **G2** = 14	**Age, yrs, mean (SD):** **G1:** 24.1 (6.0) **G2:** 24.0 (5.6) **Sex:** Female: 100% **Race/ethnicity:** NR **BMI, kg/m², mean (SD):** **G1:** 21 (1.6) **G2:** 20.6 (1.5) **Duration of illness, yrs, mean (SD):** **G1:** 8.6 (4.9) **G2:** 6.5 (4.6)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: DSM IV criteria for BN-purging type **Exclusion:** Failure to complete food diary (more than 5 days/mo or 2 wk-ends missing); requirement of hospitalization or refusal to participate	After 4 wk assessment, 6 mo study duration; TNR was prescribed a regular eating pattern; PNR involved learning to control appetite and wt based on understanding psychobiological cues. In both groups, food diary used to record patterns of eating behavior, frequency of bingeing and/or vomiting; laxative misuse, excess exercise, carbohydrate and lipid intake; In G1, degree and duration of hunger, satiety, and differential satiety of macronutrients also recorded. In 1st mo, diaries were discussed 1/wk, then bi-moly for the duration of the study. BMI, heart rate and blood pressure also taken at each visit.	Between and within group diffs evaluated using a two-way ANOVA corrected for repeated measures.	**Score:** Poor **Intent to treat:** NR **Blinding:** NA **Adverse events:** NR **Funding:** NR

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Ventura and Bauer, 1999 (continued)	Data provided through graphic display only**	
	Binge frequency (episodes/day), mean: **G1:** ** **G2:** ** *(P* = NS)	**Binge frequency (episodes/day), mean:** **Post-tx:** **G1:** ** *(P* = NR) **G2:** ** *(P* = NR) Diff between groups *(P* = 0.001) G1 better than G2 Diff between groups in change over time *(P* = NR) **3-mo FU:** **G1:** ** *(P* = NR) **G2:** ** *(P* = NR) Diff between groups *(P* = 0.001) G1 better than G2 Diff between groups in change over time *(P* = NR) **6-mo FU:** **G1:** ** *(P* = NR) **G2:** ** *(P* = NR) Diff between groups *(P* = 0.001) G1 better than G2 Diff between groups in change over time *(P* = NR)
	Vomiting frequency (episodes/day), mean (SD): **G1:** ** **G2:** ** *(P* = NS)	**Vomiting frequency (episodes/day), mean (SD):** **Post-tx:** **G1:** ** *(P* = NR) **G2:** ** *(P* = NR) Diff between groups *(P* = 0.001) G1 better than G2 Diff between groups in change over time *(P* = NR) **3-mo FU:** **G1:** ** *(P* = NR) **G2:** ** *(P* = NR) Diff between groups *(P* = 0.001) G1 better than G2 Diff between groups in change over time *(P* = NR) **6-mo FU:** **G1:** ** *(P* = NR) **G2:** ** *(P* = NR) Diff between groups *(P* = 0.001) Diff between groups in change over time *(P* = NR) **Abstinence from purging at post-tx, N (%):** **G1:** 18/20 (90%) **G2:** 2/20 (10%) *(P* = NR)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
NR	NR	NR	NR

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Ventura and Bauer, 1999 (continued)	Data provided through graphic display only**	
	Carbohydrate Intake (servings/day), mean: **G1:** ** **G2:** ** *(P* = NS)	**Post-tx:** **Carbohydrate Intake (servings/day), mean:** **G1:** ** *(P* = NR) **G2:** ** *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.001) G1 higher than G2 **9-mo FU:** **Carbohydrate Intake (servings/day), mean:** **G1:** ** *(P* = NR) **G2:** ** *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **12-mo FU:** **Carbohydrate Intake (servings/day), mean:** **G1:** ** *(P* = NR) **G2:** ** *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	Lipid intake (olive oil servings/day), mean: **G1:** ** **G2:** ** *(P* = NR)	**Post-tx:** **Lipid intake (servings/day), mean:** **G1:** ** *(P* = NR) **G2:** ** *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.001) G1 higher than G2 **9-mo FU:** **Lipid intake (servings/day), mean:** **G1:** ** *(P* = NR) **G2:** ** *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.001) G1 higher than G2 **12-mo FU:** **Lipid intake (servings/day), mean:** **G1:** ** *(P* = NR) **G2:** ** *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.001) G1 higher than G2 No diffs reported between G1 and G2 regarding number of meals ingested

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Wilfley et al. 1993 **Setting:** Outpatient; Stanford University School of Medicine, USA **Enrollment period:** NR	**Research objective:** To assess the efficacy of group CBT and group IPT for binge eating in women with nonpurging BN.	**Groups:** **G1:** group CBT (N = 18) **G2:** group IPT (N = 18) **G3:** waitlist control (N = 20) **Enrollment:** • 100 recruited via newspaper ads and screened • 56 met criteria and participated • 8 (22%) dropped out; attrition rates: **G1:** 33%, **G2:** 11% *(P* = NS)	**Age, yrs, mean (SD) (range):** 44.3 (8.3) (27-64) **Sex:** Female: 100% **Race/ethnicity:** White: 86% AA: 5% Hispanic: 5% Pacific Islander: 2% Indian: 2% **Age of onset of bingeing, yrs, mean (SD) (range):** 20.4 (12.4) (3-44) **Duration of binge eating, yrs, mean (SD) (range):** 23.7 (13.4) (2-53) **BMI, kg/m², mean (SD) (range):** 32.8 (5.2) (22.3-43.8) **Civil Status:** Never married: 10.7% Married: 58.9% Divorced: 28.6% Separated: 1.8% **Education/Employment:** College grad: 38% Some college: 50% HS grad or less: 12% Employed: 73%

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Female; aged 18-65; met modified DSM III-R criteria for BN, including full requirements for binge behavior without purging behavior **Exclusion:** Current of past hx of self-induced vomiting, laxative use or other purging behaviors; current use of antidepressants or appetite suppressants; concurrent tx for wt loss; concurrent DSM III-R dx or unipolar or bipolar affective disorder, psychosis, drug abuse, or alcoholism.	Participants randomly assigned to group CBT, IPT or waitlist condition; G1 and G2 attended wkly 90 minutes group sessions for 16 wks; groups consisted of 9 members and 2 therapists, with 2 groups per tx condition. CBT tx used Telch et al. (1990) manual and focused on eliminating BE, not wt reduction; IPT tx used Fairburn et al. (1991) manual for BN and focused on interpersonal relationships. Waitlist had no contact with assessors during the 16 wk tx period. Including the 7-day calendar, binge eating recall method, the BDI, and Three Factor Eating Questionnaire, assessments were taken for all participants at baseline and 16 wk post-tx; participants in tx conditions were also assessed at 6 mo and 1yr FU	At baseline and 16 wk post-tx, days of binge eating/wk, hunger, restraint, depression, interpersonal problems were assessed using repeated measures ANOVA. When sig interactions found, two-tailed Scheffe tests were used. When categorical measures compared, Chi-square test used. To assess change in binge behavior from baseline to 1 yr FU, paired t tests used.	**Score:** Fair **Intent to treat:** Yes **Blinding:** NA **Adverse events:** 2 dropped out of tx due to illness **Funding:** NIMH

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Wilfley et al. 1993 (continued)	**Days binged in past wk, mean (SD):** **G1:** 4.2 (1.5) **G2:** 4.7 (1.8) **G3:** 4.4 (1.8) *(P* = NS)	**Intent to treat analysis** **Post-tx:** **Days binged in past wk, mean (SD):** **G1:** 2.2 (2.4) *(P* = NR) **G2:** 1.4 (1.7) *(P* = NR) **G3:** 3.9 (1.7) *(P* = NR) Diff over time *(P* < 0.0001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.0003) G1 and G2 better than G3 *(P* = NR) G1 vs. G2 *(P* = NS) **Reduction of bingeing:** **G1:** 48% **G2:** 71% **G3:** 10% **% Abstinent:** **G1:** 28% **G2:** 44% **G3:** 0%
	TFEQ-Disinhibition, mean (SD): **G1:** 14.1 (1.8) **G2:** 14.2 (1.2) **G3:** 15.0 (0.94) *(P* = NR)	**TFEQ-Disinhibition, mean (SD):** **G1:** 13.1 (2.4) *(P* = NR) **G2:** 12.4 (2.8) *(P* = NR) **G3:** 14.9 (1.0) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.02) G1 vs. G3 *(P* < 0.02) G1 better than G3 G2 vs. G3 *(P* < 0.01) G2 better than G3 G1 vs. G2 *(P* = NS)
	TFEQ-Hunger, mean (SD): **G1:** 10.2 (2.0) **G2:** 10.5 (2.8) **G3:** 9.9 (3.3) *(P* = NR)	**TFEQ-Hunger, mean (SD):** **G1:** 9.2 (2.8) *(P* = NR) **G2:** 7.8 (4.8) *(P* = NR) **G3:** 9.2 (3.4) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BDI, mean (SD): **G1:** 13.6 (8.1) **G2:** 13.0 (7.5) **G3:** 14.6 (7.5) *(P* = NR)	**BDI, mean (SD):** **G1:** 12.3 (6.8) *(P* = NR) **G2:** 8.4 (6.7) *(P* = NR) **G3:** 14.2 (7.5) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)	**Wt, kg, mean (SD) (range):** 87.3 (14.2) (60-117.5)	**Change in wt, kg, mean:** **Post-tx:** +2.0 kg **G1:** NR **G2:** NR **G3:** NR Diff over time *(P* < 0.0007) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)
RSE, mean (SD): **G1:** 3.1 (1.7) **G2:** 3.3 (1.5) **G3:** 2.8 (1.2) *(P* = NR)	**RSE, mean (SD):** **G1:** 2.8 (1.4) *(P* = NR) **G2:** 2.4 (1.3) *(P* = NR) **G3:** 3.0 (1.5) *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)		**FU:** **G1:** no change **G2:** - 3kg **G3:** NR Diff over time *(P* < 0.03) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
Inventory of Interpersonal Problems, mean (SD): **G1:** 1.6 (0.5) **G2:** 1.7 (0.7) **G3:** 1.4 (0.5) *(P* = NR)	**Inventory of Interpersonal Problems, mean (SD):** **G1:** 1.4 (0.5) *(P* = NR) **G2:** 1.2 (0.6) *(P* = NR) **G3:** 1.2 (0.6) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)		

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Wilfley et al. 1993 (continued)	**TFEQ-Restraint, mean (SD):** **G1:** 7.3 (3.8) **G2:** 7.3 (3.2) **G3:** 8.2 (3.4) *(P* = NR)	**TFEQ-Restraint, mean (SD):** **G1:** 9.3 (3.6) *(P* = NR) **G2:** 11.0 (5.6) *(P* = NR) **G3:** 8.6 (3.7) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = 0.03) G2 vs. G3 *(P* = 0.02) G2 better than G3 G1 vs. G2 *(P* = NS) **FU:** **Change in binge frequency (days in past wk) from baseline, mean (SD):** **G1:** -2.4 *(P* < 0.003) **G2:** -2.0 *(P* < 0.001) **G3:** NR Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) Binge frequency from 16wk post-tx to 1yr FU increased in both groups *(P* < 0.05)
		Completers-only (G1: N = 10; G2: N = 13) **Post-tx:** **Binge reduction, %:** **G1:** 64% **G2:** 68% **G3:** 11% **FU:** **Binge reduction, %:** **G1:** 55% **G2:** 50% **G3:** NR **Change in binge frequency (days in past wk), mean (SD):** **G1:** -2.1 *(P* < 0.04) **G2:** -2.4 *(P* < 0.02) **G3:** NR Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) Binge frequency from 16wk post-tx to 1yr FU increased in both groups *(P* < 0.005)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Wolk and Devlin, 2001 **Companion article:** Agras et al., 2000 **Setting:** ED Unit, New York State Psychiatric Institute at Columbia Medical Center, NY, NY, USA **Enrollment period:** NR	**Research objective:** To test the hypothesis that the stage of change is a useful predictor of dropout and related to tx outcome in individuals in brief psychotherapy for BN.	**Groups (N = 110):** **G1:** CBT **G2:** IPT Sample from one site in Agras, Walsh et al. (2000) multicenter study **Enrollment:** • 129 screened • 110 randomized • 66 completed tx (G1 = 32, G2 = 34; full BN remission = 14; subthreshold BN = 34; full BN = 18)	**Age, yrs, mean (SD):** **G1:** 28.3 (7.0) **G2:** 27.9 (7.5) (*P* = NS) **Sex:** Female: NR **Race/ethnicity N (%):** **White:** **G1:** 87 (79) **G2:** 81 (74) (*P* = NR) **Hispanic:** **G1:** 11 (10) **G2:** 14 (13) (*P* = NR) **African American:** **G1:** 7 (6) **G2:** 7 (6) (*P* = NR) **Asian:** **G1:** 4 (4) **G2:** 7 (6) (*P* = NR) **American Indian:** **G1:** 1 (1) **G2:** 0 (0) (*P* = NR)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: DSM III-R criteria for BN, dx using SCID **Exclusion:** Severe physical or psychiatric condition that would interfere with tx; current AN; current psychotherapeutic tx of any type; all psychotropic meds; pregnancy; having received an adequate trial of CBT or IBT for BN prior to study	19 sessions of CBT or IPT; CBT focused on shape, wt, and eating behaviors, IPT focused on non-eating/wt-related personal issues; tx was conducted by doctoral level psychologist or psychiatrist. Prior to tx, Stage of Change scale used to predict outcome among randomized participants. Readiness to change assessed using an algorithm of the relationship between stages of change and tx response	Associations between stages of change at baseline and categorical measures of outcome examined using chi-square tests.	**Score:** Good **Intent to treat:** No **Blinding:** NA **Adverse events:** 9 withdrawn from tx, 8 of which received meds: 7 for severe depression, 1 for an acute onset of panic disorder **Funding:** NR

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Wolk and Devlin, 2001 (continued)		**Completer Analysis (N = 66):** **Stage of change as a predictor of outcome (remittance):** X^2 = 12.29 (*P* = 0.02), 0/10 “precontemplators” remitted at end of tx **Stage of change as a predictor of improvement (undefined):** **G1:** X^2 = 3.09 (*P* = NS) **G2:** X^2 = 12.11 (*P* = 0.02)

Evidence Table 7. Behavioral intervention trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
NR	NR	NR	NR

Evidence Table 8. Self-help trials for bulimia nervosa

Study Description	Objective	Design	Patient Characteristics
Author, yr: Bailer et al., 2004 **Setting:** Outpatient ED clinic, Department of General Psychiatry, University Hospital of Psychiatry, Vienna, Austria **Enrollment period:** NR	**Research objective:** To evaluate the short and long-term efficacy of an 18 wk guided self-help program versus group CBT in the tx of patients with BN.	**Groups:** **G1:** Self-help (N = 40) **G2:** CBT (N = 41) **Enrollment:** • 87 recruited via therapist or self-referral to ED clinic • 81 randomized (6 refused to participated for reasons NR) • **G1:** 30 (75%) completed tx; 25 (62.5%) completed 1 yr FU • **G2:** 26 (63.4%) completed tx; 30 (73.1%), including 5 drop-outs, completed FU • Overall dropout rate: 30.8%; Drop out rate between groups was not sig: G1: 25%; G2: 36.6%.	**Age, yrs, mean (SD):** **G1:** 23.3 (4.1) **G2:** 24.2 (4.9) *(P* = NS) **Age at onset, yrs, mean (SD):** **G1:** 17.3 (2.3) **G2:** 17.7 (3.2) *(P* = NS) **Sex:** Female: NR **Race/ethnicity:** NR **BMI, kg/m^2, mean (SD):** **G1:** 21.7 (3.1) **G2:** 20.7 (2.4) *(P* = NS) **Nonpurger, N (%):** **G1:** 5 (12.5) **G2:** 4 (9.7) *(P* = NS) **Meds, SSRIs, N (%):** **G1:** 6 (15) **G2:** 14 (34.1) *(P* = 0.046) **Lifetime AN, N (%):** **G1:** 9 (22.5) **G2:** 17 (41.4) *(P* = NS) **Lifetime major depression, N (%):** **G1:** 12 (30) **G2:** 24 (58.5) *(P* = 0.009) **Current major depression, N (%):** **G1:** 2 (5) **G2:** 11 (26.8) *(P* = 0.008) **Self-mutilation, N (%):** **G1:** 15 (37.5) **G2:** 10 (24.3) *(P* = NS) **Suicide attempts, N (%):** **G1:** 2 (5) **G2:** 9 (21.9) *(P* = 0.026)

Evidence Table 8. Self-help trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Age 17 and above; DSM IV criteria for BN **Exclusion:** Medically unstable or of severe suicide risk; unstable dosage of meds for BN over 3 mos prior to study	Upon enrollment, individuals randomized to G1 or G2; G1: self-help manual, self-paced over 18 wks, and offered 18, 20 minutes wkly visits, as needed; G2: 18 wkly, 90 minute sessions with 8-12 participants using a CBT manual (based on Fairburn, 1985, and Agras, 1987) for BN; attendance at 50% (9 sessions) defined tx completion. BN behavior self-monitored with EB-IV; EDQ, EDI, BDI, ht, wt, and vital signs, assessed at baseline, mid-tx (10 wks), and tx-end (18wks), and 1 yr FU.	One-way ANCOVAs compared the two tx at all timepoints); when post-tx data missing, pre-tx values substituted; mixed-effects linear regression analyses performed to compare changes in outcome over time by tx condition, controlling for baseline values.	**Score:** Fair **Intent to treat:** Yes, for primary analysis **Blinding:** No **Adverse events:** Except for 2 patients who moved, all other drop-outs either openly refused to participate (reasons: NR), or cancelled appts. **Funding:** Grant from the Osterreichische Nationalbank (Jubilaumsfonds Grant 6360)

Evidence Table 8. Self-help trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Bailer et al., 2004	Results from the primary, intent-to-treat analysis (N = 81), unless specified.	Mid-tx, Post-tx, FU (N = 55)
(continued)	**Binge Frequency, 4 wks, mean (SD):** **G1:** 26.15 (21.51) **G2:** 27.95 (29.66) *(P* = NR)	**Binge Frequency, 4 wks, mean (SD):** **Mid-tx:** **G1:** 12.74 (12.90) **G2:** 14.10 (16.03) *(P* = NR) **Post-tx:** **G1:** 7.67 (9.06) *(P* = NR) **G2:** 16.31 (23.65) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **1-yr FU:** **G1:** 7.54 (13.15) *(P* = NR) **G2:** 13.11 (21.76) *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	Vomiting frequency (N = 64), 4 wks, mean (SD): **G1:** 21.2 (22.8) **G2:** 30.4 (32.8) *(P* = NR)	**Vomiting frequency, 4 wks, mean (SD):** **Mid-tx:** **G1:** 9.78 (13.04) *(P* = NR) **G2:** 14.76 (18.59) *(P* = NR) **Post-tx:** **G1:** 6.00 (7.07) *(P* = NR) **G2:** 15.50 (23.99) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **1-yr FU (N = 55):** **G1:** 4.62 (13.15) *(P* = NR) **G2:** 11.89 (22.24) *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = 0.04) G1 better than G2 Diff between groups in change over time *(P* = NS)

Evidence Table 8. Self-help trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BDI, mean (SD): **G1:** 15.55 (9.98) **G2:** 17.75 (11.41) *(P* = NR)	**BDI, mean (SD):** **Mid-tx:** **G1:** 9.61 (9.59) *(P* = NR) **G2:** 13.64 (11.29) *(P* = NR) **Post-tx:** **G1:** 8.27 (8.33) *(P* = NR) **G2:** 13.83 (11.48) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **1yr FU:** **G1:** 7.61 (6.30) *(P* = NR) **G2:** 11.70 (12.99) *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = 0.05) G1 better than G2 Diff between groups in change over time *(P* = NS)	**BMI, mean (SD):** **G1:** 21.68 (3.15) **G2:** 20.69 (2.44) *(P* = NR)	**BMI, mean (SD):** **Mid-tx:** **G1:** 21.61 (2.25) *(P* = NR) **G2:** 20.94 (2.04) *(P* = NR) **Post-tx:** **G1:** 21.73 (2.28) *(P* = NR) **G2:** 20.74 (2.23) *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **1yr FU:** **G1:** 22.00 (2.25) *(P* = NR) **G2:** 20.45 (2.94) *(P* = NR) Diff over time *(P* = NS) Diff between groups (*P* = 0.02) G2 better than G1 Diff between groups in change over time *(P* = NS)

Evidence Table 8. Self-help trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Bailer et al., 2004 (continued)	**Laxative use, mean (SD):** **G1:** 5.08 (14.86) **G2:** 4.03 (8.08) *(P* = NR)	**Laxative use, mean (SD):** **Mid-tx:** **G1:** 0.19 (0.68) *(P* = NR) **G2:** 3.33 (7.47) *(P* = NR) **Post-tx:** **G1:** 0.33 (1.47) *(P* = NR) **G2:** 3.73 (8.75) *(P* = NR) Diff over time *(P* = 0.017) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **1yr FU:** **G1:** 0.08 (0.28) *(P* = NR) **G2:** 4.59 (10.15) *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = 0.025) G1 better than G2 Diff between groups in change over time *(P* = NS)
	EDI-DT, mean (SD): **G1:** 14.0 (5.9) *(P* = NR) **G2:** 14.43 (5.16) *(P* = NR	**EDI-DT, mean (SD):** **Mid-tx:** **G1:** 8.39 (6.73) *(P* = NR) **G2:** 10.00 (6.81) *(P* = NR) **Post-tx:** **G1:** 7.67 (6.53) *(P* = NR) **G2:** 10.87 (6.69) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **1yr FU:** **G1:** 6.59 (5.97) *(P* = NR) **G2:** 5.21 (5.64) *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = 0.009) G2 better than G1
	EDI-B, mean (SD): **G1:** 10.38 (5.29) **G2:** 10.25 (5.51) *(P* = NR)	**EDI-B, mean (SD):** **Mid-tx:** **G1:** 4.32 (4.45) *(P* = NR) **G2:** 5.50 (4.86) *(P* = NR) **Post-tx:** **G1:** 3.10 (4.34) *(P* = NR) **G2:** 6.57 (5.32) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = 0.01) G1 better than G2 **1yr FU (N = 55):** **G1:** 3.32 (5.18) *(P* = NR) **G2:** 4.50 (5.06) *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = 0.018) G1 better than G2 Diff between groups in change over time *(P* = NS)

Evidence Table 8. Self-help trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 8. Self-help trials for bulimia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Bailer et al., 2004 (continued)	**EDI-BD, mean (SD):** **G1:** 15.55 (8.47) **G2:** 15.45 (7.60) *(P* = NR)	**EDI-BD, mean (SD):** **Mid-tx:** **G1:** 10.96 (8.92) *(P* = NR) **G2:** 14.68 (9.34) *(P* = NR) **Post-tx:** **G1:** 9.97 (7.45) *(P* = NR) **G2:** 14.87 (8.07) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **1yr FU:** **G1:** 10.18 (8.66) *(P* = NR) **G2:** 9.29 (9.42) *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	Meal Frequency, 4 wks, mean (SD): **G1:** 77.44 (43.57) **G2:** 59.49 (29.56) *(P* = NR)	**Meal Frequency, mean (SD):** **Mid-tx:** **G1:** 80.65 (47.41) *(P* = NR) **G2:** 68.84 (33.53) *(P* = NR) **Post-tx:** **G1:** 72.76 (44.15) *(P* = NR) **G2:** 68.28 (26.13) *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = 0.048) G1 greater than G2 Diff between groups in change over time *(P* = NS) **1yr FU:** **G1:** 62.36 (29.85) *(P* = NR) **G2:** 52.37 (28.89) *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
		"Recovered", no binge or purge behavior for prior mo, N (%): **Post-tx:** **G1:** 3 (7.5) **G2:** 5 (12.2) **1 yr FU:** **G1:** 9 (22.5) **G2:** 6 (14.6)
		"Remitted", binge or purge episodes < 2x/wk in prior mo, N (%): **Post-tx:** **G1:** 16 (40) **G2:** 12 (29.3) **1 yr FU:** **G1:** 20 (50) **G2:** 15 (36.6)

Evidence Table 8. Self-help trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 8. Self-help trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Carter, Olmsted, et al., 2003 **Setting:** Individuals on a waiting list for tx at a hospital-based specialty outpatient clinic, Toronto, Canada **Enrollment period:** NR	**Research objective:** To examine the efficacy of a CBT self-help manual for tx of BN, and compare it to an "attention placebo-control" condition (i.e., non-specific self-help manual) to control for nonspecific factors. A secondary aim was to identify predictors of outcome.	**Groups enrolled (N = 85):** **G1:** CBT-based self-help (N = 28) **G2:** Non-specific self-help (N = 28) **G3:** Waitlist (N = 29) **Enrollment:** Potential subjects referred Phone screen: 245 Invited for assessment interview: 123 Completed assessment: 89 **Randomized** (N = 85) **Drop-outs, N (%):** **G1:** 5 (17.9%) **G2:** 7 (25%) **G3:** 8 (27.6%) *(P* = NS) **Completers, N:** **G1:** 23 **G2:** 21 **G3:** 21	**Age, yrs, mean (SD), range:** 27 (8), 17-53 **Sex:** Female, 100% **Race/ethnicity, %:** White: 83% Black: 25% Asian: 7% Other: 8% **Marital status, %:** Single: 71% Partnered: 22% Divorced: 6% Widowed: 1% **BMI, kg/m^2, mean (SD), range:** 23.0 (5.0), 18-41 **BN Subtype:** 93% purging **BN Onset, yrs, mean (SD), range:** 19 (6), 10-38 **BN Duration, yrs, mean (SD), range:** 7 (6), 0.5-33 **Objective Binge Episodes, past 4 wks, mean (SD, range:** 28 (23), 4-112 **Objective Purge Episodes, past 4 wks, mean (SD), range:** 41 (35), 0-112

Evidence Table 8. Self-help trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: EDE criteria for BN, met modified DSM IV binge/purge frequency criteria (1x/wk), seeking specialized tx for first time **Exclusion:** Age < 17 yrs, pregnant, medical illness known to influence wt, current or prior specialist tx for ED, BMI < 18 kg/m^2	Pre-tx assessment using subscales of EDE and EDI, wt, ht, BDI, BAI, RSE, Inventory of Interpersonal Problems, Dimensional Assessment of Personality Pathology **Randomization and Instructions** **G1:** 2-mo manualized CBT-based self-help program using 'Overcoming Binge Eating' (Fairburn, 1995). **G2:** 2-mo manualized assertiveness skill-based self-help program using 'Self-Assertion for Women' (Butler, 1992). **G3:** waitlist Post-assessment (as above) + compliance measure	ITT: 2 (Pre-and post-) x 3 (CBT vs. non-specific vs. waitlist) repeated measures ANOVA using pre-tx values carried forward for missing post-tx data. Paired t-test, 1-way ANOVA, and between-group t-test post-hoc comparisons. Chi Square tests to compared proportions of responders.	**Score:** Fair **Intent to treat:** Yes **Blinding:** No **Adverse events:** none **Funding:** Dean's fund, Department of Medicine, University of Toronto

Evidence Table 8. Self-help trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Carter, Olmsted, et al., 2003 (continued)	**Objective binge frequency, past 4 wks, median:** **G1:** 24.5 **G2:** 18.5 **G3:** 28.0 *(P* = NR)	**Objective binge frequency, past 4 wks, median:** **G1:** 10 *(P* = 0.006) **G2:** 11.5 *(P* = 0.008) **G3:** 27.0 *(P* = NS) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	Objective Purge frequency, past 4 wks, median: **G1:** 26.0 **G2:** 27.5 **G3:** 46.5 *(P* = NR) G1, G2 lower than G3	**Objective purge frequency, past 4 wks, median:** **G1:** median = 22.5 *(P* = 0.04) **G2:** median = 16.5 *(P* = 0.005) **G3:** median = 32.0 *(P* = NS) Diff over time *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
	EDE Restraint, mean (SD): **G1:** 4.1 (1.3) **G2:** 3.7 (1.4) **G3:** 3.8 (1.7) *(P* = NR)	**EDE Restraint, mean (SD):** **G1:** 3.9 (1.5) *(P* = NR) **G2:** 3.6 (1.6) *(P* = NR) **G3:** 3.7 (1.5) *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)
	EDE Eating concern, mean (SD): **G1:** 4.5 (1.1) **G2:** 4.2 (1.3) **G3:** 4.1 (1.4) *(P* = NR)	**EDE Eating concern, mean (SD):** **G1:** 4.3 (1.0) *(P* = NR) **G2:** 3.8 (1.2) *(P* = NR) **G3:** 3.8 (1.3) *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)
	EDE Shape concern, mean (SD): **G1:** 5.2 (1.1) **G2:** 4.8 (1.3) **G3:** 4.7 (1.3) *(P* = NR)	**EDE Shape concern, mean (SD):** **G1:** 5.0 (1.2) *(P* = NR) **G2:** 4.5 (1.3) *(P* = NR) **G3:** 4.6 (1.3) *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)
	EDE Wt concern, mean (SD): **G1:** 4.9 (1.2) **G2:** 4.3 (1.4) **G3:** 3.9 (1.6) *(P* = NR)	**EDE Wt concern, mean (SD):** **G1:** 4.6 (1.2) *(P* = NR) **G2:** 4.0 (1.3) *(P* = NR) **G3:** 4.0 (1.4) *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)

Evidence Table 8. Self-help trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BDI, mean (SD): **G1:** 26.5 (11.4) **G2:** 24.4 (10.5) **G3:** 22.3 (10.0) *(P* = NR)	**BDI, mean (SD):** **G1:** 26.9 (10.5) *(P* = NR) **G2:** 21.2 (11.1) *(P* = NR) **G3:** 20.9 (14.3) *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)		**Decrease in Intense Exercise:** **G1 *(P*** = 0.01) **G2 *(P*** = NS) **G3 *(P*** = NS) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.04) G1 better than G2, G3
BAI, mean (SD): **G1:** 24.4 (12.0) **G2:** 23.4 (12.8) **G3:** 21.5 (9.6) *(P* = NR)	**BAI, mean (SD):** **G1:** 25.4 (12.3) *(P* = NR) **G2:** 21.5 (12.8) *(P* = NR) **G3:** 19.6 (10.9) *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)		
Inventory of Interpersonal Problems, mean (SD): **G1:** 1.9 (0.6) **G2:** 1.9 (0.5) **G3:** 1.8 (0.6) *(P* = NR)	**Inventory of Interpersonal Problems, mean (SD):** **G1:** 2.0 (0.7) *(P* = NR) **G2:** 1.6 (0.6) *(P* = NR) **G3:** 1.9 (0.6) *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)		
Knowledge of cognitive-behavioral psycho-educational content of tx manual, mean (SD): **G1:** 7.4 (2.7) **G2:** 8.3 (2.6) **G3:** 7.6 (2.9) *(P* = NR)	**Knowledge of cognitive-behavior psycho-educational content of tx manual, mean (SD):** **G1:** 7.8 (2.7) *(P* = NR) **G2:** 8.0 (2.7) *(P* = NR) **G3:** 8.1 (2.6) *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)		
Knowledge of non-specific psychoeducational content of tx manual, mean (SD): **G1:** 5.7 (1.8) **G2:** 5.0 (1.7) **G3:** 4.7 (2.1) *(P* = NR)	**Knowledge of non-specific psychoeducational content of tx manual, mean (SD):** **G1:** 5.6 (2.2) *(P* = NR) **G2:** 6.6 (2.2) *(P* = 0.005) **G3:** 5.0 (2.3) *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = 0.02) G2 better than G1, G3		

Evidence Table 8. Self-help trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	Outcomes
Author, yr: Carter, Olmsted, et al., 2003 (continued)		

Evidence Table 8. Self-help trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
	Responders, decrease of at least 50% bingeing or purging, N (%): **G1:** 15 (53.6%) **G2:** 14 (50.0%) **G3:** 9 (31.0%) Diff between groups *(P* = NS) Compared to non-responders, responders had higher perfectionism *(P* = 0.03), higher compulsivity *(P* = 0.04), higher intimacy problems *(P* = 0.02), and lower CBT knowledge *(P* = 0.03)		
	Compliance, amount of manual read, %: **G1:** 78% **G2:** 59% *(P* = NS)		
	Compliance, completed behavioral exercises, %: **G1:** 28.6% **G2:** 21.4% *(P* = NS) Predictors of compliance included lower baseline knowledge about ED *(P* = 0.02), higher intimacy problems *(P* = 0.02), and higher compulsivity *(P* = 0.02).		

Evidence Table 8. Self-help trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Durand and King, 2003 **Setting:** Three outpatient specialist clinics, London, UK **Enrollment period:** January 1995-June 1997	**Research objective:** To assess the efficacy of a general practice-based, self-help tx versus specialist outpatient tx for women with BN.	**Groups:** **G1:** GP-supported self help (N = 34) **G2:** Specialist tx (N = 34) **Enrollment:** 209 referrals 68 (32.5%) randomized **Completed tx, N (%):** **G1:** 34 (100%) **G2:** 26 (76%) **Completed 6-mo FU, N (%):** **G1:** 22 (64.7%) **G2:** 28 (82.4%) **Completed 9-mo FU, N (%):** **G1:** 26 (76.5%) **G2:** 28 (82.4%)	**Age, yrs, mean (SD):** **G1:** 28.3 (6.5) **G2:** 24.5 (5.2) *(P* = NR) **Sex:** Female: 100% **Race/ethnicity:** **White:** **G1:** 29 (85%) **G2:** 30 (88%) *(P* = NR) **Black:** **G1:** 3 (9%) **G2:** 3 (9%) *(P* = NR) **Other:** **G1:** 1 (3%) **G2:** 1 (3%) *(P* = NR) **Missing data:** **G1:** 1 (3%) **G2:** 0 (0%) *(P* = NR) **Duration of Eating Problem, yrs, mean (SD):** **G1:** 7.7 (4.6) **G2:** 5.9 (3.9) *(P* = NR) **Civil Status:** **Single:** **G1:** 24 (71%) **G2:** 24 (71%) *(P* = NR) **Married/cohabitating:** **G1:** 5 (15%) **G2:** 9 (26%) *(P* = NR) **Other:** **G1:** 5 (15%) **G2:** 1 (3%) *(P* = NR)

Evidence Table 8. Self-help trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: General practitioner referral; dx of BN (DSM IV); aged 18 or older; female; English speaking **Exclusion:** Requiring urgent clinic assessment; pregnancy; medical disorder such as diabetes; substance or alcohol misuse problems; suicidal intent	Participants in self-help tx used manual "Bulimia Nervosa: a guide to recovery (Cooper, 1993), and advised to work through it with regular contact with GP, who also received copy of the manual and guidelines for administration. Participants in specialist tx seen by clinical tx team in one of three clinics on wkly or fortnightly basis for as long as deemed appropriate by specialist caregiver. Duration at clinician's discretion.	Repeated-measures MANOVA and MANCOVA conducted on BITE scores for two groups; Individual repeated measures analysis conducted to examine diff between BDI, EDE, and WLFL measures between groups. Power calculations conducted based on BITE.	**Score:** Fair **Intent to treat:** Yes **Blinding:** NA **Adverse events:** NR **Funding:** North Thames Regional Health Authority

Evidence Table 8. Self-help trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Durand and King, 2003 (continued)	**BITE, mean (SD):** **G1:** 34.1 (6.3) **G2:** 33.7 (5.9) *(P* = NR)	**BITE, mean (SD):** **6 mos:** **G1:** 28.9 (11.3) *(P* = NR) **G2:** 28.2 (9.9) *(P* = NR) **9 mos:** **G1:** 26.2 (12.4) *(P* = NR) **G2:** 29.6 (11.4) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	Objective bulimic episodes, past 28 days, mean (SD): **G1:** 19.0 (15.2) **G2:** 20.4 (19.6) *(P* = NR)	**Objective bulimic episodes, past 28 days, mean (SD):** **6 mos:** **G1:** 16.4 (17.4) *(P* = NR) **G2:** 12.6 (14.2) *(P* = NR) **9 mos:** **G1:** 15.0 (17.4) *(P* = NR) **G2:** 14.9 (18.9) *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	Episodes of vomiting, past 28 days, mean (SD): **G1:** 35.1 (31.0) **G2:** 37.8 (33.9) *(P* = NR)	**Episodes of vomiting, past 28 days, mean (SD):** **6 mos:** **G1:** 25.0 (25.6) *(P* = NR) **G2:** 16.5 (18.7) *(P* = NR) **9 mos:** **G1:** 20.3 (27.0) *(P* = NR) **G2:** 20.5 (23.9) *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	EDE-Restraint, mean (SD): **G1:** 3.3 (1.0) **G2:** 3.3 (0.8) *(P* = NR)	**EDE-Restraint, mean (SD):** **6 mos:** **G1:** 2.8 (1.3) *(P* = NR) **G2:** 2.6 (1.4) *(P* = NR) **9 mos:** **G1:** 2.4 (1.4) *(P* = NR) **G2:** 2.8 (1.1) *(P* = NR) Diff over time *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)

Evidence Table 8. Self-help trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BDI, mean (SD): **G1:** 27.7 (9.7) **G2:** 21.4 (10.7) *(P* = NR)	**BDI, mean (SD):** **6 mos:** **G1:** 17.8 (11.7) *(P* = NR) **G2:** 18.1 (10.6) *(P* = NR) **9 mos:** **G1:** 16.2 (9.9) *(P* = NR) **G2:** 15.5 (10.8) *(P* = NR) Diff over time *(P* = 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) A direct relationship between BDI and BITE scores found *(P* = 0.001); as BDI scores decreased over time, so did BITE scores		
Patient-rated severity, mean (SD): **G1:** 7.6 (2.2) **G2:** 7.1 (2.6) *(P* = NR)	**Patient-rated severity, mean (SD):** **6 mos:** **G1:** 6.6 (3.2) *(P* = NR) **G2:** 6.1 (3.0) *(P* = NR) **9 mos:** **G1:** 5.8 (3.1) *(P* = NR) **G2:** 4.8 (2.8) *(P* = NR) Diff over time *(P* = 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)		

Evidence Table 8. Self-help trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Durand and King, 2003 (continued)	**EDE Eating Concern, mean (SD):** **G1:** 2.4 (1.2) **G2:** 2.5 (1.0) *(P* = NR)	**EDE Eating Concern, mean (SD):** **6 mos:** **G1:** 2.0 (1.3) *(P* = NR) **G2:** 2.1 (1.3) *(P* = NR) **9 mos:** **G1:** 1.8 (1.3) *(P* = NR) **G2:** 1.9 (1.2) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)
	EDE Wt concern, mean (SD): **G1:** 3.1 (1.3) **G2:** 3.4 (1.3) *(P* = NR)	**EDE Wt concern, mean (SD):** **6 mos:** **G1:** 2.6 (1.4) *(P* = NR) **G2:** 3.0 (1.2) *(P* = NR) **9 mos:** **G1:** 2.5 (1.5) *(P* = NR) **G2:** 2.9 (1.3) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)
	EDE Shape concern, mean (SD): **G1:** 3.4 (1.2) **G2:** 3.9 (1.1) *(P* = NR)	**EDE Shape concern, mean (SD):** **6 mos:** **G1:** 2.9 (1.3) *(P* = NR) **G2:** 3.3 (1.2) *(P* = NR) **9 mos:** **G1:** 2.9 (1.3) *(P* = NR) **G2:** 3.0 (1.3) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)
	EDE Global score, mean (SD): **G1:** 3.0 (1.0) **G2:** 3.3 (0.8) *(P* = NR)	**EDE Global score, mean (SD):** **6 mos:** **G1:** 2.6 (1.2) *(P* = NR) **G2:** 2.8 (1.0) *(P* = NR) **9 mos:** **G1:** 2.4 (1.2) *(P* = NR) **G2:** 2.6 (1.0) *(P* = NR) Diff over time *(P* = 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)

Evidence Table 8. Self-help trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 8. Self-help trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Thiels et al., 1998 **Setting:** Outpatient, Germany **Enrollment period:** NR	**Research objective:** To evaluate the effectiveness of guided self-change for BN.	**Groups:** **G1:** CBT (16 wkly sessions) **G2:** Guided Self-change (8 fortnightly guided sessions) **Enrollment:** • Enrolled N = 62; 31 each group (alternating basis) • 13 (21%) dropped out during tx phase: **G1:** N = 4 (12.9%) **G2:** N = 9; (29.0%) • 14 (22.6%) of enrolled did not complete FU. No diffs in response to FU by condition.	**Age, yrs, mean (SD):** **G1:** 28.7 (9.1) **G2:** 27.5 (6.9) Diff between groups *(P* = NS) **Sex:** NR **Race/ethnicity:** NR **Duration of BN, yrs, mean (SD):** **G1:** 8.5 (9.2) **G2:** 6.1 (5.6) *(P* = NS) **Age of Onset of BN, yrs, mean (SD):** **G1:** 19.6 (4.7) **G2:** 20.3 (6.3) *(P* = NS) **Previous BN tx, N (%):** **G1:** 15 (48.4) **G2:** 12 (40.0) *(P* = NS) **Previous AN tx, N (%):** **G1:** 7 (22.6) **G2:** 3 (10.0) *(P* = NS) **Previous tx for other psychiatric problems, N (%):** **G1:** 2 (6.5) **G2:** 10 (33.3) *(P* = 0.02) **Present co-morbidity, N:** **Affective Disorders:** **G1:** 0 **G2:** 2 **Substance-use Disorders:** **G1:** 0 **G2:** 0 **Anxiety/OC Disorders:** **G1:** 4 **G2:** 2 **Somatoform Disorders:** **G1:** 2 **G2:** 2 **AN:** **G1:** 0 **G2:** 0 All *(P* = NS)

Evidence Table 8. Self-help trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: DSM III-R criteria BN or if prolonged dx of BN but recently improved and thus not currently meeting criteria. **Exclusion:** NR	**G1:** 16 wkly CBT sessions. **G2:** 16 wks but only 8 fortnightly tx sessions). First 4 sessions - chapters 1-6 of CBT manual; remaining sessions: chose most relevant chapters to focus on. **Both groups:** 50 – 50 minutes sessions.	ANCOVA: if additional tx influenced outcome; T-tests: diffs between tx and for demographics with most conservative F values (lower bound epsilon) and followed by approximate test for nonsign. Results: Yates-corrected chi-square test: categorical data; confidence interval analysis: abstinence rates.	**Score:** Fair **Intent to treat:** Yes **Blinding:** NR **Adverse events:** NR **Funding:** British council (academic research collaboration project 269), the German academic exchange service, and Bielefeld university of applied sciences

Evidence Table 8. Self-help trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Thiels et al., 1998 (continued)	Values presented for the Completer sample (N = 48) first, followed by the Randomized sample (N = 62) (when available)	Both txs led to improvements on all measures through FU (text)
	EDE Overeating, mean (SD): **G1:** 2.95 (0.82) **G2:** 3.02 (1.10) *(P* = NR)	**EDE Overeating:** **Mid-tx:** **G1:** 2.18 (1.07) *(P* = NR) **G2:** 2.44 (1.22) *(P* = NR)
	EDE Overeating, mean (SD): **G1:** 2.99 (0.85) **G2:** 3.00 (1.01) *(P* = NS)	**Post-tx:** **G1:** 1.53 (1.55) *(P* = NR) **G2:** 2.27 (1.21) *(P* = NR) **FU:** **G1:** 1.07 (1.61) *(P* = NR) **G2:** 1.17 (1.23) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	EDE Vomiting: **G1:** 3.79 (1.71) **G2:** 3.65 (1.65) *(P* = NR)	**EDE Vomiting:** **Mid-tx:** **G1:** 2.83 (1.93) *(P* = NR) **G2:** 2.83 (1.81) *(P* = NR)
	EDE Vomiting: **G1:** 3.76 (1.76) **G2:** 3.23 (1.86) *(P* = NS)	**Post-tx:** **G1:** 2.06 (2.30) *(P* = NR) **G2:** 2.57 (1.84) *(P* = NR) **FU:** **G1:** 1.38 (2.00) *(P* = NR) **G2:** 1.59 (1.82) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	EDE Shape Concern, mean (SD): **G1:** 2.98 (1.47) **G2:** 3.30 (1.82) *(P* = NR)	**EDE Shape Concern, mean (SD):** **Mid-tx:** **G1:** 2.94 (1.30) *(P* = NR) **G2:** 2.78 (1.55) *(P* = NR) **Post-tx:** **G1:** 2.37 (1.34) *(P* = NR) **G2:** 2.50 (1.53) *(P* = NR) **FU:** **G1:** 2.32 (1.68) *(P* = NR) **G2:** 1.68 (1.43) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)

Evidence Table 8. Self-help trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
		BMI, kg/m^2, mean (SD): Total sample: 21.95 (3.56) **G1:** 21.31 (3.11) **G2:** 22.57 (3.89) *(P* = NS)	**BMI at FU, kg/m^2, mean (SD):** Total sample: 21.93 (3.11) **G1:** NR **G2:** NR Diff between groups in change over time *(P* = 0.02)
BDI, mean (SD): **G1:** 21.0 (8.3) **G2:** 19.5 (8.4) *(P* = NR)	**BDI, mean (SD):** **Mid-tx:** **G1:** 12.0 (8.7) *(P* = NR) **G2:** 17.0 (10.2) *(P* = NR)		
BDI, mean (SD): **G1:** 22.4 (9.9) **G2:** 19.5 (8.6) *(P* = NS)	**Post-tx:** **G1:** 9.9 (8.8) *(P* = NR) **G2:** 14.8 (11.4) *(P* = NR) **FU:** **G1:** 11.4 (10.5) *(P* = NR) **G2:** 10.2 (9.9) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)		
Self-Concept (self-esteem) Questionnaire, mean (SD): **G1:** 95.9 (19.9) **G2:** 104.3 (22.7) *(P* = NR)	**Self-Concept (self-esteem) Questionnaire, mean (SD):** **Mid-tx:** **G1:** 111.6 (18.3) *(P* = NR) **G2:** 112.0 (30.6) *(P* = NR)		
Self-Concept (self-esteem) Questionnaire, mean (SD): **G1:** 96.3 (26.9) **G2:** 103.8 (24.1) *(P* = NS)	**Post-tx:** **G1:** 119.4 (22.9) *(P* = NR) **G2:** 118.6 (29.2) *(P* = NR) **FU:** **G1:** 121.6 (31.3) *(P* = NR) **G2:** 139.3 (33.5) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)		

Evidence Table 8. Self-help trials for bulimia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Thiels et al., 1998 (continued)	**EDE Wt Concern, mean (SD):** **G1:** 3.53 (1.40) **G2:** 3.20 (1.42) *(P* = NR)	**EDE Wt Concern, mean (SD):** **Mid-tx:** **G1:** 2.83 (1.39) *(P* = NR) **G2:** 3.05 (1.75) *(P* = NR) **Post-tx:** **G1:** 2.21 (1.63) *(P* = NR) **G2:** 2.42 (1.95) *(P* = NR) **FU:** **G1:** 1.92 (1.57) *(P* = NR) **G2:** 1.83 (1.57) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	EDE Dietary restraint, mean (SD): **G1:** 3.79 (1.71) **G2:** 3.65 (1.65) *(P* = NR)	**EDE Dietary restraint, mean (SD):** **Mid-tx:** **G1:** 2.42 (1.37) ***(P*** = NR) **G2:** 2.63 (1.44) *(P* = NR) **Post-tx:** **G1:** 1.83 (1.45) *(P* = NR) **G2:** 2.34 (1.46) *(P* = NR) **FU:** **G1:** 1.56 (1.80) *(P* = NR) **G2:** 1.46 (1.57) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	EDE Severity, mean (SD): **G1:** 4.17 (0.65) **G2:** 4.05 (0.58) *(P* = NR)	**EDE Severity, mean (SD):** **Mid-tx:** **G1:** 3.04 (1.02) *(P* = NR) **G2:** 3.41 (1.10) *(P* = NR) **Post-tx:** **G1:** 2.43 (1.44) *(P* = NR) **G2:** 3.18 (1.22) *(P* = NR) **FU:** **G1:** 2.26 (1.36) *(P* = NR) **G2:** 2.32 (1.49) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)

Evidence Table 8. Self-help trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 8. Self-help trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Thiels et al., 1998 (continued)	**BITE score, mean (SD):** **G1:** 30.1 (5.0) **G2:** 33.8 (9.4) *(P* = NR)	**BITE score, mean (SD):** **Mid-tx:** **G1:** 23.8 (9.4) *(P* = NR) **G2:** 28.1 (11.0) *(P* = NR)
	BITE score, mean (SD): **G1:** 32.0 (5.6) **G2:** 34.1 (8.5) *(P* = NS)	**Post-tx:** **G1:** 17.0 (13.1) *(P* = NR) **G2:** 27.0 (12.3) *(P* = NR) **FU:** **G1:** 15.4 (14.2) *(P* = NR) **G2:** 18.2 (12.5) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = 0.05) G2 better than G1 Diff between groups in change over time *(P* = NS)
	Eating Disorders Awareness Test, mean (SD): **G1:** 21.5 (6.9) **G2:** 22.5 (7.8) *(P* = NR)	**Eating Disorders Awareness Test, mean (SD):** **Mid-tx:** **G1:** 26.3 (6.7) *(P* = NR) **G2:** 33.0 (9.7) *(P* = NR)
	Eating Disorders Awareness Test, mean (SD): **G1:** 22.8 (7.6) **G2:** 23.1 (7.9) *(P* = NS)	**Post-tx:** **G1:** 29.6 (8.3) *(P* = NR) **G2:** 34.3 (10.3) *(P* = NR) **FU:** **G1:** 32.5 (8.0) *(P* = NR) **G2:** 35.5 (9.4) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)

Evidence Table 8. Self-help trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 8. Self-help trials for bulimia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Thiels et al., 1998 (continued)		**Abstinence rates, N (%) (95% CI):** **Stopped binge eating in previous wk:** **Mid-tx (N = 31):** **G1:** 10 (32.3%) (16.7 – 51.4) **G2:** 6 (19.4%) (7.5 – 48.0) **Post-tx (N = 31):** **G1:** 19 (61.3%) (42.2 – 78.1) *(P* = NR) **G2:** 5 (16.1%) (5.5 – 33.7) *(P* = NR) **FU (G1, N = 24; G2 N = 23):** **G1:** 17 (70.8%) (48.9 – 87.4) *(P* = NR) **G2:** 16 (69.6%) (47.1 – 86.8) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **Stopped vomiting in previous wk:** **Mid-tx (N = 31):** **G1:** 9 (29.0%) (14.2 – 48.0) **G2:** 9 (29.0%) (14.2 – 48.0) **Post-tx (N = 31):** **G1:** 17 (54.8%) (36.0 – 72.7) *(P* = NR) **G2:** 8 (25.8%) (11.9 – 44.6) *(P* = NR) **FU (G1, N = 24; G2, N = 23):** **G1:** 17 (70.8%) (48.9 – 87.4) *(P* = NR) **G2:** 14 (60.9%) (38.5 – 80.3) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **Stopped binge eating and vomiting combined:** **Mid-tx (N = 31):** **G1:** 8 (25.8%) (11.9 – 44.6) **G2:** 5 (16.1%) (5.5 – 33.7) **Post tx (N = 31):** **G1:** 17 (54.8%) (36.0 – 72.7) *(P* = NR) **G2:** 4 (12.9%) (3.6 – 29.8) *(P* = NR) **FU (G1, N = 24; G2, N = 23):** **G1:** 17 (70.8%) (48.9 – 87.4) *(P* = NR) **G2:** 14 (60.9%) (38.5 – 80.3) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)

Evidence Table 8. Self-help trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 8. Self-help trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Treasure et al., 1996 **Companion article:** Turnbull et al., 1997 **Setting:** Tertiary referral center in UK **Enrollment period:** NR	**Research objective:** Examine if sequential program (self-help manual for 8 wks followed by 8 sessions of CBT for patients who remained symptomatic) is different from standard CBT (16 wks administered consecutively or following an 8-wk waiting period).	**Groups:** **G1:** Self-help manual/sequential tx (N = 55) **G2:** standard CBT (N = 55)* **Enrollment:** • 125 consecutive referrals with a dx of BN or atypical BN were screened • 7 were excluded; 8 declined • 110 patients randomized • From G1, 41 attended assessment at 8 wks, 46 at 16 wks and 30 at 18 mos • In G2, subgroup 1 (immediate tx) consisted of 27 individuals and subgroup 2 (delayed tx) had 28 individuals. • Of the 55 in G2, 40 were reassessed at 16 wks (end of tx) and 34 at 18 mos. • 86 completed tx • 18 mos after tx (14-26 mos), all patients were contacted and sent a questionnaire. 64 responded. FU took place in person or by phone. * Half of the individuals in the CBT group (delayed tx) served as waiting list control participants in another study – Treasure et al., 1994).	**Age, yrs, mean (SD):** **G1:** 25.6 (5.5) **G2:** 25.9 (6.3) *(P* = NS) **Age at onset, yrs, mean (SD):** **G1:** 17.5 (4.8) **G2:** 17.0 (4.4) *(P* = NS) **Illness Duration, yrs, mean (SD):** **G1:** 8.0 (5.0) **G2:** 9.1 (6.5) *(P* = NS) **Sex:** NR **Race/ethnicity:** NR **BMI, kg/m^2, mean (SD):** **G1:** 23.7 (5.4) **G2:** 24.4 (6.4) *(P* = NS) **Total symptom score:** **G1:** 6 **G2:** 6 *(P* = NS) **Hx of AN:** **G1:** 29% **G2:** 28% *(P* = NS) **Previous tx:** **G1:** 44% **G2:** 55% *(P* = NS) **Current depression:** **G1:** 23% **G2:** 35% *(P* = NS) **Current amenorrhea:** **G1:** 12% **G2:** 10% *(P* = NS) **Social class (Professional class):** **G1:** 53% **G2:** 56% *(P* = NS)

Evidence Table 8. Self-help trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: ICD-10 dx of BN or atypical BN **Exclusion:** Individuals were excluded for severe comorbidity (diabetes, high risk of suicide or alcohol dependence) or pregnancy.	G1 was allocated the manual, asked to work at their own pace and were told that the manual contained all the information needed for them to overcome their BN. They were asked to keep a therapeutic diary (this was used as part of the assessment at 8 wks). After 8 wks, patients who remained symptomatic were offered up to 8 sessions of CBT. Those who no longer met criteria for BN or atypical BN were invited to come for FU at 16 wks. G2 was subdivided into two grps. Half of them were offered immediate CBT for 16 wks and the other half were offered tx after a waiting period of 8 wks after which they received 16 wks of CBT (this group was a waiting list control in Treasure, 1994). The two subgroups were combined at the end of their txs for comparisons with G1. Patients were considered fully recovered if they were not bingeing, vomiting or using any other wt control behaviors or if information was not available, their BITE symptom score was < or equal to 11 and their BITE severity score was 0.	T tests were used to test for group diffs at baseline. Chi-square analyses were done for categorical data. Wilcoxon tests were used to assess within group changes for bulimic symptom scores, which were not normally distributed.	**Score:** Poor **Intent to treat:** Yes **Blinding:** NA **Adverse events:** NR **Funding:** Mental Health Foundation and Medical Research Council

Evidence Table 8. Self-help trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Treasure et al., 1996 (continued)	**Bulimia rating scale symptom score, median:** **G1:** 6 **G2:** 6 *(P* = NR)	**End of tx:** **Bulimia rating scale symptom score, median:** **G1:** 2 *(P* = 0.00) **G2:** 2 *(P* = 0.00) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) **Total remission rate/"fully recovered" (no bingeing, vomiting or using any other wt control mechanism):** **G1:** 30% **G2:** 30% Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **18 mo FU:** **Bulimia rating scale symptom score, median:** **G1:** 1.5 *(P* = NS) **G2:** 1 *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) **Total remission rate/"fully recovered":** **G1:** 40% **G2:** 41% Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **Additional tx sought:** **G1:** 38% **G2:** 17% Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)

Evidence Table 8. Self-help trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
NR	NR	NR	NR

Evidence Table 8. Self-help trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Turnbull et al., 1997 **Companion article:** Treasure et al., 1996 **Setting:** Tertiary referral center in UK **Enrollment period:** NR	**Research objective:** Examined pre tx predictors of outcome for two tx's for BN. Outcome (i.e., severity of eating disorder psychopathology) was defined as a sum of binge frequency, vomiting, abuse of laxatives or diuretics, and intense exercising.	**Groups:** **G1:** Self-help manual/sequential tx (N = 55) **G2:** standard CBT (N = 55) **Enrollment:** • 125 consecutive referrals with a dx of BN or atypical BN were screened • 7 were excluded; 8 declined • 110 patients randomized • From G1, 41 attended assessment at 8 wks, 46 at 16 wks and 30 at 18 mos • In G2, subgroup 1 (immediate tx) consisted of 27 individuals and subgroup 2 (delayed tx) had 28 individuals. • Of the 55 in G2, 40 were reassessed at 16 wks (end of tx) and 34 at 18 mos. • 86 completed tx • 18 mos after tx (14-26 mos), all patients were contacted and sent a questionnaire. 64 responded. FU took place in person or by phone.	**Age, yrs, mean (SD):** **G1:** 25.6 (5.5) **G2:** 25.9 (6.3) *(P* = NS) **Age at onset, yrs, mean (SD):** **G1:** 17.5 (4.8) **G2:** 17.0 (4.4) *(P* = NS) **Sex:** NR **Race/ethnicity:** NR BMI, kg/m^2, mean (SD): **G1:** 23.7 (5.4) **G2:** 24.4 (6.4) *(P* = NS) **Total symptom score:** **G1:** 6 **G2:** 6 *(P* = NS) **Hx of AN:** **G1:** 29% **G2:** 28% *(P* = NS) **Previous tx:** **G1:** 44% **G2:** 55% *(P* = NS) **Current depression:** **G1:** 23% **G2:** 35% *(P* = NS) **Current amenorrhea:** **G1:** 12% **G2:** 10% *(P* = NS) **Social class (Professional class):** **G1:** 53% **G2:** 56% *(P* = NS)

Evidence Table 8. Self-help trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: ICD-10 dx of BN or atypical BN **Exclusion:** Individuals were excluded for severe comorbidity (diabetes, high risk of suicide or alcohol dependence) or pregnancy.	G1 was allocated the manual, asked to work at their own pace and were told that the manual contained all the information needed for them to overcome their BN. They were asked to keep a therapeutic diary (this was used as part of the assessment at 8 wks). After 8 wks, patients who remained symptomatic were offered up to 8 sessions of CBT. Those who no longer met criteria for BN or atypical BN were invited to come for FU at 16 wks. G2 was subdivided into two grps. Half of them were offered immediate CBT for 16 wks and the other half were offered tx after a waiting period of 8 wks after which they received 16 wks of CBT (this group was a waiting list control in Treasure, 1994). The two subgroups were combined at the end of their txs for comparisons with G1. Patients were considered fully recovered if they were not bingeing, vomiting or using any other wt control behaviors or if information was not available, their BITE symptom score was < or equal to 11 and their BITE severity score was 0.	Stepwise linear regressions to predict outcome at end of tx and at 18 mo FU. As there was no diff between the two groups, some of the data was pooled to look at predictors.	**Score:** Poor **Intent to treat:** Yes **Blinding:** NA **Adverse events:** NR **Funding:** Mental Health Foundation and Medical Research Council

Evidence Table 8. Self-help trials for bulimia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Turnbull et al., 1997 (continued)		**Global Symptoms (sum of binge frequency, vomiting, laxative and/or diuretic abuse, intense exercising):** **End of tx:** **Duration of illness as predictor:** **G1:** NR *(P* = NS) **G2:** NR *(P* < 0.02) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) **Binge frequency as predictor:** **G1:** NR *(P* < 0.05) **G2:** NR *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) **18 mo FU:** **Duration of illness as predictor:** **G1:** NR *(P* = NS) **G2:** NR *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) **Binge frequency as predictor:** **G1:** NR *(P* < 0.05) **G2:** NR *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)

Evidence Table 8. Self-help trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
NR	NR	NR	NR

Evidence Table 9. Other trials for bulimia nervosa

Study Description	Objective	Design	Patient Characteristics
Author, yr: Braun et al., 1999 **Setting:** Outpatient, New York, USA **Enrollment period:** NR	**Research objective:** During a 3-wk winter tx period, to assess the efficacy of winter bright light therapy versus dim red light (Placebo) therapy on binge and purge frequency and depressive sx in women with BN.	**Groups:** **G1:** Active light (N = 16) **G2:** Dim light/Placebo (N = 18) **Enrollment:** • Recruited via therapist or newspaper ads • Subjects matched for age, degree of seasonality (measured by Seasonal Patterns Assessment Questionnaire), and concurrent depression (DSM IV) • Total screened = N • 34 enrolled	**Age, yrs, mean (SD):** **G1:** 30.50 (7.3) **G2:** 30.50 (8.6) *(P* = NS) **Sex:** Female: 100% **Race/ethnicity:** NR **Current Major Depression:** **G1:** 25% (N = 4) **G2:** 22.2% (N = 4) **Lifetime Major Depression:** **G1:** 75% (12) **G2:** 72.2% (13) No patients met criteria for major depression with a seasonal pattern.

Evidence Table 9. Other trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Met DSM IV criteria for BN; age 18 to 50; premenopausal **Exclusion:** Current drug or alcohol abuse or dependence, bipolar disorder, schizophrenia, ophthalmologic disease, serious medical conditions, or current wt less that 90% IBW (Metropolitan Table); current anorexia; involvement in psychotherapy regimen or taking psychiatric meds for less than 3 mos prior to study; change in therapeutic tx or meds immediately preceding or during study	Parallel-design, 8 wk study, taking place during winter mos (Nov-Dec; Jan-March); 3 wk baseline data collection followed by 3 wk tx period, and 2 wks FU; all subjects received Apollo light boxes to deliver either 10,000 lux white light (G1) or 50 lux red light (G2) arriving at the retina; all used lights ½ hr/day at home between 6 and 9pm while watching television; daily phone contact with about compliance with participants, who avoided outdoor light before 8am or used sunglasses. For 8 wks, all completed daily food diaries, including B/P behaviors, urge to binge, meals and snacks, carbohydrate cravings, menstrual ad sleep logs, and BDIs. At baseline, tx-end, and 2-wk FU, wt, BDI, HAM-D, Seasonal Patterns Assessment Questionnaire (SPAQ) and YBC-EDS were assessed.	MANOVA across time points was used to assess light tx by time interaction; Pearson r correlations between the change in various outcome measures were computed in groups; ANOVA was used to assess diff between group s in change over time.	**Score:** Fair **Intent to treat:** NR **Blinding:** Double **Adverse events:** No subjects withdrew due to side effects; 5 were removed from G1 due to med change, vacation in sun, noncompliance, and failure to meet binge frequency at baseline; 5 G2 were removed due to failure to meet BN criteria. **Funding:** NIMH and fund established by the NY Community Trust by Dewitt-Wallace

Evidence Table 9. Other trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Braun et al., 1999 (continued)	**Binge Frequency, wkly, mean (SD):** **G1:** 6.7 (3.1) **G2:** 4.9 (2.9) *(P* = NS)	**Binge Frequency, wkly, mean (SD):** **Post-tx:** **G1:** 4.3 (3.9) *(P* = NR) **G2:** 3.9 (3.3) *(P* = NR) **2 wk FU:** **G1:** 4.1 (4.5) *(P* = NR) **G2:** 3.6 (3.3) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.017) G1 better than G2 in change from baseline to post-tx
	Purge Frequency, wkly, mean (SD): **G1:** 7.7 (4.8) **G2:** 6.3 (5.9) *(P* = NS)	**Purge Frequency, wkly, mean (SD):** **Post-tx:** **G1:** 5.2 (4.5) *(P* = NR) **G2:** 4.3 (4.0) *(P* = NR) **2 wk FU:** **G1:** 4.5 (6.2) *(P* = NR) **G2:** 4.2 (4.2) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	Meal Frequency, wkly, mean (SD): **G1:** 14.5 (5.0) **G2:** 16.3 (3.8) *(P* = NS)	**Meal Frequency, wkly, mean (SD):** **Post-tx:** **G1:** 16.4 (4.0) *(P* = NR) **G2:** 16.8 (3.4) *(P* = NR) **2 wk FU:** **G1:** 17.4 (3.5) *(P* = NR) **G2:** 16.5 (3.7) *(P* = NR) Diff over time *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	YBC-EDS, total, mean (SD): **G1:** 15.1 (4.5) **G2:** 16.4 (5.1) *(P* = NS)	**YBC-EDS, total, mean (SD):** **G1:** 11.4 (6.0) *(P* = NR) **G2:** 13.4 (5.9) *(P* = NR) **2 wk FU:** **G1:** 10.4 (7.4) *(P* = NR) **G2:** 11.8 (7.4) *(P* = NR) Diff over time *(P* = NR) Diff between groups (*P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 9. Other trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BDI, mean (SD): **G1:** 16.9 (9.4) **G2:** 13.1 (9.1) *(P* = NS)	**BDI, mean (SD):** **Post-tx:** **G1:** 13.0 (7.5) *(P* = NR) **G2:** 10.8 (9.1) *(P* = NR) **2 wk FU:** **G1:** 11.9 (8.7) *(P* = NR) **G2:** 10.5 (8.7) *(P* = NR) Diff over time *(P* = 0.003) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)		
HAM-D, mean (SD): **G1:** 7.9 (6.7) **G2:** 9.7 (7.6) *(P* = NS)	**HAM-D, mean (SD):** **Post-tx:** **G1:** 3.7 (3.7) *(P* = NR) **G2:** 5.5 (4.1) *(P* = NR) **2 wk FU:** **G1:** 4.4 (4.4) *(P* = NR) **G2:** 4.7 (6.4) *(P* = NR) Diff over time *(P* = 0.005) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)		
HAM-D-SAD items, mean (SD): **G1:** 5.7 (3.6) **G2:** 5.5 (4.1) *(P* = NS)	**HAM-D-SAD, mean (SD):** **Post-tx:** **G1:** 2.3 (2.3) *(P* = NR) **G2:** 2.4 (2.2) *(P* = NR) **2 wk FU:** **G1:** 5.6 (4.5) *(P* = NR) **G2:** 4.0 (5.5) *(P* = NR) Diff over time *(P* = 0.014) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)		

Evidence Table 9. Other trials for bulimia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Braun et al., 1999 (continued)	**Seasonal Patterns Assessment Questionnaire (SPAQ):** **G1:** 43.8% (16) met full criteria for SAD, 18.8% (3) met sub-threshold criteria **G2:** 44.4% (18) met SAD criteria, 16.7% (3) met sub-threshold. **SPAQ GSS, mean (SD):** **G1:** 11.1 (5.2) **G2:** 11.0 (5.3) *(P* = NS) **SPAQ Sleep, mean (SD):** **G1:** 1.5 (1.2) **G2:** 1.3 (1.1) *(P* = NS) **SPAQ -Wt, mean (SD):** **G1:** 1.8 (1.1) **G2:** 1.3 (1.1) *(P* = NS) **SPAQ Appetite, mean (SD):** **G1:** 1.7 (1.0) **G2:** 1.6 (1.2) *(P* = NS) **SPAQ Energy, mean (SD):** **G1:** 2.2 (1.1) **G2:** 2.3 (1.2) *(P* = NS) From baseline to Tx-end, SPAQ global scores were not correlated with change in binge frequency.	**Seasonal Patterns Assessment Questionnaire (SPAQ):** **G1:** NR **G2:** NR *(P* = NR) **Correlation between change in HAM-D-SAD scores and change in carbohydrate craving** **G1:** (r = 0.66) *(P* = 0.38) **G2:** (r = -.41) *(P* = 0.24) **Correlation between change in HAM-D-SAD scores and change in binge frequency** **G1:** (r = 0.44) *(P* = 0.20) **G2:** (r = -.75) *(P* = 0.012)

Evidence Table 9. Other trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 9. Other trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Esplen et al., 1998 **Setting:** Outpatient; Toronto, Canada **Enrollment period:** 20 mos	**Research objective:** To test the efficacy of a guided image therapy to enhance self-comfort in individuals with BN vs. a control tx of eating behavior journaling therapies	**Groups enrolled:** **G1:** guided imagery (N = 28) **G2:** control (N = 30) **Enrollment:** Potential subjects referred by consultation service (N = 51) or in response to advertisements (N = 7) Informed consent Pre-tx psychometric assessment Randomization 6 wks of tx Post-tx psychometric assessment **Drop-outs:** **G1:** N = 4 **G2:** N = 4 **Completers reported:** **G1:** N = 24 **G2:** N = 28	**Age, yrs, mean (SD):** **G1:** 27.2 (6.3) **G2:** 26.1 (5.8) *(P* = NS) **Sex:** 96.5% female **Race/ethnicity:** NR **BMI, kg/m^2, mean (SD):** **G1:** 21.0 (1.0) **G2:** 21.3 (1.3) *(P* = NS) **Duration of BN, mos, mean (SD):** **G1:** 83.0 (55.5) **G2:** 86.0 (63.9) *(P* = NS) **Previous AN, N (%):** Completers: 12 (24%) Drop-outs: 6 (75%) *(P* = NR)

Evidence Table 9. Other trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: DSM III-R criteria for BN CBW > 85% of avg for sex, age, and height < 15 yr illness duration no current psych tx no risk factors for inpatient tx **Exclusion:** Current psych tx or Indications for inpatient tx	Pre-tx assessment Randomization **G1:** 6 wkly sessions of manual-based guided imagery exercises on relaxation and self-exploration; take-home tape provided; journaling **G2:** 6 wkly sessions of manual-based explorations of eating pattern journals; comments on observed patterns but no guidelines Post-assessment	2 (group) x 2 (time) repeated measures ANOVA; regression analysis of psych variables on eating behaviors; correlations between psych variables; Chi Square for abstinence rates. Active dose = 4 wks of therapy, so "completer" was ≥ 4 session attendance	**Score:** Fair **Intent to treat:** No **Blinding:** No **Adverse events:** Not reported **Funding:** Ontario Mental Health Foundation

Evidence Table 9. Other trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Esplen et al., 1998 (continued)	**Binge frequency/wk, mean (SD):** **G1:** 5.6 (3.5) **G2:** 4.9 (2.6) *(P* = NS)	**Binge Frequency/wk, mean (SD):** **G1:** 1.7 (1.7) *(P* = NR) **G2:** 5.2 (2.6) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = 0.05) Diff between groups in change over time *(P* < 0.001) G1 better than G2 **% Reduction in Binge Freq:** **G1:** 73.6% (23.9) **G2:** - 9.0% (43.4) *(P* = NR)
	Purge frequency/wk, mean (SD): **G1:** 6.3 (5.8) **G2:** 5.0 (4.6) *(P* = NS)	**Purge Frequency/wk, mean (SD):** **G1:** 1.7 (1.7) *(P* = NR) **G2:** 4.8 (4.6) *(P* = NR) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* < 0.001) G1 better than G2 **% Reduction in Purge Freq:** **G1:** 72.5% (26.1) **G2:** - 6.2% (32.5) *(P* = NR)
	Abstinence/Remission: **G1:** NR **G2:** NR	**Abstinence, N:** **G1:** 6/24 **G2:** 0/26 *(P* < 0.001)

Evidence Table 9. Other trials for bulimia nervosa (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Esplen, et al., 1998 (continued)	**Eating Disorder Inventory:** **Drive for thinness (DT), mean (SD):** **G1:** 14.8 (4.5) **G2:** 14.1 (5.5) *(P* = NR)	**Eating Disorder Inventory:** **Drive for thinness (DT), mean (SD):** **G1:** 10.1 (6.4) *(P* = NR) **G2:** 15.5 (5.4) *(P* = NR) Diff over time *(P* = 0.015) Diff between groups *(P* = NS) Diff between groups in change over time *(P* < 0.001) G1 better than G2 **% Making Sig DT improvement:** **G1:** 50.0 **G2:** 3.8 Diff between groups *(P* < 0.0002)
	Bulimia (B), mean (SD): **G1:** 9.4 (5.0) **G2:** 11.5 (5.5) *(P* = NR)	**Bulimia (B), mean (SD):** **G1:** 4.7 (5.1) *(P* = NR) **G2:** 11.9 (5.7) *(P* = NR) Diff over time *(P* = 0.002) Diff between groups *(P* = 0.001) Diff between groups in change over time *(P* < 0.001) G1 better than G2 **% Making Sig B improvement:** **G1:** 37.5 **G2:** 3.8 Diff between groups *(P* < 0.004)
	Body Dissatisfaction (BD), mean (SD): **G1:** 16.1 (8.8) **G2:** 18.9 (7.9) *(P* = NR)	**Body Dissatisfaction (BD), mean (SD)** **G1:** 12.5 (8.7) *(P* = NR) **G2:** 18.7 (7.7) *(P* = NR) Diff over time *(P* = 0.028) Diff between groups *(P* = 0.05) Diff between groups in change over time *(P* < 0.043) G1 better than G2 **% Making Sig BD improvement:** **G1:** 33.3 **G2:** 7.7 Diff between groups *(P* = NS)
		% Making Clinically Sig Improvement on Eating Attitudes Test: **G1:** 58% **G2:** < 10% Diff between groups *(P* < 0.05) Diff between groups in change over time Total score *(P* < 0.001) Bulimia subscale *(P* < 0.001) Dieting subscale *(P* < 0.001) G1 better than G2

Evidence Table 9. Other trials for bulimia nervosa (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Mitchell et al., 2004 **Companion articles:** Agras, et al., 2000 and Halmi et al., 2002 **Setting:** Outpatient, Cornell University, Rutgers University and University of Minnesota, USA **Enrollment period:** NR	**Research objective:** Comparing two outpatient relapse prevention strategies for individuals with BN who have become abstinent from bingeing and purging after CBT tx.	**Groups:** **G1:** Crisis prevention (N = 30) **G2:** FU (N = 27) **Enrollment:** • In the original study, 194 participants were screened by phone, interviewed and recruited to receive CBT. • 6 participants withdrew and 48 dropped out during the CBT tx. • After 140 individuals completed CBT, between wks 16 and 17, patients were reassessed relative to their remission status. • 57 individuals achieved abstinence (defined as abstinence from bingeing and purging in the last 28 days) and were randomized to FU only or crisis intervention. • In this study, participants were reassessed at 17, 43 and 70 wks after tx. • 48 individuals completed the 17-wk FU assessment after end of tx, 41 completed the assessments at 43 wks and 34 completed the 70 wk FU.	**Age, mean (SD):** **G1:** 28.8 (8.6) **G2:** 29.8 (9.4) **Sex:** NR **Race/ethnicity:** NR **Hx of anorexia:** **G1:** 7% **G2:** 22% **Hx of depression:** **G1:** 53% **G2:** 48% **Personality disorder:** **G1:** 27% **G2:** 33% **Hx of substance abuse:** **G1:** 10% **G2:** 22% **Duration of bingeing (SD):** **G1:** 10.6 (8.1) **G2:** 12.1 (8.9) (*P* = NS) **Duration of purging (SD):** **G1:** 10.27 (7.4) **G2:** 12.0 (9.0) (*P* = NS) **Pre-CBT objective binges:** **G1:** 18 **G2:** 19 (*P* = NS) **Pre-CBT purges:** **G1:** 27 **G2:** 28 (*P* = NS)

Evidence Table 9. Other trials for bulimia nervosa (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: From the participants in the original study, individuals were included in this study if they had remained abstinent from bingeing and purging in the 28 days prior to the beginning of this tx protocol. **Exclusion:** Individuals from the original study who were bingeing or purging at the end of CBT tx.	Within the crisis intervention model, participants could request additional tx if they became symptomatic or feared they would relapse within the first 17 wks. Emphasis was placed on calling early if problems developed with the intent that participants would be seen quickly for an additional two or three sessions as necessary to reestablish the goals of therapy and to assist in relapse prevention work. Participants were allowed up to 8 sessions during the period of FU. Those in the FU group were contacted for FU assessments only and were not offered further tx.	Cox regression used to test diffs between 2 tx groups in length of time until resumption of bingeing and/or purging.	**Score:** Fair **Intent to treat:** NR **Blinding:** NA **Adverse events:** 37% of the participants resumed bingeing or purging by the end of the 17-wk FU period. An additional 16% of the participants resumed bulimic behavior within the yr after the FU tx. Of the individuals who resumed bulimic behavior, only 4 met criteria for BN according to DSM III-R. **Funding:** McKnight Foundation and Minnesota Obesity Center

Evidence Table 9. Other trials for bulimia nervosa (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Mitchell et al., 2004 (continued)		**Length of time until resumption of bingeing and purging** **G1:** Data reported in figure only **G2:** Data reported in figure only Diff between groups *(P* = NR) Diffs between groups in time to resumption *(P* = NS)

Evidence Table 9. Other trials for bulimia nervosa (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
NR	NR	NR	NR

Evidence Table 10. Medication trials for binge eating disorder

Study Description	Objective	Design	Patient Characteristics
Author, yr: Appolinario et al., 2003 **Setting:** Two sites; outpatient; locations: Obesity and Eating Disorders Group, Institute of Psychiatry, Federal University of Rio de Janeiro/Institute of Diabetes and Endocrinology of Rio de Janeiro, Rio de Janeiro, Brazil and the Eating Disorders Program from the Federal University of Sao Paulo, Sao Paulo, Brazil **Enrollment period:** October 1, 2000 through July 31, 2001	**Research objective:** To assess the efficacy and safety of sibutramine hydrochloride (a serotonin and norepinephrine reuptake inhibitor) in reducing the frequency of binge eating and its effect on wt loss, binge eating risk, and self-reported depression over the course of 12 wks.	**Groups:** **G1:** sibutramine hydrochloride (N = 30) **G2:** placebo (N = 30) **Enrollment:** • 750 screened by telephone and recruited through media ads • 233 further in-person evaluation by staff members • 79 enrolled (19 excluded from the double blind phase for presenting with only 2 binge days during the wk after the placebo run-in phase) • 60 randomized • 48 completers (**G1:** 23; **G2:** 25) *(P* = NS)	**Age yrs, mean (SD):** **G1:** 35.2 (9.0) **G2:** 36.6 (10.2) *(P* = NS) **Sex:** % Female **G1:** 87% **G2:** 90% *(P* = NS) **Race/ethnicity:** White: **G1:** 73% **G2:** 87% *(P* = NS) **Hx of major depression, N (%):** **G1:** 11 (37) **G2:** 9 (30) *(P* = NS)

Evidence Table 10. Medication trials for binge eating disorder (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Ages 18-60; BMI:30-45; DSM IV criteria for BED and BES score ≥ moderate range (i.e., > 17). **Exclusion:** Pregnant, lactating or not using medically-accepted form of contraception; current or past dx of BN; psychosis; mania; organic dementia; alcohol or other drug abuse; suicide risk; diabetes mellitus; supine diastolic arterial pressure > 110 mm Hg; unstable medical illness or clinically sig abnormal laboratory results; current or previous use of sibutramine or other investigational drugs; concurrent use of antidepressants, antipsychotics, lithium carbonate, cyproheptadine hydrochloride, bromocriptine mesylate, ergotamine tartrate and related drugs, atropine, thyroid hormones, systemic steroids (except menopause hormone therapy), antiobesity agents, drugs that interfere with the GI tract movements such as antidiarrhea and antinausea drugs, anticoagulants, digitalis, anti-Parkinson drugs that interfere with amine activity; any form of psychotherapy within 3 mos of study entry; hx of obesity surgery; smoking cessation within past 3 mos or intent to quit during study period.	After completing entry screening procedures, participants (N = 79) underwent 2-wk, single-blind placebo run-in phase prior to randomization. Subjects who reported binge eating episodes on at least 2 days w/in the last wk and who scored > 17 on the BES were randomized to 12-wks of either 15 mg of sibutramine hydrochloride (N = 30) or placebo (N = 30). Subjects' binge eating frequency, binge eating risk, self-reported depression, and wt were assessed at baseline and at 2, 4, 8, and 12 wks.	Two-tailed, unpaired *t* tests or X^2 tests for between group diff in baseline variables; repeated random regression analyses (including time trend analyses) to assess between group changes in primary and secondary variables at baseline, 2, 4, 8, and 12 wks; logistic regression to test between group diff in response (i.e., 50% reduction in binge frequency) and remission (i.e., cessation of binge eating) rates.	**Score:** Good **Intent to treat:** Yes **Blinding:** Double **Adverse events, N:** **Dry mouth:** **G1:** 22 **G2:** 3 *(P* < 0.01) **Headache:** **G1:** 6 **G2:** 14 *(P* < 0.01) **Constipation:** **G1:** 7 **G2:** 0 *(P* < 0.001) All other adverse events (i.e., nausea, insomnia, sudoresis, lumbar pain, depressive mood, flu syndrome, malaise, others) *(P* = NS). **Funding:** Abbott Laboratories, Sao Paulo, Brazil

Evidence Table 10. Medication trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Appolinario et al., 2003 (continued)	**Binge days per wk, mean (SD):** **G1:** 4.1 (1.8) **G2:** 3.9 (1.8) *(P* = NS)	**Binge days per wk, mean (SD):** **Completion** **G1 and G2:** Data presented in graph *(P* = NR) Diff between groups in change over time *(P* = 0.03): G1 better than G2 **Wk 2:** **G1:** 1.7 (1.9) **G2:** 3.3 (2.2) Within group change from baseline *(P* = NR) *(P* = NR) Diff between groups in change over time *(P* = 0.002) G1 better than G2 **Wk 4:** **G1:** 1.7 (1.6) **G2:** 3.0 (2.1) Within group change from baseline *(P* = NR) *(P* = NR) Diff between groups in change over time *(P* = NR) **Wk 8:** **G1:** 1.8 (2.2) **G2:** 2.5 (2.1) Within group change from baseline *(P* = NR) *(P* = NR) Diff between groups in change over time *(P* = NR) **Wk 12:** **G1:** 1.4 (2.0) **G2:** 2.3 (2.2) Within group change from baseline *(P* = NR) Diff between groups (*P* = NR) Diff between groups in change over time *(P* = 0.04) G1 better than G2
	BES, mean (SD): **G1:** 29.2 (7.2) **G2:** 29.1 (5.9) *(P* = NS)	**BES, mean (SD):** **Completion** **G1 and G2:** Data not presented *(P* = NR) Diff between groups in change over time *(P* < 0.001) G1 better than G2 **Wk 2:** **G1:** 26.8 (9.3) **G2:** 27.6 (6.5) Within group change from baseline *(P* = NR) *(P* = NR) Diff between groups in change over time *(P* = NR)

Evidence Table 10. Medication trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
		Wt, kg, mean (SD): **G1:** 102.8 (13.2) **G2:** 98.7 (12.9) *(P* = NS)	**Wt, kg, mean (SD): Completion** **G1 and G2:** Data presented in graph Diff between groups *(P* = NS) Diff between groups in change over time *(P* < 0.001) G1 better than G2 **Wk 2:** **G1:** 98.7 (11.0) **G2:** 99.2 (13.4) Within group change from baseline *(P* = NR) *(P* = NR) Diff between groups in change over time *(P* = NR) **Wk 4:** **G1:** 96.9 (10.8) **G2:** 99.7 (12.5) Within group change from baseline *(P* = NR) *(P* = NR) Diff between groups in change over time *(P* = 0.02) G1 better than G2 **Wk 8:** **G1:** 96.0 (11.4) **G2:** 99.9 (13.3) Within group change from baseline *(P* = NR) *(P* = NR) Diff between groups in change over time *(P* = NR) **Wk 12:** **G1:** 95.4 (12.3) **G2:** 100.1 (13.6) Within group change from baseline *(P* = NR) *(P* = NR) Diff between groups in change over time *(P* = NR)

Evidence Table 10. Medication trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Appolinario et al., 2003 (continued)		**Wk 4:** **G1:** 23.6 (11.4) **G2:** 26.1 (8.8) Within group change from baseline *(P* = NR) Diff between groups (*P* = NR) Diff between groups in change over time *(P* = 0.04) G1 better than G2 **Wk 8:** **G1:** 21.0 (12.6) **G2:** 26.4 (9.5) Within group change from baseline *(P* = NR) *(P* = NR) Diff between groups in change over time *(P* = NR) **Wk 12:** **G1:** 19.7 (12.4) **G2:** 24.4 (8.9) Within group change from baseline *(P* = NR) Diff between groups (*P* = NR) Diff between groups in change over time *(P* = 0.005) G1 better than G2
		Response, N (%) of completers: **G1:** 18 (78%) **G2:** 13 (52%) *(P* = NR) Diff between groups in change over the 12-wk study *(P* = 0.005) G1 better than G2

Evidence Table 10. Medication trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BDI, mean (SD): **G1:** 17.3 (9.7) **G2:** 18.6 (9.1) *(P* = NS)	**BDI, mean (SD):** **Completion** **G1 and G2:** Data presented in graph Diff between groups *(P* = NS) Diff between groups in change over time *(P* < 0.001) G1 better than G2 **Wk 2:** **G1:** 14.6 (7.9) **G2:** 19.4 (11.2) Within group change from baseline *(P* = NR) *(P* = NR) Diff between groups in change over time *(P* = NR) **Wk 4:** **G1:** 13.1 (8.6) **G2:** 18.4 (10.4) Within group change from baseline *(P* = NR) *(P* = NR) Diff between groups in change over time *(P* = NR) **Wk 8:** **G1:** 12.9 (8.5) **G2:** 18.3 (10.8) Within group change from baseline *(P* = NR) *(P* = NR) Diff between groups in change over time *(P* = NR) **Wk 12:** **G1:** 9.9 (7.6) **G2:** 17.9 (10.6) Within group change from baseline *(P* = NR) Diff between groups *(P* = 0.002) G1 better than G2 Diff between groups in change over time *(P* = NR)		

Evidence Table 10. Medication trials for binge eating disorder (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Arnold et al., 2002 **Setting:** Outpatient; single center; USA **Enrollment period:** February 1998 to June 2000	**Research objective:** To assess the efficacy and safety of fluoxetine in the tx of BED	**Groups:** **G1:** fluoxetine (N = 30) **G2:** placebo (N = 30) **Enrollment:** • 60 enrolled • 30 assigned to each tx group • 24 (40%) withdrew over study course (**G1:** 57%; **G2:** 23%) Diff between groups (*P* = 0.02) Of the 24, 10 withdrew, post-baseline	**Age, mean (SD):** **G1:** 41.9 (9.7) **G2:** 40.8 (9.0) (*P* = NS) **Sex:** **Female** **G1:** 93% **G2:** 93% (*P* = NS) **Race/ethnicity:** **White:** **G1:** 90% **G2:** 87% (*P* = NS) **AA:** **G1:** 10% **G2:** 13% (*P* = NS) **Duration of BED yrs, mean (SD):** **G1:** 19.9 (12.5) **G2:** 16.7 (9.5) (*P* = NS) **Current major depressive disorder:** **G1:** 27% **G2:** 23% (*P* = NS) **Lifetime (current or past) major depressive disorder (%):** **G1:** 67% **G2:** 63% (*P* = NS)

Evidence Table 10. Medication trials for binge eating disorder (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: DSM IV criteria for BED, and ≥ 3 BE episodes wkly for at least 6 mos; age 18-60; wt > 85% IBW. **Exclusion:** Pregnant or lactating; concurrent AN; concurrent or recent (within 1 yr) substance abuse or dependence; lifetime hx of psychosis, mania, hypomania, or dementia; hx of any psychiatric disorder that could interfere with diagnostic assessment, tx, or compliance; suicide risk; received psychotherapy or behavioral therapy within 3 mos of entry; clinically unstable medical illness; hx of seizures, lab abnormalities; MAOIs within 4 wks, or psychotropic meds within 2 wks of entry; received investigational meds or depot neuroleptics within 3 mos of entry; previously treated with fluoxetine; experienced < 3 binges in wk before randomization.	After 1 wk of single-blind placebo admin, subjects randomized to fluoxetine or placebo for 6 wks. Dosage began with 20mg/day for 3 days; As tolerated, dose increased to 40 mg/day for 3 days, then 60 mg/day. After 2 wks, dose could increase to 80 mg/day. At endpoint, mean dose (SD) for **G1:** 71.3 (11.4); **G2:** 67.3 (11.5). Subjects seen wkly, and assessed for number of binges since prior visit, CGI-S, meds dose and compliance (capsule count), adverse events, non-study med use, vital signs and wt. HAM-D administered at baseline, wks 2, 4, and 6.	PreTx comparisons between groups using Fisher exact test, and 2-sample t tests for continuous variables. 2 mixed-model repeated-measures analyses were made for each outcome (except response category): a time-trend analyses assessing rate of change between groups, and an endpoint analysis, assessing change between groups from baseline to wk 6. Response categories analyzed using the exact trend test; 2 analyses: for tx completers only, and for all subjects.	**Score:** Good **Intent to treat:** Yes **Blinding:** Double **Adverse events:** **Most common, reported by G1 (N):** Sedation (5), dry mouth (11), headache (9), nausea (7), insomnia (7), diarrhea (6), fatigue (6), increased urinary frequency (4), sexual dysfunction (4). Across groups, hand and foot swelling, palpitations, and apathy were also reported; no sig diff between groups. **Funding:** Investigator-initiated grant, Eli Lily and Company

Evidence Table 10. Medication trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Arnold et al., 2002 (continued)	**Binges/wk, mean (SD):** **G1:** 6.0 (2.5) **G2:** 6.1 (4.8) *(P* = NS)	**Binges/wk, mean (SE):** **8-wks:** **G1:** 1.8 (2.9) **G2:** 2.7 (3.8) Diff between groups *(P* = NS) Diff between groups in log rate of change *(P* = 0.033) G1 better than G2 **Percentage decrease in frequency of binges: N (%)** Intent to treat sample: **G1** = 29; **G2** = 21 None (< 50%): **G1:** 7 (24); **G2:** 9 (43) Moderate (50%-74% decrease): **G1:** 8 (28); **G2:** 4 (19) Marked (75%-99% decrease): **G1:** 1 (3); **G2:** 3 (14) Remission (100%): **G1:** 13 (45) *(P* = NR) **G2:** 5 (24) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **Percentage decrease in frequency of binges: N (%)** Completers sample: **G1** = 23; **G2** = 12 None (< 50%): **G1:** 4 (17); **G2:** 4 (33) Moderate (50%-74% decrease): **G1:** 5 (22); **G2:** 2 (17) Marked (75%-99% decrease): **G1:** 1 (4); **G2:** 3 (25) Remission (100%): **G1:** 13 (57); **G2:** 2 (25) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
	Abstinence rate, N (%): **G1:** NR **G2:** NR	**Abstinence rate N (%):** **G1:** 13 (45) *(P* = NR) **G2:** 5 (24) *(P* = NR) *(P* = NR)

Evidence Table 10. Medication trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
CGI-S, mean (SD): **G1:** 4.2 (0.4) **G2:** 4.3 (0.6) *(P* = NS)	**6 wks:** **CGI-S, mean (SE):** **G1:** 2.2 (1.4) **G2:** 3.3 (1.4) Diff between groups *(P* = NR) Diff between groups in change over time (time trend analysis, *P* = 0.032; endpoint analysis, *P* = 0.012) G1better than G2	**Baseline:** **Wt, kg (SD):** **G1:** 110.4 (24.1) **G2:** 103.5 (19.0) *(P* = NS)	**6 wks:** **Wt, kg (SE):** **G1:** 112.5 (25.0) **G2:** 110.3 (18.2) Diff between groups *(P* = NR) Diff between groups in change over time (time trend analysis, *P* = 0.001; endpoint analysis, *P* = 0.0001) G1 better than G2
HAM-D, mean (SD): **G1:** 4.8 (4.3) **G2:** 4.2 (2.9) *(P* = NS)	**HAM-D score (SE):** **G1:** 2.6 (3.0) **G2:** 5.5 (4.1) Diff between groups *(P* = NR) Diff between groups in change over time (time trend analysis, *P* = NS; endpoint analysis, *P* = 0.003) G1 better than G2	**BMI, kg/m² (SD):** **G1:** 39.6 (7.0) **G2:** 36.7 (6.8) *(P* = NS)	**BMI, kg/m² (SE):** **G1:** 40.0 (7.2) **G2:** 39.5 (6.3) Diff between groups *(P* = NR) Diff between groups in change over time (time trend analysis, *P* = 0.0001; endpoint analysis, *P* = 0.0001) G1 better than G2
	Interaction effects: No evidence for differential effects in subjects with and without current major depressive disorder.		

Evidence Table 10. Medication trials for binge eating disorder (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Hudson et al., 1998 **Setting:** Outpatient, Harvard Medical School/McLean Hospital, University of Cincinnati and University of Minnesota, USA **Enrollment period:** February to September 1993	**Research objective:** To assess the efficacy of the SSRI fluvoxamine in treating patients with BED in a three-center randomized placebo-controlled trial.	**Groups:** **G1:** Fluvoxamine (N = 42) **G2:** Placebo (N = 43) **Enrollment:** • 115 patients entered study • 85 randomly assigned (Boston = 26; Cincinnati = 30; Minnesota = 29) • 10 participants withdrew before end of 4 wks • Another 8 participants withdrew between wks 4 and 9 • 67 patients completed 9 wks of tx (a sigly greater proportion of patients treated with fluvoxamine discontinued tx because of an adverse medical event or for any reason)	**Age, yrs, mean (SD):** **G1:** 41.2 (9.9) **G2:** 43.0 (9.5) *(P* = NS) **Sex:** Female: **G1:** 93% **G2:** 88% *(P* = NS) **Race/ethnicity:** Caucasian: **G1:** 98% **G2:** 95% *(P* = NS) **Hx of major depression:** **G1:** 48% **G2:** 28% *(P* = NS)

Evidence Table 10. Medication trials for binge eating disorder (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Met draft criteria for BED from the DSM IV, had to have reported a hx of at least 3 BEs per wk for at least 6 mos. Binge defined using DSM IV criteria and the number of calories consumed had to be at least 1500 kcal., had to be aged 18-60, had to wt > 85% of the midpoint of IDW for height. **Exclusion:** Pregnant, lactating, displayed concurrent AN, concurrent or recent (last 1 yr) major depression or obsessive compulsive disorder or lifetime substance abuse, psychosis, mania, or organic dementia, posed a sig suicide risk and received psychotherapy or behavior therapy within 3 mos prior to entry into study, hx of psychosurgery or seizures, hx of any psychiatric disorder that could interfere with diagnostic assessment, tx or compliance, clinically unstable medical illness, clinically sig abnormal lab results, received monoamine oxidase inhibitors, tricyclics, neuroleptics, lithium or fluoxetine in the four wks before randomization, had received investigational meds or depot neuroleptics within 3 mos before randomization and had previously received fluvoxamine.	One wk lead-in period. During lead-in, patients took one capsule each evening. After that, participants randomly assigned to therapy with fluvoxamine or placebo. Participants seen wkly for a total of nine wks. Dose was 50 mg every evening for a min of three days in the initial part of tx. After day 4, dose could be adjusted on an individual basis (50 mg -300 mg) until end of tx. Adjustments to the number of capsules taken per day were made at discretion of investigator and meds was increased until a patient was asymptomatic or intolerant of higher doses. Binges measured by patient diaries including number of capsules of meds taken. Meds compliance also monitored by counting capsules at wkly visits. The diff between fluvoxamine and placebo groups in number of capsules consumed per day was diff for patients who completed 4 and 9 wks of tx *(P* < 0.008 and *P* < 0.007 respectively)	Fisher's exact test for categorical variables and a t test for continuous variables used to compare baseline characteristics. Outcomes analyzed using repeated measures random regression analysis. Analyses also done to ensure that groups did not differ in tx response by center (Boston, Cincinnati and Minneapolis).	**Score:** Fair **Intent to treat:** Yes **Blinding:** Double **Adverse events:** A sig greater percentage of patients receiving fluvoxamine experienced insomnia, nausea and abnormal dreams when compared with patients receiving placebo. The commonly reported adverse events included insomnia, headache, nausea, asthenia, depression, dizziness, somnolence, abnormal dreams, dry mouth, nervousness, and decreased libido. **Funding:** The Upjohn Co. and Solvay Pharmaceuticals

Evidence Table 10. Medication trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Hudson et al., 1998 (continued)	NR	**Binge frequency:** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.006) G1 sig greater rate of reduction than G2 **Remission (ITT):** **G1:** 38% *(P* = NR) **G2:** 26% *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **Remission (9 wk completers):** **G1:** 45% *(P* = NR) **G2:** 24% *(P* = NR) Diff between groups *(P* = 0.04) Diff between groups in change over time *(P* = NR) **Remission (> 4 wk completers):** **G1:** 44% *(P* = NR) **G2:** 24% *(P* = NR) Diff between groups *(P* = 0.04) Diff between groups in change over time *(P* = NR)

Evidence Table 10. Medication trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
HDRS, mean (SD): **G1:** 4.4 (3.6) **G2:** 4.1 (3.7) *(P* = NS)	**HDRS, mean (SD):** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)	**BMI, kg/m^2, mean (SD):** **G1:** 34.2 (6.0) **G2:** 36.8 (8.2) *(P* = NS)	**BMI:** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.04) G1 sig greater rate of reduction than G2
	CGI severity scale: **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.002) G1 sig greater rate of reduction than G2.		
	CGI Improvement scale: **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.02) G1 sig greater rate of increase than G2		

Evidence Table 10. Medication trials for binge eating disorder (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Laederach-Hoffman et al., 1999 **Setting:** Counseling center for wt problems – Medical Outpatient Clinic of the University of Berne, Switzerland **Enrollment period:** NR	**Research objective:** 1) To determine if a combination of imipramine and diet counseling with psych support is more effective in treating obese binge eaters than placebo and diet counseling with psych support. 2) If wt loss achieved during the 8 wks of drug therapy is maintained for subsequent 6 mos, with diet counseling and psyc support continuing during this time.	**Groups:** **G1:** imipramine (25 mg T.I.D.) (N = 15) **G2:** placebo (N = 16) **Enrollment:** • 500 med records screened • 100 records fit criteria • 31 agreed to participate and randomized • 29 completed	**Age, yrs, mean (SD):** **G1:** 40.7 (10.9) **G2:** 35.7 (10.3) *(P* = NS) **Sex:** Female: 27/31 **Race/ethnicity:** NR **Systolic BP, mean (SD):** **G1:** 132.3 (18.0) **G2:** 131.4 (13.5) *(P* = NS) **Diastolic BP, mean (SD):** **G1:** 87.0 (9.4) **G2:** 87.5 (9.1) *(P* = NS)

Evidence Table 10. Medication trials for binge eating disorder (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: BED per DSM IV, overwt or obese defined as BMI > 27.5 kg/m^2, age: 20-60. **Exclusion:** Endocrine disorder, diabetes mellitus, pregnancy, arterial hypertension, renal diseases, pulmonary diseases (chronic obstructive lung disease, bronchial asthma, etc), use of psychoactive meds or appetite suppressants, contraindications for drugs with anticholinergic side effects, psychiatric disorders including cyclothymia, schizophrenia, major depression, personality disorders, concomitant psychotherapy, and other eating disorders including BN (fulfilling all DSM IV criteria) and AN	8 wks of imipramine (25 mg 3X/day TID) or placebo. **Diet counseling** – 30 minutes of individual diet counseling by a dietitian biwkly. **Psych Support** – behavioral oriented: **1)** individual 15-35 minutes sessions biwkly **2)** group therapy for 1.5 hours (N = 10-14) moly guided by an assistant dietitian. Diet counseling and psych support continued for 6 mos.	Repeated measures ANOVA using Bonferroni/Dunn corrections. Fisher PLSD t test (Post-hoc) where appropriate.	**Score:** Fair **Intent to treat:** No **Blinding:** Double **Adverse events:** 2 patients dropped out due to side effects. One G2 patient complained of hunger, sweating, palpitations, arrhythmia, and general malaise. One G1 had skin eruptions and an aversion to tablet intake. After 8 wks, no diff in total number of adverse side effects using the patient termination report score. However, anticholinergic effects (constipation, dry mouth, blurred vision) were more often reported in imipramine group (7 vs 3 times, $P < 0.05$). **Funding:** NR

Evidence Table 10. Medication trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Laederach-Hoffman et al., 1999 (continued)		Estimate is change from baseline, mean (SD)
	BE, mean (SD): **G1:** 7.1 (4.1) **G2:** 7.1 (4.1) *(P* = NS)	**BE, mean** **8 wks:** **G1:** -4.5 (4.2) *(P* < 0.001) **G2:** -1.7 (2.9) *(P* = NS) *(P* = NR) Diff between groups in change over time *(P* < 0.02) G1 better than G2 **32 wks:** **G1:** -3.2 (2.9) **G2:** 0.0 (1.4) *(P* = NR) Diff between groups in change over time *(P* = 0.0001) G1 better than G2

Evidence Table 10. Medication trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
	Estimate is change over time (SD)		Estimate is change over time (SD)
SDS (SD): **G1:** 35.3 (6.3) **G2:** 35.0 (5.8) *(P* = NS)	**SDS:** **G1:** 28.9 (5.8) *(P* = NS) **G2:** 30.8 (7.3) *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)	**Body Weight Index kg/m^2, mean (SD):** **G1:** 36.1 (6.3) **G2:** 43.2 (9.4) *(P* < 0.02)	**Body Weight Index:** **G1:** NR **G2:** NR
		Body Wt, kg, mean (SD): **G1:** 96.0 (14.2) **G2:** 114.8 (29.5) *(P* < 0.05)	**Wt change, kg, mean:** **8 wks:** **G1:** -2.1 (1.7) *(P* = NR) **G2:** 0.2 (3.3) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* < 0.05) G1 better than G2 **32 wks:** **G1:** -5.0 (2.8) *(P* < 0.01) **G2:** + 2.1 (6.8) *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.0002) G1 better than G2
HAM-D, mean (SD): **G1:** 22.6 (9.8) **G2:** 21.3 (12.0) *(P* = NS)	**HAM-D, mean (SD):** **8 wks:** **G1:** -9.6 (7.1) *(P* < 0.001) **G2:** -3.5 (8.9) *(P* = NR) Diff between groups *(P* = 0.02) G1 better than G2 **32 wks:** **G1:** -6.8 (5.0) *(P* < 0.01) **G2:** 0.0 (4.9) *(P* < 0.01) *(P* = NR) Diff between groups in change over time *(P* < 0.0001) G1 better than G2	**Waist Hi*P* Ratio (SD):** **G1:** 0.96 (0.07) **G2:** 1.01 (0.07) *(P* = NS)	

Evidence Table 10. Medication trials for binge eating disorder (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: McElroy, Arnold et al., 2003 **Setting:** Outpatient, University of Cincinnati Medical Center, USA **Enrollment period:** Sept., 1998 through June, 2000	**Research objective:** To assess the efficacy of topiramate in the tx of BED associated with obesity.	**Groups:** **G1:** Topiramate (N = 30) **G2:** Placebo (N = 31) **Enrollment:** • 98 individuals were screened • 61 participants met criteria and agreed to participate • 35 participants completed 14 wks of tx	**Age, yrs, mean (SD):** **G1:** 40.9 (8.2) **G2:** 40.7 (9.1) *(P* = NS) **Sex:** NR **Race/ethnicity:** NR

Evidence Table 10. Medication trials for binge eating disorder (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Aged 18-60, DSM IV TR criteria for BED; obese (BMI > 30 kg/m2) and score > 15 on YBOCS-BE. **Exclusion:** 1) substance use disorder (DSM IV TR) within the last 6 mos, 2) unstable bipolar disorder (DSM IV TR) within the past 3 mos, 3) clinically sig suicidality, 4) any current or past psychiatric disorder that could interfere with diagnostic assessment, tx or adherence, 5) clinically unstable medical illness, 6) hx of nephrolithiasis or seizures, 7) clinically sig abnormal laboratory results, 8) need for tx with any meds that might adversely interact with or obscure the action of topiramate, 9) tx with psychoactive meds within two wks of random assignment, 10) tx with an experimental drug or an experimental device within 30 days of random assignment, or 11) previous tx with topiramate.	2-5 wk screening period, followed by 14-wk tx period (topiramate flexible-dose 25 mg- 600mg/d; median 212mg/d) and 2-wk taper and discontinuation period. Patients evaluated at least twice during screening period and after wks 1, 2, 4, 6, 8, 10 and 14 during tx. They were seen at the end of wks 15 and 16 during discontinuation. For primary efficacy measure, patients given take-home diaries at each visit and asked to record binges and meds (once begun). Study meds provided in pre-packaged bottles that were identical for placebo and meds.	Baseline characteristics compared using Fisher's exact test and t test. For primary analyses, used repeated measures random regression analyses. Also, nonparametric Wilcoxon rank sum test used to compare change from baseline for each group.	**Score:** Fair **Intent to treat:** Yes **Blinding:** Double **Adverse events:** 9 individuals withdrew because of adverse events (G1 = 6; G2 = 3) **G1:** headache, paresthesias and amenorrhea. **G2:** leg cramps, sedation and testicular soreness. Adverse events among individuals who continued in the study were reported to be "mild" or "moderate" and "resolved with time or dose reduction". **Funding:** Ortho McNeill Pharmaceutical

Evidence Table 10. Medication trials for binge eating disorder (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: McElroy, Arnold et al., 2003 (continued)	**Binge frequency per wk:** **G1:** 5.3 (2.8) **G2:** 6.3 (2.8) *(P* = NS)	**Reduction in binge frequency per wk:** **G1:** 94% **G2:** 46% Diff between groups *(P* = NS) Diff between groups in change over time *(P* = 0.02) Diff between groups in rate of change *(P* < 0.0004) G1 greater reduction than G2
	Binge day frequency per wk: **G1:** 4.3 (1.8) **G2:** 4.8 (1.8) *(P* = NS)	**Reduction in binge day frequency per wk:** **G1:** 93% **G2:** 46% Diff between groups *(P* = NS) Diff between groups in change over time *(P* = 0.02) Diff between groups in rate of change *(P* < 0.0001) G1 greater reduction than G2
	YBOCS-BE total, mean (SD): **G1:** 21.5 (3.9) **G2:** 21.6 (4.6) *(P* = NS)	**YBOCS-BE total, mean (SD):** **G1:** NR **G2:** NR *(P* = NR) Diff between groups in rate of change *(P* < 0.004) G1 greater improvement than G2
	YBOCS-BE Obsessions, mean (SD): **G1:** 10.5 (2.1) **G2:** 10.7 (2.4) *(P* = NS)	**YBOCS-BE Obsessions, mean (SD):** **G1:** NR **G2:** NR *(P* = NR) Diff between groups in rate of change *(P* < 0.04) G1 greater improvement than G2
	YBOCS-BE Compulsions, mean (SD): **G1:** 11.0 (2.1) **G2:** 10.7 (2.4) *(P* = NS)	**YBOCS-BE Compulsions, mean (SD):** **G1:** NR **G2:** NR *(P* = NR) Diff between groups in rate of change *(P* < 0.0008) G1 greater improvement than G2

Evidence Table 10. Medication trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
CGI severity, mean (SD): **G1:** 4.7 (0.9) **G2:** 4.9 (0.8) *(P* = NS)	**CGI severity, mean (SD):** **G1:** NR **G2:** NR Diff between groups *(P* = 0.01) Diff between groups in rate of change *(P* < 0.02) G1 greater improvement than G2	**BMI kg/m^2, mean (SD):** **G1:** 44.2 (7.1) **G2:** 42.0 (6.7)	**BMI:** **G1:** NR **G2:** NR *(P* = NR) Diff between groups in rate of change *(P* < 0.003) G1 greater improvement than G2
HDRS, mean (SD): **G1:** 5.9 (5.1) **G2:** 5.8 (4.8) *(P* = NS)	**HDRS, mean (SD):** **G1:** NR **G2:** NR *(P* = NR) Diff between groups in rate of change *(P* = NS)	**Wt kgs, mean (SD):** **G1:** 120.4 (18.8) **G2:** 123.4 (24.4)	**Wt loss, kg, mean:** **G1:** 5.9 **G2:** 1.2 *(P* = NR) Diff between groups in rate of change *(P* < 0.005) G1 greater improvement than G2

Evidence Table 10. Medication trials for binge eating disorder (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: McElroy et al., 2000 **Setting:** Outpatient; single center; USA **Enrollment period:** NR	**Research objective:** Placebo-controlled trial to assess the efficacy of the SSRI sertraline in the tx of BED.	**Groups:** **G1:** Sertraline (N = 18) **G2:** Placebo (N = 16) **Enrollment:** • 34 randomized and enrolled • 26 (13 in each group) completed 6 wks tx	**Age, mean (SD):** **G1:** 43.1 (9.9) **G2:** 41.0 (12.2) *(P* = NS) **Sex:** **G1:** Female: 89% **G2:** Female: 100% *(P* = NS) **Race/ethnicity:** NR **Current major depressive disorder:** **G1:** 17% **G2:** 19% *(P* = NS) **Lifetime major depressive disorder:** **G1:** 61% **G2:** 44% *(P* = NS)

Evidence Table 10. Medication trials for binge eating disorder (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: DSM IV criteria for BED and had experienced ≥ 3 BE/wk for at least prior 6 mos; BE defined by DSM IV criteria plus required size at least 1500 kcal 18-60 yrs wt > 85% of IBW. **Exclusion:** Current AN dx; substance use disorder within past 6 mos; hx of psychosis or mania; risk of suicide; use of psychotropics within 2 wks of randomization; previous use of sertraline; < 3 binges in the wk prior to randomization.	1 wk of single-blind placebo administration followed by randomization to sertraline or placebo group for 6 wks. Tx dose began at 1 capsule of 50mg/day for at least 3 days; after, adjusted as tolerated to between 1 to 4 capsules daily. Mean end of study dose in **G1:** 187 mg (SD = 30). Subjects monitored binges using diaries. Wkly clinical interviews assessed binges since last visit, CGI ratings, meds dose, and wt. At wks 0, 2, 4, 6, HDRS was administered.	Except for response category, repeated measures random regression analyses used to assess outcomes, using tx-by-time as the effect measure. Binge frequency was analyzed using logarithmic transformation to stabilize variance. Response category diff compared by exact trend test for two-by-k-ordered tables.	**Score:** Good **Intent to treat:** Yes **Blinding:** Single-blind placebo administration; double-blind randomization and tx **Adverse events:** No subjects withdrew due to adverse events **Participants experiencing insomnia:** **G1:** 7 (39%) **G2:** 1 (6%) (*P* = 0.04) **Funding:** In part by Pfizer, Inc.

Evidence Table 10. Medication trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: McElroy et al., 2000 (continued)	**Binges/wk, mean (SD):** **G1:** 7.6 (4.8) **G2:** 7.2 (5.8) *(P* = NS)	**Binges/wk, mean (SD):** **G1:** 1.13 (1.56) *(P* = NR) **G2:** 3.85 (3.81) *(P* = NR) Diff between groups (*P* = NR) Diff between groups in change over time *(P* = 0.008) G1 better than G2 **Frequency of binges:** Percentage decrease measured by categorical change in response: Remission or cessation of binges: **G1:**7; **G2:** 2 Marked = 75%-99% decrease: **G1:** 2; **G2:**3 Moderate = 50%-74% decrease: **G1:** 3; **G2:** 4 None = < 50% decrease: **G1:** 0; **G2:** 4 Diff between groups in change over time *(P* = NS)

Evidence Table 10. Medication trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
HDRS (SD): **G1:** 6.4 (3.9) **G2:** 7.5 (8.4) *(P* = NS)	**HDRS:** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Diff between groups (*P* = NR) Diff between groups in change over time (SE): 1.33 (1.00) *(P* = NS)	**BMI, kg/m², mean (SD):** **G1:** 36.4 (7.4) **G2:** 35.8 (7.5) *(P* = NS)	**BMI, kg/m²:** **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Diff between groups (*P* = NR) Diff between groups in change over time (SE): -0.596 (0.189*)* *(P* = 0.002) G1 better than G2
	CGI score: Severity **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Diff between groups (*P* = NR) diff between groups in change over time (SE): -1.007 (0.183) *(P* < 0.001) G1 better than G2		
	CGI score: Improvement: **G1:** NR *(P* = NR) **G2:** NR *(P* = NR) Diff between groups (*P* = NR) Diff between groups in change over time (SE): 0.929 (0.230*) (P* < 0.001) G1 better than G2		

Evidence Table 10. Medication trials for binge eating disorder (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: McElroy, Hudson et al., 2003 **Setting:** Single center; outpatient; USA **Enrollment period:** August 2000 through July 2001	**Research objective:** Placebo-controlled, randomized trial to assess the safety and efficacy of citalopram (Celexa), an SSRI, in BED	**Groups:** **G1:** Citalopram (N = 19) **G2:** Placebo (N = 19) **Enrollment:** • 50 screened who were recruited through advertisements (12 of these did not meet criteria and were not enrolled) • 38 enrolled (19 assigned to each group) • 31 after 4 wks	**Age, yrs, mean (SD):** **G1:** 42.0 (9.0) **G2:** 39.2 (12.0) *(P* = NS) **Sex:** Female: 95% *(P* = NS) **Race/Ethnicity:** White: **G1:** 79% **G2:** 95% *(P* = NS) **Current major depressive disorder:** **G1:** 21% **G2:** 42% *(P* = NS) **Lifetime major depressive disorder:** **G1:** 63% **G2:** 74% *(P* = NS)

Evidence Table 10. Medication trials for binge eating disorder (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Met DSM IV criteria for BED and had also experienced ≥ 3 binge-eating episodes wkly for at least the prior 6 mos; 18 to 60 yrs; wt > 85% of IBW. **Exclusion:** Pregnant or lactating; concurrent AN or BN; concurrent or recent (within 1 yr of study entry) substance abuse or dependence: lifetime hx of psychosis, mania or hypomania, or dementia: hx of any psychiatric disorder that could interfere with diagnostic assessment, tx, or compliance: posed a sig suicide risk; received psychotherapy or behavioral therapy within 3 mos of entry into study; clinically unstable medical illness; hx of seizures; clinically sig laboratory abnormalities; received monoamine oxidase inhibitors within 4 wks of randomization; received other psychotropic meds within 2 wks of randomization; received investigational meds or depot neuroleptics within 3 mos of randomization; previously treated with citalopram; experienced < 3 binges in the wk before randomization (i.e., were considered placebo responders).	1 wk of single-blind placebo administration, followed by random assignment to citalopram or placebo for 6 wks. Randomized tx began with 20 mg/day for first 7 days; increased as tolerated to 40 mg/day for 7 days, and then 60 mg/day for remainder of study. Meds could be reduced to min of 1 capsule (20 mg) daily if intolerable side effects at any time during tx period. End of study dose in G1 and G2 60 mg for 17 subjects and 40 mg for 2 subjects in each group. Subjects monitored binges and meds through diaries. Binge defined using DSM IV criteria, assessed via wkly clinical interview and subjects' diaries. Diaries recorded binges, duration of binges, food consumed during binges.	Repeated-measures random regression analyses, sometimes referred to as mixed-model repeated-measures analyses.	**Score:** Fair **Intent to treat:** Yes **Blinding:** Double **Adverse events:** Sweating *(P* = 0.008), fatigue *(P* = 0.046), dry mouth, headache, diarrhea, nausea, sedation, insomnia, sexual dysfunction *(P* = NS) **Funding:** In part by Forest Laboratories

Evidence Table 10. Medication trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: McElroy, Hudson et al., 2003 (continued)	**Binges/wk, mean (SD):** **G1:** 5.2 (3.6) **G2:** 5.7 (2.6) *(P* = NS)	**Binges/wk, mean (SD):** **G1:** 1.7 (3.1) **G2:** 3.4 (3.0) Change over time from baseline to wk 6: -0.375 (0.222) *(P* = NS) Rate of change: -0.311 (0.086) *(P* = 0.003) G1 better than G2
	Binge days/wk frequency, mean (SD): **G1:** 4.0 (1.7) **G2:** 4.0 (1.5) *(P* = NS)	**Binge days/wk, mean (SD):** **G1:** 1.2 (2.0) **G2:** 2.8 (2.2) Change over time from baseline to wk 6: -0.488 (0.199) *(P* = 0.016) G1 better than G2 Rate of change: -0.324 (0.076) *(P* = < 0.001) **Frequency of binges:** Percentage decrease measured by categorical change. diff between remission (cessation of binges): • marked (75%-99% decrease) • moderate (50%-74% decrease) • none (< 50% decrease) *(P* = NS)
	YBOCS-BE score Total, mean (SD): **G1:** 19.4 (4.2) **G2:** 18.5 (3.1) *(P* = NS)	**YBOCS-BE score Total:** **G1:** 7.6 (7.2) **G2:** 13.2 (5.9) Change over time from baseline to wk 6:-5.73 (2.33) *(P* = 0.007) G1 better than G2 Rate of change: -3.73 (1.37) *(P* = 0.007) G1 better than G2
	YBOCS-BE score Obsessions, mean (SD): **G1:** 9.3 (2.2) **G2:** 9.3 (1.8) *(P* = NS)	**YBOCS-BE Score Obsessions:** **G1:** 4.3 (3.6) **G2:** 6.8 (2.6) Change over time from baseline to wk 6: -2.48 (1.22) *(P* = 0.04) G1 better than G2 Rate of change: -1.44 (0.72) *(P* = 0.05) G1 better than G2
	YBOCS-BE score Compulsions, mean (SD): **G1:** 10.1 (2.2) **G2:** 9.2 (1.7) *(P* = NS)	**YBOCS-BE Score Compulsions:** **G1:** 3.4 (3.9) **G2:** 6.4 (3.6) Rate of change: -2.26 (0.72) *(P* = 0.002) G1 better than G2 Change over time from baseline to wk 6: -2.88 (1.27) *(P* = 0.02) G1 better than G2

Evidence Table 10. Medication trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
CGI-S, mean (SD): **G1:** 4.5 (0.7) **G2:** 5.0 (0.7) *(P* = 0.03)	**CGI-S, mean (SD):** **G1:** 2.4 (1.4) **G2:** 3.6 (1.7) Change over time from baseline to wk 6: *(P* = NS) Rate of change: -0.475 (0.217) *(P* = 0.028) G1 better than G2	**BMI, kg/m^2, mean (SD):** **G1:** 41.4 (6.9) **G2:** 34.2 (7.4) *(P* = 0.003)	**BMI, kg/m^2, mean (SD):** **G1:** 40.9 (7.0) **G2:** 35.7 (7.5) Change over time from baseline to wk 6: -0.818 (0.254) *(P* = 0.001) Rate of change: -0.525 (0.145) *(P* < 0.001) G1 greater than G2
HAM-D, mean (SD): **G1:** 3.1 (3.2) **G2:** 2.7 (3.7) *(P* = NS)	**HAM-D, mean (SD):** **G1:** 1.4 (2.3) **G2:** 1.9 (3.1) Change from baseline to wk 6 *(P* = NS) Rate of change: -1.05 (0.54) *(P* = 0.05) G1 better than G2	**Wt, kg, mean (SD):** **G1:** 116.8 (21.0) **G2:** 94.6 (23.2) *(P* = 0.004)	**Wt, kg, mean (SD):** **G1:** 114.1 (22.4) **G2:** 99.8 (24.7) Change over time from baseline to wk 6:-2.49 (0.66) *(P* < 0.001) G1 better than G2 Rate of change: -1.43 (0.40) *(P* < 0.001) G1 better than G2
			Interaction effects: No differential effects in subjects with and without current major depressive disorder or by varying BMI at baseline

Evidence Table 10. Medication trials for binge eating disorder (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Pearlstein et al., 2003 **Setting:** Outpatient program; single center; USA **Enrollment period:** NR	**Research objective:** To replicate the findings of previous double-blind RCT of fluvoxamine on BED. This trial was 12 wks rather than 9 and used EDE to classify BE; to assess tx effects on associated ED psychopathology as measured by EDE.	**Groups:** **G1:** Fluvoxamine (N = 9) **G2:** Placebo (N = 11) **Enrollment:** • 25 recruited via ads and referral • 25 screened • 20 completed	**Age, yrs, mean:** 41.0 **Sex:** Female: 17 Male: 3 **Race/ethnicity:** Caucasian: 90% **Marital status:** Currently married: 70% **Employment status:** Currently employed: 90% **Avg BMI (kg/m^2):** 41.16

Evidence Table 10. Medication trials for binge eating disorder (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: DSM IV research criteria for BED based on EDE **Exclusion:** NR	Prior to tx, all subjects completed two intake assessment sessions, 1 wk apart. At the first, BED dx was confirmed using EDE, and subjects instructed on completing food logs; At the second, the SCID, HAM-D, and CGI were administered, and SCL-90 and BDI were completed. After 1 wk of single-blind placebo, subjects randomized to flexible dose tx or placebo; tx was titrated up to 150 mg b.i.d. Avg dose for tx was 239 mg/day, 264 mg/day for placebo. Tx lasted 12 wks; first 6 wks, subjects met wkly with research nurse and psychiatrist, and biwkly for final 6 wks. Visits included collecting food logs, vital signs, noting adverse events, distributing materials on healthy eating, distributing study meds, determining dosage by response and tolerability. At wk 12, subjects received EDE and HAM-D by blinded- interview, and completed self-report questionnaires. Post-study, subjects offered continued tx.	Independent samples t-tests to measure between-group change. Repeated measures ANOVAs to determine effect of tx on outcome variables after trial end.	**Score:** Good **Intent to treat:** NR **Blinding:** Double **Adverse events, N:** **In study completers:** **Sedation:** **G1:** 8 **G2:** 3 **Nausea:** **G1:** 4 **G2:** 1 **Dry mouth:** **G1:** 4 **G2:** 3 **Decreased libido:** **G1:** 3 **G2:** 0 **Funding:** Solvay Pharmaceuticals

Evidence Table 10. Medication trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Pearlstein et al., 2003 (continued)	**Number of days with binges, past 28 days, mean (SD):** **G1:** 14.67 (55.68) **G2:** 20.00 (6.21) *(P* = NS) **Binge frequency:** **G1:** NR **G2:** NR *(P* = NS)	**Number of days with binges, past 28 days, mean (SD):** **G1:** 3.11 (4.20) **G2:** 7.31 (9.31) Diff between groups *(P* = NR) Change over time for both groups *(P* < 0.001) Diff between groups in change over time *(P* = NS)
	EDE Restraint, mean (SD): **G1:** 2.04 (1.24) **G2:** 1.60 (1.08) *(P* = NS)	**EDE Restraint, mean (SD):** **G1:** 0.91 (0.78) **G2:** 1.45 (0.98) Diff between groups *(P* = NR) Change over time for both groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	EDE Eating Concern, mean (SD): **G1:** 1.10 (0.96) **G2:** 1.82 (1.02) *(P* = NS)	**EDE Eating Concern, mean (SD):** **G1:** 0.31 (0.39) **G2:** 0.44 (0.55) Diff between groups *(P* = NR) Change over time for both groups *(P* < 0.001) Diff between groups in change over time *(P* = NS)
	EDE Shape Concern, mean (SD): **G1:** 3.38 (0.74) **G2:** 3.56 (0.43) *(P* = NS)	**EDE Shape Concern, mean (SD):** **G1:** 2.24 (0.85) **G2:** 2.50 (1.15) Diff between groups *(P* = NR) Change over time for both groups *(P* < 0.001) Diff between groups in change over time *(P* = NS)
	EDE Wt Concern, mean (SD): **G1:** 3.73 (0.49) **G2:** 3.32 (0.94) *(P* = NS)	**EDE Wt Concern, mean (SD):** **G1:** 2.40 (1.22) **G2:** 2.36 (1.07) Diff between groups *(P* = NR) Change over time for both groups *(P* < 0.001) Diff between groups in change over time *(P* = NS)

Evidence Table 10. Medication trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BDI, means per item (SD): **G1:** 0.44 (0.22) **G2:** 0.68 (0.57) *(P* = NS)	**BDI, means (SD):** **G1:** 0.32 (0.30) **G2:** 0.37 (0.26) Diff between groups *(P* = NR) Change over time for both groups *(P* < 0.01) Diff between groups in change over time *(P* = NS)	**Wt, lbs, mean (SD):** **G1:** 243 (85) **G2:** 258 (96) *(P* = NS)	**Wt, lbs, mean (SD):** **G1:** 242 (82) **G2:** 262 (99) Diff between groups *(P* = NR) Change over time for both groups *(P* = NS) Diff between groups in change over time *(P* = NS)
HAM-D, mean (SD): **G1:** 10.78 (9.22) **G2:** 14.27 (12.40) *(P* = NS)	**HAM-D, mean (SD):** **G1:** 9.38 (9.71) **G2:** 7.38 (9.71) Diff between groups *(P* = NR) Change over time for both groups *(P* = NS) Diff between groups in change over time *(P* = NS)		
SCL-90, mean (SD): **G1:** 0.62 (0.33) **G2:** 0.85 (0.55) *(P* = NS)	**SCL-90, mean (SD):** **G1:** 0.30 (0.29) **G2:** 0.40 (0.29) Diff between groups *(P* = NR) Change over time for both groups *(P* < 0.001) Diff between groups in change over time *(P* = NS)		

Evidence Table 10. Medication trials for binge eating disorder (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Stunkard et al., 1996 **Setting:** Outpatient, Wt and Eating Disorders Program, University of Pennsylvania, Philadelphia, PA, USA **Enrollment period:** NR	**Research objective:** RCT investigating use of d-fenfluramine for tx of BED	**Groups:** **G1:** d-fenfluramine (N = 14) **G2:** placebo (N = 14) **Enrollment:** • 1450 screened using two-stage procedure (structured telephone interview followed by face-to-face interview) • 50 met criteria • All received placebo for 4 wks • After 4 wks, only 28 continued to meet criteria • 14 randomly assigned to each of the two groups • 2 from each group dropped out in the first two wks of tx	**Age, mean (SD):** NR **Sex:** Female: 100% **Race/ethnicity:** NR **Binges per wk in the first wk, mean (SD):** **G1:** 2.2 (1.3) **G2:** 2.3 (2.0) **BMI, kg/m2, mean (SD):** (N = 22) 36.7 (5.8)

Evidence Table 10. Medication trials for binge eating disorder (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Met criteria for BED established by Spitzer et al. (1992) and used in DSM IV; female. **Exclusion:** None	Placebo for 4 wks. Only patients who continued to meet criteria (binges on at least 2 days per wk) were randomized. Patients in the meds group received 15 mg of d-fenfluramine once a day for the first wk, twice a day for the next 6 wks and once a day for the eighth wk.	Sig of the diff in the two groups tested by student's t test. Multiple linear regression analyses used to test for sig grp diff while controlling for baseline depression and wt. Slopes reported for change in binge days; eating inventory, eating habits checklist; but no values at FU intervals reported.	**Score:** Fair **Intent to treat:** NR **Blinding:** Double **Adverse events:** Reported for patients in both groups. Headache and diarrhea more common in meds than placebo grp. For one patient in drug grp, moderately severe rash reported which went away 3 mos after discontinuation of drug. **Funding:** Servier Amerique and NIMH

Evidence Table 10. Medication trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Stunkard et al., 1996 (continued)	**Binges per wk, mean (SD):** **G1:** 2.2 (1.3) **G2:** 2.3 (2.0) *(P* = NS)	**Binges per wk, mean (SD):** **Post tx:** **G1:** 0.6 (1.0) *(P* = 0.0001) **G2:** 2.3 (2.9) *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.02) G1 better than G2 Diff between groups in change over time (controlling for baseline wt and depression scores) *(P* = 0.01) **1 mo FU:** **G1:** 1.3 **G2:** 1.1 Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **4 mo FU:** **G1:** 1.8 **G2:** 1.3 Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
	Binge days per wk, mean (SD): **G1:** 2.45 (1.00) **G2:** 2.39 (1.32) *(P* = NS)	**Change binge days per wk, mean (SD):** **G1:** -0.24 (0.13) **G2:** -0.15 (0.16) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	Gormally Eating Habits Checklist, mean (SD): **G1:** 27.83 (10.60): **G2:** 22.25 (8.67) *(P* = NS)	**Change Gormally Eating Habits Checklist, mean (SD):** **G1:** -0.65 (1.04) **G2:** -0.08 (0.73) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	Eating Inventory – Restraint, mean (SD): **G1:** 9.63 (5.91) **G2:** 9.16 (3.76) *(P* = NS)	**Change Eating Inventory – Restraint, mean (SD):** **G1:** 0.23 (0.52) **G2:** 0.14 (0.37) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	Eating Inventory-Disinhibition, mean (SD): **G1:** 12.80 (3.24) **G2:** 12.17 (3.09) *(P* = NS)	**Change Eating Inventory-Disinhibition, mean (SD):** **G1:** -0.18 (0.54) **G2:** -0.03 (0.23) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	Eating Inventory – Hunger score, mean (SD): **G1:** 9.51 (4.17) **G2:** 8.56 (3.05) *(P* = NS)	**Change Eating Inventory – Hunger score, mean (SD):** **G1:** -0.15 (0.46) **G2:** 0.02 (0.19) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
		Abstinence % (completers): **G1:** 80% **G2:** 33% Diff between groups *(P* = NR)

Evidence Table 10. Medication trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BDI, mean (SD): **G1:** 15.31 (8.18) **G2:** 9.76 (9.75) *(P* = NS)	**Change BDI, mean (SD):** **G1:** -0.21 (0.50) **G2:** -0.04 (0.46) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)	**Wt lbs, mean (SD):** **G1:** 238.30 (50.20) **G2:** 210.0 (33.80) *(P* = NS)	**Change wt lbs, mean (SD):** **G1:** -0.02 (0.93) **G2:** 0.06 (0.70) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 11. Medication plus behavioral intervention trials for binge eating disorder

Study Description	Objective	Design	Patient Characteristics
Author, yr: Agras et al., 1994 **Setting:** Outpatient, Stanford University, CA, USA **Enrollment period:** NR	**Research objective:** To compare the effects of wt loss tx, CBT, and desipramine on binge eating and wt in a 3 group additive design in overwt participants with BED.	**Groups:** **G1:** wt loss therapy for 9 mos (N = 37) **G2:** CBT for 3 mos followed by wt loss therapy for 6 mos (CBT/WL) (N = 36) **G3:** CBT for 3 mos followed by both wt loss therapy and desipramine for 6 mos (CBT/WL-D) (N = 36) **Enrollment:** Randomized: 109 Drop out, N (%): **G1:** 10 (27%) **G2:** 6 (17%) **G3:** 8 (23%) *(P* = NS) End of tx: N = 88 **3 mo FU:** **Drop out, N:** **G1:** 6 **G2:** 5 **G3:** 3	**Age yrs, mean (SD) (range):** 45.0 (10) (22 – 65) *(P* = NR) **Sex:** Female: 100% **Race/ethnicity:** NR **BMI, mean (SD):** 38.6 (6.6) **Age of onset of BE yrs, mean (SD):** 19 (10.7) *(P* = NR) **Age of onset of overwt yrs, mean (SD):** 15.5 (10.2) *(P* = NR) **Education:** College grad: 55% Some college: 38%

Evidence Table 11. Medication plus behavioral intervention trials for binge eating disorder (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: DSM IV criteria for BED **Exclusion:** Current involvement in a wt loss program, currently taking antidepressant meds or any meds that might influence wt, sufficient suicidality that may make outpt tx with desipramine dangerous, drug/alcohol abuse, hx of purging within the prior 12 mo, BMI < 27.	**G1:** Wt loss-30 90-minutes group sessions wkly for the first 24 wks and then bi-wkly. Based on modified LEARN program (without BE materials). Focus on gradual lifestyle changes. **G2:** CBT based on manual by Telch et al., for BED for 12 wkly sessions. Followed by 18 sessions of the wt loss therapy as described above. **G3:** Following completion of CBT, received desipramine and wt loss therapy. Seen in small groups immediately before or after wt loss groups (wkly for first 4 wks, bi-wkly for 4 wks, and then at 4-wk intervals). Groups conducted by psychiatrist who explained meds. Began on 25 mg and dose increased depending on side effects and therapeutic effects to a max dose of 300 mg. Discontinued over a 2-wk period following post-tx assessment. Mean dose 285 mg with a mean blood level of 212 ng/mL. **Assessments**: baseline, wk 12, 24, 36 (Post-tx), 3-mo FU	Repeated measures ANOVA followed by ANCOVAs (controlling for baseline characteristics) at each time point. Pairwise comparisons to determine diff between groups. At wk 12, analysis of G2 and G3 are combined.	**Score:** Fair **Intent to treat:** No **Blinding:** No **Adverse events:** 24% discontinued desipramine before the post tx assessment because of side effects. **Funding:** NIH

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Agras et al., 1994 (continued)	**Binges/wk, mean (SD):** **G1:** 4.5 (1.6) **G2:** 4.4 (1.4) **G3:** 5.1 (1.4) *(P* = NS)	**Binges/wk, mean (SD):** **12 wks:** **G1:** 2.5 (1.9) **G2:** 1.5 (1.4) **G3:** 1.8 (1.3) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.01) G2 + G3 better than G1 **24 wks:** **G1:** 1.2 (1.2) **G2:** 1.1 (1.1) **G3:** 1.6 (1.8) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **36 wks (Post-tx):** **G1:** 1.5 (0.2) **G2:** 1.2 (1.3) **G3:** 0.9 (0.9) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **3 mo FU:** **G1:** 2.0 **G2:** 1.7 **G3:** 1.5 Diff between groups *(P* = NR)

Evidence Table 11. Medication plus behavioral intervention trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BDI, mean (SD): **G1:** 12.9 (6.5) **G2:** 13.5 (7.8) **G3:** 13.7 (8.1) *(P* = NS)	**BDI, mean (SD):** **12 wks:** **G1:** 11.6 (8.0) **G2:** 12.7 (9.2) **G3:** 10.8 (8.9) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **24 wks:** **G1:** 11.2 (8.5) **G2:** 8.5 (6.5) **G3:** 8.6 (8.2) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **36 wks:** **G1:** 11.3 (10.3) **G2:** 8.9 (7.6) **G3:** 7.8 (7.8) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)	**Wt, kg, mean (SD):** **G1:** 102.9 (15.8) **G2:** 102.1 (15.7) **G3:** 111.9 (17.4) *(P* = NS)	**Wt, kg, mean (SD):** **12 wks:** **G1:** 100.9 (16.8) *(P* = NR) **G2:** 102.7 (16.5) *(P* = NR) **G3:** 112.7 (18.5) *(P* = NR) Diff between groups *(P* = NR) Diff between groups (G2 + G3) vs G1 in change over time *(P* < 0.002) G1 better than G2, G3 **24 wks:** **G1:** 100.4 (17.3) **G2:** 100.7 (16.7) **G3:** 107.0 (20.1) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **36 wks:** **G1:** 99.2 (16.9) **G2:** 100.5 (17.6) **G3:** 105.9 (20.5) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **3 mo FU** **Wt change from baseline, kg, mean:** **G1:** -4.15 **G2:** 0 **G3:** -4.8 Diff between groups *(P* = NS) Diff between groups (G2 vs G3) in change over time *(P* < 0.05) G3 better than G2 G1 vs G2 *(P* = NS) G1 vs G3 *(P* = NS)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Agras et al., 1994 (continued)	**TFEQ-Disinhibition, mean (SD):** **G1:** 13.7 (1.8) **G2:** 14.0 (1.1) **G3:** 14.6 (1.2) Diff between G1 vs G3 *(P* < 0.03) G3 higher disinhibition Diff between G1 vs **G2 *(P*** = NS) Diff between G2 vs **G3 *(P*** = NS)	**TFEQ - Disinhibition, mean (SD):** **12 wks:** **G1:** 12.7 (2.6) **G2:** 12.7 (1.8) **G3:** 12.2 (2.3) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **24 wks:** **G1:** 11.7 (3.0) **G2:** 10.8 (2.7) **G3:** 9.7 (3.5) Diff between groups *(P* = NR) Diff between groups (G1 vs G3) in change over time *(P* < 0.008) G3 less disinhibited vs G1 Diff between G1 vs G2 in change over time *(P* = NS) Diff between G2 vs G3 in change over time *(P* = NS) **36 wks (Post-tx):** **G1:** 11.6 (2.6) **G2:** 10.8 (3.1) **G3:** 10.2 (4.2) *(P* = NR) Diff between groups in change over time *(P* = NS)
	TFEQ-Hunger, mean (SD): **G1:** 10.3 (2.9) **G2:** 9.1 (2.9) **G3:** 10.6 (2.6) Diff between groups *(P* = NS)	**TFEQ - Hunger, mean (SD):** **12 wks:** **G1:** 9.4 (3.2) **G2:** 7.8 (3.1) **G3:** 8.3 (2.4) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **24 wks:** **G1:** 8.5 (3.2) **G2:** 6.2 (2.9) **G3:** 5.8 (3.1) Diff between groups *(P* = NR) Diff groups in change over time G3 less hunger than G1 (*P* < 0.0004) G2 less hunger than G1*(P* < 0.03) G2 vs G3 *(P* = NS) **36 wks (Post-tx):** **G1:** 8.4 (3.2) **G2:** 6.4 (3.2) **G3:** 7.2 (2.8) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 11. Medication plus behavioral intervention trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 11. Medication plus behavioral intervention trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Agras et al., 1994 (continued)	**TFEQ Restraint, mean (SD):** **G1:** 8.7 (4.5) **G2:** 6.6 (2.8) **G3:** 8.2 (3.6) Diff between G1 vs G2 *(P* < 0.05), G1 higher restraint Diff between G2 vs G3 *(P* < 0.05) G3 higher restraint Diff between G1 vs G3 *(P* = NS)	**TFEQ Restraint mean (SD):** **12 wks:** **G1:** 11.2 (5.1) **G2:** 8.5 (3.5) **G3:** 10.4 (0.5) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **24 wks:** **G1:** 12.5 (5.1) **G2:** 10.8 (0.4) **G3:** 14.6 (3.3 Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **36 wks (Post-tx):** **G1:** 12.0 (5.1) **G2:** 10.9 (4.5) **G3:** 13.4 (3.4) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
		Remission of BE, %: **36 wks (Post-tx):** **G1:** 19% **G2:** 37% **G3:** 41% Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **3 mo FU:** **G1:** 14% **G2:** 28% **G3:** 32% Diff between groups *(P* = NR)

Evidence Table 11. Medication plus behavioral intervention trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 11. Medication plus behavioral intervention trials for binge eating disorder (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Grilo, Masheb, and Salant, 2005 **Setting:** Outpatient, Yale University Medical School, USA **Enrollment period:** NR	**Research objective:** To determine whether adding Orlistat (a lipase inhibitor used for txing obesity) to CBT facilitates wt loss in obese individuals with BED	**Groups:** **G1:** Orlistat plus CBT (N = 25) **G2:** Placebo plus CBT (N = 25) **Enrollment:** Telephone Screened: 174 Evaluated: 61 Randomized: 50 **Drop outs:** **G1:** 6 **G2:** 5 **Completed Trial, N (%):** **Total: 39 (78)** **G1:** 19 (76%) **G2:** 20 (80%) *(P* = NS)	**Age, mean (SD):** Range (35-58) **G1:** 45.2 (7.4) **G2:** 47.0 (7.0) *(P* = NS) **Age of onset, yrs, mean (SD):** **G1:** 23.5 (12.2) **G2:** 27.2 (14.0) *(P* = NS) **Sex, Female: N (%):** **G1:** 21 (84%) **G2:** 23 (92%) *(P* = NS) **Race/ethnicity, N (%):** **Caucasian:** **G1:** 22 (88%) **G2:** 22 (88%) **African American:** **G1:** 1 (4%) **G2:** 2 (8%) **Hispanic:** **G1:** 2 (8%) **G2:** 1 (4%) Race/ethnicity *(P* = NS) **Attended or completed college, N (%):** **G1:** 20 (80%) **G2:** 21 (84%) *(P* = NS) **DSM IV Dx, Lifetime, N (%):** **Any Axis 1:** **G1:** 13 (52%) **G2:** 17 (68%) *(P* = NS) **Major depressive disorder:** **G1:** 9 (36%) **G2:** 12 (48%) *(P* = NS) **Dysthymic disorder:** **G1:** 1 (4%) **G2:** 4 (16%) *(P* = NS)

Evidence Table 11. Medication plus behavioral intervention trials for binge eating disorder (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: DSM IV criteria for BED; age: 35-60; BMI ≥ 30. **Exclusion:** Concurrent tx for eating, wt, or psychiatric illness; medical conditions that influence wt or eating (e.g., diabetes or thyroid problems, as determined by laboratory testing); severe current psychiatric conditions requiring diff txs (psychosis, bipolar disorder); pregnancy or lactation.	**CBT:** Individually administered CBT using guided self-help and *Overcoming Binge Eating* (Fairburn 1995). 6 brief individual meetings (15 – 20 minute sessions) during 12 wk period. **Meds:** Orlistat (120 mg 3 times per day) or placebo for12 wks. Patients given a once-daily fat soluble multivitamin to be taken 2 hrs prior to study med at dinner. Clinical mgt of meds included brief individual meetings (10 – 15 m) held wkly during the first 4 wks and then moly. **Diet:** Instructed to eat 3 meals and 2-3 snacks per day; aim for modest balanced calorie diet with goals of 1200 kcal for women and 1500 kcal for men, limit fat to less than 30% of intake, and follow Food Guide Pyramid for balanced food choices and portion sizes. Assessments at end of 12 wks of tx and at 2 mo FU. Encouraged to continue to use CBT teachings during FU but to not take orlistat or begin new tx.	ANCOVA	**Score:** Good **Intent to treat:** Yes **Blinding:** Double **Adverse events:** General side effects were "slightly higher" in G1. Particularly, gastrointestinal events were higher for G1. **Drop out due to side effects:** **G1:** N = 2 **G2:** N = 0 (*P* = NR) **Funding:** American Heart Association; Donaghue Medical Research Foundation

Evidence Table 11. Medication plus behavioral intervention trials for binge eating disorder (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Grilo, Masheb, and Salant; 2005 (continued)			**Anxiety Disorders:** **G1:** 6 (24%) **G2:** 6 (24%) (*P* = NS) **Substance use disorders:** **G1:** 4 (16%) **G2:** 1 (4%) (*P* = NS)

Evidence Table 11. Medication plus behavioral intervention trials for binge eating disorder (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality

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Evidence Table 11. Medication plus behavioral intervention trials for binge eating disorder (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Grilo, Masheb, and Salant, 2005 (continued)		**Remission rates (No OBEs for past 28 days based on EDE), N (%):** **Post Tx:** **G1:** 16 (64%) **G2:** 9 (36%) Diff between groups *(P* = 0.05) G1 better G2 Diff between groups in change over time *(P* = NR) **FU:** **G1:** 13 (52%); *(P* = NR) **G2:** 13 (52%); *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
	EDE Binge episodes (OBE)/ mo: **G1:** 16.4 (8.0) **G2:** 13.5 (6.6) *(P* = NS)	**Binge Eating, OBEs/Mo, mean (SD):** **Post Treatment:** **G1:** 3.2 (5.5) *(P* = NR) **G2:** 3.6 (5.2) *(P* = NR) Diff between groups (*P* = NR) Diff between groups in change over time *(P* = NS) **FU:** **G1:** 3.4 (6.5) *(P* = NR) **G2:** 2.8 (5.3) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	EDE, dietary restraint, mean (SD): **G1:** 2.0 (1.4) **G2:** 2.1 (1.4) *(P* = NS)	**EDE, dietary restraint, mean (SD):** **Post Treatment:** **G1:** 2.1 (2.3) *(P* = NR) **G2:** 2.0 (1.1) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **FU:** **G1:** 2.1 (1.3) *(P* = NR) **G2:** 2.3 (1.3) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	EDE, eating concern, mean (SD): **G1:** 2.6 (1.3) **G2:** 2.7 (1.1) *(P* = NS)	**EDE, eating concern, mean (SD):** **Post Treatment:** **G1:** 0.9 (1.0) *(P* = NR) **G2:** 1.0 (1.0) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **FU:** **G1:** 1.1 (1.3) *(P* = NR) **G2:** 1.2 (1.4) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 11. Medication plus behavioral intervention trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BDI, mean (SD): **G1:** 17.1 (8.9) **G2:** 20.6 (9.6) *(P* = NS)	**BDI, mean (SD):** **Post tx:** **G1:** 10.1 (7.7) *(P* = NR) **G2:** 14.7 (9.0) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **FU:** **G1:** 9.9 (8.6) *(P* = NR) **G2:** 14.6 (10.9) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)	**BMI, kg/m^2, mean (SD):** 36.0 (4.7) **G1:** 36.2 (4.7) **G2:** 36.8 (5.1) *(P* = NS)	**Wt Loss (kg), mean (SD):** **Post-tx:** **G1: -**3.5 (3.5) *(P* = NR) **G2: -**1.6 (2.4) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.02) G1 better than G2 **FU:** **G1:** 3.4 (5.0) *(P* = NR) **G2:** 1.3 (3.1) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **Percentage Wt Loss, mean (SD):** **Post-tx:** **G1:** -3.3% (3.3); *(P* = NR) **G2:** -1.6% (2.4); *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.04) G1 better G2 **FU:** **G1:** 3.4 (5.0) *(P* = NR) **G2:** 1.3 (3.1) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **G1:** 3.3 (5.0) *(P* = NR) **G2:** 1.3 (3.0) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **Achieved ≥ 5% Wt loss, N (%):** **Post-tx:** **G1:** 9 (36%) *(P* = NR) **G2:** 2 (8%) *(P* = NR) Diff between groups *(P* = 0.02) G1 better than G2 Diff between groups in change over time *(P* = NR) **FU:** **G1:** 8 (32%); *(P* = NR) **G2:** 2 (8%); *(P* = NR) Diff between groups *(P* = 0.03) G1 better than G2 Diff between groups in change over time *(P* = NR)

Evidence Table 11. Medication plus behavioral intervention trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Grilo, Masheb, and Salant, 2005 (continued)	**EDE, wt concern, mean (SD):** **G1:** 3.9 (0.8) **G2:** 3.7 (0.7) *(P* = NS)	**EDE, wt concern, mean (SD):** **Post Treatment:** **G1:** 2.8 (1.1) *(P* = NR) **G2:** 3.0 (0.7) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **FU:** **G1:** 2.8 (1.3) *(P* = NR) **G2:** 2.7 (1.1) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	EDE, shape concern, mean (SD): **G1:** 4.3 (0.8) **G2:** 4.4 (0.8) *(P* = NS)	**EDE, shape concern, mean (SD):** **Post Treatment:** **G1:** 2.8 (1.4) *(P* = NR) **G2:** 3.3 (1.1) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **FU:** **G1:** 2.9 (1.6) *(P* = NR) **G2:** 3.0 (1.4) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	EDE interview global score, mean (SD): **G1:** 3.2 (0.9) **G2:** 3.2 (0.7) *(P* = NS)	**EDE interview global score, mean (SD):** **Post Treatment:** **G1:** 2.1 (1.0) *(P* = NR) **G2:** 2.4 (0.7) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **FU:** **G1:** 2.2 (1.1) *(P* = NR) **G2:** 2.3 (1.0) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 11. Medication plus behavioral intervention trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 11. Medication plus behavioral intervention trials for binge eating disorder (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Grilo, Masheb and Wilson, 2005 **Setting:** Outpatient,Yale University; New Haven, CT, USA **Enrollment period:** NR	**Research objective:** To test the efficacy of CBT and fluoxetine alone and in combination for BED.	**Groups:** **G1:** Placebo (N = 27) **G2:** fluoxetine (N = 27) **G3:** CBT + placebo (N = 28) **G4:** CBT + fluoxetine (N = 26) **Enrollment:** Telephone Screened: 410 Personal Interview: 200 Met criteria and were randomized: 108 **Completed, N (%):** **G1:** 23 (85%) **G2:** 21 (78%) **G3:** 22 (79%) **G4:** 20 (77%) *(P* = NS)	**Age, mean (SD):** Range (21-59) **G1:** 43.6 (8.5) **G2:** 44.3 (9.5) **G3:** 43.6 (8.5) **G4:** 44.7 (8.1) *(P* = NS) **Sex:** **Female, N (%):** **G1:** 23 (85.2) **G2:** 19 (70.4) **G3:** 22 (78.6) **G4:** 20 (76.9) *(P* = NS) **Race/ethnicity, N (%):** **Caucasian:** **G1:** 20 (74.1) **G2:** 27 (100) **G3:** 26 (92.9) **G4:** 23 (88.5) **African-American:** **G1:** 5 (18.5) **G2:** 0 (0) **G3:** 2 (7.1) **G4:** 2 (7.7) **Hispanic-American:** **G1:** 2 (7.4) **G2:** 0 (0) **G3:** 0 (0) **G4:** 1 (3.8) *(P* = NS) **Education, N (%):** **Attended/Finished College:** Total Sample: 95 (87%) **College:** **G1:** 13 (48.1) **G2:** 14 (51.9) **G3:** 14 (50.0) **G4:** 11 (42.3) **Some College:** **G1:** 12 (44.4) **G2:** 11 (40.7) **G3:** 9 (32.1) **G4:** 11 (42.3)

Evidence Table 11. Medication plus behavioral intervention trials for binge eating disorder (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: DSM IV criteria for BED; Age: 18-60; 100%-200% of ideal wt for hgt. **Exclusion:** Any concurrent tx for eating, wt, or psychiatric problems; medical conditions (diabetes, thyroid problems, hypoglycemia) that influence wt/eating; severe psychiatric conditions requiring diff txs (psychosis, bipolar disorder); and pregnancy or lactation.	**Pharmacological Treatment:** Fluoxetine (60 mg/day) started immediately and without taper at end of tx. Clinical management involved brief individual meetings (10 – 15 min) held wkly during first 4 wks and bi-wkly thereafter. Meetings focused solely on medical regimen. **CBT:** wkly individual 60-minutes sessions for 16 wks and followed Fairburn's manual for BN. Patients self monitored overeating behaviors including binge eating. Tx: 16 wks	Logistic regression analyses compared remission rates based on self-monitoring across the tx while controlling for the frequency of OBEs for the mo prior to beginning tx as determined at baseline. ANCOVA and repeated measures ANOVAs used for secondary analyses.	**Score:** Good **Intent to treat:** Yes **Blinding:** Double **Adverse events:** NR **Funding:** National Institutes of Healthy. Eli Lily and Co provided fluoxetine and matching Placebo Pills

Evidence Table 11. Medication plus behavioral intervention trials for binge eating disorder (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Grilo, Masheb, and Wilson, 2005 (continued)			HS: **G1:** 2 (7.4) **G2:** 2 (7.4) **G3:** 5 (17.9) **G4:** 4 (15.4) *(P* = NS) **DSM IV Co-morbidity Lifetime, N (%):** Any Axis I Disorder: **G1:** 17 (63.0) **G2:** 20 (74.1) **G3:** 21 (75.0) **G4:** 21 (80.8) *(P* = NS) **Major Depressive Disorder:** **G1:** 12 (44.4) **G2:** 11 (40.7) **G3:** 17 (60.7) **G4:** 14 (50.0) *(P* = NS) **Anxiety Disorders:** **G1:** 10 (37.0) **G2:** 9 (33.3) **G3:** 13 (46.4) **G4:** 8 (30.8) *(P* = NS) **Alcohol use disorders:** **G1:** 7 (25.9) **G2:** 4 (14.8) **G3:** 6 (21.4) **G4:** 9 (34.6) *(P* = NS) **Drug use disorders:** **G1:** 5 (18.5) **G2:** 4 (14.8) **G3:** 6 (21.4) **G4:** 4 (15.4) *(P* = NS) **Any Axis II personality disorder:** **G1:** 12 (44.4) **G2:** 7 (25.9) **G3:** 7 (25.0) **G4:** 8 (30.8) *(P* = NS) **Age Onset BED, mean (SD):** **G1:** 23.8 (19.0) **G2:** 24.5 (11.9) **G3:** 25.9 (18.1) **G4:** 22.4 (13.0) *(P* = NS)

Evidence Table 11. Medication plus behavioral intervention trials for binge eating disorder (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality

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Evidence Table 11. Medication plus behavioral intervention trials for binge eating disorder (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Grilo, Masheb, and Wilson, 2005 (continued)	**EDE Binge days (OBE)/mo, mean (SD):** **G1:** 13.5 (7.4) **G2:** 16.5 (7.6) **G3:** 17.4 (7.5) **G4:** 16.5 (7.2) *(P* = NS)	
	EDE Binge episodes (OBE)/mo, mean (SD): **G1:** 16.3 (11.9) **G2:** 20.0 (11.6) **G3:** 22.8 (14.7) **G4:** 22.7 (13.7) *(P* = NS)	**Binge episodes/mo (EDE-Q), mean (SD):** **G1:** 7.2 (9.2) *(P* = NR) **G2:** 10.3 (11.1) *(P* = NR) **G3:** 1.8 (3.9) *(P* = NR) **G4:** 4.7 (6.9) *(P* = NR) Diff between groups: G1 vs G2 *(P* = NS) G3 vs G4 *(P* = NS) G3 vs G1 *(P* = 0.002) G3 better than G1 G3 vs G2 *(P* = 0.000) G3 better than G2 G4 vs G1 *(P* = 0.02) G4 better than G1 G4 vs G2 *(P* = 0.001) G4 better than G2 Diff between groups in change over time *(P* = NR)
	EDE Q Binge episodes/mo, mean (SD): **G1:** 13.2 (9.3) **G2:** 17.9 (12.2) **G3:** 16.6 (8.9) **G4:** 15.2 (7.7) *(P* = NS)	**Binge episodes/mo (daily self-monitoring), mean (SD):** **G1:** 7.4 (10.2) *(P* = NR) **G2:** 11.0 (11.2) *(P* = NR) **G3:** 2.6 (5.8) *(P* = NR) **G4:** 4.2 (6.9) *(P* = NR) *(P* = NR) Diff between groups: G1 vs G2 *(P* = NS) G3 vs G4 *(P* = NS) G3 vs G1 ***(P*** = 0.004) G3 better than G1 G3 vs G2 *(P* = 0.04) G3 better than G2 G4 vs G1 *(P* = 0.05) G4 better than G1 G4 vs G2 *(P* = 0.001) G4 better than G2 Diff between groups in change over time (*P* = NR)

Evidence Table 11. Medication plus behavioral intervention trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BDI, mean (SD): **G1:** 18.7 (9.7) **G2:** 16.9 (8.4) **G3:** 16.5 (8.4) **G4:** 20.2 (12.1) *(P* = NS)	**BDI, mean (SD):** **G1:** 11.7 (10.3) *(P* = NR) **G2:** 11.8 (9.8)) *(P* = NR) **G3:** 6.5 (6.8) *(P* = NR) **G4:** 9.2 (7.3) *(P* = NR) Diff between groups: G1 vs G2 *(P* = NS) G3 vs G4 *(P* = NS) G3 vs G1 *(P* = 0.04) G3 better than G1 G3 vs G2 *(P* = 0.01) G3 better than G2 G4 vs G1 *(P* = NS) G4 vs G2 *(P* = 0.04) G4 better than G2 Diff between groups in change over time (*P* = NR)	**BMI, kg/m^2, mean (SD):** **G1:** 35.7 (7.2) **G2:** 38.9 (9.5) **G3:** 35.0 (6.2) **G4:** 35.7 (8.3) *(P* = NS)	**BMI, kg/m^2, mean (SD):** **G1:** 35.7 (7.5) *(P* = NR) **G2:** 38.1 (9.6) *(P* = NR) **G3:** 34.2 (5.8) *(P* = NR) **G4:** 34.9 (7.9) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 11. Medication plus behavioral intervention trials for binge eating disorder (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Grilo, Masheb and Wilson, 2005 (continued)	**EDE-Q Dietary Restraint, mean (SD):** **G1: 2.2 (1.5)** **G2:** 2.4 (1.7) **G3:** 2.6 (1.5) **G4:** 2.5 (1.4) *(P* = NS)	**EDE-Q Dietary Restraint, mean (SD):** **G1:** 1.8 (1.5) *(P* = NR) **G2:** 2.4 (1.6) *(P* = NR) **G3:** 1.4 (1.0) *(P* = NR) **G4:** 1.6 (1.4) *(P* = NR) Diff between groups: G1 vs G2 *(P* = NS) G3 vs G4 *(P* = NS) G3 vs G1 *(P* = NS) G3 vs G2 *(P* = 0.002) G3 better than G2 G4 vs G1 *(P* = NS) G4 vs G2 *(P* = 0.01) G4 better than G2 Diff between groups in change over time *(P* = NR)
	EDE-Q Eating Concern, mean (SD): **G1:** 3.4 (1.4) **G2:** 4.0 (1.2) **G3:** 3.6 (1.2) **G4:** 3.9 (1.2) *(P* = NS)	**EDE-Q Eating Concern, mean (SD):** **G1:** 2.1 (1.5) *(P* = NR) **G2:** 2.8 (1.8) *(P* = NR) **G3:** 1.3 (0.7) *(P* = NR) **G4:** 1.5 (1.3) *(P* = NR) Diff between groups: G1 vs G2 *(P* = NS) G3 vs G4 *(P* = NS) G3 vs G1 *(P* = 0.01) G3 better than G1 G3 vs G2 *(P* = 0.01) G3 better than G2 G4 vs G1 *(P* = 0.007) G4 better than G1 G4 vs G2 *(P* = 0.008) G4 better than G2 Diff between groups in change over time *(P* = NR)
	Wt Concern (EDE-Q), mean (SD): G1: 3.9 (1.5) **G2:** 4.1 (0.9) **G3:** 4.0 (0.8) **G4:** 4.3 (0.9) *(P* = NS)	**Wt Concern (EDE-Q), mean (SD):** **G1:** 3.0 (1.5) *(P* = NR) **G2:** 3.3 (1.3) *(P* = NR) **G3:** 2.6 (1.0) *(P* = NR) **G4:** 2.4 (1.5) *(P* = NR) Diff between groups: G1 vs G2 *(P* = NS) G3 vs G4 *(P* = NS) G3 vs G1 *(P* = NS) G3 vs G2 *(P* = 0.04) G3 better than G2 G4 vs G1 *(P* = 0.01) G4 better than g1 G4 vs G2 *(P* = 0.001) G4 better than G2 Diff between groups in change over time *(P* = NR)

Evidence Table 11. Medication plus behavioral intervention trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 11. Medication plus behavioral intervention trials for binge eating disorder (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Grilo, Masheb and Wilson, 2005 (continued)	**EDE-Q Shape Concern, mean (SD):** **G1:** 4.5 (1.4) **G2:** 5.0 (0.8) **G3:** 5.0 (0.8) **G4:** 5.1 (0.7) *(P* = NS)	**EDE-Q Shape Concern, mean (SD):** **G1:** 3.6 (1.8) *(P* = NR) **G2:** 3.9 (1.7) *(P* = NR) **G3:** 3.2 (1.4) *(P* = NR) **G4:** 3.1 (1.8) *(P* = NR) Diff between groups: G1 vs G2 *(P* = NS) G3 vs G4 *(P* = NS) G3 vs G1 *(P* = 0.02) G3 better than G1 G3 vs G2 *(P* = 0.04) G3 better than G2 G4 vs G1 *(P* = 0.003) G4 better than G1 G4 vs G2 *(P* = 0.007) G4 better than G2 Diff between groups in change over time *(P* = NR)
	EDE-Q Global Score, mean (SD): **G1:** 3.5 (1.5) **G2:** 3.9 (1.2) **G3:** 3.8 (1.1) **G4:** 4.0 (1.1) *(P* = NS)	**EDE-Q Global Score, mean (SD):** **G1:** 2.6 (1.6) *(P* = NR) **G2:** 3.1 (1.6) *(P* = NR) **G3:** 2.1 (1.0) *(P* = NR) **G4:** 2.2 (1.5) *(P* = NR) Diff between groups: G1 vs G2 *(P* = NS) G3 vs G4 *(P* = NS) G3 vs G1 *(P* = 0.007) G3 better than G1 G3 vs G2 *(P* = 0.004) G3 better than G2 G4 vs G1 *(P* = 0.002) G4 better than G1 G4 vs G2 *(P* = 0.001) G4 better than G2 Diff between groups in change over time *(P* = NR)
	TFEQ Hunger, mean (SD): **G1:** 9.6 (3.9) **G2:** 10.0 (3.3) **G3:** 9.7 (3.2) **G4:** 10.0 (3.1) *(P* = NS)	**TFEQ Hunger, mean (SD):** **G1:** 8.4 (4.3) *(P* = NR) **G2:** 8.9 (4.6) *(P* = NR) **G3:** 6.7 (3.3) *(P* = NR) **G4:** 5.7 (4.0) *(P* = NR) Diff between groups: G1 vs G2 *(P* = NS) G3 vs G4 *(P* = NS) G3 vs G1 ***(P*** = NS) G3 vs G2 *(P* = NS) G4 vs G1 *(P* = 0.008) G4 better than G1 G4 vs G2 *(P* = 0.004) G4 better than G2 Diff between groups in change over time *(P* = NR)

Evidence Table 11. Medication plus behavioral intervention trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 11. Medication plus behavioral intervention trials for binge eating disorder (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Grilo, Masheb and Wilson, 2005 (continued)	**TFEQ Cognitive Restraint, mean (SD):** **G1:** 8.1 (3.63) **G2:** 8.6 (4.0) **G3:** 7.8 (3.7) **G4:** 8.7 (4.5) *P* = NS))	**TFEQ Cognitive Restraint, mean (SD):** **G1:** 9.9 (5.0) *(P* = NR) **G2:** 9.9 (4.7) *(P* = NR) **G3:** 10.1 (3.1) *(P* = NR) **G4:** 10.0 (4.1) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	TFEQ Disinhibition, mean (SD): **G1:** 13.9 (1.9) **G2:** 14.0 (1.3) **G3:** 14.2 (1.6) **G4:** 14.0 (1.7) *(P* = NS)	**TFEQ Disinhibition, mean (SD):** **G1:** 12.1 (4.3) *(P* = NR) **G2:** 12.2 (3.6) *(P* = NR) **G3:** 9.3 (3.8) *(P* = NR) **G4:** 8.3 (4.8) *(P* = NR) Diff between groups: G1 vs G2 *(P* = NS) G3 vs G4 *(P* = NS) G3 vs G1 *(P* = 0.001) G3 better than G1 G3 vs G2 *(P* = 0.002) G3 better than G2 G4 vs G1 *(P* = 0.000) G4 better than G1 G4 vs G2 *(P* = 0.001) G4 better than G2 Diff between groups in change over time *(P* = NR)
	BSQ, Body Dissatisfaction, mean (SD) **G1:** 135.4 (35.2) **G2:** 136.3 (26.0) **G3:** 133.5 (24.3) **G4:** 139.1 (28.8) *(P* = NS)	**BSQ, Body Dissatisfaction, mean (SD):** **G1:** 123.6 (41.0) *(P* = NR) **G2:** 117.5 (41.5) *(P* = NR) **G3:** 100.9 (23.5) *(P* = NR) **G4:** 106.0 (40.2) *(P* = NR) Diff between groups: G1 vs G2 *(P* = NS) G3 vs G4 *(P* = NS) G3 vs G1 *(P* = NS) G3 vs G2 *(P* = 0.03) G3 better than G2 G4 vs G1 *(P* = 0.05) G4 better than G1 G4 vs G2 *(P* = NS) Diff between groups in change over time *(P* = NR)

Evidence Table 11. Medication plus behavioral intervention trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 11. Medication plus behavioral intervention trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Grilo, Masheb and Wilson, 2005 (continued)		**Remission rates (Per EDE), %:** **G1:** 26% **G2:** 22% **G3:** 61% **G4:** 50% Diff between groups *(P* = 0.007) G1 vs G2 *(P* = NS) G3 vs G4 *(P* = NS) G4 vs G1 *(P* = 0.05) G4 better than G1 G4 vs G2 *(P* = 0.03) G4 better than G2 G3 vs G1 *(P* = 0.008) G3 better than G1 G3 vs G2 *(P* = 0.004) G3 better than G2 **Remission rates (Per EDE-Q):** **G1:** Data in figure **G2:** Data in figure **G3:** Data in figure **G4:** Data in figure Diff between groups (*P* = 0.003) G1 vs G2 *(P* = NS) G3 vs G4 *(P* = NS) G4 vs G1 *(P* = 0.02) G4 better than G1 G4 vs G2 *(P* = 0.003) G4 better than G2 G3 vs G1 *(P* = 0.03) G3 better than G1 G3 vs G2 *(P* = 0.005) G3 better than G2

Evidence Table 11. Medication plus behavioral intervention trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 11. Medication plus behavioral intervention trials for binge eating disorder (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Ricca et al., 2001 **Setting:** Outpatient clinic for ED of the University of Florence and the Casa di Cura (villa dei pini), Florence, Italy **Enrollment period:** January 1 – July 31, 1998	**Research objective:** Compare the efficacy and tolerability of fluoxetine, fluvoxamine, and CBT, individually and combined with each other, after 6 mos of acute tx and one yr FU among patients with BED.	**Groups:** **G1:** CBT (N = 20) **G2:** CBT + Fluoxetine (N = 22) **G3:** CBT + Fluvoxamine (N = 23) **G4:** Fluoxetine (N = 21) **G5:** Fluvoxamine (N = 22) **Enrollment:** • 118 referred • 7 did not meet criteria, 3 refused • 108 were randomized. **Drop out, N (%):** **G1:** 3 **G2:** 6 (27.2) **G3:** 5 (21.7) **G4:** 5 (23.8) **G5:** 6 (27.2) *(P* = NS) Subjects allocated to tx by day of the wk of appointment. Drug tx is open label	**Age, yrs, mean (SD):** 25.9 (6.8) **G1:** 26.3 (6.7) **G2:** 25.2 (6.3) **G3:** 25.1 (6.9) **G4:** 25.1 (6.1) **G5:** 26.1 (5.9) *(P* = NS) **Sex, N:** Female: 64; Male: 44 **G1:** F: 13; M: 7 **G2:** F: 13; M: 9 **G3:** F: 13; M: 10 **G4:** F: 12; M: 9 **G5:** F:13; M:9 *(P* = NS) **Race/ethnicity:** NR **BMI, mean (SD):** **G1:** 32.0 (6.0) **G2:** 31.7 (5.6) **G3:** 32.5 (6.1) **G4:** 32.1 (3.8) **G5:** 32.7 (4.1) *(P* = NS) **Duration of BED, yrs, mean (SD):** **G1:** 6.4 (6.0) **G2:** 4.9 (5.1) **G3:** 4.8 (4.4) **G4:** 5.1 (4.7) **G5:** 5.3 (4.8) *(P* = NS) **Age of Onset, mean (SD):** **G1:** 19.9 (2.3) **G2:** 24.4 (3.2) **G3:** 20.5 (3.6) **G4:** 21.2 (3.1) **G5:** 22.1 (3.6) *(P* = NS) **Comorbidity per SCID for DSM III-R, N (%):** Total people with comorbid dx: 15 Major depression: 7 (6.4) Dysthymia: 6 (5.5) Adaptation disorder with depressed mood: 4 (3.6) OCD: 2 (1.8) Panic Disorder: 2 (1.8)

Evidence Table 11. Medication plus behavioral intervention trials for binge eating disorder (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: BED dx per DSM IV; age: 18-45; absence of diabetes mellitus, thyroid disorders, or any other disease interfering with eating behavior; absence of any contraindication to tx; absence of pregnancy or lactation. **Exclusion:** See above	**G1:** 22 individual sessions of 50 min each for 24 wks. **G2:** 20 mg/day for first wk; 40 mg/day for second wk; 60 mg/day for following 20 wks in a single dose. CBT as in G1 **G3:** 100 mg/day for the first wk; 100 mg bid for the second wk; 100 mg tid for the next 20 wks. CBT as in G1 **G4:** 20 mg/day for first wk; 40 mg/day for second wk; 60 mg/day for following 20 wks in a single dose. Visits: once per mo. Therapy interrupted if serious adverse events. **G5:** 100 mg/day for the first wk; 100 mg bid for the second wk; 100 mg tid for the next 20 wks. Visits: once per mo. Therapy interrupted if serious adverse events. After the 24th wk, therapy ended. Drugs progressively decreased up to discontinuation over a period of 1 mo. No further tx or FU for 1 yr.	Chi Square, ANOVA, Wilcoxin, Mann-Whitney U. No adjustment for multiple comparisons Data collected at end of tx (6 mos) and 1 yr FU	**Score:** Poor **Intent to treat:** Yes **Blinding:** No **Adverse events:** **G2:** 6 (27.2%) (nausea: 4, insomnia: 3; anorgasmia: 1; vomiting; reduction in drug dose: 2 **G3:** 6 (nausea: 5, hypersomnia: 2; diarrhea: 1; required reduction in drug dose: 3 **G4:** 7 (nausea: 4; headache: 3; vomiting: 2; insomnia: 1); required reduction in drug dose: 4 **G5:** 7 (nausea: 5; hypersomnia: 3; headache: 2; vomiting: 2); required a reduction in drug dose: 3 **Funding:** NR

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Ricca, et al., 2001 (continued)	**EDE total score, median:** **G1:** 3.8 **G2:** 3.8 **G3:** 4.0 **G4:** 3.4 **G5:** 3.8 *(P* = NR)	**EDE total score, median:** **Post-tx:** **G1:** 3.4 *(P* < 0.01) **G2:** 2.7 *(P* < 0.01) **G3:** 2.7 *(P* < 0.01) **G4:** 3.8 *(P* = NS) **G5:** 3.8; *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.05) G3 better than G1 or G2 **1 yr FU:** **G1:** 3.3 *(P* = NS) **G2:** 2.7 *(P* = NS) **G3:** 2.6 *(P* = NS) **G4:** 3.9 *(P* = NS) **G5:** 3.8 *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)
	EDE Restraint, median: **G1:** 3.8 **G2:** 2.6 **G3:** 3.3 **G4:** 3.8 **G5:** 3.5 *(P* = NR)	**EDE Restraint, median:** **Post-tx:** **G1:** 2.9 *(P* < 0.01) **G2:** 2.7 *(P* = NS) **G3:** 2.1 *(P* < 0.01) **G4:** 3.9 *(P* = NS) **G5:** 3.4 *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.01) G3 better than G1 or G2 **1 yr FU:** **G1:** 2.8 *(P* = NS) **G2:** 2.7 *(P* = NS) **G3:** 2.1 *(P* = NS) **G4:** 3.9 *(P* = NS) **G5:** 3.4 *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)

Evidence Table 11. Medication plus behavioral intervention trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BDI, median: **G1:** 22 **G2:** 16.5 **G3:** 22 **G4:** 20 **G5:** 21 *(P* = NR)	**BDI, median:** **Post tx:** **G1:** 14 *(P* < 0.01) **G2:** 10.5 *(P* < 0.01) **G3:** 10 *(P* < 0.01) **G4:** 15 *(P* < 0.01) **G5:** 14 *(P* < 0.01) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **1 yr FU:** **G1:** 14 *(P* = NS) **G2:** 10.5 *(P* = NS) **G3:** 10 *(P* = NS) **G4:** 16 *(P* = NS) **G5:** 14 *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)		**BMI:** **Post-tx:** **G1 - G5:** Data presented in figure only **G1:** change *(P* < 0.01) **G2:** change *(P* < 0.01) **G3:** change *(P* < 0.01) **G4:** change *(P* = NS) **G5:** change *(P* = NS) Diff between groups *(P* = NR) Diff between G1, G2, G3 in change over time *(P* = NS) **1 yr FU:** **G1 - G5:** Data presented in figure only **G1:** change *(P* < 0.01) **G2:** change *(P* < 0.01) **G3:** change *(P* < 0.01) **G4:** change *(P* = NS) **G5:** change *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)
STAI-State, median: **G1:** 46 **G2:** 47.5 **G3:** 52 **G4:** 46.2 **G5:** 48.2 *(P* = NR)	**STAI-State, median:** **Post tx:** **G1:** 37 *(P* < 0.01) **G2:** 45 *(P* = NS) **G3:** 32 *(P* < 0.01) **G4:** 44.8 *(P* = NS) **G5:** 34.1 *(P* < 0.01) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.01) G3 better than G1 **1 yr FU:** **G1:** 40 *(P* = NS) **G2:** 48 *(P* = NS) **G3:** 32 *(P* = NS) **G4:** 50.5 *(P* < 0.01) **G5:** 36.1 *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)		

Evidence Table 11. Medication plus behavioral intervention trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Ricca, et al., 2001 (continued)	**EDE Eating concern, median:** **G1:** 3.6 **G2:** 3.6 **G3:** 4.4 **G4:** 4.0 **G5:** 3.8 *(P* = NR)	**EDE Eating concern, median:** **Post-tx:** **G1:** 3.3 *(P* < 0.01) **G2:** 2.8 *(P* < 0.01) **G3:** 2.8 *(P* < 0.01) **G4:** 3.9 *(P* = NS) **G5:** 3.7 *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.01) G2 and G3 better than G1 **1 yr FU:** **G1:** 3.3 *(P* = NS) **G2:** 2.8 ***(P*** = NS) **G3:** 2.1 *(P* = NS) **G4:** 4.0 *(P* = NS) **G5:** 3.7 *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)
	EDE Wt Concern, median: **G1:** 4.4 **G2:** 4.3 **G3:** 4.2 **G4:** 4.2 **G5:** 4.3 *(P* = NR)	**EDE Wt Concern, median:** **Post-tx:** **G1:** 3.7 *(P* < 0.01) **G2:** 2.9 *(P* < 0.01) **G3:** 3.2 *(P* < 0.01) **G4:** 4.1 *(P* = NS) **G5:** 4.3 *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **1 yr FU:** **G1:** 3.6 *(P* = NS) **G2:** 2.9 *(P* = NS) **G3:** 3.0 *(P* = NS) **G4:** 4.0 *(P* = NS) **G5:** 4.2 *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)

Evidence Table 11. Medication plus behavioral intervention trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
STAI-Trait, median: **G1:** 48 **G2:** 48 **G3:** 52 **G4:** 47.5 **G5:** 49.6 *(P* = NR)	**STAI-Trait, median:** **Post tx:** **G1:** 44.5 *(P* < 0.01) **G2:** 46 *(P* = NS) **G3:** 36 *(P* < 0.01) **G4:** 46.8 *(P* = NS) **G5:** 35 *(P* < 0.01) Diff between groups *(P* = NR) Diff between groups in change over time G3 better than G1*(P* < 0.01) G5 better than G1 *(P* < 0.01) **1 yr FU:** **G1:** 44 *(P* = NS) **G2:** 48 *(P* = NS) **G3:** 36 *(P* = NS) **G4:** 47.1 *(P* = NS) **G5:** 34.9 *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)		

Evidence Table 11. Medication plus behavioral intervention trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Ricca, et al., 2001 (continued)	**EDE Shape Concern, median:** **G1:** 3.3 **G2:** 3.2 **G3:** 3.7 **G4:** 3.6 **G5:** 3.5 *(P* = NR)	**EDE Shape Concern, median:** **Post-tx:** **G1:** 3.2 *(P* < 0.01) **G2:** 2.8 *(P* < 0.01) **G3:** 2.9 *(P* < 0.01) **G4:** 3.7 *(P* = NS) **G5:** 3.6 *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **1 yr FU:** **G1:** 3.1 *(P* = NS) **G2:** 2.2 *(P* = NS) **G3:** 3.1 *(P* = NS) **G4:** 3.8 *(P* = NS) **G5:** 3.6 *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)
	Binge eating episodes /mo, mean (SD): **G1:** 18 (2.3) **G2:** 17 (3.1) **G3:** 18 (3.5) **G4:** 20 (4.3) **G5:** 20 (5.8) *(P* = NR)	**Binge eating episodes /mo, mean (SD):** **Post-tx:** **G1:** 8 (3.9) *(P* < 0.001) **G2:** 6 (4.6) *(P* < 0.001) **G3:** 8 (3.2) *(P* < 0.001) **G4:** 19 (3.5) *(P* = NS) **G5:** 18 (2.4) *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) **1 yr FU:** **G1:** 8 (5.1) *(P* = NS) **G2:** 7 (3.4) *(P* = NS) **G3:** 8 (2.4) *(P* = NS) **G4:** 21 (3.1) *(P* = NS) **G5:** 18 (1.7) *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)

Evidence Table 11. Medication plus behavioral intervention trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 12. Behavioral intervention trials for binge eating disorder

Study Description	Objective	Design	Patient Characteristics
Author, yr: Agras et al., 1995 **Setting:** Single center; outpatient: location: Stanford University School of Medicine Behavioral Medicine Program, Stanford, CA, USA **Enrollment period:** NR	**Research objective:** To assess the efficacy of a 12-wk CBT program for the tx of BED. Another primary goal is to evaluate whether the addition of 12 wks of IPT would improve primary BED outcomes among tx non-responders.	**Groups:** **G1:** CBT (N = 39) **G2:** Assessment only waitlist control (N = 11) **Enrollment:** • 262 potential subjects either referred to study or recruited via ads were phone screened • 89 invited for in-person diagnostic interview • 64 eligible for enrollment (14 did not complete baseline assessment) • 50 enrolled and randomized • 42 completers at 24 wks (**G1:** N = 31; **G2:** N = 11) (*P* = NR)	**Age, mean (SD):** Range: 24-65 **Total sample:** 47.6 (10.1) **G1:** NR **G2:** NR (*P* = NS) **Sex:** Female N (%): 43 (86%) **Race/ethnicity:** NR **Age of overwt onset, yrs, mean (SD):** 18.9 (12.8) **Mean age of binge eating onset, yrs, mean (SD):** 21.1 (12.0) **BMI, kg/m^2, mean (SD):** Total sample: 37.1 (7.3) **G1:** NR **G2:** NR (*P* = NR)

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Met proposed criteria for BED (Walsh, 1992) **Exclusion:** Current involvement in a wt loss program; currently taking anti-depressant meds or any med that could impact wt; current drug or alcohol abuse; current major psychiatric illness such as psychosis; hx of purging within the last 6 mos; BMI < 27 (i.e., not requiring tx for overwt)	Following clinical interview assessments, subjects randomized at a ratio of 4:1 to either a 12-wk CBT program or waitlist control. CBT: 12 90 minutes sessions wkly, based on manual developed by Telch, plus walking and nutritional ed. Subjects who met 3 criteria for successful response to CBT (stabilization or wt loss for at least the last 4 wks of tx; initiating a min aerobic exercise program such as walking for 30 m, 3 times per wk; and abstinence from binge eating for at least the last 2 wks of tx) were assigned to a 12-wk behavioral wt loss program. Those who did not meet the criteria for successful response after 12 wks of CBT were assigned to an additional 12 wks of IPT. IPT: group format, 90 minutes each using Wilfley (1993) design.	Repeated measure MANOVAs to assess between group diffs on primary and secondary outcome variables; signal detection methods to explore predictors of tx response.	**Score:** Poor **Intent to treat:** For some analyses as a comparison. Authors reported that comparing ITT vs. non-ITT analyses revealed no Diffs, so non-ITT results reported. **Blinding:** NA **Adverse events:** NR **Funding:** NIH

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Agras et al., 1995 (continued)	**Binge days/wk, mean (SD):** **G1:** 4.4 (1.8) **G2:** 3.7 (1.2) *(P* = NS) **G1A:** 4.2 (1.9) **G1B:** 4.5 (1.7) *(P* = NS)	**Binge days/wk, mean (SD):** **Wk 12 (end of tx)** **G1:** 0.7 (1.0) *(P* = NR) **G2:** 3.4 (2.0) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) **Wk 24:** **G1:** 1.0 (1.4) *(P* = NR) **G2:** 2.9 (2.0) *(P* = NR) Diff between groups *(P* = 0.0001) G1 better than G2 Diff between groups in change over time *(P* = NR)
	BES, mean (SD): **G1:** 29.4 (6.7) **G2:** 25.2 (7.9) *(P* > 0.01)	**BES, mean (SD)** **Wk 12 (end of tx):** **G1:** 18.1 (8.0) *(P* = NR) **G2:** 23.8 (6.6) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **Wk 24:** **G1:** 17.7 (7.1) *(P* = NS) **G2:** 24.9 (10.4) *(P* = NS) Diff between groups *(P* = 0.0001) G1 better than G2 Diff between groups in change over time *(P* = NR)
	TFEQ, mean (SD): **Disinhibition:** **G1:** 14.1 (1.6) **G2:** 13.6 (1.6) *(P* = NS)	**TFEQ, Disinhibition, mean (SD):** **Wk 12 (end of tx)** **G1:** 12.1 (2.6) *(P* = NR) **G2:** 13.6 (1.7) *(P* = NR) Diff between groups (NR) Diff between groups in change over time *(P* = NR) **Wk 24:** **G1:** 10.9 (2.9) *(P* = NR) **G2:** 13.5 (1.1) *(P* = NR) Diff between groups *(P* = 0.004) G1 lower than G2 Diff between groups in change over time *(P* = NR)

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BDI, mean (SD): **G1:** 14.6 (9.7) **G2:** 11.2 (6.8) *(P* = NS)	**BDI, mean (SD):** **Wk 12 (end of tx)** **G1:** 11.5 (8.7) *(P* = NR) **G2:** 11.9 (6.6) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **Wk 24:** **G1:** 10.5 (8.2) *(P* = NR) **G2:** 11.0 (8.3) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)	**Wt, kg, mean (SD):** **G1:** 108 (26.7) **G2:** 106.1 (20.3) *(P* = NS)	**Wt, kg, mean (SD):** **Wk 12 (end of tx):** **G1:** 109.4 (27.3) *(P* = NR) **G2:** 109.8 (23.1) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **Wk 24:** **G1:** 107.4 (28) *(P* = NR) **G2:** 110.2 (22.8) *(P* = NR) Diff between groups *(P* = 0.02) G1 less than G2 Diff between groups in change from wk 12 *(P* = NR)
SCL-90, global, mean (SD): **G1:** 0.9 (0.7) **G2:** 0.8 (0.5) *(P* = NS)	**SCL-90, global, mean (SD):** **Wk 12 (end of tx)** **G1:** 0.8 (0.5) *(P* = NR) **G2:** 0.8 (0.6) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change from baseline *(P* = NR) **Wk 24:** **SCL-90, global mean (SD):** **G1:** 0.6 (0.4) *(P* = NR) **G2:** 0.7 (0.7) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)		

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Agras et al., 1995 (continued)	**Hunger:** **G1:** 10.1 (2.7) **G2:** 9.9 (3.5) *(P* = NS)	**Wk 12 (end of tx)** **Hunger:** **G1:** 8.5 (2.6) *(P* = NR) **G2:** 10.0 (3.2) *(P* = NR) Diff between groups (NR) Diff between groups in change over time *(P* = NR) **Wk 24:** **Hunger:** **G1:** 7.5 (2.9) *(P* = NR) **G2:** 9.0 (3.7) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
	Restraint: **G1:** 7.0 (3.6) **G2:** 7.1 (3.8) *(P* = NS)	**Wk 12 (end of tx)** **Restraint:** **G1:** 9.4 (3.3) *(P* = NR) **G2:** 7.8 (4.4) *(P* = NR) Diff between groups (NR) Diff between groups in change over time *(P* = NR) **Wk 24:** **Restraint:** **G1:** 10.5 (4.3) *(P* = NR) **G2:** 8.2 (4.8) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)
		Abstinence for at least 2 wks by wk 12 (%): **G1:** 55% **G2:** 9% Diff between groups *(P* < 0.008) G1 greater than G2

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Eldredge et al., 1997 **Setting:** Outpatient; Northern California, USA **Enrollment period:** NR	**Research objective:** To assess the efficacy of CBT vs waitlist control in treating BED in obese individuals (additional analyses concerning extended tx for non-responders not reported since patients not randomized).	**Groups:** **G1:** CBT (N = 36) **G2:** Wl control (N = 10) **Enrollment:** • 75 scheduled for dx interview after meeting requirements of preliminary telephone screening • 10 subjects on waitlist for previous study re-interviewed • 46 enrolled • 37 remained at 24 wks	**Age, yrs, mean (SD):** **Total:** 45.2 (9.8) **G1:** NR **G2:** NR *(P* = NS) **Age of onset of overwt, yrs, mean (SD):** **Total:** 15.8 (11.7) **G1:** NR **G2:** NR *(P* = NS) **Age of onset of binge-eating, yrs, mean (SD):** **Total:** 22.0 (13.7) **G1:** NR **G2:** NR *(P* = NS) **Sex (N):** Female: 44 Male: 2 **Race/ethnicity:** NR **Wt, kg,mean (SD):** **Total:** 106.8 (28.2) **G1:** NR **G2:** NR *(P* = NS)

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: DSM IV proposed criteria for BED; obese (BMI ≥ 27) **Exclusion:** Concurrent additional tx which might interfere with this study (i.e., wt loss program, anti-depressant meds, any meds that could influence wt); current drug or alcohol abuse; hx of purging within the last 6 mos; current major medical or psychiatric condition that could affect tx (i.e., pregnancy, psychosis, or severe suicidality).	Randomly assigned according to 3.5 to 1 ratio to 12-wks of group CBT or waitlist control. **G1:** randomly assigned to one of three identical tx groups. Subjects who met clinical criteria of success (i.e., abstinence of binge-eating for at least the last 2 wks of tx, initiation of a min aerobic exercise program, and wt stabilization or wt loss for at least the last 4 wks of tx) by wk-12 were then provided with 12-wks of behavioral wt loss tx. Those who did not meet clinical criteria of success by the end of wk-12 received add 12-wks of CBT.	ANOVAs and repeated measures ANOVAs to assess between group diff for primary and secondary variables of interest	**Score:** Poor **Intent to treat:** NR **Blinding:** No **Adverse events:** NR **Funding:** NIH

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Eldredge et al., 1997 (continued)	**BES mean:** **G1:** 27.97 **G2:** 29.38 *(P* = NS)	**BES mean:** **G1:** 17.07 *(P* = NR) **G2:** 20.88 *(P* = NR) Change over time *(P* < 0.0001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	TFEQ restraint, mean: **Restraint:** **G1:** 8.52 **G2:** 6.88 *(P* = NS)	**TFEQ scales mean:** **Restraint:** **G1:** 11.26 *(P* = NR) **G2:** 9.38 *(P* = NR) Change over time *(P* < 0.0002) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	TFEQ Disinhibition mean: **G1:** 13.90 (NR) **G2:** 13.63 (NR) *(P* = NS)	**TFEQ Disinhibition:** **G1:** 10.94 *(P* = NR) **G2:** 12.63 *(P* = NR) Change over time *(P* < 0.0001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	TFEQ Hunger mean: **G1:** 8.94 **G2:** 9.5 *(P* = NS)	**TFEQ Hunger:** **G1:** 6.65 *(P* = NR) **G2:** 9.63 *(P* = NR) Change over Time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
		% decrease in # of binge eating days by 12-wks, mean: **G1:** 68.2 **G2:** 19.8 Diff between groups *(P* = 0.046) G1 better than G2
		Treatment-responders by 12-wks: 50% of the treated sample (N = 18)

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BDI, mean: **G1:** 13.67 (NR) **G2:** 14.38 (NR) *(P* = NS)	**BDI, mean:** **G1:** 9.17 *(P* = NR) **G2:** 7.88 *(P* = NR) Change over time *(P* = 0.002) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)	**BMI, kg/m^2 mean:** **G1:** 37.05 (NR) **G2:** 43.35 (NR) Diff between groups *(P* = NS)	**BMI, kg/m^2 mean** **G1:** 36.29 *(P* = NR) **G2:** 44.73 *(P* = NR) Diff between groups *(P* = 0.03) G1 better than G2 Diff between groups in change over time *(P* = NS)
GSI, mean: **G1:** 0.63 (NR) **G2:** 0.75 (NR) *(P* = NS)	**GSI, mean at 12-wks:** **G1:** 0.52 *(P* = NR) **G2:** 0.47 *(P* = NR) Change over time *(P* = 0.06) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)		

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Gorin et al., 2003 **Setting:** Outpatient Wt Control and Diabetes Research Center, Providence, RI, USA **Enrollment period:** NR	**Research objective:** To evaluate effects of spouse involvement in group CBT for BED and replicate previous literature on effectiveness of CBT for BED.	**Groups:** **G1:** Standard CBT (N = 32) **G2:** CBT-SI (N = 31) **G3:** Waitlist control group (CG) (N = 31) **Enrollment:** • 896 women responded to an advertisement • 399 completed brief telephone screening • 109 invited to complete baseline assessment • 15 ineligible and excluded • 94 blocked by binge eating frequency and randomly assigned to one of three conditions	**Age, yrs, mean (SD):** 45.20 yrs (10.03) **Sex:** Female: 100% **Race/ethnicity:** Caucasian: 86%

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Women, aged 18-65, meeting DSM IV criteria for BED, having BMI > = 25 and having a spouse or cohabiting partner who is willing to participate in study. **Exclusion:** Engaged in binge purging behaviors > once a mo, met DSM IV criteria for AN, BN or EDNOS, receiving concurrent tx for wt loss, taking appetite suppressants and/or pregnant.	**G1:** 90-minute group meetings (with 6 – 11 participants per group) held once a wk for 12 wks. 8 advanced clinical psychology grad students served as co-leaders. Protocol based on a BED therapist manual created by Telch and Agras (1992). **G2:** standard CBT manual modified but tx goals the same; however, in CBT-SI goals included having both partners understand BED, perceive coping resources as available, agree about course of action and feel confident about ability to deal with BED. All partners required to attend all group meetings. In each session participants start by discussing eating problems and progress with their partners. Partners encouraged to participate in discussions. In add to regular homework, husbands set behavioral goals to assist wives in decreasing frequency of BE. **G3:** completed assessments at T1 and T2 and then entered tx. FU assessments at 6 mos.	For certain analyses data from standard CBT and CBT SI were combined (and called active CBT) to compare with control group. To ensure adequate power, the study's apriori hypotheses were examined using planned orthogonal contrasts. For each set of planned orthogonal contrasts, group diffs were tested with mixed model ANOVA's. Group diff on dichotomous variables assessed with chi-square tests. Two sets of comparisons were performed: active CBT (G1 + G2) versus waitlist (G3) and standard CBT (G1) versus CBT-SI (G2).	**Score:** Fair **Intent to treat:** Yes **Blinding:** NA **Adverse events:** NR **Funding:** Dissertation grant from Society for Science of Clinical Psychology and funding from Applied Behavioral Medicine Research Institute.

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Gorin et al., 2003 (continued)	**Days binged (7-day recall) (SD):** **G1:** 3.81 (1.66) **G2:** 3.41 (2.09) **G3:** 3.77 (1.82) *(P* = NS)	**Post-tx:** **Days binged (7-day recall) (SD):** **G1:** 1.81 (1.97) *(P* = NR) **G2:** 1.18 (1.76) *(P* = NR) **G3:** 2.95 (1.84) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.04) G1 and G2 better than G3 Diff between G1 and G2 *(P* = NR) Diff between G1 and G2 in change over time *(P* = NS) **FU:** **Days binged (7-day recall) (SD):** **G1:** 1.05 (1.43) *(P* = NR) **G2:** 0.67 (0.86) *(P* = NR) **G3:** Data not provided Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	Objective Binge episodes (SD): **G1:** 7.61 (5.66) **G2:** 9.55 (6.09) **G3:** 8.47 (5.21) *(P* = NS)	**Objective Binge episodes (SD):** **G1:** 2.44 (2.83) *(P* = NR) **G2:** 3.32 (4.35) *(P* = NR) **G3:** 5.87 (4.64) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **Post tx: Standard CBT (G1) versus CBT-SI (G2) (*Means as above)** **Objective Binge episodes:** Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **FU:** **Objective Binge episodes (SD):** **G1:** 1.63 (2.09) *(P* = NR) **G2:** 3.50 (4.64) *(P* = NR) **G3:** Data not provided Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BDI (SD): **G1:** 18.71 (8.89) **G2:** 20.41 (9.96) **G3:** 17.41 (9.93) *(P* = NS)	**BDI (SD):** **G1:** 14.76 (9.32) *(P* = NR) **G2:** 11.82 (9.42) *(P* = NR) **G3:** 16.77 (9.54) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.05) G1 and G2 better than G3 **Post tx: Standard CBT (G1) versus CBT-SI (G2) (*Means as above)** Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **FU (no data reported for waitlist grp):** **G1:** 12.89 (8.05) *(P* = NR) **G2:** 12.24 (9.23) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)	**Body Mass Index, mean (SD):** **G1:** 38.72 (8.78) **G2:** 40.51 (8.29) **G3:** 39.37 (7.53) *(P* = NS)	**Body Mass Index, mean (SD):** **G1:** 38.65 (8.51) *(P* = NR) **G2:** 40.37 (8.33) *(P* = NR) **G3:** 39.73 (7.79) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.05) G1 and G2 better than G3 **Post tx: Standard CBT (G1) versus CBT-SI (G2) (*Means as above)** Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **FU (no data reported for waitlist grp):** **G1:** 37.83 (8.84) *(P* = NR) **G2:** 39.74 (8.67) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Gorin et al., 2003 (continued)		**Binge abstinence (SD):** **G1+G2 (**37%*) (P* = NR) **G3 (**9%*) (P* = NR) Diff between groups *(P* < 0.05) Active CBT higher percentage of abstinent participants. Diff between groups in change over time *(P* = NR) **Post tx: Standard CBT (G1) versus CBT-SI (G2) (*Means as above):** **G1 (**29%*) (P* = NR) **G2 (**46%*) (P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) FU (no data reported for waitlist grp) **FU:** **Binge abstinence (SD):** **G1 (**47%) *(P* = NR) **G2 (**52%) *(P* = NR) **G3:** Data not provided Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	TFEQ Restraint, mean (SD): **G1:** 9.24 (4.01) **G2:** 6.41 (2.91) **G3:** 7.32 (3.96) *(P* = NS)	**TFEQ Restraint, mean (SD):** **G1:** 9.52 (4.30) *(P* = NR) **G2:** 8.41 (3.32) *(P* = NR) **G3:** 7.30 (4.73) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **Post tx: Standard CBT (G1) versus CBT-SI (G2) (*Means as above)** **G1:** diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) **FU:** **G1:** 12.11 (3.00) *(P* = NR) **G2:** 8.24 (3.00) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Gorin et al., 2003 (continued)	**TFEQ Disinhibition, mean (SD):** **G1:** 12.48 (1.89) **G2:** 13.14 (2.23) **G3:** 13.45 (1.26) *(P* = NS)	**TFEQ Disinhibition, mean (SD):** **G1:** 10.86 (3.81) *(P* = NR) **G2:** 11.55 (3.05) *(P* = NR) **G3:** 13.23 (2.31) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.05) G1 and G2 better than G3 **Post tx: Standard CBT (G1) versus CBT-SI (G2) (*Means as above):** Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **FU (no data reported for waitlist grp):** **G1:** 9.74 (3.87) *(P* = NR) **G2:** 11.00 (3.39) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	TFEQ Hunger (SD): **G1:** 8.81 (3.64) **G2:** 10.77 (3.21) **G3:** 9.82 (2.68) *(P* = NS)	**TFEQ Hunger (SD):** **G1:** 7.14 (3.88) *(P* = NR) **G2:** 9.23 (3.18) *(P* = NR) **G3:** 9.86 (3.47) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.05) G1 and G2 better than G3 **Post tx: Standard CBT (G1) versus CBT-SI (G2) (*Means as above)** **TFEQ Hunger:** Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **FU (no data reported for waitlist grp):** **TFEQ-hunger (SD):** **G1:** 5.68 (3.62) *(P* = NR) **G2:** 8.71 (3.74) *(P* = NR) **G3:** Data not provided Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Hilbert and Tuschen-Caffier, 2004 **Setting:** Outpatient; Psychotherapeutic unit at University of Marburg, Germany. **Enrollment period:** NR	**Research objective:** Compare CBT with CBT-E and CBT along with CBT-C	**Groups:** **G1:** CBT-E (N = 14) **G2:** CBT-C (N = 14) **Enrollment:** • Recruited through ads for free group therapy. • 130 responded to ads and were screened for eligibility • 77 eligible and invited for initial contact. • 66 attended meeting • 34 remained interested • 2 excluded because of diagnostic status and 4 did not return for later appointments. • Randomization after preparation for therapy.	**Age, yrs, mean (SD):** **G1:** 42.1 (12.1) **G2:** 38.6 (8.5) *(P* = NS) **Sex:** Female: 100% **Race/ethnicity:** NR **Age of first binge, yrs, mean (SD):** **G1:** 21.7 (14.7) **G2:** 18.7 (10.4) *(P* = NS) **Duration of BED, yrs, mean (SD):** **G1:** 13.5 (10.7) **G2:** 17.7 (13.2) *(P* = NS) **Education:** **University degree:** **G1:** 14.3% **G2:** 7.1% **HS degree:** **G1:** 35.7% **G2:** 50.0% **Secondary school degree:** **G1:** 50.0% **G2:** 42.9% *(P* = NS) **Full syndrome BED:** **G1:** 71.4% **G2:** 71.4% **Subthreshold BED:** **G1:** 28.6% **G2:** 28.6% *(P* = NS)

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: DSM IV criteria for BED except for frequency criterion (frequency of 1 day per wk over last 6 mos allowed) **Exclusion:** Pregnancy, presence of psychotic symptoms; substance dependence; suicidality; use of psychoactive meds or meds affecting body wt.	19 wkly sessions within 5 mos and self-management phase of 3 sessions. Sessions 2 hrs long and groups had 4 – 5 members. Therapy based on manualized tx for CBT for BN with emphasis on body image disturbance. All group sessions conducted by a PhD level clinical psychologist. Nutritionist and physical therapist also provided services. In initial part of tx, focus was on causes and factors maintaining binge eating for the individual and included interventions aimed at increasing motivation for change. For CBT-C condition: participants trained and given homework on cognitive restructuring of neg body related cognitions. For exposure condition, multiple body exposure sessions, including in vivo mirror exposure to one's whole body. Within both conditions, info and group discussions on body image, body wt, social aspects of obesity and exercise were conducted.	Multivariate generalized linear models for repeated measures used. Univariate FU tests done for sig multivariate results. Nonparametric tests analyzed changes over time for tx diffs at each time point.	**Score:** Fair **Intent to treat:** Yes **Blinding:** N/A **Adverse events:** NR **Funding:** Deutshce Forschungsgemeinschaft DFG

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Hilbert and Tuschen-Caffier, 2004 (continued)	**Binges per wk in the past mo, mean (SD):** **G1:** 2.9 (1.8) **G2:** 3.4 (1.9) *(P* = NS)	**Binges per wk in past mo, mean (SD):** **Post-tx:** **G1:** 0.6 (0.7) **G2:** 1.0 (1.9) **4 mo FU, mean (SD):** **G1:** 1.2 (2.0) **G2:** 0.5 (1.0) Change over time *(P* = 0.045) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	Binge episodes, %: **G1:** 16.7% **G2:** 16.7% *(P* = NS)	**Binge episodes:** **Post-tx** **G1:** 0% **G2:** 0% **4 mo FU, mean (SD):** **G1:** 0% **G2:** 16.6% Change over timeNR Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	Video confrontation, neg automatic thoughts on one's body, mean (SD): **G1:** 13.3 (5.9) **G2:** 17.4 (10.8) *(P* = NS)	**Video confrontation, neg automatic thoughts on one's body, mean (SD):** **Post-tx:** **G1:** 9.7 (7.7) **G2:** 13.7 (11.7) **4 mo FU, mean (SD):** **G1:** 8.8 (8.3) **G2:** 12.8 (7.0) Change over time *(P* < 0.05) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	Test meal, mean (SD): **G1:** 5.0 (3.3) **G2:** 4.5 (3.2) *(P* = NS)	**Test meal, neg automatic thoughts on eating, mean (SD):** **Post-tx:** **G1:** 2.1 (1.5) **G2:** 6.7 (5.1) **4 mo FU, mean (SD):** **G1:** 2.8 (2.7) **G2:** 3.0 (2.3) Change over time *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BDI, mean (SD): **G1:** 19.0 (8.6) **G2:** 16.0 (7.7) *(P* = NS)	**BDI, mean (SD):** **Post-tx** **G1:** 12.8 (8.8) **G2:** 12.7 (9.0) **4 mo FU, mean (SD):** **G1:** 13.9 (8.7) **G2:** 12.3 (6.9) Change over time *(P* < 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)	**BMI kg/m^2, mean (SD):** **G1:** 34.0 (10.2) **G2:** 36.4 (10.4) *(P* = NS)	**BMI, kg/m^2, mean (SD):** **Post-tx:** **G1:** 33.1 (10.4) **G2:** 37.2 (10.3) **4 mo FU, mean (SD):** **G1:** 33.6 (11.0) **G2:** 36.4 (11.0) Change over time *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Hilbert and Tuschen-Caffier, 2004 (continued)	**EDE-Wt concern, mean (SD):** **G1:** 3.2 (0.8) **G2:** 3.8 (1.1) *(P* = NS)	**EDE-Wt concern, mean (SD):** **Post-tx:** **G1:** 2.3 (1.9) **G2:** 2.3 (1.5) **4 mo FU, mean (SD):** **G1:** 2.5 (1.7) **G2:** 2.2 (1.5) Change over time *(P* < 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	EDE- shape concern, mean (SD): **G1:** 3.7 (0.7) **G2:** 3.7 (1.2) *(P* = NS)	**EDE- shape concern, mean (SD):** **Post-tx:** **G1:** 2.6 (1.6) **G2:** 2.3 (1.5) **4 mo FU, mean (SD):** **G1:** 2.8 (1.7) **G2:** 2.1 (1.3) Change over time *(P* < 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	Body Satisfaction Questionnaire, mean (SD): **G1:** 120.7 (22.6) **G2:** 133.9 (20.0) *(P* = NS)	**Body Satisfaction Questionnaire, mean (SD):** **Post-tx:** **G1:** 94.3 (37.8) **G2:** 104.8 (29.2) **4 mo FU, mean (SD):** **G1:** 92.2 (35.8) **G2:** 97.4 (31.9) Change over time *(P* < 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
		EDE-Restraint, mean (SD): **Post-tx:** **G1:** 0.9 (1.2) **G2:** 0.9 (1.2) **4 mo FU, mean (SD):** **G1:** 1.0 (1.2) **G2:** 1.1 (1.3) Change over time *(P* < 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Hilbert and Tuschen-Caffier, 2004 (continued)	**EDE-eating concern, mean (SD):** **G1:** 0.7 (0.8) **G2:** 1.1 (1.0) *(P* = NS)	**EDE-eating concern, mean (SD):** **Post-tx:** **G1:** 0.2 (0.3) **G2:** 0.4 (0.6) **4 mo FU, mean (SD):** **G1:** 0.2 (0.3) **G2:** 0.4 (0.6) Change over time *(P* < 0.001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
		Recovered (abstinent for last 28 days): **Post-tx:** **G1:** 33.3% **G2:** 75% Diff between groups *(P* = NS) **4 mo FU:** **G1:** 50.0% **G2:** 66.7% Diff between groups *(P* = NS)

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Pendleton et al., 2002 **Setting:** NR **Enrollment period:** NR	**Research objective:** To evaluate the effects of adding exercise and maintenance to CBT for BED in obese women.	**Groups:** **G1:** CBT with exercise and maintenance (N = 28) **G2:** CBT with exercise, without maintenance (N = 27) **G3:** CBT without exercise and with maintenance (N = 27) **G4:** CBT without exercise or maintenance (N = 28) **Enrollment:** • 114 enrolled • 26 did not return after baseline assessment: **G1:** N = 4 **G2:** N = 7 **G3:** N = 4 **G4:** N = 11 • 84 completed 6 mos **Completion rate:** 1 in each group did not complete all assessments. **G1:** 24 **G2:** 20 **G3:** 23 **G4:** 17	**Age, yrs, mean (SD):** 45 (8.3) **Sex:** Female: 100% **Race/ethnicity:** Caucasian: 76% Black: 13% Black Mexican Am: 8% Other: 3% (*P* = NS)

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Female; age: 25-60; > 30 lbs overwt; profile for BE as per QEWP-R; hx of sedentary lifestyle and occ. Also - $200 deposit and physician clearance to participate. **Exclusion:** No hx of cardiovascular disease, diabetes, metabolic disorder, GI disorder/surgery; nonsmoker; not pregnant/lactating; not receiving tx for psych problems or major depression; no hx of drug abuse	**CBT:** wkly 90-minutes group sessions for 4 mos based on CBT tx for BED (based on Telch et al., 1990) facilitated by experienced RDs. **Exercise:** info and instructions on incorporating and maintaining exercise in routine; provided membership to a center and encouraged to gradually increase aerobic exercise; expectations were at least 45 minutes per session, 3 x per wk (attendance was recorded). **Maintenance:** 12 biwkly meetings over 6 mos (mos 4-10; exercisers continued to meet and exercise, CBT only continued with sessions only). FU at 16 mos.	ANOVA and chi-square for comparison of completers and noncompleters. Kruskal-Wallace ANOVA by ranks to analyze binge days. Repeated Msrs ANOVA for BMI. Bivariate correlations for exploratory analyses.	**Score:** Poor **Intent to treat:** No **Blinding:** No **Adverse events:** NR **Funding:** NIDDK

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Pendleton et al., 2002 (continued)	**Binge days, mean (SD):** **G1:** 4.2 (2.3) **G2:** 4.6 (2.1) **G3:** 4.6 (1.9) **G4:** 4.8 (2.0) *(P* = NS)	**Binge Days, mean (SD):** **4 mos:** **G1:** 0.6 (1.1) *(P* = NR) **G2:** 1.0 (1.3) *(P* = NR) **G3:** 2.4 (2.2) *(P* = NR) **G4:** 1.9 (2.0) *(P* = NR) Diff between groups *(P* = 0.004) Diff between G1 vs G4 *(P* = 0.039) G1 better than G4 Diff between groups in change over time Exercisers (G1 + G2) > non-exercisers (G3 + G 4) *(P* = 0.001) Maintenance (G1 + G3) vs no maintenance (G2 + G4) *(P* = NS) **10 mos:** **G1:** 0.5 (0.8) **G2:** 1.0 (1.3) **G3:** 1.3 (1.6) **G4:** 2.0 (1.6) Change over time *(P* = NR) Diff between groups *(P* = 0.018). diff between G1 vs G4: *(P* = 0.002) G1 better than G4 Diff between groups in change over time Exercisers (G1 + G2) > non-exercisers (G3 + G 4) *(P* = 0.012) Maintenance (G1 + G3) vs no maintenance (G2 + G4) *(P* = NS). **16 mos:** **G1:** 1.0 (1.7) *(P* = NR) **G2:** 0.8 (1.4) *(P* = NR) **G3:** 1.8 (2.2) *(P* = NR) **G4:** 2.5 (1.8) *(P* = NR) Change over time *(P* = NR) Diff between groups *(P* = 0.006) Diff between G1 vs G4 *(P* = 0.007); G1 better than G4 Diff between groups in change over time Exercisers (G1 + G2) > non-exercisers (G3 + G 4) *(P* = 0.002) Maintenance (G1 + G3) vs no maintenance (G2 + G4) *(P* = NS)

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BDI, mean (SD): **G1:** 15.7 (9.7) **G2:** 18.1 (10.7) **G3:** 19.0 (10.5) **G4:** 18.0 (7.2)	**BDI, mean (SD):** **4 mos:** **G1:** 6.4 (5.5) *(P* = NR) **G2:** 7.3 (7.8) *(P* = NR) **G3:** 9.7 (6.2) *(P* = NR) **G4:** 11.8 (9.6) *(P* = NR) Diff between groups NR G1 + G2 change over time *(P* = 0.007) **10 mos:** **G1:** 5.2 (5.1) *(P* = NR) **G2:** 11.0 (1.07) *(P* = NR) **G3:** 9.1 (8.1) *(P* = NR) **G4:** 8.7 (5.6) *(P* = NR) Diff between G1 vs **G2:** *(P* = 0.025) Diff between groups in change over time *(P* = NR) **16 mos:** **G1:** 5.1 (5.9) *(P* = NR) **G2:** 8.2 (8.6) *(P* = NR) **G3:** 8.0 (7.7) *(P* = NR) **G4:** 10.4 (8.2) *(P* = NR) Diff between G1 + G3 vs G2 + G4 *(P* = NS) Diff between groups in change over time *(P* = NR)	**Wt:** 97.2 (17.8) kg **BMI, kg/m^2, mean:** 36.2 (6.5) kg/m2 *(P* = NS)	**Change in BMI (SD):** **4 mos:** **G1:** -1.04 (2.1) *(P* = NR) **G2:** -0.46 (1.3) *(P* = NR) **G3:** -0.11 (1.2) *(P* = NR) **G4:** 0.77 (1.3) *(P* = NR) **10 mos:** **G1:** -2.53 (4.0) *(P* = NR) **G2:** -0.12 (16) *(P* = NR) **G3:** -83 (2.4) *(P* = NR) **G4:** 0.54 (2.0) *(P* = NR) **16 mos:** **G1:** -2.26 (3.9) *(P* = NR) **G2:** -0.75 (2.4) *(P* = NR) **G3:** -0.24 (3.0) *(P* = NR) **G4:** 1.33 (2.0) *(P* = NR) Change over entire period: G1 + G2 vs G3 + G4 *(P* = 0.004) G1 + G2 better than G3 + G4 G1 + G3 vs G2 + G4 *(P* = 0.006). G1 + G3 better than G2 + G4. G1 vs G4 *(P* = 0.001) G1 better than G4

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Pendleton et al., 2002 (continued)		**Abstinence (no binge days):** **4 mos:** **G1:** 67% **G2:** 50% **G3:** 22% **G4:** 41% *(P* = NR) **10:** **G1:** 63% **G2:** 45% **G3:** 43% **G4:** 23% *(P* = NR) **16 mos:** **G1:** 58% **G2:** 65% **G3:** 39% **G4:** 18% Diff between groups *(P* = NR)

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Riva et al., 2003 **Setting:** Inpatient; Eating Disorders Unit, Istituto Auxologico Italiano, Verbania, Italy **Enrollment period:** NR	**Research objective:** To compare psychological and eating-related outcomes of ECT, CBT, NG, and waitlist control in patients with BED at 6 mo FU.	**Groups (N = 36):** **G1:** ECT (N = NR) **G2:** CBT (N = NR) **G3:** NG (N = NR) **G4:** waitlist (N = NR) **Enrollment:** • 120 consecutive patients screened • 36 met criteria, and consented	**Age, mean (SD):** 33.07 (8.08) **Sex:** Female: 100% **Race/ethnicity:** NR **Wt, kg, mean (SD):** 105.44 (17.73) **Ht, cm, mean (SD):** 1.62 (0.06) **BMI, kg/m², mean (SD):** 39.80 (6.10)

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Women aged 18 to 50; met DSM IV criteria for BED at least 6 mos; written and informed consent to participate **Exclusion:** Concurrent: severe psychiatric disturbance, involvement in other tx including meds, medical condition not related to BED	Inpatient, lasting 6 wks; Assessments administered at baseline, post-tx, and 6 mo FU. NG: 5 wkly groups held by dieticians, low-calorie diet and physical training; ECT: NG plus 15 additional, sessions over 6 wks (5 wkly group, 10 bi-wkly VREDIM). CBT:NG plus 15 CBT sessions (5 wkly group, 10 bi-wkly individual.	Power analysis revealed low/medium power due to small sample and high SD. Accordingly, repeated and independent measures were assessed using marginal homogeneity test, an exact measure, non-parametric algorithm reliable with small, sparse or tied data.	**Score:** Poor **Intent to treat:** NR **Blinding:** NR **Adverse events:** NR **Funding:** Commission of the European Communities (CEC); specifically, the IST program through the VEPSY Updated research project.

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Riva, Bacchetta et al., 2003 (continued)	NR	**6 mo FU:** **Bulimia scores, EDI:** **G1:** 9.33 **G2:** 14.56 **G3:** 18.11 **G4:** NR Diff over time *(P = NR)* Diff between groups *(P* < 0.05) G1 better than G2 and G3 Diff between groups in change over time *(P* = NR) **Resisting Temptations scores, DIET:** **G1:** 19.11 **G2:** 12.00 **G3:** 10.89 **G4:** NR Diff over time *(P = NR)* Diff between groups *(P* < 0.05) G1 better than G2 and G3 Diff between groups in change over time *(P* = NR) **Body Satisfaction Scale, Total scores:** **G1:** 8.5 **G2:** 17.3 **G3:** 16.2 **G4:** NR Diff over time *(P = NR)* Diff between groups *(P* = < 0.05) G1 better than G2 and G3 Diff between groups in change over time *(P* = NR) **Abstinence, bingeing:** **G1:** 77% **G2:** 56% **G3:** 22% **G4:** NR Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
State Anxiety scores, STAI X2: **G1:** 49.44 **G2:** NR **G3:** 49.77 **G4:** NR *(P* = NS) **BDI scores:** **G1:** 22.23 **G2:** 20.55 **G3:** NR **G4:** NR *(P* = NS)	**Post–tx:** **State Anxiety scores, STAI X2:** **G1:** 36.77 *(P* = NS) **G2:** NR *(P* = NS) **G3:** 38.77 *(P* = 0.013) **G4:** NR *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) **BDI scores:** **G1:** 8.11 *(P* = 0.008) **G2:** 12.11 *(P* = 0.05) **G3:** NR *(P* = NS) **G4:** NR *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)	**Wt, kg (SD):** **G1:** 103.7 (17.2) **G2:** 109.3 (10.5) **G3:** 103.8 (21.3) **G4:** NR *(P* = NS)	**Post-tx:** **Wt, kg (SD):** **G1:** 97.2 (15.6) *(P* = NR) **G2:** 102.1 (9.14*) (P* = NR) **G3:** 103.8 (21.3*) (P* = NR) **G4:** NR Diff over time *(P* = NR) reported as sig in text Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **6 mo FU:** **G1:** NR **G2:** NR Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Telch, Agras and Linehan, 2001 **Setting:** Outpatient; Stanford University, USA **Enrollment period:** NR	**Research objective:** Assess the efficacy of DBT tx compared to a waitlist control in women with BED.	**Groups:** **G1:** DBT (N = 22) **G2:** Waitlist (N = 22) **Enrollment:** • 465 screened by telephone • 88 scheduled for clinical screening; 77 attended • 44 enrolled and randomized • **G1:** 18 completed through 6-mo FU; **G2:** 14 accepted waitlist tx, and 10 completed.	**Age, mean (SD):** 50 (9.1) **Age of drop-outs, mean (SD):** Drop-outs: 41.0 (10.5) Non-drop-outs: 50. (9.2) (*P* < 0.04) **Sex:** Female: 100% **Race/ethnicity:** Caucasian: 94% **Marital Status:** Married: 47% Divorced: 35% Never married: 18% **Educational Status:** Completed college: 70% Completed HS: 100% **Lifetime psychopathology:** Major depression: 38% Anxiety disorders: 35% Psychotic disorders: 3% Bulimia nervosa: 6% Substance abuse or dependence: 27% **Current psychopathology:** Major depression: 9% Anxiety disorder: 18% Personality disorder: 27% **Age of onset, binge eating, yrs, mean (SD):** 20.9 (11.7) **Duration of binge eating, yrs, mean (SD):** 29.2 (11.7) **BMI, kg/m², mean (SD):** 36.4 (6.6)

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Age 18 to 65; met full DSM IV diagnostic research criteria for BED **Exclusion:** Current involvement in psychotherapy, wt loss tx, or use of psychotropic meds; current substance abuse or dependence; current suicidality or psychosis; pregnancy	Over 20 wks, tx was delivered at wkly, group 2hr sessions to teach DBT skills; tx manual was adapted from Linehan's DBT for borderline personality disorder For all participants, assessments, and ht and wt measures were taken at baseline, post-tx (20 wks), 3-, and 6-mo FU.	T-test or chi-square analyses were completed to compare baseline measures, as well as dropouts versus tx completers; tx outcomes were assessed using a one-way ANCOVA with baseline measures as covariates. Analyses were restricted to those who completed tx.	**Score:** Fair **Intent to treat:** No **Blinding:** No **Adverse events:** During FU period, 3 women in G1 were treated with either psychotherapy or meds for a major depressive episode, and 1 enrolled in a very-low-calorie diet program. **Funding:** NIMH

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Telch, Agras and Linehan, 2001	Note: Means are reported; square root transformations were used in analyses.	
(continued)	**Binge days, per 28 days, median (SD):** **G1:** 10.5 (9.0) **G2:** 14.0 (5.0) *(P* = NS)	**Binge days, per 28 days, median (SD):** **G1:** 0 (0) *(P* = NR) **G2:** 8.5 (10.0) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.001) G1 better than G2
	Binge episodes, per 28 days, median (SD): **G1:** 11.5 (10.8) **G2:** 14.5 (7.5) *(P* = NS)	**Binge episodes, per 28 days, median (SD):** **G1:** 0 (0) *(P* = NR) **G2:** 10.0 (14.0) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.001) G1 better than G2
	EDE, Wt Concerns, median (SD): **G1:** 3.4 (1.1) **G2:** 3.6 (0.6) *(P* = NS)	**EDE, Wt Concerns, median (SD):** **G1:** 2.2 (0.9) *(P* = NR) **G2:** 3.1 (1.0) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.02) G1 better than G2
	EDE, Shape Concerns (SD): **G1:** 3.7 (0.7) **G2:** 4.0 (0.8) *(P* = NS)	**EDE, Shape Concerns (SD):** **G1:** 2.3 (0.9) *(P* = NR) **G2:** 3.1 (1.0) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.03) G1 better than G2
	EDE, Eating Concerns, median (SD): **G1:** 1.6 (1.1) **G2:** 1.8 (1.0) *(P* = NS)	**EDE, Eating Concerns, median (SD):** **G1:** 0.4 (0.4) *(P* = NR) **G2:** 1.4 (0.9) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.001) G1 better than G2
	EDE, Restraint, median (SD): **G1:** 1.6 (1.0) **G2:** 1.9 (1.1) *(P* = NS)	**EDE, Restraint, median (SD):** **G1:** 1.4 (1.0) *(P* = NR) **G2:** 1.8 (1.3) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	BES, median (SD): **G1:** 28.8 (6.1) **G2:** 31.8 (6.0) *(P* = NS)	**BES, median (SD):** **G1:** 15.7 (9.4) *(P* = NR) **G2:** 28.2 (8.3) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.001) G1 better than G2

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BDI, median (SD): **G1:** 12.8 (7.4) **G2:** 13.8 (9.1) *(P* = NS)	**BDI, median (SD):** **G1:** 9.9 (10.0) *(P* = NR) **G2:** 12.8 (8.3) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)	**Wt, lbs, median (SD):** **G1:** 214.7 (49.8) **G2:** 223.4 (37.1) *(P* = NS)	**Wt, lbs, median (SD):** **G1:** 209.2 (49.8) *(P* = NR) **G2:** 223.8 (37.1) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
RSE, median (SD): **G1:** 26.0 (6.8) **G2:** 28.9 (5.0)	**RSE, median (SD):** **G1:** 29.4 (6.1) **G2:** 29.2 (4.5) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)		

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Telch, Agras and Linehan, 2001 (continued)	**EES, Anxiety, median (SD):** **G1:** 2.3 (0.9) **G2:** 2.7 (0.6) *(P* = NS)	**EES, Anxiety, median (SD):** **G1:** 1.5 (0.9) *(P* = NR) **G2:** 2.4 (1.0) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	EES, Depression, median (SD): **G1:** 3.0 (0.7) **G2:** 3.3 (0.7) *(P* = NS)	**EES, Depression, median (SD):** **G1:** 2.4 (1.0) *(P* = NR) **G2:** 3.0 (0.8) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Wilfley et al., 2002 **Setting:** Outpatient; Eating disorder clinics at Yale U and at San Diego State U, USA **Enrollment period:** NR	**Research objective:** Compare effects of group CBT and group IPT on overwt individuals with BED.	**Groups:** **G1:** CBT (N = 81) **G2:** IPT (N = 81) **Enrollment:** • 974 individuals expressed interest • 320 met criteria based on phone screens • 195 met criteria after being interviewed • 162 interested, eligible and randomized • Participants randomly assigned to two groups of 9 participants each within 9 cohorts • 146 completed tx and some assessments • 133 completed all three FU CBT (N = 65); IPT (N = 68)	**Age, mean (SD):** **G1:** 45.6 (9.6) **G2:** 44.9 (9.6) (*P* = NS) **Sex:** Female: **G1:** 82.7% **G2:** 82.7% (*P* = NS) **Race/ethnicity:** **White:** **G1:** 93.9% **G2:** 91.4% (*P* = NS) **AA:** **G1:** 3.7% **G2:** 3.7% (*P* = NS) **Hisp:** **G1:** 1.2% **G2:** 4.9% (*P* = NS) **Native American:** **G1:** 1.2% **G2:** 0% (*P* = NS) **Age at onset of disorder, yrs, mean (SD):** **G1:** 24.1 (13.5) **G2:** 25.7 (12.9) (*P* = NS) **DSM III-R current Mood dx:** **G1:** 25.9% **G2:** 18.5% (*P* = NS) **DSM III-R current anxiety dx:** **G1:** 12.3% **G2:** 13.6% (*P* = NS) **DSM III-R current substance use dx:** **G1:** 6.2% **G2:** 1.2% (*P* = NS)

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: DSM IV research criteria for BED: avg of ≥2 days of binge eating per wk for at least 6 mos, marked distress regarding binge eating, at least 3 of 5 associated behavioral features (e.g., eating when not physically hungry), no regular use of inappropriate compensatory behavior, age: 18 – 65, BMI: 27 – 48 $kg/m^{2.}$ **Exclusion:** Pregnant or planning to become pregnant, taking wt affecting or psychotropic meds, psychiatric conditions warranting immediate tx (e.g., psychotic symptoms, substance dependence or suicidality) and currently enrolled in psychotherapy or wt loss program.	Both: 20 90-minutes wkly group sessions and 3 individual sessions. Wkly personalized written feedback detailing progress. Both groups manual-based and led by two therapists. **G1:** 3 phases focusing on behavioral strategies, cognitive skills and relapse prevention. **G2:** focused on problem resolution within 4 social domains: Grief, interpersonal role disputes, role transitions and interpersonal deficits.	GEE approach. Used to test hypotheses about tx effects, time course and tx x time interactions with linear, quadratic and cubic components of time as the within-subjects factors and tx and interactions between time components and tx as between-subjects factors. Primary analyses included post tx and FU time points for three primary outcomes: recovered (no objective binge episodes in the last mo), improved (fewer than 4 days of objective binge episodes in the last mo) and being at or below a comparative level of eating disorder attitudes and behaviors.	**Score:** Good **Intent to treat:** Yes **Blinding:** NA **Adverse events:** NR **Funding:** NIMH

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Wilfley et al., 2002 (continued)			**Any current Axis I DSM III-R dx:** **G1:** 37.0% **G2:** 29.6% (*P* = NS) **Any current Axis II DSM III-R dx:** **G1:** 37.0% **G2:** 38.3% (*P* = NS)

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Wilfley et al., 2002 (continued)	**Binge days, mean (SD):** **G1:** 17.3 (6.9) **G2:** 16.3 (7.2) *(P* = NS)	**Binge days, mean (SD):** **Post tx** **G1:** 0.6 (1.6) *(P* < 0.001) **G2:** 0.9 (2.0) *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **4 mos post tx vs. post-tx:** **G1:** 2.0 (4.6) (GEE quadratic: *P* < 0.001, GEE cubic: *P* = 0.002) **G2:** 1.5 (3.9) (GEE quadratic: *P* < 0.001, GEE cubic: *P* = 0.002) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **8 mos post tx vs. post-tx:** **G1:** 2.1 (5.0) (GEE quadratic *P* < 0.001) GEE cubic *(P* = 0.002) **G2:** 1.9 (4.5) (GEE quadratic *(P* < 0.001) GEE cubic *(P* = 0.002) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **12 mos post tx vs. post-tx:** **G1:** 1.7 (4.3) *(P* = NR) **G2:** 1.2 (2.6) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
Total GSI, mean (SD): **G1:** 43.3 (7.8) **G2:** 42.0 (8.9) *(P* = NS)	**Total GSI, mean (SD):** **Post tx:** **G1:** 32.8 (8.8) *(P* < 0.001) **G2:** 32.3 (8.5) *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **4 mos post tx:** **G1:** 33.0 (8.4) **G2:** 33.2 (10.9) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **8 mos post tx** **G1:** 31.9 (9.7) **G2:** 32.7 (10.6) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **12 mos post tx:** **G1:** 32.0 (8.9) **G2:** 30.7 (10.6) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)	**BMI, mean (SD):** **G1:** 37.4 (5.3) **G2:** 37.4 (5.1) *(P* = NS)	**BMI, mean (SD):** **Post tx** **G1:** 37.5 (5.3) *(P* = NS) **G2:** 37.2 (5.2) *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **4 mos post tx vs. post-tx:** **G1:** 37.4 (5.3) **G2:** 36.6 (5.3) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **8 mos post tx vs. post-tx:** **G1:** 37.5 (5.1) **G2:** 36.4 (5.5) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **12 mos post tx vs. post-tx:** **G1:** 37.2 (5.1) **G2:** 36.3 (5.4) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) Linear main effect of time since FU *(P* = 0.008)

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Wilfley et al., 2002 (continued)	**EDE Restraint, mean (SD):** **G1:** 1.8 (1.2) **G2:** 2.1 (1.3) *(P* = NS)	**EDE Restraint, mean (SD):** **Post tx** **G1:** 0.9 (0.9) *(P* = 0.001) **G2:** 1.5 (1.1) *(P* = 0.001) Diff between groups *(P* = *0*.001) Diff between groups in change over time *(P* < 0.001) G2 better than G1 **4 mos post tx:** **G1:** 0.9 (0.9) *(P* = 0.001) **G2:** 1.3 (1.2) *(P* = 0.001) Diff between groups *(P* = 0.04) Diff between groups in change over time *(P* = 0.04); G1 better than G2 **8 mos post tx:** **G1:** 0.8 (0.8*) (P* = 0.001) **G2:** 1.2 (1.2*) (P* = 0.001) Diff between groups *(P* = 0.08) Diff between groups in change over time *(P* = 0.04) **12 mos post tx:** **G1:** 1.0 (1.1) **G2:** 1.3 (1.3) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = 0.04)
	EDE Shape Concern, mean (SD): **G1:** 3.8 (1.0) **G2:** 3.8 (0.9) *(P* = NS)	**EDE Shape Concern, mean (SD):** **Post tx** **G1:** 2.3 (1.4) *(P* < 0.001) **G2:** 2.4 (1.1) *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **4 mos post tx:** **G1:** 2.3 (1.2) *(P* = NS) **G2:** 2.4 (1.2); *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **8 mos post tx:** **G1:** 2.3 (1.3*) (P* = NS) **G2:** 2.2 (1.2*) (P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **12 mos post tx:** **G1:** 2.2 (1.3*) (P* = NS) **G2:** 2.2 (1.3) *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
SCL Depression, mean (SD): **G1:** 44.3 (8.3) **G2:** 42.4 (9.6) *(P* = NS)	**SCL Depression, mean (SD):** **Post tx:** **G1:** 34.8 (7.9) *(P* < 0.001) **G2:** 33.6 (8.6) *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **4 mos post tx:** **G1:** 34.2 (8.3) **G2:** 34.6 (10.6) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **8 mos post tx:** **G1:** 33.3 (8.6) **G2:** 34.4 (10.7) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **12 mos post tx:** **G1:** 33.1 (8.2) **G2:** 32.2 (10.3) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)		

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Wilfley et al., 2002 (continued)	**EDE Wt Concern, mean (SD):** **G1:** 3.3 (1.1) **G2:** 3.2 (1.1) *(P* = NS)	**EDE Wt Concern, mean (SD):** **Post tx** **G1:** 2.0 (1.2) *(P* < 0.001) **G2:** 2.1 (1.2) *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **4 mos post tx:** **G1:** 2.0 (1.1*) (P* = NS) **G2:** 2.2 (1.3*) (P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **8 mos post tx:** **G1:** 2.1 (1.2*) (P* = NS) **G2:** 1.9 (1.1*) (P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **12 mos post tx:** **G1:** 1.9 (1.3) *(P* = NS) **G2:** 1.9 (1.3) *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	EDE Eating Concern, mean (SD): **G1:** 2.4 (1.2) **G2:** 2.3 (1.5) *(P* = NS)	**EDE Eating Concern, mean (SD):** **Post tx** **G1:** 0.6 (0.8) *(P* < 0.001) **G2:** 0.7 (0.8) *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **4 mos post tx:** **G1:** 0.6 (0.8*) (P* = NS) **G2:** 0.8 (1.0*) (P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **8 mos post tx:** **G1:** 0.6 (0.7*) (P* = NS) **G2:** 0.7 (0.9*) (P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **12 mos post tx:** **G1:** 0.6 (0.8) *(P* = NS) **G2:** 0.6 (0.9) *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Wilfley et al., 2002 (continued)		**Abstinence from binge-eating:** **Post tx** **G1:** (82%) *(P* = NR) **G2:** (74%) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **12 mos post tx:** **G1:** (72%) *(P* = NR) **G2:** (70%) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)

Evidence Table 12. Behavioral intervention trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 13. Self-help trials for binge eating disorder

Study Description	Objective	Design	Patient Characteristics
Author, yr: Carter and Fairburn, 1998 **Setting:** Single center; outpatient; Dept. of Psychiatry, University of Oxford, UK **Enrollment period:** NR	**Research objective:** To assess effectiveness of two self-help programs for treating BED symptoms in comparison to a waitlist control. In addition to evaluating changes in eating- and wt-related outcomes, authors investigated potential group diffs in overall psychiatric symptom reporting and in knowledge of the educational content of the self-help materials.	**Groups:** **G1:** guided self-help (N = unclear) **G2:** pure self-help (N = unclear) **G3:** waitlist control (N = unclear) **Enrollment:** • 234 potential subjects responded to media advertisements and received an initial phone screen • 91 were invited for an in-person assessment interview • 72 were enrolled and randomized into the two self-help tx conditions • 65 remained after 12 wks (G1 = 8 and G3 = 1; *P* = NR) * Group numbers inconsistent in text and figures: text indicates 72 randomized; tables and figures refer to total N = 93.	**Age, yrs mean (SD) (range):** **Total Sample:** 39.7 (10.0) (21-59) *(P* = NS) **Sex:** Female: 100% **Race/ethnicity:** White: 97% **Age of onset, yrs, mean (SD):** 23.6 (11.1) *(P* = NS) **Medically obese (BMI>30):** 60% *(P* = NS) **Marital Status:** Married or cohabitating: 63% Divorced: 12% Widowed: 3% Single: 22% **Employed:** 67%

Evidence Table 13. Self-help trials for binge eating disorder (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: DSM IV and EDE criteria for BED including wkly objective BE over the last 3 mos without compensatory behaviors; aged: 18-65 **Exclusion:** Pregnancy; medical disorder or tx known to impact eating or wt; BN or AN; previous tx for binge-eating; current psychiatric tx	12 wks of a guided self-help or a pure cognitive-behavioral self-help program for binge-eating; In the pure self-help condition, subjects sent a copy of *Overcoming Binge Eating* and asked to follow program as best as possible on their own; In the guided self-help, subjects received 6-8 25-minute sessions with trained facilitator who provided assistance in adhering to the program outlined in *Overcoming Binge Eating*; Outcome variables assessed after 12 wks of tx in all 3 groups, and at 3-mo, and 6-mo FU for the two tx groups only.	Primary analyses included repeated measures ANOVAs and post-hoc comparisons to test between group diffs over course of the study; Chi-square tests used to test between group diffs in remission/abstinence rates.	**Score:** Good **Intent to treat:** Yes **Blinding:** NA **Adverse events:** NR **Funding:** Wellcome Prize Studentship and Wellcome Principal Fellowship

Evidence Table 13. Self-help trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Carter and Fairburn, 1998 (continued)	**Binge eating/28 days, mean (SD):** **G1:** 17.8 (10.6) **G2:** 19.7 (12.9) **G3:** 21.6 (12.5) *(P* = NS)	**Binge eating/28 days, mean (SD):** **12 wks (end of tx)** **G1:** 4.3 (7.8) *(P* = 0.01) **G2:** 9.3 (11.7) *(P* = 0.01) **G3:** 13.5 (10.3) *(P* = NS) Diff between groups G1 vs G3 *(P* = 0.001) G1 better than G3 G2 vs G3 *(P* < 0.05) G2 better than G3 G1 vs. G2 *(P* = NS) Diff between groups in change over time *(P* = NR) **3-mos:** **G1:** 3.6 (3.5) *(P* = NS) **G2:** 5.0 (4.3) *(P* = NS) **G3:** NA *(P* = NR) G1 better than G2 Diff between groups in change over time *(P* = NS) **6-mos:** **G1:** 3.7 (4.2) *(P* = NR) **G2:** 4.7 (4.0) *(P* = NR) **G3:** NA Diff between groups *(P* = NR) G1 better than G2 Diff between groups in change over time *(P* = NS)
		Abstinence/cessation rates: **12 wks (end of tx)** **G1:** 50% **G2:** 43% **G3:** 8% Diff between groups G1 vs G3 *(P* = 0.001) G1 better than G3 G2 vs G3 *(P* = 0.008) G2 better than G3 **3-mos:** **G1:** 41% **G2:** 37% **G3:** NA Diff between groups *(P* = NS) **6-mos:** **G1:** 50% **G2:** 40% **G3:** NA Diff between groups *(P* = NS)

Evidence Table 13. Self-help trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
GSI, mean (SD): **G1:** 0.9 (0.6) **G2:** 1.3 (0.8) **G3:** 1.2 (0.8) *(P* = NS)	**GSI, mean (SD):** **12 wks (end of tx):** **G1:** 0.7 (0.6) *(P* = 0.01) **G2:** 0.8 (0.6) *(P* = 0.01) **G3:** 1.2 (0.7) *(P* = NS) Diff between groups G1 vs G3 *(P* = 0.003) G1 better than G2 G2 vs G3 *(P* = 0.04) G1 better than G3 G1 vs G2 *(P* = NS) Diff between groups in change over time *(P* = NS) **3-mos:** **G1:** 1.6 (1.4) *(P* = NR) **G2:** 1.7 (1.5) *(P* = NR) **G3:** NA Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **6-mos:** **G1:** 1.5 (1.4) *(P* = NR) **G2:** 1.8 (1.5) *(P* = NR) **G3:** NA Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)	**Wt, kg, mean (SD):** Total sample: 85.8 (19.7) **G1:** NR **G2:** NR	**Wt, kg, mean (SD):** **G1:** NR **G2:** NR
		BMI kg/m^2, mean (SD): **G1:** 32.2 (6.4) **G2:** 30.6 (6.6) **G3:** 31.5 (6.6) *(P* = NS)	**BMI kg/m^2, mean (SD):** **12 wks (end of tx):** **G1:** 31.7 (6.1) *(P* = NR) **G2:** 30.7 (6.6) *(P* = NR) **G3:** 31.9 (7.4) *(P* = NR) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **3-mos:** **G1:** 30.8 (5.9) *(P* = NR) **G2:** 29.4 (5.6) *(P* = NR) **G3:** NA Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **6-mos:** **G1:** 31.6 (6.2) *(P* = NR) **G2:** 30.4 (6.5) *(P* = NR) **G3:** NA Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)

Evidence Table 13. Self-help trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Carter and Fairburn, 1998 (continued)	**Global EDE, mean (SD):** **G1:** 3.6 (0.8) **G2:** 3.7 (0.8) **G3:** 3.6 (1.0) *(P* = NS)	**Global EDE, mean (SD):** **12 wks (end of tx)** **G1:** 2.1 (1.2) *(P* = 0.01) **G2:** 2.7 (1.3) *(P* = 0.01) **G3:** 3.5 (0.8) *(P* = NR) Diff between groups G1 vs G3 *(P* = 0.001) G1 better than G3 G2 vs G3 *(P* = 0.03) G2 better than G3 G1 vs. G2 *(P* = NS) Diff between groups in change over time *(P* = NR) **3-mos:** **G1:** 2.1 (1.3) *(P* = NS) **G2:** 2.6 (1.5) *(P* = NS) **G3:** NA Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **6-mos:** **G1:** 2.4 (1.3) *(P* = NS) **G2:** 2.6 (1.5) *(P* = NS) **G3:** NA Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	Restraint, mean (SD): **G1:** 2.5 (1.4) **G2:** 2.4 (1.5) **G3:** 2.4 (1.4) *(P* = NS)	**Restraint, mean (SD):** **12 wks (end of tx)** **G1:** 1.2 (1.3) *(P* = 0.01) **G2:** 2.1 (1.4) *(P* = NS) **G3:** 2.6 (1.4) *(P* = NS) Diff between groups G1 vs G3 *(P* = 0.002) G1 better than G3 G1 vs. G2 *(P* = 0.006) G1 better than G2 G2 vs G3 *(P* = NS) Diff between groups in change over time *(P* = NR) G1 > G2, G3 **3-mos:** **G1:** 1.0 (1.0) *(P* = NS) **G2:** 1.9 (1.6) *(P* = NS) **G3:** NA Diff between groups G1 vs G2 *(P* = 0.01) G1 better than G2 **6-mos:** **G1:** 1.3 (1.2) *(P* = NR) **G2:** 2.0 (1.6) *(P* = NR) **G3:** NA Diff between groups G1 vs G2 *(P* = NS)

Evidence Table 13. Self-help trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 13. Self-help trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Carter and Fairburn, 1998 (continued)	**Eating Concern, mean (SD):** **G1:** 3.4 (1.2) **G2:** 3.5 (1.0) **G3:** 3.6 (1.3) *(P* = NS)	**Eating Concern, mean (SD):** **12 wks (end of tx)** **G1:** 1.4 (1.3) *(P* = NR) **G2:** 2.0 (1.6) *(P* = NR) **G3:** 3.7 (1.1) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) **3-mos:** **G1:** 1.6 (1.5) *(P* = NR) **G2:** 2.2 (1.7) *(P* = NR) **G3:** NA Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) **6-mos:** **G1:** 1.8 (1.5) *(P* = NR) **G2:** 2.2 (1.6) *(P* = NR) **G3:** NA Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)
	Shape Concern, mean (SD): **G1:** 4.8 (1.0) **G2:** 4.9 (0.8) **G3:** 4.8 (1.3) *(P* = NS)	**Shape Concern, mean (SD):** **12 wks (end of tx)** **G1:** 3.3 (1.5) *(P* = NR) **G2:** 3.7 (1.6) *(P* = NR) **G3:** 4.6 (0.9) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) **3-mos:** **G1:** 3.3 (1.6) *(P* = NR) **G2:** 3.6 (1.8) *(P* = NR) **G3:** NA Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) **6-mos:** **G1:** 3.6 (1.6) *(P* = NR) **G2:** 3.7 (1.7) *(P* = NR) **G3:** NA Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)

Evidence Table 13. Self-help trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 13. Self-help trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Carter and Fairburn, 1998 (continued)	**Wt Concern, mean (SD):** **G1:** 3.8 (1.0) **G2:** 4.0 (1.1) **G3:** 3.6 (1.3) *(P* = NS)	**Wt Concern, mean (SD):** **12 wks (end of tx)** **G1:** 2.5 (1.6) *(P* = NR) **G2:** 3.1 (1.4) *(P* = NR) **G3:** 3.7 (1.1) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) **3-mos:** **G1:** 2.6 (1.5) *(P* = NR) **G2:** 2.8 (1.7) *(P* = NR) **G3:** NA Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR) **6-mos:** **G1:** 2.8 (1.5) *(P* = NR) **G2:** 2.7 (1.7) *(P* = NR) **G3:** NA Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)

Evidence Table 13. Self-help trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 13. Self-help trials for binge eating disorder (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Peterson et al., 2001 **Setting:** Eating disorders research clinic, University of Minnesota, Minneapolis, USA Outpatient **Enrollment period:** NR	**Research objective:** To compare the short and long-term outcomes of three models of delivery of group CBT for patients with BED.	**Groups:** **G1:** Therapist led (TL) (N = 16) **G2:** Partial self-help (PSH) (N = 19) **G3:** Structured self-help (SSH) (N = 16) **Enrollment:** • screened by phone for eligibility • Potential participants attended orientation session and completed self-report questionnaires • Participants scheduled for assessment session for structured interviews • Participants assigned to one of four conditions with group size ranging from 4 to 10 (avg = 6) • Total of ten groups conducted at different time points • Of 51 participants, 44 completed 8 wks of tx.	**Age, mean (SD):** Total sample: 42.9 yrs (10.1) **G1:** NR **G2:** NR **G3:** NR (*P* = NS) **Sex:** Female: 100% **Race/ethnicity:** Caucasian: 96% African American: 2% Native American: 2% **G1:** NR **G2:** NR **G3:** NR (*P* = NS)

Evidence Table 13. Self-help trials for binge eating disorder (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Met criteria for BED as listed in appendix for disorders warranting further investigation in the DSM IV using the SCID-patient version. **Exclusion:** Taking any current psychoactive meds or involved in psychotherapy; substance abuse or dependence within 6 mos prior to enrollment in study, medical instability and acute risk of self-injury; met criteria for full or subthreshold BN, i.e., individuals who engaged in any compensatory behaviors in last six mos, including self-induced vomiting, abuse of diuretics or laxatives, fasting or excessive exercise	For all participants, active tx 8 wks. Tx modified from manual-based CB intervention for BN. All participants given detailed manual that included psychoeducational materials and homework assignments. Included 14 one-hour sessions held twice wkly in the first 6 wks and wkly for final two wks. Each session included: psychoeducational info for the first 30 minutes and a discussion focusing on review of homework assignment for the second 30 min. Groups not conducted simultaneously. **G1:** psychologist provided psychoeducational info and led group discussion and homework review. In **G2:** participants viewed videotape of psychologist delivering psychoeducational info followed by psychologist joining group and leading discussion in second 30 min. In **G3:** participants watched videotape and led their own discussion and review of homework, were given detailed list of discussion topics and group members facilitated discussion on rotating basis. The videotapes viewed by G2 and G3 were filed during the TL condition psychoeducational component.	ANOVA and chi-square analyses used to compare groups on baseline demographic variables. A mixed effects model used to evaluate group, time and group x time interaction for the primary and secondary outcome variables. Chi-square analyses used to evaluate outcome based on SCID dx at post and FU assessments as well as on abstinence rates.	**Score:** Fair **Intent to treat:** No **Blinding:** NA **Adverse events:** None reported **Funding:** McKnight Foundation; Minnesota Obesity Center; NIH; Neuropsychiatric Research Institute

Evidence Table 13. Self-help trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Peterson et al., 2001 (continued)	**Objective Binge Episodes – based on Eating Behavior – IV (SD):** **G1:** 3.4 (1.7) **G2:** 5.5 (6.7) **G3:** 2.9 (2.2) *(P* = NR)	**Objective binge episodes, mean (SD):** **Post tx:** **G1:** 0.6 (1.4) *(P* = NR) **G2:** 0.7 (1.5) *(P* = NR) **G3:** 0.7 (2.2) *(P* = NR) Diff over time *(P* < 0.0001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **One mo FU:** **G1:** 0.8 (1.1) *(P* = NR) **G2:** 1.1 (2.5) *(P* = NR) **G3:** 0.9 (1.6) *(P* = NR) Diff over time *(P* < 0.0001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **Six mo FU:** **G1:** 0.7 (0.9) *(P* = NR) **G2:** 0.4 (0.7) *(P* = NR) **G3:** 1.7 (3.9) *(P* = NR) Diff over time *(P* < 0.0001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **12 mo FU:** **G1:** 0.5 (0.8) *(P* = NR) **G2:** 1.1 (2.7) *(P* = NR) **G3:** 1.0 (2.0) *(P* = NR) Diff over time *(P* < 0.0001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)

Evidence Table 13. Self-help trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BDI, mean (SD) **G1:** 15.5 (9.9) **G2:** 11.1 (9.1) **G3:** 13.5 (9.5) *(P* = NR)	**BDI, mean (SD)** **Post tx:** **G1:** 10.5 (9.9) **G2:** 5.6 (3.6) **G3:** 9.0 (8.1) Diff over time: *(P* < 0.0001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **One mo FU:** **G1:** 6.6 (7.2) **G2:** 5.7 (4.6) **G3:** 6.4 (7.3) Diff over time *(P* < 0.0001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **Six mo FU:** **G1:** 6.4 (7.0) **G2:** 6.3 (5.6) **G3:** 6.9 (6.0) Diff over time *(P* < 0.0001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **12 mos FU:** **G1:** 7.8 (8.1) **G2:** 3.9 (3.7) **G3:** 6.6 (7.4) Diff over time *(P* = 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)	**BMI kg/m^2, mean (SD):** Total sample: 34.1 (7.04) **G1:** 32.6 (8.2) **G2:** 35.8 (6.0) **G3:** 33.6 (7.0) *(P* = NR)	**BMI, kg/m^2, mean (SD)** **Post tx:** **G1:** 32.5 (8.9) **G2:** 36.2 (5.5) **G3:** 32.4 (7.2) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **One mo FU:** **G1:** 31.5 (9.0) **G2:** 35.8 (5.7) **G3:** 33.3 (7.6) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **Six mo FU:** **G1:** 30.2 (7.7) **G2:** 36.2 (6.5) **G3:** 32.0 (8.6) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **12 mo FU:** **G1:** 31.2 (7.9) **G2:** 35.8 (7.0) **G3:** 32.8 (7.4) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)

Evidence Table 13. Self-help trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Peterson et al., 2001 (continued)	**Total binge episodes, mean (SD):** **G1:** 8.3 (3.1) **G2:** 9.2 (6.7) **G3:** 6.6 (2.2) *(P* = NR)	**Total binge episodes, mean (SD):** **Post tx:** **G1:** 2.8 (3.2) **G2:** 2.0 (3.4) **G3:** 2.4 (6.6) Diff over time *(P* < 0.0001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **One mo FU:** **G1:** 4.4 (4.0) **G2:** 3.7 (5.5) **G3:** 1.2 (1.6) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **Six mo FU:** **G1:** 3.7 (3.9) **G2:** 3.2 (3.0) **G3:** 3.0 (3.6) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **12 mo FU:** **G1:** 3.5 (3.4) **G2:** 3.1 (4.8) **G3:** 3.3 (3.6) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
	Body Shape Questionnaire (BSQ) (SD) **G1:** 140.6 (40.0) **G2:** 141.1 (28.0) **G3:** 127.7 (25.5)	**Body Shape Questionnaire (BSQ), mean (SD)** **G1:** 108.4 (45.3) **G2:** 113.7 (26.9) **G3:** 110.2 (23.8) Diff between groups (*P* = NS) Diff between groups in change over time (*P* = NS) **One mo FU:** **G1:** 92.2 (28.7) **G2:** 112.9 (27.5) **G3:** 103.5 (28.6) Diff between groups (*P* = NS) Diff between groups in change over time (*P* = NS) **Six mo FU:** **G1:** 94.0 (30.5) **G2:** 113.9 (23.0) **G3:** 103.7 (23.2) Diff between groups (*P* = NS) Diff between groups in change over time (*P* = NS) **12 mo FU:** **G1:** 91.1 (36.4) **G2:** 109.9 (33.0) **G3:** 105.2 (24.1) Diff between groups (*P* = NS) Diff between groups in change over time (*P* = NS)

Evidence Table 13. Self-help trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
HDRS, mean (SD) **G1:** 13.3 (7.3) **G2:** 8.8 (6.9) **G3:** 7.7 (5.9) *(P* = NR)	**HDRS, mean (SD)** **Post tx:** **G1:** 10.5 (7.3) **G2:** 4.8 (3.3) **G3:** 8.0 (6.4) Diff over time (baseline to post tx) *(P* = 0.03) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **One mo FU:** **G1:** 7.6 (3.7) **G2:** 6.3 (4.9) **G3:** 7.0 (7.0) Diff over time (baseline to 1 mo) *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **Six mo FU:** **G1:** 6.5 (4.4) **G2:** 7.7 (7.9) **G3:** 5.5 (4.6) Diff over time (baseline to 6 mos) *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **12 mos FU:** **G1:** 9.9 (8.6) **G2:** 3.8 (3.9) **G3:** 6.2 (4.7) Diff over time (baseline to 12 mos) *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)		

Evidence Table 13. Self-help trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Peterson et al., 2001 (continued)	**Hours binged, mean (SD):** **G1:** 9.0 (6.6) **G2:** 13.5 (13.4) **G3:** 10.0 (5.4) *(P* = NR)	**Hours binged, mean (SD):** **Post tx:** **G1:** 2.6 (3.2) **G2:** 2.1 (3.4) **G3:** 3.2 (8.9) Diff over time *(P* < 0.0001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **One mo FU:** **Hours Binged (SD):** **G1:** 3.0 (2.4) **G2:** 3.8 (5.8) **G3:** 2.5 (3.8) Diff over time *(P* < 0.0001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **Six mo FU:** **Hours binged (SD):** **G1:** 2.3 (2.3) **G2:** 3.0 (2.5) **G3:** 3.6 (5.0) Diff over time *(P* < 0.0001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **12 mo FU:** **Hours binged (SD)** **G1:** 2.4 (1.8) **G2:** 2.8 (4.6) **G3:** 4.5 (5.2) Diff over time *(P* < 0.0001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)

Evidence Table 13. Self-help trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 13. Self-help trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Peterson et al., 2001 (continued)	**Percent abstinent from objective binge for last wk:** **G1:** 0% **G2:** 0% **G3:** 0% *(P* = NR)	**Percent abstinent from Objective Binge for last wk:** **Post tx:** **G1:** 78.6% **G2:** 75.0% **G3:** 90.0% Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **One mo FU:** **G1:** 54.5% **G2:** 69.2% **G3:** 63.6% Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **Six mo FU:** **G1:** 55.6% **G2:** 70.0% **G3:** 75.0% Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **12 mo FU:** **G1:** 66.7% **G2:** 84.6% **G3:** 75.0% Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)

Evidence Table 13. Self-help trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 13. Self-help trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Peterson et al., 2001 (continued)	**TFEQ Restraint, mean (SD):** **G1:** 8.9 (4.8) **G2:** 8.4 (4.2) **G3:** 8.4 (4.4) *(P* = NR)	**TFEQ Restraint, mean (SD):** **Post tx:** **G1:** 8.4 (3.5) **G2:** 10.2 (4.3) **G3:** 8.4 (3.9) Diff over time *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **One mo FU:** **G1:** 9.2 (3.7) **G2:** 10.2 (4.1) **G3:** 9.3 (4.0) Diff over time (baseline to 1 mo) *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **Six mo FU:** **G1:** 9.1 (4.6) **G2:** 10.1 (3.8) **G3:** 9.7 (5.1) Diff over time (baseline to 6 mos) *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **12 mo FU:** **G1:** 8.2 (3.2) **G2:** 10.8 (5.0) **G3:** 10.2 (5.6) Diff over time (baseline to 1 mo) *(P* = NS) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)

Evidence Table 13. Self-help trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 13. Self-help trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Peterson et al., 2001 (continued)	**TFEQ Disinhibition (SD):** **G1:** 13.6 (2.0) **G2:** 13.7 (2.3) **G3:** 13.9 (1.7) *(P* = NR)	**TFEQ Disinhibition (SD):** **Post tx:** **G1:** 10.9 (2.7) **G2:** 11.2 (2.4) **G3:** 10.9 (3.9) Diff over time *(P* < 0.0001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **One mo FU:** **G1:** 9.7 (3.1) **G2:** 12.3 (2.2) **G3:** 10.8 (3.5) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **Six mo FU:** **G1:** 9.8 (2.6) **G2:** 12.4 (2.2) **G3:** 10.7 (3.4) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **12 mo FU:** **G1:** 11.1 (2.6) **G2:** 10.0 (3.2) **G3:** 11.2 (3.6) Diff over time *(P* < 0.001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)

Evidence Table 13. Self-help trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 13. Self-help trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Peterson et al., 2001 (continued)	**TFEQ Hunger, mean (SD):** **G1:** 10.9 (3.2) **G2:** 8.7 (3.7) **G3:** 9.7 (3.8) *(P* = NR)	**TFEQ Hunger, mean (SD):** **Post tx:** **G1:** 7.3 (3.3) **G2:** 6.9 (2.5) **G3:** 7.7 (4.7) Diff over time *(P* < 0.0001) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **One mo FU:)** **G1:** 6.8 (3.7) **G2:** 8.3 (3.2) **G3:** 7.3 (5.1) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **Six mo FU:** **G1:** 7.4 (3.5) **G2:** 9.8 (3.3) **G3:** 7.1 (5.0) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS) **12 mo FU:** **G1:** 8.4 (3.7) **G2:** 8.4 (4.0) **G3:** 7.2 (5.2) Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NS)
		Abstinent from objective binge episodes: **Post tx:** Data: NR Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **One mo FU:** Data: NR Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **Six mo FU:** Data: NR Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **12 mo FU:** Data: NR Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)

Evidence Table 13. Self-help trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 13. Self-help trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Peterson et al., 2001 (continued)		**Abstinent from total binge episodes:** **Post tx:** Data: NR Diff between groups *(P* = 0.05) G3 > G1 and G2 Diff between groups in change over time *(P* = NR) **One mo:** Data: NR Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **Six mo FU:** Data: NR Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR) **12 mo FU:** Data: NR Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)

Evidence Table 13. Self-help trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 13. Self-help trials for binge eating disorder (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Peterson et al., 1998 **Setting:** Single center; outpatient; University of Minnesota, Minneapolis, MN, USA **Enrollment period:** NR	**Research objective:** Compare the efficacy of a therapist-led versus self-guided group CBT interventions for BED	**Groups:** **G1:** Therapist-led (N = 16) **G2:** Partial self-help (N = 19) **G3:** Structured self-help (N = 15) **G4:** Waitlist control (N = 11) **Enrollment:** • 238 screened who were recruited through newspaper ads • 61 randomized (50 total to the active conditions) • 42 participants from the active conditions (G1, G2, and G3) remained at 8 wks, no sig diff in rate of retention	**Age, yrs, mean (SD):** Total sample: 42.4 (10.2) *(P* = NS) **Sex:** Female: 100% **Race/ethnicity:** White: 96.5% *(P* = NS) **Education:** College-educated: 51.7% *(P* = NS) **Marital status:** Married: 46.4% Divorced: 30.4% Never married: 19.6% Other: 3.6% other *(P* = NS)

Evidence Table 13. Self-help trials for binge eating disorder (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Met DSM IV criteria for BED **Exclusion:** Receiving current psychotropic meds or psychotherapy; substance abuse or dependence within the past 6 mos; assessed to be medically unstable or at risk of self-injury; engaged in compensatory behaviors (e.g., self-induced vomiting, laxative or diuretic abuse, excessive exercising or fasting) within the last six mos	Tx: manualized 8 wk-14 session CBT protocol adapted for BED. Subjects randomized in groups to waitlist, therapist-led, partial self-help, or structured self-help conditions. All groups met twice wkly for first six wks then wkly for final 2 wks. All 1 hr. sessions divided into two 30 minute parts: 1) reviewing psychoed material related to improving BED symptoms and 2) discussion and review of homework. In partial and structured self-help conditions, group members first watched videotape of therapist who was leading the therapist led group. In partial self-help condition, therapist led discussion for second part of the group while in structured self-help condition, group member on a rotating basis was responsible for leading discussion component for each session.	Regression analysis using a mixed effects linear regression model to est mean changes over time in the primary outcome variables of interest for the active tx conditions only; ANCOVAs for comparing between group diffs on secondary outcomes while controlling for baseline assessment; survival analysis for comparing retention rates of randomized subjects.	**Score:** Fair **Intent to treat:** Yes **Blinding:** Single **Adverse events:** NR **Funding:** McKnight Foundation grant; Minnesota Obesity Center

Evidence Table 13. Self-help trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Peterson et al., 1998 (continued)	**Objective binge-eating episodes/wk, mean (SD):** **G1:** 3.4 (1.7) **G2:** 5.5 (6.5) **G3:** 3.1 (2.1) **G4:** 3.5 (4.9) *(P* = NS)	**Mean objective binge-eating episodes/wk (SD):** **G1:** 0.7 (1.3) **G2:** 1.3 (3.4) **G3:** 0.4 (1.1) **G4:** 4.7 (4.7) Change over time *(P* < 0.0001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* < 0.001) G1, G2, G3 better than G4 **Abstinence rate:** **G1:** 68.8% **G2:** 68.4% **G3:** 86.7% **G4:** 12.5% Diff between groups G1 vs G2 vs G3 *(P* = NS) Diff between G1 + G2 + G3 vs G4 *(P* = 0.004) Diff between groups in change over time *(P* = NR)
	Total binge-eating episodes/wk, mean (SD): **G1:** 7.7 (3.8) **G2:** 8.2 (5.9) **G3:** 6.8 (2.4) **G4:** 5.7 (6.0) *(P* = 0.008) G1, G2 > G3	**Mean total binge-eating episodes/wk (SD):** **G1:** 3.3 (3.6) **G2:** 2.7 (4.3) **G3:** 1.8 (2.9) **G4:** 6.6 (4.5) Change over time *(P* < 0.0001) Diff between groups (*P* =NR) Diff between groups in change over time *(P* = 0.002) G1, G2, G3 better than G4 **Abstinence rates for total binges:** **G1:** 18.8% **G2:** 36.8% **G3:** 53.3% **G4:** 0% Diff between groups G4 vs G1, G2, G3 *(P* = 0.04): G4 worse than G1, G2, and G3 Diff between G1, G2, and G3 *(P* = NS)
	Hours spent binge-eating/wk, mean (SD): **G1:** 9.0 (6.7) **G2:** 13.4 (13.0) **G3:** 9.8 (5.5) **G4:** 8.3 (7.6) *(P* = NS)	**Mean hours spent binge-eating/wk (SD):** **G1:** 4.2 (6.9) **G2:** 3.2 (5.9) **G3:** 2.3 (3.3) **G4:** 9.6 (6.5) Change over time *(P* < 0.0001) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.005) G1, G2, G3 better than G4 **Abstinence rate for hours spent bingeing:** Data: NR Diff between groups G4 vs G1, G2, G3 *(P* = 0.04) G4 worse than G1, G2, and G3 Diff between G1, G2, and G3 *(P* = NS)

Evidence Table 13. Self-help trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
HDRS (SD): Data NR	**HDRS:** Data NR Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)	**BMI, kg/m^2:** Data NR	**BMI, kg/m^2:** Data NR Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 13. Self-help trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Peterson et al., 1998 (continued)	**BES:** NR	**BES:** Data NR Diff between groups *(P* = NR Diff between groups in change over time *(P* = 0.024) G4 < (G1 = G2 = G3)
	TFEQ: NR	**TFEQ Restraint:** Data NR Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS) **TFEQ Disinhibition:** Data NR Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.003) G4 < (G1 = G2 = G3) **TFEQ Hunger:** Data NR Diff between groups (*P* = NR) Diff between groups in change over time *(P* = 0.010) G4 < (G1 = G2 = G3)
	BSQ: NR	**BSQ:** NR Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 13. Self-help trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 14. Other trials for binge eating disorder

Study Description	Objective	Design	Patient Characteristics
Author, yr: Levine, Marcus, and Moulton, 1996 **Setting:** NR **Enrollment period:** NR	**Research objective:** To examine the effects of an exercise intervention in the tx of obese women with BED.	**Groups:** **G1:** Active tx (N = 44) **G2:** Delayed control (N = 33) **Enrollment:** • 77 recruited, randomized, and completed post-tx assessments	**Age, yrs, mean (SD):** **G1:** 36.3 (6.8) **G2:** 37.0 (6.1) (*P* = NS) **Sex:** Female: 100% **Race/ethnicity:** **Caucasian** **G1:** 88.6% **G2:** 78.8% (*P* = NS) **Education:** **Attended college:** **G1:** 84.1% **G2:** 75.8% (*P* = NS) **Married:** **G1:** 56.8% **G2:** 60.6% (*P* = NS)

Evidence Table 14. Other trials for binge eating disorder (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: NR **Exclusion:** NR	Participants randomized to one of two identical 24-wk tx programs or to a delayed tx control; active tx included exercise and calorie goal components. As preliminary analyses found no diff between identical active tx groups, they were combined for analyses. Assessments were conducted at baseline and post-tx; physical activity and binge eating status was assessed using the PEI and EDE respectively.	Repeated measures ANOVAs used to assess diff between groups over time. Data reporting diff between groups based on exercise and abstinence, not reported in evidence table.	**Score:** Poor **Intent to treat:** NR **Blinding:** NR **Adverse events:** NR **Funding:** NR

Evidence Table 14. Other trials for binge eating disorder (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Levine, Marcus, and Moulton, 1994 (continued)	**Binge days/28 days, mean (SD):** **G1:** 21.8 (11.8) **G2:** 20.7 (11.9) *(P* = NS)	NR
	Exercise, days/wk, mean (SD): **G1:** 0.61 (1.4) **G2:** 0.62 (1.3) *(P* = NR)	**Exercise, days/wk, mean (SD):** **G1:** 2.4 (2.4) *(P* = NR) **G2:** NR Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.003) G1 better than G2
	Calorie expenditure, kcal/wk, mean (SD): **G1:** 680.6 (823.0) **G2:** 610.9 (481.1) *(P* = NR)	**Calorie expenditure, kcal/wk, mean (SD):** **G1:** 1103.2 (1111.1) *(P* = NR) **G2:** 610.9 (481.1) *(P* = NR) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NR)
		At post-tx, 82.4% tx group achieved abstinence.

Evidence Table 14. Other trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
BDI score, mean (SD): **G1:** 18.3 (7.8) **G2:** 20.2 (7.8) *(P* = NS)	NR	**BMI, kg/m², mean (SD):** **G1:** 35.7 (4.6) **G2:** 38.2 (6.0) *(P* = 0.05)	NR

Evidence Table 14. Other trials for binge eating disorder (continued)

Study Description	Objective	Design	Patient Characteristics
Author, yr: Riva et al., 2002 **Setting:** Inpatient, wt-control tx program, Eating Disorders Unit of the Istituto Auxologico Italiano, Verbania Italy **Enrollment period:** NR	**Research objective:** To preliminarily test the efficacy of VR-based tx of body image attitudes and related constructs in women with BED.	**Groups (N = 20):** **G1:** VR (N = NR) **G2:** psycho-nutritional control (N = NR) **Enrollment:** • 20 patients from ED program randomized, enrolled, and completed	**Age, yrs, mean (SD):** **G1:** 30.50 (6.72) **G2:** 30.10 (6.95) (*P* = NR) **Sex:** Female: 100% **Race/ethnicity:** NR

Evidence Table 14. Other trials for binge eating disorder (continued)

Inclusion/Exclusion Criteria	Treatment	Statistical Methods	Quality
Inclusion: Aged 18 to 45; met DSM IV research criteria for BED for a min of 6 mos **Exclusion:** Taking antidepressant or any meds that might influence wt; hx of drug or alcohol abuse; current major psychiatric condition such as psychosis; hx of purging within previous 6 mos; BMI < 30	For **G1** and **G2**, tx lasted approximately 6.5 wks; **G1** received 7 sessions of Virtual Reality for Eating Disorders Modification (VREDIM) tx plus a low calorie diet (1200 cal/day) and physical training (30 minutes walking 2 times/wk); **G2** received low cal diet, physical training, and psycho-nutritional, CBT-based group therapy, 3 times/wk. Assessments given at baseline and post-tx.	Power analysis revealed low/medium power due to small sample and high SD. Accordingly, repeated and independent measures assessed using exact measures, non-parametric algorithms reliable with small, sparse or tied data. Specifically, the marginal homogeneity test was used.	**Score:** Fair **Intent to treat:** NR **Blinding:** NR **Adverse events:** No participants experienced stimulation sickness, often associated with VR. **Funding:** Commission of the European Communities (CEC) and the IST Programme (Project VESPY)

Evidence Table 14. Other trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Riva et al., 2002 (continued)	**BIAQ, total score, mean:** **G1:** 33.20 **G2:** 31.00 *(P* = NR)	**BIAQ, total score, mean:** **G1:** 32.40 *(P* = NS) **G2:** 29.50 *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	BIAQ, Eating Restraint score, mean: **G1:** 3.00 **G2:** 4.40 *(P* = NR)	**BIAQ, Eating Restraint, mean:** **G1:** 5.20 *(P* = NS) **G2:** 5.00 *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	CDRS, Real Body score, mean: **G1:** 7.80 **G2:** 8.40 *(P* = NR)	**CDRS, Real Body score, mean:** **G1:** 8.10 *(P* = NS) **G2:** 8.00 *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	CDRS, Ideal Body score, mean: **G1:** 4.40 **G2:** 4.40 *(P* = NR)	**CDRS Ideal Body score, mean:** **G1:** 5.10 *(P* = 0.035) **G2:** 4.80 *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	CDRS, Body Satisfaction Index, mean: **G1:** 1.87 **G2:** 2.55 *(P* = NR)	**CDRS, Body Satisfaction Index, mean:** **G1:** 1.66 *(P* = NS) **G2:** 2.29 *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	BSS, total score, mean: **G1:** 51.30 **G2:** 57.20 *(P* = NR)	**BSS, total score, mean:** **G1:** 47.60 *(P* = NS) **G2:** 53.70 *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	WELSQ, total score, mean: **G1:** 107.60 **G2:** 129.10 *(P* = NR)	**WELSQ, total score, mean:** **G1:** 146.80 *(P* = 0.050) **G2:** 130.30 *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.005) G1 better than G2

Evidence Table 14. Other trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**
STAI-State, total score, mean: **G1:** 47.80 **G2:** 39.20 *(P* = NR)	**STAI-State, total score, mean:** **G1:** 38.80 *(P* = 0.023) **G2:** 37.70 *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.035) G1 better than G2	**Wt., kg, mean (SD):** **G1:** 120.06 (28.34) **G2:** 109.82 (21.48) *(P* = NR)	NR
		BMI, kg/m², mean (SD): **G1:** 44.07 (10.10) **G2:** 42.35 (8.55) *(P* = NR)	NR

Evidence Table 14. Other trials for binge eating disorder (continued)

Study Description	Eating Related Measures	
	Baseline	**Outcomes**
Author, yr: Riva et al., 2002 (continued)	**FRS Real Body score, mean:** **G1:** 6.90 **G2:** 6.80 *(P* = NR)	**FRS Real Body score, mean:** **G1:** 6.80 *(P* = NS) **G2:** 6.60 *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	FRS Ideal Body score, mean: **G1:** 3.80 **G2:** 3.80 *(P* = NR)	**FRS Ideal Body score, mean:** **G1:** 3.90 *(P* = NS) **G2:** 3.80 *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	FRS Body Satisfaction Index, mean: **G1:** 1.87 **G2:** 2.35 *(P* = NR)	**FRS Body Satisfaction Index, mean:** **G1:** 1.82 *(P* = NS) **G2:** 2.28 *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	DIET total score, mean: **G1:** 48.80 **G2:** 46.87 *(P* = NR)	**DIET total score, mean:** **G1:** 39.03 *(P* = NS) **G2:** 45.90 *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	DIET Positive Social score, mean: **G1:** 54.00 **G2:** 47.57 *(P* = NR)	**DIET Positive Social score, mean:** **G1:** 34.57 *(P* = 0.06) **G2:** 45.06 *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	DIET Overeating score, mean: **G1:** 53.33 **G2:** 44.67 *(P* = NR)	**DIET Overeating score, mean:** **G1:** 31.50 *(P* = 0.30) **G2:** 44.00 *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = 0.05) G1 better than G2
	DIET Negative Emotions score, mean: **G1:** 47.40 **G2:** 44.60 *(P* = NR)	**DIET Negative Emotions score, mean:** **G1:** 37.60 *(P* = NS) **G2:** 47.20 *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)

Evidence Table 14. Other trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 14. Other trials for binge eating disorder (continued)

	Eating Related Measures	
Study Description	**Baseline**	**Outcomes**
Author, yr: Riva et al., 2002 (continued)	**DIET Resisting Temptations score, mean:** **G1:** 40.00 **G2:** 38.75 *(P* = NR)	**DIET Resisting Temptations score, mean:** **G1:** 43.75 *(P* = NS) **G2:** 37.75 *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over *(P* = NS)
	DIET Exercise score, mean: **G1:** 46.00 **G2:** 57.00 *(P* = NR)	**DIET Exercise score, mean:** **G1:** 36.25 *(P* = NS) **G2:** 53.25 *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
	DIET Food Choice score, mean: **G1:** 40.50 **G2:** 40.75 *(P* = NR)	**DIET Food Choice score, mean:** **G1:** 43.00 *(P* = NS) **G2:** 41.75 *(P* = NS) Diff between groups *(P* = NR) Diff between groups in change over time *(P* = NS)
		Abstinence (No binge-eating in last 2 wks), mean: **G1:** 100% **G2:** 100% Diff between groups *(P* = NS) Diff between groups in change over time *(P* = NR)

Evidence Table 14. Other trials for binge eating disorder (continued)

Psychological/Psychiatric Measures		Biomarkers	
Baseline	**Outcomes**	**Baseline**	**Outcomes**

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Evidence Table 15. Anorexia nervosa outcomes

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Ben-Tovim et al., 2001 **Design:** Case series **Comparison Group:** No **Location:** Adelaide, South Australia **Yrs followed:** 5	To identify predictors of outcome and to assess effects of available txs for AN or BN	**Inclusion:** 15 yrs old and older; living in Adelaide, South Australia; either making first contact with secondary or tertiary services for tx of ED or were recontacting such services after a tx break of at least 6 mos. **Exclusion:** None **Recruitment:** Agreement to participate was obtained from all identifiable specialist service providers in Adelaide, apart from one psychiatrist in individual practice. **Sample Size:** Fulfilled criteria: N = 235 Agreed to participate: N = 220 **Baseline sample:** **AN**: N = 95 **BN:** N = 88 **Reasons for loss to FU:** **Anorexia:** 3 deaths, of which, 2 related to ED **BN:** 2 lost, reason NR **Analysis Sample Size at FU:** **AN:** N = 92 **BN:** N = 86	**Mean Age (SD)** **AN:** 22.5 (6.9) **BN:** 23.8 (6.4) **Sex:** Female: 100% **Race/ethnicity:** NR **Wt, kg, Mean (SD):** **AN:** 44.8 (6.5) **BN:** 62.6 (10.8) **Height, m, Mean (SD):** **AN:** 1.65 (0.07) **BN:** 1.65 (0.06) **BMI, Mean (SD):** **AN:** 16.5 (1.9) **BN:** 23.1 (3.9) **Duration of ED, yrs:** **AN:** 7.4 (7.0) **BN:** 6.4 (4.7) **AN subtype at initial assessment:** Abstainers: 59% Binge-purgers: 41%	**Score:** Good **Method of dx:** Dx made by treating clinician and confirmed by Flinders Symptom Score (FSS) interview. Dx was according to DSM III-R **Funding:** Australian National Health and Medical Research Council, Flinders 2000, and the Centre for Applied Research in Mental Health

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods Evaluation in person or by telephone annually. **Statistical Methods** Dependent variable: Total scores from M-R-H scales at 5 yrs **Multiple Regression** **M-R-H Subscales:** Subscale A: Dietary and eating patterns, body concern, and body wt Subscale B: Menstrual pattern Subscale C: Mental State Subscale D: Psychosexual state Subscale E: Work and Family Relations	**Descriptive Results** **AN:** **Dx at 5 yrs:** AN: 20 (21%) BN: 5 (5%) EDNOS: 9 (9%) No ED: 56 (59%) Unknown: 2 (2%) Died: 3 (3%) **M-R-H Outcomes:** Good (mean score: 8 – 12): 32 (34%) Intermediate (score 4 - < 8): 51 (54%) Poor **(**score 0 - < 4) 12 (13%) **BN** **Dx at 5 yrs:** AN: 1 (1%) BN: 7 (8%) EDNOS: 11 (13%) No ED: 65 (74%) Unknown: 4 (5%) Died: 0 **M-R-H Outcomes:** Good: 67 (76%) Intermediate (score 4 - < 8): 17 (19%) Poor (score 0 - < 4) 2 (2%) Unknown: 2 (2%) **Multivariate Results** **Predictors of higher M-R-H total mean score at 5 yrs:** **AN:** **Model 1** Age *(P* = 0.48) M-R-H subscale A at baseline *(P* = 0.02) pos assoc. M-R-H subscale B at baseline *(P* = 0.11) M-R-H subscale C at baseline *(P* = 0.13) M-R-H subscale D at baseline *(P* = 0.23) M-R-H subscale E at baseline *(P* = 0.17) Duration of Illness (yrs) *(P* = 0.18) BMI at baseline *(P* = 0.08) pos assoc Goodness of fit model *(P* < 0.0001), R^2 = 0.0.33 **Model 2** Disability adjustment scale, subscale 2 at baseline *(P* = 0.0006) neg assoc Flinders Medical Centre Symptom Score at baseline *(P* = 0.03) neg assoc Body Attitudes Questionnaire Subscales: Attractiveness at 6 mo: *(P* = 0.008) pos assoc Change in salience of wt and shape over first 6 mos *(P* = 0.024) pos assoc Goodness of fit model *(P* < 0.0001), R^2 = 0.25

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Ben-Tovim et al., 2001 (continued)				

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods Evaluation in person or by telephone annually. **Statistical Methods** Dependent variable: Total scores from M-R-H scales at 5 yrs **Multiple Regression** **M-R-H Subscales:** Subscale A: Dietary and eating patterns, body concern, and body wt Subscale B: Menstrual pattern Subscale C: Mental State Subscale D: Psychosexual state Subscale E: Work and Family Relations	**Descriptive Results** **BN:** **Model 1** Age *(P* = 0.47) M-R-H subscale A at baseline *(P* = 0.01) neg assoc M-R-H subscale B at baseline *(P* = 0.50) M-R-H subscale C at baseline *(P* = 0.16) M-R-H subscale D at baseline *(P* = 0.28) M-R-H subscale E at baseline *(P* = 0.28) Duration of Illness (yrs) *(P* = 0.11) BMI at baseline *(P* = 0.27) Goodness of fit model *(P* < 0.056); R^2 = 0.085 **Model 2** Disability adjustment scale, subscale 2 at recruitment *(P* = 0.009) neg assoc Body Attitudes Questionnaire Subscales: Feeling fat at recruitment *(P* = 0.02) neg assoc Attractiveness at 6 mo *(P* = 0.001) pos assoc Change in Zung Depression over first 6 mos *(P* = 0.0003) pos assoc Goodness of fit model *(P* < 0.0001), R^2 = 0.31

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality Adverse Events
Authors, year: Birmingham et al, 2005 **Design:** Case series **Comparison Group:** No **Location:** Vancouver, British Columbia, Canada **FU duration, years, Mean (SD):** 7.3 (4.9) for AN pts 8.7 (5.2) for all patients	SMR	**Inclusion:** DSM-III dx of an ED **Exclusion:** None stated **Recruitment:** Referrals to adult tertiary care ED program in Vancouver, BC from 1981-2000 evaluated and given dx of ED using DSM criteria. **Sample Size:** (N = 954) AN (N = 326) BN (N = 474) **Loss to FU:** None reported	**Age at tx start, mean (SD):** Total: 26.1 (8.6) AN: 24.7 (9.6) **Sex:** Total, N (%): Females: 927 (97.2%) Males: 27 (2.8%) **AN, N (%):** Females: 312 (95.7%) Males: 14 (4.3%) **Race/ethnicity:** NR **Age at death, mean (SD):** 36.3 (10.7) **Time to death, years, mean (SD):** 6.2 (4.8)	**Score:** Fair **Method of diagnosis:** DSM III criteria for ED during clinical assessment (In discussion, authors state they use DSM III, DSM III-R, and DSM V criteria, but not mentioned in methods.) **Funding:** NR

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods: Vital status assessed by searching Vital Statistics Agency of the BC Ministry of Health. For each death record, ICD-10 code recorded. Expected number of deaths obtained by applying age gender and year specific mortalities of general BC pop to cumulative person-yrs of the study cohort. **Statistical Method:** SMR	**AN Results**: 17 pts died • suicide (n=7) • pneumonia (n=2) • hypoglycemia (n=2) • liver disease (n=2) • cancer (n=2) • alcohol poisoning (n=1) • subdural hemorrhage (n=1) SMR for AN = 10.5 (95% CI = 5.5-15.5) **BN Results**: 7 pts died Cause of death NR SMR for BN = 2.0 (95% CI = 0.5-3.5)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research objective	Eligibility Criteria Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Bulik, Sullivan et al., 2000 **Companion article:** Sullivan, Bulik et al., 1998 **Design:** Case series **Comparison Group:** Yes **Location:** Christchurch, New Zealand **Yrs followed:** 12 yrs from tx referral	To explore what distinguished women who were fully recovered from women who recovered partially or who developed a chronic illness. To examine diff between women who recovered fully and community controls to identify residual diff despite remission of the ED. To examine distinguishing characteristics of women who continued to suffer from an ED on avg 15 yrs after initial dx	**Inclusion:** **Cases**: Newly dx via DSM III-R criteria for definite or "probable" AN, all determined meet lifetime DSM III-R criteria for AN; age 23-45 **Comparisons**: Age matched to AN cases; age 23-45 **Exclusion:** **Cases**: None Comparisons: subthreshold AN symptoms **Recruitment:** **Cases**: Newly dx via DSM III-R criteria during inpatient, outpatient or assessment from 1981-1984 among those who received ED services at Princess Margaret Hospital, Christchurch, New Zealand, for definite or "probable" AN **Comparisons**: randomly selected names obtained from 1993 Christchurch electoral record Both: letter to invite participation; FU phone call; personal interview **Initial Sample Size:** Records reviewed: 239 Potential AN: 89 Potential Controls: 111 **Reasons for loss to FU:** **Death**: 1 due to suicide while being treated for AN, 3 could not be located, 8 did not give consent, and 7 did not meet criteria for AN	**Mean Age:** Values NR: **Diff between groups** G4 older than G1, G2, G3 (*P* = NR) **Sex:** Female: 100% **Race/ethnicity:** NR **Lowest past BMI, mean (SD):** **G1:** 14.8 (1.2) **G2:** 14.8 (2.0) **G3:** 14.3 (1.4) **G4:** NR (*P* = NS) **Highest past BMI, mean (SD):** **G1:** 23.1 (3.4) **G2:** 23.1 (2.9) **G3:** 21.7 (2.4) **G4:** 27.3 (6.7) (*P* < 0.001) **G4** higher than other groups **Age at first diet, mean (SD):** **G1:** 14.5 (2.7) **G2:** 16.6 (4.4) **G3:** 14.7 (3.3) **G4:** 21.5 (6.6) (*P* < 0.001) **G4** older than other groups **Age of onset of AN, mean (SD):** **G1:** 16.4 (2.6) **G2:** 17.4 (5.1) **G3:** 16.4 (3.5) (*P* = NS) **Lifetime BN** **G1:** 100% **G2:** 24% **G3:** 80% **G4:** 4% (*P* < 0.001)	**Score:** Good **Method of dx:** Criteria for DSM III or DSM IIIR determined through review of hospital records. **Funding:** Canterbury Medical Research Foundation

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods **Cases**: Hospital record of AN patients reviewed by 2 trained abstractors Interview using Diagnostic Interview for Genetic Studies and rated on the GAFS. Completed the EDI, TFEQ, Parental Bonding Instrument and the Temperament and Character Inventory **Statistical Analysis:** Chi-Square, ANOVA, ANCOVA to compare the 3 recovery groups and controls. Age was included as a covariate in all analyses. Critical *P* adopted to control for multiple comparisons *(P* < 0.01)	**Descriptive Results** **Diff between groups (controlling for age):** **Current BMI, mean (SD):** **G1:** 20.6 (2.1) **G2:** 20.4 (1.4) **G3:** 18.5 (2.6) **G4:** 25.6 (6.5) *(P* < 0.0001) G4 higher than all other groups **Desired BMI, mean (SD):** **G1:** 20.1 (1.8) **G2:** 20.2 (1.3) **G3:** 17.9 (2.5) **G4:** 22.6 (2.6) *(P* < 0.001) G4 higher than other groups; G3 lower than G1 and G2 **GAF Scale, mean (SD):** **G1:** 75.5 (11.2) **G2:** 72.0 (15.1) **G3:** 52.5 (12.2) **G4:** 80.3 (10.0) *(P* < 0.001) G3 lower functioning than other groups; G2 lower functioning than G4 **TFEQ, Cognitive Restraint, mean (SD):** **G1:** 9.9 (5.9) **G2:** 11.4 (5.3) **G3:** 15.2 (5.3) **G4:** 6.5 (4.8) *(P* < 0.001) G3 higher restraint than other groups; G4 lower restraint than G1 and G2 **TFEQ, Disinhibition, mean (SD):** *(P* = NS) **TFEQ, Hunger, mean (SD):** *(P* = NS) **EDI, Drive for Thinness, mean (SD):** **G1:** 4.5 (5.1) **G2:** 4.7 (4.9) **G3:** 11.8 (8.0) **G4:** 3.1 (1.2) Diff between groups *(P* < 0.0001) G3 worse than other groups **EDI, Bulimia, mean (SD):** **G1:** 1.3 (1.9) **G2:** 0.5 (1.0) **G3:** 4.0 (4.4) **G4:** 1.0 (1.6) *(P* < 0.0001) G3 worse than all other groups

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research objective	Eligibility Criteria Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Bulik, Sullivan et al., 2000 **Companion article:** Sullivan, Bulik et al., 1998 (continued)		**Analysis sample:** Cases = 70 Comparisons = 98 **G1:** Cases fully recovered (no current ED dx; > 85% IBW, no current bingeing and purging): N = 21 **G2:** Cases partially recovered (no current ED dx but reported current bingeing or purging or maintained a wt < 85% IBW): N = 34 **G3:** Cases chronically ill (met criteria for ED at time of interview): N = 15 **G4:** Comparisons: N = 98		

Study Methods and Analytic Strategy	Main Outcomes and Results
	EDI, Body Dissatisfaction, mean (SD): **G1:** 8.4 (8.2) **G2:** 9.0 (8.3) **G3:** 15.6 (9.8) **G4:** 11.5 (9.3) Diff between groups *(P* = NS) **EDI, Perfectionism, mean (SD):** **G1:** 7.3 (4.5) **G2:** 5.6 (4.9) **G3:** 8.2 (4.4) **G4:** 3.4 (3.3) Diff between groups *(P* < 0.0001) G4 had less perfectionism than all other groups G1 had less perfectionism than G3 **TCI, Harm Avoidance, mean (SD):** **G1:** 16.9 (6.8) **G2:** 20.1 (6.9) **G3:** 24.8 (9.6) **G4:** 17.6 (7.8) Diff between groups *(P* < 0.007) G3 had higher harm avoidance than G1 or G4 **TCI, Reward Dependence, mean (SD):** **G1:** 17.3 (3.9) **G2:** 16.6 (3.4) **G3:** 14.8 (3.9) **G4:** 17.5 (3.4) Diff between groups *(P* = NS) **TCI, Self-Directedness, mean (SD):** **G1:** 33.8 (8.1) **G2:** 28.7 (8.6) **G3:** 24.5 (9.1) **G4:** 33.7 (7.2) Diff between groups *(P* < 0.001) G1 did better than G2 or G3 G4 did better than G2 or G3 **PBI, Maternal Care, mean (SD):** **G1:** 22.2 (10.2) **G2:** 23.8 (9.1) **G3:** 15.8 (11.2) **G4:** .26.0 (7.9) Diff between groups *(P* < 0.002) G3 lower score than G1, G2, G4 **PBI, Maternal Protection, mean (SD):** **G1:** 18.1 (8.8) **G2:** 15.1 (9.3) **G3:** 14.2 (8.4) **G4:** 13.2 (7.5) Diff between groups *(P* = NS)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research objective	Eligibility Criteria Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Bulik, Sullivan et al., 2000 **Companion article:** Sullivan, Bulik et al., 1998 (continued)				

Study Methods and Analytic Strategy	Main Outcomes and Results
	PBI, Maternal Protection, mean (SD): **G1:** 18.1 (8.8) **G2:** 15.1 (9.3) **G3:** 14.2 (8.4) **G4:** 13.2 (7.5) Diff between groups *(P* = NS) **PBI, Paternal Care, mean (SD):** **G1:** 19.9 (8.5) **G2:** 22.8 (10.0) **G3:** 13.0 (13.1) **G4:** 23.2 (9.2) Diff between groups *(P* < 0.004) G3 lower score than G1 or G4 **PBI, Paternal Protection, mean (SD):** **G1:** 15.2 (8.0) **G2:** 11.8 (5.7) **G3:** 17.4 (10.6) **G4:** 12.5 (7.5) Diff between groups *(P* = NS)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Crisp et al., 1992 **Design:** Case series **Comparison Group:** No **Location:** England and Scotland **Yrs followed:** **G1:** 21.8 (5.1) **G2:** 22.1 (4.9)	20 yr FU to determine the long-term mortality of AN in two cohorts	**Inclusion:** Both Crisps criteria and DSM III-R criteria for AN. **Exclusion:** NR **Recruitment:** **G1:** Received tx at St George's Hospital in London between May 1968-December 1973 **G2:** Registered on the Aberdeen Psychiatric Case Register in Aberdeen, Scotland between January 1965 and December 1973. Contact through telephone, physician, letter, friends and family, Social Services and Death Registry. **Sample Size:** **G1:** N = 105 **G2:** N = 63 **Reasons for loss to FU:** **G1:** Died = 4 (2 from complications of AN, 1 from suicide, and 1 other; Untraced = 4 **G2:** Died = 8 (3 complications of AN, 4 suicides, 1 other); Untraced: 2	**Mean Age at FU (yrs):** **G1:** 38.8 (6.7) **G2:** 40.9 (7.5) **Sex:** Female: 100% **Race/ethnicity:** NR **Mean age at onset of illness (yrs):** **G1:** 16.8 (3.8) **G2:** 19.1 (5.3) Diff between groups *(P* < 0.01) **Duration of illness (yrs):** **G1:** 3.7 (4.1) **G2:** 2.0 (2.4) Diff between groups *(P* < 0.01)	**Score:** Fair **Method of dx:** NR **Funding:** NIMH

Study Methods and Analytic Strategy	Main Outcomes and Results
Treatment Intervention: **G1:** Intensive individual and family therapy coupled with nutritional tx. **G2:** Medical ward, outpt, inpatient (consisted of various tx's including: refeeding, nursing, meds, ECT, and/or modified insulin) **Study Methods:** Record review **Statistical Methods:** SMR, %	**Descriptive Findings:** **Mortality** **Death in 0 – 12 yrs, N (%):** **G1:** 2 (2%) **G2:** 3 (5%) **Death in 12 – 24 yrs, N (%):** **G1:** 2 (2%) **G2:** 5 (8%) **SMR:** **G1:** 1.36 times more likely to die than women of the same age in England and Wales during 1973 – 1989 **G2:** 4.71 times more likely to die than women of the same age in Scotland in 1973 – 1979. Diff between groups *(P* = NS) **Causes of Death:** **Anorexia, N:** **G1:** 2 (2%) **G2:** 3 (5%) **Suicide, N:** **G1:** 1 (1%) **G2:** 4 (6%) **Other, N:** **G1:** 1 (1%) cancer **G2:** 1 (2%) cancer

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Dancyger et al., 1997 **Design:** Case series **Comparison Group:** No **Location:** Minnesota and Iowa **Yrs followed:** 10	To assess the relationships among MMPI clinical scales over a 10-yr period in a sample of AN patients	**Inclusion:** Initial inclusion criteria involved modified Feighner et al. 1972, and subsequently covered DSM III-R and DSM IV for AN. **Exclusion:** NR **Recruitment:** All participants at intake were part of a larger collaborative study and were admitted into a 35-day hospital inpatient tx for AN, 40 from U of Iowa and 36 from U of Minnesota **Sample Size:** **Initial Sample:** N = 76 **Reasons for loss to FU:** Excluded because of incomplete data: N = 7 Died: N = 5 Refused participation: N = 9 Did not complete MMPI: N = 3 **Analysis sample** N = 52	**Mean Age at Admission for sample of N = 76, yrs (SD):** 19.29 (4.97) **Mean age of FU sample:** NR **Sex:** Female: 100% **Race/ethnicity:** NR	**Score:** Fair **Method of dx: Independent Clinician Dx** At intake: use of Feighner et al., 1972, DSM III-R and DSM IV criteria. Outcome classification was determined at FU using the M-R scale. **Funding:** NR

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods Participants administered the MMPI at admission, at discharge and at 10-yr FU. During FU interview, participants' outcome assessed via M-R score using last 6-mos prior to the FU as window for evaluation of clinical status. **Outcome categories:** Poor: < 85% of IBW with amenorrhea or frequent bingeing and purging (i.e., met criteria for BN, AN, or both) Intermediate: intermittently at < 85% IBW, had some disturbed menses or some bingeing and purging behavior (i.e., subthreshold AN, BN, or EDNOS) Good: > 85% IBW, normal menses but binged and purged < once/mo Recovered: above the 85% IBW cutoff, had no menstrual disturbances, reported no bingeing or purging behavior, and free from any other eating or body image disturbance Raw MMPI scale scores were K-corrected and converted to T-scores (mean = 50, SD = 10). Clinical elevation is defined as a T-score of 70 or higher **Statistical Analyses** Repeated measures MANOVAs used to detect diff between outcome status groups' MMPI scale scores at the three assessment time points. MANOVA's were followed by pairwise comparisons with alpha level corrected using Bonferroni procedure Correlational analyses performed to assess relationships between MMPI scale scores at the three time points Individual configural analyses of MMPI conducted to determine MMPI configurations at the three assessment points Backward elimination stepwise multiple regression models with MMPI scales as predictors of outcome status at FU were conducted	**Descriptive Findings** **Outcome status at 10-yr FU:** Recovered: N = 16 Good: N = 7 Intermediate: N = 11 Poor: N = 18 **Mean changes in MMPI scale scores from Admission to Discharge to FU** Lying *(P* = NS) Frequency *(P* = NS) Defensiveness *(P* = NS) Hypochondriasis (1) *(P* < 0.05) Admission > Discharge and FU Depression (2) *(P* < 0.05) Admission > Discharge and FU Hysteria (3) *(P* < 0.05) Discharge < Admission and FU Psychopathic Deviate (4) *(P* = NS) Masculinity-Femininity (5) *(P* = NS) Paranoia (6) *(P* = NS) Psychasthenia (7) *(P* < 0.05) (Admission > Discharge and FU) Schizophrenia (8) *(P* = NS) Hypomania (9) *(P* = NS) Social Introversion (10) *(P* = NS) **Configural Analysis of MMPI at FU** Impulsive/characterological: 9 Normal/Depressive: 32/3 Other: 8 **Percentage of Subjects with each Single Peak MMPI Score at FU** Depression (2): 14% Hysteria (3): 18% Psychopathic Deviate (4): 17% Paranoia (6): 13% Psychasthenia (7): 12% Hypomania (9): 7% Social Introversion (10): 8% **Percentage of Outcome Groups with at least one MMPI Clinical Elevation at FU** Poor: 67% Intermediate: 45% Good: 14% Recovered: 12% **Correlations Between MMPI Scale Scores at Discharge and FU** Hypochondriasis: r = 0.32 *(P* = NS) Depression: r = 0.56 *(P* < 0.003) Hysteria: r = 0.37 *(P* < 0.05) Psychopathic Deviate: r = 0.39 *(P* < 0.05) Masculinity/Femininity: r = 0.17 *(P* = NS) Paranoia: r = 0.41 *(P* < 0.05) Psychasthenia: r = 0.52 *(P* < 0.003) Schizophrenia: r = 0.37 *(P* < 0.05) Hypomania: r = 0.31 *(P* = NS) Social Introversion: r = 0.68 *(P* < 0.003)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Dancyger et al., 1997 (continued)				

Study Methods and Analytic Strategy	Main Outcomes and Results
	Diff in MMPI Scale Scores at FU By Outcome Groups (Recovered versus Poor) Lying *(P* = NS) Frequency *(P* = NS) Defensiveness *(P* = NS) Hypochondriasis: (*P* < 0.05) (Recovered < Poor) Depression: (*P* < 0.05) (Recovered < Poor) Hysteria: (*P* < 0.05) (Recovered < Poor) Psychopathic Deviate: (*P* < 0.05) (Recovered < Poor) Masculinity-Femininity *(P* = NS) Paranoia *(P* = NS) Psychasthenia: (*P* < 0.05) (Recovered < Poor) Schizophrenia: (*P* < 0.05) (Recovered < Poor) Hypomania *(P* = NS) Social Introversion *(P* = NS) **Change in Overall MMPI score admission to FU** *(P* < 0.001) Recovered greater decline than poor **Multivariate Result** **Predictors of outcome at 10 yr FU using backward-elimination stepwise multiple regression. (Predicted 25% of the variance)** Hypochondriasis (scale 1):higher scores associated with poorer outcome Paranoia (scale 6): higher scores associated with poorer outcome. Psychopathic deviate: higher scores associated with poorer outcome

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Deter and Herzog, 1994 **Companion article:** Herzog, Schellberg, and Deter, 1997 **Design:** Case series **Comparison Group:** No **Location:** Germany **Yrs followed:** Mean: 11.8 yrs (Range: 9-19)	To determine if long term outcomes of AN patients are associated with higher recovery (> 50%) and mortality rates (>5%) and lower rates of chronicity and poor outcome; whether inclusion of psychiatric and medical comorbidity and social adaptation influence results compared with mere evaluation of the physical status using M-R criteria and which predictors remain sig over time	**Inclusion:** Fulfilled dx criteria for AN according to Feighner et al., and on retrospective analysis, the DSM III-R criteria. **Exclusion:** Somatic diseases at first presentation which did not have any direct etiologic relation to AN; Male **Recruitment:** All AN patients admitted and treated consecutively between 1/71 and 10/80 at University Medical Clinic of Heidelberg. **Sample Size:** **Initial Sample** N = 84 Restricting AN: N = 29 (35%) Mild purging: N = 19 (23%) Severe purging: N = 36 (43%) **Reasons for loss to FU:** Death: N = 9. Of these, suicide: N = 2 **Analysis sample:** N = 75	**Mean Age** 32.5 (6.1) **Sex:** Female: 100% **Race/ethnicity:** NR	**Score:** Fair **Method of dx:** Feighner et al., and on retrospective analysis DSM III-R **Funding:** German Ministry for Research and Technology

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods: Interview using ANSS, physical examination and medical record review **Statistical Methods** ANOVA, MANOVA T test or Student-Newman-Keuls Spearman correlations and factor analyses Step-wise multiple regression Comparisons: ANOVA and Student-Newman-Keul's **Outcome categories** Permanent recovery: rated as good according to M-R scale and remained so Relapse: rated as good according to M-R scale but afterwards assessed as intermediate or poor Persistent ED: not defined	**Descriptive Results** **Wt, kg, mean (SD):** At first presentation: 36.3 (6.2) FU: 53.1 (9.5) Diff over time *(P* < 0.0001) **Wt, %ABW, 37:** At first presentation: 65.2 (9.9) FU: 88.4 (14.8) Diff over time *(P* < 0.0001) **BMI** At first presentation: 13.3 (2.0) FU: 19.6 (3.3) Diff over time *(P* < 0.0001) **Amenorrhea, %:** At first presentation: 100% FU: 14.9% Diff over time *(P* < 0.0001) **ED Morbidity at FU:** BN: 10/74 (14%) Mild bulimic symptoms: 12 (16%) Laxative abuse without binge eating: 8% **ANSS Avg Outcome Score, mean (SD)** At first presentation: 20.1 (3.9) FU: 8.7 (5.3) Diff over time *(P* < 0.0001) **ANSS Pathological findings (%), mean (SD)** At first presentation: 67.2 (12.3) FU: 29.6 (17.4) Diff over time *(P* < 0.0001) **ANSS Somatic symptoms, mean (SD)** At first presentation: 61.7 (15.9) FU: 23.5 (18.6) Diff over time *(P* < 0.0001) **M-R Scale, Avg Outcome Score, mean (SD)** At first presentation: 2.4 (1.4) FU: 8.6 (2.8) Diff over time *(P* < 0.0001) **M-R Scale, Menstrual function, mean (SD)** At first presentation: 0.5 (0.3) FU: 10.1 (3.9) Diff over time *(P* < 0.0001) **M-R Scale, Mental state, mean (SD)** At first presentation: 4.0 (0.8) FU: 8.1 (2.5) Diff over time *(P* < 0.0001)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Deter and Herzog, 1994 (continued)				

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
	M-R Global Outcome at FU (modified by Eckert, 1990): Good: 53.6% Intermediate: 25.0% Poor:10.7% Deceased: 10.7% **Psychiatric Morbidity, DSM III-R at FU:** Phobic Disorders: 12.2% Substance Abuse: 13.5% Major Depression: 8.1% Personality Disorders: 17.6% Chronic Psychosis: 5.4% OCD: 8.1% Psychiatric morbidity: 32.4% Somatic Morbidity at FU: 32% **Healthy according to M-R scale criteria:** 2 yr FU: 5% 4 yr FU: 23% 6 yr FU: 37% 9 yr FU: 43% 11 yr FU: 52% **AN dx:** 2 yr FU: 67% 4 yr FU: 40% 6 yr FU: 23% 9 yr FU: 17% Diff between recovered patients (N = 36) Persistent eating disorders/dead (N = 31) Relapsing patients (N = 17) **Age at onset of illness, yrs, mean:** Permanent recovery: 16.8 Persistent: 18.8 Relapsing: 18.1 Diff between groups *(P* = NR) **Age at first presentation, yrs, mean:** Permanent recovery: 19.3 Persistent: 23.3 Relapsing: 18.9 Diff between groups *(P* = 0.007) Permanent recovery younger than Persistent Persistent older than Relapsing **Duration of illness prior to first presentation, yrs, mean:** Permanent recovery: 2.4 Persistent: 4.5 Relapsing: 0.8 Diff between groups *(P* = 0.005) Persistent longer duration than Relapsing **Somatic symptoms (%):** Permanent recovery: 57.2 Persistent: 67.5 Relapsing: 62.6 Diff between groups *(P* = 0.03) Recovery less symptoms than Persistent

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Deter and Herzog, 1994 (continued)				

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
	Laxatives at first presentation (rating 0 – 4): Permanent recovery: 1.1 Persistent: 2.1 Relapsing: 1.6 Diff between groups *(P* = 0.04) Recovery did better than Persistent **Vomiting at first presentation (rating 0 – 4):** Permanent recovery: 1.6 Persistent: 2.1 Relapsing: 0.5 Diff between groups *(P* = 0.03) Persistent higher rating than Relapsing

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Deter et al., 2005 **Design:** Prospective and retrospective **Comparison Group:** No **Location:** Heidelberg, Germany **Yrs followed:** 11.8 (2.4) Range: 9-19	In a long-term FU of AN patients, develop simple, clinically interpretable data that can be helpful in clinical decision-making	**Inclusion:** • Met criteria for AN according to Feighner et al.; DSM III-R **Exclusion:** • Male; additional somatic diseases not related to AN **Recruitment:** • All AN inpatients who were treated consecutively from 1/1/1971 and 10/31/1980 at the Department of General Clinical and Psychosomatic Medicine, University of Heidelberg Medical School. **Sample Size:** **Initial sample:** N = 84 **Reasons for loss to FU:** **Death:** 9 due to ED (electrolyte disturbances) and secondary consequences of chronic AN such as infections or renal failure; 2 due to suicide. • Not available for examination: N = 5 **Analysis sample size:** N = 70	**Mean Age at Intake, mean (SD):** 20.7 (4.1) **Avg length of illness before inclusion:** 2.7 (3.9) **Mean relative ABW at first admission:** 65.2% (9.9) **BMI (SD):** 13.3 (2.0) **Sex:** Female; 100% **Race/ethnicity:** NR **Social Class:** Lower: 45.2% Middle: 48.8% Upper: 6.0%	**Score:** Fair **Method of dx:** Feighner criteria and DSM III-R in retrospective analysis. Method of dx NR **Funding:** NR

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods: Predictor variables, including medical data, collected at inpatient admission, interviews and diagnostics with physicians, psychotherapists. Annual collections of MR outcome categories by general practitioner or information provided by health insurance agencies. FU assessments made an avg of 3.6 yrs and again 11.8 yrs after first admission. Isolated predictors known from the literature over longer time periods and carried out a separate investigation of predictors of the Heidelberg-Mannheim study over a mean period of 12 yrs (range 9-19yrs). Calculated separate hierarchic regression analyses on the bases of the course of the M-R categories for four individually recorded areas: anamnestic, psychological, somatic and social data sets. **Outcomes** **Global score:** Sum of 6 predictor variables (age of onset, purging, albumin, GOT, ANSS psychic findings, ANSS social findings) **Statistical methods:** Univariate analysis to predict M-R outcome categories at 4, 8, and 12 yrs; and the Deter-Herzog criteria after 12 yrs (U test calculated for quantitative predictors and the Chi-square for dichotomized variables). Multivariate testing to obtain most sig predictors. Survival analyses to assess "survival rate." Similarity or diff between strata checked by the log-rank test.	**Descriptive Results** **Univariate Analysis:** **Factors associated with good somatic M-R outcome at 4 yrs *(P* values NR):** Early onset of disease No strong vomiting or laxative abuse No vomiting Positive M-R eating habits and psychological status scales at baseline Positive ANSS social status score No sexual partner No amenorrhea **Factors associated with good somatic M-R outcome at 8 yrs *(P* values NR):** Younger age overall Early onset of disease Lower strong vomiting or laxative abuse Low M-R values for eating habits and social activities at baseline Low ANSS values for low occupational integration, body image disturbance, self-destructive tendencies, pathological findings Higher social activities Potassium and albumin levels **Factors associated with good somatic M-R outcome at12 yrs *(P* values NR):** Positive ANSS psychic and social scale scores Younger age overall Earlier onset of disease Good M-R ratings of psycho-sexual integration, personal contacts, eating habits, abundance of family, social activities Low ANSS values for low occupational integration, low understanding of family of origin, % pathological findings Potassium level Albumin level Low addictive tendencies **Predictor of favorable psychosocial and somatic Deter-Herzog course at 12 yrs (some *P* values NR):** Good social integration *(P* = 0.05) No severe psychic symptoms *(P* = 0.04) Earlier onset of disease Lower strong vomiting or laxative abuse Low M-R values for eating habits at baseline Potassium level Glucose level Albumin level **Multivariate Analysis:** **Predictors of Deter-Herzog criteria at 12 yrs:** Serum albumin level *(P* = 0.01) ANSS social integration score *(P* = 0.03)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Deter et al., 2005 (continued)				

Study Methods and Analytic Strategy	Main Outcomes and Results
	Survival Analysis: **Predictors of Persistence ("survival) of AN symptoms at 12 yrs (N = 81):** Age of onset and purging *(P* = 0.001) • Poor outcome (high AN symptoms) = disease onset > 18 yrs • Moderate outcome = onset < 18 yrs + purging • Good outcome = onset < 18 yrs, no purging Albumin and glutamic-oxalo acetic transaminase (GOT) levels *(P* = 0.013) • Poor outcome = low albumin level • Moderate outcome = normal albumin, high GOT • Good outcome = normal albumin and GOT Global prognosis score *(P* = 0.019) • Poor outcome = high global score • Good outcome = low global score

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Eckert et al., 1995 **Design:** Case series **Comparison Group:** No **Location:** USA **Yrs followed:** 10 **Mean:** 9.6 (0.8) (range: 8.5 – 10.5)	To describe the clinical course and outcome of the core symptoms of AN who participated 10 yrs previously in a collaborative hospital tx study.	**Inclusion:** Feighner's and DSM III-R criteria for AN. **Exclusion:** NR **Recruitment:** 76 of the 105 patients who participated in a 35 day hospital tx study which compared the efficacy of a behavior therapy program with a cyproheptadine regimen. 76 is the total enrollment of all patients from 2 of the three collaborative referral hospitals participating in the tx study. **Sample Size:** N = 76	**Mean Age (SD) (range):** 20.0 (5.2) (12 – 36) **Sex:** Female: 100% **Race/ethnicity:** Caucasian: 100% **Marital Status:** Single: 62 (82%) Married/Divorced: 14 (18%) **Duration of illness, yrs, mean (SD) (range):** 3.0 (3.2) (0.3 – 19) **Avg wt below normal, %, mean (SD) (range):** 31.1 (8.8) (9.8 – 47.4) **Binge-eating:** 36 (47%) **Vomiting:** 29 (38%) **Laxative abuse:** 31 (41%) **Previous hospitalizations for AN:** 37 (49%) **Previous outpt therapy for AN:** 36 (47%) **Age at FU, Median (range):** 28 (21 – 47)	**Score:** Fair **Method of dx:** Structured Clinical Interview: Diagnostic Interview Schedule **Funding:** NIMH

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods Where possible, subjects and their parents were interviewed personally by two well-trained research assistants either in their homes or at the hospital. **Outcomes (based upon clinical status for the 1 yr interval preceding FU):** **Recovered:** Wt within 15 % of ideal wt, cyclical menses, and no sig disturbance in eating or wt control behavior or body image disturbance. **Good:** Wt within 15% of IBW, cyclical menses, and the presence of sig eating or wt control behavior (e.g., binge eating, vomiting, laxative diuretic abuse, diet pill use, undue dieting) or sig body image disturbance. **Intermediate:** Wt only intermittently within 15% of IBW and/or presence of menstrual disturbances. **Poor:** Wt has remained below 15% of IBW and menstruation has been absent or virtually absent. **Statistical Methods** Frequencies and chi-squares	**Descriptive Results:** **Deaths:** 5 (crude mortality rate: 6.6%) All complications of AN (no suicides) all showed early signs of poor outcome (very low wt at hospitalization and time of death, older age of onset, disturbance in wt control behavior. **Expected mortality rate:** 0.39 **Ratio of observed to expected deaths:** 12:82 Diff *(P* < 0.05); study population had a sigly increased mortality. **Various sociodemographic characteristics:** Compared to expected age-sex scales from the US, the study population had: more subjects living alone, not in a conjugal relationship, lived more often with non-relatives, had never been married, and were more often childless or had fewer children *(P* < 0.001) and more induced abortions *(P* < 0.01). **Menses:** **First onset or return of menses during FU:** 60 (85%); 49 (69%) spontaneously and 11 (16%) with meds. **Of spontaneous remissions:** Within first yr: 35% Within 5 yrs: 85% Within last 5 yrs of study: 15% Mean % of IBW when regained menses spontaneously: 92.0% (11.4) (range: 70.9 – 138.3%); Wt was achieved and maintained at 12.4 (14.0) (range: 1 – 72) mos before menses returned. **Regularity of menstrual pattern in last 6 mos preceding FU, N (%):** Regular: 34 (48%) Somewhat irregular (variation 4 – 10 days): 6 (18%) Very irregular (variation > 10 days): 6 (8%) Skipped or rare menses: 7 (19%) Never menstruated: 11 (15%) **Wt at FU:** Below normal wt (BMI < 17.5 and < 85% below avg wt): 16 (22.5%) Normal wt (BMI: 17.5 – 23.5 and between 85 – 115% of avg wt): 52 (73.2%) Mild obesity (BMI 23.6 – 26.5 and between 116 – 125% of avg wt): 2 (2.8%) Severe obesity (BMI > 26.5 and > 125% of avg wt): 1 (1.4%) **Relapse (first wt loss below normal at any time after the index hospitalization):** n = 34 during the first 8 yrs of FU **Probability of relapse:** 0.37; 24 (37%) of all 66 subjects who attained normal wt during FU relapsed before they had been normal wt for 1 yr. If they maintained their wt for at least 1 yr, their chance of continuing to remain in normal wt improved considerably.

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Eckert et al., 1995 (continued)				

Study Methods and Analytic Strategy	Main Outcomes and Results
	Correlates of wt at FU per Anorectic Outcome Scale (Lower wt was associated with): Greater food faddiness *(P* < 0.01) Greater laxative abuse *(P* < 0.01) Other wt loss behavior *(P* < 0.01) Greater body image disturbance *(P* < 0.01) Greater fear of becoming fat *(P* < 0.05) Greater disturbed sexual adjustment *(P* < 0.01) Worse psychological adjustment *(P* < 0.01) Disturbed menses *(P* < 0.01) Bingeing *(P* = NS) Vomiting *(P* = NS) Sense of ineffectivenss *(P* = NS) Dependency *(P* = NS) Social and educational/vocational adjustment *(P* = NS) **Distribution among the categories of outcome by symptoms, N** Recovered: 18 Good: 20 Intermediate: 24 Poor: 9 **Mean BMI:** Total: 18.5 Recovered: 20.2 Good: 20.3 Intermediate: 18.0 Poor: 13.7 Diff between groups *(P* = NR) **Educational/vocational:** Recovered: 0.11 Good: 0.60 Intermediate: 0.25 Poor: 1.0 Diff between groups *(P* < 0.001) Pairwise group comparisons *(P* = NR) **Comorbid psychiatric dx:** **Any Lifetime dx:** Diff between recovered vs 3 other groups *(P* = NS) **Current psychiatric dx:** **Diff between recovered versus all other groups:** Major affective disorder *(P* < 0.01) Anxiety disorders *(P* < 0.05) Phobias *(P* < 0.05) Recovered less comorbidity. Diff between good and intermediate *(P* = NS) **ED dx and outcome category at 10 yr FU:** **No dx:** Total: 18 (23.7%) Recovered: 18 Good: 0 Intermediate: 0 Poor: 0 Diff between groups *(P* = NR)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Eckert et al., 1995 (continued)				

Study Methods and Analytic Strategy	Main Outcomes and Results
	EDNOS: Total: 27 (35.5%) Recovered: 0 Good: 10 Intermediate: 17 Poor: 0 Diff between groups *(P* = NR) **BN:** Total: 17 (22.4%) Recovered: 0 Good: 10 Intermediate: 7 Poor: 0 Diff between groups *(P* = NR) **AN:** Total: 7 (9.2%) Recovered: 0 Good: 0 Intermediate: 0 Poor: 7 Diff between groups *(P* = NR) **AN/BN** Total: 2 (2.6%) Recovered: 0 Good: 0 Intermediate: 0 Poor: 2 Diff between groups *(P* = NR) **Treatment during FU:** Rehospitalized for tx of AN during FU: 23 (32%) # hospitalization, mean (SD*) (*range): 2.7 (2.3) (1 – 8) Rehospitalized for psychiatric problems other than AN: 11 (16%) # hospitalizations, mean (SD*) (*range): 3.3 (3.1) (1- 10) **Outpatient tx:** 54 (76%) **Mos of tx, mean (SD) (range):** 23.5 (26.4) (1 – 111)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality Adverse Events
Authors, year: Eddy, Keel, Dorer et al., 2002 **Design:** Case series **Comparison Group:** No **Location:** Boston, MA **Years followed:** 8-12 (minimum 7 yrs, median 8 yrs FU)	To compare patients with restricting AN and binge/purge AN on measures of impulsivity, course and long-term (8-12 yrs) outcome	**Inclusion:** DSM III-R criteria for AN and/or BN. Reclassified to DSM IV criteria for subtype. Female, age 12 or older, residence within 200 miles of study site **Exclusion:** Evidence of organic brain syndrome or terminal illness and lack of fluency in English **Recruitment:** Patients who sought tx at one of participating facilities and met DSM III-R criteria for AN, restricting type, AN, binge/purge type, or BN recruited **Sample Size:** N = 246 subjects (136 AN) N = 51 AN restricting type (ANR) • N = 24 ANR "pure" • N = 27 ANR "not pure N = 85 AN binge/purge (ANBP) N = 110 BN **Loss to FU Reasons:** 9 (3.7%) died (all AN: N = 2; AN Pure: N = 2; AN Not Pure: N = 5 ANBP). Cause of death NR Attrition rate: 7%.	**Mean Age at Intake, yrs:** ANR Pure: 20.8 ANR Not Pure: 23.8 ANBP: 22.7 **Sex:** Female: 100% **Race/ethnicity:** Not reported	**Score:** Fair **Method of diagnosis:** Independent Clinician Diagnosis **Funding:** Not reported

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods Schedule for Affective Disorders and Schizophrenia - Lifetime Version to diagnose Axis I disorders, Structured Interview for DSM III Personality Disorders to diagnose Axis II disorders. FU interviews were conducted using the Eating Disorders Longitudinal Interview FU Evaluation modified to include a section on eating disorders derived from the Diagnostic Interview Schedule. 6 point Psychiatric Status Rating scale was used to determine ED outcome. **Outcome Categories:** **ANR Pure:** No lifetime history of binging or purging at intake or during first 3 mos. of study **ANR Not Pure**: History of binging and purging behavior at intake, infrequent binge/purge behavior at intake (i.e. at least once weekly), or binge/purge behavior during first 3 mos. of study **ANBP:** full criteria for AN and regularly (at least once weekly) engaged in binge/purge behaviors (defined as vomiting, diuretic use, laxative use) **Full recovery**: absence of symptomatology or the presence of minimal symptomatology for at least 8 consecutive weeks. **Relapse**: return of full criteria symptomatology for at least 1 week following a period of full recovery. **Overall functioning and symptomatology**: based on monthly 100-point Global Assessment of Severity scale ratings. **Statistical Analyses** For ordered variables, two-way comparisons using Wicoxon rank sum test and three way comparisons using Kendall's tau. For dichotomous outcomes, two-way comparisons using chi-square or Fisher exact test and three way comparisons using exact logistic models containing linear and quadratic contrasts. Exact logistic regression and ordinary regression models used to control for duration of illness.	**Descriptive Findings** **At intake:** **Duration of illness, years:** ANR Pure: 3.4 ANR Not Pure: 3.4 ANBP: 6.5 Diff between groups (P = 0.002) **Percent IBW:** ANR Pure: 75% ANR Not Pure: 75% ANBP: 82% Diff between groups (P <0.001) **History of MDD, %:** ANR Pure: 71% ANR Not Pure: 59% ANBP: 71% Diff between groups (P = NS) **History of Hospitalization:** ANR Pure: 54% ANR Not Pure: 70% ANBP: 40% Diff between groups (P = NS) **Personality Disorder, %:** ANR Pure: 22% ANR Not Pure: 55% ANBP: 38% Diff between groups (P = NS) **Global Assessment of Severity Scale:** ANR Pure: 53.5 ANR Not Pure: 42.5 ANBP: 50.0 Diff between groups (P = NS) **History of Alcohol Abuse:** ANR Pure: 4% ANR Not Pure: 11% ANBP: 19% Diff between groups (P =NS) **History of Drug Abuse:** ANR Pure: 0% ANR Not Pure: 13% ANBP: 16% Diff between groups (P = 0.04) **History of Kleptomania:** ANR Pure: 0% ANR Not Pure: 7% ANBP: 13% Diff between groups (P = NS) **History of Suicidality:** ANR Pure: 4% ANR Not Pure: 29% ANBP: 27% Diff between groups (P = .04)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality Adverse Events
Authors, year: Eddy, Keel, Dorer et al., 2002 (continued)				

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
Cox models used to compare survival across diagnostic groups and control for duration of illness.	**Borderline Personality Disorder:** ANR Pure: 0% ANR Not Pure: 10% ANBP: 9% Diff between groups (*P* = NS) **Association between binge-purge behaviors in AN and course and outcome variables:** **Full recovery:** ANR Pure: 45.6% ANR Not Pure: 21.5% ANBP: 38.6% Diff between groups (*P* = NS) **Partial Recovery:** ANR Pure: 87.5% ANR Not Pure: 85.9% ANBP: 87.1% Diff between groups (*P* = NS) **Relapse:** ANR Pure: 31.4% ANR Not Pure: 46.7% ANBP: 67.8% Diff between groups (*P* = NS) **Deaths:** ANR Pure: 8.3% ANR Not Pure: 7.4% ANBP: 5.9% Diff between groups (*P* = NS) **Global Assessment of Severity Scale:** ANR Pure: 59 ANR Not Pure: 52 ANBP: 55 Diff between groups (*P* = NS) **Category Crossovers by 8 yrs FU (median):** ANRs: N = 28 of the ANR's became ANBP N = 10 of ANR Pure became ANBP N = 18 of ANR Not Pure became ANBP N = 4 of ANR Pures who became ANBP had onset of binging and purging N = 3 of ANR Pures who became ANBP had onset binging only N = 3 of ANR Pures who became ANBP had onset purging only N = 14 of ANR group did not develop ANBP N = 4 of those who remained ANR were fully recovered N = 4 of those who remained ANR were partially recovered N = 6 of those who remained ANR continued to meet full criteria for ANR For those who crossed over from ANR to ANBP, the majority (ANR, 51.5%; ANR Pure, 37.8%; ANR Not Pure, 65%) occurred during the first five years of FU or by a median of 8.4 yrs of illness

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Fichter and Quadflieg, 1999 **Design:** Case Series **Comparison Group:** No **Location:** Germany **Yrs followed:** 2 yr FU: 2.5 (0.9) 6 yr FU: 6.2 (.9)	To examine issues regarding course and long-term outcome of AN.	**Inclusion:** Females DSM IV for AN Admitted to inpatient ED tx **Exclusion:** None stated **Recruitment:** Females who where dx'ed with AN and admitted to ED inpatient program (Klinik Roseneck) in Upper Bavaria Germany from 1985-1988. **Sample Size:** **Initial Sample:** (N = 103) **Loss to FU:** Death (N = 6) Traffic accident during exercise = 1 Cardiac and renal failure = 2 Hypocalcemia = 2 Cardiac failure and cachexia = 1 Not reached (N = 1) Refused to participate (N = 1) **Analysis Sample:** 2 yr FU (N = 98) 6 yr FU (N = 95)	**Mean Age at tx start (SD)** 24.9 (6.7) yrs **Sex:** Female 100% **Race/ethnicity:** NR **Mean BMI (kg/cm^2) at tx start (SD)** 14.3 (1.7) **Duration of AN symptoms before tx start (SD)** 6.3 (4.8) yrs **Age onset (SD)** 18.5 (6.4) yrs **Discharge status** Normal: 85 Premature: 1 By team: 3 By mutual agreement: 13 **Improvement at discharge:** Sig: 16 (15.8%) Marked: 44 (43.6%) Slight: 30 (29.7%) Unchanged: 9 (8.9%) Slightly worse: 1 Marked worse: 1 **Duration of tx (days) (SD):** 118.6 (49) **Education:** < 9 yrs: 1.9% > 9 yrs: 68.9% 13+ yrs: 26.2% University degree: 2.9%	**Score:** Good **Method of dx:** Specially trained psychologists or physician using DSM IV criteria for AN based on interview and/or questionnaire data. **Funding:** Wilhelm-Sander-Stiftung, Munich Germany; Bundesministerium fur Bildung, Forschung und Technologie in Germany

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods: Patients assessed at admission to inpatient, discharge from inpatient, 2 yrs, 6 yrs FU. For FU, patients sent questionnaire packet to complete. After packet returned, interview conducted by specially trained psychologists and physicians. Those not able to do long interview were given shorter version. Long interview were face to face or by phone, short by phone only.	**Results**: **Descriptives** **Mean BMI (kg/cm^2) (SD)** Tx start - 14.3 (1.7) Discharge from tx – 15.5 (1.7) 2 yr FU – 17.1 (3.4) 6 yr FU – 17.9 (2.8)
Statistical Method: Repeated measures MANOVAs Pairwise t tests Longitudinal comparisons used sets complete for all time points.	**ED diagnostic outcome (DSM IV):** **2 yr FU:** AN: 36.6% BN: 9.9% BED: 0 EDNOS: 3.0% None: 45.5% **6 yr FU:** AN: 26.8% BN: 9.9% (16.8% cumulative) BED: 0 EDNOS: 2.0% None: 55.4%
Outcomes SIAB-P, supplemented by PSR Global outcomes: aggregate of 10 outcome categories • Good – outcome of 1 or 0 • Intermediate – outcome of 2 • Poor – outcome of 3-4 M-R general outcome • Good – within normal range and normal menstruation • Intermediate – wt not consistently in normal range or menstrual irreg. • Poor – wt below normal, menstruation absent or nearly absent	**PSR ED Symptoms Ratings:** **2 yr FU:** Marked: 30.4% Partial Remission: 30.4% Residual: 23.9% Usual self: 15.3% **6 yr FU:** Marked: 30.4% Partial Remission: 25.0% Residual: 21.4% Usual self: 23.2%
	Global outcomes Good: 34.7% Intermediate: 38.6% Poor: 20.8% Dead: 5.9%

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Fichter and Quadflieg, 1999 (continued)				

Study Methods and Analytic Strategy	Main Outcomes and Results
	Menstruation: **2 yr FU:** Normal Menses: 21 (22.8%) Irreg menses: 9 (9.8%) Amenorrhea: 48 (52.2%) No period other reasons: 2 (2.2%) OCP or hormones: 12 (13.0%) **6 yr FU:** Normal Menses: 34 (37%) Irreg menses: 12 (13.0%) Amenorrhea: 22 (23.9%) No period other reasons: 7 (7.6%) OCP or hormones: 17 (18.5) **M-R outcomes:** **2 yr** Good: 13 (12.9%) Intermediate: 20 (19.8%) Poor: 63 (62.3%) **6 yr** Good: 25 (26.9%) Intermediate: 23 (24.7%) Poor: 39 (41.9%) Diff in course of disease AN-R and AN-B*P (P* = NS) **Comorbidity rates ar 6 yr FU (N = 75):** Borderline Personality Disorder: 12% Substance abuse (excl. lax): 20% Mood disorders: 53% Anxiety disorders: 32%

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Fichter and Quadflieg, 1999 (continued)				

Study Methods and Analytic Strategy	Main Outcomes and Results
	Change over time in EDI (N = 59) **Total** Beginning of therapy vs 2 yr FU *(P* < 0.05) Improved Beginning of therapy vs 6 yr FU *(P* < 0.01) Improved End of therapy vs 2 yr FU *(P* < 0.001) Worsened End of therapy vs 6 yr FU *(P* < 0.05) Worsened **Drive for Thinness** Beginning of therapy vs 2 yr FU *(P* < 0.01) Improved Beginning of therapy vs 6 yr FU *(P* < 0.01) Improved End of therapy vs 2 yr FU *(P* < 0.001) Worsened End of therapy vs 6 yr FU *(P* < 0.01) Worsened **Bulimia** Beginning of therapy vs 2 yr FU *(P* = NS) Beginning of therapy vs 6 yr FU *(P* = NS) End of therapy vs 2 yr FU *(P* < 0.001) Worsened End of therapy vs 6 yr FU *(P* < 0.001) Worsened **Body dissatisfaction** Beginning of therapy vs 2 yr FU *(P* = NS) Beginning of therapy vs 6 yr FU *(P* = NS) End of therapy vs 2 yr FU *(P* = NS) End of therapy vs 6 yr FU *(P* = NS) **Ineffectiveness** Beginning of therapy vs 2 yr FU *(P* < 0.05) Improved Beginning of therapy vs 6 yr FU *(P* < 0.01) Improved End of therapy vs 2 yr FU *(P* < 0.001) Worsened End of therapy vs 6 yr FU *(P* < 0.05) Worsened **Perfectionism** Beginning of therapy vs 2 yr FU *(P* = NS) Beginning of therapy vs 6 yr FU *(P* = NS) End of therapy vs 2 yr FU *(P* = NS) End of therapy vs 6 yr FU *(P* = NS)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Fichter and Quadflieg, 1999 (continued)				

Study Methods and Analytic Strategy	Main Outcomes and Results
	Change over time in SIAB (N = 52) **Total scale** Beginning of therapy vs 2 yr FU *(P* < 0.001) Improved Beginning of therapy vs 6 yr FU *(P* < 0.001) Improved End of therapy vs 2 yr FU *(P* < 0.01) Worsened End of therapy vs 6 yr FU *(P* = NS) 2 yr FU vs 6 yr FU *(P* < 0.001) Improved **Body image and ideal of thinness** Beginning of therapy vs 2 yr FU *(P* < 0.001) Improved Beginning of therapy vs 6 yr FU *(P* < 0.001) Improved End of therapy vs 2 yr FU *(P* = NS) End of therapy vs 6 yr FU *(P* = NS) 2 yr FU vs 6 yr FU *(P* = NS) **Depression** Beginning of therapy vs 2 yr FU *(P* = NS) Beginning of therapy vs 6 yr FU *(P* < 0.001) Improved End of therapy vs 2 yr FU *(P* < 0.01) Worsened End of therapy vs 6 yr FU *(P* < 0.01) Improved 2 yr FU vs 6 yr FU *(P* < 0.001) Improved **Anxieties and obsessions** Beginning of therapy vs 2 yr FU *(P* = NS) Beginning of therapy vs 6 yr FU *(P* < 0.001) Improved End of therapy vs 2 yr FU *(P* < 0.01) Worsened End of therapy vs 6 yr FU *(P* < 0.05) Improved 2 yr FU vs 6 yr FU *(P* < 0.001) Improved

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Fichter and Quadflieg, 1999 (continued)				

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
	Change over time SCL-90 (N = 53) **Global Severity Index** Beginning of therapy vs 2 yr FU (*P* < 0.01) Improved Beginning of therapy vs 6 yr FU (*P* < 0.01) Improved End of therapy vs 2 yr FU (*P* < 0.01) Worsened End of therapy vs 6 yr FU (*P* = NS) **Positive Symptom Total** Beginning of therapy vs 2 yr FU (*P* < 0.01) Improved Beginning of therapy vs 6 yr FU (*P* < 0.001) Improved End of therapy vs 2 yr FU (*P* < 0.05) Worsened End of therapy vs 6 yr FU (*P* = NS) **Positive Symptom Distress Index** Beginning of therapy vs 2 yr FU (*P* < 0.01) Improved Beginning of therapy vs 6 yr FU (*P* < 0.01) Improved End of therapy vs 2 yr FU (*P* < 0.001) Worsened End of therapy vs 6 yr FU (*P* < 0.05) Worsened **Somatization** Beginning of therapy vs 2 yr FU (*P* < 0.05) Improved Beginning of therapy vs 6 yr FU (*P* < 0.05) Improved End of therapy vs 2 yr FU (*P* = NS) End of therapy vs 6 yr FU (*P* = NS) **Obsessive-compulsive disorder** Beginning of therapy vs 2 yr FU (*P* = NS) Beginning of therapy vs 6 yr FU (*P* < 0.01) Improved End of therapy vs 2 yr FU (*P* < 0.01) Worsened End of therapy vs 6 yr FU (*P* = NS) **Interpersonal Sensitivity** Beginning of therapy vs 2 yr FU (*P* < 0.05) Improved Beginning of therapy vs 6 yr FU (*P* < 0.01) Improved End of therapy vs 2 yr FU (*P* < 0.001) Worsened End of therapy vs 6 yr FU (*P* < 0.05) Worsened **Depression** Beginning of therapy vs 2 yr FU (*P* < 0.01) Improved Beginning of therapy vs 6 yr FU (*P* < 0.001) Improved End of therapy vs 2 yr FU (*P* < 0.01) Worsened End of therapy vs 6 yr FU (*P* < 0.05) Worsened **Anxiety** Beginning of therapy vs 2 yr FU (*P* = NS) Beginning of therapy vs 6 yr FU (*P* = NS) End of therapy vs 2 yr FU (*P* = NS) End of therapy vs 6 yr FU (*P* = NS) **Anger-hostility** Beginning of therapy vs 2 yr FU (*P* = NS) Beginning of therapy vs 6 yr FU (*P* < 0.01) Improved End of therapy vs 2 yr FU (*P* < 0.05) Worsened End of therapy vs 6 yr FU (*P* = NS) **BDI (N = 62)** Beginning of therapy vs 6 yr FU (*P* < 0.001) Improved End of therapy vs 6 yr FU (*P* < 0.05) Worsened

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Fichter and Quadflieg, 1999 (continued)				

Study Methods and Analytic Strategy	Main Outcomes and Results
	Prognostic factors based on PSR **2 yr FU** Early onset AN *(P* < 0.05) Worse Low BMI at end of tx *(P* < 0.01) Worse **6 yr FU** Binge in mo before tx *(P* < 0.05) Worse Other mental dx prior to tx *(P* < 0.05) Worse Low body wt at end of tx *(P* < 0.05) Worse

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Franko et al., 2004 **Design:** Case series **Comparison Group:** No **Location:** Massachusetts, USA **Yrs followed:** Mean: 8.6	To determine predictors of serious suicide attempts in women with AN and BN.	**Inclusion:** Female, English speaking, meet full criteria for AN and/or BN, at least 12 yrs of age, reside within 200 miles of the study site. **Exclusion:** Organic brain syndrome or terminal illness. **Recruitment:** 554 consecutive women who sought tx for eating disorder at Massachusetts General Hospital or other Boston area clinics between October 1987 and June 1990. **Sample Size** **Initial Sample:** Met dx criteria: N = 268 Agreed to participate: N = 229 Additional participants identified: N = 21 **Reasons for loss to FU:** Drop out prior to first FU: N = 4 **Analysis Sample** N = 246 AN-Restricting: 51 AN-Binge Purge: 85 BN: 110	**Mean Age:** 24.8 (range: 13 – 45) at entry to the study. **Sex:** Female:100% **Race/ethnicity:** Non-Caucasian: 4% **Mean duration of illness:** 6.7 yrs (range: 3 mos – 21 yrs)	**Score:** Good **Method of dx:** LIFE-EAT-II and the PSR scale **Funding:** NIMH, Rubenstein Foundation, and Harvard Eating Disorders Care

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods FU interviews conducted every 6 – 12 mos in person when possible. **Statistical Methods** Non-parametric tests to examine diff on self-report measures administered at intake between subjects who made suicide attempts and those who did not. Kaplan-Meier survival analyses to determine time to first suicide attempt, and time-varying proportional hazards (Cox) regression models used to determine influence of baseline and course variables on time to first suicide attempt. Multiple regression to predict time to first suicide attempt.	**Descriptive Results** **Baseline, Reported hx of suicide attempts prior to study entry:** AN: 30.1% BN: 22.7% **Rates of suicide attempts:** AN: 30 (22.1%) BN: 12 (10.9%) Death from suicide: N = 4 (none had a previous suicide attempt). Diff between baseline self report measures for suicide attempters and non-attempters, mean (SD): **AN** EDI, drive for thinness *(P* = NS) EDI, Bulimia *(P* = NS) EDI, body dissatisfaction *(P* = NS) EDI, ineffectiveness: • attempters: 15.2 (8.6) • non-attempters: 11.4 (7.8) • *(P* = 0.04); Attempters did worse EDI, perfectionism *(P* = NS) EDI, interpersonal distrust *(P* = NS) EDI, interoceptive awareness *(P* = NS) EDI, maturity fears *(P* = NS) **BDI:** attempters: 27.6 (12.1) non-attempters: 22.7 (11.3) *(P* = 0.05). Attempters had greater depression. Symptom distress *(P* = NS) Global severity index *(P* = NS) Positive symptom total *(P* = NS) **BN** EDI, drive for thinness *(P* = NS) EDI, Bulimia *(P* = NS) EDI, body dissatisfaction *(P* = NS) EDI, ineffectiveness: • attempters: 14.6 (7.1) • non-attempters: 8.4 (6.1) • *(P* = 0.007); Attempters did worse EDI, perfectionism *(P* = NS) EDI, interpersonal distrust: • attempters: 7.1 (4.0) • non-attempters: 4.5 (3.4) • *(P* = 0.04). Attempters did worse. EDI, interoceptive awareness • attempters: 17.7 (7.6) • non-attempters: 10.9 (5.9) • *(P* = 0.003). Attempters did worse EDI, maturity fears: • attempters: 7.6 (7.3) • non-attempters: 3.7 (4.3) • *(P* = 0.03). Attempters did worse.

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Franko et al., 2004 (continued)				

Study Methods and Analytic Strategy	Main Outcomes and Results
	BDI: attempters: 27.0 (11.7) non-attempters: 19.6 (9.5) *(P* = 0.03). Attempters had greater depression. Symptom distress: • attempters: 2.2 (0.46) • non-attempters: 1.9 (1.4) • *(P* = 0.006). Attempters did worse Global severity index: • attempters: 1.6 (0.49) • non-attempters: 1.0 (0.54) • *(P* = 0.002). Attempters did worse. Positive symptom total: • attempters: 64.0 (11.7) • non-attempters: 47.7 (18.0) • *(P* = 0.003). Attempters did worse. **Multivariate Results** **Predictors of time to first suicide attempt during course of study-hypothesis testing results:** **AN** Hx of suicide attempt at intake *(P* < 0.009) Eating disorder symptomatology *(P* = NS) Severity of drug use *(P* < 0.01) Alcohol use *(P* = NS) **BN** Laxative use *(P* < 0.05) Hx of drug use disorder prior to start of the study *(P* < 0.01) **AN** Hx of suicide attempt at intake: HM = 1.09, 95% CI (1.31 – 6.71) *(P* = 0.009); Shorter time to first attempt Drug use: HM = 0.92, 95% CI (1.40 – 4.52) *(P* = 0.01); Greater use shorter time Individual therapy: HM = 3.54, 95% CI (1.20 – 10.42) *(P* = 0.013); Yes, shorter time Neuroleptic meds: HM = 5.03, 95% CI (1.50 – 16.86*) (P* = 0.02); Yes, shorter time Age of onset: HM = 1.06, 95% CI (1.00 – 1.12) *(P* = 0.05); Older age, shorter time Group therapy: HM = 2.35, 95% CI (1.00 – 5.53) *(P* = 0.06) Severity of depression: HM = 1.21, 95% CI (0.99 – 1.50) *(P* = NS) Alcohol use: HM = 1.54, 95% CI (0.99 – 1.04) *(P* = NS)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Franko et al., 2004 (continued)				

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
	BN Group therapy: HM = 11.32, 95% CI (2.33 – 55.02) *(P* = 0.002) Yes, shorter time Age of onset: HM = 0.82, 95% CI (0.70 – 0.97) *(P* = 0.008) Younger age, shorter time Hx of drug use disorder: HM = 8.94, 95% CI (1.87 – 42.77) *(P* = 0.009) Greater hx, shorter time Individual therapy: HM = 10.39, 95% CI (1.03– 105.12) *(P* = 0.020) Yes, shorter time Paranoid personality disorder at intake: HM = 66.5, 95% CI (3.60 – 129.84) *(P* = 0.020) Yes, shorter time Severity of laxative use: HM = 1.21, 95% CI (1.50 – 46.30) *(P* = 0.022) More, shorter time Psychiatric hospitalization: HM = 10.75, 95% CI (1.16 – 99.86) *(P* = NS)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Gillberg, Råstam, and Gillberg, 1995 **Companion article:** Gillberg, Råstam, Gillberg, 1994 **Design:** Prospective cohort **Comparison Group:** Yes **Location:** Göteburg, Sweden **Yrs followed:** 6.7 from onset of AN (6.3-7.0) **Cases**: 4.9 from first exam **Comparisons**: 4.6 from first exam	To analyze stability of personality disorders over a 6-yr period after reported AN onset	**Inclusion:** **Cases:** DSM III-R for AN Born 1970 AN onset < 18 yrs old **Comparison:** Matched to cases on age, sex, school **Exclusion:** Cases: None Comparisons: None **Recruitment:** **Cases:** From total population of Göteburg, Sweden, born in 1970 and developing AN before age 18; pooled with second population screening sample reported by school and hospital health care workers during FU. Some clinically referred and some screened through school nurses and doctors, pediatricians, and child psychiatrists **Comparisons:** Same schools as AN group **Sample Size:** Cases: 51 Comparisons: 51	**Age, mean (95% CI):** Cases: 21.0 (20.5-21.4) Comparisons: 20.8 (20.3-21.3) **Sex:** Women in AN sample: N = 48 **Race/ethnicity:** NR **Age of AN onset, mean (range):** 14.3 (13.9-14.7)	**Score:** Good **Method of dx:** Structured interview using the SCID-I **Funding:** Swedish Medical Research Council, Swedish Social Research Council, Swen Jerring Foundation, Fulbright Commission, Wilhelm and Martina Lundgren Foundation, Sennerdahl Foundation

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods: Psychiatric interview, blinded to original disease status. Performed the SCID-II, Dewey Social Awareness Test, examined individual neurodevelpmentally/ neuro-logically, and administered the Wechsler Adult Intelligence Sale-Revised. **Statistical Methods:** Chi-square comparisons	**Descriptive Results** AN Recovery (self report): 47% Comparison of Personality Disorders between AN and control group at age 21 (mean of 6 yrs after onset) **Cluster A** All categories *(P* = NS) **Cluster B** All categories *(P* = NS) **Cluster C** Avoidant: Cases (14%) Comparison (2%) *(P* < 0.07) Dependent *(P* = NS) Obsessive-compulsive: Cases (29.5%) Comparison (6%) *(P* < 0.001) Passive-aggressive *(P* = NS) Any cluster C: Cases (37%) Comparison (10%) *(P* < 0.001) **Other** Self-defeating *(P* = NS) Any SCID personality disorder: Cases (41%) Comparison (18%) *(P* < 0.02) 2 or more SCID personality disorders: Cases (23.5%) Comparison (2%) *(P* < 0.01) **Comparison of Autism Spectrum Disorders and Empathy Disorders** Asperger's syndrome: Cases (12%) Comparison (0%) *(P* < 0.05) Any autistic like condition: Cases (20%) Comparison (0%) *(P* < 0.001) Empathy disorder: Cases (29.5%) Comparison (4%) *(P* < 0.002) OCD/OCPD/Asperger syndrome/autistic-like condition at both 16 and 21: Cases (N = 23) Comparison (N = 2) *(P* < 0.01) **Concurrence of Axis II and Axis I Disorders** No axis II/ASD-no axis I: Cases (25.5%) Comparison (70%) *(P* < 0.0001) No axis II/ASD-at least 1 axis I *(P* = NS) At least 1 axis II/ASD-at least 1 axis I: Cases (31%) Comparison (12%) *(P* < 0.01) At least 1 axis II/ASD-no axis I *(P* = NS)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Gillberg, Råstam, Gillberg 1994 **Design:** Prospective cohort **Comparison Group:** Yes **Location:** Göteburg, Sweden **Yrs followed:** 6.7 from onset of AN (6.3-7.0) **Cases**: 4.9 from first exam **Comparisons**: 4.6 from first exam	To analyze whether in the intermediate-term, outcome is worse in AN than comparisons; to evaluate the contribution of empathy deficit associated with AN to outcomes; to compare AN outcome in this sample to those of previous studies using the M-R scales	**Inclusion:** **Cases:** DSM III-R for AN Born 1970 AN onset < 18 yrs old **Comparison:** Matched to cases on age, sex, school **Exclusion:** Cases: None Comparisons: None **Recruitment:** **Cases:** From total pop of Göteburg, Sweden, born in 1970 and developing AN before age 18; pooled with second population screening sample reported by school and hospital health care workers during FU. Some clinically referred and some screened through school nurses and doctors, pediatricians, and child psychiatrists **Comparisons:** Same schools as AN group **Sample Size:** Cases: 51 Comparisons: 51	**Age of AN onset:** 14.3 yrs Range: 13.9-14.7 **Mean Age at First Exam:** Cases: 16.1 (95% CI: 15.7-16.5) Comparisons: 16.0 (95% CI: 15.5-16.5) **Mean Age at FU:** Cases: 21 (95% CI: 20.5-21.4) Comparisons: 20.8 (95% CI: 20.3-21.3) **Sex (both groups), N:** Females: 96 Males:6 **Race/ethnicity:** NR **Min BMI kg/m², mean:** Cases: 14.9 (2.6) Comparisons: NR **BMI at first exam, kg/m², mean:** Cases: 18.3 (2.9) Comparisons: NR **BMI at FU, kg/m², mean:** Cases**:** 21.2 (3.5) Comparisons: NR	**Score:** Good **Method of dx:** Structured interview using the SCID-I **Funding:** NR

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods: At time of dx, all participants, then children and adolescents, and their mothers were interviewed by a psychiatrist. At FU, both groups were screened by another psychiatrist/psychologist blind to the original group status, via SCID-II for personality disorder dx, clinician-based capacity for empathy, Dewey social awareness test, neurological testing, WAIS-R, wt, and ht (self-report). All individuals also examined by psychiatrist to administered the first interview, using SCID-I for Axis I disorders, the M-R AN outcome scales and a rating of empathic skills. At end of interview, DSM III-R dx made independently by both clinicians; empathy dx was made conjointly by both. **Outcome measures** Recovered/not-recovered for individuals dx in teenage yrs (interview data from M-R scale), Avgd scale scores according to Morgan-Russell interview Good, intermediate and poor outcome: good = nrml body wt (100 +- 15%avg body wt.), Intermediate = normal or near normal wt and/or menstrual abnormalities, poor = low wt and absent or scanty menstruation. (BMI or % wt details regarding these definitions were NR). **Statistical Methods:** Chi square tests for matched pairs were used.	**Descriptive Results** **Recovery status AN group, Morgan Russell self-progress rating:** Recovered: 47% Not-recovered: 53% Not recovered but improved: 39% Not recovered but static: 12% Not recovered and worse: 2% Some type of ED in AN group: 44% **Avg total M-R Scores:** Cases: very poor: 39% (avg score of 8.5 or less) **Good-Intermediate and Poor Outcome for AN group:** Good: 41% Intermediate: 35% Poor: 24% **Dietary Restriction and concern about body wt, M-R scale:** Dietary Restriction None: Cases: 47%, Comparisons: 88% Less than ½ timeCases: 18%, Comparisons: 12% About ½ timeCases: 6%, Comparisons: 0 More than ½ timeCases: 4% Comparisons: 0 All the timeCases: 26% Comparisons: 0 Diff between groups *(P* < 0.001) **Worry about body wt or appearance** None: Cases:16% Comparisons: 57% Less than ½ timeCases: 35% Comparisons: 31% About ½ timeCases: 2% Comparisons: 8% More than ½ timeCases: 10% Comparisons: 0 All the timeCases:37% Comparisons: 4% Diff between groups *(P* < 0.001) **Body wt during last 6 mos:** Near avg all timeCases: 53% Comparisons:96% Usually near avg, but occasionally deviant: Cases: 16% Comparisons: 4% Always deviated: Cases: 18% Comparisons: 0 Always much deviated: Cases: 14% Comparisons: 0 Diff between groups *(P* < 0.001) **Menstruation:** Cases: halted menstruation never returned: 8%, Regular or cyclical menarche: 50% Comparisons: Regular or cyclical menarche: 90% Diff between groups *(P* < 0.001) **AN group tx type (specifically for ED) and outcome status:** Poorest outcome: 5 had no tx, 10 had only psychiatric tx (2, outpatient only; 9, family therapy, 1, individual psychotherapy). Best outcomes, 3 no tx, 3 pediatrician support and zinc supplements, 2 met with psychiatrist (< 8 times), 7 received therapy (>8 times) Diff between groups *(P* = NS)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Gillberg, Råstam, and Gillberg 1994 **Companion article:** Gillberg, Råstam, and Gillberg 1995 **Design:** Prospective cohort **Comparison Group:** Yes **Location:** Göteburg, Sweden **Yrs followed:** 6.7 from onset of AN (6.3-7.0) **Cases:** 4.9 from first exam **Comparisons:** 4.6 from first exam	To analyze the associated physical and neuro-developmental problems over 5 yrs in individuals with AN, and matched comparisons.	**Inclusion:** **Cases:** DSM III-R for AN Born 1970 AN onset < 18 yrs old **Comparison:** Matched to cases on age, sex, school **Exclusion:** Cases: None Comparisons: None **Recruitment:** **Cases:** From total pop of Göteburg, Sweden, born in 1970 and developing AN before age 18; pooled with second population screening sample reported by school and hospital health care workers during FU. Some clinically referred and some screened through school nurses and doctors, pediatricians, and child psychiatrists **Comparisons:** Same schools as AN group **Sample Size:** Cases: 51 Comparisons: 51	**Age of AN onset:** 14.3 yrs Range: 13.9-14.7 **Mean Age at First Exam:** Cases: 16.1 95% CI (15.7-16.5) Comparisons: 16.0 95% CI (15.5-16.5) **Mean Age at FU:** Cases: 21 95% CI (20.5-21.4) Comparisons: 20.8 95% CI (20.3-21.3) **Sex (both groups), N:** Females: 96 Males:6 **Race/ethnicity:** NR	**Score:** Good **Method of dx:** Structured interview using the SCID-I **Funding:** NR

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods: At time of dx, all participants, then children and adolescents, and their mothers were interviewed by a psychiatrist. At FU, another psychiatrist/psychologist blind to the original group status, screened both groups: via SCID-II for personality disorder dx, clinician-based capacity for empathy, Dewey social awareness test, neurological testing, WAIS-R, wt, and ht (self-report). All individuals also examined by psychiatrist who administered first interview, using SCID-I for Axis I disorders, M-R AN outcome scales, and a rating of empathic skills. At end of interview, DSM III-R dx made independently by both clinicians; empathy dx was made conjointly by both. Neurodevelopmental exam included growth charts of wt and ht development from age 7 through time of 1st exam; wt and ht immediately before onset of AN were compared to FU data **Outcome measures** At 16 yrs: Extreme underwt = BMI≤17; Extreme overwt = BMI ≥25. At 21 yrs: Extreme underwt = lowest wt ≤45kg; Extreme overwt = heaviest ≥80kg. Extreme shortness was dx in individuals who were shorter than the shortest individual in the comparison group. **Statistical Methods:** Wilcoxon test for matched pairs were used.	**Descriptive Results** **Wt at first screen, kg (SD):** Cases: 49.4 (8.8), 95% CI (47.0-51.8) Comparisons: 56.2 (6.6), 95% CI (54.4-58.0) Diff between groups *(P* < 0.01) **Wt at FU, kg (SD):** Cases: 58.9 (6.6), 95% CI (54.4-58.0) Comparisons: 58.2 (7.9), 95% CI (58.2-62.6) Diff between groups *(P* = NR) **Ht at first screen, cm (SD):** Cases: 164.3 (5.8), 95% CI (162.7-165.9) Comparisons: 166.7 (6.9), 95% CI (164.8-168.8) Diff between groups *(P* = NS) **Ht at FU, cm (SD):** Cases: 166.2 (6.4), 95% CI (164.4-168.8) Comparisons: 169.1 (6.8), 95% CI (167.2-171.0) Diff between groups *(P* < 0.05) **BMI at first screen, kg/m² (SD):** Cases: 18.3 (2.9) 95% CI (17.5-19.1) Comparisons: 20.2 (1.9) (95% CI (19.7-20.8) Diff between groups *(P* = NS) **BMI at FU, kg/m² (SD):** Cases: 21.2 (3.5) 95% CI (20.2-22.2) Comparisons: 21.2 (2.3) 95% CI (20.5-21.8) Diff between groups *(P* = NS) **Extremely Underwt at first screen:** **G1:** 15 **G2:** 1 Diff between groups *(P* < 0.001) **Extremely Underwt at FU:** **G1:** 4 **G2:** 0 Diff between groups *(P* < 0.05) **Extremely Overwt at first screen:** **G1:** 1 **G2:** 0 Diff between groups *(P* = NR) **Extremely Overwt at FU:** **G1:** 3 **G2:** 0 Diff between groups *(P* < 0.05) **Extremely Short at first screen:** **G1:** 0 **G2:** 0 Diff between groups *(P* = NS)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Gillberg, Råstam, Gillberg 1994 (continued)				

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods: At time of dx, all participants, then children and adolescents, and their mothers were interviewed by a psychiatrist. At FU, another psychiatrist/psychologist blind to the original group status, screened both groups: via SCID-II for personality disorder dx, clinician-based capacity for empathy, Dewey social awareness test, neurological testing, WAIS-R, wt, and ht (self-report). All individuals also examined by psychiatrist who administered first interview, using SCID-I for Axis I disorders, M-R AN outcome scales, and a rating of empathic skills. At end of interview, DSM III-R dx made independently by both clinicians; empathy dx was made conjointly by both. Neurodevelopmental exam included growth charts of wt and ht development from age 7 through time of 1st exam; wt and ht immediately before onset of AN were compared to FU data **Outcome measures** At 16 yrs: Extreme underwt = BMI≤17; Extreme overwt = BMI ≥25. At 21 yrs: Extreme underwt = lowest wt ≤45kg; Extreme overwt = heaviest ≥80kg. Extreme shortness was dx in individuals who were shorter than the shortest individual in the comparison group. **Statistical Methods:** Wilcoxon test for matched pairs were used.	**Extremely Short at FU:** **G1:** 6 **G2:** 0 Diff between groups *(P* < 0.05) Physical Disorders: Diff between groups at baseline or FU *(P* = NS) **Neurodevelopmental:** Fine and gross motor skills, tremor, mirror movements, handedness *(P* = NS) Dysdiadochokinesis, at both time patients: **G1:** 10 **G2:** 1 Diff between groups *(P* < 0.01) In terms of outcome, 20 AN individuals had “poor outcome” based on the Morgan Russell scale. Of those, 8 were dysdiadochokinesis group *(P* = NS).

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Gowers et al., 2000 **Design:** Case series **Comparison Group:** No **Location:** Britian **Yrs followed:** **G1:** 2 **G2:** 3 to 7	To clarify the relationship between a range of presenting features, tx received, and medium to long-term outcome in AN.	**Inclusion:** DSM III-R criteria for AN **Exclusion:** NR **Recruitment:** 75 consecutive cases of adolescent-onset AN were drawn from a series attending a regional adolescent service. Of these, **G1:** 35 had participated in a prospective study of family values in AN and **G2:** 40 were immediately preceding cases presenting to the department **Sample Size:** **Initial sample:** N = 75 **Reasons for loss to FU:** Insufficient information: N = 1 Deceased: N = 2 **Analysis sample:** N = 73 Full outcome (including ht and wt) available for 56	**Mean Age** 15.2 **G1:** 14.10 **G2:** 15.6 **Sex:** Males: N = 4 (all from **G1**) Females: N = 71 **Race/ethnicity:** NR **Length of Illness (mos):** 13.0 **G1:** 14.1 **G2:** 12.0 **Wt, as % of expected wt:** 76.5 **G1:** 78.2 **G2:** 75.1 **M-R Global Assessment Score:** 4.61 **G1:** 5.05 **G2:** 4.24 **Subtype, Restricting, N: 44** **G1:** 21 **G2:** 23 **Purging:** **N:** 31 **G1:** 14 **G2:** 17	**Score:** Poor **Method of dx:** **G1:** K-SADS diagnostic interview **G2:** clinical assessment Funding: NR **Funding:** NR

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods Interviews in-person or by telephone. Some interviews with relatives or physician informants. Calculation of M-R Global Assessment Score **Outcome categories** **Good**: wt maintained > 85% expected body wt, menstruation resumed and social functioning satisfactory; M-R Global Assessment Score ≥ 9 **Intermediate:** substantial improvement in ED obtained with wt maintained > 85% of expected wt, but either menstruation not resumed or sig concern about eating and wt or was another psychosocial difficulty; M-R Global Assessment Score 6 – 9 **Poor:** still suffering ED and wt maintained < 85%; M-R Global Assessment Score < 6: 15 (20.0%) **Statistical Analyses** Data were examined for diffs between the two series on key presentation variables using ANOVA and chi square. Stepwise multiple regression to determine the relationship between covarying predictor variables with M-R Global Assessment Score at FU.	**Descriptive Outcomes** **M-R Global Assessment Score Outcomes:** Good:45.3% Intermediate:30.7% Poor: 20.0% Inadequate Information: 4.0% **Descriptive variables by outcomes:** **Age at onset, mean, yrs, mos:** Good: 14, 3 Intermediate: 13, 10 Poor: 13, 11 Diff between groups *(P* = NS) **Length of illness, mean, mos:** Good: 11.1 Intermediate: 14.5 Poor: 15.3 Diff between groups *(P* = NS) **Wt as % of mean matched population wt:** Good: 81.3 Intermediate: 73.3 Poor: 70.7 Diff between groups *(P* = 0.001) Higher wt associated with better outcome **Presenting M-R Global Assessment Scale:** Good: 5.3 Intermediate: 4.15 Poor: 3.68 Diff between groups *(P* = 0.001) Higher MRGAS associated with better outcome **Never an inpatient:** Good: 31 Intermediate: 13 Poor: 7 Diff between groups *(P* = 0.001) Never inpatient associated with better outcome **Multivariate Results** **Predictors of M-R Global Assessment Scale score in step-wise regression** Inpatient admission *(P* = 0.0006) Presenting MRGAS *(P* = 0.001)

Evidence Table 15. Anorexia Nervosa Outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality Adverse Events
Authors, year: Halmi, Eckert et al., 1991 **Companion article:** Schork et al., 1994 **Design:** Case series **Comparison Group:** Yes **Location:** USA (Iowa City, IA; Minneapolis, MN; White Plains, NY **Years followed:** 10	To determine the prevalence of lifetime and current psychiatric diagnoses in AN patients compared to comparisons.	**Inclusion:** All patients met modified Feighner diagnostic criteria for AN. Other details in Halmi et al., 1979. Comparisons matched patients on age, sex, and socioeconomic class. **Exclusion:** Hx of eating disorder or body weight above normal range for comparisons; See Halmi et al., 1979, for more details. **Recruitment:** Cases had previously participated in a 35-day hospital tx study comparing behavior therapy vs.medication (cyproheptadine). Comparisons recruited via advertisements in local newspapers and on local college campuses. **Sample Size (N):** Completed tx: 76 Completed FU: Patients: 62 Comparisons: 62 Patients' mothers: 57 Patients' fathers: 49 Comparisons mothers: 57 Comparisons fathers: 49 **Reasons for Loss to FU:** 9 refused to participate, 5 deceased (causes unknown).	**Mean Age, yrs (SD):** Pre-tx: 20 (5.2) 10 yr FU: 29 (5.2) **Sex:** Female **Race/ethnicity:** NR	**Score:** Fair **Method of diagnosis:** Prospective assessment using Feighner criteria; retrospective DSM-III-R. **Funding:** NR

Evidence Table 15. Anorexia Nervosa Outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
For General Psychiatric diagnoses: Diagnostic Interview Schedule (Version III) used to interview patients, comparisons, and parents of both patients groups. Results were computer-scored, yielding a positive or negative score on every diagnosis for each subject. Any dx within the past year was considered 'current'. A positive dx of a drug or alcohol disorder was made for "abuse without dependence", "dependence without abuse", abuse, and dependence. Obsessive-compulsive behaviors concerning food, weight, or body image were excluded as positive evidence of criteria for obsessive-compulsive behaviors. The Research Diagnostic Criteria-Family History (RDC-FH) method was used to obtain psychiatric dx of first-degree relatives from mothers of patients and comparisons. **For ED dx at FU**: A structured ED history was created from detailed information about binge frequency, laxative and diuretic abuse, typical anorectic attitudes, menstrual function, and weight changes. Pearson's Chi-square test was used to compare differences in the prevalence of psychiatric disorders between patients and comparisons.	**Descriptive Findings**: **Eating Disorder Dx at 10-yr FU:** AN =2, BN = 2, normal weight bulimia (NWB) = 14, ED-NOS = 24, no ED = 17. **Lifetime DSM-III-R Dx in Patients by Dx at 10 yr FU and in Matched Comparisons, N:** **Any Affective Disorder:** Patients: 52; Comparisons: 14 Diff between groups (*P* = NR) **Major depression:** Patients: 42; Comparisons: 13 Diff between groups (*P* < 0.01) **Mania:** Patients: 2; Comparisons: 1 Diff between groups (*P* = NS) **Dysthymia:** Patients: 20; Comparisons: 2 Diff between groups (*P* < 0.01) **Bipolar:** Patients: 2; Comparisons: 0 Diff between groups (*P* = NS) **Atypical Bipolar:** Patients: 6; Comparisons: 0 Diff between groups (*P* < 0.01) **Anxiety Disorders:** Patients: 40; Comparisons: 13 Diff between groups (*P* = NS) **Obsessive-compulsive:** Patients: 16; Comparisons: 4 Diff between groups (*P* < 0.01) **Agoraphobia:** Patients: 9; Comparisons: 2 Diff between groups (*P* < 0.05) **Simple phobia:** Patients: 8; Comparisons: 9 Diff between groups (*P* = NS) **Social phobia:** Patients: 21; Comparisons: 2 Diff between groups (*P* < 0.01) **Panic:** Patients: 5; Comparisons: 0 Diff between groups (*P* = NS) **Schizophrenia:** Patients: 4; Comparisons: 0 Diff between groups (*P* = NS) **Alcohol abuse:** Patients: 5; Comparisons: 9 Diff between groups (*P* = NS) **Cannabis abuse:** Patients: 8; Comparisons: 15 Diff between groups (*P* = NS) **Amphetamine abuse:** Patients: 1; Comparisons: 5 Diff between groups (*P* = NS)

Evidence Table 15. Anorexia Nervosa Outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality Adverse Events
Authors, year: Halmi, Eckert et al., 1991 (continued)				

Evidence Table 15. Anorexia Nervosa Outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
	Barbiturates: Patients: 0; Comparisons: 2 Diff between groups (*P* = NS) **Opioids:** Patients: 0; Comparisons: 1 Diff between groups (*P* = NS) **Hallucinogens:** Patients: 0; Comparisons: 1 Diff between groups (*P* = NS) **Antisocial personality:** Patients: 0; Comparisons: 2 Diff between groups (*P* = NS) **Tobacco:** Patients: 9; Comparisons: 11 Diff between groups (*P* = NS) **Psychosexual dysfunction:** Patients: 28; Comparisons: 16 Diff between groups (*P* < 0.05) **Homosexual:** Patients: 0; Comparisons: 1 Diff between groups (*P* = NS) **Comorbid DSM-II Dx at 10 yr FU, N (%):** **No Dx:** Patients: 29 (46.8); Comparisons: 40 (64.5) Diff between groups (*P* < 0.05) **Major depression:** Patients: 18 (29.0); Comparisons: 4 (6.4) Diff between groups (*P* < 0.01) **Obsessive-compulsive:** Patients: 7 (11.3); Comparisons: 1 (1.6) Diff between groups (*P* < 0.05) **Phobia:** Patients: 15 (24.2); Comparisons: 8 (12.9) Diff between groups (*P* = NS) **Mania:** Patients: 1 (1.6); Comparisons: 1 (1.6) Diff between groups (*P* = NS) **Dysthymia:** Patients: 15 (24.2); Comparisons: NR **Bipolar:** Patients: 2 (3.2); Comparisons: 0 (0) Diff between groups (*P* = NS) **Panic disorder:** Patients: 3 (4.8); Comparisons: 1 (1.6) Diff between groups (*P* = NS) **Alcohol abuse:** Patients: 2 (3.2) Comparisons: 4 (6.4) Diff between groups (*P* = NS) **Schizophrenia:** Patients: 2 (3.2); Comparisons: 0 (0) Diff between groups (*P* = NS) **Tobacco:** Patients: 9 (14.5); Comparisons: 8 (12.9) Diff between groups (*P* = NS)

Evidence Table 15. Anorexia Nervosa Outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality Adverse Events
Authors, year: Halmi, Eckert et al., 1991 (continued)				

Evidence Table 15. Anorexia Nervosa Outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
	Substance abuse: Patients: 0 (0); Comparisons: 2 (3.2) Diff between groups (*P* = NS) **Antisocial personality disorder:** Patients: 0 (0); Comparisons: 2 (3.2) Diff between groups (*P* = NS) **Gambling:** Patients: 0 (0); Comparisons: 1 (1.6) Diff between groups (*P* = NS) **Homosexuality:** Patients: 0 (0); Comparisons: 1 (1.6) Diff between groups (*P* = NS) **Affective disorders:** No-ED group better than normal weight bulimics (*P* = 0.003). **Dysthymia:** No-ED group better than normal weight bulimics (*P* = 0.02).

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Halvorsen, Anderson, and Heyerdahl, 2004 **Design:** Case series **Comparison Group:** No **Location:** Drammen, Norway **Yrs followed:** 8.8 (3.4) (3.5-14.5)	To investigate the intermediate to long-term outcome of adolescent onset AN in a group referred to child and adolescent psychiatric services.	**Inclusion:** Females DSM IV for AN Referred by a physician and accept for tx at Buskerud Hospital **Exclusion:** None stated **Recruitment:** Females who where dx'ed with AN and admitted to Child and Adol Psychiatry program at Buskerud Hospital from 1986-1998. These former patients contacted to participate in FU study. **Sample size:** **Initial sample:** (N = 55) **Reasons for loss to FU:** Refusal to participate (N = 4) **Analysis sample:** (N = 51) Interviewed (N = 47) **Patients complete questionnaire:** (N = 2) Parents complete questionnaire (N = 2)	**Mean Age at tx start** (SD) 14.9 (1.7) yrs Range: 9.2-17.8 **Sex:** Female 100% **Race/ethnicity:** NR **Mean BMI (kg/cm^2) at tx start (SD)** 15.1 (1.5) **Mean wt loss at tx start (SD)** 23.2% (8.2) **Mean wt loss at tx start corrected for increase in ht. (SD)** 24.4% (7.7) **Duration of sx before tx start (SD)** 11.2 (6.7) mos **Age onset (SD)** 14.0 (1.7) yrs Range: 8.2-16.8 **Lowest BMI during tx (kg/cm^2) (SD)** 14.8 (1.6) **Onset prior to menarche:** 24% **Vomit before or during tx:** 28% **SES background** Upper: 16 (31%) Middle: 22 (43%) Lower: 13 (25%) **Age at FU** 23.8 (3.4) yrs **Patients in family tx** 51 (100%) **Patients in ind. psychotx.** 17 (33%) **Pt hospitalized in pediatric ward:** 61%	**Score:** Fair **Method of dx:** DSM IV criteria for AN, BN, EDNOS from EDE info and body wt. 3 experienced specialists conducted interviews. Where no interview, questionnaire and telephone interview with patient or parent **Funding:** Norwegian Research Council, the Norwegian Foundation for Health and Rehabilitation, the Regional Centre for Child and Adol Psychiatry, Regions East and South, and Buskerud Hospital.

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods: Demographic and tx data obtained retrospectively from med. records. 3 experienced specialist conducted semi-structured interviews and patients completed questionnaire packets. Patients not interviewed were interviewed by telephone and completed questionnaires. Parents were interviewed when patients unavailable. Interviews: • Eating Disorder Examination • Mini International Neuropsychiatric Interview • Yale-Brown Obsessive Compulsive Scale • Global Assessment of Functioning Questionnaires • Eating Disorder Inventory (EDI) • Overall Life Satisfaction **Statistical Methods:** ANOVA and t-tests Wilcoxon (Mann-Whitney) Tukey HSD Chi-Square Pearson's correlations **Outcomes** Recovered = no DSM IV dx for AN, BN, EDNOS based on EDE and wt. Where EDE not administered, dx based on telephone and questionnaires. M-R general outcome • Good – within 15% of ABW and normal menstruation • Intermediate – wt below 15% of ABW or menstrual irregular • Poor – wt below 15% ABW, menstruation absent or nearly absent, or BN	**Descriptive Results**: **Outcomes:** No ED at FU: 42 (82%) AN: 1 (2%) BN: 1 (2%) EDNOS: 7 (14%) Deaths: 0 **M-R Scale** Good: N = 40 (80%) Intermediate: N = 8 (16%) Poor: N = 2 (4%) **Psychiatric dx at FU:** No dx including no ED N = 28 (55%) No dx excluding ED: N = 31 (61%) Depression: N = 11 (22%) Anxiety (not OCD): N = 13 (27%) OCD: N = 1 (2%) Post-traumatic stress disorder: N = 5 (10%) Tourettes: N = 1 (2%) **Diff in psychiatric dx between patients with and without ED at FU:** No DSM dx (excluding ED) *(P* = NS) Two or more dx: No ED at FU: 13%, ED at FU: 56% *(P* = 0.004) Depression: No ED at FU: 13%, ED at FU: 67% *(P* < 0.001) Anxiety disorder (except OCD): No ED at FU: 20%, ED at FU: 56% *(P* = 0.047) OCD *(P* = NS) Post-traumatic stress disorder *(P* = NS) Dissociative disorder *(P* = NS) Psychosis *(P* = NS) Tourettes *(P* = NS) GAF-S >80: Very good functioning: No ED at FU: 48%, ED at FU: 0 *(P* = 0.008) GAF-F >80: Very good functioning: No ED at FU: 65%, ED at FU: 0 *(P* = 0.001 GAF-S Mod to severe problems: No ED at FU: 8%, ED at FU: 67% (*P* < 0.001) GAF-F Mod to severe problems *(P* = NS) Hx of suicide ideation *(P* = NS) Hx of suicide attempts *(P* = NS)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Hebebrand et al., 1997 **Design:** Case series **Comparison Group:** No **Setting:** Marburg, Germany **Yrs followed: Mean (SD):** 9.5 (5.3) Range: 0-33.6 yrs	To investigate whether AN patients with a low BMI at referral have low BMI at long-term FU	**Inclusion:** DSM III-R AN, female **Exclusion:** 24 males, 7 females with additional somatic diseases at referral, 7 females pretreated whose BMI at referral were > 17.5 kg/m^2 **Recruitment:** Composite of 5 study cohorts with a total of 341 consecutively ascertained inpatients with AN. **Initial sample size:** N = 341 **Reasons for loss to FU:** Excludes: N = 37 (see above) Deaths: N = 12 (10 due to emaciation after a mean of 4.2 (4.0) yrs (range: 0-13) and 2 due to suicide) **Other:** N = 19 (Reasons NR) **Analysis sample size:** N = 272	**Mean Age at referral:** 16.7 (4.5) **Range:** 10-42 **Mean Age at FU:** 26.2 (6.9) **Range:** 15-58 **Sex:** Female: 100% **Race/ethnicity:** NR **Duration of ED before referral, yrs, mean (SD) (range): BMI < 13 at referral:** 2.2 (3.3) (0 – 19) **BMI ≥ 13 at referral:** 1.3 (1.73) (0 – 16) Diff between groups *(P* < 0.05)	**Score:** Fair **Method of dx:** DSM III-R **Funding:** Deutsche Forschungsgemeinschaft

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods Record review **Statistical Methods** Corrected for multiple U tests Post hoc U; chi-square Fisher's exact test Logistic regression	**Descriptive Results** Correlation between BMI at referral and FU: r = 0.33 *(P* < 0.00001) **BMI at FU, mean (SD) (range):** BMI < 13 at referral 18 (3.4) (9.5 – 25.3) **BMI at FU, mean (SD) (range):** **BMI ≥ 13 at referral:** 20.0 (2.6) (13.4 – 27.1) Diff between groups at endpoint *(P* < 0.05) Mortality rate patients with BMI < 13 at referral: 11% (11/100 patients) Mortality rate patients ≥ 13 BMI at referral: 0.6% (1/172 patients) Diff between groups *(P* = 0.0001) **Multivariate Results** **Predicting Lower BMI at FU:** ≤17.5 or > 17.5 (ICD-10 criteria for dx of AN) BMI at referral *(P* = 0.00002) Lower at referral predicts lower BMI at FU Age at referral *(P* = 0.03) Older at referral predicts lower BMI at FU Age at FU *(P* = 0.007) Younger at FU predicts lower BMI at FU Age at onset *(P* = NS)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Herzog, Schellberg, and Deter, 1997 **Companion article:** Deter and Herzog, 1994 **Design:** Case Series **Comparison Group:** No **Location:** Heidelberg, Germany **Yrs followed:** 11.7 (2.43)	Examine the time course structure of likelihood of first recovery periods for AN patients. Identify patient characteristics that influence the occurrence and timing of first recovery.	**Inclusion:** Feighner criteria for AN and, later, DSM III-R criteria. **Exclusion:** None **Recruitment:** Patients who received inpatient tx at Dept. of General Clinical and Psychosomatic Medicine, U of Heidelberg Medical School between 1971-1980 **Sample Size:** **Original Sample:** (N = 88) (Feighner criteria) (N = 84) 4 excluded who did not meet DSM III-R criteria. **Reasons for loss to FU:** Death: 9 (7 due to AN complications, 2 suicides) Unavailable for examination (no explanation given): 5 Incomplete data: 1 **Analysis sample size:** (N = 69)	**Mean Age at tx intake (SD):** 20.7 (4.1) **Sex:** Female: 100% **Race/ethnicity:** NR **Avg. length of illness prior to study inclusion (SD):** 2.7 (3.9) yrs **% ABW at study inclusion (SD)** 65.2 (9.9) **Mean BMI at study inclusion (kg/m^2) (SD)** 13.3 (2.0) **SES at study inclusion:** Lower**:** 45.2% Middle: 48.0% Upper: 6.0%	**Score:** Fair **Method of dx:** Feighner et al. (1972) criteria, confirmed using DSM III-R criteria, 6 patients diagnosed AN retrospectively. **Funding:** German Ministry of Technology and Research

Study Methods and Analytic Strategy	Main Outcomes and Results
Treatment All patients had received 3 mo inpatient including individual psychotherapy with behavioral elements, psychodynamic elements, group psychotherapy, and counseling by a social worker. **Study Methods:** Predictor variables, collected at admission for inpatient tx include: Social class, duration of illness, wt, purging, vomiting, laxative abuse, glucose, calcium, phosphate, albumin, creatinine, alkaline phosphatase, and the AN Symptom Score (Deter, 1992) including psychological, social and physical subscores. FU assessments by physician or psychotherapist. M-R outcome criteria obtained annually from general practitioner. Records of add hospitalizations, if reported by general physician or insurance carrier, were requested. **Statistical Methods:** Discrete-time Survival Analysis **Outcomes** M-R outcome criteria: Good: wt normal, menstruation regular Intermediate (wt < 85% ABW or amenorrhea Poor: wt < 85% ABW and amenorrhea Outcome assessment made based on lowest known wt and most unfavorable menstruation status of that yr. “First recovery” is first rating of ”Good” outcome.	**Descriptive Results:** **Recovery:** Greater chance of recovery in first 6 yrs than in later period Recovery sooner than 6 yrs after first tx: 50% of patients Avg. patient in sample had first recovery by 5.8 yrs. Throughout 12 yrs, likelihood of recovery remained below 0.2. **Avg duration to first recovery:** Low serum ceatinine at baseline (.7 mg/dl): 3.3 yrs. Medium serum creatinine at baseline (1.1 mg/dl):6.1 yrs. High serum creatinine at baseline (1.5 mg/dl): > 11 yrs. **Multivariate Results:** **Sig predictors of change over time in the likelihood of first recovery:** Serum creatinine levels at baseline *(P* < 0.008) lower is better Purging behavior *(P* < 0.0049) less is better Purging and social ANSS interaction: *(P* < 0.04); less purging and fewer social disturbances is better Non purging patients with high or low social ANSS scores and purging patients with low social ANSS scores all had median survival time of 3.9 -5.2. Purging patients with high social ANSS had different course with only 33% having a first recovery by 11 yrs.

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Author, Yr: Herzog et al., 1999 **Design:** Case series **Comparison Group:** No **Location:** Boston, MA, USA **Yrs followed:** Median = 7.5; interviews conducted every 6 mos for 11 yrs	To assess factors associated with recovery and relapse in AN and BN	**Inclusion:** DSM III-R for AN and BN at tx intake (participants reclassified according to DSM IV criteria during the study); anorexic and bulimic episodes not separated by a period of remission of at least 8 wks duration. **Exclusion:** None **Recruitment:** Women who sought tx in eating disorder programs in Boston, MA between 1987 and 1990. An additional 21 women with AN recruited in 1991. **Sample size** **Initial sample size:** ANR: 51 ANBP: 85 BN: 110 **Reasons for loss to FU:** Drop outs: 17 Died (dx group and reasons NR): 7 **Analysis sample size:** NR	**Mean age at tx intake (SD):** ANR: 23.9 (8.5) ANBP: 24.5 (5.9) BN: 25.5 (6.5) **Sex:** Female: 100% **Race/ethnicity:** NR **Age at ED onset (SD):** ANR: 17.5 (6.1) ANBP: 16.9 (4.7) BN: 19.4 (5.8) **Proportion ABW:** ANR: 0.73 (0.09) ANBP: 0.82 (0.10) BN: 1.03 (0.15) **Lifetime hx major depression:** ANR: 64.7% ANBP: 71.3% BN: 60.7% **Lifetime hx Axis I:** ANR: 62.7% ANBP: 78.1% BN: 74.1% **Lifetime hx Axis II:** ANR: 25.5% ANBP: 37.9% BN: 23.2% **Lifetime hx substance use disorder:** ANR: 5.9% ANBP: 16.1% BN: 12.3% **Duration intake episode:** ANR: 6.4 (6.7) ANBP: 7.6 (5.4) BN: 6.1 (6.3)	**Score:** Good **Method of dx:** Modified version of Schedule for Affective Disorders and Schizophrenia – Lifetime version **Funding:** NIMH, Rubenstein Foundation, Harvard Eating Disorders Center

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods: FU interviews generally conducted by telephone by trained interviewers. Instruments included: Eating Disorders Longitudinal Interval FU Evaluation (LIFE-EAT-II)-semi-structured **Statistical Methods:** Survival analysis, proportional hazards (Cox) regression **Outcome Categories:** Full recovery (absence of symptoms or presence of only residual symptoms for at least 8 consecutive wks) at some point over 90 mos Partial recovery (reduction of symptoms to < full recovery for ≥ 8 consecutive wks	**AN Findings** **Descriptive Results** **Full recovery:** 33.7% At 2 yrs: ANR: 8%; ANBP: 13% At 7 yrs: ANR: 34%; ANBP: 32% **Partial recovery**: 83.7% At 2 yrs: ANR: 61%; ANBP: 67% At 7 yrs: ANR: 83%; ANBP: 82% **Median time to partial recovery (wks):** ANR: 78; ANBP: 53 Diff ANR and ANBP *(P* = NS) **Relapse after full recovery:** 40% **No remission through yr 7:** ANR: 17% ANBP: 18% **Multivariate Results** **Sig predictors of time to full recovery (adjusted):** Percent of ABW at intake: HM = 250.1, 95% CI (6.90-9.066) heavier is better Duration of intake episode: HM = 0.89, 95% CI (0.81-0.96), shorter is better **Sig predictors of time to partial recovery (adjusted):** Duration of intake episode: HM = 0.63, 95% CI (0.45-0.87) Shorter is better Percent ABW at intake: HM = 18.89, 95% CI (0.32-1.105) Higher is better Hx of hospitalization: HM = 29.60, 95% CI (1.11-791.21) Fewer hospitalizations is better Hx of major depression: HM = 1.64, 95% CI (1.07-2.51) Not having major depression is better Duration of intake episode x proportion ABW: HM = 1.65, 95% CI (1.10-2.47); ABW values >93% and shorter intake episode is better than ABW < 93% and longer duration of intake episode Percent ABW x hx of hospitalization: HM = 0.007, 95% CI (0.0001-0.44); ABW values ≤ 69% and having hx of hospitalization is better than ABW > 69% and no hx of hospiatlization **BN Findings** **Descriptive Results** **Full recovery:** 73.8% At 2 yrs: BN: 53% At 7 yrs: BN 73%

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Author, Yr: Herzog et al., 1999 (continued)				

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
	Partial recovery: 99.0% At 2 yrs: BN: 88% At 7 yrs: BN: 98% Median time to partial recovery (wks): BN: 14 **Relapse after full recovery:** 35.3% **Multivariate Results** Sig predictors of time to full recovery: none identified Sig predictors of time to partial recovery: none identified

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Herzog et al., 1997 **Design:** Case Series **Comparison Group:** No **Location:** Germany **Yrs followed:** 11.9 Range: 9-18	Examine relationship between laboratory findings and AN disease outcomes	**Inclusion:** Feighner criteria for AN and, later, DSM III-R criteria. **Exclusion:** None **Recruitment:** Patients who received inpatient tx at U of Heidelberg Medical School between 1971-1980 **Sample Size:** **Original Sample:** (N = 84) met Feighner and DSM III-R criteria for AN. **Reasons for loss to FU:** Missing lab data: 9 Refused to participate: 9 **Analysis sample size:** (N = 66)	**Mean Age at tx intake (SD):** 20.7 (6.0) Range: 15-36 **Mean Age at FU (SD):** 32.2 yrs **Sex:** Female: 100% **Race/ethnicity:** NR **% ABW at study inclusion (SD)** 65.2 (9.9)	**Score:** Poor **Method of dx:** Feighner et al. (1972) criteria, confirmed using DSM III-R criteria, method of making determination not reported Medical comorbidity was ICD-9 criteria **Funding:** German Ministry of Technology and Research

Study Methods and Analytic Strategy	Main Outcomes and Results
Treatment All patients had received 3 mo inpatient including individual psychotherapy with behavioral elements, psychodynamic elements, group psychotherapy, and counseling by a social worker. **Study Methods:** FU exam on patients who received inpatient tx. Baseline is records at first admission. FU assessments by physician or psychotherapist at U. of Heidelberg Med Clinic. FU included 1) past and present histories, lab exam, physical exam, and bone mineral density 2)standardized and open interviews re course of illness 3) discharge letters of all inpatient tx btween tx and FU. M-R outcome criteria obtained annually from general practitioner. Records of add hospitalizations, if reported by general physician. **Statistical Methods:** Wilcoxon signed rank test Students t-test Discriminant Analysis of T0 data Multiple linear regression analysis **Outcomes** **M-R outcome criteria:** Good: wt normal, menstruation regular Intermediate (wt < 85% ABW or amenorrhea Poor: wt < 85% ABW and amenorrhea Chronicity score: sum of outcome categories of every yr. Underwt score: index of underwt x time.	**Descriptive Results:** **M-R outcome at FU:** Good: 47% Intermediate: 27% Poor: 14% Death:12% **Mean ABW:** Baseline: 65% FU: 87% **Mean BMI:** Baseline: 13.7; FU: 19.3 **BN (DSM III-R) at FU:** 16% **Diff in baseline lab findings by M-R scale outcomes (good/intermediate vs poor/deceased):** Albumin *(P* = 0.004) Poor/deceased lower Uric acid *(P* = 0.02) Poor/deceased higher Potassium *(P* = 0.03) Poor/deceased lower Creatinine *(P* = 0.04) Poor/deceased higher **Diff in having at least 1 comorbidity by M-R scale outcome categories (good/intermediate vs poor/deceased)** Poor/deceased: 67% Good/intermediate: 27% Age matched German females: 8% **Mortality (N = 8)**: SMR: 9.6 Mean age of death: 29 yrs Mean duration of AN: 9 yrs (range 1-14) with death avg 4.2 (0-13) yrs after first presentation. All met DSM III-R of AN at death, Severe purging (N = 7). BMI < 11: N = 5. Suicide: N = 1. **Lab predictors of death and chronicity** Low serum albumin at baseline: OR = 4.7, 95% CI (1.1 – 20.2) Discriminant Analyses btwn surviving and deceased patients showed baseline albumin *(P* < 0.0001) and wt *(P* = 0.011) discriminated best, correctly classifying 88% of deceased and 86% of surviving patients. Adding age onset, duration at first presentation, freq. vomit and lax, social class, social or psych of ANSS did not improve model. **Multivariate Analysis** **Baseline predictors of chronicity in step-wise model:** Creatinine *(P* < 0.0001) Albumin *(P* = 0.024) Glucose levels *(P* = 0.04)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Herzog et al., 1996 **Design:** Case series **Comparison Group:** No **Location:** Boston, MA **Yrs followed:** 4	To assess the rates of recovery for restrictor and bulimic anorexics to determine whether bulimic behavior sig affects the course of AN. To assess possible subtypes of BN based on the presence or absence of a hx of AN.	**Inclusion:** DSM III-R criteria for BN and or AN **Exclusion:** NR **Recruitment:** Participants who sought evaluation for an eating disorder at the Massachusetts General Hospital Eating Disorders Unit and at other Boston-area eating disorders programs between 10/87 and 6/90. **Sample Size:** **Initial sample:** Telephone Screen: N = 554 Met criteria: N = 268 Participated: N = 229 Drop out: N = 4 **Analysis Sample:** N = 225 **ANR (**AN and no regular bingeing or purging)**:** N = 39 **ANBP** (AN and regularly engage in bingeing or purging): N = 37 **BNPAN** (BN now and hx of AN): N = 28 **BNSAN** (BN now, underwt at intake and do not meet full criteria for AN): N = 36 **BN** (BN with no prior hx of AN): N = 89	**Age, mean (SD) (range), yrs** 24.5 (6.7) **ANR:** 21 (18 – 27) **ANBP:** 22 (19 – 25) **BNSAN:** 25 (21 – 29) **BNPAN:** 23 (20 – 27) **BN:** 24 (20 – 30) Diff between groups *(P* = NS) **Sex:** Female: 100% **Race/ethnicity:** NR **Age at onset of first disorder, mean (range), yrs** **ANR:** 17 (15 – 20) **ANBP:** 17 (15– 19) **BNSAN:** 17 (14 – 19) **BNPAN:** 16 (15 – 18) **BN:** 18 (16 – 20) Diff between groups *(P* = NS) **% attempted suicide:** **ANR:** 18 **ANBP:** 33 **BNSAN:** 53 **BNPAN:** 19 **BN:** 28 Diff between groups BNSAN had higher rates of suicide attempts versus BN and BNPAN *(P* < 0.001)	**Score:** Good **Method of dx:** Semi-structured interview (Schedule for Affective Disorders and Schizophrenia-Lifetime Version modified to include diagnostic criteria for DSM III-R eating disorders derived from the Diagnostic Interview Schedule). Eating Disorders Longitudinal FU Evaluation. **Funding:** NIMH, Rubenstein Foundation, Eli Lilly and Co, The Boston Obesity, Nutrition Research Center

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods FU interviews conducted every 3 mos. Anniversary (12, 24, 36 mo) FUs conducted in person whenever possible. **Full recovery:** asymptomatic (Psychiatric Status Rating PSR < 3) for at least 8 consecutive wks. **Partial recovery:** maintaining for at least 8 consecutive wks a PSR level of 3 or 4. Do not meet full criteria for AN or BN but still experience sig symptomatology. **Analytic Strategy** Fisher's Exact Test and Wilcoxon Rank Sum Test Kaplan-Meier survival method for probability of recovery. Cox proportional hazards models to identify prognostic factors	**Descriptive Results** **% at least partially recovered:** **BN:** 91% Trend *(P* < 0.01) **% fully recovered:** **BN:** 62% Trend *(P* < 0.01) **Multivariate Results** **BN Predictors of recovery; Adjusted for duration of the current episode (N = 150):** Duration of current episode *(P* = NS) Age at onset of eating disorder *(P* = NS) Age at onset of first eating disorder *(P* = NS) Current disorders involving a lack of impulse control *(P* = NS) Wt < 90% of ideal *(P* = NS) Bingeing frequency *(P* = NS) Purging frequency *(P* = NS) Current depression *(P* = NS) Personality disorder *(P* = NS) Any current Axis I disorder *(P* = NS) **AN Predictors of recovery: Adjusted for duration of the current episode (N = 75):** **Duration of current episode:** RR = 0.50, 95% CI (0.27 – 0.94) Age at onset of eating disorder *(P* = NS) Age at onset of first eating disorder *(P* = NS) Current disorders involving a lack of impulse control *(P* = NS) Bulimic behaviors *(P* = NS) Current depression *(P* = NS) Any current Axis I disorder *(P* = NS)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Herzog et al., 2000 **Design:** Case series **Comparison Group:** No **Location:** Boston, MA, USA **Yrs followed:** 11	To assess rates and causes of death for a cohort of women with AN or BN and provide descriptive information on their ED and comorbid dx.	**Inclusion:** Initially, meeting DSM III-R criteria for AN, AN/BN, or BN; Subsequently, using DSM IV definitions, met criteria for AN-R, ANBP, or BN. **Exclusion:** None **Recruitment:** Between October 1987 and June 1990, tx seekers at Massachusetts General Hospital. 556 recruited. **Sample Size:** Using DSM IV criteria, participants classified as AN-R (N = 51), ANBP (N = 85), and BN (N = 110) status **Reasons for loss to FU:** NR	**Mean Age** NR **Sex:** Female: 100% **Race/ethnicity:** NR **Mean duration of illness:** 7.2 yrs	**Score:** Fair **Method of dx:** SADS-L modified to include diagnostic criteria for DSM III-R as well as psychiatric hx, later updated to DSM IV criteria **Funding:** NIMH ROI Grant, sponsor: Rubenstein Foundation and Harvard Eating Disorders Center.

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods Data on mortality collected as part of a longitudinal study of AN and BN. Other data sources included death certificates, autopsy reports, relative interviews, and a National Death Index search. The Eating Disorders Longitudinal FU Evaluation (LIFE-EAT II) was administered to subjects at 6-mo intervals. General information regarding subjects' functioning in the mos prior to death was obtained by interviewing a family member.	**Descriptive findings:** **AN** At 11th yr FU: # of AN deaths: 7 (Crude mortality rate = 5.1%, 7 / 136) 3 subjects committed suicide. SMR indicates a sigly raised mortality rate for death at 9.6 times the expected rate *(P* = 0.001), 95% CI (3.86 -19.8) and for suicide at 58.1times the expected rate *(P* = 0.001), 95% CI (11.7 -169.7). Characteristics of deceased participants: • At intake, 5 met ANBP dx: 2 met full AN and BN criteria; 2 met full AN criteria with BN sx; 1 met full BN criteria with AN sx. • Ages: 24-46 yrs. • Yrs ill at death: 9-28 • 2 met ANR criteria at intake, but later exhibited BN sx • At time of death, of the 5 ANBP participants, 2 were classified as ANBP, 2 met AN-partial recovery criteria, 1 met AN-full recovery criteria. • All had a hx of comorbid Axis I disorders: most common dx was alcoholism. Other comorbid disorders included bipolar disorder major depressive disorder and drug abuse. • All participated in multiple types of tx: both individual psychotherapy and pharmacotherapy • Hospitalized at least once: N = 6 • Participated in group therapy: N = 6 • Nutritional counseling: N = 5 • Participated in family therapy: N = 4 • All 3 subjects who committed suicide had reported suicidal ideation and 2 subjects had made at least one prior suicide attempt. **BN** At 11th yr FU, # of BN deaths: 0

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Isager et al., 1985 **Design:** Case series **Comparison Group:** No **Location:** Copenhagen, Denmark **Mean Yrs followed:** 12.5 (range = 4-22)	To assess the time to death and time to first relapse in a group of consecutively treated AN patients between 1960-1976 utilizing survival analytic procedures	**Inclusion:** Dx of AN by the following criteria: Wt loss via reduced food intake, vomiting or excessive activity; Amenorrhea (if reproductive age); Distorted body image; clinical picture not explained by other somatic or psychiatric illness **Exclusion:** Inpatient < 1 wk or < 2 outpatient visits; Other somatic dx (e.g., ulcer, psychosis) **Recruitment:** Patients who made first contact with a university hospital in Copenhagen for AN tx between 1960-1976. Review of all hospital records with a dx of AN from three departments at Rigshospital, University of Copenhagen, Child Psychiatry, Psychiatry, and Internal Medicine. **Sample Size:** 151 (142 living: 114 contacted via direct semistructured interview; information about the remaining patients was obtained via hospital records and from official Danish registers) **Loss to FU Reasons:** Death: N = 9 (N = 6 from suicide; N = 2 from AN complications; N = 1 who was severely underwt with probable suicide)	**Mean Age, yrs (range):** At primary contact: 19.0 (8-43) At onset of AN: 16.6 (7-41) **Sex:** Female: 93% **Race/ethnicity:** NR **Mean Duration of Illness, yrs (range):** 2.4 (0.1-15) **Previous Hospitalizations for AN (%):** 65% **Females, onset of AN before Menarche:** 18% **Mean Wt at primary contact, kgs (range):** 36.8 (19-60) **% ABW at primary contact (range):** 68% (40-102) **Bulimia:** 28% **Vomiting:** 41% **Duration of primary contact, mos (range):** 12 (0.3-76)	**Score:** Fair **Method of dx:** Review of records by authors to meet the diagnostic inclusion criteria **Funding:** The Danish Medical Council; The Gangsted-Rasmussen Fonde af; the Enkefru C. Hermansens Mindelegat and the Petra Slettens Fond

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods FU data obtained by direct semistructured interview of 80% of the original cohort (N = 114). Hospital records, the National Registry of Patients, the Central Persons Registry, and the Registry of Causes of Death used to assess patient relapse and mortality. **Statistical Methods** Survival probability curves for time to first relapse and time to death were calculated. **Outcome measure** Relapse: lost 15% or more of wt gained during course of tx within a yr's time (i.e., wt = 50 kg or less).	**Descriptive Findings** **Deceased Patients** Total Sample (N = 9): 6% Previous Hospitalization (N = 6): 30% (30 per 1000 per yr) Nonhospitalized (N = 3): 2% (2 per 1000 per yr) Diff between groups *(P* < 0.001) **Remission Rate by End of Primary Contact (N = 120):** 80% **Relapse Rates During FU (N = 120):** First yr: N = 17 (14% hazard rate) Second yr: N = 4 (4% hazard rate) Third-Tenth yr: N = 1-3 per yr (hazard rate NR) **Total FU period: 3% avg annual hazard rate** Duration of therapeutic contact < 1 yr (N = 75): 4% per yr hazard rate Duration of therapeutic contact > or = 1 yr (N = 45): 2% per yr hazard rate Diff between groups based on therapeutic contact *(P* < 0.05)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Ivarsson et al., 2000 **Companion article:** Nilsson et al., 1999 Råstam, Gillberg and Gillberg, 1995 Wentz et al., 2001 Wentz et al., 2000 **Design:** Prospective cohort **Comparison Group:** Yes **Location:** Göteberg, Sweden **Yrs followed:** 10 (1985-1996)	To assess and compare the prevalence and course of depressive disorders in a sample of adolescents with and without AN at baseline over a 10-yr period.	**Inclusion:** **Cases:** DSM III-R or DSM IV criteria for AN Born 1970 or later AN onset < 18 yrs old **Comparisons:** No eating disorder dx, matched to cases on age, sex, school **Exclusion:** **Cases:** None **Comparisons:** None **Recruitment:** **Cases:** From total population of Göteburg, Sweden, born in 1970 and developing AN before age 18; pooled with second population screening sample reported by school and hospital health care workers during FU. Some clinically referred and some screened through school nurses and doctors, pediatricians, and child psychiatrists **Comparisons:** Same schools as AN group selected by the school nurse **Sample Size:** AN: N = 51 Comparisons: N = 51 **Reasons for loss to FU:** No attrition reported	**Mean Age at Baseline, yrs (SD):** AN: 16.1 (NR) **Comparisons:** 16.0 (NR) **Age at 5-yr FU:** 21 **Age at 10-yr FU:** 24 **Mean Age of Onset of AN, yrs (SD):** 14.3 (NR) **Sex:** Female: 94% **Race/ethnicity:** NR	**Score:** Good **Method of dx:** At baseline evaluation, clinical dx made via a psychiatric interview based on DSM III-R criteria Current and Lifetime prevalence of eating disorder, depressive disorder, and other Axis I dx made using SCID-P, DSM III-R version via record review of initial interviews at baseline and via clinical interview at FU **Funding:** None reported

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods All participants initially underwent a thorough psychiatric interview at baseline, a standardized clinical interview at age 21 and again at age 24 to assess current and lifetime hx of eating disorders and depressive disorders. Family hx of depressive disorders in first degree relatives also obtained. Dx made in person-N = 102 for first FU, N = 99 for second FU; by phone for second FU, N = 3 Participants who did not meet diagnostic criteria for an eating disorder were categorized as "no ED". The same categorization strategy was used to classify those who did not meet diagnostic criteria for a depressive disorder (i.e., major depression, dysthymia, or bipolar disorder). The timeframes for assessing FU outcomes are: "outcome 2" = assessment of current and lifetime hx of ED or Depressive Disorder between baseline and age 21 "outcome 3" = assessment of current and lifetime hx of ED or Depressive Disorder between age 21 and age 24 **Statistical Analyses** Chi-square tests, Fisher's exact test, and McNemar tests to evaluate and compare linear associations between dichotomous variables. Backward stepwise multivariate logistic regression to assess risk of depressive disorder over time, controlling for diagnostic group status.	**Descriptive Findings** **Lifetime Prevalence of Depressive Disorder:** AN: 84% Comparisons: 18% *(P* < 0.001) **Rate of Depressive Disorder prior to AN:** AN: 2% Comparisons: 4% *(P* = NS) **Rate of Depressive Disorder by FU Period:** Outcome 2: AN: 57% Outcome 3: NR **Stability of Depressive Disorder between FU Periods:** Baseline-Outcome 2 *(P* = NS) Outcome 2-Outcome 3 *(P* < 0.05) **Number of Periods of Lifetime Dx of Depressive Disorder (N):** 0: AN (8) Comparisons (42) 1: AN (18) Comparisons (6) 2: AN (18) Comparisons (3) 3: AN (7) Comparisons (0) *(P* < 0.0001) AN > Comparisons **Types of Depressive Disorder in AN and Comparisons (N):** None: AN (8), Comparisons (42) Dysthymia: AN (9) Comparisons (2) MDD: AN (28) Comparisons (6) Double Depression: AN (3) Comparisons (0) Bipolar Disorder: AN (3) Comparisons (1) *(P* < 0.0001) AN > Comparisons **Rates of Depressive Disorder by ED status at Outcome 3, N (%):** No ED /No Depressive Disorder (77): 84.6% No ED/Depressive Disorder (14): 15.4% ED/No Depressive Disorder (3): 27.2% ED/Depressive Disorder (8): 72.8% *(P* < 0.0001) Lower rates of Depressive Disorder in resolved ED **Rates of Familial Depressive Disorder by Participant Depressive Disorder Status:** *(P* = NR) **Multivariate Results** **Predictors of Depressive Disorder at Outcome 2:** Diagnostic Group *(P* < 0.00001), OR = 7.7, 95% CI (3.0 to 19.6) Depressive Disorder at Baseline (I = NS) Family Hx of Depressive Disorder *(P* = NS) **Predictors of Depressive Disorder at Outcome 3:** Diagnostic Group *(P* < 0.05), OR = 4.03, 95% CI (1.15 to 14.19) Depressive Disorder at Outcome 2 *(P* < 0.05), OR = 3.17 (1.05 to 9.58) Family Hx of Depressive Disorder *(P* = NS)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Keel et al., 2003 **Design:** Case series **Comparison Group:** No **Location:** Boston, Mass **Yrs followed:** Mean: 8.6 Median: 9	To determine mortality ratios and predictors of fatal outcome in women dx with AN or BN.	**Inclusion:** (1) DSM III-R dx of AN or BN retrospectively (2) female (3) min age of 12 yrs (4) residence within 200 miles of Boston (5) English speaking, and (6) no evidence of organic brain syndrome or terminal illness. **Exclusion:** None **Recruitment:** 294 women recruited for participation in a prospective longitudinal study between January 1, 1987, and December 31, 1991. Virtually all seeking outpatient tx for their Ed at the Massachusetts General Hospital Eating Disorders Unit or other Boston area eating disorder programs (37% received inpatient). **Sample Size:** N = 294 met study criteria N = 250 agreed to participate N = 246 randomized and participated (4 dropped out after intake interview) Retrospectively application of DSM IV criteria: Met AN criteria: N = 136 Met BN criteria: N = 110	**Mean Age** NR **Sex:** Female: 100% **Race/ethnicity:** NR	**Score:** Fair **Method of dx:** Structured diagnostic interview **Funding:** NIMH; Eli Lily and Co.; Rubenstein Foundation; Harvard Eating Disorders Center

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods During FU interviews, the Longitudinal Interval FU Evaluation adapted for EDs used to assess ED and comorbid psychiatric disorders. Course of disorder coded on a wk-by-wk basis using PSR. Social adjustment evaluated on a 5-point scale. GAF used to evaluate overall level of symptom severity from all disorders and psychosocial function. Social adjustment, GAF scores, and tx rated on a wk-by-wk basis throughout FU. Interviews conducted, in person when possible, every 6 to 12 mos. FU telephone calls conducted to determine vital status for all longitudinal study participants as of October 2000. **Statistical Methods** Crude mortality rates and SMRs calculated. Expected number of deaths derived from US decennial life tables for 1989-1991. Expected number of suicides derived from *1995 Annual Report: Vital Statistics of Massachusetts*. Cox regression models used to determine predictors of fatal outcome. Multivariate regression model used to predict death.	**Descriptive** **Number of Deaths:** 11 (4.5%) AN: 10 ANR: 5 ANBP: 5 Diff by subtype *(P* = NS) BN: 1 **Crude mortality:** AN: 7.4% BN: 0.9% **SMR** AN: 11.6; 95% CI (5.5-21.3) BN: 1.3; 95% CI (0.0-7.2) Mortality rates elevated in AN but not BN **Cause of death** ANBP: Pneumonia ANR (N = 3) Suicide ANBP: Cardiac dysrythmia ANBP: Alcohol poisoning ANBP: Diabetes mellitus BN: Mitral valve prolapse ANR: Amyotrophic lateral sclerosis ANBP: Suicide ANR: Heart and liver failure SMR associated with suicide for AN: 56.9, 95% CI (15.3-145.7), sig higher **Multivariate Results** **Sig predictors of death among AN patients (controlling for age and duration of illness before intake):** Greater severity of alcohol use disorders *(P* < 0.001) Greater severity of substance use disorders *(P* = 0.03) Worse social adjustment *(P* = 0.02) Worse GAF scores at FU *(P* = 0.01) Using the Bonferroni-corrected *P* = 0.0016, only severity of alcohol use disorder remained sig. **Predictors of time to death among AN patients** Duration of illness at tx intake: HM = 1.48, 95% CI (1.11-1.99) *(P* = 0.001) Affective disorder hospitalization at intake: HM = 0.0001, 95% CI (0.00-0.27) *(P* = 0.001) Suicidality associated with mental illness other than ED and substance abuse: HM = 23.92, 95% CI (0.81-705.52) *(P* = 0.05) Severity of alcohol use over course of illness: HM = 5.55, 95% CI (1.68-18.29) *(P* = 0.001)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Lee et al., 2005 **Companion article:** Lee, Chan, and Hsu, 2003 **Design:** Case series **Comparison Group:** No **Location:** Hong Kong **Yrs followed:** 9	To examine the relationship between control and the intermediate term outcome of Chinese patients with AN.	**Inclusion:** DSM III-R criteria for AN including: Typical (N = 63) and Atypical (N = 25; all criteria except "fat phobia") **Exclusion:** NR **Recruitment:** Individuals contacted from January 2000-June 2001with onset of illness at least 4 yrs before study who had been seen at psychiatric and eating disorders clinics of a university-affiliated general hospital between May 1984 – June 2000. **Sample Size:** **Initial sample size:** N = 88 **Reasons for loss to FU:** Deaths: N = 3 (Suicide: N = 2; Emaciation: N = 1); Mortality rate 3.4%; SMR**:** 10.5 Refused to participate: N = 2 Alive but could not be traced**:** N = 3 **Analysis sample size:** N = 80 Of these, 74 completed self-rated scales including: Typical (N = 56) and Atypical (N = 18; all criteria except "fat phobia"), also categorized as Restrictive (N = 51); Bulimic (N = 23)	**Mean age at onset of illness:** 18.1 (3.9) **Mean age at clinical presentation:** 20.4 (5.4) **Mean age at time of study:** 27.0 (6.9) **Sex:** Female: 100% **Race/ethnicity:** Chinese: 100% **BMI, before illness, mean:** 19.6 (2.4) **BMI, mean, at clinical presentation:** 14.6 (1.9)	**Score:** Fair **Method of dx:** SCID, M-R Outcome Assessment Schedule **Funding:** Research Grant Council, Hong Kong

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods: Interviewer assessed M-R Outcomes, SCI **Statistical Analyses:** Simple t-tests, ANOVA, post-hoc Bonferroni t-test **Outcomes (based on avg score from M-R Outcome Assessment Schedule):** Good (>8) Intermediate (>4 and ≤8) Poor: 0-4	**Descriptive Results** **M-R Outcome:** Good: 62.2% Intermediate: 32.9% Poor: 5.3% **M-R Outcome categories in relation to SCI profile scale categories:** **Overall general sense of control (scale 1):** Good: 4.28 (0.70) Intermediate: 3.73 (0.89) Poor: 2.86 (0.97) Diff between groups *(P* = 0.001) Good group higher sense of control than other groups **Positive sense of control (scale 2):** Good: 4.04 (0.74) Intermediate: 3.69 (0.93) Poor: 2.95 (1.41) Diff between groups *(P* = 0.026) Good group higher pos sense of control than poor group **Negative sense of control (scale 3):** Good: 3.19 (0.99) Intermediate: 4.17 (1.07) Poor: 5.35 (0.53) Diff between groups *(P* = 0.001) Good group lower neg sense of control than other groups **Specific sense of control (scale 4):** Good: 4.65 (0.72) Intermediate: 4.03 (0.73) Poor: 3.18 (0.81) Diff between groups *(P* = 0.001) Good group higher sense of control than other groups **Positive assertive mode of control (scale 5):** Diff between groups *(P* = NS) **Positive yielding mode of control (scale 6):** Diff between groups *(P* = NS) **Negative assertive mode of control (scale 7):** Good: 2.04 (0.38) Intermediate: 2.39 (0.46) Poor: 2.23 (0.72) Diff between groups *(P* = 0.007) Good group lower neg assertives than other group **Good group less neg assertive than intermediate group** **Negative yielding mode of control (scale 8):** Good: 2.10 (0.63) Intermediate: 2.43 (0.52) Poor: 2.95 (0.81) Diff between groups *(P* = 0.009) Good group less neg yielding than poor group

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Lee et al., 2005 **Companion article:** Lee, Chan, and Hsu, 2003 (continued)				

Study Methods and Analytic Strategy	Main Outcomes and Results
	Desire for control (scale 9): Good: 4.19 (0.80) Intermediate: 4.86 (1.07) Poor: 4.66 (1.37) Diff between groups *(P* = 0.016) Intermediate group higher desire for control than poor group **Diff between typical and atypical patients on control:** Typical lower sense of control in the domain of body *(P* = 0.033) Typical lower sense of control in the domain of mind *(P* = 0.036) Typical stronger desire for control *(P* = 0.014)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, Yrs: Lee, Chan, and Hsu, 2003 **Companion article:** Lee et al., 2005 **Design:** Case series **Comparison Group:** No **Location:** Hong Kong **Yrs followed (SD):** Avg 9 (5.2) after onset of illness	To determine intermediate-term outcomes for AN among Chinese patients in Hong Kong.	**Inclusion:** DSM III-R criteria for AN including: Typical (N = 63) and Atypical (N = 25; all criteria except "fat phobia") **Exclusion:** NR **Recruitment:** Onset of illness at least 4 yrs before study who had been seen at psychiatric and eating disorders clinics of a university-affiliated general hospital between May 1984 – June 2000. **Sample Size:** **Initial sample size:** N = 88 **Reasons for loss to FU:** **Deaths:** N = 3 (Suicide: N = 2; Emaciation: N = 1); Mortality rate 3.4%; SMR**:** 10.5 Refused to participate: N = 2 Alive but could not be traced: N = 3 **Analysis sample size:** N = 80 Of these, 74 completed self-rated scales	**Mean age (SD):** 26.9 (6.7) Range: 16.2 – 47.7 **Mean onset age (SD)** 18.1 (3.8) Range: 11.2 – 28.0 **Age at clinical presentation (SD):** 20.4 (5.3) Range: 12.3 – 38.0 **Premorbid BMI:** 19.6 (2.4) **Typical:** 20.1 (2.3) **Atypical:** 18.5 (2.2) *(P* = 0.004) **BMI at clinical presentation:** 14.4 (2.0) **Typical:** 14.8 (1.9) **Atypical:** 13.2 (1.6) *(P* < 0.001) **Current BMI:** 18.5 (2.8) **Sex:** Female: 100% **Race/ethnicity:** Chinese: 100% **AN Subtypes:** Restrictive: 67.0% Bulimic: 33.0% **Hospitalized:** 72% **Social Class (as defined by U.K. Registrar General's classification of paternal occupation):** I: 5.7% II: 9.1% III: 27.3% IV: 47.7% V: 10.2%	**Score:** Fair **Method of dx:** SCID, M-R Outcome Assessment Schedule **Funding:** Research Grant Council, Hong Kong

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods: Interviewer assessed M-R Outcome Assessment Schedule, Hamilton Depression Rating Scale, and Structured Clinical Interview. Self-rated evaluations included EDI, EAT, EDE, 36-Item Short-Form Health Survey, SCL-90, Beck Depression Inventory, Rosenberg Self-Esteem Scale **Statistical Methods** Chi-Square, t-tests, ANOVA, correlation coefficients to compare diff in outcome. **Outcomes (based on avg score from M-R Outcome Assessment Schedule):** Good (>8) Intermediate (>4 and ≤8) Poor: 0-4	**Descriptive Results** **Median duration for recovery (BMI ≥ 17.5):** 3.7 yrs, 95% CI (3.2 – 4.2) **3 consecutive menstrual cycles:** 5.0 yrs, 95% CI (3.9 – 6.1) **MR-Scale Outcomes** **(**N = 74) **Good:** Total: 61.8% Typical: 52.6% Atypical: 89.47% **Intermediate:** Total: 32.9% Typical: 42.11% Atypical: 5.26% **Poor:** Total: 5.3% Typical: 5.26% Atypical: 5.26% Diff between typical and atypical *(P* = 0.006); Atypical did better **ED Dx Outcomes:** No ED: N = 34 AN: N = 11 BN: N = 15 EDNOS: N = 14 **ED Dx Outcomes:** **No ED:** Typical: 40.68% Atypical: 57.14% **BN:** Typical: 25.42% Atypical: 4.76% **EDNOS:** Typical: 15.25% Atypical: 28.57% **AN, restricting:** Typical**:** 4 (6.78%) Atypical: 9.52% **AN, bulimic:** Typical: 11.86% Atypical: 0.00% Diff between groups *(P* = 0.06) **EAT-26, mean (SD):** Typical**:** 28.75 (16.94) Atypical**:** 14.00 (8.90) Diff between groups *(P* = 0.001) Atypical better

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, Yrs: Lee, Chan, and Hsu, 2003 (continued)			**Never married:** 80% **Fully employed:** 62.5%	

Study Methods and Analytic Strategy	Main Outcomes and Results
	EDE-Q, mean (SD): Typical: 2.56 (1.53) Atypical: 1.02 (0.80) Diff between groups *(P* = 0.001) Atypical better **EDI Drive for thinness, mean (SD):** Typical: 7.48 (7.00) Atypical: 1.61 (3.96) Diff between groups *(P* = 0.001) Atypical better **EDI Bulimia, mean, SD:** Typical: 4.20 (5.70) Atypical: 1.78 (3.06) Diff between groups *(P* = 0.03) Atypical better

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Author, yr: Löwe et al., 2001 **Design:** Case series **Comparison Group:** No **Location:** Germany **Yrs followed:** Mean (SD) = 21.3 (2.9)	Examine clinical course, predictors and outcome of patients 21 yrs after first inpatient tx for AN.	**Inclusion:** Feighner diagnostic criteria for AN (at initial assessment) and DSM IV criteria (retrospectively) **Exclusion:** No severe somatic disorders **Recruitment:** Patients who received inpatient tx between 1971-1980 at U Medical Hospital in Heidelberg, Germany **Sample Size:** **Initial sample:** 84 participants evaluated at 3.6 and 11.7 yr FU **Reasons for loss to FU:** Deceased N = 14 (12 directly due to AN), could not contact or refused, N = 7. **Analysis sample:** N = 63	**Mean Age at FU (SD):** 42.0 (6.5) **Sex:** Female: 100% **Race/ethnicity:** NR **Mean BMI at FU (SD):** 20.2 (3.1) **Marital Status:** Never married: 17.5% Divorced/separated/widowed: 11.1% Married/living with partner: 71.4% **Living arrangements:** Alone: 20.6% With partner: 60.3% With family members: 19.1% **Has children:** 68.3% **Able to work:** 71.4%	**Score:** Fair **Method of dx:** Feighner's diagnostic criteria for AN (on initial assessment) and Psychiatric Status Rating Scale for AN (at FU) **Funding:** German Ministry of Technology and Research and Medical faculty of University of Heidelberg

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods: Psychiatric interview, physical examination, and standardized psychological questionnaires Outcome groups defined corresponding to Psychiatric Status Rating Scale for AN (PSR): Good (full recovery): 1 Intermediate (Partially recovered): 2,3,4 Poor (including mortality): 5,6 **Statistical Methods** Subjects-yrs method (to calculate mortality), ANOVA, Fischer's exact tests, paired t-tests, ordered logistic regressions.	**Descriptive Findings** **Percentage of Individuals with outcome according to PSR scale:** Good: 50.6% Intermediate: 20.8% Poor: 26% **Mean BMI by PSR scale outcome groups (SD):** Good: 21.6 (2.3) Intermediate: 19.7 (2.1) Poor: 15.3 (2.7) Diff between groups *(P* < 0.001) **GAF scores by PSR scale outcome groups (SD):** Good: 73.7% (12.2) Intermediate: 66.6% (14.5) Poor: 39.4% (15.2) Diff between groups *(P* < 0.001) **Psychosocial outcomes by PSR scale outcome groups:** Marital status *(P* = NS) Living arrangement *(P* < 0.001) worse outcome more likely to live alone Percentage who have children *(P* = 0.03) Poor outcome less likely Percentage able to work *(P* < 0.001) worse outcome less able to work **Mood disorders by PSR scale outcome groups:** Good: 7.7% Intermediate: 31.3% Poor: 37.5% Diff between groups *(P* = 0.02) **Anxiety disorders by PSR scale outcome groups:** Good 10.3% Intermediate:18.8% Poor: 37.5% Diff between groups *(P* = NS) **Substance related disorders by PSR outcome groups:** Good: 5.1% Intermediate: 6.3% Poor: 50.0% Diff between groups *(P* < 0.001) **Regression predicting PSR scale outcome at T3 FU (21 yrs from inpatient admission) based on variable values from T2 (12 yrs from inpatient admission) (each analyzed separately):** **BMI:** OR = 0.68, 95% CI (0.55 - 0.84) (*P* < 0.001); higher is better **Severity of psychological symptoms:** OR = 1.30, 95% CI (1.16-1.47) (*P* < 0.001); less severe is better **Severity of social problems:** OR = 1.25, 95% CI (1.10-1.42) *(P* < 0.001); less severe is better **EDI-Ineffectiveness:** OR = 1.20, 95% CI (1.07-1.35) (*P* = 0.003); lower is better **EDI-Perfectionism:** OR = 1.18, 95% CI (1.01-1.37) (*P* = 0.042); lower is better

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Author, yr: Löwe et al., 2001 (continued)				

Study Methods and Analytic Strategy	Main Outcomes and Results
	EDI-Interpersonal distrust: OR = 1.21, 95% CI (1.03-1.44) (*P* = 0.023) Lower is better **EDI-Interoceptive awareness:** OR = 1.16, 95% CI (1.02-1.31) (*P* = 0.021) Lower is better **Haemoglobin (mmol/l):** OR = 0.46, 95% CI (0.23-0.91) (*P* = 0.025) Higher is better **Alkaline Phosphatase:** OR = 1.02, 95% CI (1.01-1.04) (*P* = 0.013) Lower is better

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Møller-Madsen, Nystrup, and Nielsen, 1996 **Design:** Case series **Comparison Group:** No **Location:** Denmark **Mean Yrs followed:** 7.8 Range: < 1-17	To assess the mortality rates of AN patients living in Denmark who were admitted for inpatient tx between 1970 and 1987	**Inclusion:** All former AN inpatients whose data was recorded in the Danish Central Register on Psychiatric Admission between 1/1/70 and 12/31/86 with an ICD-8 AN primary or secondary dx **Exclusion:** None **Recruitment:** See inclusion criteria above **Sample Size:** N = 853 probands identified through Danish Central Register on Psychiatric Admission during specified time period. **Reasons for loss to FU:** Death: N = 50 (N = 13 from AN complications; N = 11 from natural causes; N = 18 from suicide; N = 2 from accidents; N = 1 from unknown causes; N = 3 could not be determined in time for the analysis)	**Mean Age, yrs (SD):** At First Psychiatric Admission: AN as primary dx (women): 21.3 (7.5) AN as secondary dx (women): 27.4 (12.1) *(P* < 0.001) AN as primary dx (male): NR AN as secondary dx (male): NR *(P* = NS) **At Death:** Female (N = 45): 36 (range = 18.1-64.7) Male (N = 5): 24.5 (range = 14.2-48.1) *(P* = NR) **Sex:** Female:93% **Race/ethnicity:** NR	**Score:** Fair **Method of dx:** Verification of ICD-8 AN primary or secondary dx from Danish Central Register on Psychiatric Admission; How the dx was ascertained was not reported **Funding:** Fru C. Hermansens Mindelegat, Snedkermester J. Wichmann og fru else Wichmann's Fond; Dansk Psykiatrisk Forskningsfond af 1967; Foundation for Research into Mental Disorders

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods Mortality status of the sample assessed through linking data obtained from Danish Central Register on Psychiatric Admission between 1970 and 1987 to information in the Danish Central Persons Registry and the Register on Causes of Death at the Danish National Health Board. Mortality status was assessed on 11/15/87. Also reviewed from Register on Causes of Death, a list of individuals who had ICD-8 ED dx on their death certificate to evaluate the accuracy of utilizing the Danish Central Register on Psychiatric Admission for quantifying the number of persons with AN. SMR standardized against age, sex, and period in the population from which patients were drawn. **Statistical Methods** SMRs were calculated for male and female probands separately, for age at first psychiatric admission (females only), for period of first psychiatric admission within the first five yrs (females only), and for length of FU (females only). Chi-square tests used to test for diff between observed and expected mortality for each of the above categories.	**Descriptive Findings** **Patient mortality:** 60% due to AN or suicide **SMR By Gender** Female (N = 45 died): 9.2, 95% CI (6.7-12.3) *(P* < 0.001) diff from expected Male (N = 5 died): 8.2, 95% CI (2.7-19.1) *(P* < 0.001) diff from expected Diff between groups *(P* = NS) **SMR By Length of FU in yrs (Females only; N = 790)** < 1 (N = 14 died): 30.5, 95% CI (16.7-51.2) *(P* < 0.001) diff from expected 1-4 (N = 14 died): 8.6, 95% CI (4.7-14.5) *(P* < 0.001) diff from expected 5-9 (N = 10 died): 5.9, 95% CI (2.8-10.9) *(P* < 0.001) diff from expected 10-14 (N = 6 died): 5.7, 95% CI (2.1-12.4) *(P* < 0.001) diff from expected > or = 15 (N = 1 died): 10.5, 95% CI (0.27-58.5) *(P* = NS) **SMR By Age at First Psychiatric Admission (Females only; N = 790)** < 15 (N = 0 died): NA 15-19 (N = 6 died): 6.6, 95% CI (2.4-14.4) *(P* < 0.001) diff from expected 20-24 (N = 13 died): 17.5, 95% CI (9.3-29.9) *(P* < 0.001) diff from expected 25-29 (N = 10 died): 17.0, 95% CI (8.1-31.3) *(P* < 0.001) diff from expected 30-34 (N = 4 died): 7.7, 95% CI (2.1-19.7) *(P* < 0.005) diff from expected > or = 35 (N = 12 died): 6.6, 95% CI (3.4-11.5) *(P* < 0.001) diff from expected **SMR By Period of First Psychiatric Admission (Females only; N = 658-cases admitted)** 1970-1974 (N = 6 died): 11.0, 95% CI (4.03-23.9) *(P* < 0.001) diff from expected 1975-1979 (N = 8 died): 11.3, 95% CI (4.9-22.3) *(P* < 0.001) diff from expected 1980-1984 (N = 12 died): 18.8, 95% CI (9.7-32.8) *(P* < 0.001) diff from expected 1970-1984 (N = 26 died): 13.8, 95% CI (8.9-20.2) *(P* < 0.001) diff from expected Diff between periods *(P* = NS) No change in pattern over time

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Morgan, Purgold, and Welbourne, 1983 **Design:** Case series **Comparison Group:** None **Location:** Bristol, UK **Mean Yrs followed:** 5.8 Range (4-8.5)	To assess both long-term outcomes and sig predictors of outcome in a group of former AN patients treated in a specialized, community-based outpatient program	**Inclusion:** Met diagnostic criteria specified by Russell (1970): endorsement of wt loss behaviors such as food avoidance, self-induced vomiting, purging, excessive exercise; presence of an endocrine disorder (i.e., amenorrhea, impotence, loss of libido); marked fear of becoming fat and a distorted judgment of body size; non-specific depressive, phobic, obsessional or hysterical symptoms may accompany other features **Exclusion:** NR **Recruitment:** Participants were a series of consecutive referrals to the Bristol Royal Infirmary AN clinic between 1973 and 1978. Approximately half had received inpatient tx. **Sample Size:** N = 78 **Reasons for loss to FU:** Death: N = 1 Insufficient FU info obtained: N = 4	**Age at Presentation (%):** < 18: 35% 18-30: 62% >30: 4% **Mean Age at onset of Food Difficulties, yrs (SD):** 17.2 (3.3) **Sex:** Female: N = 73 **Race/ethnicity:** NR **Social Class at Presentation (%):** I: 6% II: 49% III: 33% IV: 8% V: 0% **Marital Status at Presentation (%):** Single: 87% Married/Divorced: 13% **Duration of Food Difficulties, yrs (%):** < 1: 38% 1-2: 17% 2-3: 15% 3-7: 15% >7: 15% Median: 1.6 **Previous psych tx for AN (%):** 12% **Lowest Mean ABW (Matched Normals (SD):** 67.8 (8.2) **Binge-eating at presentation:** 37% **Vomiting at presentation:** 35%	**Score:** Fair **Method of dx:** Russell (1970) criteria for AN via clinical interview at presentation and at FU **Funding:** South Western Regional Health Authority Research Committee

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods During the FU period, outcome information gathered directly from patient via interview (69%), directly from interviews with relative of the patient (8%), through a questionnaire sent to the patient (9%), or from other informants either directly or indirectly (14%). M-R scales used to quantify clinical outcome status at FU utilizing last 6-mos prior to FU interview as timeframe for assessment. This yielded both an avg outcome score (i.e.,, composite rating based on 12-pt scales for nutritional status, mental status, sexual adjustment, menstrual functioning, and SES, with high scores more indicative of good prognosis) and the general outcome category (i.e., based on body wt and menstrual functioning: Good = maintained ABW w/in 15% of avg norms and regular menstrual cycles; Intermediate = intermittent maintenance of ABW w/in 15% of avg norms and/or there is continued menstrual dysfunction; Poor = ABW never reached w/in 15% of avg norms and menses have been absent or sporadic. **Statistical Analyses** Percentages, frequencies, means, ranges, and medians Chi-square analyses to assess predictors of clinical outcome status at FU.	**Descriptive Findings** **Binge-eating at FU:** 27% **Vomiting at FU:** 9% **General Outcome Status Category:** Good: 58% Intermediate: 19% Poor: 19% Deceased: 1% Unknown: 3% **Predictors of poorer general M-R outcome category:** Greater duration of food difficulties *(P* < 0.05) Greater duration of amenorrhea *(P* = 0.029) Family hostility towards patient *(P* = NS) Disturbed relationship between patient and family *(P* = 0.02) Personality difficulties *(P* = NS) Age of onset *(P* = NS) Degree of wt loss *(P* = NS) Vomiting *(P* = NS) Binge-eating *(P* = NS) Father's social class *(P* = NS) Neurotic/behavioral disorder at school *(P* = NS) Previous psychological tx *(P* = NS) Mental illness in nuclear family *(P* = NS) Sibling rivalry *(P* = NS) Anomalous family situation *(P* = NS) **Predictors of poorer avg M-R outcome scores:** Greater duration of food difficulties *(P* < 0.01) Duration of amenorrhea *(P* < 0.0042) Family hostility towards patient *(P* < 0.05) Disturbed relationship between patient and family *(P* = 0.018) Personality difficulties *(P* = 0.05) Vomiting *(P* = NS) Binge-eating *(P* = NS) Father's social class *(P* = NS) Neurotic/behavioral disorder at school *(P* = NS) Previous psychological tx *(P* = NS) Mental illness in nuclear family *(P* = NS) Sibling rivalry *(P* = NS) Anomalous family situation *(P* = NS)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Nilsson et al., 1999 **Companion article:** Ivarsson et al., 2000 Råstam, Gillberg and Gillberg, 1995 Wentz et al., 2001 Wentz et al., 2000 **Design:** Prospective cohort **Comparison Group:** Yes **Location:** Göteberg, Sweden **Yrs followed:** 10 (1985-1996)	To assess and compare the prevalence of personality disorders, obsessive-compulsive disorder and autism spectrum disorders in a group of adolescents with and without AN at baseline over a 10-yr period	**Inclusion:** **Cases:** DSM III-R or DSM IV criteria for AN Born 1970 AN onset < 18 yrs old **Comparisons**: no eating disorder dx, matched to cases on age, sex, school **Exclusion:** Cases: None Comparisons: None **Recruitment:** **Cases:** From total population of Göteburg, Sweden, born in 1970 and developing AN before age 18; pooled with second population screening sample reported by school and hospital health care workers during FU. Some clinically referred and some screened through school nurses and doctors, pediatricians, and child psychiatrists **Comparisons:** Same schools as AN group selected by the school nurse **Sample Size:** **Initial sample:** AN: N = 51 Control: N = 51 **Reasons for loss to FU:** Did not complete outcome assessment: N = 1 (AN group) **Analysis Sample:** AN: 50 Control: 51 FU 1 = 6 yrs from AN onset FU 2 = 10 yrs from AN onset	**Mean Age at Baseline, yrs (range):** AN: 16.1 (15.7-16.5) Comparisons: 16.0 (15.5-16.5) *(P* = NS) Mean Age at AN Onset, yrs (range): 14.3 (13.9-14.7) **Mean Age at FU 1, yrs:** AN: 21.0 Comparisons: 20.8 *(P* = NS) **Mean Age at FU 2, yrs:** AN: 24.5 Comparisons: 24.2 *(P* = NS) **Mean Time of AN Onset to FU 1, yrs (range):** 6.7 (6.3-7.0) Mean Time of AN Onset to FU 2, yrs (range): 10.2 (9.7-10.6) **Mean Time Between Baseline and FU 1, yrs (range):** AN: 4.9 (4.7-5.2) Comparisons: 4.6 (4.3-4.9) *(P* = NS) **Mean Time Between Baseline and FU 2, yrs (range):** AN: 8.4 (8.1-8.8) Comparisons: 8.1 (7.7-8.4) *(P* = NS) **Mean Time Between FU 1 and FU 2, yrs:** AN: 3.5 Comparisons: 3.4 *(P* = NS) **Sex:** Female: 94% **Race/ethnicity:** NR	**Score:** Good **Method of dx:** Psychiatric interview at baseline consistent with DSM III-R Structured, standardized clinical interviews (SCID-II, DSM III-R version) to assess for personality disorder prevalence; Pervasive developmental disorder prevalence according to DSM III-R criteria also obtained via clinical interview Structured standardized clinical interviews (SCID-I, DSM III-R version) to assess prevalence of Axis I psychiatric disorders Semi-structured interview (Schedule for the Assessment of Conduct Disorder, Hyperactivity, Anxiety Disorder, Mood Disorder, and Psychoactive Substance Abuse—CHAMPS) to evaluate prevalence of ADHD Structured, standardized clinical interview (SCID-II for DSM III-R) for PD dx, for Axis I dx (SCID-I for DSM III-R), for Asperger's disorder (Asperger Syndrome Diagnostic Interview), for impulsivity symptoms (CHAMPS), and the Y-BOCS for OCD at FU 2 **Funding:** NR

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods The prevalence of PD's, PDD's/Aspergers, impulsivity symptoms, obsessive compulsive symptoms and Axis I dx assessed at baseline and at 6- and 10-yr FU via standardized clinical interview methods. Participants also administered the M-R outcome scales, an alexithymia questionnaire (i.e., TAS-20) and underwent a battery of neuropsychological tests at the final FU. Clinicians rated participants for difficulties with reciprocal interactions at the 10-yr FU (e.g., mimicry, gestures, eye contact in communication, mental status). Although standard interviews for DSM III-R were used to assess PD prevalence, PD's in this sample were also coded separately according to the DSM IV criteria at final FU. **Statistical Analyses** Chi-square tests for matched and unmatched pairs for categorical, diagnostic status. Two-sample t-tests performed for continuous variables (Y-BOCS and TAS-20)	**10-yr FU findings** **Descriptive Results** Rates of Eating Disorders in AN group: 27% Prevalence of Tx for AN: 75% **Mean Wt, kg (95% CI):** AN: 62.3 (58.5-66.1) Comparisons: 63.7 (60.8-66.5) *(P* = NS) **Mean BMI, kg/m^2 (95% CI):** AN: 22.2 (21.0-23.4) Comparisons: 22.2 (21.2-23.2) *(P* = NS) **Prevalence of OCD (N):** AN: 8 Comparisons: 1 *(P* < 0.05) AN > Comparisons **Mean TAS-20:** AN: 42.2, 95% CI (38.7-45.9) Comparisons: 38.6, 95% CI (36.0-41.1) *(P* = NS) **Prevalence of Impulsivity (N):** AN: 13 Comparisons: 9 *(P* = NS) **Personality Disorder Prevalence:** Any Cluster A *(P* = NS) Any Cluster B *(P* = NS) Any Cluster C *(P* < 0.05) AN > Comparisons, particularly for OCPD Any PD *(P* < 0.05) AN > Comparisons **Prevalence of Autism Spectrum Disorder (N):** AN: 9 Comparisons: 1 *(P* < 0.02) AN > Comparisons **Clinical Severity Outcome of AN sample using M-R Scale by subgroup status (consistent comorbid dx across all three time points):** AN with OCPD/ASD: 7.3 (1.3) AN without OCPD/ASD: 9.8 (2.1) *(P* < 0.01) Comorbid group worse than non-comorbid group **Mean TAS-20 Scores for AN sample by Subgroup status (consistent comorbid dx across all three time points):** AN with OCPD/ASD: 54.5 (14.4) AN without OCPD/ASD: 39.9 (11.0) *(P* = 0.002) Higher alexithymia in comorbid AN group

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Patton, 1988 **Design:** Case series **Comparison Group:** No **Location:** United Kingdom **Yrs followed, mean (SD):** AN: 7.6 (3.0) BN: 5.7 (2.1) Range: 4-15	Calculate a standardized mortality rate for eating disorders in a large population	**Inclusion:** Eating disorder dx AN (Russell, 1970): Loss of 25% of BW Amenorrhea Fear of putting on wt BN (Russell, 1979): Uncontrollable urge to overeat (binge) Self-induced vomiting or laxative abuse *(P*urge) Feat of becoming fat **Exclusion:** NR **Recruitment:** Reviewed records of all eating disordered patients assessed in the eating disorders unit of the Academic Department of Psychiatry at Royal Free Hospital, 1971-81. **Sample Size:** **Initial:** N = 481 **Reasons for loss to FU:** Lost to FU: N = 21 Deaths: N = 14 • AN: N = 11 • Suicide: N = 6 • Low wt: N = 5 • BN: N = 3 • Car accident: N = 2 • Low wt: N = 1 **Analysis sample:** Located / Analyzed: N = 460 • AN: 332 (72.1%) • BN: 96 (20.9%) • Other: 32 (7.0%)	**Mean Age (yrs):** AN: 22.4 BN: 23.5 **Mean Wt (kg):** AN: 41 BN: 58.9 **Sex:** Female: 95.9% Male: 4.1% **Race/ethnicity:** NR **Mean Age of Onset (yrs):** AN: 18.9 BN: 18.6 **Mean Duration of Illness (yrs):** AN: 3.5 BN: 4.9 **2nd Dx at Assessment:** Depression, N = 52 AN: N = 26 BN: N = 26	**Score:** Fair **Method of dx:** Russell diagnostic criteria for AN and BN applied retrospectively to case note description of presentation **Funding:** Grant from the Wellcome Foundation

Study Methods and Analytic Strategy	Main Outcomes and Results
Study methods Attempted to locate by: Contact with referring physician Last known address National Health Service Central Registry **Located 95.6%** FU conducted, 1985-86 Sex specific death rates derived from 1981 death rates for England and Whales **Analysis methods** Observed mortality rate (study population) Expected mortality rate (general population) Standardized mortality ratio (SMR) = observed / expected Stepwise linear discriminant function analysis: to examine the relationship of crude mortality to the prognostic variables	**Descriptive Results** **Mortality rate** Crude mortality rate (%): AN: 3.1 BN: 3.3 Expected mortality rate: AN: 1.83 BN: 0.32 Standardized mortality rate AN: 6.01 *(P < 0.01)* Higher than expected BN: 9.38 *(P* = NS) **AN mortality rate (by length of FU):** Actual mortality Overall: 11 After 4 yrs: 6 After 8 yrs: 1 Expected mortality rate Overall: 1.83 After 4 yrs: 1.04 After 8 yrs: 0.37 Standardized mortality rate Overall: 6.01 *(P < 0.01)* Higher than expected After 4 yrs: 5.76 *(P < 0.05)* Higher than expected After 8 yrs: 2.70 *(P = NS)* **Predictors of mortality in individuals with AN** wt < 35 kg at presentation: Crude (%): 8.1 (N = 5) Expected: 0.33 Standardized: 15.15 *(P < 0.05)* Higher than expected More than one inpatient admission: Crude (%): NR Expected: NR Standardized: NR *(P < 0.01)* Higher than expected age < 20 yrs at presentation: Crude (%): 2.8 (N = 4) Expected: 0.41 Standardized: 9.76 *(P = NS)* age 20-29 yrs at presentation: Crude (%): 2.9 (N = 4) Expected: 0.56 Standardized: 7.09 *(P = NS)* age ≤ 30 yrs at presentation: Crude (%): 6.0 (N = 3) Expected: 0.86 Standardized: 3.49 *(P = NS)*

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Pinter et al., 2004 **Design:** Case series **Comparison Group:** No **Location:** Kortenberg, Belgium **Yrs followed:** 1	To identify a sensitive BMI cutoff at admission in order to predict low BMI at 1-yr FU in a sample of AN patients who had gone through an inpatient tx program.	**Inclusion:** Met DSM IV criteria for AN; were able to obtain FU data **Exclusion:** Co-morbid somatic problems **Recruitment:** 252 consecutive patients admitted into inpatient Eating Disorders Unit of the U Centre Sint-Jozef in Kortenberg, Belgium for AN between 1994 and 2001. 232 patients met inclusion criteria. **Sample Size:** **Initial Sample** 252 admitted **Reasons for loss to FU:** Not reported **Analysis Sample** 232 had 1-yr FU data	**Mean Age at Admission, yrs (SD):** 21.7 (6.68) Range: 12-40 **Mean BMI at Admission, kg/m^2 (SD):** 14.5 (1.62) **Mean BMI at 6-mo FU, kg/m^2 (SD):** 18.7 (1.22) **Mean BMI at 1-yr FU, kg/m^2 (SD):** 18.2 (1.8) **Sex:** Female: 100% **Race/ethnicity:** NR	**Score:** Poor **Method of dx:** Not reported **Funding:** NR

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods All included participants underwent intensive, multi-dimensional inpatient tx program for AN. This first phase of tx typically lasted 5-6 mos. Following this, patients were then followed in an aftercare program that consisted of attending outpatient group meeting every two wks for an additional 6 mos. Wt assessments conducted at end of inpatient tx (i.e., approximately 6 mos) and at the termination of the outpatient FU (i.e., at 1-yr). Patients' BMI and clinical severity assessed using Maudsley Body Mass Index Chart. **Statistical Analyses** Pearson's product moment correlations to evaluate linear associations between BMI values at intake and at 1-yr FU. Mann-Whitney U tests performed to identify sig BMI cut points inclusive of the range of 12-16 kg/m^2 to separate those with high versus low BMIs at 1-yr FU based on baseline or admission BMI.	**Descriptive Findings** **Changes in BMI from 6-m to 1-yr (% of sample):** Unchanged: 12.5% Increase: 45.2% Decrease: 42.2% **BMI and Clinical Status Severity Category at 1-yr FU (N):** **<** 12 (life threatening AN): 0 12-13.5 (Critical AN): 4 13.5-15 (Severe AN): 6 15-17.5 (AN): 62 17.5-20 (Underwt): 131 20-25 (Normal wt): 29 **Correlations Between BMI at Admission and 1-yr FU:** r = 0.24 **Admission BMI Cut-offs Predicting 1-yr FU BMI:** < / = or > 12 *(P* = NS) < / = or > 13 *(P* = NS) < / = or > 14 *(P* < 0.01) < / = or > 15 *(P* < 0.001) < / = or > 16 *(P* < 0.001)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Råstam, Gillberg, and Gillberg; 1995 **Companion article:** Ivarsson et al., 2000 Nilsson et al., 1999 Wentz et al., 2001 Wentz et al., 2000 **Design:** Prospective cohort **Comparison Group:** Yes **Location:** Göteburg, Sweden **Yrs followed:** From onset to FU Cases: 6.7 from onset From first exam to FU: Cases: 4.9, Comparisons: 4.6	To analyze the associated physical and neurodevelop mental problems in individuals with AN over 6 yrs after disease onset, and a matched comparison group.	**Inclusion:** **Cases:** DSM III-R for AN Born 1970 AN onset < 18 yrs old **Comparison:** Matched to cases on age, sex, school **Exclusion:** **Cases:** None **Comparisons:** None **Recruitment:** **Cases:** From total population of Göteburg, Sweden, born in 1970 and developing AN before age 18; pooled with second population screening sample reported by school and hospital health care workers during FU. Some clinically referred and some screened through school nurses and doctors, pediatricians, and child psychiatrists **Comparisons:** Same schools as AN group **Sample Size:** Cases: 51 Comparisons: 51	**Age of AN onset (yrs):** 14.3 Range:13.9-14.7 **Mean Age at First Exam:** **G1:** 16.0 (95% CI: 15.5-16.5) **G2:** 16.0 (95% CI: 15.5-16.5) **Mean Age at FU:** **G1:** 21 (95% CI: 20.5-21.4) **G2:** 20.8 (95% CI: 20.3-21.3) **Sex (both groups), N:** Females: 96 Males: 6 **Race/ethnicity:** NR	**Score:** Good **Method of dx:** Structured interview using the SCID-I **Funding:** Swedish Medical Research Council, Swedish Social Research Council, Swen Jerring Foundation, Fulbright Commission, Wilhelm and Martina Lundgren Foundation

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods: At time of dx, all participants and their mothers were interviewed by a psychiatrist. At FU, were screened by another psychiatrist/psychologist blind to the original group status. Both groups screened: via SCID-II for personality disorder dx, clinician-based capacity for empathy, Dewey social awareness test, neurological testing, WAIS-R, wt, and ht (self-report). All individuals examined by psychiatrist who administered first interview, using SCID-I for Axis I disorders, M-R AN outcome scales, and rating of empathic skills. At end of interview, DSM III-R dx made independently by both clinicians; empathy dx was made conjointly by both. Neurodevelopmental exam included growth charts of wt and ht development from age 7 through time of 1st exam; wt and ht immediately before onset of AN compared to FU data. **AN Outcomes classifications** (1) recovered/not-recovered (2) avg M-R scale scores (3) good, intermediate and poor outcome: good = nrml body wt (100 +- 15% avg body wt.), intermediate = normal or near normal wt and/or menstrual abnormalities, poor = low wt and absent or scanty menstruation. (BMI or % wt details regarding these definitions were NR). **Statistical Methods:** Chi-square tests for matched pairs were used.	**Descriptive Results** **Axis I Dx:** **ED at FU in AN group:** AN: 6% BN: 22% EDNOS: 14% None: 59% **EAT Scores at FU, mean:** **Cases**: 19.2, 95% CI (13.1-25.1) **Comparisons**: 5.3, 95% CI (4.2-6.4) Diff between groups *(P* < 0.001) **Comparison Axis I disorders between AN and control group at age 21 (mean of 6 yrs after onset)** **Affective Disorders** Unipolar major depression *(P* = NS) Any affective disorders *(P* = NS) **Anxiety Disorders** Agoraphobia *(P* = NS) Social phobia *(P* = NS) Panic disorder *(P* = NS) Generalized anxiety disorder *(P* = NS) Any anxiety disorder except OCD *(P* = NS) **OCD:** **Cases**: N = 10 **Comparisons**: N = 3 (*P* < 0.05) **Psychotic Disorders** Schizoaffective disorder *(P* = NS) Psychosis NOS *(P* = NS) Schizophrenic disorder *(P* = NS) Any psychotic disorder *(P* = NS) **Somatoform Disorders:** Somatization disorder *(P* = NS) Hypochondria *(P* = NS) Body dysmorphic disorder *(P* = NS) Any somatization disorder *(P* = NS) **Tic Disorders:** Tourette's disorder *(P* = NS) **Impulse control Disorders:** Trichotillomania *(P* = NS) Any tic disorder *(P* = NS) **Simple Phobias:** *(P* = NS) **Comparisons of any Axis I Dx in AN and control groups over time:** All but 1 Case, and 39% of Comparison group met criteria for at least one Axis 1 disorder in their lifetime. *(P* < 0.001)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Råstam, Gillberg, and Wentz 2003 **Design:** Prospective cohort **Comparison Group:** Yes **Location:** Göteburg, Sweden **Yrs followed:** 10	To analyze overall outcome, and associated physical and mental health problems at 10 yr FU among teenage-onset AN population and matched controls.	**Inclusion:** **Cases:** DSM III-R for AN Born 1970 AN onset < 18 yrs old **Comparison:** Matched to cases on age, sex, school **Exclusion:** **Cases:** None **Comparisons:** None **Recruitment:** **Cases:** From total population of Göteburg, Sweden, born in 1970 and developing AN before age 18; pooled with second population screening sample reported by school and hospital health care workers during FU. Some clinically referred and some screened through school nurses and doctors, pediatricians, and child psychiatrists. 48 screened via personal interview, 3 via phone **Comparisons:** Same schools as AN group; 51 screened in person **Sample Size:** Cases: 51 Comparisons: 51	**Age of AN onset:** 14.3 yrs Range: 13.9-14.7 Restrictors: 13.3 yrs; 95% CI (12.1-14.6) Bingers/purgers: 14.6; 95% CI (14.2-15.0) *(P* < 0.05) **Mean Age at First Exam:** **Cases:** 16.0 (95% CI: 15.5-16.5) **Comparisons**: 16.0 (95% CI: 15.5-16.5) **Mean Age at FU:** **Cases:** 24.5 (95% CI: 24.0-25.0) **Comparisons:** 24.2 (95% CI: 23.7-24.7) **Sex, N:** Females: 96 Males:6 **Race/ethnicity:** NR **Full-time employment/ study:** Cases: 65%, Comparisons: 88% *(P* < 0.01) **Mean duration of AN, yrs:** Cases: 3.3, 95% CI (2.7-3.8) **Total duration of EDs, yrs:** Cases: 6.3 95% CI (5.4-7.2)	**Score:** Good **Method of dx:** Structured interview using the SCID-I **Funding:** Swedish Medical Research Council, Göteburg Medical Society, Wilhelm and Martina Lundgrem Foundation, Soderstrom-Konigska Nursing Home Foundation, and state grants under LUA agreement.

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
Treatment received by Cases: Lifetime tx for ED: 29 (57%) Conjoint family therapy: 19 Individuals with ASD and/ or OCPD: 6/8 No tx: 12 Tx for individuals with persisiting ED: 11/14 Tx for recovered AN: 18/37 **Study Methods:** Each individual seen by 3 psychiatrists, 1 blind to the original dx group status. Measurements: SCID-I and SCID-II for DSM IV; Y-BOCS; ASDI (Asperger Syndrome Diagnostic Interview); Modified M-R Scales; GAF scale. Full recovery with respect to ED symtomatology; Psychiatric tx; Neuropsychiatric exam; physical exam, Self report: EAT, BDI. **Statistical Methods:** Chi-square tests for matched pairs were used.	**AN Outcomes classification:** Full recovery: free of symptoms of AN or BN for not less than 8 consecutive wks including sustained absence of wt deviation, compensatory behaviors, deviant attitudes regarding wt and shape including wt phobia. Also relaxed attitude towards eating in general for not < 6 mos. **Modified M-R Outcome categories:** Good: normal body wt (100 +- 15%avg body wt.) + normal menstruation Intermediate: normal or near normal wt or normal menstrual but not both, Poor: under wt and absent or scanty menstruation. (BMI or % wt details regarding these definitions were NR). **Descriptive Results at 10 yr FU** **ABW (kg):** Cases: 62.3,95% CI (58.5-66.1) Comparisons: 63.7, 95% CI (60.8-66.5) *(P* = NS) **Mean BMI:** Cases: 22.2, 95% CI (21.0-23.4) Comparisons: 22.2, 95% CI (20.5-21.8) *(P* = NS) **ED in AN group:** AN 3 (6%) BN 2 (4%) EDNOS 9 (18%) Any ED 14 (27%) **Absence of any ED symptoms for at least 6 mos:** Cases: 20 (39%) Comparisons: 46 (90%) Diff between groups *(P* < 0.0001) Cases less likely than Comparisons **Diff in current Axis I Psychiatric Dx:** Any affective disorder, current *(P* = NS) Current Axis I, excluding ED *(P* = NS) Panic disorder, social phobia, simple phobia, general anxiety disorder, any anxiety disorder *(P* = NS) Current OCD: Cases: N = 8; Comparisons: N = 1; *(P* = 0.05) Psychotic disorders *(P* = NS) Impulse control disorders *(P* = NS) Somatoform dx *(P* = NS) Tic disorders *(P* = NS) **Diff in lifetime Axis I Psychiatric Dx:** Major Depression and Dysthymic disorders *(P* = NS) Any affective disorder: Cases: N = 49; Comparisons: N = 12 *(P* < 0.0001) Panic disorder, social phobia, simple phobia, general anxiety disorder, any anxiety disorder excluding OCD *(P* = NS) OCD: Cases: 18; Comparisons: 5 *(P* = 0.01) Any anxiety disorder, including OCD: Cases: 29, Comparisons:16 *(P* = 0.02) Psychotic disorders *(P* = NS) Impulse control disorders *(P* = NS) Somatoform dx *(P* = NS) Tic disorders *(P* = NS) Any Axis I, including ED: Cases: 51, Comparisons: 26; *(P* = 0.0001) Any Axis I, excluding ED: Cases: 51, Comparisons: 26; *(P* = 0.0001)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Råstam, Gillberg, and Wentz 2003 (continued)				

Study Methods and Analytic Strategy	Main Outcomes and Results
	Diff in Axis II disorders: **Cluster A** All categories currently *(P* = NS) All cluster A ever *(P* = NS) **Cluster B** All categories currently *(P* = NS) All categories ever *(P* = NS) **Cluster C** Avoidant: Cases currently *(P* = NS) Dependent currently *(P* = NS) Obsessive-compulsive currently *(P* = NS) Passive-aggressive currently *(P* = NS) Any cluster C currently: Cases: 11, Comparisons: 4; *(P* < 0.05) Any cluster C ever: Cases: 32, Comparisons: 11; *(P* < 0.01) Autistic disorder, Asperger syndrome, Autistic-like condition, OCPD currently *(P* = NS) OCPD ever: Cases: 28, Comparisons: 7; *(P* < 0.001) ASD currently: Cases: 9; Comparisons:1; *(P* < 0.02) ASD ever: Cases: 12, Comparisons: 1; *(P* < 0.01) Any OCPD/ASD currently: Cases 14, Comparisons: 6 *(P* < 0.05) Any OCPD/ASD ever: Cases: 32, Comparisons: 8; *(P* < 0.001) Any OCPD/ASD at baseline, 1st and 2nd FU: Cases: 8, Comparisons: 0; *(P* < 0.02) **Other personality disorders** Self-defeating *(P* = NS) Any SCID personality disorder *(P* = NS) Mean age of OCD onset *(P* = NS) **Overall Outcome Measures:** **Diff in avg M-R Scale Outcomes:** Cases: Good: 49%; Intermediate: 41%; Poor: 10% Cases: 9.4, 95% CI (8.8-10.0), Comparisons: 11.2, 95% CI (10.8-11.5*)* *(P* < 0.0001) **Diff in modified M-R Scale Outcomes:** **Cases:** Good: 43% Intermediate: 29% Poor: 27% **Diff in dietary Restriction:** Cases: 47% Comparisons: 16% *(P* < 0.01) **Diff in worry about wt and appearance:** Cases: 69% Comparisons: 27% *(P* < 0.001) **Diff in normal menstruation:** Cases: 65% Comparisons: 85% *(P* < 0.05) **AN group very poor overall outcome (M-R score < 8.5) (N):** Cases at 6 yr FU: 20 Cases at 10 yr FU: 16 Correlation between avg FU scores at 6 and 10 yrs: r = 0.72 (*P* < 0.0001)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Råstam, Gillberg, and Wentz 2003 (continued)				

Study Methods and Analytic Strategy	Main Outcomes and Results
	Diff GAF scale, mean scores: Case: 65.3, 95% CI (61.0-69.7) Comparisons: 84.8, 95% CI (81.7-87.9) *(P* < 0.0001) **AN group outcomes in relation to psychiatric disorders and PDs:** **M-R Score:** Cases OCPD/ASD at baseline, 1st and 2nd FU: 7.3 All other cases: 9.8 *(P* < 0.01) **Median GAF score:** Cases with Axis 1: 60 All other cases: 75 *(P* < 0.01) **Mean GAF score:** Cases with OCD: 50 All other cases: 70 *(P* < 0.02) **Diff neurodevelopmental and other physical problems:** Fine and gross motor skills, tremor, mirror movements, handedness *(P* = NS) **Dysdiadochokinesis:** Cases: 11 Comparisons: 2 *(P* < 0.02) **GI problems:** Cases: 47% Comparisons: 27% *(P* < 0.05; *P* < 0.055 adj)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Saccomani et al., 1998 **Design:** Case series **Comparison Group:** No **Location:** Genoa, Italy **Yrs followed:** Mean 9.6 yrs, Range 4 to 19 yrs	To assess outcomes and comorbid mood and personality disorders in patients dx with AN during childhood or adolescence.	**Inclusion:** AN dx at admission based on Feighner's, DSM III, or DSM III-R criteria. Dx reclassified at FU using DSM IV **Exclusion:** None **Recruitment:** Record survey of patients admitted to Gaslini Dept of Neurology and Psychiatry between 1976-1990. **Sample Size:** **Initial sample:** Identified through records: N = 87 **Reasons for loss to FU:** 2 not found, 4 refused **Analysis sample:** Agreed to participate at FU: N = 81	**Mean Age:** NR **Mean Age of Onset, yrs, mean (range):** 14.5 (9 to 21) **% Wt Loss, mean (SD):** 28.3 (6.3) **BMI kg/m^2, mean (SD):** 13.9 (1.8) **Sex:** Female, N = 72 Males, N = 9 **Amenorrhea:** 100% of females **Menses resumed:** 87% **Race/ethnicity:** NR	**Score:** Poor **Method of dx:** Initial inclusion dx: Feighner's, DSM III, or DSM III-R criteria by chart review No info provided about qualifications of reviewers or method. Dx reclassified at FU using DSM IV. No info provided about diagnosticians or method. **Funding:** None reported

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods: Records survey of all patients admitted between 1976-1990 meeting criteria for AN by Feighner's, DSM III, DSM III-R criteria. At FU, patients sent a questionnaire designed by investigators to evaluate AN clinical features, social adjustment, familial and sexual relations, mental state, and psychiatric disorders in the previous 6 mos; and the Middlesex Hospital Questionnaire (MHQ). Information used to determine Jeammet scale (modified M-R Scale). Corraborative data gathered from semi-structured interview of family or boyfriends. Of 81 patients contacted, all completed both questionnaires, 28 had face-to-face semi-structured interview, 39 agreed only to phone interview, and 2 patients had info provided by psychotherapist. **Statistical Method:** Kruskal-Wallis analysis of variance for continuous data Fisher tests for categorical data **Outcomes:** Jeammet (modified M-R Outcome Scale): Good – 8 of 10 items score a 1 or 2 (on 4 patient. scale) Intermediate – 4 to 7 items score 1 or 2 (on 4 patient. scale) Poor - < 3 items score 1 or 2 (on 4 patient. scale)	**Descriptive Results**: **AN Outcome:** Good: 43 (53%) Intermediate: 27 (33%) Poor: 11 (14%) **Binge eating by outcome group** Poor: 45% Intermediate: 28% Good: 14% *(P* = 0.034) **Medical emergencies by outcome group** Poor: 55% Intermediate: 21% Good: 4% *(P* = 0.0003) **Length/type of tx by outcome group:** **Outpatient tx** Good: 49% Intermediate: 26% Poor: 0% **Medium-term hospitalization** Good: 32% Intermediate: 11% Poor: 36% **Long-term hospitalization** Good: 0% Intermediate: 37% Poor: 36% **Co-morbid psych dx by outcome group:** **Personality disorders** Good: 0% Intermediate: 41% Poor: 73% *(P* < 0.001) **Mood disorders** Good: 14% Intermediate: 63% Poor: 73% *(P* = 0.002) **Other diff by outcome group:** For eating behavior, wt, menstruation, body image, occupation, social contact, familial relationships, sexual relations, insight, mental state *(P* = 0.001). Good better than Poor For social, familial and sexual relationships, insight, and mental state *(P* = 0.001). Good better than Intermediate For wt and sexual relationships *(P* = 0.001). Intermediate better than Poor

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality Adverse Events
Authors, year: Schork et al., 1994 **Companion articles:** Halmi, Eckert et al., 1991 **Design:** Case series **Comparison Group:** No **Location:** USA (Iowa City, IA; Minneapolis, MN; White Plains, NY **Years followed:** 10	To compare general psychopathology, eating disorder dx status, and clinical outcome in women 10 yrs after their hospital tx for AN.	**Inclusion:** Modified Feighner dx criteria for AN. Other details in Halmi et al., 1979 and Halmi et al., 1991. **Exclusion:** See Halmi et al., 1979, for details. **Recruitment:** Patients who completed 35-day hospital tx study for AN. **Sample Size (N):** Completed tx: 76 Completed FU: 59 **Reasons for Loss to FU:** 3 did not complete the MMPI, 9 refused to participate, 5 deceased (causes unknown).	**Mean Age, Yrs (SD):** NR **Sex:** Female **Race/ethnicity:** NR	**Score:** Poor **Method of diagnosis:** Prospective assessment using Feighner criteria; retrospective DSM-III-R. **Funding:** NR

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods **ED clinical status at FU:** DSM III-R ED diagnostic categories, plus two versions of the Categories of General Outcome classification scheme 1) M-R scale: Recovered: within 15% of IBW, normal menses, no sig disturbance in eating or body image Good: within 15% IBW, normal menses, but with presence of binge-eating, self-induced vomiting, laxative abuse, or other clearly abnormal eating behavior Intermediate: weight only intermittently within 15% IBW, or some menstrual disturbance, or both Poor: weight always more than 15% below IBW during the year prior to assessment 2) Modified Ratnasuriya et al. (1991) scheme: Good: weight within 15% of IBW, normal menses Intermediate: weight only intermittently within 15% IBW, or some menstrual disturbance, or both Poor: weight always more than 15% below IBW during the year before assessment and absent or sporadic menses, or the occurrence of either overeating or vomiting weekly or more, regardless of weight or menstrual status Minnesota Multiphasic Personality Inventory used to assess general psychopathology at FU. **Statistical Approach** Chi-square tests to assess diff across groups MANOVA to assess outcome group differences in MMPI followed by univariate ANOVAs and Tukey-Kramer pairwise post-hoc comparisons for separate clinical scales.	**Descriptive Findings**: **M-R outcome at 10-yr FU by current ED Dx, N:** Recovered: 16 (No ED: 16; EDNOS: 0; BN: 0; AN: 0; AN+BN: 0) Good: 15 (No ED: 0; EDNOS: 8; BN: 7; AN: 0; AN+BN: 0) Intermediate: 21 (No ED: 0; EDNOS: 14; BN: 7; AN: 0; AN+BN: 0) Poor: 7 (No ED: 0; EDNOS: 0; BN: 0; AN: 5; AN+BN: 2) **Ratnasuriya outcome at 10-yr FU by current ED Dx, N:** Good: 24 (No ED: 16; EDNOS: 8; BN: 0; AN: 0; AN+BN: 0) Intermediate: 13 (No ED: 0; EDNOS: 13; BN: 0; AN: 0; AN+BN: 0) Poor: 22 (No ED: 0; EDNOS: 1; BN: 14; AN: 5; AN+BN: 2) **Multivariate Results:** **MMPI Scales by M-R Outcome:** Recovered had sig lower score vs. poor outcome group: hypochondriasis (P = 0.004), depression (P = 0.017), psychasthenia (P = 0.005), and schizophrenia (P = 0.027). Recovered sig lower score vs. intermediate outcome group: psychasthenia (P = 0.04) and schizophrenia (P = 0.019). **MMPI Scales by Ratnasuriya Outcome:** Good outcome group better than poor outcome: hypochondriasis (P = 0.001), depression (P < 0.001), hysteria (P = 0.001), psychopathic deviate (P = 0.007), paranoia (P = 0.012), psychasthenia (P < 0.001), and schizophrenia (P = 0.002). Intermediate Outcome group better than Poor Outcome group: on depression (P = 0.036), psychopathic deviate (P = 0.049), and schizophrenia (P = 0.042). **MMPI Scales by ED Dx at FU:** No-ED group better than AN group: hypochondriasis (P = 0.008), depression (P = 0.006), psychasthenia (P = 0.001), and schizophrenia (P = 0.012). No-ED group better than BN group: hysteria (P = 0.05) and psychasthenia (P = 0.01). **Number of Clinically Elevated MMPI Scales by Current ED Dx at FU (N):** No ED: none (14); 1 (2); 2 (0); ≥ 3 (0) ED-NOS: none (13); 1 (4); 2 (1); ≥ 3 (4) Severe ED (AN, BN, AN+BN): none (7); 1 (1); 2 (5); ≥ 3 (8) Patients with no ED more likely to have no clinically elevated scales vs. “severe ED” outcome groups (AN, BN, or AN+BN) (P = 0.001).

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality Adverse Events
Authors, year: Schork et al., 1994 (continued)				

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
	Number of MMPI Scales in Clinical Range by M-R Outcome (N): Recovered: none (14); 1 (2); 2 (0); ≥ 3 (0) Good: none (10); 1 (0); 2 (2); ≥ 3 (3) Intermediate: none (9); 1 (4); 2 (2); ≥ 3 (6) Poor: none (1); 1 (1); 2 (1); ≥ 3 (4) Recovered + Good Outcome groups less likely to have clinically elevated scales vs. Intermediate + Poor Outcome groups (P = 0.003). **Number of MMPI Scales in Clinical Range by Ratnasuriya Outcome (N):** Good: none (21); 1 (2); 2 (0); ≥ 3 (1) Intermediate: none (6); 1 (4); 2 (0); ≥ 3 (3) Poor: none (8); 1 (1); 2 (4); ≥ 3 (9) Good Outcome groups more likely to have no clinically elevated scales vs. Poor Outcome groups (P < 0.001).

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Strober et al., 1996 **Design:** Case series **Comparison Group:** No **Location:** USA **Yrs followed:** 10	To examine the predictive power of binge eating behavior in predicting first-onset substance use disorder in AN patients.	**Inclusion:** Met DSM III-R criteria for AN at intake; 12-17 yrs 11 mos at intake **Exclusion:** See original study (Strober and Yager, 1984) for more specific details **Recruitment:** Consecutive inpatient admissions to UCLA Neuropsychiatric Institute, Los Angeles, CA, USA, for the tx of AN between 1980 and 1985. **Sample Size:** **Original sample:** N = 97 **Reasons for loss to FU:** Subjects dropped out of tx w/in 10 days of admission and refused participation in FU. **Analysis sample:** N = 95 Binge-eaters at intake (N = 18) Restrictors at intake (N = 77) Binge-eaters at intake and FU: including 23 who developed binge eating during FU (N = 41) Restrictors at both intake and FU, no binge eating **(**N = 54) Binge eaters at FU only (N = 23)	**Mean Age at Intake:** 15.1 **Sex:** Female: 94% **Race/ethnicity:** White: 93% **Family structure:** 2-parent: 79% **SES:** Middle-upper class: 91% **BMI at Intake (SD):** 14.1 (1.9)	**Score:** Good **Method of dx:** Method of ED dx NR, Structured clinical interviews using the SADS, Kiddie-SADS, and LIFE **Funding:** NR

Study Methods and Analytic Strategy	Main Outcomes and Results
Intervention: Inpatient tx **Study Methods** Semi-structured interview, information from knowledgeable informants, M-R scale completed, LIFE completed, interview every 6 mos for 5 yrs and annually for 5 yrs. **Statistical Methods** Fisher's exact test for comparisons of dichotomous variables; Survival analyses to compare groups' time to onset of SUD and effects of covariates on time-to-response were assessed via stepwise Cox regression analyses.	**Descriptive Results** **SUD Incidence During 10-yr FU:** Substance abuse: N = 11 Substance dependence: N = 7 **Mean Onset of SUD from Intake:** Total sample: 199 wks (range: 48-401) Binge eaters at intake: 163 wks Restrictors at intake: 235 wks **Cumulative Probability and Relative Risk of SUD During 10-yr FU:** **Binge eaters at intake: 0.50 (SE = 0.12)** Restrictors at intake: 0.12 (SE = 0.04) Diff between groups' survival distributions: RR = 5.80 *(P* = 0.0001) Binge eaters faster rate of developing SUD than restrictors Binge eaters at intake or FU: 0.34 (SE = 0.07) Restrictors at both intake and FU: 0.07 (SE = 0.04) Diff between groups' survival distributions: RR = 5.53 *(P* = 0.0007) Binge eaters faster rate of developing SUD than restrictors Diff between groups *(P* = NS) Binge eaters at intake: 0.50 (SE = 0.12) Binge eaters at FU only: 0.22 (SE = 0.09) Diff between groups' survival distributions: RR = 2.89 *(P* = 0.05) Binge eaters at intake faster rate of developing SUD than binge eaters at FU only Restrictors at both intake and FU: 0.07 (SE = 0.04) Binge eaters at FU only: 0.22 (SE = 0.09) Diff between groups' survival distributions *(P* = 0.06) Binge eaters at intake: 0.50 (SE = 0.12) Restrictors at both intake and FU: 0.07 (SE = 0.04) Diff between groups' survival distributions: RR = 9.20 *(P* = 0.0001) Binge eaters faster rate of developing SUD than restrictors **Incidence of SUD in First Degree Relatives (%):** Binge eaters at intake: 55.6 Restrictors at intake: 14.3 Binge eaters at intake or FU: 31.7 Restrictors at both intake and FU: 14.8 Binge eaters at FU only: 13.0 **Binge-eating status in relation to SUD in first degree relatives:** Binge eaters at intake v. Restrictors at intake: OR = 7.5, 95% CI (2.4-23.2) worse in binge eaters Binge eaters at intake v. Restrictors at both intake and FU: OR = 7.2, 95% CI (2.2-23.8) worse in binge eaters Binge eaters at intake or FU v. Restrictors at both intake and FU: OR = 2.7, 95% CI (1.0-7.2) worse in binge eaters Binge eaters at intake v. Binge eaters at FU only: OR = 8.3, 95% CI (1.8-38.4) worse in early binge-eating Restrictors at both intake and FU v. Binge eaters at FU only *(P* = NS)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Strober et al., 1996 (continued)				

Study Methods and Analytic Strategy	Main Outcomes and Results
	Multivariate Results **SUD Onset** Binge-eating at Intake *(P* = 0.001) Family Hx of SUD *(P* = NS) BMI at Intake *(P* = NS) Highest-Lowest BMI *(P* = NS) Parental Separation/Divorce *(P* = NS) Current/Lifetime Hx of Depression or Anxiety at Intake *(P* = NS) New Onset of Depression or Anxiety at FU *(P* = NS)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Strober, Freeman and Morrell, 1997 **Design:** Case series **Comparison Group:** No **Location:** USA **Yrs followed:** 10 to 15 yrs from time of index admission	To assess the long-term course of recovery and relapse and predictors of outcome in AN.	**Inclusion:** DSM III criteria for AN **Exclusion:** NR **Recruitment:** All consecutive admissions to ED inpatient tx program for AN at UCLA Neuropsychiatric Institute between 1/1/80 and 12/31/85. **Sample Size:** **Initial Sample:** N = 95 **Loss to FU**: 2 patients left hospital within 10 days of admission and refused further participation. **Analysis Sample:** N = 93	**Age Range At Time of Intake** 12 to 17 yrs, 11 mos **Age range at FU:** 22 – nearly 33 yrs **Sex:** Female: N = 85 (89.5%) **Race/ethnicity:** White: N = 88 (92.6%) **BMI, mean (SD):** 14.1 (1.9); 69% of avg expected body wt **Duration of illness, mos, mean (range):** 29 mos (8 – 88 mos) **Hx of binge eating:** N = 18 (18.9%) **Restrictor at intake:** N = 77 (81.1%) **Hx of self-induced vomiting:** 11 (61.1%) of intake binge eaters; 17 (22.1%) of intake restrictors **Prior Hospitalizations:** Psych tx for AN (24.2%) Med tx for wt loss complications (35.8%) **Prior psych care** (82.1%)	**Score:** Fair **Method of dx:** Examinations conducted by two senior faculty members. **Funding:** NR

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods Participants had all received inpatient tx. Interviews were scheduled at 6-mo intervals from the point of discharge throughout the first 5 yrs, and annually thereafter until completion of FU. **Outcome definitions** **Full recovery**: free of all symptoms of AN or BN for at least 8 consecutive wks. **Partial recovery**: wt within 15% of avg and normal cyclical menstruation is sustained for at least 8 consecutive wks. **Intermediate outcome:** wt within 15% of avg not maintained with consistency, and/or there is menstrual irregularity **Poor**: wt < 85% of avg and menstruation iabsent, or nearly always so, or if patient exhibits BN. **Post-discharge relapse**: drop in body wt to < 85 of avg, occurring prior to point at which patient meets criteria for partial recovery. **Post-recovery relapse:** when patient had prospectively observed exacerbation of illness following either partial recovery or full recovery. For those following full recovery, new illness further categorized as subsyndromal if patient had reappearance of psychological symptoms but remained at least 85% of avg body wt, and syndromal if wt fell below this criterion. **Statistical Methods** Chi Square, t tests, life tables, Kaplan-Meier extension of survival analysis. Pairwise comparisons of survival curves for particular subgroups of interest: log rank test and Breslow (Gehen-Wilcoxon) test Individual predictor variables: univariate and multivariate Cox proportional hazards regression models Isolate sig of individual predictors: stepwise multiple logistic regression	**Descriptive Results** Partial recovery: 82/95 (86.3%) Full recovery: 72/95 (75.8%) Current dx of chronically ill (did not achieve full/partial recovery) (N = 13): BN (9/13; 9.5%); AN, restricting (3/13; 3.2%); AN, binge eating (1/13; 1.1%) Median time to partial recovery: 57.4 mos Median time to full recovery: 79.1 mos **Cumulative Probability of Recovery Through FU by interval start time, mos:** 0 mos: Partial = 2%, Full = 0% 12: Partial = 10%, Full = 0% 24: Partial = 21%, Full = 1% 36: Partial = 33%, Full = 9% 48: Partial = 55%, Full: 18% 60: Partial = 70%, Full = 37% 72: Partial = 74%, Full = 59% 84: Partial = 75%, Full = 63% 96: Partial = 80%, Full = 67% 108: Partial = 84%, Full = 73% 120: Partial = 87%, Full = 73% 132-180 mos: Partial = 87%, Full = 77% **Diff in psychosocial adjustment by partial recovery or better or not:** **Good work status, yr 5:** Partial recovered: 71% Not partial recovered: 26% OR = 7.3, 95% CI (2.9 – 18.3) *(P* < 0.0001) **Good work status, yr 10:** Partial recovered:80% Not partial recovered:25% OR = 11.8, 95% CI (3.4 – 41.6) *(P* < 0.0001) **Good social relating, yr 5:** Partial recovered:73% Not partial recovered**:**54% OR = 2.3, 95% CI (0.9 – 5.6) *(P* = NS) **Good social relating, yr 10:** Partial Recovered**:** 85% Not partial recovered:38% OR = 9.3 95% CI (2.8 – 30.4) (*P* < 0.0002) **Higher life satisfaction, yr 5:** Partial Recovered: 41% Not partial recovered:15% OR = 3.8, 95% CI (1.4 – 10.6) *(P* < 0.012) **Higher life satisfaction, yr 10:** Partial Recovered: 68% Not partial recovered: 6% OR = 32.4, 95% CI (4.1 – 259.2) (*P* < 0.0001)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Strober, Freeman and Morrell, 1997 (continued)				

Study Methods and Analytic Strategy	Main Outcomes and Results
	Diff in psychosocial adjustment by full recovery or not: **Good work status, yr 5:** Recovered: 87% Not recovered**:**67% OR = 3.2, 95% CI (1.1 – 9.2) *(P* = 0.029) **Good work status, yr 10:** Recovered:96% Not recovered: 62% OR = 13.8, 95% CI (3.4 – 55.8) *(P* < 0.0001) **Good social relating, yr 5:** Recovered: 91% Not recovered: 65% OR = 5.6, 95% CI (1.7 – 18.2) *(P* = 0.003) **Good social relating, yr 10:** Recovered: 90% Not recovered: 73% OR = 3.3, 95% CI (1.0 – 10.5) *(P* = 0.053) **Higher life satisfaction, yr 5:** Recovered: 89% Not recovered**:** 69% OR = 11.9, 95% CI (4.0 – 35.3) *(P* < 0.0001) **Higher life satisfaction, yr 10:** Recovered: 87% Not recovered: 54% OR = 5.7, 95% CI (2.0 – 16.2) *(P* = 0.002) **Onset of binge eating during FU among those who were restrictors at baseline. N = 23/77 (29%)** Time to onset of binge eating: median (range): 24 mos (3 – 59 mos); 95% CI (16.2 – 31.8). Binge eating commenced when patient within 85% of avg body expected wt: 19/23 (82.6%) Fulfilled BN criteria: 16/23 (65.2%) Post discharge relapse: N = 28 (29.5%) **Survival time, mos (mean):** Entire sample: 129.3, 95% CI (114.4 – 144.2) In patients who relapsed: 15.0, 95% CI (10.2 – 19.9); median: 11.0, 95% CI (5.8 – 16.2) Mean time to post-discharge relapse, mos: Chronically ill group: 10.8, 95% CI (4.9 – 16.6); median: 7.0, 95% CI (5.6 – 8.4) Patients who eventually recovered: 19.9, 95% CI (12.3 – 27.5); median: 13.0, 95% CI (4.2 – 21.8) **Post-Recovery Relapse:** Following partial recovery: N = 8 (9.8%) by 13 mos from time of partial recovery Syndromal relapses following full recovery: N = 0 Subsyndromal relapses following full recovery: N = 5 (7.1%) by 19 mos

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Strober, Freeman and Morrell, 1997 (continued)				

Study Methods and Analytic Strategy	Main Outcomes and Results
	Multivariate Results **Predictors of Chronic Outcome (Intermediate or Poor):** Extreme, compulsive drive to exercise**:** OR **=** 4.3, 95% CI (1.2 – 15.3) *(P* = 0.023) Hx of poor social relating preceding onset of illness: OR = 3.5, 95% CI (1.2 – 12.8) *(P* = 0.044) Early age of onset *(P* = NS) **Predictors of longer time to full recovery** Hostile attitudes toward family: HR = 0.67, 95% CI (0.5 – 0.9) *(P* = 0.046) Extreme compulsivity in daily routines: HR = 0.59, 95% CI (0.4 = 0.9) *(P* = 0.035) Early age of onset *(P* = NS) **Predictors of binge eating during FU among those who were restrictors at baseline:** Hostile attitudes toward family: OR = 6.7, 95% CI (2.2 – 20.2) *(P* = 0.0007) Lack of parential-expressed empathy/affection toward patient: OR = 3.1, 95% CI (1.1 – 8.6) *(P* = 0.028) **Predictors of earlier time to relapse (adj for duration of hospitalization):** Final outcome status (chronic versus partial or full recovery): HR = 2.5, 95% CI (1.1 – 5.5) *(P* = 0.027) Compulsive drive to exercise at time of discharge: HR = 2.2, 95% CI (1.1 – 4.9) *(P* = NR)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality Adverse Events
Authors, yr: Sullivan, Bulik et al., 1998 **Design:** Case Series **Comparison Group:** Yes **Location:** Christchurch, New Zealand **Yrs followed:** 12	To ascertain the intermediate to long-term outcomes for women who had been referred for tx for AN an avg of 12 yrs earlier – using clear diagnostic defs and a structured method. To compare outcomes to a community sample.	**Inclusion:** **Cases**: Newly dx via DSM III-R criteria for definite or "probable" AN, all determined to meet lifetime DSM III-R criteria for AN; age 23-45 **Comparisons**: Age matched to AN cases; age 23-45 **Exclusion:** **Cases**: None **Comparisons**: subthreshold AN symptoms **Recruitment:** **Cases**: Newly dx via DSM III-R criteria during inpatient, outpatient or assessment from 1981-1984 among those who received ED services at Princess Margaret Hospital, Christchurch, New Zealand, for definite or "probable" AN **Comparisons**: randomly selected names obtained from electoral record Both: letter to invite participation; FU phone call; personal interview **Sample Size:** **Initial Sample** Records reviewed: 239 Potential AN: 89 Potential comparisons: 111 **Reasons for loss to FU:** Death: 1 due to suicide while being treated for AN, 3 could not be located, 8 did not give consent, and 7 did not meet criteria for AN **Analysis sample:** Cases = 70 Comparison = 98	**Mean Age (yrs)** At interview: Cases: 32.4 (7.8) Comparison: 35.5 (6.2) *(P* < 0.01*)* **Cases:** AN onset: 16.9 yrs (4.1) Age at first tx: 20.9 (8.0) **Interval between onset and interview (yrs):** 15.4 (7.0) **Sex:** Female: 100% **Race/ethnicity:** European Cases: 98.6% Comparison: 96.0% *(P* = NS) **Never married:** Cases: 45.7% Comparison: 16.3% *(P* < 0.01) **Managerial or professional occ:** Cases: 21.4% Comparison: 25.5% **Morbidity:** **Lifetime AN** Cases: 100%: Comparison: 0% **Current full syndrome AN** Cases: 10% Comparison: 0% **Current subtrhreshold AN:** Cases: 5.7% Comparisons: 0% **Lifetime BN** Cases: 54.3% Comparison: 2% **Current BN** Cases: 11.4% Comparison: 0%	**Score:** Good **Method of dx:** Criteria for DSM III or DSM IIIR determined through review of hospital records. **Funding:** Cantebury Medical Research Foundation New Zealand Health Research Council

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods **Cases**: Hospital record of AN patients reviewed by 2 trained abstractors ED attitudes measured via EDI and TFEQ Psychiatric disorders defined according to DSM III-R criteria Current assessment of social and occupational functioning using GAFS **Statistical Methods** Chi-square, ANOVA, ANCOVA Outcome: diff between AN and Comparison groups. All analyses adjust for age.	**Descriptive Findings** **Diff in percentage of groups with dx at 12 yr FU:** **Lifetime Mood Disorders** Major depression: Cases: 51.4%; Comparisons: 35.7% *(P* ≤ 0.05) Bipolar I disorder *(P = NS*) Bipolar II disorder *(P = NS*) Any mood disorder: Cases: 60.0%; Comparisons: 41.8% *(P* ≤ 0.05) **Lifetime Drug Use Disorders** Alcohol dependence: Cases: 27.1%; Comparisons: 10.2% *(P* ≤ 0.05) Cannabis dependence *(P = NS*) Other drug dependence *(P = NS*) Any drug dependence: Cases: 30.0%; Comparisons: 12.2% *(P* ≤ 0.05) **Lifetime Anxiety Disorders** OCD: Cases: 15.9%; Comparisons: 2.0% *(P* ≤ 0.01) Panic Disorder *(P* < 0.05) Cases worse Social Phobia *(P* = NS) Separation Anxiety Disorder: Cases: 17.1%; Comparisons: 2.0% *(P* ≤ 0.01) Overanxious Disorder: Cases: 37.1%; Comparisons: 3.1% *(P* ≤ 0.001 Any Anxiety Disorder: Cases: 60%; Comparisons: 32.7% *(P* ≤ 0.001) **Multivariate Results** **BMI at interview (kg/m2), Mean (SD)** Cases: 20.1 (2.1); Comparison: 25.6 (6.4) Diff between groups at endpoint controlling for age *(P* ≤ 0.001) Diff between groups at endpoint controlling for age and current AN *(P ≤ 0.001)* **Ideal BMI, Mean (SD)** Cases: 19.6 (2.0); Comparison: 22.6 (2.6) Diff between groups at endpoint controlling for age *(P* ≤ 0.001) Diff between groups at endpoint controlling for age and current AN *(P* ≤ 0.001*)* **EDI Subscale Scores:** **Drive for Thinness, Mean (SD)** Cases: 6.2 (6.4); Comparison: 3.1 (4.2) Diff between groups at endpoint controlling for age *(P ≤ 0.01)* Diff between groups at endpoint controlling for age and current AN *(P* ≤ 0.05*)* **Bulimia, Mean (SD)** Cases: 1.5 (2.7); Comparison: 1.0 (1.6) Diff between groups at endpoint controlling for age *(P* = NS) Diff between groups at endpoint controlling for age and current AN *(P = NS)* **Body Dissatisfaction, Mean (SD)** Cases: 10.3 (8.9); Comparison: 11.5 (9.3) Diff between groups at endpoint controlling for age *(P* = NS) Diff between groups at endpoint controlling for age and current AN *(P* = NS*)*

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality Adverse Events
Authors, yr: Sullivan, Bulik et al., 1998 (continued)				

Study Methods and Analytic Strategy	Main Outcomes and Results
	Perfectionism, Mean (SD) Cases: 6.7 (4.7); Comparison: 3.4 (3.3) Diff between groups at endpoint controlling for age *(P* ≤ 0.001) Diff between groups at endpoint controlling for age and current AN *(P* ≤ 0.001*)* **Three Factor Eating Questionnaire Scale Score: Cognitive Restraint, Mean (SD)** Cases: 11.7 (5.7); Comparison: 5.5 (4.8) Diff between groups at endpoint controlling for age *(P* ≤ 0.001*)* Diff between groups at endpoint controlling for age and current AN *(P* ≤ 0.001) **Disinhibition, Mean (SD)** Cases: 5.7 (4.1); Comparison: 5.9 (4.0) Diff between groups at endpoint controlling for age *(P* = NS*)* Diff between groups at endpoint controlling for age and current AN *(P* = NS) **Hunger, Mean (SD)** Cases: 3.8 (2.4); Comparison: 4.8 (3.0) Diff between groups at endpoint controlling for age *(P* ≤ 0.01*)* Diff between groups at endpoint controlling for age and current AN *(P* ≤ 0.05*)* **Global Assessment of Functioning Score** Diff between groups adjusting for case/control status, age, current ED, mood, anxiety or dependence disorder *(P* = 0.002*)* Worse in AN group

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Tanaka et al., 2001 **Design:** Case series **Comparison Group:** No **Location:** Osaka, Japan **Yrs followed:** 8.3 (SD 3.8) Range 4.0-17.7	To investigate: the intermediate-term outcomes of AN patients who had inpatient tx at least 4 yrs prior, and prognostic factors associated with later FU outcomes.	**Inclusion:** Women Retrospectively fit DSM IV for AN, inpatient tx min. of 4 yrs prior to study. **Exclusion:** BN **Recruitment:** Completing inpatient tx at Osaka City University Hospital between January 1982 and December 1999, a min. of 4 yrs prior to study were contacted by telephone. Received face-to-face or telephone semi-structured interviews or just FU questionnaires if not available for interviews. Information re: deceased patients obtained from patient's parents. **Sample size:** **Initial sample:** Patients treated (N = 185) Met DSM IV for AN and 4 yrs had passed (N = 69) **Reasons for loss to FU:** Deceased (N = 7) Emaciation (N = 3) Suicide (N = 2) Murdered (N = 1) Burn to death (N = 1) Refused (N = 1) **Analysis sample:** N = 61 (not including 7 deceased patients)	**Mean Age (SD):** 22.7 (6.0) yrs Range: 13.7-37.4 yrs **Sex:** Female 100% **Age onset (SD):** 18.8 (4.3) yrs **Duration illness (SD):** 4.1 (4.3) yrs **#Admissions (SD):** 1.1 (1.5) **Education (SD):** 12.3 (2.8) yrs **BMI (SD) (kg/m^2):** 14.0 (2.1) **Premorbid BMI (SD) (kg/m^2):** 20.5 (2.8) **Max BMI (SD) (kg/m^2):** 21.9 (4.0) **Min BMI (SD) (kg/m^2):** 12.9 (2.4) AN-R: 44.3% AN-BP: 55.7% **Suicide attempts:** 39.3% **Alcohol abuse:** 8.2% **At FU:** **Duration of illness after onset (SD):** 12.4 (5.3) yrs **BMI (SD) (kg/m^2):** 18.2 (3.4) **BMI** < 17.5: 31%	**Score:** Fair **Method of dx:** Retrospective using DSM IV **Funding:** NR

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods: Retrospectively identified 61 patients with DSM IV crit. for AN who had inpatient tx at least 4 yrs prior. Contacted by telephone for face-to-face or telephone semi-structured interview and assessment. Those not participating in interview were given only assessments packets. Data confirmed by interviewing spouse or parent. Information on deceased patients provided by parent. Japanese version of EDI, EAT administered **Statistical Method:** One way ANOVA Chi Square Kruskal-Wallis **Outcomes** M-R Outcome Assessment Schedule for prior 6 mos: Avg composite outcome from ratings on 12 patient scale of avg of 5 subscales (eating difficulties, menstrual state, mental state, psychosexual state, socioeconomic state). General outcome based on wt and menstrual function for prior 6 mos: Good: Wt within 15% ABW and regular menses Intermediate: Wt within 15% ABW, but not sustained and/or menstrual disturbances. Poor: Wt less than within 15% ABW and menses absent or near absent OR bingeing and or purging wkly	**Descriptive Results:** **FU menstruation status:** Regular menses = 63.0% Amenorrhea = 22.2% **M-R Outcomes:** Good: 31 (51%) Intermediate: 8 (13%) Poor: 15 (25%) Deceased: 7 (11%) **Predictors of general outcome categories:** **Good vs Poor:** Younger at referral *(P* = 0.01) Younger at admission *(P* = 0.01) Higher BMI at FU *(P* < 0.001) Higher min BMI *(P* = 0.005) **Good vs. Intermediate:** Higher BMI at FU *(P* < 0.001) **Good vs. Deceased:** Fewer number of admissions *(P* = 0.001) **Intermediate vs. Deceased:** Fewer number of admissions *(P* = 0.001) **Poor vs. Deceased:** Fewer number of admissions *(P* = 0.001) **Predictors at FU of M-R outcome categories:** **Good vs. Poor:** Higher food intake *(P* < 0.001) Higher body wt *(P* < 0.001) Better menstrual state *(P* < 0.001) Better mental state *(P* < 0.001) Better attitude towards sexual matters *(P* = 0.002) Greater overt sexual behavior *(P* < 0.001) Better relationship with family *(P* < 0.001) Greater emancipation from family *(P* < 0.001) Greater social contacts outside family *(P* = 0.03) Greater social activities outside family *(P* < 0.001) **Good vs. Intermediate:** Higher food intake *(P* < 0.001) Higher body wt *(P* < 0.001) Better menstrual state *(P* < 0.001) Greater emancipation from family *(P* < 0.001)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Tolstrup et al., 1985 **Design:** Case series through record review and FU **Comparison Group:** No **Location:** Copenhagen, Denmark **Yrs followed:** Mean = 12.5 Range (4-22)	Report the long-term outcome of AN using an intensive and comprehensive evaluation at FU in a large enough sample for statistical validity after an adequate observation period. Comparing outcome across three hospital points of contact.	**Inclusion:** Dx of AN by the following criteria: Wt loss via reduced food intake, vomiting or excessive activity; Amenorrhea (if reproductive age); Distorted body image; clinical picture not explained by other somatic or psychiatric illness **Exclusion:** Inpatient < 1 wk or < 2 outpatient visits; Other somatic dx (e.g., ulcer, psychosis) **Recruitment:** Review of all hospital records with a dx of AN from three departments at Rigshospital, University of Copenhagen, Child Psychiatry, Psychiatry, and Internal Medicine, 1960-1976. **Sample Size:** **Initial sample:** Records reviewed: 192 Records selected: 151 Child Psychiatry: 64 Psychiatry: 51 Internal Medicine: 36 **Reasons for loss to FU:** Deaths: N = 9 **Analysis sample:** N = 142 surviving at FU Interviewed: 114 Questionnaire: 19 Hospital records: 6 Central Registry only: 3	**Mean Age at baseline (yrs):** Total: 19 Child Psychiatry: 15.2 Psychiatry: 24.2 Internal Med: 21.7 **Sex:** Female: 140 Male: 11 **Race/ethnicity:** NR **Mean % Underwt (at baseline):** Total: 32 Child Psychiatry: 29 Psychiatry: 34 Internal Med: 34 **Mean duration of Illness at baseline (yrs):** Total: 2.4 Child Psychiatry: 1.4 Psychiatry: 3.2 Internal Med: 2.1 **Mean Duration of Treatment (mos):** Total: 12 Child Psychiatry: 17 Psychiatry: 13 Internal Med: 2.5 **Previous hospitalization (before primary contact):** Total: 64% Child Psychiatry: 69% Psychiatry: 65% Internal Med: 56% **Mean age at FU, yrs (range):** 31 (16-63) **Mean wt at FU**: 84% of reference	**Score:** Poor **Method of dx:** Review of records by authors to meet the diagnostic inclusion criteria **Funding:** the Danish Medical Research Council, the Gangsted-Rasmussen Fonde, the Enketru C. Hermansens Mindelegat, the Petra Slettens Fond

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods FU record review conducted 1981-82 Surviving subjects contacted and invited to participate in semi-structured interview lasting approx 120 min (87 were audiotaped; 12 were videotaped) The interview included: • Determination of socioeconomic status (SES) • Global clinical evaluation General somatic outcome: Good: wt ≥ 86% ABW, normal menstruation (if female) Intermediate: Wt 71 – 85% ABW Poor: wt ≤70 % ABW; Psychiatric dx Subjects who were also parents were invited to participate in supplementary interview on parental functioning For those subjects who could not be interviewed in person, interview was mailed as a questionnaire when possible. In some cases, hospital records or government records were only information available **Outcomes:** Global clinical evaluation: Interviewer's evaluation **General somatic outcome, modification of M-R criteria:** Good: wt 86-114% of ABW, menstruation normal Intermediate: wt 71%-85% of ABW, and menstruation mostly absent or sporadic Poor: wt 70% of ABW or less, menstruation mostly absent or sporadic	**Subjects deceased**: 9 Cause of death: suicide 6; malnutrition 2; unclear: 1 Mean age at death: 27.1 yr Department of primary contact for the deceased: Child Psychiatry: 1; Psychiatry: 5; Internal Medicine: 3 **Global Clinical Evaluation:** Well-functioning: 49 (43%) Moderately impaired: 44 (39%) Poorly functioning: 21 (18%) **General somatic outcome, N (%)** Good: 60 (40) Intermediate: 44 (29) Poor: 29 (19) Dead: 9 (5) Diff between departments *(P* = NS) Diff between departments over time *(P* = NS) **Psychiatric dx, N (%)** No mental disorder: 61 (47) AN: 37 (25) (includes 8 with BN variants) Neurosis: 15 (11) Psychotic depression: 9 (6) Schizophrenia: 3 (2) Borderline psychosis: 4 (3) Character disorder: 2 (1) Diff between departments *(P* = NS) Diff between departments over time *(P* = NS)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Wentz et al., 2001 **Companion article:** Gillberg, Råstam and Gillberg, 1995 Ivarsson et al., 2000 Nilsson et al., 1999 Wentz et al., 2000 **Companion article:** Wentz et al., 2001 **Design:** Prospective cohort **Comparison Group:** Yes **Location:** Göteberg, Sweden **Yrs followed:** 10 (1985-1996)	Compare the rate of psychiatric disorders in an AN group with a community matched sample, 10 yrs after reported AN onset Examine whether long term outcome is worse in AN group and related to specific personality and/or psychiatric disorders.	**Inclusion:** **Cases:** DSM III-R for AN Born 1970 AN onset < 18 yrs old **Comparison:** Matched to cases on age, sex, school **Exclusion:** **Cases:** None **Comparisons:** None **Recruitment:** **Cases:** From total population of Göteburg, Sweden, born in 1970 and developing AN before age 18; pooled with second population screening sample reported by school and hospital health care workers during FU. Some clinically referred and some screened through school nurses and doctors, pediatricians, and child psychiatrists **Comparisons:** Same schools as AN group **Sample Size:** Cases: 51 Comparisons: 51	**Mean Age (yrs):** Cases: 24.5 95% CI (24.0-25.0) Comparisons: 24.2 95% CI (23.7-24.7) **Age at onset:** 14.3 Range: 13.9-14.7 **Sex:** **Cases**: Female: 48 Male: 3 **Comparison:** Female: 48 Male: 3 **Race/ethnicity:** NR **Full-time employment** Cases: 65% Comparison: 88% (*P* < 0.01) **Cases with at least 8 sessions of some form of tx:** N = 29 **AN duration:** **Cases**: 3.3yrs; 95% CI (2.7-3.8) **ED duration Cases:** 6.3yrs; 95% CI (5.4-7.2) **BN symptoms:** **Cases**: 75%	**Score:** Good **Method of dx:** AN evaluation by school nurse and psychiatrist by structured interview using SCID; personality disorder and/or autism via blind evaluation of case hx by psychiatrist **Funding:** Swedish Medical Research Council, Göteborg Medical Society, Wilhelm and Martina Lundgren Foundation, Göteborg Freemasons, Söderström-Königska Nursing Home Foundation, and grants from the state under the LUA agreement

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods Assessment evaluation by a psychiatrist for Axis 1 dx; by another blinded psychiatrist for Axis 2 and ASD dx via SCID-1 and 2 structured interview (3 by telephone). Eating behavior evaluated using EAT. Outcomes based on M-R Scales, GAF **Statistical Methods** Chi-square test for matched and unmatched pairs for psych dx Two-sample t-test for BMI, anthropometric data McNemar test for for MR subscales Wilcoxon (Mann-Whitney) rank sum test for median GAF scores Spearman rank order correlation coefficient for correlations between the M-R and GAF scores **Outcome Definitions** **Full recovery from ED:** no disturbed eating attitude or behavior in respect to food and shape for at least 6 mos before assessment	**Descriptive Results** **Current body wt** AN: 62.3 kg, 95% CI (58.5-66.1) Comparisons: 63.7 kg, 95% CI (60.8 – 66.5) Diff between groups *(P* = NS) **Current BMI** AN: 22.2 kg/m2, 95% CI (21.0-23.4) Comparisons:22.2 kg/m2 95% CI (21.2-23.2) Diff between groups *(P* = NS) **Free from ED Symptoms/Full Recovery from ED:** AN: 39% Comparisons: 90% Diff between groups *(P* < 0.001) **Diff between groups in current psychiatric disorders** Major depression unipolar *(P* = NS) Major depression bipolar I *(P* = NS) Major depression bipolar II *(P* = NS) Dysthymic disorder *(P* = NS) Any effective disorder *(P* = NS) Panic disorder *(P* = NS) Social phobia *(P* = NS) Simple phobia *(P* = NS) OCD, AN: 8; Comparisons: 1 *(P* < 0.05) General anxiety disorder *(P* = NS) Any anxiety disorder *(P* = NS) Psychotic disorder *(P* = NS) Substance abuse *(P* = NS) Any axis I disorder (inc ED) AN: 27; Comparisons: 14 *(P* < 0.05) Any axis I disorder (exc ED) *(P* = NS) **Diff between groups in lifetime psychiatric disorders** Major depression unipolar *(P* = NS) Major depression bipolar I *(P* = NS) Major depression bipolar II *(P* = NS) Dysthymic disorder *(P* = NS) Any effective disorder: AN: 49; Comparisons: 12 *(P* < 0.0001) Panic disorder *(P* = NS) Social phobia *(P* = NS) Simple phobia *(P* = NS) OCD: AN: 18; Comparisons: 5 *(P* < 0.01) General anxiety disorder *(P* = NS) Any anxiety disorder: AN: 29; Comparisons: 16 *(P* < 0.02) Psychotic disorder *(P* = NS) Substance abuse *(P* = NS) Any axis I disorder (inc ED) AN: 51; Comparisons: 26 *(P* < 0.0001) Any axis I disorder (exc ED): AN: 51; Comparisons: 26 *(P* < 0.0001) **Current Eating Disorders** AN: AN 6%; Comparisons: 0% BN: AN 4%; Comparisons: 0% EDNOS: AN:18%; Comparisons: 0%

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Wentz et al., 2001 (continued)				

Study Methods and Analytic Strategy	Main Outcomes and Results
	Avg M-R Scale Score AN: 9.4, 95% CI (8.8-10.0) Comparisons: 11.2, 95% CI (10.8-11.5) Diff between groups *(P* < 0.0001*)* **Dietary restriction** AN: 47%; Comparison: 16% Diff between groups *(P* < 0.01*)* **Worry about body wt and appearance** AN: 69%; Comparisons: 27% Diff between groups *(P* < 0.001) **Normal menstruation** AN: 65%; Comparisons: 85% Diff between groups *(P* < 0.05) **Mean GAF Score** AN: 65.3, 95% CI (61.0-69.7) Comparisons: 84.8, 95% CI (81.7-87.9) Diff between groups *(P* < 0.0001)

Evidence Table 15. Anorexia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality Adverse Events
Authors, yr: Wentz et al., 2000 **Companion article:** Ivarsson et al., 2000 Nilsson et al., 1999 Råstam, Gillberg and Gillberg, 1995 Wentz et al., 2001 **Design:** Prospective cohort **Comparison Group:** Yes **Location:** Göteberg, Sweden **Yrs followed:** 10 (1985-1996)	To examine prospectively the long-term medical complications in a community-based study of AN	**Inclusion:** **Cases:** DSM III-R for AN Born 1970 AN onset < 18 yrs old **Comparison:** Matched to cases on age, sex, school **Exclusion:** **Cases:** None **Comparisons:** None **Recruitment:** **Cases:** From total population of Göteburg, Sweden, born in 1970 and developing AN before age 18; pooled with second population screening sample reported by school and hospital health care workers during FU. Some clinically referred and some screened through school nurses and doctors, pediatricians, and child psychiatrists **Comparisons:** Same schools as AN group **Sample Size:** Cases: 51 Comparisons: 51	**Mean age at first examination:** Cases: 16.1, 95% CI (15.7-16.5) Comparisons: 16.0, 95% CI (15.5-16.6) **Mean Age at FU** Case: 24.5, 95% CI (24.0 -25.0) Comparisons: 24.2, 95% CI (23.7-24.7) **Sex:** Cases: Females: 48 Males: 3 **Race/ethnicity:** NR	**Score:** Good **Method of dx:** Independent clinician, used SCID at FU **Funding:** Medical Research Council grant, Wilhelm and Martina Lundgren Foundation, Göteborg Medical Society, Göteborg Freemasons, Söderström-Königska Nursing Home Foundation, and grants from the State

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods: The two groups were examined by a psychiatrist blind to diagnostic group status, who performed all neurodevelopmental and neurological examinations. Physical examinations were also conducted on all participants, and gross motor skills, tremor, and diadochokinesis (DDK) were measured using a battery of tests. Poor outcome was defined by M-R classification, based on low wt and absent or scanty menstruation. Ratnasuriya et al. (1991) Modified outcome criteria was used, including persisting eating disorder in the poor outcome definition. **Statistical methods:** Neurodevelopmental tests and the frequencies of physical disorders were analysed with the χ2 tests.	**Descriptive Results:** **Mean (SD) wt, height, and BMI of AN and Comparisons groups at 16, 21, and 24 yrs (10 yr FU):** **Wt, kg:** Cases: 16 yrs: 49.4 (8.8) diff between cases and comparisons *(P* < 0.01) 21 yrs: 58.9 (11.8) 24yrs: 62.3 (12.7) Comparisons: 16 yrs: 56.2 (6.6) 21 yrs: 60.4 (7.9) 24yrs: 63.7 (10.0) **BMI, kg/m2:** Cases: 16 yrs: 18.3 (2.9) 21 yrs: 21.2 (3.5) 24yrs: 22.2 (4.1) Comparisons: 16 yrs: 20.2 (1.9) 21 yrs: 21.2 (2.3) 24yrs: 22.2 (3.4) **Diff between groups in psychiatric disorders at FU** **Overall** Cases: 53% Comparisons 27% *(P*<= 0.05) **Anxiety disorders** Cases: 35% Comparisons 22% *(P* = NS) **OCD:** Cases: 16% Comparisons 2% *(P* < 0.05) **Depressive disorder, lifetime dx** Cases: 96% Comparisons: 24% *(P* < 0.0001) **Current depressive disorder:** Cases: 10% Comparisons 4% *(P* = NS) **Diff between groups in physical complaints/disorders:** **Gastrointestinal problems** Cases: 47% Comparisons: 27% (*N* = 14) *(P* = 0.05) Hirsuitism: more prevalent in cases *(P* = 0.05) **Diff between groups in neurodevelopmental findings:** Fine and gross motor skills, coordination, tremor, mirror movements, or handedness *(P* = NS) Dysdiadochokinesis Cases: N = 11 Comparisons: N = 2 *(P* < 0.01)

Evidence Table 16. Bulimia nervosa outcomes

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Ben-Tovim et al., 2001 **Design:** Case series **Comparison Group:** No **Location:** Adelaide, South Australia **Yrs followed:** 5	To identify predictors of outcome and to assess effects of available txs for AN or BN	**Inclusion:** 15 yrs old and older; living in Adelaide, South Australia; either making first contact with secondary or tertiary services for tx of ED or were recontacting such services after a tx break of at least 6 mos. **Exclusion:** None **Recruitment:** Agreement to participate was obtained from all identifiable specialist service providers in Adelaide, apart from one psychiatrist in individual practice. **Sample Size:** Fulfilled criteria: N = 235 Agreed to participate: N = 220 **Baseline sample:** **AN**: N = 95 **BN:** N = 88 **Reasons for loss to FU:** **Anorexia:** 3 deaths, of which, 2 related to ED **BN:** 2 lost, reason NR **Analysis Sample Size at FU:** **AN:** N = 92 **BN:** N = 86	**Mean Age (SD):** **AN:** 22.5 (6.9) **BN:** 23.8 (6.4) **Sex:** Female: 100% **Race/ethnicity:** NR **Wt, kg, Mean (SD):** **AN:** 44.8 (6.5) **BN:** 62.6 (10.8) **Height, m, Mean (SD):** **AN:** 1.65 (0.07) **BN:** 1.65 (0.06) **BMI, Mean (SD):** **AN:** 16.5 (1.9) **BN:** 23.1 (3.9) **Duration of ED, yrs:** **AN:** 7.4 (7.0) **BN:** 6.4 (4.7) **AN subtype at initial assessment:** Abstainers: 59% Binge-purgers: 41%	**Score:** Fair **Method of dx:** Dx made by treating clinician and confirmed by Flinders Symptom Score (FSS) interview. Dx was according to DSM III-R **Funding:** Australian National Health and Medical Research Council, Flinders 2000, and the Centre for Applied Research in Mental Health

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods Evaluation in person or by telephone annually. **Statistical Methods** Dependent variable: Total scores from M-R-H scales at 5 yrs **Multiple Regression** **M-R-H Subscales:** Subscale A: Dietary and eating patterns, body concern, and body wt Subscale B: Menstrual pattern Subscale C: Mental State Subscale D: Psychosexual state Subscale E: Work and Family Relations	**Descriptive Results** **AN:** **Dx at 5 yrs:** AN: 20 (21%) BN: 5 (5%) EDNOS: 9 (9%) No ED: 56 (59%) Unknown: 2 (2%) Died: 3 (3%) **M-R-H Outcomes:** Good (mean score: 8 – 12): 32 (34%) Intermediate (score 4 - < 8): 51 (54%) Poor **(**score 0 - < 4) 12 (13%) **BN** **Dx at 5 yrs:** AN: 1 (1%) BN: 7 (8%) EDNOS: 11 (13%) No ED: 65 (74%) Unknown: 4 (5%) Died: 0 **M-R-H Outcomes:** Good: 67 (76%) Intermediate (score 4 - < 8): 17 (19%) Poor (score 0 - < 4) 2 (2%) Unknown: 2 (2%) **Multivariate Results** **Predictors of higher M-R-H total mean score at 5 yrs:** **AN:** **Model 1** Age *(P* = 0.48) M-R-H subscale A at baseline *(P* = 0.02) pos assoc. M-R-H subscale B at baseline *(P* = 0.11) M-R-H subscale C at baseline *(P* = 0.13) M-R-H subscale D at baseline *(P* = 0.23) M-R-H subscale E at baseline *(P* = 0.17) Duration of Illness (yrs) *(P* = 0.18) BMI at baseline *(P* = 0.08) pos assoc Goodness of fit model *(P* < 0.0001), R2 = 0.0.33 **Model 2** Disability adjustment scale, subscale 2 at baseline *(P* = 0.0006) neg assoc Flinders Medical Centre Symptom Score at baseline *(P* = 0.03) neg assoc Body Attitudes Questionnaire Subscales: Attractiveness at 6 mo *(P* = 0.008) pos assoc Change in salience of wt and shape over first 6 mos *(P* = 0.024) pos assoc Goodness of fit model *(P* < 0.0001), R2 = 0.25

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Ben-Tovim et al., 2001 (continued)				

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods Evaluation in person or by telephone annually. **Statistical Methods** Dependent variable: Total scores from M-R-H scales at 5 yrs **Multiple Regression** **M-R-H Subscales:** Subscale A: Dietary and eating patterns, body concern, and body wt Subscale B: Menstrual pattern Subscale C: Mental State Subscale D: Psychosexual state Subscale E: Work and Family Relations	**Descriptive Results** **BN:** **Model 1** Age *(P* = 0.47) M-R-H subscale A at baseline: *(P* = 0.01) neg assoc M-R-H subscale B at baseline *(P* = NS) M-R-H subscale C at baseline *(P* = NS) M-R-H subscale D at baseline *(P* = NS) M-R-H subscale E at baseline *(P* = NS) Duration of Illness (yrs) *(P* = NS) BMI at baseline *(P* = NS) Goodness of fit model *(P* < 0.056); R^2 = 0.085 **Model 2** Disability adjustment scale, subscale 2 at recruitment *(P* = 0.009) neg assoc Body Attitudes Questionnaire Subscales: Feeling fat at recruitment *(P* = 0.02) neg assoc Attractiveness at 6 mo *(P* = 0.001) pos assoc Change in Zung Depression over first 6 mos *(P* = 0.0003) pos assoc Goodness of fit model *(P* < 0.0001), R^2 = 0.31

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Fairburn et al., 1995 **Design:** Case series **Comparison Group:** No **Location:** Oxford, England **Mean Yrs followed (SD):** 5.8 (2.0)	To assess and compare the long-term outcomes of patients with BN and identify predictors of outcomes.	**Inclusion:** Female, over 17 yrs of age, BN according to Russell criteria, wt > 79% of matched mean wt (Fairburn et al., 1986) For prior 6 mos, met criteria for BN (DSM IIII-R); aged 17 yrs or older; BMI > 17 (Fairburn et al., 1991) **Exclusion:** Co-existing major psychiatric disorder other than depressive, anxiety, or obsessional state, current physical dependence on alcohol or drugs, need for hospitalization, on-going tx from another source, not available through 1 yr FU (Fairburn et al., 1986) Concurrent AN (Fairburn et al., 1991) **Recruitment:** Tx referrals from general practitioners and psychiatrists within community (Oxfordshire, England) Recruited for first trial 1982-1984: N = 24 Recruited for second trial 1985-1988: N = 75 **Sample Size:** **Initial sample:** Total = 99 Trial 1: N = 20 Trial 2: N = 69 CBT: N = 35 FIT: N = 32 BT: N = 22 **Reasons for loss to FU:** Untraceable: N = 2 Declined participation: N = 3 Did not respond: N = 3 Refused face-to-face or phone interview: N = 1 Died: N = 1 **Analysis sample:** N = 89 (those who participated in either a face-to-face or phone FU interview)	**Mean number of binge days per 28 days at baseline (SD):** 24.8 (18.5) **Mean number of self-induced vomiting episodes per 28 days at baseline (SD):** 31.9 (38.8) **Mean number of laxative misuse episodes per 28 days at baseline (SD):** 4.3 (10.0) **Body wt at baseline, kg (SD):** 60.6 (10.1) **BMI at baseline, kg/m^2 (SD):** 22.0 (3.1) **Mean Age at FU, yrs (SD):** 29.6 (5.5) **Mean duration of ED at Baseline, yrs (SD):** 6.7 (5.1) **Marital Status at FU (%):** Single: 30% Married/living as married: 69% Divorced: 1% **Employment Status at FU (%):** Paid: 71% Students: 9% At home: 15% Unemployed or disabled: 5% **Sex:** Female: 100% **Race/ethnicity:** NR **Mean age at study recruitment:** Trial 1: 22.5 (3.8) Trial 2: 24.3 (6.0)	**Score:** Fair **Method of dx:** EDE with an experienced clinician based on DSM IV criteria for eating disorders Sections from the SCID (DSM III-R version) were used to assess for mood, anxiety, and psychoactive substance use disorders **Funding:** United Kingdom Medical Research Council; Wellcome Trust

Study Methods and Analytic Strategy	Main Outcomes and Results
Treatment: Analysis combines samples drawn from 2 similar RCTs that compared effectiveness of various psychotherapy techniques for the tx of BN symptomatology (i.e., CBT, BT, FIT = focal interpersonal therapy). **Study 1:** Short term psychological tx (CBT) administered in 19 sessions over 18 wks **Study 2:** Either CBT, BT or FIT **Study Methods** FU participants did not have to complete tx. At FU, participants administered EDE, portions of SCID, Brief Symptom Inventory (for general psychiatric symptoms), and Adult Personality Functioning Assessment interview (for dimensions of social functioning). Each participant's physical hth and medical hx also queried at time of the FU interview. **Statistical Analyses** Both parametric and nonparametric tests used to evaluate sig diffs in variables of interest. Forward stepwise regression analyses performed to test for sig predictors of outcome. A 3x4 repeated measures ANOVA conducted to identify any sig tx effects on outcome. Log-odds models of tx were computed.	**Descriptive Findings** **Eating Disorder Diagnostic Status at FU (%):** AN: 3% BN: 19% EDNOS: 24% **Psychiatric Status at FU:** Major depressive disorder: N = 8 Anxiety: N = 16 Substance use: N = 3 AN/BN (60%) versus non-AN/BN (19%) *(P* < 0.001) Higher rates of general psychiatric disorders in the ED group **Remission Status (no DSM ED) at 12-mo and 6-yr FU (%):** Had ED at end of tx and remission at 12 mos: 24% Had ED at end of tx and remission at 6 yr: 41% No ED end of tx and 12 mo FU: 82% No ED end of tx and 6 yr FU: 71% **Proportion with AN or BN at FU by original tx received:** CBT: 20% FIT: 27% BT: 22% *(P* = NS) **Change in Eating-related Measures from recruitment to FU:** Mean binge episodes/28 days: *(P* < 0.0001) reduction Mean vomiting episodes/28 days *(P* < 0.0001) reduction Mean laxative misuse episodes/28 days *(P* < 0.0001) reduction Dietary restraint *(P* < 0.0001) reduction Overeating *(P* < 0.0001) reduction Eating concern *(P* < 0.0001) reduction Shape concern *(P* < 0.0001) reduction Wt concern *(P* < 0.0001) reduction Global EDE *(P* < 0.0001) reduction Psychiatric symptom *(P* < 0.0001) reduction **Change in Body-related Measures from Baseline to FU:** Body wt: *(P* = 0.018) increase 1.57 (6.14) kg BMI *(P* = NS) **Remission Rates at FU based on original tx received:** CBT: OR = 3.43, 95% CI (1.77-6.63) FIT: OR = 2.58, 95% CI (1.32 to 5.02) BT: comparison *(P* < 0.001) **Abstinence rates for key behavioral features of BN at FU by original tx received:** CBT: 50% FIT: 52% BT: 18% Diff between groups *(P* = 0.044) at end point No sig overall effect of tx on proportion of abstinent subjects and no diff effect of tx over time.

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Fairburn et al., 1995 (continued)				

Study Methods and Analytic Strategy	Main Outcomes and Results
	Mean reductions in Global EDE from baseline to FU by original tx condition (SD): CBT: 2.22 (1.00) FIT: 1.51 (1.00) BT: 1.36 (1.32) Change over time *(P* = 0.04) **Mean Eating Disorder symptom level at FU by original tx received (SD):** CBT: 1.27 (1.12) FIT: 1.50 (1.20) BT: 2.08 (1.27) Diff between CBT and FIT *(P* = 0.049) CBT had fewer symptoms Diff between CBT and BT *(P* = 0.015) CBT had fewer symptoms **Multivariate Results** **Predictors of Current AN or BN Outcome Status (adjusted for type of tx received and duration of FU):** Paternal obesity: OR = 5.73, 95% CI (1.56 -21.1) *(P* = 0.007) Premorbid obesity: OR = 4.31, 95% CI (1.35 -13.7) *(P* = 0.01) **Predictors of Change in Global EDE score Outcome:** Paternal obesity *(P* = 0.007) More severe is worse **Premorbid obesity:** *(P* = 0.005) More severe is worse

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Fairburn et al., 2000 **Companion article:** Fairburn et al., 2003 Stice and Fairburn, 2003 **Design:** Prospective cohort **Comparison Group:** No **Location:** Oxford, England **Yrs followed:** 5 yrs	To assess the natural course of primary and secondary symptoms in two community-based cohorts of BN and BED participants over a 5-yr span of time.	**Inclusion:** Met DSM IV diagnostic criteria for BN; Age 16 to 35 **Exclusion:** None **Recruitment:** Participants were originally recruited to take part in case-control studies investigating risk factors for BN. Potential participants were initially identified from among women registered with family practices within Oxfordshire, England. **Initial Sample Size:** At Recruitment: BN: N = 102 **Reasons for loss to FU:** BN: N = 1 untraceable; N = 2 nonresponders; N = 7 declined **Analysis sample size:** At 5-yr FU: BN: N = 92 (90%): 87 in-person interviews, 5 phone interviews Data on BED sample not reported due to small sample size (< 50)	**Mean Age at Baseline, yrs (SD):** 23.9 (5.0) **Marital status at Baseline (%):** Single: 59% Married/cohabitating: 36% Separated/divorced: 5% **Social Class at Baseline (%):** 1-2: 46% 3 (non-manual): 8% 3 (manual): 36% 4-5: 9% other: 2% **Sex:** Female: 100% **Race/ethnicity:** NR **Hx of AN (%):** 15% **Current Treatment for ED (%):** 10% **Past Treatment for ED (%):** 16% **Mean Age at Onset of ED, yrs (SD):** 15.7 (4.3)	**Score:** Good **Method of dx:** EDE interview **Funding:** Wellcome Trust program grant; Henry J. Kaiser Family Foundation and the Center's Foundations' Fund for Research in Psychiatry

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods Participants were contacted at 15-mo intervals over the course of a 5-yr period. They were administered a series of self-report questionnaires including the BSI, the Robson self-esteem questionnaire, and the Social Adjustment Scale. Eating disorder primary (i.e., objective bulimic episodes, self-induced vomiting, laxative misuse) and secondary (i.e., restraint, wt concern, eating concern, shape concern) symptoms were assessed through clinical interview with the EDE at each time point. **Statistical Analyses** Descriptive statistics for reporting means, standard deviations, and percentages of variables at different time points. Paired t-tests and Wilcoxon matched pairs or McNemar tests to assess sig changes from recruitment to 5-yr FU.	**Descriptive Findings** **% BN at each FU Time Point (N = 74):** 15-mos: 31% 30-mos: 20% 45-mos: 19% 60-mos: 15% **%BED at each FU Time Point:** 15-mos: 4% 30-mos: 8% 45-mos: 5% 60-mos: 7% **%AN at each FU Time Point:** 15-mos: 3% 30-mos: 3% 45-mos: 4% 60-mos: 1% **%EDNOS at each FU Time Point:** 15-mos: 32% 30-mos: 40% 45-mos: 35% 60-mos: 32% **% Any DSM IV ED at each FU Time Point:** 15-mos: 66% 30-mos: 64% 45-mos: 58% 60-mos: 49% **% Remission (No DSM IV ED Dx):** 15-mos: 34% 30-mos: 20% 45-mos: 28% 60-mos: 35% **% Relapse (Any DSM IV ED Dx):** 30-mos: 32% 45-mos: 33% 60-mos: 26% **Psychoactive Drug Use at 5-yr FU (%):** 3% **BMI Status at 5-yr FU (%):** < 20.0: 12% 20-24.9: 53% 25.0-29.9: 15% > or = 30: 20% **Exposure to Treatment (%):** During FU: 28% By end of FU: 40%

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Fairburn et al., 2000 (continued)				

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
	Outcomes at 5 yr FU: **Mean Objective Bulimic Episodes (Binge-eating) w/in last 3 mos (SD):** 15.3 (29.4) Reduction from baseline *(P* < 0.001) **Mean Self-induced Vomiting Episodes w/in last 3 mos (SD):** 15.5 (42.9) Reduction from baseline *(P* < 0.001) **Mean Laxative Misuse w/in last 3 mos (SD):** 3.4 (14.8) Reduction from baseline *(P* < 0.001) **Mean EDE Restraint (SD):** 1.82 (1.59) Reduction from baseline *(P* < 0.001) **Mean EDE Shape Concern (SD):** 2.55 (1.49) Reduction from baseline *(P* < 0.001) **Mean EDE Wt Concern (SD):** 2.35 (1.50) Reduction from baseline *(P* < 0.001) **Mean EDE Eating Concern (SD):** 0.84 (1.13) Reduction from baseline *(P* < 0.001) **Mean BSI (SD):** 0.90 (0.77) Reduction from baseline *(P* < 0.01) **Alcohol Misuse (%):** 26% Increase from baseline *(P* < 0.05) **Mean Self-esteem (SD):** 42.3 (9.7) Change from baseline *(P* = NS) **Mean Social Adjustment (SD):** 1.40 (0.28) Change from baseline *(P* = NS) **Mean Wt, kg (SD):** 69.8 (19.2) Increase from baseline *(P* < 0.01) **Mean BMI (SD):** 25.5 (6.4) Increase from baseline *(P* < 0.05)

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Fairburn et al., 2003 **Companion article:** Fairburn et al., 2000 Stice and Fairburn, 2003 **Design:** Case series **Comparison Group:** No **Location:** England **Yrs followed:** 5	To identify predictors of persistence of BN and to test hypotheses derived from cognitive behavior theory of persistence.	**Inclusion:** Women DSM IV for BN **Exclusion:** None **Recruitment:** Patients in family practices in Oxfordshire, England. Screened with self-report version of the EDE. **Sample Size:** Sample size: N = 102 No loss to FU	**Mean Age at recruitment (SD):** 23.7 (4.9) **Sex:** Female: 100% **Race/ethnicity:** NR **Social class:** I or II (high): 47% III (middle): 45% IV or V (low): 9% **Age of full BN onset:** 19.0 (4.0) **No prior tx for ED:** 82% **No current tx for ED:** 89% **Some tx for ED during 5 yr FU:** 24%	**Score:** Good **Method of dx:** Interview using EDE **Funding:** Wellcome Trust program grant, NIMH

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods: Interviewer administered EDE, Brief Symptom Inventory **Statistical Methods:** ANOVA or chi-square comparing remitted and persistent outcome groups **Multiple regression used for change over time analyses.** **Binge eating outcome classifications:** **Persistent:** at least 2 episodes of behavior at 1 or both of last 2 assessments **Remitted:** not engaged in any relevant behavior (over past 3 mos) at 2 consecutive assessments and all subsequent assessments **Not classified** Analyses compares binge eating outcomes separately based on: 1) binge eating behaviors and 2) compensatory behaviors	**Descriptive Findings** **Binge eating outcome classification based on binge eating behavior (N):** Remitted: 39 (38%) Persistent: 45 (44%) Not classified: 18 (18%) *(P* = NR) **Binge eating outcome classification based on compensatory behavior (N):** Remitted: 39 (38%) Persistent: 49 (48%) Not classified: 14 (14%) *(P* = NR) **Relationship between remitted vs. persistent binge eating outcome (based on binge eating behaviors) and baseline variables:** Age at onset *(P* = NS) Duration of disturbed eating: Persistent: 9.8; Remitted: 6.9 *(P* < 0.01) Binge eating frequency *(P* = NS) Compensatory behavior frequency *(P* = NS) Global EDE Score *(P* = NS) Overevaluation of shape and wt: Persistent: 3.2; Remitted: 2.6 (*P* < 0.05) Dietary restraint *(P* = NS) General psychiatric symptoms *(P* = NS) Self-esteem *(P* = NS) Social adjustment: Persistent: 1.5; Remitted: 1.3; *(P* < 0.05) BMI *(P* = NS) Proportion with hx of AN: *(P* = NS) Proportion with hx of childhood obesity: RR = 1.9, 95% CI (1.1-3.5) *(P* < 0.05) Proportion classified as persistent based on compensatory behavior: RR = 2.6, 95% CI (1.6-4.2) *(P* < 0.0001) **Relationship between remitted vs persistent binge eating outcome (based on compensatory behavior) and baseline variables:** Age at onset *(P* = NS) Duration of disturbed eating *(P* = NS) Binge eating frequency *(P* = NS) Compensatory behavior frequency *(P* = NS) Global EDE Score *(P* = NS) Overevaluation of shape and wt *(P* = NS) Dietary restraint *(P* = NS) General psychiatric symptoms *(P* = NS) Self-esteem *(P* = NS) Social adjustment *(P* = NS) BMI *(P* = NS) Proportion with hx of AN: *(P* = NS) Proportion with hx of childhood obesity *(P* = NS) Proportion classified as having persistent course based on binge eating behavior: RR = 3.0, 95% CI (1.6-5.4) *(P* < 0.0001)

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Fairburn et al., 2003 (continued)				

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
	Multivariate Findings **Change over time:** Change in frequency of binge eating: • Related to initial overall evaluation of shape and wt *(P* < 0.07) • Initial level of overevaluation of shape and wt nonsig when effects of change in dietary restraint sig controlled in model. **Change in level of restraint:** • Pos related to initial level of overevaluation of shape and wt *(P* < 0.01)

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Fichter and Quadflieg, 2004 **Design:** Case series **Comparison Group:** Yes **Location:** Upper Bavaria, Germany **Yrs followed:** 12	To describe the longer-term course and outcome of BN and to identify risk factors for an unfavorable course.	**Inclusion:** **Cases:** BN-Purging type per DSM IV *(*Patients reassessed in later yrs per DSM IV and were included if met diagnostic criteria at time of hospital admission) **Comparisons:** Females, aged 18-30, never suffered from eating disorder **Exclusion:** None reported **Recruitment:** Cases: Of 635 consecutively admitted patients with eating disorders between 9/85 – 6/88, 196 met inclusion criteria. **Comparisons:** general population **Sample Size:** **Cases:** Began tx: N = 196 Completed 2 yr FU: 194/196 (99%) Completed 6 yr FU: 185/194 alive (95.4%) Completed 12 yr FU: 163/192 alive (84.9%) Comparisons: N = 202 **Reasons for Loss to FU** Unable to reach: N = 3 Refused participation: N = 26	**Age at admission, mean (SD):** 25.6 (6.7) **Sex:** Female: 100% **Race/ethnicity:** NR **Length of inpatient tx, days, mean (SD):** 95.5 (42.6)	**Score:** Fair **Method of dx:** Structured Interview for AN and Bulimic Syndromes (SIAB-EX) **Funding:** Wilhelm Sander-Stiftung, Munich, Germany; German Bundesministerium fur Bildung Forschung und Technologie (BMBF)

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods Patients were assessed at the beginning of inpatient tx, at the end of tx, at 2, 6, and 12 yr FU. Each FU consisted of two steps: all patients completed a questionnaire and were then contacted for an interview **Analytic Strategy** MANOVA with repeated measures based on five time points. Post hoc Scheffe range tests when appropriate. Logistic regression with all predictors entered in step one. Standardized mortality ratio computed on the basis of expected deaths between 1/87 and 9/99 in the West German female population controlled by age groups.	**Descriptive Results** Body image, ideal of slimness, and bulimic behavior decreased in severity at 12 yr FU when compared with any previous time –point *(P* < 0.001). Values NR **BMI:** End of tx: 21.1 (4.5) 12 yr FU: 22.1 (5.3) Diff over time *(P* = NR) **Obesity (BMI > 30), N (%):** 2 yr FU: 12/192 (6.3%) 6 yr FU: 11/182 (6.0%) 12 yr FU: 14/163 (8.6%) Diff over time *(P* = NR) **BMI < 17.5, N (%):** 2 yr FU: 12/192 (6.3%) 6 yr FU: 12/182 (6.6%) 12 yr FU: 8/163 (4.9%) Diff over time *(P* = NR) **EDI, drive for thinness:** Baseline: 12.5 (5.5) End of tx: 6.8 (5.5) 2 yr FU: 7.5 (6.0) 6 yr FU: 5.1 (5.7) 12 yr FU: 3.3 (4.2) Diff over time *(P* < 0.001) **EDI, bulimia:** Baseline: 12.5 (4.7) End of tx: 3.3 (4.3) 2 yr FU: 6.1 (5.8) 6 yr FU: 4.0 (5.1) 12 yr FU: 2.4 (4.0) Diff over time *(P* < 0.001) **EDI, body dissatisfaction:** Baseline: 16.7 (8.5) End of tx: 10.4 (9.2) 2 yr FU: 12.2 (9.1) 6 yr FU: 10.2 (8.4) 12 yr FU: 8.9 (8.2) Diff over time *(P* < 0.001) **EDI, perfectionism:** Baseline: 6.8 (4.8) End of tx: 5.4 (3.7) 2 yr FU: 5.7 (3.9) 6 yr FU: 5.2 (3.7) 12 yr FU: 4.7 (3.3) Diff over time *(P* < 0.001)

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Fichter and Quadflieg, 2004 (continued)				

Study Methods and Analytic Strategy	Main Outcomes and Results
	Diagnostic Outcome at 2 yrs (N = 162), N (%): Recovered and no ED dx: 86 (53.1%) AN-restricting: 1 (0.6%) AN-binge/purge type: 2 (1.2%) BN-purging type: 48 (29.6%) BN-nonpurging type: 7 (4.3%) BED: 0 EDNOS: 12 (7.4%) Deceased: 0 **Diagnostic Outcome at 6 yrs (N = 162), N (%):** Recovered and no ED dx: 108 (66.7%) AN-restricting: 2 (1.2%) AN-binge/purge type: 5 (3.1%) BN-purging type: 34 (21.0%) BN-nonpurging type: 1 (0.6%) BED: 2 (1.2%) EDNOS: 2 (1.2%) Deceased: 2 (1.2%) **Diagnostic Outcome at 12 yrs (N = 162), N (%):** Recovered and no ED dx: 107 (66.0%) AN-restricting: 1 (0.6%) AN-binge/purge type: 2 (1.2%) BN-purging type: 16 (9.9%) BN-nonpurging type: 1 (0.6%) BED: 3 (1.9%) EDNOS: 22 (13.6%) Deceased: 4 (2.5%) **Standard Mortality Ratio:** 2.36, 95% CI (0.05 – 4.67) **Bingeing at 12 yr FU:** At least twice per wk: 22.1% Less than twice per wk: 18.4% Not binged in the preceding three mos: 59.5% **Vomiting at 12 yr FU:** At least twice per wk: 20.8% Less than twice per wk: 11.3% Not at all: 67.9% **SIAB-EX Score at 12 yr FU:** Total scale: BN recovered (N = 114): 0.5 (0.3) BN all (N = 158): 0.6 (0.4) Healthy Comparisons (N = 202): 0.3 (0.2) Diff between BN recovered and healthy comparisons *(P* < 0.001) BN recovered greater than comparisons Diff between BN all and healthy comparisons *(P* < 0.01) BN all greater than comparisons **Amenorrhea:** Beginning of tx: 18.1% 12 yr FU: 1.6%

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Fichter and Quadflieg, 2004 (continued)				

Study Methods and Analytic Strategy	Main Outcomes and Results
	Psychiatric Co-morbidity at 12 yr FU: Lifetime 79.7%; current 1 mo: 41.1% Mood disorders: Lifetime 69.0%; current 1 mo: 16.5% Major depression: Lifetime 58.2%; current 1 mo: 10.8% Dysthymic: Lifetime 14.6%; current 1 mo: 5.1% Anxiety: Lifetime 36.1%; current 1 mo: 22.2% Substance use: Lifetime 36.1%; current 1 mo: 14.6% Borderline Personality Disorder: 9.5% **Additional Treatment** Inpatient tx days, mean (SD): 2 yr FU: 15.1 (37) 2 – 6 yr FU: 9.5 (29) 6 – 12 yr FU: 6.4 (14) **Patients who received at least one inpatient tx during 12 yrs:** 140/158 (88.6%) **Admissions per yr to any type of institution, N:** 2 yr FU: 31.5 2 – 6 yr FU: 22 6 – 12 yr FU: 18.5 **Multivariate Results** **Predictors of any ED at FU:** **Lifetime psychiatric comorbidity predicted poor outcome:** 2 yr: OR: 2.53, 95% CI (1.06 – 6.06) *(P* < 0.05) 6 yr: OR: 2.81, 95% CI (1.02 – 7.71) *(P* < 0.05) 12 yr: OR: 2.52, 95% CI (0.93 – 6.80) *(P* = NS) **With PSR as outcome criterion:** 2 yr: OR: 3.55, 95% CI (1.34 – 9.41) *(P* < 0.05) 6 yr: OR: 2.40, 95% CI (0.88 – 6.58) *(P* = NS) 12 yr: OR: 3.71, 95% CI (1.16 – 11.91) *(P* < 0.05) **Positive hx of AN predicted poor outcome:** 2 yr *(P* = NS) (values NR) 6 yr: OR: 2.05, 95% CI (0.94 – 4.45) *(P* = NS) 12 yr *(P* = NS) (Values NR) **With PSR as outcome criterion:** 2.38, 95% CI (1.03 – 5.50) *(P* < 0.05) **Childhood obesity** 2 yr: OR: 2.86, 95% CI (1.02 – 8.06) *(P* < 0.05) Other yrs *(P* = NS) **Higher age at onset of ED** 12 yr: OR: 1.01, 95% CI (1.01 – 1.16) *(P* < 0.05) Other yrs *(P* = NS) **Longer duration of ED:** All yrs *(P* = NS) **Higher frequency of binges:** All yrs: *(P* = NS) **Having undergone tx for ED prior to index tx:** All years *(P* = NS)

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, year: Fichter and Quadflieg, 1997 **Design:** Case Series **Comparison Group:** No **Location:** Upper Bavaria, Germany **Yrs followed:** 6.2 (0.9) from end of tx	To assess the 2 and 6 yr course and outcome of BN among a group of women with BN-purging type.	**Inclusion:** Females DSM-IV for BN-purging type Admitted to inpatient ED tx **Exclusion:** None stated **Recruitment:** Females who where dx'ed with BN and admitted to ED inpt program at Klinik Roseneck in Upper Bavaria Germany from 1985-1988. **Sample Size:** Initial (N = 196) Finished tx (N=166) 2 yr FU (N = 184) 6 yr FU (N=185) **Loss to FU at 6 yr:** Death (N=2) (pneumonia = 1 pneumonia & heart problems = 1) Not reached (N=6) Refused to participate (N=3)	**Mean Age at inpt admission (SD):** 25.6 (6.7) yrs **Sex:** Female 100% **Race/ethnicity:** NR **Duration of sx before tx start (SD):** 8.1 (4.9) yrs **Age of onset (SD):** 17.6 (4.8) yrs **Inpatient days (SD):** 95.5 (43) **Discharge Status:** Normal: 166 Premature: 10 By team: 1 By mutual agreement: 18 **Improvement at discharge:** Sig improvement: 47 (24.1%) Marked improvement: 77 (39.5%) Slight improvement: 60 (30.8%) Unchanged: 9 (4.6%) Slightly worse: 1 (0.5%) Marked worse: 1 (0.5%) **Education:** < 9 yrs: 1% ≥ 9 yrs: 69% ≥ 13 yrs: 25% **University degree:** 5%	**Score:** Fair **Method of diagnosis:** Specially trained psychologists or physician used. DSM-IV criteria for BN based on interview and/or SIAB data. **Funding:** Wilhelm-Sander-Stiftung

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods: Patients assessed at admission to inpt, discharge from inpt, 2 yrs, 6 yrs. For FU, pts sent questionnaire packet to complete. After packet returned, interview conducted by specially trained psychologists and physicians. Those not able to do long interview, given shorter version. Long interview were face to face or by phone, short by phone only. **Questionnaires:** SIAB, EDI, AN Inventory for Self-Rating, BN version of PSR, SCL-90, Complaint List, BDI, Munich Diagnostic Checklist for DSM-III-R **Assessments:** 2.0 (0.7) yrs and 6.2 (0.9) yrs **Statistical Method:** Repeated measures MANOVAs Pairwise t tests Longitudinal comparisons used sets complete for all time points. **Outcomes** SIAB, supplemented by PSR Global outcomes: aggregate of 10 outcome categories including overconcern with eating and wt, binge attacks, counterregulatory measures, body wt, depression, obsessions, anxiety, substance abuse, sexual problems, problems in social behavior Good – outcome of 1 or 0 Intermediate – outcome of 2 Poor – outcome of 3-4 PSR Good – outcome of 1 or 2 Intermediate – outcome of 3-4 Poor – outcome of 5-6	**Results**: **Descriptive** **Binge 2 times per wk (self-report):** Tx start: 100% Discharge: 46% 2 yr and 6 yr FU: 42% **Vomiting (≥ 2 times per wk):** Tx start: 88.1% Discharge: 49.7% 2 yr FU: 42.7% 6 yr FU: 33.6% **Mean BMI (SD):** Tx start : 21.5 (5.0) Discharge from tx : 21.1 (4.4) 2 yr FU: 21.5 (4.3) 6 yr FU: 21.8 (4.6) **Wt outcome:** Good: (19<BMI<30): 73.9% Intermediate: (BMI 30-40, or 17.5-19): 17.0% Poor: (BMI< 17.5, BMI > 40): 9.1% **Dx outcome (DSM-IV):** **At 2 yr FU:** BN:35.8% AN: 1.6% BED: 0% EDNOS: 8.0% No ED dx: 54.5% **At 6 yr FU:** BN: 21.4% AN: 3.7% BED: 1.1% EDNOS: 1.6% No ED dx: 71.1%: **PSR ED sx ratings (N):** **At 2 yr FU:** Marked sx: 29 Partial remission: 25 Residual sx: 25 Usual self: 20 **At 6 yr FU:** Marked sx: 25 Partial remission: 26 Residual sx: 45 Usual self:37 **Global outcome at 6 yr FU:** Good: 59.9% Intermediate: 29.4% Poor: 9.6% Deceased: 1.1%

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, year: Fichter and Quadflieg, 1997 (continued)				

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods: Patients assessed at admission to inpt, discharge from inpt, 2 yrs, 6 yrs. For FU, pts sent questionnaire packet to complete. After packet returned, interview conducted by specially trained psychologists and physicians. Those not able to do long interview, given shorter version. Long interview were face to face or by phone, short by phone only. **Questionnaires:** SIAB, EDI, AN Inventory for Self-Rating, BN version of PSR, SCL-90, Complaint List, BDI, Munich Diagnostic Checklist for DSM-III-R **Assessments:** 2.0 (0.7) yrs and 6.2 (0.9) yrs **Statistical Method:** Repeated measures MANOVAs Pairwise t tests Longitudinal comparisons used sets complete for all time points. **Outcomes** SIAB, supplemented by PSR Global outcomes: aggregate of 10 outcome categories including overconcern with eating and wt, binge attacks, counterregulatory measures, body wt, depression, obsessions, anxiety, substance abuse, sexual problems, problems in social behavior Good – outcome of 1 or 0 Intermediate – outcome of 2 Poor – outcome of 3-4 PSR Good – outcome of 1 or 2 Intermediate – outcome of 3-4 Poor – outcome of 5-6	**Change over time EDI** **Total** Beginning of tx vs 2 yr FU: ($P < 0.001$) Improved Beginning of tx vs 6 yr FU: ($P < 0.001$) Improved Discharge vs 2 yr FU: ($P < 0.01$) Worsened Discharge vs 6 yr FU: (P = NS) 2 yr FU vs 6 yr FU: ($P < 0.0001$) Improved **Drive for Thinness** Beginning of tx vs 2 yr FU: ($P < 0.001$) Improved Beginning of tx vs 6 yr FU: ($P < 0.001$) Improved Disharge vs 2 yr FU: (P = NS) Discharge vs 6 yr FU: ($P < 0.05$) Worsened 2 yr FU vs 6 yr FU: ($P < 0.001$) Improved **Bulimia:** Beginning of tx vs 2 yr FU: ($P < 0.001$) Improved Beginning of tx vs 6 yr FU: ($P < 0.001$) Improved Discharge vs 2 yr FU: ($P < 0.001$) Worsened Discharge vs 6 yr FU: ($P < 0.05$) Worsened 2 yr FU vs 6 yr FU: ($P < 0.001$) Improved **Body dissatisfaction** Beginning of tx vs 2 yr FU: ($P < 0.001$) Improved Beginning of tx vs 6 yr FU: ($P < 0.001$) Improved Discharge vs 2 yr FU: (P = NS) Discharge vs 6 yr FU: (P = NS) 2 yr FU vs 6 yr FU: ($P < 0.001$) Improved **Ineffectiveness** Beginning of tx vs 2 yr FU: ($P < 0.001$) Improved Beginning of tx vs 6 yr FU: ($P < 0.001$) Improved Discharge vs 2 yr FU: ($P < 0.001$) Worsened Discharge vs 6 yr FU: (P = NS) 2 yr FU vs 6 yr FU: ($P < 0.001$) Improved **Perfectionism** Beginning of tx vs 2 yr FU: ($P < 0.01$) Improved Beginning of tx vs 6 yr FU: ($P < 0.001$) Improved Discharge vs 2 yr FU: (P = NS) Discharge vs 6 yr FU: (P = NS) 2 yr FU vs 6 yr FU: (P = NS) **Change over time AN SIAB** **Total** Beginning of tx vs 2 yr FU: ($P < 0.001$) Improved Beginning of tx vs 6 yr FU: ($P < 0.001$) Improved Discharge vs 2 yr FU: ($P < 0.01$) Worsened Discharge vs 6 yr FU: ($P < 0.001$) Improved 2 yr FU vs 6 yr FU: ($P < 0.001$) Improved **Body image and ideal of slimness** Beginning of tx vs 2 yr FU: ($P < 0.001$) Improved Beginning of tx vs 6 yr FU: ($P < 0.001$) Improved Discharge vs 2 yr FU: (P = NS) Discharge vs 6 yr FU: ($P < 0.05$) Improved 2 yr FU vs 6 yr FU: ($P < 0.01$) Improved

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, year: Fichter and Quadflieg, 1997 (continued)				

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
	Depression Beginning of tx vs 2 yr FU: (P < 0.001) Improved Beginning of tx vs 6 yr FU: (P < 0.001) Improved Discharge vs 2 yr FU: (P < 0.01) Worsened Discharge vs 6 yr FU: (P < 0.001) Improved 2 yr FU vs 6 yr FU: (P < 0.001) Improved **Anxieties and obsessions** Beginning of tx vs 2 yr FU: (P < 0.001) Improved Beginning of tx vs 6 yr FU: (P < 0.001) Improved Discharge vs 2 yr FU: (P < 0.01) Worsened Discharge vs 6 yr FU: (P < 0.001) Improved 2 yr FU vs 6 yr FU: (P < 0.001) Improved **Bulimic behavior** Beginning of tx vs 2 yr FU: (P < 0.001) Improved Beginning of tx vs 6 yr FU: (P < 0.001) Improved Discharge vs 2 yr FU: (P < 0.01) Worsened Discharge vs 6 yr FU: (P < 0.001) Improved 2 yr FU vs 6 yr FU: (P < 0.001) Improved **Laxative abuse** Beginning of tx vs 2 yr FU: (P < 0.001) Improved Beginning of tx vs 6 yr FU: (P < 0.001) Improved Discharge vs 2 yr FU: (P < 0.01) Improved Discharge vs 6 yr FU: (P < 0.001) Improved 2 yr FU vs 6 yr FU: (P = NS) **Psychiatric comorbidities at 2 yr FU (N=184) and 6 yr FU (N=165)** **Borderline Personality Disorder** 2 yr FU: 5.4% 6 yr FU: 3.6% Lifetime: 8.9% **Substance abuse (excluding laxatives)** 2 yr FU: 23.9% 6 yr FU: 21.2% Lifetime: 41.6% **Mood disorders** 2 yr FU: 29.9% 6 yr FU: 45.5% Lifetime: 55.3% **Anxiety disorders** 2 yr FU: 13.0% 6 yr FU: 31.5% Lifetime: 34.2% **SCL-90: general psychopathology (N=118)** **Global severity index** Beginning of tx vs 2 yr FU: (P < 0.001) Improved Beginning of tx vs 6 yr FU: (P < 0.001) Improved Discharge vs 2 yr FU: (P < 0.001) Worsened Discharge vs 6 yr FU: (P < 0.001) Improved 2 yr FU vs 6 yr FU: (P = NS)

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, year: Fichter and Quadflieg, 1997 (continued)				

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
	Positive symptom total (PST) Beginning of tx vs 2 yr FU: (P < 0.001) Improved Beginning of tx vs 6 yr FU: (P < 0.001) Improved Discharge vs 2 yr FU: (P < 0.001) Worsened Discharge vs 6 yr FU: (P < 0.001) Improved 2 yr FU vs 6 yr FU: Improved **Positive Symptom Distress Index (PSDI)** Beginning of tx vs 2 yr FU: (P < 0.001) Improved Beginning of tx vs 6 yr FU: (P < 0.001) Improved Discharge vs 2 yr FU: (P < 0.001) Worsened Discharge vs 6 yr FU: (P < 0.001) Improved 2 yr FU vs 6 yr FU: (P = NS) **Somatization** Beginning of tx vs 2 yr FU: (P < 0.001) Improved Beginning of tx vs 6 yr FU: (P < 0.001) Improved Discharge vs 2 yr FU: (P < 0.01) Worsened Discharge vs 6 yr FU: (P = NS) 2 yr FU vs 6 yr FU: (P = NS) **Obsessive-compulsive symptoms** Beginning of tx vs 2 yr FU: (P < 0.001) Improved Beginning of tx vs 6 yr FU: (P < 0.001) Improved Discharge vs 2 yr FU: (P < 0.001) Worsened Discharge vs 6 yr FU: (P = NS) 2 yr FU vs 6 yr FU: (P < 0.001) Improved **Depression** Beginning of tx vs 2 yr FU: (P < 0.001) Improved Beginning of tx vs 6 yr FU: (P < 0.001) Improved Discharge vs 2 yr FU: (P < 0.001) Worsened Discharge vs 6 yr FU: (P = NS) 2 yr FU vs 6 yr FU: (P < 0.01) Improved **Anxiety** Beginning of tx vs 2 yr FU: (P < 0.001) Improved Beginning of tx vs 6 yr FU: (P < 0.001) Improved Discharge vs 2 yr FU: (P < 0.01) Worsened Discharge vs 6 yr FU: (P < 0.001) Improved 2 yr FU vs 6 yr FU: (P < 0.01) Improved **BDI** Beginning of tx vs 6 yr FU: (P < 0.001) Improved Discharge vs 6 yr FU: (P = NS)

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Franko et al., 2004 **Design:** Case series **Comparison Group:** No **Location:** Massachusetts, USA **Yrs followed:** Mean: 8.6	To determine predictors of serious suicide attempts in women with AN and BN.	**Inclusion:** Female, English speaking, meet full criteria for AN and/or BN, at least 12 yrs of age, reside within 200 miles of the study site. **Exclusion:** Organic brain syndrome or terminal illness. **Recruitment:** 554 consecutive women who sought tx for eating disorder at Massachusetts General Hospital or other Boston area clinics between October 1987 and June 1990. **Sample Size** **Initial Sample:** Met dx criteria: N = 268 Agreed to participate: N = 229 Additional participants identified: N = 21 **Reasons for loss to FU:** Drop out prior to first FU: N = 4 **Analysis Sample** N = 246 AN-Restricting: 51 AN-Binge Purge: 85 BN: 110	**Mean Age:** 24.8 (range: 13 to 45) at entry to the study. **Sex:** Female:100% **Race/ethnicity:** Non-Caucasian: 4% **Mean duration of illness:** 6.7 yrs (range: 3 mos – 21 yrs)	**Score:** Good **Method of dx:** LIFE-EAT-II and the PSR scale **Funding:** NIMH, Rubenstein Foundation, and Harvard Eating Disorders Care

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods FU interviews conducted every 6 – 12 mos in person when possible. **Statistical Methods** Non-parametric tests to examine diff on self-report measures administered at intake between subjects who made suicide attempts and those who did not. Kaplan-Meier survival analyses to determine time to first suicide attempt, and time-varying proportional hazards (Cox) regression models used to determine influence of baseline and course variables on time to first suicide attempt. Multiple regression to predict time to first suicide attempt.	**Descriptive Results** **Baseline, Reported hx of suicide attempts prior to study entry:** AN: 30.1% BN: 22.7% **Rates of suicide attempts:** AN: 30 (22.1%) BN: 12 (10.9%) Death from suicide: N = 4 (none had a previous suicide attempt) Diff between baseline self report measures for suicide attempters and non-attempters, mean (SD): **AN** EDI, drive for thinness *(P* = NS) EDI, Bulimia *(P* = NS) EDI, body dissatisfaction *(P* = NS) EDI, ineffectiveness: • attempters: 15.2 (8.6) • non-attempters: 11.4 (7.8) • *(P* = 0.04); Attempters did worse EDI, perfectionism *(P* = NS) EDI, interpersonal distrust *(P* = NS) EDI, interoceptive awareness *(P* = NS) EDI, maturity fears *(P* = NS) **BDI:** attempters: 27.6 (12.1) non-attempters: 22.7 (11.3) *(P* = 0.05). Attempters had greater depression. Symptom distress *(P* = NS) Global severity index *(P* = NS) Positive symptom total *(P* = NS) **BN** EDI, drive for thinness *(P* = NS) EDI, Bulimia *(P* = NS) EDI, body dissatisfaction *(P* = NS) EDI, ineffectiveness: • attempters: 14.6 (7.1) • non-attempters: 8.4 (6.1) • *(P* = 0.007); Attempters did worse EDI, perfectionism *(P* = NS) EDI, interpersonal distrust: • attempters: 7.1 (4.0) • non-attempters: 4.5 (3.4) • *(P* = 0.04). Attempters did worse. EDI, interoceptive awareness • attempters: 17.7 (7.6) • non-attempters: 10.9 (5.9) • *(P* = 0.003). Attempters did worse EDI, maturity fears: • attempters: 7.6 (7.3) • non-attempters: 3.7 (4.3) • *(P* = 0.03). Attempters did worse.

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Franko et al., 2004 (continued)				

Study Methods and Analytic Strategy	Main Outcomes and Results
	BDI: attempters: 27.0 (11.7) non-attempters: 19.6 (9.5) *(P* = 0.03) Attempters had greater depression. Symptom distress: • attempters: 2.2 (0.46) • non-attempters: 1.9 (1.4) • *(P* = 0.006). Attempters did worse Global severity index: • attempters: 1.6 (0.49) • non-attempters: 1.0 (0.54) • *(P* = 0.002). Attempters did worse. Positive symptom total: • attempters: 64.0 (11.7) • non-attempters: 47.7 (18.0) • *(P* = 0.003). Attempters did worse. **Multivariate Results** **Predictors of time to first suicide attempt during course of study-hypothesis testing results:** **AN** Hx of suicide attempt at intake *(P* < 0.009) Eating disorder symptomatology *(P* = NS) Severity of drug use *(P* < 0.01) Alcohol use *(P* = NS) **BN** Laxative use *(P* < 0.05) Hx of drug use disorder prior to start of the study *(P* < 0.01) **AN** Hx of suicide attempt at intake: HM = 1.09, 95% CI (1.31 – 6.71) *(P* = 0.009); Shorter time to first attempt Drug use: HM = 0.92, 95% CI (1.40 – 4.52) *(P* = 0.010); Greater use shorter time Individual therapy: HM = 3.54, 95% CI (1.20 – 10.42) *(P* = 0.013); Yes, shorter time Neuroleptic meds: HM = 5.03, 95% CI (1.50 – 16.86*) (P* = 0.02); Yes, shorter time Age of onset: HM = 1.06, 95% CI (1.00 – 1.12) *(P* = 0.05); Older age, shorter time Group therapy: HM = 2.35, 95% CI (1.00 – 5.53) *(P* = 0.06) Severity of depression: HM = 1.21, 95% CI (0.99 – 1.50) *(P* = 0.06) Alcohol use: HM = 1.54, 95% CI (0.99 – 1.04) *(P* = 0.08)

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Franko et al., 2004 (continued)				

Study Methods and Analytic Strategy	Main Outcomes and Results
	BN Group therapy: HM = 11.32, 95% CI (2.33 – 55.02) *(P* = 0.002); Yes, shorter time Age of onset: HM = 0.82, 95% CI (0.70 – 0.97) *(P* = 0.008); Younger age, shorter time Hx of drug use disorder: HM = 8.94, 95% CI (1.87 – 42.77) *(P* = 0.009); Greater hx, shorter time Individual therapy: HM = 10.39, 95% CI (1.03– 105.12) *(P* = 0.020); Yes, shorter time Paranoid personality disorder at intake: HM = 66.5, 95% CI (3.60 – 129.84) *(P* = 0.020); Yes, shorter time Severity of laxative use: HM = 1.21, 95% CI (1.50 – 46.30) *(P* = 0.022); More, shorter time Psychiatric hospitalization: HM = 10.75, 95% CI (1.16 – 99.86) *(P* = NS)

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Gendall et al., 2000 **Design:** Case series **Comparison Group:** No **Location:** New Zealand **Yrs followed:** 1	To determine the clinical and nutritional variables associate with menstrual disturbance in women presenting for tx for BN at 1 yr FU.	**Inclusion:** Women, age 17-45, DSM IV criteria for BN, purging type **Exclusion:** AN, BMI < 17 or >30 kg/m^2 Current use of psychoactive meds, hysterectomy or using oral contraceptives **Recruitment:** Women participating in outpatient tx trial recruited through media ads general practitioner and mental health worker referrals **Sample Size:** N = 82 **Loss to FU:** None	**Mean Age, yrs (SD)** 26.2 (6.2) **Sex:** Female 100% **Race/ethnicity:** NR **Mean BMI (kg/cm^2) (SD)** 23.0 (2.7) **Age Menarche (SD)** 13.0 (1.5) **PreTx Irregular Menses:** 45.1% **Hx of Amenorrhea** 46.3% **Wt. Min (kg) (SD)** 51.9 (6.9) **Wt. Max (kg) (SD)** 69.5 (10.8) **Wt Max-min (kg) (SD)** 17.6 (8.4) **BN duration (mos) (SD)** 65.5 (64.7) **# Binges prior 2 wks (SD)** 10.2 (10.6) **# Purges prior 2 wks (SD)** 11.7 (12.1) **Hx of AN** 20.7% **Recency AN (mos) (SD)** 18.5 (7.9) **PreTreatment Maj. Dep:** 22.0% **PreTx smoker:** 25.6% **PreTx substance abuse:** 23.2%	**Score:** Good **Method of dx:** Clinician administered SCID for DSM III-R, Global Assessment of Functioning, Structured clinical interview for core BN symptoms in past fortnight **Funding:** NR

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
Intervention: Outpatient tx testing use of exposure with response prevention to cognitive behavioural therapy for BN **Study Methods:** Assessed PreTx and at 1 yr Post-Tx. At pre-Tx and 1 yr FU clinician administered SCID-III-R, Global Assessment of Functioning Scale, structured clinical interview of core BN sx., Hamilton Depression Rating Scale (HDRS) adjusted for wt. and appetite items. Body wt and height measures. **Statistical Method:** Log transformation of non-normal distributions ANOVA Chi-Square Logistic regression analyses **Outcomes** Irregular menstruators: Absent or irregular menstrual cycles within past 3 mos.	**Descriptive Results:** **Women with vs. without regular menses – 1 yr FU** Women with irregular menses – 30.5% Irregular menses at 1 yr FU associated with following baseline measures: Low past min. body wt. *(P* = 0.05) Greater max.-min. wt diff *(P* = 0.001) Current smoking *(P* = 0.03) **At FU, dx of major depression in past 6 mos:** Regular menstruators: 18.5% Irregular menstuators: 44% *(P* = 0.03) Irregular at PreTx became regular at FU: 56.8% **Multivariate Results** Sig predictors of irregular menses at 1 yr FU: Greater max.-min. wt diff *(P* = 0.003) Current smoking *(P* = 0.01)

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Herzog et al., 2000 **Design:** Case series **Comparison Group:** No **Location:** Boston, MA, USA **Yrs followed:** 11	To assess rates and causes of death for a cohort of women with AN or BN and provide descriptive information on their ED and comorbid dx.	**Inclusion:** Initially, meeting DSM III-R criteria for AN, AN/BN, or BN; Subsequently, using DSM IV definitions, met criteria for AN-R, ANBP, or BN. **Exclusion:** None **Recruitment:** Between October 1987 and June 1990, tx seekers at Massachusetts General Hospital. 556 recruited. **Sample Size:** Using DSM IV criteria, participants classified as AN-R (N = 51), ANBP (N = 85), and BN (N = 110) status **Reasons for loss to FU:** NR	**Mean Age** NR **Sex:** Female: 100% **Race/ethnicity:** NR **Mean duration of illness:** 7.2 yrs	**Score:** Fair **Method of dx:** SADS-L modified to include diagnostic criteria for DSM III-R as well as psychiatric hx, later updated to DSM IV criteria **Funding:** NIMH ROI Grant, sponsor: Rubenstein Foundation and Harvard Eating Disorders Center.

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods Data on mortality collected as part of a longitudinal study of AN and BN. Other data sources included death certificates, autopsy reports, relative interviews, and a National Death Index search. The Eating Disorders Longitudinal FU Evaluation (LIFE-EAT II) was administered to subjects at 6-mo intervals. General information regarding subjects' functioning in the mos prior to death was obtained by interviewing a family member.	**Descriptive findings:** **AN** At 11th yr FU: # of AN deaths: 7 (Crude mortality rate = 5.1%, 7 / 136) 3 subjects committed suicide. SMR indicates a sigly raised mortality rate for death at 9.6 times the expected rate *(P* = 0.001), 95% CI (3.86 -19.8) and for suicide at 58.1times the expected rate *(P* = 0.001), 95% CI (11.7 -169.7). Characteristics of deceased participants: • At intake, 5 met ANBP dx: 2 met full AN and BN criteria; 2 met full AN criteria with BN sx; 1 met full BN criteria with AN sx. • Ages: 24-46 yrs. • Yrs ill at death: 9-28 • 2 met ANR criteria at intake, but later exhibited BN sx • At time of death, of the 5 ANBP participants, 2 were classified as ANBP, 2 met AN-partial recovery criteria, 1 met AN-full recovery criteria. • All had a hx of comorbid Axis I disorders: most common dx was alcoholism. Other comorbid disorders included bipolar disorder major depressive disorder and drug abuse. • All participated in multiple types of tx: both individual psychotherapy and pharmacotherapy • Hospitalized at least once: N = 6 • Participated in group therapy: N = 6 • Nutritional counseling: N = 5 • Participated in family therapy: N = 4 • All 3 subjects who committed suicide had reported suicidal ideation and 2 subjects had made at least one prior suicide attempt. **BN** At 11th yr FU, # of BN deaths: 0

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Author, Yr: Herzog et al., 1999 **Design:** Case series **Comparison Group:** No **Location:** Boston, MA, USA **Yrs followed:** Median = 7.5; interviews conducted every 6 mos for 11 yrs	To assess factors associated with recovery and relapse in AN and BN	**Inclusion:** DSM III-R for AN and BN at tx intake *(*Participants reclassified according to DSM IV criteria during the study); anorexic and bulimic episodes not separated by a period of remission of at least 8 wks duration. **Exclusion:** None **Recruitment:** Women who sought tx in eating disorder programs in Boston, MA between 1987 and 1990. An additional 21 women with AN recruited in 1991. **Sample size** **Initial sample size:** ANR: 51 ANBP: 85 BN: 110 **Reasons for loss to FU:** Dro*p*outs: 17 Died (dx group and reasons NR): 7 **Analysis sample size:** NR	**Mean age at tx intake (SD):** ANR: 23.9 (8.5) ANBP: 24.5 (5.9) BN: 25.5 (6.5) **Sex:** Female: 100% **Race/ethnicity:** NR **Age at ED onset (SD):** ANR: 17.5 (6.1) ANBP: 16.9 (4.7) BN: 19.4 (5.8) **Proportion ABW:** ANR: 0.73 (0.09) ANBP: 0.82 (0.10) BN: 1.03 (0.15) **Lifetime hx major depression:** ANR: 64.7% ANBP: 71.3% BN: 60.7% **Lifetime hx Axis I:** ANR: 62.7% ANBP: 78.1% BN: 74.1% **Lifetime hx Axis II:** ANR: 25.5% ANBP: 37.9% BN: 23.2% **Lifetime hx substance use disorder:** ANR: 5.9% ANBP: 16.1% BN: 12.3% **Duration intake episode:** ANR: 6.4 (6.7) ANBP: 7.6 (5.4) BN: 6.1 (6.3)	**Score:** Good **Method of dx:** Modified version of Schedule for Affective Disorders and Schizophrenia – Lifetime version **Funding:** NIMH, Rubenstein Foundation, Harvard Eating Disorders Center

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods: FU interviews generally conducted by telephone by trained interviewers. Instruments included: Eating Disorders Longitudinal Interval FU Evaluation (LIFE-EAT-II)-semi-structured. **Statistical Methods:** Survival analysis, proportional hazards (Cox) regression **Outcome Categories:** Full recovery (absence of symptoms or presence of only residual symptoms for at least 8 consecutive wks) at some point over 90 mos Partial recovery **(**reduction of symptoms to < full recovery for ≥ 8 consecutive wks	**AN Findings** **Descriptive Results** **Full recovery:** 33.7% At 2 yrs: ANR: 8%; ANBP: 13% At 7 yrs: ANR: 34%; ANBP: 32% **Partial recovery**: 83.7% At 2 yrs: ANR: 61%; ANBP: 67% At 7 yrs: ANR: 83%; ANBP: 82% **Median time to partial recovery (wks):** ANR: 78; ANBP: 53 Diff ANR and ANBP *(P* = NS) **Relapse after full recovery:** 40% **No remission through yr 7:** ANR: 17% ANBP: 18% **Multivariate Results** **Sig predictors of time to full recovery (adjusted):** Percent of ABW at intake: HM = 250.1, 95% CI (6.90-9.066) heavier is better Duration of intake episode: HM = 0.89, 95% CI (0.81-0.96), shorter is better **Sig predictors of time to partial recovery (adjusted):** Duration of intake episode: HM = 0.63, 95% CI (0.45-0.87) Shorter is better Percent ABW at intake: HM = 18.89, 95% CI (0.32-1.105) Higher is better Hx of hospitalization: HM = 29.60, 95% CI (1.11-791.21) Fewer hospitalizations is better Hx of major depression: HM = 1.64, 95% CI (1.07-2.51) Not having major depression is better Duration of intake episode x proportion ABW: HM = 1.65, 95% CI (1.10-2.47); ABW values >93% and shorter intake episode is better than ABW < 93% and longer duration of intake episode Percent ABW x hx of hospitalization: HM = 0.007, 95% CI (0.0001-0.44); ABW values ≤ 69% and having hx of hospitalization is better than ABW > 69% and no hx of hospiatlization **BN Findings** **Descriptive Results** **Full recovery:** 73.8% At 2 yrs: BN: 53% At 7 yrs: BN 73%

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Author, Yr: Herzog et al., 1999 (continued)				

Study Methods and Analytic Strategy	Main Outcomes and Results
	Partial recovery: 99.0% At 2 yrs: BN: 88% At 7 yrs: BN: 98% Median time to partial recovery (wks): BN: 14 **Relapse after full recovery:** 35.3% **Multivariate Results** Sig predictors of time to full recovery: none identified Sig predictors of time to partial recovery: none identified

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Herzog et al., 1996 **Design:** Case series **Comparison Group:** No **Location:** Boston, MA **Yrs followed:** 4	To assess the rates of recovery for restrictor and bulimic anorexics to determine whether bulimic behavior sig affects the course of AN. To assess possible subtypes of BN based on the presence or absence of a hx of AN.	**Inclusion:** DSM III-R criteria for BN and or AN **Exclusion:** NR **Recruitment:** Participants who sought evaluation for an eating disorder at the Massachusetts General Hospital Eating Disorders Unit and at other Boston-area eating disorders programs between 10/87 and 6/90. **Sample Size:** **Initial sample:** Telephone Screen: N = 554 Met criteria: N = 268 Participated: N = 229 Dropout: N = 4 **Analysis Sample:** N = 225 ANR (AN and no regular bingeing or purging): N = 39 ANBP (AN and regularly engage in bingeing or purging): N = 37 BNPAN (BN now and hx of AN): N = 28 BNSAN (BN now, underwt at intake and do not meet full criteria for AN): N = 36 BN (BN with no prior hx of AN): N = 89	**Age, mean (SD) (range), yrs** 24.5 (6.7) ANR: 21 (18 – 27) ANBP: 22 (19 – 25) BNSAN: 25 (21 – 29) BNPAN: 23 (20 – 27) BN: 24 (20 – 30) Diff between groups (*P* = NS) **Sex:** Female: 100% **Race/ethnicity:** NR **Age at onset of first disorder, mean (range), yrs** ANR: 17 (15 – 20) ANBP: 17 (15– 19) BNSAN: 17 (14 – 19) BNPAN: 16 (15 – 18) BN: 18 (16 – 20) Diff between groups *(P* = NS) **% attempted suicide:** ANR: 18 ANBP: 33 BNSAN: 53 BNPAN: 19 BN**:** 28 Diff between groups BNSAN had higher rates of suicide attempts versus BN and BNPAN *(P* < 0.001).	**Score:** Good **Method of dx:** Semi-structured interview (Schedule for Affective Disorders and Schizophrenia-Lifetime Version modified to include diagnostic criteria for DSM III-R eating disorders derived from the Diagnostic Interview Schedule). Eating Disorders Longitudinal FU Evaluation. **Funding:** NIMH, Rubenstein Foundation, Eli Lilly and Co, The Boston Obesity, Nutrition Research Center

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods FU interviews conducted every 3 mos. Anniversary (12, 24, 36 mo) FUs conducted in person whenever possible. **Full recovery:** asymptomatic (Psychiatric Status Rating PSR < 3) for at least 8 consecutive wks. **Partial recovery:** maintaining for at least 8 consecutive wks a PSR level of 3 or 4. Do not meet full criteria for AN or BN but still experience sig symptomatology. **Analytic Strategy** Fisher's Exact Test and Wilcoxon Rank Sum Test Kaplan-Meier survival method for probability of recovery. Cox proportional hazards models to identify prognostic factors	**Descriptive Results** **% at least partially recovered:** **BN:** 91% Trend *(P* < 0.01) **% fully recovered:** **BN:** 62% Trend *(P* < 0.01) **Multivariate Results** **BN Predictors of recovery; Adjusted for duration of the current episode (N = 150):** Duration of current episode *(P* = NS) Age at onset of eating disorder *(P* = NS) Age at onset of first eating disorder *(P* = NS) Current disorders involving a lack of impulse control *(P* = NS) Wt < 90% of ideal *(P* = NS) Bingeing frequency *(P* = NS) Purging frequency *(P* = NS) Current depression *(P* = NS) Personality disorder *(P* = NS) Any current Axis I disorder *(P* = NS) **AN Predictors of recovery: Adjusted for duration of the current episode (N = 75):** **Duration of current episode:** RR = 0.50, 95% CI (0.27 – 0.94) Age at onset of eating disorder *(P* = NS) Age at onset of first eating disorder *(P* = NS) Current disorders involving a lack of impulse control: *(P* = NS) Bulimic behaviors *(P* = NS) Current depression *(P* = NS) Any current Axis I disorder *(P* = NS)

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Author, yr Herzog et al., 1993 **Design:** Prospective cohort **Comparison Group:** No **Setting:** Boston, MA, USA **Yrs followed:** 1 yr (with some having 2 yr FU)	To asses the course and outcome of BN at 1 yr in a large cohort of women with ED.	**Inclusion:** DSM III-R dx of AN and/or BN; Female; age ≥ 12; residence within 200 mi of Boston; English speaking; no evidence of organic brain syndrome or terminal illness. **Exclusion:** None **Recruitment:** Patients who sought tx between 10/1987 and 6/1990 at the Massachusetts General Hospital Eating Disorders Unit and other Boston area eating disorder programs. Tx not controlled at study intake. 554 telephone screened 268 (48%) met criteria for AN/BN 229 (85%) agreed to participate **Sample Size** **Initial sample:** AN: N = 41 BN: N = 98 **Analysis sample size:** Final N for 1 yr FU = 225 AN = 41 BN = 96 AN/BN = 88 Completed 18 mo: 79% Completed 24 mos: 45% Only BN results presented in ET due to sample size and disease definition restrictions.	**Mean Age At Intake, mean (SD):** 22.8 (7.4) **Age when first met criteria, mean (SD):** 18.8 (4.0) **Duration of episode, mos, mean (SD):** 57.7 (62) **IBW at intake, %, mean (SD):** 104% (15%) **Comorbid Axis I dx, %:** 61% **In tx at 12-mo FU, %:** 79% **Sex:** Female: 100% **Race/ethnicity:** NR **Intake duration, mean (SD):** 79 (73) mos range: 3 mos - > 10 yrs.	**Score:** Good **Method of dx:** Schedule for Affective Disorders and Schizophrenia – Lifetime Version (SADS-L), modified to include dx criteria for DSM III-R eating disorders. **Funding:** NIMH

Methods and Statistical Analysis	Main Outcomes and Results
Study Methods Inperson FU interviews conducted every 3 mo after intake into the study. Axis II: Structured Interview for DSM III Personality Disorders (SIDP). FU: Eating Disorders Longitudinal Interval FU Evaluations (LIFE Eat II) For all disorders, Psychiatric Status Ratings (PSR) completed each FU point. Full recovery: at least 8 consecutive wks at a PSR level of 1 or 2; partial recovery: at least 8 consec wks at PSR level 3 or 4 or less than 8 consec wks at a PSR of 1 or 2. **Statistical Methods** Kaplan-Meier survival method for cumulative probability of recovery. Log rank to compare times to recovery across three dx. Cox regression to determine if intake psychopathology or eating disorder characteristics predicted time to recovery.	**Descriptive Results** **Rate of recovery at 1 yr FU:** First shift to subclinical (loss of full criteria without considering duration), N (%): 83 (86%) Partial recovery, N (%): 68 (71%) Full recovery, N (%): 53 (56%) **Predictors of partial recovery** **IBW:** Hazard multiplier: 1.07 95% CI (0.97 – 1.18) Percent IBW did not predict time to recovery.

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Jäger et al., 2004 **Design:** Case series **Comparison Group:** No **Location:** Hanover, Germany **Yrs followed:** 8.1 (0.6)	To investigate the long-term social adjustment of women with BN after tx and the course of sx and related dimensions over time.	**Inclusion:** Women DSM III-R for BN **Exclusion:** Acute drug abuse Acute psychosis **Recruitment:** Continuation of Hanover BN study with add FU 8 yrs after start of tx. Initially 92 women offered systemic outpatient or analytic inpatient tx at Department of Psychosomatics and Psychotherapy, Hanover Medical School. **Sample Size:** **Initial sample:** Patients in tx sample (N = 83) **Reasons for loss to FU:** Refused (N = 3) **Analysis sample:** Participated through FU (N = 80)	**At FU:** **Mean Age (SD):** 31.7 (4.1) yrs **Sex:** Female 100%	**Score:** Fair **Method of dx:** DSM III-R, method not reported **Funding:** Robert-Bosch-Foundation, Stuttgart, Germany for 5 yrs and Lilly-Pharma, Germany for final assessment

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods: Patients were followed up 8 yrs after tx completion. FU patients were interviewed by telephone and completed a mailed questionnaire. Telephone interview covering symptomatology and general health. Mailed questionnaire including: Depression scale An inventory of bodily complaints Freiburg Personality Inventory Eating Attitude Inventory Eating Disorders Inventory Bulimia Severity Score Collateral info obtained by family and friends (no method reported) **Statistical Method:** Chi^2 and binomial tests Repeated measure ANOVA Huynh-Feld-Epsilon correction Friedman ANOVA or Cochran Q test 0.9% of missing values substituted by mean of adjacent measures **Outcomes** Interview screen of ED symptoms and general health Depression scale An inventory of bodily complaints Freiburg Personality Inventory Eating Attitude Inventory Eating Disorders Inventory Bulimia Severity Score Calculated total score of intake restrictions	**Descriptive Results:** **Social adaptation: BN study sample vs general population** Married: 29.9% vs 61.4% *(P* < 0.001) Living with partner: 56.4% vs 73.4% *(P* < 0.001) Proportion of hospitalized patients/yr due to all reasons: 21.9% vs 10.7% *(P* < 0.001) No diff between BN and general pop. on employment, receive unemploy. benefits, welfare as main income source. **Mental Health outcomes:** Comorbid clinical neurotic or psychosomatic dx in addition to BN reduced from 35 at intake to 8 at FU. Personality disorders reduced from 13 at intake to 3 at FU. **Eating related outcomes** Number binges per wk:62.5% Still DSM III-R for BN: 28.9% EDNOS (bulimic): 8.8% EDNOS (anorexic): 1.3% No DSM III-R ED dx: 61.2% **Change over time (Discharge through 8 yr FU)** Binges decreased over time to FU in both tx groups *(P* < 0.001) Severity index decreased over time to FU in both tx groups *(P* < 0.001) Analytic inpatients better improvement over time *(P* < 0.007) Number normal meals per wk increased over time to FU *(P* < 0.001) Number restrictions of intake decreased over time to FU *(P* < 0.001) Analytic inpatients fewer restrictions *(P* = 0.048) EAT-Bulimia decreased over time to FU *(P* < 0.001) Analytic inpatients having greater decrease *(P* = 0.005) EAT-Dieting decreased over time to FU *(P* < 0.001) EDI-Ineffectiveness decreased over time to FU *(P* < 0.001) Depressiveness decreased over time to FU *(P* < 0.001) Analytic inpatients having greater decrease *(P* = 0.036)

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Johnson, Tobin, and Dennis, 1990 **Design:** Case series **Comparison Group:** No **Location:** University of Chicago, IL, USA **Yrs followed:** 1	To compare bulimics with and without Borderline Personality Disorder at 1 yr FU after initiation of tx.	**Inclusion:** DSM III-R criteria for BN **Exclusion:** NR **Recruitment:** Patients who sought tx at University of Chicago Medical Center **Sample Size:** N = 55 BPD: N = 21 NBPD: N = 19	**Mean Age:** 25 (5.1); Mode: 15 yrs; diff between groups *(P* = NS) **Sex:** Female: 100% **Race/ethnicity:** Mode: Caucasian **Age of onset of bingeing:** 16.7 Diff between groups *(P* = NS) **Duration of binge eating behavior, mean yrs:** 6.8 Diff between groups *(P* = NS) **Age of onset of vomiting:** 19.1 Diff between groups *(P* = NS) **Duration of vomiting, mean yrs:** 5.6 Diff between groups *(P* = NS) **Number of dieting attempts during last yr, mean:** 20 Diff between groups *(P* = NS) **Controlled dieting behavior:** Diff between groups *(P* < 0.05) NBPD engaged in more controlled dieting **Current wt, mean (lbs):** 127 Diff between groups *(P* = NS) **Previous low wt, mean (lbs):** 113 Diff between groups *(P* = NS) **Previous high wt, mean (lbs):** 146 Diff between groups *(P* = NS) **Frequency of binges per wk:** 10 Diff between groups *(P* = NS) **Binge days per wk:** 5 Diff between groups *(P* = NS) **Frequency of purging per wk:** 13 Diff between groups *(P* = NS)	**Score:** Poor **Method of dx:** Diagnostic Survey of Eating Disorders, revised; Borderline Syndrome Index (BSI): Borderline group: ≥ 23; Nonborderline group: ≤ 12 **Funding:** Barr and Dunagan Foundation

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods FU assessments were conducted by mail 1 yr after entry into tx. Tx intervention: Combination of CBT and psychodynamic; frequency: 1 – 2X per wk (depending on patient) for some portion of the yr. **Analytic Strategy** Chi-square comparisons **Outcomes:** **Remission:** no episodes of binge eating or purging during two wks prior to FU **Sigly improved:** Reduced frequency of binge/purge by 50% from initial assessment to 1 yr FU.	**Family Hx of psychiatric illness:** Borderline: 76% Nonborderline: 32% Diff between groups *(P* < 0.01) **Family hx of affective disorder:** Borderline:48% Nonborderline: 32% Diff between groups *(P* = NS) **Family hx of alcoholism:** Borderline:48% Nonborderline:16% *(P* = NR) **Continued to meet DSM III-R criteria for BN:** Borderline: 62% Nonborderline: 21% Diff between groups *(P* < 0.05); Borderline did worse. **Complete remission:** Borderline: 10% Nonborderline: 47% **Sigly improved:** Borderline: 48% Nonborderline: 42% **Unimproved:** Borderline: 24% Nonborderline: 5% **Increase in symptoms:** Borderline: 19% Nonborderline: 5% **BDI, mean:** Borderline: 18 Nonborderline: 4 *(P* = NR) **GSI/SCL-90:** Borderline: 1.24 Nonborderline: 0.34 *(P* = NR) **In tx at end of 1 yr, N:** Borderline: 14 Nonborderline: 7 Diff between groups *(P* < 0.05) **Mean number of tx sessions:** Borderline: 67 Nonborderline: 35 Diff between groups *(P* < 0.05)

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Johnson, Tobin, and Dennis, 1990 (continued)			**Purge days per wk:** 5 Diff between groups *(P* = NS) **BDI:** Borderline**:** 27 Nonborderline: 9 Diff between groups *(P* < 0.001) Borderline more depressed **Global Severity Index of SCL-90:** Borderline**:** 1.93 Nonborderline**:** 0.69 Diff between groups *(P* < 0.001) Borderline greater severity **Drive for thinness:** Diff between groups *(P* < 0.01) Borderline worse **Distorted body image:** Diff between groups *(P* < 0.01) Borderline worse	

Study Methods and Analytic Strategy	Main Outcomes and Results

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Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Keel et al., 2003 **Design:** Case series **Comparison Group:** No **Location:** Boston, Mass **Yrs followed:** Mean: 8.6 Median: 9	To determine mortality ratios and predictors of fatal outcome in women dx with AN or BN.	**Inclusion:** (1) DSM III-R dx of AN or BN retrospectively (2) female (3) min age of 12 yrs (4) residence within 200 miles of Boston (5) English speaking, and (6) no evidence of organic brain syndrome or terminal illness. **Exclusion:** None **Recruitment:** 294 women recruited for participation in a prospective longitudinal study between January 1, 1987, and December 31, 1991. Virtually all seeking outpatient tx for their Ed at the Massachusetts General Hospital Eating Disorders Unit or other Boston area eating disorder programs (37% received inpatient). **Sample Size:** N = 294 met study criteria N = 250 agreed to participate N = 246 randomized and participated (4 dropped out after intake interview) Retrospectively application of DSM IV criteria: Met AN criteria: N = 136 Met BN criteria: N = 110	**Mean Age** NR **Sex:** Female: 100% **Race/ethnicity:** NR	**Score:** Fair **Method of dx:** Structured diagnostic interview **Funding:** NIMH; Eli Lily and Co.; Rubenstein Foundation; Harvard Eating Disorders Center

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods During FU interviews, the Longitudinal Interval FU Evaluation adapted for EDs used to assess ED and comorbid psychiatric disorders. Course of disorder coded on a wk-by-wk basis using PSR. Social adjustment evaluated on a 5-point scale. GAF used to evaluate overall level of symptom severity from all disorders and psychosocial function. Social adjustment, GAF scores, and tx rated on a wk-by-wk basis throughout FU. Interviews conducted, in person when possible, every 6 to 12 mos. FU telephone calls conducted to determine vital status for all longitudinal study participants as of October 2000. **Statistical Methods** Crude mortality rates and SMRs calculated. Expected number of deaths derived from US decennial life tables for 1989-1991. Expected number of suicides derived from *1995 Annual Report: VitalStatistics of Massachusetts*. Cox regression models used to determine predictors of fatal outcome. Multivariate regression model used to predict death.	**Descriptive** **Number of Deaths:** 11 (4.5%) AN:10 ANR: 5 ANBP: 5 Diff by subtype *(P* = NS) BN: 1 **Crude mortality:** AN: 7.4% BN: 0.9% **SMR** AN: 11.6; 95% CI (5.5-21.3) BN: 1.3; 95% CI (0.0-7.2) Mortality rates elevated in AN but not BN **Cause of death** ANBP: Pneumonia ANR (N = 3) Suicide ANBP: Cardiac dysrythmia ANBP: Alcohol poisoning ANBP: Diabetes mellitus BN: Mitral valve prolapse ANR: Amyotrophic lateral sclerosis ANBP: Suicide ANR: Heart and liver failure SMR associated with suicide for AN: 56.9, 95% CI (15.3-145.7), sig higher **Multivariate Results** **Sig predictors of death among AN patients (controlling for age and duration of illness before intake):** Greater severity of alcohol use disorders *(P* < 0.001) Greater severity of substance use disorders *(P* = 0.03) Worse social adjustment *(P* = 0.02) Worse GAF scores at FU *(P* = 0.01) Using the Bonferroni-corrected *P* = 0.0016, only severity of alcohol use disorder remained sig. **Predictors of time to death among AN patients** Duration of illness at tx intake: HM = 1.48, 95% CI (1.11-1.99) *(P* = 0.001) Affective disorder hospitalization at intake: HM = 0.0001, 95% CI (0.00-0.27) *(P* = 0.001) Suicidality associated with mental illness other than ED and substance abuse: HM = 23.92, 95% CI (0.81-705.52) *(P* = 0.05) Severity of alcohol use over course of illness: HM = 5.55, 95% CI (1.68-18.29) *(P* = 0.001)

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Keel et al., 2001 **Design:** Case Series **Comparison Group:** No **Location:** USA **Yrs followed (SD):** 10 (0.7)	To determine the independence of the association between body dissatisfaction and depression from bulimic symptoms among women who had BN at the time of the baseline assessment.	**Inclusion:** Met DSM III criteria for BN, with the add criterion of binge eating coupled with purging episodes occurring at least 3 times per wk for at least 6 mos prior to study participation. Additional inclusion and exclusion criteria reported in the original study (Mitchell et al., 1990). **Exclusion:** One woman removed from analyses because baseline and FU assessments indicated she had never met full DSM IV criteria for BN because her binge eating episodes were not objectively large. **Recruitment:** Women with BN who completed participation in a controlled tx outcome study at the U of Minnesota's ED Research offices, Minneapolis, MN between 1985 and 1987 (Mitchell et al., 1990) were mailed an invitation to participate in FU study. **Sample Size:** Original sample Recruited: N = 125 **Reasons for loss to FU:** Located: N = 115 (92%) Exclusion due to not meeting DSM IV criteria: N = 1 Reasons NR: N = 13 **Analysis sample:** N = 101	**Mean Age (SD):** 34.3 (5.2) **Sex:** Female: 100% **Race/ethnicity:** Caucasian: N = 100, 99% Non-Caucasian N = 1, 1% **Education:** Not completed HS: 1% 4-yr college: 42% Graduate school: 15% **Occupational level:** Administrative: 37% Clerical/sales: 29% with approximately 10% Manual position: 11% Professional position: 10%	**Score:** Fair **Method of dx:** NR **Funding:** McKnight Center Grant; NIH Obesity Grant

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods: Participants were mailed consent forms and questionnaires to complete at home, and asked to complete an interview either over the telephone or in person. Face-to-face interviews were conducted either at the University of Minnesota's Eating Disorders research office or within subjects' homes. Participants were administered the HDRS (depression), EDI (ED symptoms), SCID-I, and BDQ (body dissatisfaction) at baseline and FU. **Analytic Strategy:** Multiple regression analyses utilized to test the independence and strength of concurrent and prospective associations of body dissatisfaction, depression, and BN symptoms.	**Multivariate Findings:** **Regression of body dissatisfaction on bulimic symptoms and depression:** Baseline concurrent body dissatisfaction (N = 101) (R2 = 0.21) Bulimic symptoms β (*SE* B), β: 0.59 (0.15), 0.36 (P < 0.001) Depression, β (*SE* B), β: 0.22 (0.11), 0.19 (P < 0.05) FU concurrent body dissatisfaction (N = 97) (R2 = 0.32) Bulimic symptoms, β (*SE* β), β: −7.32 (1.73), -0.37 (P < 0.001) Depression, β (*SE* β), β: 1.92 (0.49), 0.35 (P < 0.001) Prospective (N = 97) (R2 = 0.19) Bulimic symptoms, β (*SE* β), β −1.22 (0.76), -0.17 (P = NS) Depression, β (*SE* β), β 1.26 (0.54),0.24 (P < 0.5) Baseline body dissatisfaction, β (*SE* β), β: 1.54 (0.47), 0.35 (P < 0.01) **Regression analyses for depression and body dissatisfaction** Baseline concurrent (N = 101) (R@ = 0.09), β = 0.33 *(P* < 0.01) Depression on Body Dissatisfaction, β (*SE* β): 0.27 (0.08) Body dissatisfaction on Depression, β (*SE* β): 0.35 (0.11) FU concurrent *(*N = 97) (R2 = 0.19) β = −0.44 *(P* < 0.001) Depression on Body Dissatisfaction, β (*SE* β): 0.08 (0.02) Body dissatisfaction on Depression, β *SE* β: 2.45 (0.51) Prospective – baseline to FU (N = 97) Depression on Body Dissatisfaction (controlling for baseline depression, $R^{2,}$ = 0.08 β (*SE* β) β: 0.08, 0.01 (0.08), 0.01 *(P* = NS) Body dissatisfaction on Depression (controlling for baseline body dissatisfaction), R2 = 0.016, β (*SE* β) β: 1.04 (0.52), 0.20 *(P* < 0.05)

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Keel, Mitchell, Davis et al., 2000 **Companion article:** Keel et al., 1999 Keel, Mitchell, Miller et al., 2000 **Design:** Case Series **Comparison Group:** No **Location:** USA **Yrs followed:** Mean: 11.5 (1.9)	To compare definitions of ED outcome found in the BN literature and to determine the impact of definitions on the description and prediction of outcome.	**Inclusion:** Met the DSM III criteria for BN and the additional criterion of binge eating coupled with vomiting or laxative abuse at least 3 times each wk for 6 mos preceding presentation **Exclusion:** None **Recruitment:** Participation in two previous studies on BN (Mitchell, Pyle et al., 1988, and Mitchell, Pyle et al., 1990) who were initially evaluated at the University of Minnesota's Eating Disorders Clinic between 1981-1987.Subjects from 2 previous studies recontacted via letter from one of investigators. Final participation rate = 80.5% No diff in participation rates between the 2 studies **Sample Size:** Original (N = 222) **Reasons for loss to FU:** Not located (confirmed not deceased) (N = 22) Deceased (N = 1) Severely disabled and blind (N = 1) Refused (N = 21) Did not meet DSM IV criteria for BN based on initial assessment and SCID-I/P at FU (N = 4) Final sample (N = 173) **Analysis sample size:** N = 173	**Mean Age** 35.3 (5.1) yrs **Sex:** Female: 100% **Race/ethnicity:** White: 99%, N = 171 Not White: 1%, N = 2 **Mean duration of FU, yrs (SD):** 11.5 (1.9) **Education:** HS: 99% College: 30% Graduate school:15% **Ever married:** 75% Still in 1st marriage: 50% **Vocation:** Manual labor: < 10% Clerical/sales: 26.6% Administration: 33.5% Professional: < 10%	**Score:** Fair **Method of dx:** DSM IV SCID-I/P for Axis I disorders + addendum for impulse control disorders at FU. **Funding:** McKnight Center Grant for Eating Disorders Research, NIH Obesity Center; NIMH; American Psychological Association; Minnesota Women Psychologists' Association, University of Minnesota.

Study Methods and Analytic Strategy	Main Outcomes and Results
Study methods Definitions of outcome used in different studies involving a FU duration of at least 5 yrs compared. Diffs examined at 10 yr FU. Defs of outcome varied in 3 ways: • Duration of abstinence required for full remission or full recovery. Required abstinence varied from 2 - 12 mos across studies, with modal duration of 2 mos. • Number of categories into which outcome is placed varies from 2-4 classifications. • How ED outcome categories prior to performing statistical analyses combined. **Outcome measures:** 1.Hsu and Sobkiewicz (1989): Full recovery (no binge eating or purging over previous six mos) 2. Fallon et al. (1991): Full recovery (Psychiatric Status Rating < 3 for 8 consecutive wks) 3. Collings and King (1994): Full recovery (no symptoms during 12 mos preceding assessment 4. Fairburn et al. (1995): No ED or EDNOS of clinical severity that does not meet criteria for AN or BN 5. Reiss and Johnson-Sabine et al. (1995): Good outcome (not bingeing and/or vomiting/ purging at all or doing so < 1x/mo)/ Keel et al. (1999): Full remission – narrow (no binge eating or purging over previous 6 mos and wt and shape cannot unduly influence self-evaluation), broad (Psychiatric Status Rating < 3 over 8 consecutive wks); partial remission (less remitted than full remission but more remitted than EDNOS)/ Abraham (1998): Recovered (did not meet DSM IV criteria for AN, BN, or EDNOS) 6. Herzog (1999): Full recovery (episode is over if psychiatric status rating is less than 5 for 8 consecutive wks (or less than 8 consecutive wks at psychiatric status rating < 3)	**Descriptive Results:** Full recovery ranged across defs from 47% to 38% in this sample in a linear relationship with required duration of abstinence *(P* = 0.01). For every add mo of abstinence required for full recovery, approx 1% of women reclassified from fully to partially remitted. Diffs in def affected description of outcome for 9% of the sample (N = 16). At the trend level, a lifetime hx of substance use disorders was consistently associated with ED outcome *(P* < 0.10). There were no other consistent prognostic variables across studies. **Associations between other outcomes variables and ED outcomes across definitions of ED outcome:** Depression: 1. *(P* = 0.04) 2. *(P* < 0.001) 3. *(P* = 0.05) 4. *(P* = 0.003) 5. *(P* < 0.001) 6. *(P* = 0.02) Affective: 1. *(P* = 0.09) 2. *(P* < 0.001) 3. *(P* = 0.02) 4. *(P* < 0.001) 5. *(P* < 0.001) 6. *(P* = 0.03) Substance use: 1. *(P* = 0.09) 2. *(P* < 0.001) 3. *(P* = 0.02) 4. *(P* < 0.001) 5. *(P* < 0.001) 6. *(P* = 0.03) Current therapy: 1. *(P* = NS) 2. *(P* = NS) 3. *(P* = 0.008) 4. *(P* = NS) 5. *(P* = 0.002) 6. *(P* = 0.04) Current meds: 1. *(P* = 0.01) 2. *(P* < 0.001) 3. *(P* = NS) 4. *(P* = 0.001) 5. *(P* = 0.002) 6. *(P* = 0.007) Body mass index: 1. *(P* = NS) 2. *(P* = NS) 3. *(P* = NS) 4. *(P* = NS) 5. *(P* = NS) 6. *(P* = NS) Body image: 1. *(P* < 0.001) 2. *(P* < 0.001) 3. *(P* < 0.001) 4. *(P* < 0.001) 5. *(P* < 0.001) 6. *(P* < 0.001) Impulse control: 1. *(P* = 0.02) 2. *(P* < 0.001) 3. *(P* = 0.02) 4. *(P* = 0.01) 5. *(P* = 0.01) 6. *(P* = 0.01) Social adjustment: 1. *(P* < 0.001) 2. *(P* < 0.001) 3. *(P* < 0.001) 4. *(P* = 0.001) 5. *(P* < 0.001) 6. *(P* < 0.001)

Evidence Table. **Authors: Keel, Mitchell, Davis et al., 2000 (LR/JS/BN)**

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Keel, Mitchell, Davis et al., 2000 (continued)				

Study Methods and Analytic Strategy	Main Outcomes and Results
Measures: • Hamilton Depression Rating Scale • Structured Clinical Interview for the DSM IV Axis I Disorders • Body Shape Questionnaire • SAS-SR • Control Scale of the Multidimensional Personality Questionnaire (MPQ-8) • Eating Disorders Questionnaire **Analytic Strategy:** All analyses performed with all available data. The specific analytic strategies utilized not reported.	**Associations between prognostic variables and ED outcomes across definitions of outcome:** Depression: 1. *(P* = NS) 2. *(P* = NS) 3. *(P* = NS) 4. *(P* = NS) 5. *(P* = NS) 6. *(P* = NS) Affective disorder: 1. *(P* = 0.007) 2. *(P* = NS) 3. *(P* = 0.002) 4. *(P* = NS) 5. *(P* = NS) 6. *(P* = 0.05) Substance use: 1. *(P* = NS) 2. *(P* = 0.004) 3. *(P* = 0.04) 4. *(P* = 0.005) 5. *(P* = 0.01) 6. *(P* = NS) Hx of AN: 1. *(P* = NS) 2. *(P* = NS) 3. *(P* = NS) 4. *(P* = NS) 5. *(P* = NS) 6. *(P* = NS) Personality disorder: 1. *(P* = NS) 2. *(P* = NS) 3. *(P* = NS) 4. *(P* = NS) 5. *(P* = NS) 6. *(P* = NS) Tx: 1. *(P* = NS) 2. *(P* = NS) 3. *(P* = NS) 4. *(P* = NS) 5. *(P* = NS) 6. *(P* = NS) Age of onset: 1. *(P* = NS) 2. *(P* = 0.05) 3. *(P* = NS) 4. *(P* = 0.027) 5. *(P* = NS) 6. *(P* = NS) Age of present: 1. *(P* = NS) 2. *(P* = NS) 3. *(P* = 0.001) 4. *(P* = NS) 5. *(P* = NS) 6. *(P* = 0.009) Severity of symptoms: 1. *(P* = NS) 2. *(P* = NS) 3. *(P* = 0.02) 4. *(P* = NS) 5. *(P* = NS) 6. *(P* = NS) Duration of symptoms: 1. *(P* = 0.004) 2. *(P* = NS) 3. *(P* = 0.01) 4. *(P* = NS) 5. *(P* = NS) 6. *(P* = 0.009)

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Keel et al., 1999 **Companion article:** Keel, Mitchell, Miller et al., 2000 Keel, Mitchell, Davis et al., 2000 **Design:** Case series **Comparison Group:** No **Location:** USA **Yrs followed:** Mean duration of FU 11.5 (1.9)	To determine and describe predictive factors of long-term outcome for females with BN	**Inclusion:**. At baseline, participants needed to meet DSM III criteria for BN and also needed to purge ≥ 3 times/wk during 6 mos prior to baseline evaluation; needed to meet criteria for past BN on SCID-I/P at FU evaluation. **Exclusion:** NR **Recruitment:** Participation in two previous studies on BN (Mitchell, Pyle et al., 1988, and Mitchell, Pyle et al., 1990) who were initially evaluated at the University of Minnesota's Eating Disorders Clinic between 1981-1987.Subjects from 2 previous studies recontacted via letter from one of investigators. Final participation rate = 80.5% No diff in participation rates between the 2 studies **Sample Size:** Original (N = 222) Not located (confirmed not deceased) (N = 22) Deceased (N = 1) Severely disabled and blind (N = 1) Refused (N = 21) Did not meet DSM IV criteria for BN based on initial assessment and SCID-I/P at FU (N = 4) Final sample (N = 173) **Analysis sample size:** N = 173 but varies based on completion of scales. Scales had to be 80% complete for inclusion.	**Mean Age** 35.3 (5.1) yrs **Duration of FU:** 11.5 (1.9) **Mean age at onset:** 16.8 (2.5) **Sex:** Female: 100% **Race/ethnicity:** White: 99% Not White: 1% **Education:** HS: 99% College: 30% Graduate sch: 15% Ever married: 75% Still in 1st marriage: 50% **Vocation:** Manual labor: < 10% Clerical/sales: 26.6% Administration: 33.5% **Professional:** < 10%	**Score:** Fair **Method of dx:** DSM IV SCID-I/P for Axis I disorders + addendum for impulse control disorders at FU. **Funding:** McKnight Center grant for Eating Disorders Research; Obesity Center grant P30 DK50456, NIH; research training grant, dissertation grants from APA and Minnesota Women Psychologists' Assoc., dissertation fellowshipfrom U of Minn

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods Questionnaires sent by mail: Eating Disorders Questionnaire, Hamilton Depression Rating Scale, Hamilton Anxiety Rating Scale, Multidimensional Personality Questionnaire Scale 8: Control/Impulsiveness, Body Shape Questionnaire Personal interview conducted either at the Eating Disorders Research Office or at home (54%), or over phone (46%). Structured interviews (DSM IV SCID-I/P) conducted by authors or trained research assistants. **Outcome definitions** Full Remission: Narrow definition: freedom from disordered eating for at least 6 mos; wt and shape could not unduly influence how subject felt about or evaluated herself Broad definition: absence from disordered eating for at least 8 wks with no restrictions based on influence of wt or shape on self-evaluation. Partial remission: not meeting criteria for full remission and not meeting DSM IV criteria for any ED **Analytic Methods** Parametric and nonparametric tests used to assess diff in means and proportions. Due to large # of tests, sig level = $\alpha < 0.01$ and family-wise error controlled with Dunn test corrections. **Outcomes** Measured both categorically (remission – full and partial – or not in remission) and continuously (log of the number of mos since last binge/purge episode) Duration of FU between 2 subsamples not different for categorical variables (*P* = 0.09), but sig different (*P* = 0.005) for continuous variables so continuous prognostic variables controlled for the variance explained by duration of FU. Eating Disorder Outcome did not differ based on the narrow (*P* = NS) or full (*P* = NS) defs of remission or on # of mos since last ED symptom.	**Descriptive Results:** **Outcome for total population:** AN: 1 (0.6%) BN: 19 (11%) BED: 1 (0.6%) EDNOS: 31 (17.9%) **By narrow def of remission** Full remission: 72 (41.6%) Partial remission: 49 (28.3%) **By broad def of remission** Full remission: 81 (46.8%) Partial remission: 40 (23.1%) **Comparisons of wt variables measured at Baseline and FU:** **Change in BMI:** Baseline: 21.2 (2.7) FU: 22.1 (3.6) (*P* < 0.001) **Change in actual wt:** Baseline: 58.3 (8.5) FU: 60.7 (10.9) (*P* < 0.01) **Change in desired wt:** Baseline: 53.1 (5.2) FU: 56.5 (6.2) (*P* < 0.001) **Change in highest wt:** Baseline: 66.38 (11.43) FU, 69.79 (13.18) (*P* < 0.001) **Change In lowest wt:** Baseline 50.91 (7.38) FU: 50.91 (8.07) (*P* = NS) Change in wt not clinically sig due to aging of the sample **Body Shape Questionnaire** FU: Mean score = 86.8 (36.7) Compared to a community sample of 535 women: 81.5 (28.4) (*P* = NS) Compared to cohort with BN: 136.9 (22.5) (*P* < 0.001) Subjects with ED at FU had higher BSQ scores at FU (categorical) (*P* < 0.001), continuous (*P* < 0.001) **Prognostic Factors for ED outcome (measured categorically and continuously):** Remission: N = 121 Disordered eating: N = 52 **Outcome analysis measurement approach:** Cat: categorical Con: continuous Both: measured both ways **Age of onset:** 16.8 (2.5) yrs Both *(P = NS)*

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Keel et al., 1999 (continued)				

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Study Methods and Analytic Strategy	Main Outcomes and Results
	Duration of symptoms at baseline: 5.9 (3.6) yrs Both *(P* < 0.01)
	Baseline severity of ED symptoms: Both *(P* = NS)
	AN prior to BN: Cat *(P* = NS)
	Lifetime Mood Disorder Remission: 62.8% Disordered eating: 71.2% Both *(P* = NS)
	Baseline Depression Remission: 7.7% Disordered eating: 8.0% Both *(P* = NS)
	Lifetime Anxiety Disorder Remission: 29.8% Disordered eating: 34.6% Both *(P* = NS)
	Baseline Anxiety Disorder Remission: 4.6% Disordered eating: 6.1% Both *(P* = NS)
	Lifetime Substance Use Remission: 53.8% Disordered eating: 74.0% Cat *(P* < 0.05); Con *(P* < 0.01)
	Baseline Substance Use Remission: 19.2% Disordered eating: 43.8% Cat *(P* < 0.05); Con *(P* < 0.001)
	Lifetime Impulse Control Remission: 16.5% Disordered eating: 21.2% Both *(P* = NS)
	Baseline Impulse Control Remission: 46.3% Disordered Eating: 58.1% Both *(P* = NS)
	Multidimensional Personality Questionnaire **Cross-sectional:** Cat *(P* < 0.01); Con *(P* < 0.05)
	Treatment received in past Took meds
	Remission: 69.4%

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Keel et al., 1999 (continued)				

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Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
	Disordered eating: 82.7% Cat (*P* = NS); Con *(P* < 0.05)
	Therapy in past Remission: 95% Disordered eating: 94.2% Both *(P* = NS)

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Keel, Mitchell, Miller et al., 2000 **Companion article:** Keel et al., 1999 Keel, Mitchell, Davis et al., 2000 **Design:** Case Series **Comparison Group:** No **Location:** USA **Yrs followed:** Mean duration of FU: 11.5 (1.9)	To investigate the predictive validity of BN as a diagnostic category, using 10+ yr FU data in a sample of women with BN.	**Inclusion:** Met the DSM III criteria for BN and the additional criterion of binge eating coupled with vomiting or laxative abuse at least 3 times each wk for 6 mos. **Exclusion:** None **Recruitment:** Participation in two previous studies on BN (Mitchell, Pyle et al., 1988, and Mitchell, Pyle et al., 1990) who were initially evaluated at the University of Minnesota's Eating Disorders Clinic between 1981-1987.Subjects from 2 previous studies recontacted via letter from one of investigators. Final participation rate = 80.5% No diff in participation rates between the 2 studies **Sample Size:** Original (N = 222) **Reasons for loss to FU:** Not located (confirmed not deceased) (N = 22) Deceased (N = 1) Severely disabled and blind (N = 1) Refused (N = 21) Did not meet DSM IV criteria for BN based on initial assessment and SCID-I/P at FU (N = 4) Final sample (N = 173) **Analysis sample size:** N = 173	**Mean Age** 35.3 (5.1) **Sex:** Female: 100% **Race/ethnicity:** Caucasian (N = 176) 98.9% Non-caucasian (N = 1) 1% **Mean duration of FU, yrs (SD):** 11.5 (1.9)	**Score:** Fair **Method of dx:** DSM IV SCID-I/P for Axis I disorders + addendum for impulse control disorders at FU. **Funding:** McKnight Grant, Obesity Center grant from National Institute of Diabetes and Digestive and Kidney Diseases, NIMH grant, and dissertation grants from the American Psychological Association, the Minnesota Women Psychologists' Association, and the University of Minnesota

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods: Participants completed the SCID-I for DSM IV Axis I Disorders and the HRSD. **Outcomes:** ED outcome was defined both as categorical and continuous variables. Categorical def: distinguished between those who met DSM IV criteria for an ED and those free from recurrent ED symptoms 1 mo prior to assessment. Continuous def: natural log of mos between most recent binge or purge episode and assessment. **Analytic Strategy:** Chi Square and t-tests. Tests were two-tailed with an alpha of 0.01.	**Descriptive:** At FU, 19 (11.0%) met BN criteria 62 (35.8%) had a lifetime hx of AN 1 had current AN. 19 (11.0% of total sample) had a lifetime hx of BED 1 had current BED. 32 (18.5% of total sample) had current EDNOS. EDNOS was most common ED at FU *(P* < 0.001); Among these women, recurrent binge-purge episodes or purging alone were sig more common than recurrent binge eating alone *(P* = 0.01). **Relation of ED Outcome to Axis I Disorders at 10-Yr FU:** **ED measured as categorical variable (Remitted versus Present)** Remitted: N = 121; Present: N = 52 Mood Disorder: Remitted: 2 (1.7%); Present: 11 (21.2%) *(P* < 0.001) Anxiety Disorder: Remitted: 20 (16.5%); Present: 6 (11.5%) *(P* = NS) Substance Disorder: Remitted: 1 (0.08%); Present: 8 (15.4%) *(P* < 0.001) Impulse Control Disorder: Remitted: 2 (1.7%); Present: 9 (17.3%) *(P* < 0.001) Mood disorders and HDRS scale scores: Data: NR *(P* = 0.002) **ED measured as continuous variable (natural log of mos between most recent binge/purge episode and assessment):** Mood Disorder: Axis I Absent: 2.6 (2.0%); Axis I Present: 0.4 (1.3%) *(P* < 0.001) Anxiety Disorder: Axis I Absent: 2.3 (2.0%); Axis I Present: 2.9 (2.0%) *(P* = NS) Substance Disorder: Axis I Absent: 2.5 (2.0%); Axis I Present: 0.2 (0.5%) *(P* < 0.001) Impulse Control Disorder: Axis I Absent: 2.5 (2.0%); Axis I Present: 0.5 (1.3%) *(P* < 0.001) Mood disorders and HDRS scale scores: Data: NR *(P* = 0.01)

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Patton, 1988 **Design:** Case series **Comparison Group:** No **Location:** United Kingdom **Yrs followed, mean (SD):** AN: 7.6 (3.0) BN: 5.7 (2.1) Range: 4-15	Calculate a standardized mortality rate for eating disorders in a large population	**Inclusion:** Eating disorder dx AN (Russell, 1970): Loss of 25% of BW Amenorrhea Fear of putting on wt BN (Russell, 1979): Uncontrollable urge to overeat (binge) Self-induced vomiting or laxative abuse *(*Purge) Feat of becoming fat **Exclusion:** NR **Recruitment:** Reviewed records of all eating disordered patients assessed in the eating disorders unit of the Academic Department of Psychiatry at Royal Free Hospital, 1971-81. **Sample Size:** **Initial:** N = 481 **Reasons for loss to FU:** Lost to FU: N = 21 Deaths: N = 14 AN: N = 11 Suicide: N = 6 Low wt: N = 5 BN: N = 3 Car accident: N = 2 Low wt: N = 1 **Analysis sample:** Located / Analyzed: N = 460 AN: 332 (72.1%) BN: 96 (20.9%) Other: 32 (7.0%)	**Mean Age (yrs):** AN: 22.4 BN: 23.5 **Mean Wt (kg):** AN: 41 BN: 58.9 **Sex:** Female: 95.9% Male: 4.1% **Race/ethnicity:** NR **Mean Age of Onset (yrs):** AN: 18.9 BN: 18.6 **Mean Duration of Illness (yrs):** AN: 3.5 BN: 4.9 **2nd Dx at Assessment:** Depression, N = 52 AN: N = 26 BN: N = 26	**Score:** Fair **Method of dx:** Russell diagnostic criteria for AN and BN applied retrospectively to case note description of presentation **Funding:** Grant from the Wellcome Foundation

Study Methods and Analytic Strategy	Main Outcomes and Results
Study methods Attempted to locate by: Contact with referring physician Last known address National Health Service Central Registry **Located 95.6%** FU conducted, 1985-86 Sex specific death rates derived from 1981 death rates for England and Whales **Analysis methods** Observed mortality rate (study population) Expected mortality rate (general population) Standardized mortality ratio (SMR) = observed / expected Stepwise linear discriminant function analysis: to examine the relationship of crude mortality to the prognostic variables	**Descriptive Results** **Mortality rate** Crude mortality rate (%) AN: 3.1 BN: 3.3 Expected mortality rate: AN: 1.83 BN: 0.32 Standardized mortality rate AN: 6.01 *(P* < 0.01) Higher than expected BN: 9.38 *(P* = NS) **AN mortality rate (by length of FU):** Actual mortality Overall: 11 After 4 yrs: 6 After 8 yrs: 1 Expected mortality rate Overall: 1.83 After 4 yrs: 1.04 After 8 yrs: 0.37 Standardized mortality rate Overall: 6.01 *(P < 0.01)* Higher than expected After 4 yrs: 5.76 *(P < 0.05)* Higher than expected After 8 yrs: 2.70 *(P = NS)* **Predictors of mortality in individuals with AN** wt < 35 kg at presentation: Crude (%): 8.1 (N = 5) Expected: 0.33 Standardized: 15.15 *(P < 0.05)* Higher than expected More than one inpatient admission: Crude (%): NR Expected: NR Standardized: NR *(P < 0.01)* Higher than expected Age < 20 yrs at presentation: Crude (%): 2.8 (N = 4) Expected: 0.41 Standardized: 9.76 *(P = NS)* Age 20-29 yrs at presentation: Crude (%): 2.9 (N = 4) Expected: 0.56 Standardized: 7.09 *(P = NS)* Age ≤ 30 yrs at presentation: Crude (%): 6.0 (N = 3) Expected: 0.86 Standardized: 3.49 *(P = NS)*

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Stice and Fairburn, 2003 **Companion article:** Fairburn et al., 2000 Fairburn et al., 2003 **Design:** Prospective Cohort **Comparison Group:** No **Setting:** United Kingdom **Yrs followed:** At 15 mo intervals for 5 yrs. **Final FU:** 5.0 yrs (0.3)	In an independent, community-based sample, to replicate the validity of the prior finding that women with BN can be classified by dietary and dietary-depression subtypes.	**Inclusion:** Female; met DSM IV criteria for BN; provided complete data at baseline. **Exclusion:** NR **Recruitment:** Community-recruited **Sample Size:** **Baseline:** (N = 102) **Reasons for loss to FU:** NR **Analysis sample:** (N = 82) **Dietary:** Dietary Restraint (N = 46) Dietary-Depressive: Dietary Restraint- Depressive Affect (N = 36)	**Mean Age:** 23.7 (4.9) **Sex:** Female: 100% **Race/ethnicity:** NR **Social Class** Social Class I or II (high): 47% Social Class III (middle): 45% Social Class IV or V (low): 9% **Mean BMI, kg/m²:** 24.3 (4.6) **Received prior tx for ED at baseline:** 27%	**Score:** Fair **Method of dx:** EDE was used to asses DSM IV criteria. **Funding:** Programme Grant, Wellcome Principal Research Fellowship, and NIMH Career Award

Evidence Table 16. Bulimia nervosa outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods: EDE: to asses BN and attitudinal disturbances at each time point; Depression was assessed using the BSI subscale; the SCID-I assessed current disorders at each FU; Robson Self-Esteem scale assessed general self worth. **Statistical Methods** Iterative cluster analysis of baseline scores relating to Restraint, Depression, and Self-Esteem Scales used to categorize participants as dietary or dietary-depression subtypes. Chi-square diffs between groups	**Cluster Analysis Results** Dietary classification: Dietary Restraint (N = 46) Dietary-Depressive classification: Dietary Restraint-Depressive Affect (N = 36) **Descriptive Results** **Lifetime psychiatric tx for ED at baseline:** Dietary: 17.4% Dietary-depressive: 38.9% Diff between groups RR = 2.24 *(P* < 0.05) **Psychiatric tx for ED during FU:** Dietary: 17.4% Dietary-depressive: 30.6% Diff between groups RR = 1.76 *(P* = NS) **BN symptoms: Persistence of binge eating:** Dietary: 43.9% Dietary-depressive: 67.7% Diff between groups RR = 1.54 *(P* < 0.044) **BN symptoms: Persistence of compensatory behaviors:** Dietary: 57.1% Dietary-depressive: 60.6% Diff between groups RR = 1.06 *(P* = NS) **Major depression dx** Dietary: 60.9% Dietary-depressive: 80.6% Diff between groups RR = 1.32 *(P* < 0.05) **Panic disorder dx** Dietary: 15.2% Dietary-depressive: 33.3% Diff between groups RR = 2.19 *(P* < 0.05) **OCD dx** Dietary: 2.2% Dietary-depressive: 25.0% Diff between groups RR = 11.32 *(P* < 0.01) **Social phobia dx** Dietary: 15.2% Dietary-depressive: 33.3% Diff between groups RR = 2.19 *(P* < 0.05) **Generalized anxiety disorder dx** Dietary: 10.9% Dietary-depressive: 47.2% Diff between groups RR = 4.33 *(P* < 0.001) **Agoraphobia dx** Dietary**:** 4.3% Dietary-depressive**:** 36.1% Diff between groups RR = 8.39 *(P* < 0.001)

Evidence Table 17. BED outcomes

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Busetto et al., 2005 **Design:** Case series **Comparison Group:** Yes **Location:** Padova, Italy **Yrs followed:** 5	To investigate 5 yr outcome of morbidly obese patients with BED treated surgically with LAGB.	**Inclusion:** **Cases**: BED dx based on proposed diagnostic criteria of DSM IV **Comparisons**: Obese non-BED patients selected according to the inclusion criteria standardized by the NIH for obesity. **Exclusion:** NR **Recruitment of cases and comparisons:** Homogeneous cohort of morbidly obese patients who underwent LAGB surgery at the University of Padova between January 1996 and December 1998. **Sample Size:** 379 morbidly obese patients **Including:** • Cases (BED): N = 130 • Comparisons (No BED): N = 249	**Age, mean (SD):** Cases: 36.0 (10.3) Comparisons: 38.3 (10.9) *(P* < 0.05) **Height, m, mean (SD):** Cases: 1.66 (0.09) Comparisons: 1.66 (0.09) *(P* = NS) **Wt, kg mean (SD):** Cases: 129.4 (23.9) Comparisons: 132.2 (24.2) *(P* = NS) **BMI, kg/m2, mean (SD):** Cases: 47.6 (7.4) Comparisons: 46.6 (7.3) *(P* = NS) **Female Sex (%):** Cases: 72.9 Comparisons: 71.5 *(P* < 0.05) **Race/ethnicity:** NR **Family hx of obesity (%):** Cases: 65.4 Comparisons: 62.2 *(P* = NS) **Current smokers (%):** Cases: 39.2 Comparisons: 36.5 *(P* = NS) **Eating behavior** **Sweet eating (%)** Cases: 43.8 Comparisons: 43.8 *(P* = NS) **Night eating (%)** Cases: 10.8 Comparisons: 0.8 *(P* < 0.001) **Grazing (%)** Cases: 49.2 Comparisons: 32.5 *(P* < 0.01)	**Score:** Fair **Method of dx:** Independent clinical interviews **Funding:** NR

Evidence Table 17. BED outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods: All participants underwent the same LAPD surgery, and followed the same modified liquid diet for 4 wks, followed by a solid food diet. Band adjustments were not performed before 3 mos post-surgery. All patients with BED received brief course of psychological therapy before LAGB and psychological support was offered as needed during FU. **Statistical Methods:** Paired t-test for comparisons of pre- and post-surgery. t-tests and Chi-square tests for comparisons across groups	**Descriptive Results:** Diff % excess wt loss (EWL) at any time after surgery *(P* = NS) **5 yr FU:** **% of patients with % EWL >50%:** Cases: 23.1% Comparisons: 25.7% *(P* = NR) **% patients with %EWL < 20%:** Cases: 23.8% Comparisons: 24.1% Diff between groups (*P* = NR) **% of patients with wt regain (at least 20% of baseline excess wt):** Cases: 20.8% Comparisons: 22.5% *(P* = NR) **Postoperative complications at FU:** ***Band-related complications*** **Stoma Stenosis:** Cases: 34/130 (26.2%) Comparisons: 65/249 (26.1%) *(P* = NS) **Pouch Dilatation** Cases: 33/130 (25.4%) Comparisons: 44/249 (17.7%) *(P* = 0.05) **Esophageal Dilatation** Cases: 13/130 (10.0%) Comparisons: 12/249 (4.8%) *(P* = 0.05) **Stomach Slippage:** Cases: 11/130 (8.5%) Comparisons: 13/249 (5.2%) *(P* = NS) **Erosion** Cases: 1/130 (0.8%) Comparisons: 3/249 (1.2%) *(P* = NS) **Port-related complications:** **Port Leakage** Cases: 40/130 (30.8%) Comparisons: 68/249 (27.3%) *(P* = NS) **Port twisting** Cases: 1/130 (0.08%) Comparisons: 1/249 (0.4%) *(P* = NS)

Evidence Table 17. BED outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Busetto et al., 2005 (continued)				

Evidence Table 17. BED outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
	Port Infection Cases: 2/130 (1.5%) Comparisons: 1/249 (0.4%) (*P* = NS) **Revisional surgery requested related to pouch dilatation:** Cases: 33.3% 3 Comparisons: 4.1% (*P* = NS) **Revisional surgery requested in cases of esophageal dilatation:** Cases: 23.1% Comparisons: 8.3% (*P* = NS) **Revisional Surgery:** Cases: 15 (11.5%) Comparisons: 22 (8.8%) (*P* = NS) **Band removed:** Cases: 7 (5.4%) Comparisons: 9 (3.6%) (*P* = NS) **Band repositioned:** Cases: 7 (5.4%) Comparisons: 11 (4.4%) (*P* = NS) **Revised to a secondary operation.** Cases: 2 (0.8%) Comparisons: 11 (4.4%) (*P* = NS) **Minor portrelated surgery:** Cases: 28 (21.5%) Comparisons: 54 (21.7%) (*P* = NS) **Postoperative band adjustments:** Cases 3.0 (2.1) Comparisons 2.6 (1.9) (*P* = 0.05) **Max band fill-volume after surgery:** Cases: 3.2 (1.2) Comparisons: 2.8 (1.3) (*P* < 0.01)

Evidence Table 17. BED outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Fichter, Quadflieg, and Gnutzmann, 1998 **Design:** Case series **Comparison Group:** No **Location:** Upper Bavaria, Germany **Yrs followed, mean (SD):** 3.2 (0.8) and 6.6 (0.9) yrs after tx.	To assess 3 and 6 yr course and outcome of treated females with BED.	**Inclusion:** DSM IV criteria for BED **Exclusion:** NR **Recruitment:** Of the 635 consecutive admissions for inpatient tx to Hospital for Behavioral Medicine at the Klinik Roseneck in Upper Bavaria, Germany, 68 met criteria. **Sample Size:** **Initial Sample** N = 68 **3 yr FU:** Answered questionnaires: 61 (89.7%) Short telephone interview: 2 (2.9%); Could not be reached: 4 (5.9%) Refused: 1 (1.5%) **6 yr FU:** N = 62 Death: 1 (1.5%) (due to extrauterine pregnancy). Reassessed: 67 (questionnaire and interview = 53; questionnaire and short interview = 1; interview = 9; short interview = 4)	**Age at Admission, yrs, mean (SD):** 29.3 (8.4) **Age of Onset, yrs, mean (SD):** 17.7 (8.9) **Sex:** Female: 100% **Race/ethnicity:** NR **Duration of tx, days, mean (SD):** 76.7 (40) **Duration of eating disturbance, ys, mean (SD):** 11.6 (7.3) **Education, N (%):** < 9 yrs: 3 (4.4%) At least 9 yrs: 52 (76.5%) At least 13 yrs: 10 (14.8%) University degree: 3 (4.4%) **Axis IV (severity of psychosocial stressors) at admission, N (%):** Unspecified: 2 (3.1%) None: 2 (3.1%) Minimal: 5 (7.7%) Mild: 18 (27.7%) Moderate: 20 (30.8%) Severe: 14 (21.5%) Extreme: 3 (4.6%) Catastrophic: 1 (1.5%) **Axis V (highest level of adaptive function for mos before admission, N (%):** Superior: 0 Very good: 2 (3.1%) Good: 11 (16.9%) Satisfactory: 27 (41.5%) Poor: 23 (35.4%) Very Poor: 2 (3.1%) Grossly Impaired: 0	**Score:** Fair **Method of dx:** Self ratings on admission and discharge. Questionnaire used to determine DSM IV categories for BED, supplemented by patient charts and therapist dx. **Funding:** German Bundesministerium fur Bildung, Forschung and Technologie (BMBF) and Wilhelm-Sander-Stiftung, Munich, Germany

Evidence Table 17. BED outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods: Tx: inpatient, behaviorally oriented tx. Assessments at admission, discharge, 3 yr (questionnaire), and 6 yr (questionnaire and phone interview) **Analytic Strategy:** MANOVA with repeated measures. For longitudinal comparisons, only sets of data complete for all time points were analyzed. Wilcoxon matched-pair tests used when appropriate. **Codes used:** BT = Before Therapy B: Beginning of therapy E: End of therapy F3: 3 yr FU F6: 6 yr FU	**Discharge, N (%):** Regular: 60 (89.6%) Discontinued tx prematurely: 1 (1.5%) Discharged prematurely: 2 (3.0%) Discharged prematurely by mutual agreement with patient: 4 (6.0%) **Discharge ratings by therapists, N (%):** Sigly improved: 11 (16.4%) Markedly improved: 37 (55.2%) Slightly Improved: 16 (23.9%) Unchanged: 2 (3.0%) Slightly worse: 1 (1.5%) **Met criteria for BN at 6 yr FU: N = 5** **BMI, kg/m^2, mean (SD):** **B:** 33.7 (9.0) **E:** 31.9 (8.7) **F3:** 31.9 (9.9) **F6:** 32.7 (10.1) Change over time *(P* = NR) **BMI in 44 obese patients (BMI ≥ 30) at B, kg/m^2, mean (SD)** **B:** 39.0 (6.8) **E:** 36.9 (6.8) **F3:** 37.0 (8.2) **F6:** 38.3 (8.1) Change over time *(P* = NR) **Structured Interview for Anorexic and Bulimic Syndromes (SIAB) (N = 53):** **SIAB Depression Scale, mean (SD):** BT: 2.32 (1.0) B: 2.33 (0.9) E: 1.48 (0.9) F3: 1.71 (0.9) F6 (expert rating): 0.94 (0.8) Change over time in BT vs E and F6 *(P* < 0.001); vs. F3 *(P* < 0.01) Change over time in B vs E, F3, and F6 *(P* < 0.001) Change over time in E vs F6 *(P* < 0.001) Change over time in F3 vs F6 *(P* < 0.001) **SIAB Anxieties and Obsessions Scale, mean (SD):** BT: 1.32 (0.9) B: 1.31 (0.8) E: 0.76 (0.7) F3: 1.00 (0.7) F6 (expert rating): 0.46 (0.4) Change over time in BT vs E and F6 *(P* < 0.001); vs F3 *(P* < 0.05) Change over time in B vs E and F6 *(P* < 0.001); vs F3 *(P* < 0.01) Change over time in E vs F3 *(P* < 0.01); vs F6 *(P* < 0.001) Change over time in F3 vs F6 *(P* < 0.001)

Evidence Table 17. BED outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Fichter, Quadflieg, and Gnutzmann, 1998 (continued)				

Evidence Table 17. BED outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
	SIAB Bulimic Behavior, mean (SD): BT: 1.60 (0.6) B: 1.48 (0.5) E: 1.08 (0.4) F3: 1.21 (0.6) F6 (expert rating): 0.81 (0.6) Change over time in BT vs E and F6 *(P* < 0.001); vs F3 *(P* < 0.01) Change over time in B vs E, F3, and F6 *(P* < 0.001) Change over time in E vs F6 *(P* < 0.001) Change over time in F3 vs F6 *(P* < 0.001) **SIAB Laxative Abuse, mean (SD):** BT: 1.39 (1.3) B: 0.82 (0.9) E: 0.66 (0.9) F3: 0.38 (0.8) F6 (expert rating): 0.23 (0.6) Change over time in BT vs B, E, and F3 *(P* < 0.001) Change over time in B vs F3 *(P* < 0.01) Change over time in B vs F6 *(P* < 0.01) **Diagnostic outcome at 6 yrs, N (%):** BED: 4 (5.9%) BN, purging type: 5 (7.4%) EDNOS: 5 (7.4%) No ED: 53 (77.9%) **Outcomes at 6 yr FU (N = 62):** **Body wt, N (%):** Good: 26 (41.9%) Intermediate: 22 (35.5%) Poor: 14 (22.6%) *(P* = NR) **Overconcern with eating and wt, N (%):** Good: 22 (35.5%) Intermediate: 20 (32.3%) Poor: 20 (32.3%) *(P* = NR) **Binge eating:** Good: 39 (62.9%) Intermediate: 13 (21.0%) Poor: 10 (16.2%) *(P* = NR) **Counterregulatory measures, N (%):** Good: 44 (71.0%) Intermediate: 11 (17.7%) Poor: 10 (11.3%) *(P* = NR) **Depression, N (%):** Good: 35 (56.5%) Intermediate: 12 (19.4%) Poor: 15 (24.2%) *(P* = NR)

Evidence Table 17. BED outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Fichter, Quadflieg, and Gnutzmann, 1998 (continued)				

Evidence Table 17. BED outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
	Obsessions, N (%): Good: 49 (79.0%) Intermediate: 10 (16.1%) Poor: 3 (4.8%) *(P* = NR) **Anxiety, N (%):** Good: 39 (62.9%) Intermediate: 19 (30.6%) Poor: 4 (6.5%) *(P* = NR) **Substance abuse, N (%):** Good: 58 (93.5%) Intermediate: 1 (1.6%) Poor: 3 (4.8%) *(P* = NR) **Sexuality, N (%):** Good: 24 (38.7%) Intermediate: 16 (25.8%) Poor: 22 (35.5%) *(P* = NR) **Social Behavior, N (%):** Good: 32 (51.6%) Intermediate: 15 (24.2%) Poor: 15 (24.2%) *(P* = NR) **Global outcome based on reduced sample (N = 62), N (%):** Good: 39 (62.9%) Intermediate: 21 (33.9) Poor: 2 (3.2%) *(P* = NR) **Global outcome on total sample (N = 68), %:** Good: 57.4% Intermediate: 35.3% Poor: 5.9% *(P* = NR) **Comorbidity at 6 yrs, %:** Substance use disorder: 9.7% Affective disorder: 51.6% Anxiety disorder: 40.3% **Hospitalized in the 6 yr FU period:** 44/67 **Duration of stay, days, mean (SD):** 114 (208) **Number of admissions, mean (SD):** 1.6 (1.6)

Evidence Table 17. BED outcomes (continued)

Study Description	Research Objective	Eligibility Criteria, Recruitment and Sample Size	Demographic and Other Characteristics	Quality
Authors, yr: Wilfley, Friedman et al., 2000 **Design:** Case series **Comparison Group:** No **Location:** USA **Yrs followed:** 1	To examine the relation of comorbid Axis I and Axis II psycho-pathology on tx outcomes at 1 yr FU among BED patients	**Inclusion:** Participated in an outpatient RCT and received either CBT or IPT conducted at 2 outpatient, university-based eating disorder clinics, one in Northeast and one in Southwest DSM IV criteria for BED ages 18-65 BMI (kg/m^2):27-48 **Exclusion:** Inappropriate compensatory behaviors; pregnant or planning to become pregnant; participating in additional psychotherapy or wt loss programs; currently taking wt loss, psychotropic, or wt-affecting prescription meds; current drug or alcohol dependence; current psychiatric conditions warranting hospitalization **Recruitment:** Newspaper articles and ads **Sample Size:** Participated in RCT, N = 162 **# of completers at 1-yr FU:** NR	**Mean Age (SD):** 45.2 (9.6) **Sex:** Women: 83% **Race/ethnicity:** Caucasian: 93% African American: 4% Hispanic: 3% Native American: 1% **Marital status:** Married: 60% Single: 15% Divorced: 24% Widowed: 2% **Education (mean):** 15.6 yrs **Mean Income range:** $40,000-$50,000 **Comorbid Axis I general dx (current):** Mood disorders: 22% Anxiety disorders: 13% Substance abuse disorders: 4% **Comorbid Axis I general dx (lifetime):** Mood disorders: 61% Anxiety disorders: 29% Substance abuse disorders: 33% **Comorbid Axis II:** Cluster A: 6% Cluster B: 12% Cluster C: 42% Personality disorder NOS: 13% **Avg. BMI (kg/m^2) (SD):** 37.1 (5.1)	**Score:** Good **Method of dx:** BED: EDE interview Comorbid Axis I and Axis II disorders: SCID and the SCID-II **Funding:** NIMH grants

Evidence Table 17. BED outcomes (continued)

Study Methods and Analytic Strategy	Main Outcomes and Results
Study Methods: EDE and SCID administered by trained and experienced interviewers **Statistical Methods:** Repeated measures MANOVAs to assess whether the presence of Axis I or Axis II pathology predicts BED outcome at 1-yr FU. **Dependent variables:** # of binge days EDE Global Scale of Eating Psychopathology	**Descriptive Findings** **Mood disorder dx:** Current: 22% Lifetime61% **Anxiety disorder dx:** Current: 13% Lifetime29% **Substance abuse dx:** Current: 4% Lifetime33% **Interaction of Time X presence of Axis I psychopathology (i.e., mood, anxiety, and substance abuse disorders) predicting:** # of binge days *(P* = NS) **EDE Global Scale of Eating Psychopathology *(P* = NS)** **Interaction of Time x Presence of Axis II psychopathology (i.e., cluster A, B, and C) predicting:** # of binge day *(P* = NS) EDE Global Scale of Eating Psychopathology *(P* = NS**)** **Interaction of Time X Presence of specific Axis I psychopathology predicting:** # of binge days *(P* = NS) EDE Global Scale of Eating Psychopathology *(P* = NS) **Interaction of Time X Presence of Axis II Cluster A *(P*aranoid, schizoid, schizotypal) predicting:** # of binge days *(P* = NS) EDE Global Scale of Eating Psychopathology *(P* = NS) **Interaction of Time X Presence of Axis II Clusters B (narcissistic, borderline, histrionic, antisocial) predicting:** # of binge days *(P* = 0.022) Those with Cluster B > # of binge days EDE Global Scale of Eating Psychopathology *(P* = NS) **Interaction of Time X Presence of Axis II Cluster C (dependent, obsessive-compulsive, avoidant, passive-aggressive) predicting:** # of binge days *(P* = NS) EDE Global Scale of Eating Psychopathology *(P* = NS)

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Wolk SL, Devlin MJ. Stage of change as a predictor of response to psychotherapy for bulimia nervosa. Int J Eat Disord 2001;30(1):96-100.

Appendix D. List of Excluded Articles

Excluded Articles

Full Text Article Exclusion Criteria Codes for Database

X1 Sample size too small
X2 No control or comparison group
X3 No original data (e.g., letters, reviews, etc.)
X4 Does not focus on subjects with primary problem of AN, BN, BED
X5 Study published in abstract form only
X6 Wrong study design (e.g., case series only)
X7 Wrong (or no) outcome
X8 Insufficient statistical analysis to make comparisons
X9 Wrong year (i.e., outside of our inclusion period of 1980-2005)
X10 Drug no longer on the market
X11 Uses DSM-III definition for BN
X12 Does not follow individuals (AN or BED) for at least 1 year
X13 Does not follow BN patients 3 months
XL Not retrievable from library

Excludes

Abraham S. Sexuality and reproduction in bulimia nervosa patients over 10 years. J Psychosom Res 1998;44(3-4):491-502.
Call Number: Reason for exclusion: X1

Adami GF, Meneghelli A, Scopinaro N. Night eating and binge eating disorder in obese patients. Int J Eat Disord 1999;25(3):335-8.
Call Number: Reason for exclusion: X1

Affenito SG, Lammi-Keefe CJ, Vogel S, et al. Women with insulin-dependent diabetes mellitus (IDDM) complicated by eating disorders are at risk for exacerbated alterations in lipid metabolism. Eur J Clin Nutr 1997;51(7):462-6.
Call Number: Reason for exclusion: X4

Agras WS, Crow SJ, Halmi KA, et al. Outcome predictors for the cognitive behavior treatment of bulimia nervosa: data from a multisite study. Am J Psychiatry 2000;157(8):1302-8.
Call Number: Reason for exclusion: X2

Agras WS, Dorian B, Kirkley BG, et al. Imipramine in the treatment of bulimia: a double-blind controlled study. Int J Eating Disorders 1987;6(1):29-38.
Call Number: Reason for exclusion: X1

Alger SA, Schwalberg MD, Bigaouette JM, et al. Effect of a tricyclic antidepressant and opiate antagonist on binge-eating behavior in normoweight bulimic and obese, binge-eating subjects. Am J Clin Nutr 1991;53(4):865-71.
Call Number: Reason for exclusion: X1

Ames-Frankel J, Devlin MJ, Walsh BT, et al. Personality disorder diagnoses in patients with bulimia nervosa: clinical correlates and changes with treatment. J Clin Psychiatry 1992;53(3):90-6.
Call Number: Reason for exclusion: X1

Anderson CB, Joyce PR, Carter FA, et al. The effect of cognitive-behavioral therapy for bulimia nervosa on temperament and character as measured by the temperament and character inventory. Compr Psychiatry 2002;43(3):182-8.
Call Number: Reason for exclusion: X2

Anderson KP, LaPorte DJ, Brandt H, et al. Sexual abuse and bulimia: response to inpatient treatment and preliminary outcome. J Psychiatr Res 1997;31(6):621-33.
Call Number: Reason for exclusion: X12

Andrewes DG, O'Connor P, Mulder C, et al. Computerised psychoeducation for patients with eating disorders. Aust N Z J Psychiatry 1996;30(4):492-7.
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Andrews B, Valentine ER, Valentine JD. Depression and eating disorders following abuse in childhood in two generations of women. Br J Clin Psychol 1995;34 (Pt 1):37-52.
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Bachar E, Latzer Y, Kreitler S, et al. Empirical comparison of two psychological therapies. Self psychology and cognitive orientation in the treatment of anorexia and bulimia. J Psychother Pract Res 1999;8(2): 115-28.
Call Number: Reason for exclusion: X1

Baell WK, Wertheim EH. Predictors of outcome in the treatment of bulimia nervosa. Br J Clin Psychol 1992;31 (Pt 3):330-2.
Call Number: Reason for exclusion: X12

Bara-Carril N, Williams CJ, Pombo-Carril MG, et al. A preliminary investigation into the feasibility and efficacy of a CD-ROM-based cognitive-behavioral self-help intervention for bulimia nervosa. Int J Eat Disord 2004;35(4):538-48.
Call Number: Reason for exclusion: X6

Barbarich NC, McConaha CW, Gaskill J, et al. An open trial of olanzapine in anorexia nervosa. J Clin Psychiatry 2004;65(11):1480-2.
Call Number: Reason for exclusion: X2

Barkmeier WW, Peterson DS, Wood LW. Anorexia nervosa: recognition and management. J Oral Med 1982;37(2):33-7.
Call Number: Reason for exclusion: X1

Barlow J, Blouin J, Blouin A, et al. Treatment of bulimia with desipramine: a double-blind crossover study. Can J Psychiatry 1988;33(2):129-33.
Call Number: Reason for exclusion: X11

Bean P, Loomis CC, Timmel P, et al. Outcome variables for anorexic males and females one year after discharge from residential treatment. J Addict Dis 2004;23(2):83-94.
Call Number: Reason for exclusion: X1

Bergh C, Brodin U, Lindberg G, et al. Randomized controlled trial of a treatment for anorexia and bulimia nervosa. Proc Natl Acad Sci U S A 2002;99(14):9486-91.
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Bjorck C, Clinton D, Sohlberg S, et al. Interpersonal profiles in eating disorders: ratings of SASB self-image. Psychol Psychother 2003;76(Pt 4):337-49.
Call Number: Reason for exclusion: X6

Blais MA, Becker AE, Burwell RA, et al. Pregnancy: outcome and impact on symptomatology in a cohort of eating-disordered women. Int J Eat Disord 2000;27(2):140-9.
Call Number: Reason for exclusion: X7

Blouin AG, Blouin JH, Iversen H, et al. Light therapy in bulimia nervosa: a double-blind, placebo-controlled study. Psychiatry Res 1928;60(1):1-9.
Call Number: Reason for exclusion: X1

Blouin AG, Blouin JH, Perez EL, et al. Treatment of bulimia with fenfluramine and desipramine. J Clin Psychopharmacol 1988;8(4):261-9.
Call Number: Reason for exclusion: X1

Blouin J, Blouin A, Perez E, et al. Bulimia: independence of antibulimic and antidepressant properties of desipramine. Can J Psychiatry 1989;34(1):24-9.
Call Number: Reason for exclusion: X1

Blouin JH, Carter J, Blouin AG, et al. Prognostic indicators in bulimia nervosa treated with cognitive-behavioral group therapy. Int J Eat Disord 1994;15(2):113-23.
Call Number: Reason for exclusion: X12

Bossert S, Laessle RG, Meiller C, et al. Visual palatability of food in patients with eating disorders and dieting women. Behav Res Ther 1991;29(4):337-41.
Call Number: Reason for exclusion: X1

Bossert S, Schmolz U, Wiegand M, et al. Predictors of short-term treatment outcome in bulimia nervosa inpatients. Behav Res Ther 1992;30(2):193-9.
Call Number: Reason for exclusion: X1

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Call Number: Reason for exclusion: X1

Box J, Arnold LE, Smeltzer DJ. Protriptyline weight loss in compulsive eaters: a placebo-controlled study. J Psychiat Treat Eval 1983;5:387-91.
Call Number: Reason for exclusion: X4

Brambilla F, Brunetta M, Draisci A, et al. T-lymphocyte concentrations of cholecystokinin-8 and beta-endorphin in eating disorders: II. Bulimia nervosa. Psychiatry Res 1929;59(1-2):51-6 .
Call Number: Reason for exclusion: X7

Brambilla F, Brunetta M, Peirone A, et al. T-lymphocyte cholecystokinin-8 and beta-endorphin concentrations in eating disorders: I. Anorexia nervosa. Psychiatry Res 1929;59(1-2):43-50.
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Appendix E. Acknowledgments

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Technical Expert Panel

We extend our appreciation to the members of our Technical Expert Panel (TEP), who provided advice and input during our research process. The RTI-UNC EPC team solicited the views of TEP members from the beginning of the project. TEP members also provided insights into and reactions to work in progress and advice on substantive issues or possibly overlooked areas of research. TEP members participated in refining the analytic framework and key questions and discussing the preliminary assessment of the literature, including inclusion/exclusion criteria, and also provided input on the information and categories, including evidence tables. The TEP was both a substantive resource and a "sounding board" throughout the study. It was also the body from which expertise was formally sought at several junctions. TEP members are listed below:

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