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Effectiveness of Weight Management Programs in Children and Adolescents

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Prepared by:
Oregon Evidence-based Practice Center, Portland, OR

Investigators
Evelyn P. Whitlock M.D., M.P.H.
Elizabeth A. O'Connor, Ph.D.
Selvi B. Williams, M.D, M.P.H.
Tracy L. Beil, M.S.
Kevin W. Lutz, M.F.A.

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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 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.**

Carolyn M. Clancy, M.D.
Director
Agency for Healthcare Research and Quality

Jean Slutsky, P.A., M.S.P.H.
Director, Center for Outcomes and Evidence
Agency for Healthcare Research and Quality

Beth A. Collins Sharp, R.N., Ph.D.
Director, EPC Program
Agency for Healthcare Research and Quality

Stephanie S. Chang, M.D., M.P.H.
EPC Program Task Order Officer
Agency for Healthcare Research and Quality

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Structured Abstract

Objectives. To examine available behavioral, pharmacological, and surgical weight management interventions for overweight (defined as BMI $\geq$ 85th to 94th percentile of age and sex-specific norms) and/or obese (BMI $\geq$ 95th percentile) children and adolescents in clinical and nonclinical community settings.

Data Sources. We identified two good quality recent systematic reviews that addressed our research questions. We searched Ovid MEDLINE®, PsycINFO, Database of Abstracts of Reviews of Effects, the Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, and Education Resources Information Center from 2005 (2003 for pharmacological studies) to December 11, 2007 to identify literature that was published after the search dates of prior relevant systematic reviews; we also examined reference lists of five other good-quality systematic reviews and of included trials, and considered experts' recommendations. We identified two good quality systematic reviews and 2355 abstracts from which we identified 45 primary studies and trials that addressed our research questions.

Review Methods. After review by two investigators against pre-determined inclusion/exclusion criteria, we included existing good-quality systematic reviews, fair-to-good quality trials, and case series (for bariatric surgeries only) to evaluate the effects of treatment on weight and weight-related co-morbidities; we would have included large comparative cohort studies to evaluate longer term followup and harms of behavioral and pharmaceutical treatment and noncomparative cohort studies for surgical treatments if they had been available. Investigators abstracted data into standard evidence tables with abstraction checked by a second investigator. Studies were quality-rated by two investigators using established criteria.

Results. Available research primarily enrolled obese (but not overweight) children and adolescents aged 5 to 18 years and no studies targeted those less than 5 years of age. Behavioral interventions in schools or specialty health care settings can result in small to moderate short-term improvements. Absolute or relative weight change associated with behavioral interventions in these settings is generally modest and varies by treatment intensity and setting. More limited evidence suggests that these improvements can be maintained completely (or somewhat) over the 12 months following the end of treatments and that there are few harms with behavioral interventions. Two medications (sibutramine, orlistat) combined with behavioral interventions can result in small to moderate short-term weight loss in obese adolescents with potential side effects that range in severity. Among highly selected morbidly obese adolescents, very limited data from case series suggest bariatric surgical interventions can lead to moderate to substantial weight loss in the short term and to some immediate health benefits through resolution of comorbidities, such as sleep apnea or asthma. Harms vary by procedure. Short-term severe complications are reported in about 5 percent and less severe short-term complications occur in 10 to 39 percent. Very few cases provide data to determine either beneficial or harmful consequences more than 12 months after surgery.

Conclusions. The research evaluating the treatment of obese children and adolescents has improved in terms of quality and quantity in the past several years. While there are still significant gaps in our understanding of obesity treatment in children and adolescents, the current

body of research points the way to further improvements needed to inform robust policy development. Publication of additional research and policy activities by others, including the U.S. Preventive Services Task Force, is expected in the near future. And, in considering this important public health issue, policymakers should not ignore the importance of obesity prevention efforts as well as treatment.

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

Executive Summary

Introduction

Childhood and adolescent obesity has increased dramatically during the past 30 years and now represents one of the most pressing national and international public health priorities. During the early 1970s, 3 to 6 percent of American children and adolescents were obese. By 2004, this number had increased five fold to 16 to 18 percent of all US 6 to 19 year olds. This increase is especially troubling as obese children and adolescents have a greater risk for adult obesity, with its attendant health risks, and may experience obesity-related health conditions before adulthood, including type 2 diabetes mellitus, fatty liver disease, and elevated cardiovascular risk factors. Severe obesity in children and adolescents can be associated with severe health consequences and dire impacts on quality of life.

The true toll of childhood obesity must be calculated across the lifespan since it often continues into adulthood. Thus, an important step to preventing adult obesity and its related health consequences is effectively treating childhood obesity. To this end, we conducted this systematic review to determine which treatments could effectively address child and adolescent obesity and overweight, including behavioral, pharmacological, and surgical treatment options.

Methods

Key Questions

In conjunction with a Technical Expert Panel, we developed a set of five key research questions to evaluate the effectiveness and safety of behavioral, pharmacological, and surgical treatments for obese and overweight children and adolescents who were 2 to 18 years old. These research questions addressed various measures of the health impact of treatments to reduce or stabilize weight, including: short-term impacts on weight control (6 to12 months after enrolling in treatment); maintenance of weight changes in the medium-term (between 1 to 5 years after enrollment) or longer-term (5 or more years after enrollment); adverse effects of treatment (immediate and over time); beneficial effects of treatment, aside from weight control or weight loss; and treatment components or other factors that influence the effectiveness of treatments.

Literature Searches

In 2006, the National Institute for Health and Clinical Excellence (NICE) published a comprehensive report based on a good-quality systematic review of obesity in adults and children including literature published through December, 2005. Relevant portions of this report served as a basis for our literature search, supplemented by another good-quality review of pharmacological treatments. We also conducted update searches in Ovid MEDLINE®, PsycINFO, Database of Abstracts of Reviews of Effects, the Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, and Education Resources Information Center from 2005 (2003 for pharmacological treatments) through December 11, 2007. We supplemented these literature searches (and use of existing systematic reviews) by evaluating citations from several other good-quality reviews of childhood obesity treatment, suggestions from experts, and reviewing reference lists of included trials.

We searched for trials that used a control group and evaluated behavioral and/or pharmacological treatments for weight reduction or stabilization in overweight and obese children who were 2 to 18 years old. Since we could not find any surgical trials or studies that used a control group, we searched for systematically selected case series of children or adolescents undergoing bariatric surgical treatment to determine the immediate and longer-term effectiveness and harms of different types of bariatric surgeries. We also searched for, but did not find, large observational studies to consider adverse events related to behavioral, pharmacological, and surgical weight reduction treatments.

Literature Review and Data Abstraction

Two investigators independently reviewed 2355 abstracts and 338 articles against pre-specified inclusion/exclusion criteria for each key question. Discrepancies were resolved by consensus. We required that studies be designed to promote weight management and reported weight outcomes a minimum of 6 months after treatment began, although we included immediate harms when reported. We excluded studies of children with idiosyncratic weight management issues, such as genetic conditions that affect weight or eating disorders. One pharmacological agent (mazindol) and one type of bariatric surgery (jejunal-ileal bypass) were excluded because they are no longer used. Behavioral intervention trials were required to include a minimal or no-treatment arm to establish absolute effectiveness. For evaluating specific treatment components, however, we also included comparative effectiveness trials to help clarify how specific components affect overall treatment. Trials of pharmacological treatment were required to include a pill placebo control condition. Most trials also included a behavioral intervention for both active and placebo groups. All systematically selected surgical case series were permitted. For all included articles, key elements regarding patient characteristics, treatment components, weight-related outcomes, adverse treatment effects, treatment effects on co-morbidities, and elements related to study design and execution were abstracted into standard evidence tables. For behavioral intervention trials, treatment intensity (hours of contact) was categorized as very low (less than 10 hours), low (10 to 25 hours), medium (26 to 75 hours), or high (over 75 hours). Two investigators quality rated articles using design-specific criteria, with discrepancies resolved by consensus. Articles rated poor quality were excluded, except in the case of bariatric surgeries where, due to very limited data, we retained all surgical case series.

Literature Synthesis

Data were synthesized using quantitative methods, when possible. For most questions, however, we relied on qualitative synthesis due to significant heterogeneity in setting, age range, intervention approach, weight outcome reported, and timing of outcome. We modeled typical cases to more clearly describe the magnitude of weight change in pounds. In these cases, we used growth charts published by the Centers for Disease Control and Prevention to estimate average height for the average age of the participants in a trial, and then converted body mass index (BMI) and measures of relative weight (such as percentile scores) to estimated average weight in pounds, based on average height.

Results

Behavioral Interventions

We identified 18 fair- or good-quality trials of behavioral weight management interventions in a total of 1794 obese children and adolescents aged 5 to 18 years. All incorporated a minimal- or no-treatment control group. These trials were conducted in school settings (n=5 studies), specialty health care settings (n=5), primary care (n=2), residential treatment (n=1), child health/sports center (n=1), and the internet (n=1) with three trials conducted in unspecified settings. Behavioral weight management trials varied in other important ways, such as age of participants, intensity and length of the intervention, baseline weight, and treatment approach (e.g., approach to changing diet and physical activity, involvement of the family, role of behavioral management). We also evaluated 14 supplementary trials that did not meet our primary inclusion criteria, but were applicable to some specific key questions. Two of these reported only very short-term (<6-month) outcomes, but were relevant to the question of adverse effects. The remaining 12 all compared two intervention approaches to each other, rather than including a control group, but were relevant for assessing the importance of specific intervention components.

What are the short-term outcomes for behavioral interventions? Sixteen trials reported differences in some measure of weight immediately or within several months after treatment (6 to 12 months after enrollment); these trials enrolled children and adolescents aged 5 to 18 years whose BMI ranged from 20-24 (in trials of children 12 and younger) to 31-35 (in trials of adolescents) on average; these generally represented BMI percentiles above the 97th percentile. Behavioral interventions in either schools or specialty health care settings produced modest weight changes, reflecting weight loss as well as weight gain prevention. Most participants remained at or above the 95th percentile after completing the intervention. Intervention effects varied by treatment intensity and setting. In school settings, intervention trials that were mostly of medium intensity reported 0.4 to 2.07 kg/m^2 difference in mean BMI change from baseline between a total of 191 treated and 247 control-group participants aged 6-14 years, with a pooled estimate of -0.82 kg/m^2 (CI: -0.46, -1.18) lower BMI in those treated. For an 8-year old boy or girl, this would translate to about a three pound difference (assuming growth of two inches or less) and about a four pound difference for a 12 year old boy or girl under the same growth assumptions. In specialty health care settings, medium-to-high intensity intervention trials reported between 1.9 to 3.3 kg/m^2 difference in mean BMI change between a total of 299 treated and 126 control-group participants aged 6 to16 years. For an 8-year old boy or girl, the largest achieved BMI difference (3.3 kg/m^2) would translate to about 12 to 13 pounds difference, assuming two inches of growth, and about 16.6 to 17.8 pounds difference for a 12-year old boy or girl under the same growth assumptions. For girls aged 16 years, assuming 2 inches of growth, this BMI difference would translate to about 20 pounds, while the difference would be between 22 and 23 pounds for boys aged 16 with two inches of growth. In the most intensive intervention, children and adolescents in a 10-month residential program dropped from 75 percent overweight to 25 percent overweight, compared with a slight increase in overweight in children and adolescents who were on the waiting list for this program.

How well are weight changes maintained after behavioral interventions? Five trials (three in specialty health care, one in schools, one in primary care) reported medium-term weight outcomes, 1 to 5 years since beginning the intervention. Four of these trials suggested modest differences between a total of 632 treated and control patients aged 5 to 19 years after 1 to 5

years. Three of these (one in specialty health care, one in schools, one in primary care) also reported short-term outcomes, so we could evaluate whether short-term changes were maintained. In two of three trials, short-term benefits were largely maintained 12 months later. The third study in primary care that did not maintain short-term benefits was a very low intensity (4 hours), short-duration (3 months) intervention with initially very small intervention effects. Limited evidence suggests that programs providing a lower-intensity intervention targeting maintenance after the end of primary treatment allows greater maintenance of weight loss than programs with little or no maintenance support.

Are behavioral interventions harmful to participants? We found no evidence that behavioral interventions are harmful for participants. Most studies did not report on harms, however, and those that did could address only short-term harms due to length of followup. Based on this limited evidence, studies documented no adverse effects on growth, eating disorder pathology, or mental health, and little risk of exercise-induced injuries among obese children participating in exercise programs.

Do behavioral interventions have positive effects besides weight loss? Behavioral interventions can have a number of positive effects aside from changes in weight. These include reducing adiposity, improving cardiovascular and diabetes risk factors, and increasing physical fitness. Children and adolescents participating in behavioral intervention programs, particularly those that produce greater effects on BMI (such as those in specialty healthcare settings), may also see reduced adiposity. Increased physical fitness was less commonly measured, but was improved, particularly if the treatment involved organized exercise sessions. While some studies showed an impact on a range of risk factors, results were mixed and reporting was limited. Participants in behavioral intervention programs were less obese than in pharmacological or surgical treatments, and thus may have been less likely to have elevated cardiovascular or diabetes risk factors.

What components make a behavioral intervention successful? Because the trials of behavioral interventions showed so much variability, we could not draw any firm conclusions about the importance of specific treatment components. Brief synopses of treatment components for the effective behavioral intervention programs are shown in Table 7 (Chapter 3). We specifically examined three specific factors thought to be related to treatment success: provision of organized physical activity sessions as part of intervention; parental involvement for younger children; and utilization of behavioral management principles. Training in behavioral management techniques was commonly employed in these trials and may improve the likelihood of success. Over half of behavioral intervention trials provided physical activity sessions, and most of these were successful in changing weight or adiposity measures. Parent involvement is clearly important in younger children. The benefit of including parents in interventions targeted at adolescents, however, remains less clear. A primary factor in the effectiveness of interventions reviewed here was their intensity and setting: the greatest treatment effects were seen in residential treatment and in high-intensity interventions in specialty health care treatment settings; more modest treatment effects from primarily medium-intensity interventions were seen in school settings; and little or no treatment effects came from the few studies conducted in very low intensity primary care or over the internet. Other patient factors (age of children, degree of overweight or obesity, ethnicity/nationality, socioeconomic status) that could affect treatment success could not be evaluated.

Pharmacological Plus Behavioral Intervention

We found seven fair-to-good quality trials evaluating a pharmacological agent taken over six to twelve months along with behavioral interventions to treat obesity in a total of 1,294 obese adolescents. At baseline, participants met adult criteria for obesity, with mean entry BMI typically between 35 to 38 kg/m^2. All trials provided behavioral interventions for the adolescents in both treatment arms. All trials involved adolescents age 12 and older, were double-blind, and included a pill placebo control group. Five trials in a total of 715 obese adolescents examined sibutramine and two in a total of 579 examined orlistat. We also found two small trials testing the weight effects of taking the diabetes medication, metformin, for 6 to 12 months in a total of 60 obese children and adolescents with evidence of insulin resistance or hyperinsulinemia. Those reports are not directly applicable to the general population of obese adolescents.

What are the short-term outcomes for pharmacological plus behavioral interventions compared with behavioral interventions alone? Almost all the sibutramine trials found group differences in BMI change. After 6 to 12 months, adolescents treated with sibutramine plus a behavioral intervention reduced their BMI by 1.6 to 2.7 kg/m^2 more than those in the placebo plus behavioral intervention groups. Weight loss with orlistat was somewhat less: average BMI was 0.5 to 0.85 kg/m^2 lower after 6 to 12 months in the group taking orlistat plus behavioral intervention than in the placebo plus behavioral intervention group. In the trials of metformin, those taking metformin reduced their BMI by 1.3 to 1.4 kg/m^2 more than those taking the placebo.

How well are weight changes maintained after pharmacological treatments? No trials assessed maintenance of weight loss after the end of six or twelve months of treatment with sibutramine, orlistat, or metformin.

Are pharmacological treatments harmful to participants? Although no differences were reported in overall adverse events, serious adverse events, or discontinuation due to adverse events, adolescents taking sibutramine were more likely to develop small increases in heart rate and, in some cases, in blood pressure. Among orlistat users, mild-to-moderate gastrointestinal side effects, such as abdominal pain, oily spotting, or fecal urgency, occurred commonly (in 20 to 30 percent), with fecal incontinence reported in 9 percent of adolescents taking orlistat, compared with 1 percent of placebo participants. Limited evidence suggests no impact on growth for either medication. Neither trial of metformin in children and adolescents at risk for diabetes reported any serious adverse events, but these were very small studies.

Do pharmacological treatments have positive effects besides weight loss? Most studies suggested that both sibutramine and orlistat patients had greater reductions in adiposity than the placebo groups. Few other differences in cardiovascular or diabetes risk factors were found in those taking either medication, compared with placebo, except for reported improvements in HDL cholesterol, triglycerides, and insulin resistance/sensitivity among adolescents taking sibutramine in the single largest study. Similarly, in the single large study of orlistat, patients treated with orlistat had a small mean reduction in diastolic blood pressure. Both metformin trials reported improvements in fasting glucose and insulin measures.

What components make pharmacological treatments successful? We found insufficient data on effective pharmacological plus behavioral interventions to describe which components were most effective. Using proven behavioral treatments in conjunction with effective pharmacological agents, and ensuring their delivery, could be an important improvement.

Surgical Treatment

We identified 18 case series reporting on weight change, complications, and other outcomes from weight loss surgical interventions in a total of 612 morbidly obese adolescents, most of whom had failed previous weight management approaches. Where reported, 23 to 62 percent had one or more co-morbidities such as hypertension, diabetes, and dyslipidemia. Six of the studies explored the safety and efficacy of laparoscopic adjustable gastric banding (LAGB) and the remaining focused on gastric bypass procedures. The average ages for surgical patients in these studies ranged from 15 to 18 years. Mean baseline BMI was generally between 43 and 48 kg/m^2 in LAGB studies and in the high 40s to mid 50s in the gastric bypass studies. Results must be interpreted with caution, however, because loss to followup, incomplete reporting, and small samples limits our confidence in the generalizability of these results.

What are the short-term outcomes for surgical treatment? Morbidly obese adolescents undergoing laparoscopic adjustable gastric banding experienced an average BMI decline of 5.0 to 8.1 kg/m^2 six months after surgery, and a 9.4 to 10.2 kg/m^2 decline one year after surgery. Bypass procedures showed somewhat greater weight loss at one year, with average BMI reductions in the 15 to 20 kg/m^2 range.

How well are weight changes maintained after surgical treatments? Surgical treatments for obese adolescents have only been performed in recent years. In general, patients tend to lose the most weight at around 12 to18 months, after which their weight loss generally stabilizes. While we have only limited data on long-term outcomes, and insufficient data on all individuals, most patients seem to maintain their maximal weight loss after gastric banding (or experience a minimal amount of regain) for two to three years after surgery. One small study in 25 individuals after gastric banding found that BMI decreases were generally maintained 5 years after surgery. While we were only able to find very limited data on Roux-en-Y gastric bypass, based on 33 adolescents, BMI reductions were maintained at 5 years, with some regain suggested by 10 to 14 years. While there are clearly individuals who experience treatment failures, absolute rates for success or failure cannot be estimated with current data.

Are surgical treatments harmful to participants? Roughly 10 to 15 percent of adolescents undergoing laparoscopic adjustable banding require additional surgery for repositioning or removal of the band, but no serious adverse events or deaths were reported. Roux-en-Y gastric bypass is a more invasive procedure and, not surprisingly, appears to have higher rates of adverse effects. Serious adverse effects (involving threat to life or major organ system failures, but no deaths) occurred in approximately 5 percent of patients while in the hospital. In another study, 25 to 39 percent experienced non-life-threatening adverse events requiring additional treatment, special tests, endoscopy, or hospital readmission in the first year after surgery. Very limited numbers of cases and lack of long-term systematic follow-up limits our ability to assign absolute risks, including risk of death, over the longer term.

Do surgical treatments have positive effects besides weight loss? Not all studies measured or reported changes in co-morbidities after surgery. However, all cases of sleep apnea and most cases of reported asthma were resolved after surgery, with reported improvements in many with type II diabetes, hypertension, or dyslipidemia. More complete reporting would be very beneficial in assessing these potential health benefits that occur with weight loss after bariatric surgery in morbidly obese adolescents.

What components make surgical treatments successful? We have insufficient information to determine the relative benefits of different types of surgical approaches. Likewise, we found insufficient data to determine the impact of factors such as surgeon training or patient characteristics.

Conclusions

Evidence to support the effective management of obese children and adolescents is rapidly accumulating. We evaluated a total of 45 studies reporting weight management outcomes after behavioral interventions, pharmacological approaches combined with behavioral interventions, or bariatric surgeries in obese children and/or adolescents aged 5 to 18 years (See Table 13 Chapter 4). Behavioral interventions were applicable to obese children and adolescents over age 5 years, while pharmacological plus behavioral approaches were tested only in very obese adolescents aged 12 to 18 years. Bariatric surgeries were reserved primarily for morbidly obese adolescents aged 12 to 18 years who usually had co-morbidities and had failed conservative weight management strategies. Available studies did not evaluate effective treatment options for overweight (but not obese) children or adolescents, nor study those under aged 5 years.

Our review identified a progression of weight management treatment options, ranging from interventions with a smaller benefits and very low risk of adverse effects to treatments with both higher risk and higher weight loss potential. Behavioral interventions have been the most studied, with interventions conducted in schools, specialty health care, primary care, and other settings. These interventions have small-to-moderate impacts on weight, but minimal to non-existent risks. More intensive interventions, in terms of contact hours, appear to have larger treatment effects. Effective behavioral interventions generally addressed dietary improvement, physical activity promotion, and usually involved behavioral management principles and/or treatments, such as teaching parents and/or children about goal-setting, relapse prevention, problem-solving, and managing the environment to encourage healthy lifestyle. Providing children with organized physical activity as part of the intervention may improve successful weight management. Programs variously involved parents or focused on the family, but particularly did so in younger children. More research is needed to pinpoint the most effective elements of comprehensive, multi-focus behavioral interventions, and whether these differ by age, degree of overweight, or other factors.

For more severely obese adolescents, there is limited data evaluating pharmacological plus behavioral interventions and bariatric surgeries. The weight impact of two pharmacological treatments (orlistat, sibutramine) combined with behavioral interventions in obese adolescents produced small to moderate degrees of weight loss, which were comparable to the weight loss from more intensive behavioral interventions alone. Maintenance effects after pharmacological treatments have ended have not been well-studied and both medications have side-effects to consider. Among the highly selected extremely obese adolescent candidates for bariatric surgeries, more substantial weight loss was achieved, with some reversal of comorbidities, particularly severe ones such as sleep apnea. However, since little is known about long-term risks, and there are short-term risks that vary by the type of surgery, candidates must be carefully evaluated first for any bariatric surgery and then for type of surgery.

The body of research we reviewed implicitly suggests an approach to treating overweight and obesity in children and adolescents which balances considerations of the degree of risk related to treatment choice with the degree of impact on weight in order to improve health. Thus, the most risky treatments (e.g. bariatric surgeries) have been studied in adolescents with comorbidities and severe obesity, even by adult standards. A similar staged approach to treatments has been recently recommended by the Expert Committee, a committee convened by the American Medical Association (AMA) and co-funded in collaboration with the Department of Health and Human Services' Health Resources and Services Administration (HRSA) and the CDC. This group has delineated consensus-based along with evidence-based approaches that range from simple preventive messages for younger children and those who are not overweight, to

approaches increasing in intensity as the child grows older and/or more obese, and with more associated health problems. Behavioral intervention programs are seen as the best first line treatment for overweight and most obese children and adolescents. Our review found that they can be effective and are likely to be safe when delivered to obese children aged five years and older.

Knowledge development continues at a rapid pace in this arena, with publication of additional research and policy activities by others, including the US Preventive Services Task Force, expected in the near future.

While this report focuses on the effectiveness and benefits of treatments in children and adolescents who are already overweight or obese, the challenge of achieving significant weight loss (and the uncertainty as to how well any weight reduction can be maintained) reaffirms the importance of obesity prevention. Obesity prevention is a critical component of the full breadth of a public health approach to overweight and obesity among American children and adolescents. Preventive approaches address some of the factors discussed above and emphasize helping children and adolescents develop lifelong healthy habits to prevent the development of overweight or obesity during childhood and into adulthood. Obesity prevention should be conceptualized broadly to include ecological interventions as well as health promotion campaigns in schools, communities, and health care settings.

Recommendations for Future Research

While childhood overweight has been the focus of considerable research in recent years, longer-term followup is needed to confirm maintenance of treatment effects for all types of treatment, but for pharmacological and surgical treatments in particular. Longer term followup should also describe the rate and severity of longer-term adverse effects, particularly for more invasive treatments. Given the central role of behavioral treatments, much more research is needed in this area. Replication of behavioral treatment trials is needed to confirm the benefits of programs and estimate their likely effects in real-world settings. Finally, understanding important components of behavioral interventions is an ongoing need. More studies are needed in minority children and adolescents, as well as in younger children (5 years and under).

Evidence Report

Chapter 1. Introduction

Scope and Purpose

This review examines available *behavioral*[*], pharmacological, and surgical weight management treatments for *overweight* and/or obese children and adolescents (defined as those between 2 and 18 years of age). Our work builds on our previous review conducted for the United States Preventive Services Task Force in 2005 and leverages a recently released report by the National Institute for Health and Clinical Excellence (NICE).[1] Since this review focuses on treating children and adolescents who are already overweight or obese, it does not address programs preventing the development of overweight and *obesity* among children and adolescents in the general population. Prevention, however, is a critical component of an overall public health strategy to address the dramatic increase in childhood and adolescent overweight in the United States. Preventive programs have been addressed by several comprehensive reports elsewhere.[1-3]

Background

Definition and Measurement of Overweight and Obesity in Children and Adolescents

In contrast to colloquial usage, where obesity and overweight generally refer to culturally undesirable body size ("being fat"), these terms represent specific conditions with unique criteria in the medical and scientific literature. While obesity is a condition of excess body fat (adiposity), which is associated with adverse health states and risk for future disease, the medical definition of obesity in children and adolescents is not as straight forward as for adults. At present, there is no universally accepted definition that distinguishes children with normal or healthy weight from those whose level of adiposity is unhealthy. While the presence of obesity in some children and adolescents is obvious with simple observation, it is difficult to determine when a child who is not obviously overweight faces health risks from adiposity. In the absence of a clear, health-based definition of obesity, children are instead categorized as "overweight" and "obese" based on how they compare with a normative sample of children of the same age and sex.

Body mass index (BMI) is the most common measure used to define overweight and obesity in children, adolescents, and adults. BMI is a height-adjusted weight measure that is calculated from measured weight (in kg) and height (in meters) as kilograms divided by meters-squared (kg/m^2). Clinicians compare a child's BMI to that of other children of the same age and sex to determine a *percentile* score based on published norms, such as those developed by the Centers for Disease Control and Prevention in the United States.[4] (see Figures 1 and 2) Because BMI naturally changes with age, percentile scores based on age- and sex-specific norms are used to determine overweight and obesity and monitor growth and development in children and adolescents. Over time, changes in percentile scores can show clearly when a developing child has become fatter or slimmer. Thus, while BMI might increase in an overweight growing child, a

[*] Words found in the glossary are italicized on first mention.

decrease in percentile score would indicate a positive outcome, as their growth in height outstripped their weight gain Table 1 shows the BMI-based terms that denote different levels of excess weight in children and adolescents and compares them to terms in adults. We've provided adult terminology and classification both for context, to help the reader interpret BMI values reported in children and adolescents, and because the categorizations may be valid for older adolescents who have achieved their adult height. Figures 1 and 2 also provide comparisons between various height (inches or centimeters) and weight (pounds and kilograms) measures and absolute BMI, BMI percentiles, and BMI standard deviation scores (SDS). The Expert Committee (A committee convened by the American Medical Association (AMA) and co-funded in collaboration with the Department of Health and Human Services' Health Resources and Services Administration (HRSA) and the CDC) recommends using the term "overweight" to refer to children with BMI in the 85th to 94th percentiles for their age and sex. They recommend the term "obese" to refer to children with BMI at or above the 95th percentile for their age and sex or with a BMI at or above 30, which is the adult standard for defining obesity.[5] These definitions were originally derived from population norms rather than health states, and research continues to focus on clarifying the health risks associated with various definitions of overweight and obesity in children, adolescents, and adults. These and other definitions can be found in the glossary.

Although it is not a direct measure of adiposity, BMI-for-age percentile measures in boys and girls correlate reasonably well with percentile rankings of directly measured percent body fat (correlations generally between 0.78 to 0.88).[6] Obesity (primarily defined as BMI $\geq$ 95th percentile) has also been correlated with childhood health consequences and with risk factors for obesity-related morbidity in adults.[7-9] Since BMI is an imperfect measure of body fat, however, categorizing children and adolescents as obese based on BMI definitions can be problematic. Recent data from the Bogalusa Heart Study found that 35 percent of children aged 5 to 17 years with BMI > 95th did not have excess body fat.[10] At or above the 99th percentile, however, almost all (94 percent) had excess adiposity. Those with the highest BMI percentiles ($\geq$ 99th) were also much more likely to have two or more cardiovascular risk factors (59 percent) compared with those in the broader group at or above the 95th percentile (39 percent). Noting these differences, experts have recently proposed distinguishing the "severely obese", defined by the 99th percentile, as those in particular need of clinical evaluation and treatment.[11,12]

An absolute BMI level can indicate very different weight states in children and adolescents of different ages, as is clear from Table 2 and Figures 1 and 2. A BMI of 20 would categorize an 8 year old as obese, but would categorize a 16 year old as normal weight. Absolute BMI levels may be more informative for clinical and research outcomes than percentiles in children and adolescents, particularly those above the 95th percentile, where there can be a broad range of actual BMIs (and therefore weights). Above the 99th percentile, BMI measures can overlap with BMI levels used to define obesity in adults (30 kg/m^2). Thus, experts recommend that obesity in children and adolescents be defined as BMI $\geq$ 95th percentile or BMI $\geq$ 30 kg/m^2, whichever is lower.[12] Since no measure is ideal for every age, many youth obesity researchers report multiple measures, including BMI, BMI percentiles, *BMI standard deviation scores* (SDS, also known as z-scores), or an older measure, "percent overweight."

Prevalence of Children and Adolescents Obesity in the United States

Between the early 1970s and 2003 to 2004, the prevalence of obesity (defined as age- and sex-specific BMI $\geq$ 95th percentile) increased three- to six-fold, depending on age, sex, and

ethnicity.[13] In 2003 to 2004, the prevalence of obesity among 6- to 19 year-old children and adolescents was approximately 16 to 18 percent.[14,15] When children and adolescents who are overweight (defined as age- and sex-specific BMI in the 85th to 94th percentile) are also included, this prevalence increases to almost one in three children and adolescents identified as overweight or obese (31 to 33 percent).[13,15] Looking at the youth with the most severe levels of obesity, 3 to 6 percent of boys aged 13 to 17 years are at or above the 99th percentile. For girls, the comparable figure is 1 to 3 percent.[10]

The prevalence of obesity varies somewhat with age. Children aged 6 to 11 years have the highest prevalence of obesity (18.8 percent), compared with younger children (13.9 percent) and adolescents (17.4 percent), according to data from the 2003 to 2004 National Health and Nutritional Evaluation Survey (NHANES).[13] Males have slightly higher prevalence of obesity for all age categories. Childhood obesity is increasing all around the world, not just in the United States. A meta-analysis calculated that the annualized change in prevalence of obesity in school children in the United States from 1971 until 2000 was approximately 0.4 percentage points per year.[16] Twenty-three North American, Eastern European, Western European, and Asian countries reporting comparable data also showed increases in childhood obesity, with annualized changes ranging from less than 0.1 percentage points (in Finland and the Netherlands) to over 0.7 percentage points (Singapore and East Germany).[16] The estimated prevalence of overweight (including obesity) in children and adolescents in the Americas as a whole is 27.7 percent. Europe has the next-highest estimate at 25.5 percent, then Eastern Mediterranean countries (23.5 percent), followed by countries in the West Pacific (12.0 percent) and South East Asia (10.6 percent). Prevalence of overweight and obesity are low in African nations (1.6 percent).

High-Risk Groups for Child and Adolescent Obesity and Overweight

In the United States, minority children and adolescents are disproportionately obese and overweight at all ages.[13] One large nationally representative study using NHANES data found that 43 percent of Mexican-American boys age 6 years or older were obese or overweight, which was higher than nonHispanic White (29 percent) and nonHispanic Black (31 percent) boys in the same age range.[15] Native American boys are also more likely to be obese—39 percent of Native American adolescent boys in the National Longitudinal Study of Adolescent Health (Add Health) were categorized as obese in the mid-1990s, compared with 10 to 15 percent among other ethnic groups.[17] NonHispanic White girls have lower prevalence of obesity or overweight (26 percent), compared with nonHispanic Black (42 percent), and Mexican American (39 percent) girls.[15] These racial/ethnic disparities are consistent with prevalence figures reported by the Add Health study, which reported obesity in Black (18 percent), Hispanic (13 percent), and Native American (14 percent) adolescent girls, compared with Asian (4 percent) and nonHispanic White girls (10 percent). Statistical tests of these differences were not reported. Racial differences are also seen in the persistence of obesity into adulthood among children and adolescents aged 5 to 14 years. One study found that 65 percent of obese White girls and 84 percent of obese Black girls remained obese into adulthood. Results were similar for obese boys (71 percent of White boys versus 82 percent of Black boys).[18]

There is also clear correlation between income level and obesity prevalence in White children and adolescents. Obesity prevalence is highest in the lowest income bracket, and those with highest income levels have the lowest obesity prevalence.[19] This correlation is less clear for Black and Hispanic ethnic groups, however, where data suggest no clear linear relationship between income and obesity.[19]

Children of obese parents have a higher risk of obesity,[20] with children with two obese parents having the highest risk of obesity.[21] A large-scale epidemiological study published in 1976 found that by age 17, children with two obese parents had three times larger triceps *skinfold* measures as those with two lean parents.[21] Compared to children without obese mothers, children with obese mothers are three to ten times more likely to be obese themselves. White and Black children of obese mothers are three times more likely to be obese, Hispanic children of obese mothers are twice as likely to be obese, and Asian children of obese mothers may be as much as ten times more likely to be obese.[22] In addition, maternal obesity has been associated with earlier age of obesity onset in children.[22]

Health and Psychosocial Consequences of Child and Adolescent Obesity

Although the data on the health and psychosocial consequences of obesity in children and adolescents are almost exclusively observational, and therefore causal relationships cannot be established, there is growing evidence that childhood and adolescent obesity can have a substantial health impact.[7,9] While most children will not experience the health consequences of persistent childhood obesity for decades, some of these consequences can occur prior to adulthood, particularly in those who are severely obese.[9] Obese children and adolescents have a higher risk of *type 2 diabetes* mellitus, asthma, and nonalcoholic fatty liver disease, are more likely to have cardiovascular risk factors, such as *hypertension* and hyperlipidemia. These children and adolescents are also more likely to experience other adverse health-related events, such as perioperative adverse respiratory events when undergoing procedures requiring anesthesia.[7,9,23] Obese children may be more likely to experience mental health and psychological issues, such as depression [24] and low self-esteem,[9,24,25] than nonobese children. The risk of mental health issues increases with age and is higher in girls,[7] likely reflecting the pressures of the social environment. For severely obese children, impacts on quality of life can be severe and other serious conditions such as obstructive sleep apnea, orthopedic problems, infertility, and increased intracranial pressure can occur.[7,9,11,26]

One of the greatest concerns about childhood obesity is that it may persist into adulthood.[27] Adult obesity, in turn, has a detrimental effect on adult health[2,28,29] and mortality.[28,30] Other systematic reviews have examined the persistence of obesity from childhood into adulthood.[31] Factors associated with greater persistence of obesity from childhood into young adulthood included older age and higher BMI (above the 95th percentile or higher). Recent data from the Bogalusa Heart Study confirm these findings.[27]

Although it is difficult to distinguish childhood obesity's effects on morbidity and mortality independent of the effect of adult obesity, a systematic review reporting on the long-term consequences of pediatric obesity concluded that obesity-related cardiovascular disease can originate in childhood obesity.[7] This review, and others, indicate that childhood obesity has also been associated with adverse social and economic outcomes in young adulthood.[7,9,32]

Current Interventions for Child and Adolescent Obesity and Overweight

Behavioral intervention. Behaviorally based interventions are the first-line treatment for overweight and obesity in children and adolescents.[11] Behavioral weight management interventions promote weight loss through modifications in diet and activity level without the use

of adjuncts, such as pharmacologic agents. Typical behavioral interventions aim to modify food consumption to emphasize healthy eating and reduce consumption of high calorie-low nutrient snack foods and sugary foods and beverages. A range of approaches has been used to encourage more healthy patterns of dietary intake and physical activity, which are discussed in detail elsewhere.[5,11,33] Behavioral interventions often involve parents or entire families, particularly for younger children. Optimally, behavioral interventions include cognitive and behavioral management techniques to help participants initiate and sustain needed lifestyle changes, and a range of approaches have been utilized.[33,34] We refer to programs that focus on dietary counseling and brief lifestyle change advice without more extensive use of behavioral management principles as "behavioral counseling" interventions. We use the term "behavioral management intervention" to denote programs that are more extensive and include principles of cognitive and/or behavioral management. We use the term "behavioral intervention" as a general term to refer to both behavioral counseling and management interventions.

Pharmacologic treatment. A number of pharmacological agents are also being used to promote weight loss among obese adults as adjuncts to behavioral intervention. Weight loss drugs can be divided into two main categories based on their putative mechanism of action—appetite suppressants and lipase inhibitors. Appetite suppressants may be divided further based on the specific neurotransmitters they are thought to affect. Sibutramine and orlistat are the two most well studied weight loss drugs among adults. Sibutramine is a centrally acting appetite suppressant that selectively inhibits the reuptake of serotonin and norepinephrine, increasing their levels in the brain. Orlistat is a lipase inhibitor that is thought to promote weight loss by reversibly binding to the active center of the enzyme lipase, preventing digestion and absorption of some dietary fats. It also reduces the absorption of fat-soluble vitamins.

The United States Food and Drug Administration (FDA) has approved some medications for the treatment of obesity in adults. Only one medication has been approved for prescription use in obese children and adolescents (aged 12 and older). Medications not specifically approved for obesity treatment in children and adolescents may be considered for off-label use by physicians. The FDA approved the use of sibutramine and orlistat for the long-term treatment of obese adults in 1997 and 1999, respectively.[35] In 2003, the FDA approved orlistat for treatment of overweight among pediatric populations (ages $\geq$ 12 years).[36] In 2007, the FDA also approved orlistat for over-the-counter use among adults ages 18 years and older.[37] Several other appetite suppressants are FDA-approved only for short-term treatment of overweight adults (benzphetamine, diethylpropion, phendimetrazine, and phentermine).[38] Additional drugs that are not FDA-approved for treating overweight or obesity have been considered as potential weight loss agents such as some antidepressants (fluoxetine, sertraline, and bupropion), antiepileptic drugs (topiramate, zonisamide, lamotrigine), and the antidiabetic biguanide *metformin*.[38]

A recent systematic evidence review found that numerous different drugs produced modest weight loss among adults when combined with dietary recommendations: sibutramine, orlistat, phentermine, bupropion, fluoxetine, topiramate, and probably diethylpropion.[39] The additional weight loss attributable to these drugs has been less than five kg at 1 year. The drugs have not been compared directly against each other, and the report found no evidence that any particular drug produced more weight loss than any other. All of the drugs had side effects. Sibutramine was associated with modest increases in heart rate and blood pressure and with preventing decreases in blood pressure that may have occurred with weight loss. Orlistat is associated with numerous gastrointestinal side effects such as diarrhea, flatulence, bloating, abdominal pain, and dyspepsia.

Surgical treatment. Surgical approaches to weight loss (*bariatric surgeries*) have been developed to treat those in whom more conservative measures have failed. The criteria for undertaking bariatric surgery for adolescents have largely followed expert-based criteria for adults from a 1991 NIH consensus conference,[40] although expert-based criteria for selecting severely obese adolescents for bariatric surgery have also been published.[41] These criteria specify that surgery be considered for persons who have attained skeletal maturity with a body mass index (BMI) greater than 40 and with high-risk co-morbid conditions responsive to weight loss, such as obstructive sleep apnea or severe diabetes mellitus. Recent followup data from severely obese adults undergoing bariatric surgeries indicate reduced risk factors, such as hypertension, *dyslipidemia*, or incidence of type 2 diabetes, and reduced all-cause mortality (29 percent).[42]

Surgeries can induce weight loss through two means—restriction and malabsorption. Restrictive approaches reduce the stomach size to limit the amount of food that can be consumed at a single meal. Malabsorptive approaches bypass portions of the intestines to limit the proportion of calories absorbed from ingested food. In the case of gastric bypass, a very common bariatric procedure, restrictive and malabsorptive approaches are combined. Bariatric surgeries are associated with risks for complications, however, including death. Treatment failures can be caused by inability to tolerate surgery-related changes requiring reversals, or post-surgical changes in behavior or anatomy that in effect override the surgically induced restrictions in stomach size. With the advent of minimally invasive surgery, some risks are reduced when procedures are performed using a laparoscope instead of an open procedure (*laparotomy*).

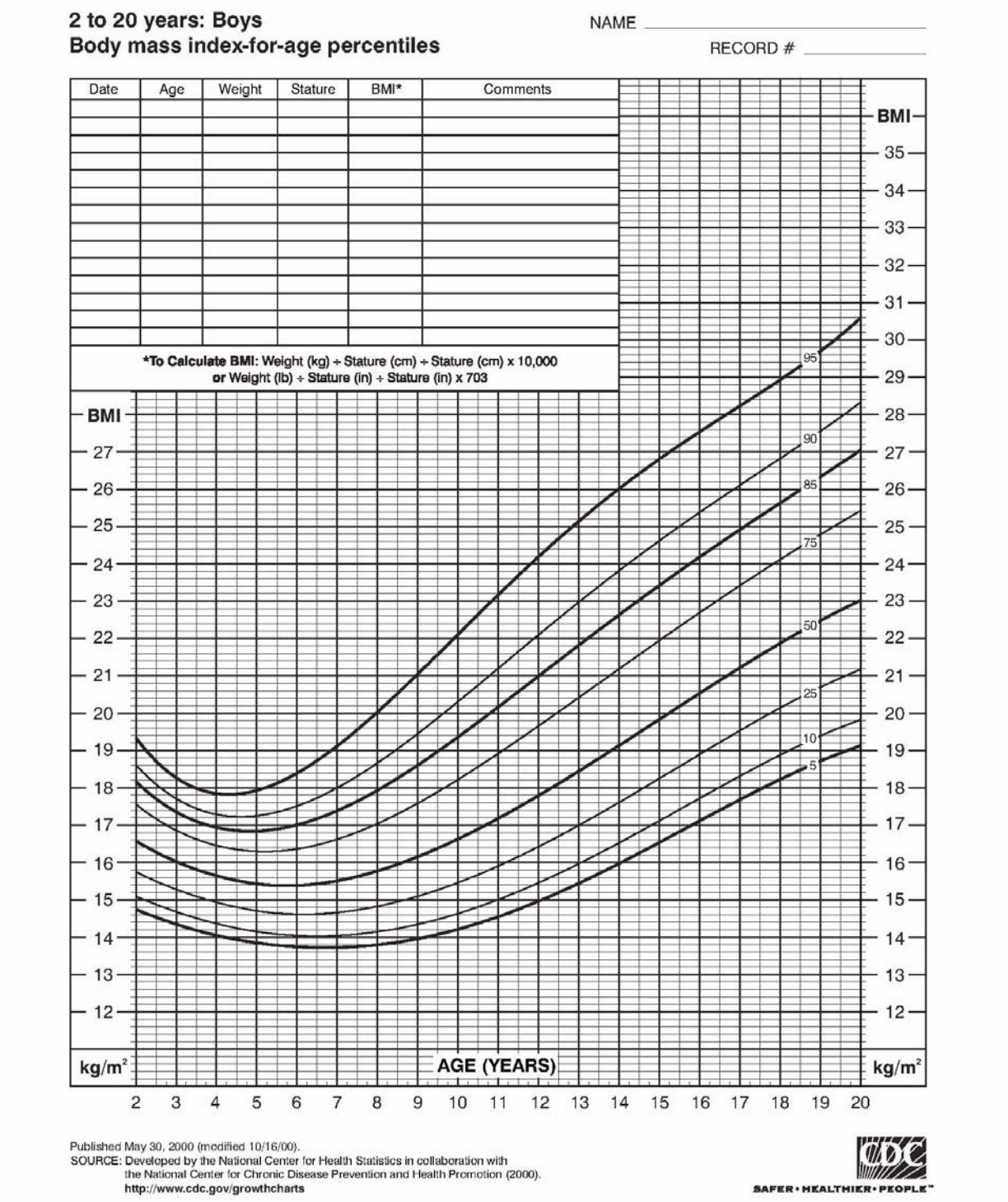
Major types of bariatric surgeries include gastric banding, gastroplasties, and bypass procedures. Gastric banding positions a band outside the stomach to create a smaller pouch (15 to 30 cc) in the uppermost portion of the stomach in order to restrict food intake. While bands were fixed in circumference at the time of surgery in the past, they are now adjustable through injection of saline into an accessible subcutaneous port. Adjustable gastric bands can be adjusted over time in response to rates of symptoms and weight loss. Bypass procedures reduce caloric intake (and, unfortunately, absorption of essential nutrients) through rerouting food around a portion of the intestinal tract. The bypassed section is generally not removed, which theoretically allows for reversals. Gastric bypass is the most common bariatric surgery in the United States since other forms of bypass (jejunal-ileal; biliopancreatic diversion; biliopancreatic diversion with duodenal switch) have been associated with numerous complications.[39,40]

Surgeons have developed a variety of surgical approaches to gastric bypass, with some variations even for the most commonly performed type, Roux-en-Y gastric bypass (RYGB). RYGB restricts the size of the stomach to about 30 cc and then bypasses the duodenum to reduce absorption. Gastroplasties mechanically reduce the stomach's size and architecture by creating a stapled anterior gastric pouch with a reduced outlet to the remainder of the stomach. Types of gastroplasty include vertical-banded gastroplasty (VBG), which also uses a band to constrict the stomach and prevent dilatation, gastric partitioning with a band, and horizontal gastroplasty. Gastroplasties are less commonly performed, given their higher degree of recidivism than with gastric bypass, and because less invasive restrictive approaches using gastric banding are now available.

Banding approaches, particularly *laparoscopic* adjustable gastric banding (LAGB), are particularly appealing for adolescents since they do not involve surgical removal or realignment of the intestine and are therefore more reversible. Banding also retains the entire absorptive area of the stomach and intestines, which lowers risk of malabsorption of essential nutrients. Malabsorptive concerns are particularly important since adolescents are still developing and young females could become pregnant. Finally, banding can routinely be done laparoscopically, which reduces peri-operative complication risks. In the United States, however, FDA approval has not been granted for these devices in those under 18 years.[43]

Potential surgically related risks and the degree of desired weight loss are factors in the choice of bariatric surgical approaches, since these may differ between bariatric procedures.[42] Banding procedures have been more common outside the United States, but recent utilization data suggest this procedure is becoming relatively more common among obese adults and adolescents undergoing bariatric surgeries in the United States.[44] Both adjustable gastric banding and gastric bypass are currently considered for severely obese adolescents with serious obesity-related comorbid conditions who have failed medical treatment, but only when performed by highly trained and skilled bariatric surgeons in a program with close nutritional, psychological, and surgical evaluation and followup.[45]

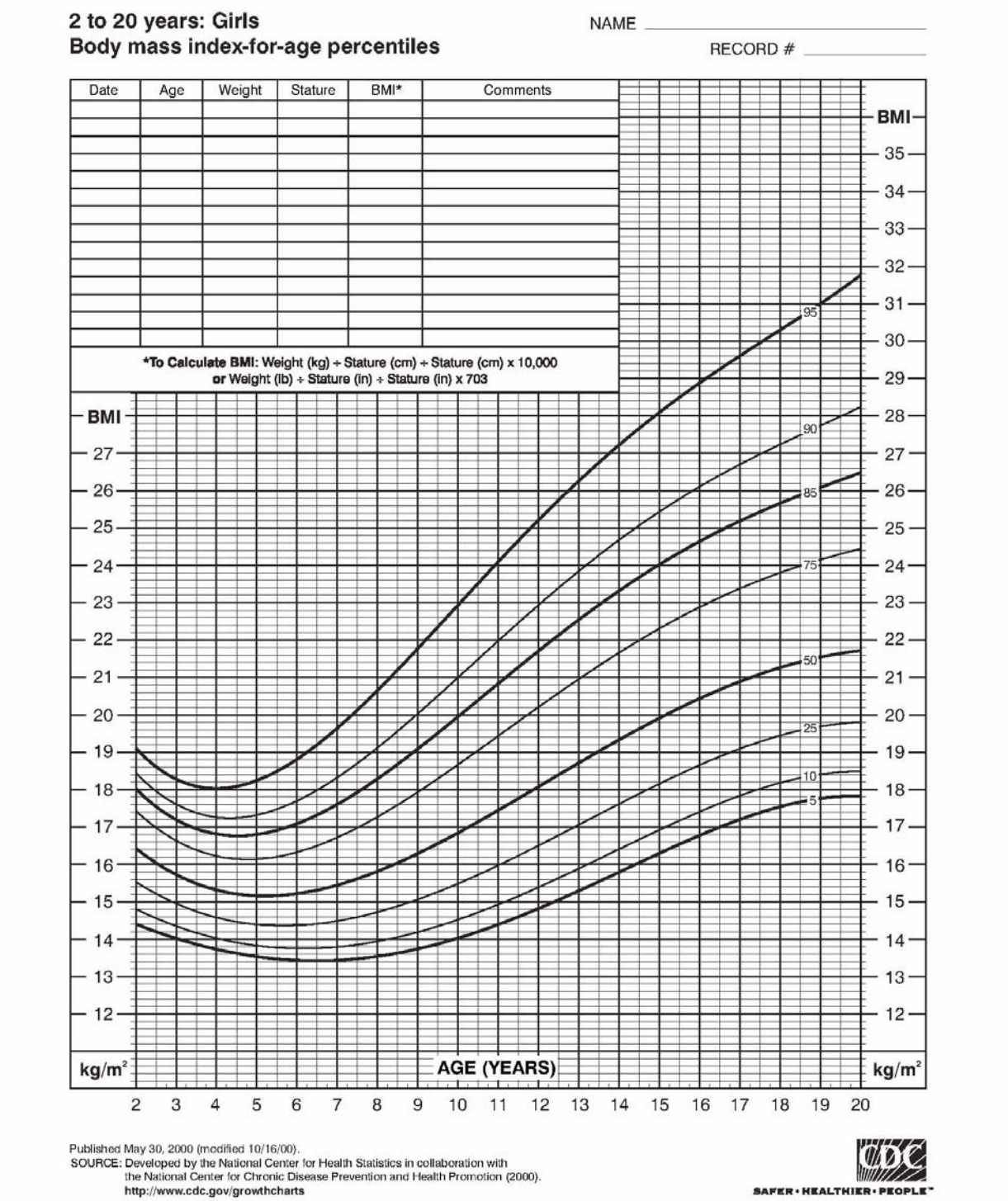
Figure 1. Illustrative BMI percentile chart with table of weight and BMI standard deviation score for selected percentiles: Boys



Age	Height		50th percentile Weight		BMI	BMI	85th percentile Weight		BMI	BMI	95th percentile Weight		BMI	BMI
yrs	in	cm	lbs	kg		SDS	lb	kg		SDS	lbs	kg		SDS
8	50.5	128.3	57.2	26.0	15.8	0.0	64.8	29.5	17.9	1.0	72.4	32.9	20.0	1.6
12	58.5	148.6	86.5	39.3	17.8	0.0	102.0	46.4	21.0	1.0	117.6	53.4	24.2	1.6
16	68.5	174.0	136.5	62.1	20.5	0.0	161.2	73.3	24.2	1.0	183.2	83.3	27.5	1.6

BMI-body mass index; SDS-standard deviation score

Figure 2. Illustrative BMI percentile chart with table of weight and BMI standard deviation score for selected percentiles: Girls



Age	Height		50th percentile Weight		BMI	BMI	85th percentile Weight		BMI	BMI	95th percentile Weight		BMI	BMI
	in	cm	lbs	kg		SDS	lb	kg		SDS	lbs	kg		SDS
8	50.5	128.3	57.2	26.0	15.8	0.0	66.3	30.1	18.3	1.0	75.0	34.0	20.7	1.7
12	59.5	151.1	90.9	41.3	18.1	0.0	109.0	49.5	21.7	1.0	126.6	57.5	25.2	1.6
16	64	162.6	118.7	53.9	20.4	0.0	143.1	65.0	24.6	1.0	168.1	76.4	28.9	1.6

BMI-body mass index; SDS-standard deviation score

Table 1. Definition of overweight and obesity terms for children and adolescents, and adults

Children and adolescents		Adult	
Overweight	85th-94th percentile BMI (age-sex specific)	Overweight [46]	BMI 25-29 kg/m^2
Obese	≥ 95th percentile BMI or BMI ≥ 30 kg/m^2, whichever is lower[5]	Obesity Class I Class II Class III (also called morbid, severe)	 BMI 30-34.9 kg/m^2 BMI 35.0-39.9 kg/m^2 BMI ≥ 40 kg/m^2
Severe obesity[5]	> 99th percentile BMI	NIH criteria for bariatric surgery in adults[40]	BMI >40 kg/m^2 Or BMI >35 kg/m^2 with co-morbidities

Table 2. BMI at 50th, 85th, 95th, and 99th percentiles and weight in pounds for BMI of 25, 30, 35, and 40 at ages 8, 12, and 16 years

		BMI (kg/m^2) at percentiles* Children and adolescents				Weight (lbs) at BMI levels** Adults			
	50th Percentile for Height		Over-weight[5]	Obesity	Severe Obesity	Over-weight	Obesity Class I	Obesity Class II	Obesity Class III
Age (Sex)	**inches**	**50th**	**85th**	**95th**	**99th**	**25**	**30**	**35**	**40**
8 (Male)	50.5	15.8	17.9	20.0	25.6	91	109	127	145
8 (Female)	50.5	15.8	18.3	20.7	26.4	91	109	127	145
12 (Male)	58.5	17.8	21.0	24.2	31.8	122	146	170	195
12 (Female)	59.5	18.1	21.7	25.2	33.1	126	151	176	201
16 (Male)	68.5	20.5	24.2	27.5	33.9	167	200	234	267
16 (Female)	64	20.4	24.6	28.9	39.1	146	174	204	233

*Estimated average height for age from 50th percentile on CDC Growth Chart "Stature-for-age percentiles: Boy (or Girls), 2 to 20 years".

**Pounds = (BMI x inches^2) /703 was used to convert from BMI to pounds.

Chapter 2. Methods

Terminology

A glossary of terms used throughout this report can be found at the end of the report*. The first occurrences of terms that are included in the glossary are italicized in the body of the text.

Key Questions and Analytic Framework

We developed five key questions (KQ) and an analytic frame work (Figure 3) in conjunction with a Technical Expert Panel to evaluate the effectiveness and safety of behavioral, pharmacological, and surgical treatments for overweight and/or obese children. KQ1 evaluates the effectiveness of interventions in reducing or stabilizing weight using short-term (6-12 months since enrolling in treatment), while KQ2 focuses on the maintenance of BMI improvements through medium-term (between 1 to 5 years since enrollment and at least 12 months since treatment ended) or longer term measurements (5 or more years since enrollment). KQ3 assesses adverse effects of behavioral, pharmacological, and surgical interventions. Other beneficial outcomes arising from the interventions and were captured in KQ4. KQ5 considers whether specific program components and population or environmental factors can be identified for effective weight control programs.

Literature Search Strategy

In 2006, NICE published a comprehensive report which addressed the prevention and management of obesity in adults and children.[2] Relevant portions of this report served as a basis for the primary search for the literature included in the current report. The NICE report only included orlistat and sibutramine. Therefore, we used another good-quality review of pharmacological treatments[39] as the basis for our search for pharmacological treatments. We conducted update searches in Ovid MEDLINE®, PsycINFO, Database of Abstracts of Reviews of Effects, the Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, and Education Resources Information Center from 2005 (2003 for pharmacological treatments) to December 11, 2007, to identify literature that was published after the search dates of the these reports (Appendix A*). The literature search and reports[2,39] were supplemented by hand-searching the reference lists of other good-quality reviews of childhood obesity treatment,[31,33,47-49] suggestions from experts, and reviewing reference lists of included trials. We did not search for data from non-peer-reviewed sources.

Article Review and Data Abstraction

Two investigators independently reviewed 2355 abstracts and 338 articles for inclusion in each key question. Discrepancies were resolved by consensus. Detailed inclusion/exclusion criteria can be found in Appendix G†. Briefly, the study population included overweight or obese 2 to 18 year-olds. We excluded studies of children with idiosyncratic weight management issues. Trials were required to be designed to promote weight loss or maintenance and report weight

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

outcomes of at least 6 months, although we included immediate harms when these were also reported. Interventions of mazindol and jejunal-ileal bypass were excluded because they are no longer used in current practice. Behavioral and pharmacology trials were required to have a minimum intervention or control group with at least 10 participants in each arm. Trials included for KQ5 were allowed to compare active treatments to help clarify the role of specific program components. Systematically selected case series were permitted for surgical studies (for both short-term and maintenance efficacy as well as harms of treatment). Only controlled trials (RCTs and CCTs) were included for efficacy (short-term and maintenance) of behavioral and pharmacological treatments. Weight management programs reporting pre-specified adverse events resulting in death, hospitalization, or need for urgent medical or psychiatric treatment were included to assess harms (KQ3) for all treatment modalities, even if they did not report one of our specified weight outcomes. In addition, we abstracted all reports of harms or potential harms in included studies. We would have included large comparative cohort studies to evaluate harms of behavioral and pharmacological treatments if they had been available.

Other beneficial outcomes (KQ4) were only examined using trials that were included for KQ1 (short-term efficacy) or KQ2 (maintenance efficacy). The presence of any other beneficial outcome was abstracted, including impact on comorbidities if reported.

One investigator abstracted data from included studies into evidence tables. A second investigator verified the evidence tables' content. All studies were quality-rated independently by two investigators using established design-specific criteria (Appendix H[†]), with discrepancies resolved by consensus or a third investigator. Poor quality studies were excluded, except in the case series of bariatric surgeries, where all available case series in adolescents were included due to very limited data. Five trials of behavioral interventions and one of pharmacological treatment were excluded because they did not meet our quality criteria.

Treatment intensity was categorized by hours of contact as follows: very low intensity (less than 10 hours); low (10 to 25 hours); medium (26 to 75 hours), high (over 75 hours). Weight outcomes were categorized as short-term (6 to 12 months since beginning treatment), medium term (between 1 and 5 years after beginning treatment and at least 12 months after ending active treatment), or longer term (5 or more years after beginning treatment). Maintenance was evaluated where possible using multiple measurements in the same individuals at least 12 months after an active intervention ended or by using single post-baseline measurements in the medium or longer term. For behavioral interventions, short-term weight outcomes were those that were either measured immediately after treatment ended (post-treatment) or some months after active treatment ended, but still within the first 12 months after entering treatment (followup). Weight outcomes were abstracted as reported for a variety of different methods: endpoint BMI, absolute change in BMI from baseline, percent change in BMI from baseline, absolute change in BMI SDS from baseline, endpoint weight, and absolute change in weight from baseline.

We used two approaches to determine which specific intervention components we examined for KQ5. First, based on prior literature we identified several factors that may affect weight outcomes in behavioral interventions. These include whether or not studies included organized physical activity sessions,[50] behavioral modification[31,51] (for dietary and physical activity), or involved parents or families in addition to the child (clarifying extent to which parental involvement is important, for what ages).[33,51,52] Next, we examined the distribution of treatment elements between successful and unsuccessful treatment trials. To do this, we coded participants' age (C=only included children aged 12 and under; A=only included those aged 10 and older;

B=Age range included both younger children and adolescents) and the three main components of behavioral interventions as follows: (1) presence of organized physical activity sessions (0=did not provide organized physical activity session, 1=provided organized physical activity); (2) use of behavioral modification principles (0=no or minimal use of behavioral modification principles,1=applied behavioral modification principles in treatment); (3) family involvement (0=no parental involvement beyond consent/receiving materials; 1=parent attended 1 to 3 sessions, less intensive involvement than child; 2=parent was also a primary recipient of treatment).

For our second approach to examining important treatment components, we identified comparative treatment trials where the comparison could illuminate the importance of one of the components described above: organized physical activity, extent of behavioral modification principles, and family involvement. We examined all studies meeting the same inclusion criteria as those used for KQ1 and KQ2, except that no minimal-treatment control group was required. We found three trials comparing programs with and without organized physical activity sessions,[53-55] five with varying forms of family involvement,[56-60] and two comparing programs with and without cognitive-behavioral therapy techniques.[61-64] Trial details can be found in Appendix C[†] Table 2.

Literature Synthesis

We cover three major types of interventions in this review: behavioral, pharmacological, and surgical. We address each of the five key questions listed in our analytic framework within the framework of each type of intervention.

Where possible, data were synthesized using quantitative methods. For most questions, however, we relied on qualitative synthesis due to significant heterogeneity in setting, age range, intervention approach, weight outcome reported, and timing of outcome reporting among the limited number of studies available for each overall type of intervention. To more clearly articulate the magnitude of weight or weight change in pounds, we modeled typical cases. In these cases, we used growth charts published by the CDC[4] to estimate average height for weight and to translate between percentile scores, BMI, and percent overweight (based on CDC-published 50th percentile scores for weight or BMI). We also employed on-line calculators provided at the CDC web site[65,66] for calculating BMI and BMI percentiles. To convert BMI to pounds for an illustrative child of a given age and height, we used the following formula: Pounds = (BMI*inches^2)/703.

Studies reported a variety of weight outcomes including BMI, BMI percentile scores, BMI standard deviation or z-scores, and percent overweight. All of these measures have strengths and limitations. BMI is reliably measured and widely used, but can be problematic when averaging BMI change over a wide age range, where younger children would naturally show smaller changes. Percentile scores are helpful when describing weight change in children of many ages because they are a measure of relative overweight, rather than absolute weight. The limitation of percentile scores, however, is that there can be a large range in the highest extremes (above the 99th percentile).

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

To avoid the difficulties with an limited upper range of BMI percentile scores, many researchers report BMI standard deviation scores (SDS, also known as z-scores) or measures of "percent overweight." Both of these are measures of the relative degree of overweight similar to percentile scores, but without a truncated upper limit. BMI SDS is calculated as the number of standard deviation units above or below the median, based on statistically derived curves.[67] BMI SDS requires the use of published computer programs that access reference data and formulae, such as that published by the CDC.[68] Percent overweight is calculated by the simple formula:

$$100*(\text{child's BMI}/50^{th}\text{ percentile BMI for child's age and sex}).$$

This method was used chiefly in earlier studies, published before programs were available to calculated BMI SDS. The disadvantage of using percent overweight scores is that they do not account for the known weight distribution. When given multiple weight outcomes, we selected them according to the following hierarchy: (1) BMI (this was the most commonly reported outcomes and the outcome used for meta-analyses), (2) BMI percentile, (3) BMI SDS, and (4) percent overweight.

We focused on the change in BMI from baseline as the preferred measure of weight change when it was available. In many cases, the standard deviations of the change in BMI was not reported and could not be calculated or estimated. In those cases, we could not consider quantitative pooling of results.

Quantitative Synthesis

For the behavioral interventions, we conducted meta-analyses of short-term (KQ1) and maintenance (KQ2) outcomes within each setting. Twelve[69-80] of the sixteen trials reporting short-term weight outcomes were included in the meta-analysis for KQ1. Five were in school settings,[69-72,75] and there were two each in specialty health care[73,74] and primary care[77,78] settings. The final trial in this analysis was the only included trial conducted on-line.[76] It was, therefore, not statistically combined with other trials, although it appears on the visual display of the meta-analysis for qualitative comparison purposes.

Four[72,73,78,81] of the five trials reporting maintenance outcomes were included in the meta-analysis of KQ2, grouped by setting. Two of these trials were conducted in specialty health care settings,[73,81] and one trial each was conducted in school[72] and primary care[78] settings; all of these are presented on the summary display but not all were statistically combined with other trials. Three [72,73,78] of the trials reported both short-term and maintenance outcomes and are included in both meta-analyses.

If mean change scores from baseline for each group were not reported, we calculated an unadjusted difference between the mean baseline and mean followup scores for each group using simple subtraction. Standard deviations (SDs) of the change scores were reported in five trials with post-treatment outcomes and one trial with followup outcome. In addition, three authors who did not report them in published articles provided us with these unpublished data.[69,76,80] We calculated standard deviations for trials that did not report them. Baseline BMI is highly correlated with post-treatment and follow-up BMI, and we had to take this correlation into account when calculating the standard deviations of the change scores. In order to estimate the degree of correlation, we examined data from a trial[70] that reported both the SDs of the change scores (which we were attempting to calculate) and the SDs of the baseline and post-treatment BMIs (which we would use to calculate of the SDs of the change scores). From this trial, we

ascertained that the correlation between the baseline and post-treatment score was approximately 0.90. Therefore, we assumed a correlation of 0.90 for the remaining trials and calculated SDs of BMI change using the following formula:

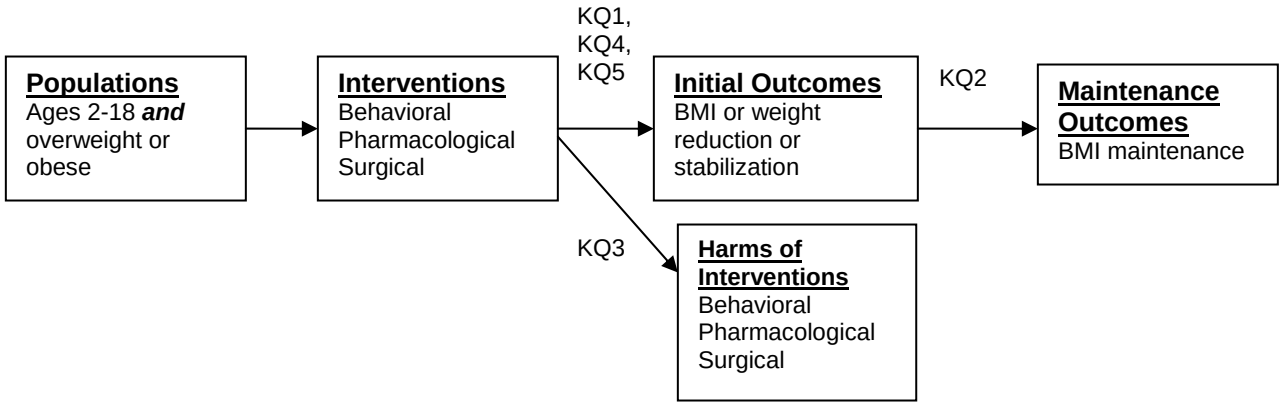
$$SD_{baseline\text{-}followup} = sqrt(SD^2_{baseline} + SD^2_{followup} - 2*0.90*SD_{baseline}*SD_{followup}).$$

When given standard errors rather than standard deviations, we calculated standard deviations by multiplying the standard error by the square root of n. When given symmetric confidence limits rather than standard deviations, we determined the standard deviation using the following formula:

$$\text{Std Dev} = \frac{(\text{CI width})(\sqrt{n})}{2*(1.96)}$$

We used random effects models because the trials varied considerably along many dimensions that would impact both baseline BMI (e.g., age, minimum overweight inclusion criteria) and change in BMI (e.g., intensity of intervention, comprehensiveness of treatment program). All meta-analyses were conducted using the "metan" procedure of Stata 9.2 with the "random" option, and then confirmed the results using RevMan 4.2. Forest plots are taken from our RevMan output.

Figure 3. Analytic framework and key questions



Key Questions (KQ)

1. Do weight management interventions lead to **BMI reduction or stabilization** in children and adolescents who are obese (≥95th BMI percentile) or overweight (85-94th BMI percentile)?
    (a) Behavioral Interventions
    (b) Pharmacological Interventions
    (c) Surgical Interventions

2. Do weight management interventions help children and adolescents who were initially obese (≥95th BMI percentile) or overweight (85-94th percentile) **maintain BMI improvements** after the completion of an active intervention?
    (a) Behavioral Interventions
    (b) Pharmacological Interventions
    (c) Surgical Interventions

3. Are there **harms** associated with weight management interventions to help children and adolescents reduce or stabilize BMI who are obese (≥95th BMI percentile) or overweight (85-94th BMI percentile)?
    (a) Behavioral Interventions
    (b) Pharmacological Interventions
    (c) Surgical Interventions

4. Are there **other beneficial outcomes** to weight management interventions in children and adolescents who are obese (≥95th BMI percentile) or overweight (85-94th BMI percentile) (i.e., improvements in diet or physical activity or reduction in risk factors, such as lipid level, insulin resistance, etc.)?

5. If effective behavioral weight management interventions are found (see KQ1),
    (a) are there **specific components** of the interventions that affect the effectiveness of the programs?
are there **population or environmental factors** that affect the effectiveness of the programs?

Chapter 3. Results

Behavioral Interventions

Trial Characteristics

We identified 18 fair- or good-quality trials, in 21 publications,[69,70,72-75,75-89] that evaluated a total of 1,794 overweight or obese children and adolescents. (Tables 3 and 4) These trials compared weight-related outcomes of behavioral weight management interventions to minimal or no treatment control conditions, with outcomes reported at least 6 months after the start of the intervention. Participants in eight [70,72,78-81,83,88] of the 18 trials were aged 5 to 12 years (n=900). Four trials[69,77,82,89] enrolled 12 to 18 year olds (n=246). The remaining six trials[71,73-75,85,87] enrolled both children and adolescents (n=648). Trial participants were mostly female, with the proportion of males generally one third to one half. Before treatment, the mean BMI indicated that most participants in these trials far exceeded the 95th percentile for BMI, and in some cases met adult criteria for Class I obesity.

Two trials were conducted in primary care settings,[77,78] five in specialty health care settings,[73,74,79,83,87] five in school settings,[69-72,75] one in a residential setting,[85] one in a child health/sports center,[79] one using the internet,[89] and three in settings that were not described.[80,81,88] Eight studies were conducted in the United States, three in Australia, three in Germany, two in Israel, and one each in Belgium, Finland, and Sweden. A total of 22 different active treatment arms were evaluated. Duration of treatment ranged from 3 to 12 months, with the exception of one study with a "rapid pace" treatment arm lasting only 4 weeks,[88] and a longer trial that lasted for 14 to 18 months.[81] Treatment intensity (estimated in hours of contact) ranged from 3.8 to 3,520 hours, with 16.7 percent (n=3) providing less than 10 hours, 33.3 percent (n=6) providing 10-25 hours, and 33.3 percent (n=6) providing 26-75 hours. The remaining three trials provided considerably more than 75 hours (97.5, 175.5, and 3,520 hours).

Ten of the trials involved the parents as primary participants in the intervention.[70,72-74,78-81,83,88] All but one[74] of these trials involved children aged 11 years and younger on average. Parental involvement took many forms in these trials, including weight control educational sessions (with or without their overweight child),[70,72,74,78-80,84,86,88] family therapy,[73,81] or parenting skills training.[83] Family involvement in the remaining eight trials ranged from no involvement to including parents in one to three counseling sessions. The trials with less parent involvement primarily targeted older children, although three included those as young as 10 years,[71,75,85] and one included children as young as 7 years.[87]

Participants engaged in organized physical activity sessions as part of the intervention in eleven of the trials.[69-75,79,82,83,85] Four additional trials[77,78,88,89] applied behavioral modification principles to help participants increase their physical activity on their own time. Three trials provided only information and encouragement for physical activity, but did not apply behavioral modification principles such as problem-solving and goal-setting to physical activity.[80,81,87]

While all 18 trials provided short- or long-term changes in weight after treatment, not all trials provided data on all outcomes (Tables 3 and 4). Sixteen trials reported short-term weight outcomes (within 6-12 months from enrollment) measured immediately or several months after treatment ended.[69-75,77-80,83,85,87-89] Five trials addressed maintenance outcomes more than 12 months after treatment ended.[72,73,78,81,82] Eight trials reported adverse events,[69,73,74,77,78,82,83,85,89]

and 11 reported other beneficial outcomes in addition to weight.[69-71,73-75,79,81,83,87,88] (Further trial details included in Appendix C[†] Table 1.)

Additional trials that did not meet inclusion criteria for weight outcomes, but did for other key questions, are detailed in the sections addressing those key questions.

Study design and quality. We rated eight[71,72,74,75,77,78,83,89] of the 18 trials as good-quality. The remaining trials were rated as fair-quality. Most trials (n=14) were randomized controlled trials but three were nonrandomized controlled trials.[73,81,85] It was unclear whether one fair-quality trial involved randomization.[82] Eleven of the 16 trials using randomization failed to report whether treatment allocation was blinded. Fifteen of the 18 trials did not report whether those conducting followup assessments were blind to the treatment condition. Many of the trials were also quite small, with 12 of 18 trials including 40 or fewer participants per treatment arm. While most trials reported retention of around ninety percent or higher, but it was below 70 percent in three trials.[74,87,88] One trial [74] among these used statistical methods to compensate for attrition. Several trials tested for differential attrition statistically (none found differential attrition between treatment and control groups), but most did not. While two smaller trials[77,90] appeared to have differential attrition, these differences were not tested statistically. The majority of trials (13/18, 72.2 percent) were published in 2005 or later.

Short-term (6-12 month) Weight Outcomes with Behavioral Interventions (KQ1)

Sixteen trials[69-75,77-80,83,85,87-89] measured short-term weight outcomes (6 to 12 months after entry into treatment). Two[73,83] of these trials reported actual BMI measures between groups, but tested only whether BMI trends from baseline to followup were significantly different. Most trials reported weight outcomes as post-intervention BMI or changes in BMI from baseline and compared these changes between intervention and control groups. Among trials that did not report BMI or change in BMI, two trials, reported weight outcomes as changes in BMI standard deviation scores (SDS),[83,87] two trials reported changes in percent overweight,[85,88] and one trial reported change in BMI percentile.[80] All studies involved children and/or adolescents whose BMI exceeded the 97th percentile on average.

All trials except one[80] were consistent with a beneficial effect of treatment on BMI change compared with controls. Not all of these differences, however, were statistically significant. Programs conducted in the outpatient setting or the community generally showed only modest differences in BMI change between treatments and controls. In most cases participants remained at or above the 95th percentile after completing the interventions. The greatest level of weight loss was seen in 76 youth aged 10 to 17 years participating in a very high-intensity (3250 hours), 10-month residential program. Average weight decreased from 75 percent overweight to 24 percent overweight in the intervention group, compared to a 6 percent increase in those on a waiting list.[85]

Most (12 of 15) outpatient or community trials reported weight outcomes as mean post-test BMI or change in BMI (Figure 4). In these programs, short-term BMI changes in intervention groups ranged from dropping 2.4 kg/m^2 in BMI to increasing BMI by 0.5 kg/m^2. Control group BMI changes ranged from dropping 0.43 kg/m^2 to increasing BMI by 2.0 kg/m^2. Net short-term [*]improvements in BMI change between intervention and control groups ranged from 0.3 to 3.30 kg/m^2 and these differences reflected weight loss as well as weight gain prevention among

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

treated participants. Two of the other four trials reporting weight outcomes other than BMI change showed a benefit with treatment. One of these, conducted in a health care setting, showed a significant difference (1.2 BMI SDS) favoring treatment 6 months after a low-intensity (8 hours) intervention in young people aged 7 to 16 years (n=27),[87] while another, also in a health care setting, showed no treatment benefit (measured in BMI SDS) at one year after either 10 or 21 hours of treatment delivered over 5 months to 6 to 9 years olds (n=111).[83] In a community setting, both a very-low (3 hours) or low-intensity (21 hours) behavioral intervention delivered over 3 months to 5 to 12 year olds (n=98) resulted in an increased BMI percentile in the intervention group, and a decreased BMI percentile in the control group, with no overall statistical differences.[80] In one study, conducted in an unknown setting, a low-intensity (12 hours) intervention in 6-12 year olds (n=35) significantly reduced the mean percent overweight (13 to 19 percentage points), compared with a 6 percent reduction in the minimally treated control condition.[88]

A meta-analysis of the 12 trials reporting sufficient data to analyze group differences in short-term BMI change after behavioral interventions found an average difference in BMI change of 1.22 kg/m^2 between treatment and control participants that favored treatment (CI: 0.75, 1.69). Statistical testing for heterogeneity (I^2=84.3 percent), however, indicated large differences in estimates across studies. Statistical heterogeneity was reduced when stratified by setting. (Figure 4).

School setting. Among the five studies of predominantly medium-intensity behavioral interventions in school settings,[69-72,75] (Figure 4, sub-category 1) average BMI change was 0.81 kg/m^2 greater in treatment than control participants (CI: 0.45, 1.18). Results were relatively homogeneous across studies (I^2=47.2 percent) and studies included a range of ages (6 to14 years).

Health care referral or specialty settings. Short-term outcomes from the three trials of medium- to high-intensity interventions in health care referral or specialty treatment settings (Figure 4, sub-category 2) showed the largest difference in mean BMI change between treatment and controls of all community settings (1.9 kg/m^2 to 3.3 kg/m^2).[73,74] These trials had a pooled estimate of 2.73 kg/m^2 (CI: 1.72, 3.73) and a statistical result (I^2 =70.9 percent) indicating these three estimates of specialty treatment do not appear to be comparable. When absolute weight reduction was considered as a percentage of baseline BMI, these treatments resulted in comparable weight differences (7 to 9 percent difference). As discussed above, results of the two lower-intensity interventions in health care settings that were not included in the meta-analysis resulted in mixed findings.[83,87]

Primary care setting. Short-term changes in weight in two trials [77,78] of very-low-intensity (4 hours) interventions conducted in primary care settings (Figure 4, sub-category 3) were smaller than in specialty settings (0.3 to 1.3 kg/m^2). The pooled average BMI change indicated statistical heterogeneity (I^2=62.5 percent), consistent with noncomparable treatment effects. These studies addressed very different ages (5-9 years in one compared with 12-16 years in the other) and, as such, mean BMIs at baseline were very different (20 kg/m^2 vs. 31 kg/m^2). Thus, while a modest benefit for low-intensity primary care interventions is adolescents is possible, this type of intervention was not clearly beneficial in the single trial of younger children and their families.

Other settings. A single study in a self-referred community setting using pedometers (with or without additional weight management education) to increase physical activity and affect BMI showed little effect on BMI. After nine months, control participant's BMI dropped by an average of 0.43 kg/m^2 and intervention participant's BMI decreased by 0.87 kg/m^2 (Figure 4 sub-

category 4).[80] Similarly, a single study examining an internet-based intervention in adolescents (12-18 years) showed little impact on followup BMI at 8 months (4 months after treatment ended). Participants in the intervention group decreased BMI by 0.15 kg/m^2, while those in the control group increased by 0.39 kg/m^2 (p=0.10) (Figure 4 sub-category 5).[89]

Best case example from a healthcare setting. One good-quality trial conducted by Savoye and colleagues[74] illustrates a realistic best-case scenario, reporting the largest effect size of the outpatient programs included in this review and a comprehensive program in which many families with overweight children could realistically participate, if it were available to them and affordable. This year-long program (Bright Bodies Weight Management) at a pediatric obesity clinic in the United States accepted children ranging from age 8 to 16 years, with an average age of 12.1 years. Sixty-one percent of the 174 participants were girls. The Bright Bodies program involved approximately 98 hours of contact and an extensive educational program providing information on nutrition, physical activity, behavior change strategies, coping skills, and relapse prevention. They provided organized exercise sessions twice per week during the first 6 months, then once every two weeks during the next 6 months. Parents or caregivers attended all educational sessions. Children and adolescents in the intervention group began the program with an average BMI of 35.8 kg/m^2, which dropped by an average of 1.7 kg/m^2 by the end of the intervention, compared with an average increase of 1.6 kg/m^2 in the control group. This trial suffered from somewhat low retention (77.6 percent at 6 months and 66.7 percent at 12 months), but took statistical measures to examine and combat the effects of attrition, including comparing results in completers only with results involving multiple imputation and *Last Observation Carried Forward (LOCF)* data replacement methods.

To provide a more concrete example of the average impact of the Bright Bodies program, we modeled the impact on a 12-year-old girl who began the program at an assumed height of 5'0", with the average entry BMI of 35.8, and who experienced the average reduction in her BMI by 1.7 kg/m^2 over the course of the intervention year, while growing 2 inches (an average for this age and sex). This would amount to a change from 183 pounds to 186 pounds one year after she participated in the program, compared with an expected 21 pound weight gain and an increase of 1.6 BMI kg/m^2 if she had not participated.

Maintenance of Weight Changes After Behavioral Interventions (KQ2)

Five trials in six publications[72,73,78,81,82,84] reported medium-term outcomes at least 12 months after the intervention began and 1-5 years since beginning treatment. Three of these trials also reported short-term (6 to12 month) weight outcomes.[72,73,78] No trials reported longer-term (more than 5 years) outcomes. Three trials were set in specialty health care treatment settings,[73,81,82] one in primary care,[78] and one in schools.[72] All of these trials reported weight outcomes in kg/m^2, except an older study reporting change in percent overweight (see Table 4).[82]

Three of the five interventions in trials reporting maintenance outcomes tested low-,[81] medium-,[72] or high-intensity[73] interventions delivered over 6 months or longer. The remaining two trials tested interventions lasting 3 months that were very low[78] or low intensity.[82] Some of these trials also report 6-to 12-month outcomes that were described under KQ1.

We considered the results of the five trials reporting maintenance outcomes qualitatively, as there was significant statistical heterogeneity when we pooled them (I^2 =89.5 percent) or stratified to include those in the health care setting (I^2 =55.6 percent) (Figure 5). Four of the five trials, including one reporting results as change in percent overweight,[82] found that intervention groups had beneficial changes in BMI compared to controls at least one year after treatment began.[72,73,81,82] However, BMI in the intervention groups decreased from baseline in only one of

five studies (that only included adolescents).[82] These results suggest that the primary sustained benefit of treatment, particularly in younger children, was preventing the degree of weight gain seen in controls. Two of the three trials reporting both short-term and maintenance outcomes 12 months later confirmed that BMI benefits seen at 6-12 months were largely maintained.[72,73] The third trial with both short-term and maintenance outcomes did not find improved weight outcomes at either 12 or 15 months and was a very low-intensity (4 hours), short-duration (3 month) treatment.[78] In one trial testing a low-intensity (24 hours), short-duration (3 month) intervention, there was a greater difference in overweight measures between intervention and controls at 15 months than at 3 months.[82] This result was the only one to suggest that treatment effects could be enhanced beyond the end of active treatment.

Post-treatment strategies. Two comparative-effectiveness trials also tested post-treatment strategies to enhance weight maintenance after a high-intensity inpatient treatment program and a moderate-intensity outpatient treatment program (see Appendix C Table 2 for detailed information on these supplementary trials).[91,92] After 10 months of intensive residential treatment for 20 adolescents, Deforche and colleagues found that 1.7 hours (compared with 0.25 hours) of telephone and mail contact over 6.5 months was beneficial in preventing some weight regain. After completion of a moderate-intensity outpatient treatment program that reduced BMI (measured in standard deviations) in 150 children aged 7 to 12 years, those who received 16 hours of behavioral self-management support or social support over four months maintained BMI improvements, compared with those who received no support. However, between group differences were no longer apparent 8 and 20 months after the end of maintenance treatment.

Adverse Effects of Behavioral Interventions (KQ3)

Eight[69,74,77,78,82,83,85,89] of 18 trials addressing weight outcomes also reported potential harms of behavioral weight management interventions (Table 5). In order to more fully illuminate serious adverse events (i.e., those requiring urgent medical treatment), we eliminated the minimal followup time criterion of 6 months for beneficial outcomes based on the assumption that adverse effects could happen well before a treatment effect is apparent. We also eliminated the requirement that the trial be conducted in a country with a United Nations Human Development Index (HDI) (http://hdrstats.undp.org/indicators/1.html) of >0.90, based on our assumption that cultural conditions are unlikely to affect likelihood of injury. Thus, two supplementary trials[93,94] reporting on injury rates in exercise programs with obese children were included. These trials did not meet criteria for inclusion for the previous questions because they only reported weight outcomes of less than 6 months.

We found no evidence that behavioral intervention programs may be harmful. Among the eight trials, three [74,83,85] reported no group differences in change in height measured at 10 to 12 months. Four trials [69,77,78,89] reported either favorable or no effects on several measures of eating disorder pathology or body image/physical self-concept. One trial[82] reported that depression symptomatology improved in intervention group participants, but did not change in the control group, which represents an added benefit rather than an adverse effect. In addition, Nemet and colleagues[79] reported that no adverse events were noted, but did not describe what events they examined or how they elicited information on adverse events. In the two trials examining injuries in exercise programs, Sung and colleagues[94] reported that none of the 41 obese children in their exercise condition were injured, and only one of the 73 obese children in the trial by Davis and colleagues[93] fractured a bone. No children in the control groups of either of these trials reported any injuries.

Other Beneficial Outcomes of Behavioral Interventions (KQ4)

Eleven [69-71,73-75,79,81,83,87,88] of the 18 trials reported other beneficial outcomes, including measures of adiposity, cardiovascular risk factors, and physical fitness (Table 6). Intermediate outcomes included improved nutrition and activity level, and self-reported measures of self-concept, mental health, or eating disorder-related behaviors. Results in all areas were mixed, but the outcomes that primarily showed improvement in the intervention group relative to the control groups were measures of adiposity, fasting *insulin*, and *glucose* tolerance. Improvements in physical fitness appeared related to whether organized physical activity sessions were provided.

Measures of adiposity. Nine of these eighteen trials [69-71,74,75,79,81,83,88] reported measures of adiposity. In most cases these trials found that the intervention groups showed greater improvement in these measures than those in the control groups. Six trials[69,74,75,79,81,88] found positive effects in both the primary weight outcome and either skinfold measures or body fat, as measured by *bio-electrical impedance*. One more trial [83] that did not have positive primary weight outcomes did show improvement in adiposity (as measured by DEXA)[69] and *waist circumference*.[70,83] The remaining two trials did not see group differences in adiposity as measured by bio-electrical impedance[71] or waist circumference.[70]

Health outcomes. Other outcomes explored included lipid levels, glucose tolerance, blood pressure, and physical fitness. Results for all of these outcomes were quite mixed. Reported differences were most commonly reductions in *LDL* cholesterol levels, reduced fasting insulin, and reduced *insulin resistance*. Three[69,73,74] of the six[69,71,73-75,83] trials reporting on fasting insulin found reductions of fasting insulin in the intervention groups relative to the control group. Two of these trials[73,74] also reported significant reductions in insulin resistance, as measured by the *homeostasis model assessment of insulin resistance (HOMA)*. By contrast, none of the six trials [70,71,73-75,83] reporting lipid levels found group differences in *HDL* or triglyceride levels, and only two found reductions in LDL levels.[71,73]

None of the four trials[71,73,75,83] reporting on blood pressure found group differences on diastolic blood pressure and only one[73] reported reductions in systolic blood pressure. Similarly, none of the five trials [71,73-75,83] reporting on glucose levels found any group differences.

Four trials [69,79,81,87] reported on physical fitness, each using a different measure. Results suggest that organized physical activity increased physical fitness, though one trial [81] did achieve improvement without organized exercise sessions (further details in Appendix C† Table 1). The trial by Carrel and colleagues [69] found that the intervention group improved their maximum oxygen consumption more than the control group in a trial comparing a specially designed, limited-enrollment physical education class that emphasized noncompetitive, lifestyle movement activities (e.g., walking, cycling, and snowshoeing) with a typical physical education class. Nemet and colleagues[79] reported increased endurance in the participants in their intervention group after completing a 14-week, twice-weekly exercise program along with up to six meetings with a dietitian. This study measured endurance by the number of seconds participants were able to continue a treadmill test. One trial[87] that did not include organized exercise sessions did not see group differences in scores on the Harvard Step Test. On the other hand, Flodmark and colleagues[81] did not provide organized physical activity, yet children in one of the treatment conditions had greater physical work capacity at one-year followup than those in the control group, controlling for baseline scores. So, the provision of organized physical activity sessions was not necessary to improve children's fitness.

Behavior changes. The interventions in these trials appeared to have a minimal impact on the intermediate outcomes of diet and activity level. While four trials[77-79,87] explored dietary changes, only one[78] found group differences. The only dietary differences found in this study

were that children in the intervention group reported consuming less whole milk, while consuming more skim milk and water. Five trials[77-80,87] reported on changes in physical activity levels and/or sedentary behavior. Only one reported positive effects.[79] This trial provided organized physical activity sessions during the 3-month intervention, and measured the amount of sedentary and physical activity participants reported 1 year later. Participants in the intervention group reported an average of 6 fewer minutes of screen time per day and 9.1 more weighted metabolic-equivalent units of habitual activity. This suggests that long-term changes in physical activity can be sustained even after only 3 months of intervention. The remaining four trials, which showed no group differences, included one trial targeting physical activity,[80] two low-intensity primary care-based trials,[77,78] and a small (n=27), low-intensity trial involving weekly brief contact with a case manager.[87]

Eating disorders. Finally, several trials measured constructs such as impacts on eating disorders or body image that may be a potential harm or benefit of a treatment program. No group differences were found in either of the two trials [77,89] reporting on eating disorder pathology. Instead, Doyle and colleagues[89] reported reduced levels of shape concern in the intervention participants in their trial. Mellin and colleagues [82] found reductions in depression scores among intervention participants and no changes in depression scores in control participants. They did not, however, directly test the groups against each other. Also, Mellin and colleagues did not find group differences in change in self-esteem and both groups showed improvement in repeated measures tests.

Important Components of Behavioral Interventions (KQ5a)

We approached the question of identifying important components of treatment by first examining the results of the primary group of eighteen KQ1 and KQ2 trials. Treatment approaches generally focused on making healthy lifestyle improvements, emphasizing healthy eating, and increased physical activity. Table 7 provides more detailed information on intervention components used in trials that found significant treatment effects. However, treatment approaches and the components of treatments were quite heterogeneous (Table 3 and 4 and Appendix C† Table 1). The number of trials was also too small to permit quantitative examination of the variation in treatment components through meta-regression. Therefore, we coded three treatment components possibly related to treatment success: the provision of organized physical activity sessions as part of the intervention, parental involvement within age groups, and the utilization of behavior modification principles. We then sorted the trials by each of these variables and examined the overall patterns of variation in treatment components and their association with statistically significant effects on weight outcomes (see Appendix J†). We supplemented this approach by including comparative effectiveness trials addressing any of these three treatment components that met all criteria for KQ1 and/or KQ2, except that they did not include a minimal-treatment control group.

We discuss our findings from this exercise, but these should be considered primarily as hypothesis-generating. The degree of variability among this small number of treatment programs, including important differences in effects due to setting, age and treatment intensity, greatly limits our ability to examine other treatment components.

Organized physical activity sessions. Programs that provided organized physical activity sessions (rather than encouraging participants to exercise at home) appeared to be more likely to improve BMI. Group differences were seen in eight of 11 programs with organized physical activity sessions. The three trials that did not see beneficial changes in BMI reported improvements in other weight or adiposity measures. We did not have sufficient data to

[†]determine whether programs with organized physical activity or those that improved physical activity or fitness were more likely to have a positive impact on other health outcomes (such as fasting insulin or blood pressure). The physical activity sessions ranged from seven 1-hour sessions at 2- to 4-week intervals, which consisted of fun, noncompetitive physically active games and activities,[83] to twice-weekly 50-to 60-minute sessions for 6 to 9 months.[70,74] Efforts were generally made to present a variety of enjoyable activities, including team sports, noncompetitive games, dancing, swimming, walking, jogging, and obstacle courses. Several trials[72,79,83] employed activities to help develop motor skills and one[69] reported making efforts to personalize the skill level of the activities to the skill levels of the child. One trial [74] used exercise physiologists to facilitate the exercise sessions and help children maintain a target heart rate of 65 to 80 percent of their age-adjusted maximal heart rate.

We identified three supplementary trials in four publications that unfortunately contributed little to the elucidation of the role of physical activity sessions.[53-55,95]

Parental involvement. The role of parental involvement in weight management programs can only be considered in the context of the child's age. None of the seven trials that focused on adolescents included parents as primary participants of the intervention. However, three of the trials[71,75,82] in adolescents did invite parents to one or more intervention sessions, and all three of those trials did show positive weight outcomes. Thus, parental participation may increase the likelihood of successful weight loss in adolescents.

All eight of the trials limited to children aged 12 or younger had high levels of parental involvement, as did two of the trials that included both younger children and adolescents. Due to the lack of variability we could not explore the importance of parental involvement further than concluding that weight-loss researchers consider parental involvement crucial for successful weight loss in young children. Parental involvement took many forms in the trials with high levels of involvement. In some trials parents and children attended weight control educational sessions together,[72,78,79,88] while others provided family therapy, [73,74,80,81] or parenting skills training [83] in addition to traditional weight control topics. In one trial the children participated only in fun, physical play sessions or family activities, while only parents received instruction in weight management.[70]

Similarly, few conclusions could be drawn from the five supplementary comparative effectiveness trials[57-60,96] attempting to isolate the importance of child vs. parental involvement. Data suggest that it may be helpful to have both parents and children involved in interventions with young children. Parent training in child management principles may also be helpful with parents of young children. These conclusions, however, are tentative because they are based on only a few trials, with limited generalizability to the population of the United States.

Five of the supplementary trials (in six publications) examined the impact of varying types of parental involvement in weight loss interventions, four in younger children[56,57,59,60,96] and one in adolescents.[58] Among the trials in younger children, three [56,59,96] compared interventions involving parents or children only with those involving both children and parents, with conflicting results: two[59,96] suggested it was most helpful to have both child and parent involved, but this was not supported by the third.[56] The fourth supplementary trial [57] in younger children found that children had greater weight loss when parents were taught child management techniques in addition to weight management principles. This contrasts with one of our primary trials[83] conducted by Golley and colleagues, which taught child management techniques to parents without enhancing weight loss. However, Golley and colleagues provided only about half

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

of the treatment hours of the supplementary trial.

One trial[58] in black adolescent girls explored the role of parental involvement in families categorized as lower to lower-middle class, largely single-parent households. Researchers randomized families to one of three groups: adolescents attending treatment sessions without mothers, mothers and daughters attending sessions together, and mothers and daughters attending separate, concurrent groups. Groups did not differ on any measure of weight loss, nor did the groups differ from their own baseline measures. The authors reported low attendance among mothers in this program, which suggests that the burden of attending a treatment program in these primarily single-parent families is likely quite high.

Behavior management techniques. Among the primary 18 trials, programs that included participant training and support in the use of behavioral management techniques were more likely to be successful than those that did not. None of the four trials[69,80,81,87] that lacked instruction in behavior management techniques were successful in improving weight outcomes. Eleven of the 14 trials that taught participants to use behavioral management techniques did show group differences in BMI or other weight outcomes. These trials all appeared to provide broad advice on using these techniques for changing diet, activity, and other related behaviors.

We identified two supplementary trials in four publications[61-64] comparing standard weight loss management programs without cognitive behavioral treatment or techniques with the same programs, adding behavioral management techniques. One of these, conducted by Epstein and colleagues,[61] provided 40 hours of contact to 24 5- to 8-year-old girls and their parents over 12 months. This trial included a 5-week intensive treatment phase and once monthly maintenance contacts thereafter. Behavioral management principles were provided to parents in one of the treatment groups, but not the other. The second trial [64] compared a group of adolescents receiving nutrition counseling from a dietitian without behavioral management techniques with a group receiving the same nutrition counseling plus an intervention delivered over the internet. This intervention was based on the treatment methods developed by Epstein and colleagues, which included behavior management techniques. The addition of behavioral management training improved weight outcomes in both of these trials at the end of the treatment phase, although the effect was not seen in long-term followup in the trial that measured weight outcomes 21 months after the end of treatment.[64]

Factors Influencing the Effectiveness of Behavioral Interventions (KQ5b)

Treatment effects varied by intervention setting and by intervention intensity. Residential treatment and high-intensity interventions in specialty health care treatment settings (both inpatient and outpatient) had the largest treatment effects; medium-intensity interventions in school settings had consistent, but modest effects; some low-intensity interventions in primary care or other settings have more modest effects; and, limited data from very low-intensity primary care or internet-based interventions suggest no treatment effects. We were unable to isolate other population or environmental factors that may influence the effectiveness of a treatment because of the limited number of trials and the great heterogeneity in intervention, population, and environmental factors.

Pharmacological Agents

Trial Characteristics

We identified seven trials (all fair- or good-quality RCTs)[97-103] evaluating a pharmacological agent's effect on overweight or obesity in a total of 1,294 adolescents aged 12 to 19 years (Table 8). Five obesity treatment trials[97,98,100,101,103] evaluated the effectiveness of 10-15 mg/day of sibutramine in 715 patients. Two trials[99,102] evaluated the effectiveness of orlistat (120 mg three times a day) in 579 patients. All pharmacological obesity treatment trials compared the active medication plus behavioral counseling about diet and physical activity (with or without a behavioral management program) to the effects of placebo plus the same behavioral counseling. We describe weight-related and other outcomes separately from two additional trials whose primary aim was testing the effect of metformin on preventing glucose intolerance or improving insulin sensitivity in obese adolescents with additional risk factors for diabetes [104,105] (see Table 10).

Participants in the sibutramine and orlistat trials all met some type of BMI-based criteria for obesity (either above the age- and sex-specific 95 to 97th percentile or above a BMI of 30 kg/m^2), and mean BMI was typically 35 to 38 kg/m^2 at baseline. Most trials excluded those at or above the midpoint for Class III (morbid) obesity (BMI exceeding 44 kg/m^2) and those who had type I or type II diabetes mellitus. The sibutramine trials also generally excluded patients who had cardiovascular disease or hypertension. About two-thirds of participants in these trials were females. The majority of trials did not report race/ethnicity of participants. However, in the two largest multi-center RCTs, almost half of the sibutramine patients were racial/ethnic minorities,[98] as were one-quarter of orlistat patients.[99] The sibutramine trial included 21 percent Black, 16 percent Hispanic, and 7 percent other nonWhite patients. The orlistat trial included 17 percent Black and 7 percent participants of other race-ethnicity. A small (n=52) sibutramine trial conducted in Mexico could have applicability to adolescents of Mexican heritage living in the United States.[100]

The minimal behavioral intervention provided to all participants consisted of advice to follow a calorie-restricted diet (e.g., 500 kcal/day deficit) and meet physical activity goals (e.g., at least 30 min of aerobic activity per day). All but one trial[101] also included a behavior management program, ranging in intensity from seven to 19 sessions with a dietitian, psychologist, or psychiatrist. Family members attended behavioral management sessions in only two of the seven trials.[97,103] The length of drug therapy lasted for either 3, 6, or 12 months (in one, four, and two trials, respectively). In the single trial evaluating 3 months of drug therapy (sibutramine), we report the follow-up results at 6 months. No other trials reported followup results describing weight patterns after the pharmacologic treatment ended.

Of the six trials that reported the source of funding, all but one trial was funded by the pharmaceutical industry, either completely or partially. Two of these pharmaceutically sponsored trials were large (about 500 participants), multi-center RCTs (over 30 study sites) conducted in the United States and Canada. One evaluated sibutramine[98] and the other evaluated orlistat.[99] The remaining trials randomized much smaller samples (n = 24 to 82), were conducted at single sites, and reported outcomes after only six months of treatment.

Additional details on study and participant characteristics are presented in Appendix C[†], Table (3).[†]

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

Study design and quality. All included studies were double-blinded, placebo-controlled RCTs of fair- or good- quality (see Appendix H[†] for quality criteria). Most trials used appropriate randomization methods and took explicit measures to conceal allocation assignment. In all of the trials, intervention and control groups were similar at baseline for age, sex, and anthropometric characteristics. Descriptions of drug protocols were clear. Descriptions of behavioral interventions were generally adequate, but much less detailed than trials evaluating behavioral interventions. Adherence to medication protocols (measured by pill counts) was 80 percent or higher in the majority of the trials. Adherence was slightly lower (72 to 73 percent) in the large multi-center orlistat RCT. In contrast, most of the trials did not report how the behavioral intervention program was supervised, whether it was delivered as intended, or any data on adherence to diet, physical activity, or other behaviors. Most of the trials specified that outcomes were assessed by personnel blinded to treatment status.

Attrition rates ranged from 10 to 35 percent. Notably, both of the large, multi-center trials had fairly high attrition. Overall attrition was 35 percent in the large orlistat trial. In the large sibutramine trial, the attrition rate was 28 percent overall and was differential between groups (24 percent in the sibutramine group and 38 percent in the control group, p=0.001). All of the trials analyzed main weight outcomes among the *intent-to-treat* (ITT) or modified ITT population. The modified ITT population included any participant who had at least one post baseline efficacy measurement. Missing values were replaced using the LOCF method in most trials and/or a linear mixed-effects model for repeated measures over time. One trial[100] excluded 10 percent of patients, even in the modified ITT population analyses, because they dropped out before one month.

Short-term (6-12 month) Weight Outcomes With Sibutramine Treatment (KQ1)

Five trials reported outcomes 6 or 12 months after starting sibutramine treatment (in seven publications) (Table 9).[97,100,101,103,106,107] One small trial (n=24) evaluated 3 months of a behavioral intervention plus sibutramine (10 mg) or placebo treatment, followed by 3 months of a behavioral intervention alone.[103] Based on our calculations, BMI was not reduced more in those receiving sibutramine plus a behavioral intervention compared with placebo treatment plus a behavioral intervention. Both groups had similar, modest (-0.8 kg/m^2 to -1.4 kg/m^2) mean reduction in BMI at 6 months. All three trials reporting weight outcomes immediately after 6 months of treatment with sibutramine plus a behavioral intervention found a statistically significant difference between the intervention and control groups, favoring a greater reduction in BMI in the group treated with sibutramine.[97,100,101] Among patients treated with sibutramine plus a behavioral intervention, the mean reduction in BMI ranged from -3.2 kg/m^2 to -3.6 kg/m^2. In contrast, the mean reduction in BMI among patients treated with placebo plus behavioral therapy ranged from -0.9 kg/m^2 to -1.8 kg/m^2. Budd and colleagues. 2007[106] presented a secondary analysis of the data from one of these trials,[97] reporting outcomes separately for the 34 Black and 45 White participants. At month six, there were no statistically significant differences in the outcomes between racial groups. This trial, however, was not designed to have adequate power to detect differences between racial groups. [†]

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

The single large trial that reported weight outcomes after 12 months of sibutramine plus a behavioral intervention also found statistically significant results in favor of the sibutramine group.[98] The mean reduction in BMI in the sibutramine group was -2.9 kg/m^2 compared to -0.3 kg/m^2 in the control group ($p < 0.001$). As noted, this trial had higher attrition in the placebo control group (38 percent) than the sibutramine group (24 percent, $p = 0.001$), reducing our confidence in these findings. BMI measures over time were also analyzed using a linear mixed-effects model to predict missing values. In these analyses, the mean change in BMI between treatment and control groups was statistically significantly different at all study visits from week 1 through month 12. The difference between the changes in BMI z-scores was also statistically significant. In this trial, the mean change in body weight (± SE) at month 12 was -6.5 ± 0.31 kg in the sibutramine group versus 1.9 ± 0.56 kg in the placebo group (difference -8.4 kg, or 18.5 pounds (CI: -9.7 ,-7.2 kg); $p < 0.001$ by linear mixed-effects model).

Maintenance of Weight Changes After Sibutramine Treatment (KQ2)

No trials reported on maintenance of weight loss after sibutramine was discontinued.

Adverse Effects of Sibutramine Treatment (KQ3)

Adverse effects results are reported in Table 9. A more detailed account is included in Appendix C[†] Table 3. All sibutramine trials evaluated the effects on heart rate and systolic and diastolic blood pressure. Three of the five sibutramine trials found statistically greater increases in heart rate and systolic and/or diastolic blood pressure in the sibutramine group compared to the control group after 6 or 12 months of treatment, but differences were small in magnitude. In the 12-month, multi-center sibutramine trial, tachycardia occurred more commonly in the sibutramine than the control group (12.5 percent vs. 6.2 percent, $p = 0.049$). Withdrawals due to tachycardia, however, were similar between groups.

None of the sibutramine trials reported statistically significant differences between groups in the overall rates of having any adverse event, any serious adverse event, or discontinuation due to adverse events. In the large, 12-month sibutramine trial, serious adverse events were reported by 2.7 percent of patients in the sibutramine group and less than 1 percent of the control group. Only one of these events (excessive nausea and vomiting) was thought to be related to sibutramine. Two trials examined growth and maturation, including the 12-month, multi-center trial. Neither trial found a significant difference between the groups. Abdominal complaints and constipation were also found to be statistically higher in the sibutramine group in the shorter-term trials.

Other Beneficial Outcomes With Sibutramine Treatment (KQ4)

Physiological outcomes in the sibutramine trials are also presented in Table 9. Three of the four trials that reported changes in waist circumference found statistically significant differences favoring the sibutramine groups. In these three trials, the sibutramine groups reduced the waist circumference on average by seven to eight cm. In contrast, the placebo groups reduced waist circumference on average by two to three cm ($p < 0.001$ for all three trials). Four trials reported[†]

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

the effects on lipid profiles or glycemic parameters at 6 or 12 months followup. Of these, statistically significant differences were only reported in the large, multi-center, 12-month trial,[96] which found greater improvements in HDL cholesterol, triglycerides, serum insulin, and HOMA, compared to the placebo group. Differences in LDL cholesterol and fasting serum glucose were not statistically different between groups.

Components of Effective Sibutramine Treatment (KQ5a)

Data were largely insufficient to explore the importance of specific treatment components. Based on the limited number of trials, shorter treatment (3 as compared with 6 or 12 months) may be related to reduced beneficial effects on BMI. There are other possible explanations for these between trial differences, however, such as lack of placebo run in or differences in population or setting.

Factors Influencing the Effectiveness of Sibutramine (KQ5b)

Data were insufficient to explore the importance of population or environmental factors.

Short-term (6-12 month) Weight Outcomes With Orlistat Treatment (KQ1)

Two trials reported the weight outcomes after 6 or 12 months of orlistat therapy plus a behavioral intervention and results were mixed. The large (n=539), multi-center trial evaluating 12 months of orlistat therapy found a statistically significant difference between the change in BMI, favoring the orlistat plus a behavioral intervention group (-0.55 kg/m^2 vs. 0.3 kg/m^2, $p < 0.001$).[99] The absolute mean body weight increased in both groups during the 12-month trial, but increased less in the orlistat group (0.53 kg vs. 3.14 kg, $p <0.001$). Attrition in this trial was quite high (33 to 34 percent), but analyses of primary weight outcomes included over 98 percent of randomized participants and replaced missing data using the LOCF method. Also, baseline characteristics were not different for completers or those who dropped out within each group. Nevertheless, the high level of attrition in the trial somewhat limits its validity. A smaller trial (n=40) that evaluated the effects of six months of orlistat plus a behavioral intervention found that the orlistat group had a larger BMI reduction than the control group (-1.3 kg/m2 vs. -0.8 kg/m2), but this difference was not statistically significant.[102]

Maintenance of Weight Changes After Orlistat Treatment (KQ2)

No trials reported on maintenance of weight loss after orlistat was discontinued.

Adverse Effects of Orlistat (KQ3)

Rates of serious adverse effects and discontinuation of therapy due to adverse effects were low in both trials and were not reported to be statistically different between groups. In the Chanoine and colleagues trial,[99] one or more serious adverse effects occurred in 3 percent of both groups. Discontinuation of therapy due to a serious adverse event occurred among 12 of 357 (3 percent) of orlistat patients and 3 of 182 (2 percent) patients in the placebo group. In the orlistat group, only one event was thought to be study-related: asymptomatic cholelithiasis in a 15-year-old female who had lost 15.8 kg by the time of the event. In the Maahs and colleagues trial,[102] 2 of 20 patients in the orlistat group and 0 of 20 patients in the placebo group withdrew from the trial due to adverse effects. One suicide death occurred in the orlistat group to a patient who was

under a psychiatrist's care. No deaths occurred in the placebo group.

Gastrointestinal (GI) side effects were very common among patients taking orlistat. Chanoine and colleagues reported that among patients taking orlistat: 50 percent reported fatty or oily stools; 20 to 30 percent reported oily spotting, oily evacuation, abdominal pain, fecal urgency, or flatus with discharge; 10 to 15 percent experienced soft stool, nausea, and increased defecation. Notably, 9 percent of orlistat patients reported fecal incontinence, compared with less than 1 percent of placebo patients. Chanoine and colleagues also reported that the GI side effects were mostly mild- to moderate-intensity and led to discontinuation of treatment among only two percent of orlistat patients. In the smaller 6-month orlistat trial, Maahs and colleagues also reported that numerous adverse gastrointestinal effects occurred significantly more frequently in the orlistat group than the placebo group, including: soft stools, oily spotting, fatty or oily stools, oily evacuation, liquid stools, cramping, flatus with discharge, and fecal incontinence. Soft stools, oily spotting, fatty or oily stools, oily evacuation, and liquid stools all occurred in over 50 percent of patients treated with orlistat. Flatus with discharge occurred in 20 to 47 percent of patients treated with orlistat (varying by study month), in contrast to 0 percent in all but the first month for the control group. Fecal incontinence occurred in 6 to 13 percent of the orlistat group at each month, in contrast to 0 percent of the control group during any month. The authors report that the oily spotting, fatty or oily stools, and cramping improved more over time in the orlistat group than in the placebo group.

Both orlistat trials measured vitamin A, D, and E levels and reported that levels were not different between groups. In the Maahs trial, quality of life measured using four different scales showed no statistically significant differences between groups over time. Possible lack of blinding in the outcome assessors, however, could have influenced these results. No between-group differences in growth, bone mineral density, and sexual maturation were reported.[99]

Other Beneficial Outcomes of Orlistat Treatment (KQ4)

Chanoine and colleagues reported that both waist circumference and hip circumference decreased significantly more in those receiving orlistat and a behavioral intervention, compared with placebo plus behavioral intervention controls, at 12 months (p=0.01 for both in least squares mean (LSM) analysis). The LSM reduction for waist and hip were -2.67 and -1.52 cm, respectively, for the orlistat group, compared with -0.89 and -0.10 cm in the control group. In a subset of patients evaluated with *dual-energy x-ray absorptiometry (DEXA)*, patients in the orlistat group lost significantly more fat mass than patients in the placebo group (-2401 g vs. -380 g; p =0.03). In contrast, percent body fat at 6 months was measured using bioelectrical impedance analysis in the Maahs trial, and no statistically significant differences were found between groups. Levels of LDL, HDL, TG, FPG, and insulin were measured in both Orlistat trials, and no significant differences were found between groups in either trial. The Chanoine and colleagues trial, however, reported a small reduction in diastolic blood pressure in the orlistat group (-0.51 mm Hg), compared to an increase in the placebo patients (+1.30 mm Hg; p=0.04). Change in systolic BP was similar in both groups and not statistically different.

Components of Effective Orlistat Treatment (KQ5a)

Data were insufficient to explore the importance of specific treatment components.

Factors Influencing the Effectiveness of Orlistat (KQ5b)

Data were insufficient to explore the importance of population or environmental factors.

Metformin Treatment in Obese Patients at High-Risk for Type 2 Diabetes

We identified two small, fair-quality trials (a RCT and a cross-over RCT; total randomized N = 60) that reported weight outcomes after 6 months of metformin therapy among obese children or adolescents with additional risk factors for developing type 2 diabetes mellitus (Table 10). Both trials compared the effect of metformin to placebo therapy, either with minimal[105] or no[104] concurrent behavioral counseling intervention.

Short-Term (6-12 month) Weight Outcomes with Metformin Treatment (KQ1)

Both trials found statistically significant differences between groups for BMI or BMI SDS at 6 months, with results favoring the metformin group. Results should be interpreted with caution, however, because analyses in these trials included only patients who completed the trial (attrition rates were 9 and 21 percent), which could have caused bias.

Maintenance of Weight Changes with Metformin (KQ2)

No data were reported on maintenance of weight loss after metformin was discontinued.

Adverse Effects of Metformin (KQ3)

Trials were limited in their ability to detect adverse effects due to small sample size and limited duration. Neither trial reported any serious adverse events. One trial specifically reported that no episodes of vomiting or lactic acidosis occurred. Serum lactate, liver, and renal function parameters were reported as remaining normal or not different between groups in both trials. In both trials, some patients were reported to have nausea which, in three cases, required a 25 to 50 percent dose reduction in order to continue in the trial.

Other Beneficial Outcomes of Metformin Treatment in High-risk Obese Adolescents (KQ4)

One of the trials[105] found statistically significant improvements favoring the metformin group for waist circumference and subcutaneous *adipose tissue*, but no difference for visceral abdominal adipose tissue. These parameters were not reported in the other trial. Both trials reported improvements in fasting glucose and insulin, either between groups or only within the metformin group. Neither trial found statistically significant differences between groups for insulin sensitivity when using minimal model analyses, glucose effectiveness, acute insulin response disposition index, or glucose disposal. No lipid parameters were found to be statistically different between groups in the only trial that measures them.[104]

Bariatric Surgeries

We identified 18 fair- or poor-quality case series in 22 publications[108-130] reporting on weight change, complications, and other outcomes from various bariatric surgeries performed in a total of 612 children and adolescents. Overall quality of reporting was fair at best. Many case series are limited in value because they only represent the experience of single institution (and often a single surgeon). Relying on retrospective medical record review limited the completeness of outcomes measurement and the consistency with which other variables, such as comorbidities,

were determined on all patients. Further, considerable attrition occurred in all case series and results were reported for complete cases only. These results likely represent a best case scenario. We calculated intention to treat results, assuming those that were eligible, but lost to followup, experienced no weight reduction. We report both complete cases (CC) and intention-to-treat (ITT) here, where possible, to provide a range of realistic estimates. Completed cases are the reported decreases in BMI for those patients returning for followup, while the Intention-to-Treat analyses (ITT, indicated with an asterisk on Table 11) reflect the conservative assumption that patients not returning for followup had no change in BMI.

To reflect differences in invasiveness and the way case series were reported, we grouped the surgeries into two main types: 1) laparoscopic adjustable gastric banding (LAGB); 2) Roux-en-Y gastric bypasses (RYGB), vertical-banded gastroplasty (VBG) and other bypass procedures. Where possible, we distinguish individual case series that focus on a single surgical procedure (e.g. RYGB or VBG) and indicate whether RYGB was performed via laparoscope or laparotomy.

Of the six case series of laparoscopic adjustable gastric banding (LAGB), three reported short-term weight changes (6-12 months) after surgery,[111,114,115] four reported medium-term weight changes (1 to 5 years) after surgery,[111,114,115,126,129] and one reported longer term post-surgery weight changes (5 and 7 years) (Table 11).[114] One additional LAGB case series that relied on retrospective self-reported weight changes after surgery was used to estimate shorter term adverse effects, as these were retrieved from medical records, but not weight outcomes.[127]

Of two case series of Roux-en-Y gastric bypasses performed by laparoscope,[110,112] only one reported usable weight-change data, and these were short-term (12 month).[112] The other series provided only data useful for adverse effect estimates (Table 11).[110]

Nine case series included open Roux-en-Y Gastric Bypass (RYGB), vertical-banded gastroplasty (VBG), and other surgeries, but only four of these reported post-operative weight outcomes at the same time point for all patients. Two reported short-term (6 to 12 month) weight changes after open RYGB.[108,120] An older series of primarily open RYGB cases reported 3 year and 4-year weight outcomes,[124] and one case series that provided 1-year RYGB outcomes also reported 5-, 10-, and 14-year outcomes for a decreasing subset of eligible patients.[108] A single case series of VBG reported outcomes at 5 and 10 years only.[119] The remaining five case series that included open RYGB, VBG, jejunal-ileal bypass and biliopancreatic diversion combined weight outcomes from different lengths of followup for different patients, which varied from a minimum of 13 months to 10 years or more.[113,118,122,125,128] Results from all case series are reported in Table 11.

Laparoscopic Adjustable Gastric Banding (LAGB)

Six case series, detailed in nine publications,[111,114,115,117,126,127,129,130] reported on LAGB performed primarily outside the United States on or after January 1996 in a total of 306 children and adolescents. The single surgical series conducted in the United States was a recent, fair-quality prospective study conducted in a university center with a comprehensive bariatric surgery program.[111] This was the only study reporting on race/ethnicity. Among the 53 adolescents undergoing LABG in this trial, 81 percent were White, 13 percent were Hispanic and 6 percent were Black. Across the body of literature, most LAGB patients were adolescents, with a mean age for participants in each study from 15.7 to 18.0 years (age range from 9 to 19 years). Most surgical patients were females (n=223, 73 percent) and most met NIH adult criteria for morbid obesity (BMI > 40 or $\geq$ 35 with at least one-comorbidity).[40] Most patients had also previously failed conservative weight management approaches. Across studies, the mean BMI prior to

surgery ranged from 43.1 kg/m^2 to 47.6 kg/m^2, which roughly corresponds to a mean weight at baseline between 129.19 kg (284 pounds) and 135 kg (297 pounds). In studies reporting comorbidities,[126,127,129] 23 percent to 62 percent had at least one comorbidity (see Table 12). Hypertension, diabetes, and dyslipidemia were the most commonly cited. In two studies, 17 percent of LAGB patients had sleep apnea.[114,127] In two other studies, five percent had asthma.[127,129]

Short-term (6-12 month) Weight Changes After LAGB (KQ1)

Three studies [111,114,115] reported mean decrease in BMI for the cohort at discrete time-points (6 months, 12 months after surgery, presumably for all participants who were eligible during this duration of followup). Two of these studies also provided data on the same cohort at longer term followup.[114,115] Two case series averaged data for participants across a broad duration of followup,[126,129] while a third reported weight data based on retrospective self-report only.[127]

Loss to followup and the small number of cases (n=122) make any conclusions drawn from these case series tentative. Available data, however, suggest following gastric banding, patients experienced an average BMI decrease of 5.0 kg/m^2 (ITT) to 8.1 kg/m^2 (CC) at 6 months and 9.4 kg/m^2 (ITT) to10.2 kg/m^2 (CC) at 1 year. Based on one study in 17 patients,[115] 77 percent achieved a BMI less than 35 at 1 year.

Maintenance of Weight Changes After Laparoscopic Adjustable Gastric Banding (KQ2)

Four studies reported weight outcomes measured 2 or 3 years after LAGB and results were in similar range at both time points.[114,115,126,129] Mean decrease in BMI ranged from 8.2 kg/m^2 (ITT) to 14.5 kg/m^2 (ITT) at 2 years, and 7.3 kg/m^2 (ITT) to 12.6 kg/m^2 (ITT) at 3 years. In the two studies that also measured BMI at 12 months,[114,115] ITT analysis suggests that on average, some weight is regained at 2 years (1.9 kg/m^2) and at 3 years (2.1 kg/m^2). While experience certainly varies among individuals, these data are roughly consistent with plots of repeated weight measures in individual patients from several case series that suggest BMI decreases after surgery to its nadir at 12-18 months in most patients and then stabilizes or slightly rebounds in those with longer term followup.[115,126] The single study with results at time points beyond 3 years suggests that mean BMI decrease was at least maintained at 5 years (ITT analysis), based on followup of 25 individuals.[114] Estimates for 7 years followup represent only 10 individuals.

Adverse Effects of LAGB (KQ3)

There was no peri- or post-operative mortality or major morbidity among 306 children and adolescents undergoing LAGB.[111,114,115,117,126,127,129,130] We confine estimates of adverse effects to the four largest case series (defined as those series representing at least 50 patients). In one large case series,[114] a number of patients required reoperations (6/58, 10.3 percent) for band removal or repositioning and one of 58 patients required conversion to laparotomy. In a second large case series, 13.3 percent (8/60) had band slippage or removal.[127] In the third series, a dislocated port was reported (1/50), but no band slippage. In the fourth series (from the United States), nutrition-related issues (mild hair loss in 5/53 or iron deficiency in 4/53) were reported, along with other less common issues occurring in one or two patients, such as hiatal hernia, gastroesophageal reflux, and wound infection. (Table 12)

Other Beneficial Outcomes of LAGB (KQ4)

Across the three LAGB studies reporting whether comorbidities "resolved" post-surgery,[126,127,129] 6/13 with hypertension, 8/9 with type II diabetes, 6/7 with dyslipidemia, and 20/20 with sleep apnea were reported as resolved, as were 9/9 with asthma. Two studies also reported some improvements in quality of life, self-esteem, body image, and satisfaction with having chosen surgery, although the quality and timing of these measurements are not clear.[127,129]

Components of Effective LAGB Surgery (KQ5a)

Data were inadequate to examine this question.

Factors Influencing the Effectiveness of LAGB Surgery (KQ5b)

Data were inadequate to examine this question.

Roux-en-y Gastric Bypass (RYGB), Open Vertical-banded Gastroplasty (VBG), and Other Bariatric Surgeries

Eleven fair- or poor-quality case series reported weight and other beneficial outcomes in 41 adolescents after laparoscopically performed RYGB,[110,112] in 51 adolescents after open RYGB,[108,120] and in 47 adolescents after VBG.[119] The remaining six case series (n=167 youth) provided primarily adverse effects data,[113,118,122,124,125,128] as weight outcomes were either self-reported or averaged across very different post-operative time periods. All but two of these series (one evaluating RYGB[122] and one evaluating biliopancreatic diversion[128]) were further limited by mixing different types of surgeries. Inpatient adverse effects but not weight outcomes, associated with 566 open, primarily RYGB, procedures in youth have also been reported from the Healthcare Cost and Utilization Project (HCUP) Nationwide Inpatient Sample.[109]

Short-term (6-12 month) Weight Changes After RYGB, VBG, and Other Bariatric Surgeries (KQ1)

Two fair-quality case series in three publications[110,112,123] address laparoscopic RYGB performed in the United States in 41 adolescents and young adults (aged 13 to 21 years). Mean BMI before surgery was 50.5 kg/m^2 (SD, 2.0 kg/m^2) in one group (n=11) [110] and 56.5 kg/m^2 (SD, 5.2 kg/m^2) in the other (n=30).[112] Few other patient data were reported, although patients met or exceeded NIH adult criteria for bariatric surgery and had failed previous medical attempts at weight loss. Comorbidities were reported in the smaller case series. Diabetes (6/11), hypertension (6/11), sleep apnea (2/11), and hepatic steatosis (5/11) were most common.[110]

Laparoscopic RYGB. Measured weight outcomes were available in one of these two series[112] and limited to 30 of 36 patients that had accrued sufficient time post-surgically (although 3/6 not included were actually lost to followup). Among these 30 patients, mean decrease in BMI at 12 months was 20.7 kg/m^2 (SD, 8.1 kg/m^2) and individual BMI reductions ranged from 3.3 kg/m^2 to 43.5 kg/m^2. Treatment failures in the first year (those who regained up to 50 percent of the weight lost) were reported in two of 30 patients.

Open RYGB. A large fair-quality case series conducted in the United States of 33 adolescents undergoing bariatric surgery at a single institution over 20 years reported on short-term outcomes at 12 months (but also reported outcomes 5, 10, and 14 years after surgery).[108]

Most cases (28/33) underwent open gastric bypass, two had laparoscopic gastric bypass, and the remaining three underwent vertical banded or horizontal gastroplasty. Eligible patients were 12 to18 years of age (mean age 16 years) and met NIH bariatric surgery criteria for adults. Almost 60 percent were female, 82 percent were White, and 15 percent were Black. The mean pre-operative BMI of these patients was 52 kg/m^2 (SD 11 kg/m^2, range 28 to 91). Hypertension was present in 30 percent (10/33), sleep apnea in 18 percent (6/33), and diabetes mellitus II in 3 percent (1/33) of patients. At 1 year, mean decrease in BMI was 15.5 kg/m^2 according to intention-to-treat analysis (ITT) and 16 kg/m^2 according to complete cases (CC). The only other case series followed primarily open gastric bypass bariatric surgeries performed in 18 genetically normal adolescents (under aged 20 years, median age 19) between 1969 and 1973 at a single university hospital pediatric surgery department in the United States.[120] Median pre-operative weight in eight female and 10 male patients was 147 kg. At 6 months, the median percentage of body weight lost was 14 percent (ITT). At 10 to 15 months, the median percentage of body weight lost was 23 percent (ITT). Complete case analysis at 10-15 months was slightly more optimistic (30 percent body weight lost).

Maintenance of Weight Changes after RYGB, VBG, and other Bariatric Surgeries (KQ2)

Laparoscopic RYGB. Longer-term data on maintenance are not available on laparoscopically performed RYGB.

Open RYGB or VBG. The one large case series, conducted in the United States, of 33 adolescents also reported on longer term outcomes (5, 10, and 14 years) after surgery.[108] Based on complete cases, mean BMI reductions appear to be maintained or enhanced at 5, 10, and 14 years, compared with results at one year. Based on ITT analyses, mean BMI reduction is maintained at 5 years, with some regain of weight suggested by 10 to 14 years. By these time points, however, only a limited number of participants (less than 20) were eligible for followup due to the recency of the surgery and about one-third of these were not actually measured. Long-term (5 or more years) estimates of BMI reduction are very tentative, due to small numbers and the considerable difference between CC and ITT estimates, which vary by 3 to 5 kg/m^2. While these data provide estimates of average effects at various time points after surgery, they are not very instructive in estimating weight maintenance for individuals, particularly given the drastic reduction in those eligible for long-term followup. In terms of treatment failures, however, five patients of 33 regained most or all of their weight 5 to 10 years after surgery. One patient with horizontal gastroplasty maintained weight loss after 15 years, but then regained the weight.[108]

One case series provided longer term outcomes after VBGs, which were performed from 1980-1994 in 47 adolescents aged 14 to 20 years. Mean BMI was decreased 8.7 kg/m^2 (ITT) to 12.2 kg/m^2 (CC) at 5 years and 6.8 kg/m^2 (ITT) to 9.2 kg/m^2 (CC) after 10 years.[119] These results are limited due to unclear methods that may have mixed self-reported and measured weights. These results provide a point of comparison only, since this procedure is not currently widely used.

The other case series of RYGB, VGB, or other gastroplasties averaged weight outcomes from individuals measured over a broad duration of followup rather than at the same post-operative time points.[113,118,122,124] These averaged weight changes measured at short-term, medium term, and longer term followup were generally across more than 10 years. A recent study on biliopancreatic diversions performed in 68 Italian adolescents over 29 years similarly averaged weight outcomes measured between 2 and 23 years after surgery.[128] While these studies

reported their outcomes for the mean followup time (5 or more years), the combination of weight outcomes over such different time periods of followup makes them of limited use in estimating weight outcomes.

Adverse Effects After Bariatric Surgeries (KQ3)

Laparoscopic RYGB. Among 47 adolescents undergoing laparoscopically performed RYGB, around 39 percent experienced some short-term complications during the first 12 months.[110,112] More than 25 percent (13/47) experienced minor complications (requiring a special test, treatment, endoscopy, or hospital readmission for seven days or less). Moderate complications (unanticipated intensive care unit admission, reoperation, or hospital readmission for more than seven days) occurred in about 14 percent (5/36) of patients. Severe complications (threat to life or major organ system failure) were uncommon (2/36), although one death occurred due to infectious colitis. Two of 36 patients undergoing laparoscopic RYGB had to be converted to an open procedure. During the first post-operative year, noncompliance with recommendations for multivitamin use or for clinical monitoring occurred in one-quarter (11/47) of adolescent surgical patients.

Open RYGB. Among 33 adolescents who primarily underwent open RYGB,[108] 30 percent (10/33) experienced early complications, including one pulmonary embolus, one major wound infection, one minor wound infection, three stomal stenoses requiring endoscopic dilatation, and four marginal ulcers requiring medical therapy. In 21 percent of patients (7/33), late complications requiring surgical treatments primarily included incisional hernias, and one of 33 patients required conversion to another type of bypass due to severe protein calorie malnutrition. In other case series[113,118,124,125] of a mixture of 89 cases undergoing open gastric bypasses and gastroplasties, two deaths were reported at 15 months and 3.5 years post-operatively: it is difficult to determine whether deaths outside the immediate post-operative period are surgery-related. Other complications included cholecystectomies or gallstones reported in six patients, nutritional deficiencies in five patients, and dumping syndrome or hypoglycemia in three patients.

Since outcomes from case series were not systematically assessed, and relied on retrospective review of medical records or patient recall, absolute rates for complications cannot be determined from these data or from another poor quality case series.[122] However, data from the Nationwide Inpatient Sample on 566 bariatric surgeries (90 percent gastric bypasses) performed in adolescents from 1996 through 2003 found no in-hospital deaths, but did find major complications in 5.5 percent of cases. Over three-quarters (119/152) of major complications were respiratory, including aspiration, postoperative pulmonary edema, pulmonary insufficiency, acute respiratory failure, prolonged ventilation, tracheostomy, or pneumonia.[109]

Bilio-pancreatic diversion. In a retrospective medical record review of 68 biliopancreatic diversions performed in Italy in those under aged 18 years, while immediate complications were uncommon (1/68) longer term complications were not.[128] Long-term mortality was 4.4 percent (3/68), protein malnutrition within 1 to 10 years post-operatively occurred in 11 of 68 (16 percent) patients, and 14 patients underwent 19 reoperations. These data are consistent with findings that BPD incurs higher complication and mortality rates.

Other Beneficial Outcomes After RYGB (KQ4)

Very limited data on patients after laparoscopic or open RYGB suggest decreasing need for hypoglycemic medications in 4/7 of those with diabetes, resolution of hypertension in 11/16 and

no longer needing continuous positive airway pressure or resolution in 8/8 patients with sleep apnea.[108,110] The reported resolution of comorbidities in a series including various bariatric surgeries, including RYGB, confirms that sleep apnea resolves in all patients (13/13).[113,124] Very limited data supports benefits for hypertension (5/5), asthma (2/3), and diabetes (1/1).[113]

Components of Effective Bariatric Surgery (KQ5a)

Since the absolute number of bariatric surgeries in adolescents is small, particularly when categorized by surgical type, there are no good data that examine the effectiveness of specific factors, such as surgeon training, experience, or institutional expertise on outcomes, particularly harms. Other potentially important issues include the intensity and professional disciplines involved in both pre-operative evaluation and post-operative followup management.

Factors Influencing the Effectiveness of Bariatric Surgery (KQ5b)

Similarly, limited data prevent the examination of potentially important population or environmental factors, including degree of overweight, medical and psychological history, family factors (including parental overweight and history of parental bariatric surgery), previous nonsurgical weight loss attempts, and compliance with post-operative management.

Figure 4. Pooled analysis: Short-term effect size of behavioral interventions (KQ1)

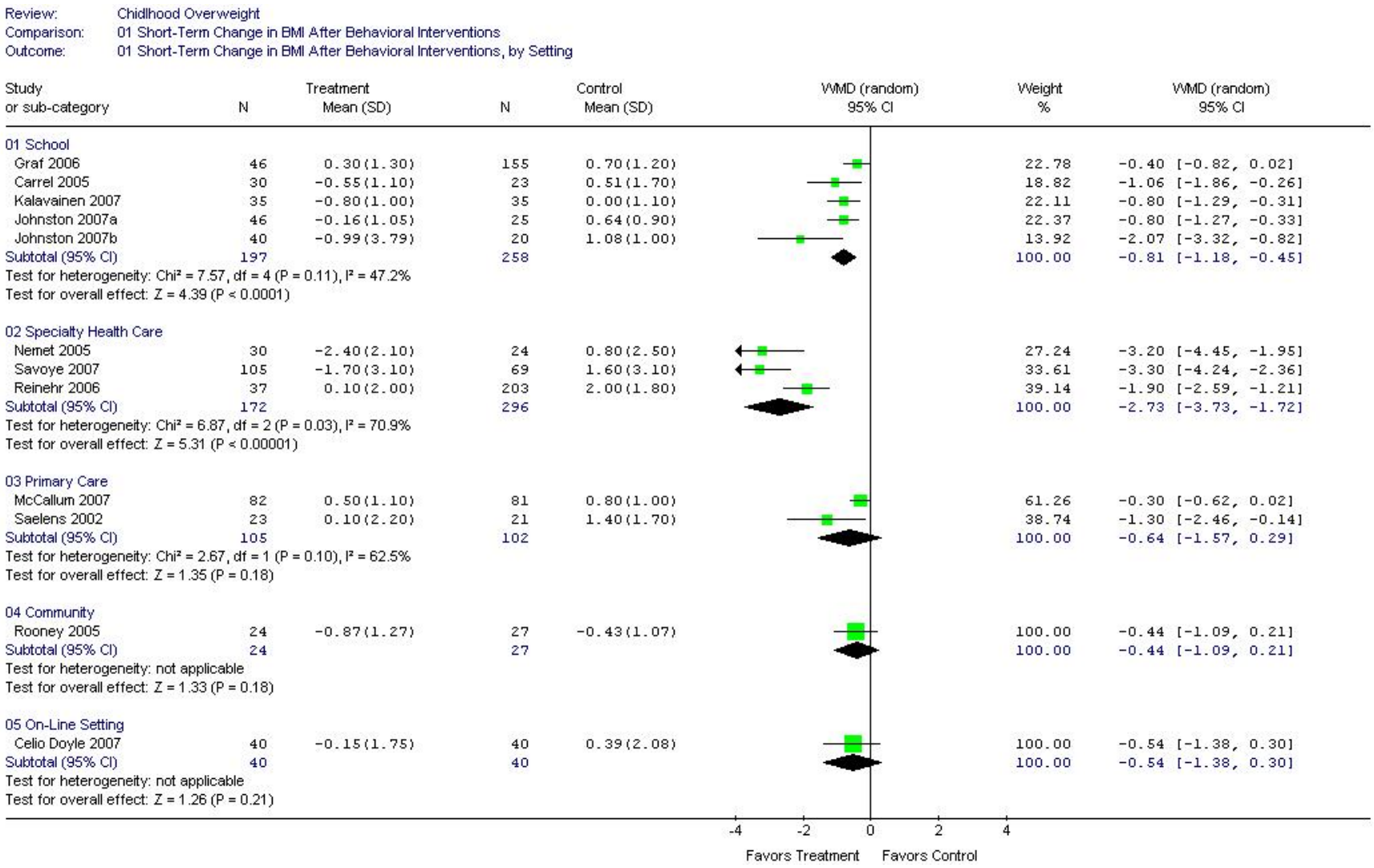


Figure 5. Pooled analysis: Maintenance effect size of behavioral interventions (KQ2)

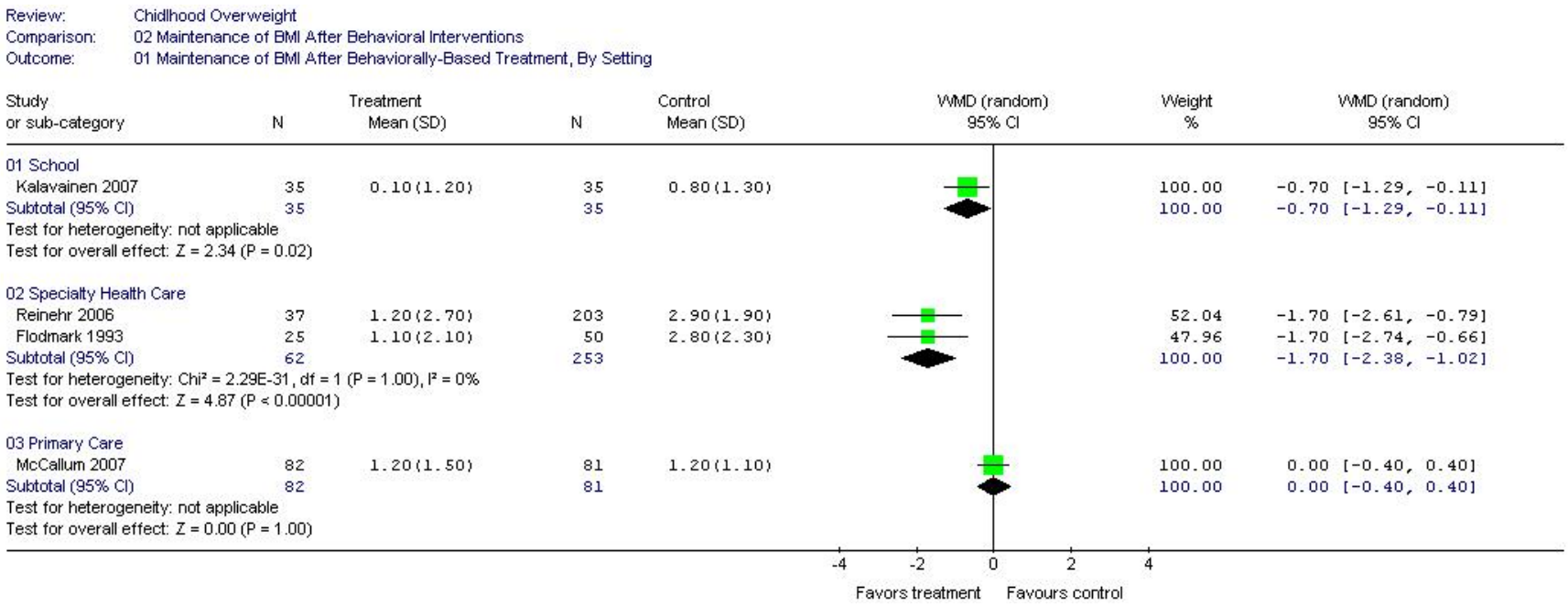


Table 3. Short-term outcomes of behavioral interventions

Study reference setting	N randomized Age Baseline BMI	Intervention hours (I-C) /intensity Intervention Components	Short-term BMI change: Mean change (SD of change)
Graf et al 2006[70,86] School	N: 276 Age 6-11 BMI: I (participants): 22.8 ± 3.6 I (non-participants): 21.1 ± 2.4 C: 21.7 ± 2.7	175.5 hrs/High I: PA, BehMod, Fam C: Usual school curriculum	9-mo (post-tx) I (participants): +0.3 ± 1.3 I (non-participants): +0.5 ± 1.3 C: +0.7 ± 1.2
Carrel et al 2005[69] School	N: 53 Age 12-13 BMI: I: 32 ± 6 C: 30 ± 4	67.5 hrs/Medium I: PA C: Typical PE class	**9-mo (post-tx)** I: -0.55 ± 1.1‡ C: +0.51± 1.7‡
Kalavainen et al 2007[72] School	N: 70 Age 6-9 BMI: I: 23.4 ± 2.6 C: 22.9 ± 2.5	45 hrs/Medium I: PA, BehMod, Fam, C: Handouts, 2 counseling meetings	**6-mo (post-tx)**** I: -0.8 ± 1.0 C: 0.0 ± 1.1
Johnston et al 2007a[75] School	N: 71 Age 10-14 BMI: I: 27.7 ± 5.0 C: 25.6 ± 3.4	41.5 hrs/Medium I: PA, BehMod, C: Self-help materials	**6-mo (post-tx)**** I: -0.16 ± 1.05 C: +0.64 ± 0.90
Johnston et al 2007b[71] School	N: 60 Age 10-14 BMI: I: 25.4 ± 4.7 C: 26.7 ± 5.5	41.5 hrs/Medium I: PA, BehMod C: Self-help materials	**6-mo (post-tx)**** I: -0.99 ± 3.79 C: +1.08 ± 1.00
Savoye et al 2007[74] Health Care	N: 174 Age 8-16 BMI: I: 35.8 ± 7.6 C: 36.2 ± 6.2	97.5 hrs/High I: PA, BehMod, Fam, MHTx C: Brief semi-annual counseling	**12-mo (post-tx)**** I: -1.7 (3.1) C: +1.6 (3.1)
Reinehr et al 2006[73] Health Care	N: 240 Age 6-14 BMI: I: 27.0 (26.4, 27.6) C: 26.1 (25.2, 27.8)	76 hrs/High I: PA, BehMod, Fam, MHTx C: No treatment due to distance from clinic	**12-mo (post-tx)**** I: +0.1 (SD NR) C: +2.0 (SD NR)
Golley 2007[83] Health Care	N=111 Age 6-9 BMI: 24.3 ± 2.6 (overall)	10.3 hrs (I1), 22 hrs (I2)/Low I1: Fam, MHTx I2: PA, BehMod, Fam, MHTx C: Wait List	12-mo (7-mos post-tx): NR† BMI SDS: I1: 2.56 ± 0.79 I2: 2.43 ± 0.68 C: 2.60 ± 0.57
Gillis 2007[87] Health Care	N: 27 Age 7-16 BMI: I: 1.98 ± 0.21 C: 2.16 ± 0.34	8 hrs/Very low I: Case manager C: 1 counseling session	6-mo (post-tx) NR† BMI SDS: I: -0.045 ± 0.19 C: +0.075 ± 0.08
Nemet et al 2005[79] Child Health and Sports Center	N=54 Average age 11.1 BMI: I: 28.5 ± 4.1 C: 27.8 ± 5.0	35.75 hrs/Medium I: PA, BehMod, Fam C (n=24): Nutritional counseling	**12-mo (9-mo post-tx)*** I: -2.4 (SD NR) C: +0.8 (SD NR)
McCallum et al, 2007[78,84] Primary Care	N=163 Age 5-9 BMI: I: 20.5 ± 2.2 C: 20.0 ± 1.8	4 hrs/Very low I: BehMod, Fam C: Usual primary care treatment	9-mo (6-mo post-tx): I: +0.5 (SD NR) C: +0.8 (SD NR)

Study reference setting	N randomized Age Baseline BMI	Intervention hours (I-C) /intensity Intervention Components	Short-term BMI change: Mean change (SD of change)
Saelens et al 2002[77] Primary Care	N=44 Age 12-16 BMI: I: 31.0 ± 3.5 C: 30.7 ± 3.1	3.8 hrs/Very low I: BehMod C: Usual primary care treatment	**7-mo (3-mo post-tx)*:** I: +0.1 (NR) C: +1.4 (NR)
Doyle et al, unpub; Celio et al 2006[76] E-mail, Internet	N=83 Age 12-18 BMI: I: 34.6 ± 7.8 C: 33.9 ± 6.9	16 hrs/Low I: BehMod C: Information only	8-mo (4-mo post-tx): I: -0.2 (SD NR) C: +0.4 (SD NR)
Braet et al 2003[85] Residential	N: 76 Age 10-17 BMI: I: 33 (SD NR), C: 33 (SD NR)	3,520 hrs/Very high I: PA, BehMod, MHTx C: Wait List	**10-mo (post-tx)****: NR† %OW: I: -51 (SD NR) C: +6 (SD NR)
Rooney 2005[80] Community	N=98 families Age 5-12 BMI: NR	3 hrs (I1), 21 hrs (I2)/Very low; Low I1: Fam I2: Fam C: Not described	9-mo (6 mo post-tx): NR‡ I1&I2: -0.87 ± 1.27 C: -0.43 ± 1.07
Senediak et al 1985[88] Setting NR	N=35 Age 6-12 BMI: I: 20.5 ± 2.2 C: 20.0 ± 1.8	12 hrs (I1, I2, C)/Low I1: BehMod, Fam I2: BehMod, Fam C: Social support, relaxation, mood monitoring	**6-mo (3-5 mo post-tx)*:** NR† (%OW I1: -13.04 (SD NR) I2: -19.22 (SD NR) C: -5.86 (SD NR))

Note: Interventions ordered first by setting and second by intensity.
Abbreviations: I- Intervention group; C- Control group; NR-Not Reported; PA-organized physical activity sessions; BehMod-behavioral modification principles; Fam-parent participant; MHTx-mental health treatment beyond behavioral modification; post-tx-post treatment; SD-standard deviation
* $p<0.05$; ** $p<0.01$, **bold** if $p<0.05$
†BMI not reported, so other outcome listed
‡Unpublished data supplied by author

Table 4. Maintenance outcomes of behavioral interventions

Study reference	N randomized Age range Baseline BMI Setting	Intervention hours (in excess of control group hours of contact) /Intensity; Intervention components	Maintenance BMI Change: Mean change (SD of change)
Kalavainen et al 2007[72] School	N=70 Age 6-9 BMI: I: 23.4 ± 2.6 C: 22.9 ± 2.5	45 hrs/Medium I: PA, BehMod, Fam C: Handouts, 2 counseling mtgs	**18-mo (12-mos post-tx)*** I: 0.1 ± 1.2 C: 0.8 ± 1.3
Reinehr et al 2006[73] Health Care	N=240 Age 6-14 BMI: I: 27.0 (26.4, 27.6) C: 26.1 (25.2, 27.8)	76 hrs/High I: PA, BehMod, Fam, MHTx C: No treatment d/t distance	**24-mo (12-mos post-tx)**** I: +1.2 (SD NR) C: +2.9 (SD NR)
Mellin et al 1987[82] Health Care	Age 12-18 (15.6) N=66 BMI: NR	24 hrs/Low I: PA, BehMod C: No treatment	**15-mo (12-mo post-tx)†:** NR‡ *Percent Overweight*: I: -9.9 ± 15.0 (p<0.01)** C: -0.1 ± 13.2 (n.s.)**
Flodmark 1993[81] Health Care	N=93 Age 10-11 BMI: I1: 25.5 ± 0.53* I2: 24.7 ± 0.36* C: 25.1 ± 0.35*	12 hrs (I1), 24 hrs (I2)/Low I1: Fam I2: Fam, MHTx C: Matched controls, no treatment	**~48-mo (30-34 mo post-tx)*:** I1: +1.6 (SD NR) I2: +1.1 (SD NR) C: +2.8 (SD NR)
McCallum et al, 2007[78,84] Primary Care	N=163 Age 5-9 BMI: I: 20.5 ± 2.2 C: 20.0 ± 1.8	4 hrs/Very low I: BehMod,Fam C: Usual primary care treatment	15-mo (12-mo post-tx): I: +1.2 (NR) C: +1.2 (NR)

Note: Interventions ordered first by setting and second by intensity.
Abbreviations: I- Intervention group; C- Control group; NR- Not Reported; PA- Intervention included organized physical activity sessions; BehMod- Intervention included instruction in behavioral modification principles; Fam- Parent was a primary participant in the intervention; MHTx- Mental Health treatment beyond behavior modification related to diet and exercise was provided; n.s.-not statistically significant; post-tx-post treatment; SD-standard deviation.
*p<0.05 or believed likely to be p<0.05; **p<0.01; **bold** if p<0.05 or likely to be p<0.05.
†no direct comparisons reported, but differences between paired t-tests suggests p<0.05.
‡BMI not reported, so other outcome listed.

Table 5. Potentially harmful effects of behavioral interventions for childhood overweight

Study reference	Patient characteristics	Description of intervention groups	Outcomes of all potential harmful effects examined
Height			
Braet et al 2003[85]	10-17 (13) N=76 Residential Belgium	I (n=38): 10-month residential weight loss treatment, minimal parental involvement, included organized PA C (n=38): Waiting list	No group differences in change in height at 10 months
Savoye et al 2007[74]	Age 8-16 (12.1) N=174 Health Care USA	I (n=105): Bright Bodies Weight Management: nutrition education and behavior modification class, substantial parental involvement, included organized PA C (n=69): Brief semi-annual counseling	No group difference in changes in height at 6 months or 12 months
Golley 2007[83]	Age 6-9 (8.2) N=111 Health Care Australia	I1 (n=37): Parenting skills training with emphasis on dietary and PA issues, no organized PA I2 (n=38): Above + Intensive weight loss education (lifestyle approach), included organized PA C (n=36): Wait-list Control, 3-4 brief phone calls to encourage retention in study	No group difference in changes in height at 12 months
Eating Pathology and Body Image			
Carrel et al 2005[69]	Age 12-13 (12.5) N=53 School USA	I (n=27): PE class emphasizing non-competitive movement activities, small class size; minimal parental involvement, included organized PA C (n=26): PE class, typical competitive, team sports emphasis	Among treatment participants, measures of "drive for thinness" and "external eating" declined, self-reported ratings of physical appearance, athletic competence, and social acceptance improved.
Saelens et al 2002[77]	Age 12-16 Mean 14.2 ± 1.2 N=44 Primary Care USA	I (n=23): Healthy habits intervention: Primary care-based tailored weight loss intervention, minimal parental involvement, no organized PA C (n=21): Usual primary care treatment	Problematic eating/eating disorder psychopathology did not differ between groups
Doyle et al, unpub; Celio et al 2006[76]	Age 12-18 (14.5) N=83 Internet USA	I (n=42): Internet-delivered, interactive, moderated cognitive-behavioral program, limited parental involvement, no organized PA C (n=41): Basic, non-interactive information on nutrition and physical activity	Control group showed greater decline in Shape Concern than Intervention group; no other differences in eating disorder pathology
McCallum et al, 2007[78,84]	Age 5-9 (7.4) N=163 Primary Care Australia	I (n=82): Primary care-based wt loss intervention, including brief solution-focused intervention, parent as agent of change; no organized PA C (n=81): Usual care	No differences on child-reported ratings of body satisfaction or appearance/self-worth

Study reference	Patient characteristics	Description of intervention groups	Outcomes of all potential harmful effects examined
Other			
Mellin et al 1987[82]	Age 12-18 (15.6) N=66 Health Care USA	I (n=37): SHAPEDOWN program, comprehensive weight loss treatment, minimal parental involvement, included organized PA C (n=29): no treatment controls	Depression improved in treatment group, did not change in control group.
Supplementary Trials, Injuries Related to Physical Activity			
Sung et al 2002[94]	Age 8-11 N=82 NR China	I (n=41): 6-week diet program + supervised physical training C(n=41) 6-week diet program, no organized PA	No training-related injuries. (Baseline BMI 25.5)
Davis et al 2006[93]	Age 7-11 N=100 Health Care USA	I1: 13 weeks low-dose aerobic exercise (20 min/day) I2: 13 weeks High-dose aerobic exercise (42 min/day) C: No exercise control	1 bone fracture in exercising group (11 and I2 combined) (Baseline BMI 26.5)

Abbreviations: PA-physical activity; PE-physical education; tx-treatment

Table 6. Other positive medical outcomes reported in behavioral intervention trials

Study reference	Increase in high-density lipids (HDL)	Decrease in Low-density lipids (LDL) †	Decrease in triglycerides	Decrease in systolic BP	Decrease in diastolic BP	Decrease in fasting glucose	Decrease in fasting insulin	Decrease in HOMA-IR	Adiposity (Measure)
Carrel et al 2005[69]	--	--	--	--	--	N	IG	--	IG: DEXA; decrease in % of body fat
Flodmark 1993[81]	--	--	--	--	--	--	--	--	IG: Triceps, subscapular, suprailiac skinfold; decrease in thickness
Gillis 2007[87]	N	N	N	--	--	--	--	--	--
Golley 2007[83]	N	--	N	N	N	N	N	--	IG: decrease in Waist circumference
Graf et al 2006[70,86]	--	--	--	--	--	--	--	--	N: decrease in Waist circumference
Johnston et al 2007a[75]	N	N	N	N	N	N	N	--	IG: Bioelectric impedance; decrease in body fat percentage
Johnston et al 2007b[71]	N	IG	N	N	N	N	N	--	N: Bioelectric impedance; decrease in body fat percentage
Nemet et al 2005 [79]	--	--	--	--	--	--	--	--	IG: Triceps, subscapular skinfold; decrease in thickness
Reinehr et al 2006[73]	N	IG	N	IG	N	N	IG	IG	--
Savoye et al 2007[74]	N	N	N	--	--	N	IG	IG	IG: Bioelectric impedance; decrease in body fat percentage
Senediak et al 1985[88]	--	--	--	--	--	--	--	--	IG: Subscapular skinfold; decrease in thickness

N - No group differences, IG - Result favors intervention group

†HDL and LDL differences are reported separately; trials do not report on the ratio of HDL to LDL

BP- blood pressure; DEXA - Dual-energy x-ray absorptiometry; HOMA - homeostasis model assessment of insulin resistance

Table 7. Effective behavioral interventions for overweight or obesity

Study reference	Age range, N, Intervention hours (Intensity)	Description of intervention
Short-Term Outcomes		
Carrel et al 2005[69] School	12-13 n=53 67.5 hrs (Medium)	***Diet:*** Nutrition handouts describing food pyramid, recommended servings of food, appropriate portion sizes, healthier food choices, benefits of healthier eating. ***PA:*** P.E. class limited to 14 students, personalized to match skill level and encourage participation. Emphasized lifestyle-focused activities (walking, cycling, snowshoeing). Including warm-up, total movement time averaged 42 min per 45-min class (vs. 25 minutes in typical P.E. class) ***Beh Tx***: None ***Family:*** None
Kalavainen 2007[72] School	6-9 n=70 45 hrs (Medium)	***Diet:*** Recommended diet and meal pattern "in line with" general recommendations for Finnish families ***PA:*** 15 sessions over 6 months, most sessions included non-competitive physical activities aimed to develop children's motor skills and to motivate them to increase recreational physical activity. ***Beh Tx***: Family-centered group program based on behavioral and solution-focused therapy approaches. Focus on promoting health lifestyle and well-being rather than weight loss. Details of topics covered not provided. Children given workbook and separate group meeting that included both education/counseling and PA. ***Family:*** 15 parent behavioral/solution-focused/educational sessions. Parents given treatment manuals and considered agents of change for the family.
Johnston 2007a[75] School	10-14 n=71 41.5 hrs (Medium)	***Diet:*** Provided healthy snack 5 days/wk, once/wk nutrition education, focus on healthier food choices, reading labels, controlling portion sizes, categorizing foods as "safety", "caution", and "danger" zone foods. Biweekly quizzes and extra tutoring to low-scoring children. ***PA:*** First 6 weeks: Activities included sports and fitness drills for building endurance, strength, and flexibility, teach children to maintain heart rate within target zone and develop basic level of fitness. Second 6 weeks: focus on skill development for activities available in neighborhood or school (e.g., basketball, soccer, jumping rope, dance, kickboxing). ***Beh Tx***: Learned to self-monitor, set goals, address self-identified barriers to improving health. Also used token economy, children earned points for trying new fruits and vegetables, keeping bodies moving during physical activity, and meeting program and individual goals. ***Family:*** Parents invited to culturally sensitive monthly meetings to teach them how to adapt family meals and activities to facilitate health changes.
Johnston 2007b[71] School	10-14 n=60 41.5 hrs (Medium)	***Diet:*** Provided healthy snack 5 days/wk, once/wk nutrition education, focus on healthier food choices, reading labels, controlling portion sizes, categorizing foods as "safety", "caution", and "danger" zone foods. Biweekly quizzes and extra tutoring to low-scoring children. ***PA:*** First 6 weeks: Activities included sports and fitness drills for building endurance, strength, and flexibility, teach children to maintain heart rate within target zone and develop basic level of fitness. Second 6 weeks: focus on skill development for activities available in neighborhood or school (e.g., basketball, soccer, jumping rope, dance, kickboxing). ***Beh Tx***: Learned to self-monitor, set goals, address self-identified barriers to improving health. Also used token economy, children earned points for trying new fruits and vegetables, keeping bodies moving during physical activity, and meeting program and individual goals. ***Family:*** Parents invited to culturally sensitive monthly meetings to teach them how to adapt family meals and activities to facilitate health changes.

Study reference	Age range, N, Intervention hours (Intensity)	Description of intervention
Savoye et al 2007[74] Health Care	8-16 n=174 97.5 hrs (High)	***Diet:*** Non-dieting approach emphasizing low-fat, nutrient-dense foods of moderate portion sizes. ***PA:*** Two 50-min sessions/wk for first 6 months, then 1 session every 2 weeks. Each session included warm-up, high-intensity aerobic exercise, cool-down. Goal to sustain 65% to 80% of age-adjusted max heart rate for duration of aerobic exercise. Also encouraged to exercise 3 additional days/week at home and to decrease sedentary behaviors. ***Beh Tx***: One 50-min session/wk for first 6 months, then 1 session every 2 weeks. Topics included self-awareness, goal-setting, stimulus control, coping skills training, cognitive behavior strategies, contingency management. ***Family:*** Parents attended separate group during children's behavioral treatment groups. Emphasized parents' role modeling health behavior, coping skills training.
Reinehr et al 2006[73] Health Care	6-14 n=240 76 hrs (High)	***Diet:*** Recommended diet of 30% fat, 15% protein, 55% carb (only 5% sugar). Categorized foods using Traffic Light system: red="stop", yellow="consider the amount", green="OK when hungry or thirsty. Total kcal went from 1459 ± 379 pre-treatment to 1250 ± 299 kcal post-treatment ***PA:*** Once per week for 12 months, consisted of ballgames, jogging, trampoline, instruction in physical activity as part of everyday life, and encouragement to reduce amount of time spend watching TV ***Beh Tx***: In first 3 months, 6-session nutrition course and 6-session behavior therapy groups for children. Family therapy provided for the next 3 months, with up to 3-month extension as needed. Lifestyle modification approach, details of topic covered not reported. ***Family:*** 6-session parents' course for parents, 3 "Talk rounds for parents", plus family therapy described above.
Gillis 2007[87] Health Care	7-16 n=27 8 hrs (Very low)	***Diet:*** Two discussions of healthy diet; asked to record food intake once/week. No details of recommended diet reported. ***PA:*** Two sessions discussing exercise; asked to record exercise once/week. No details of exercise recommendations reported. ***Beh Tx***: None ***Family:*** None
Nemet et al 2005[79] Health Care ("Child Health and Sports Center")	Avg age 11.1 n=54 35.75 hrs (Medium)	***Diet:*** 6 one-on-one meetings with a dietitian plus four group lectures, covering reasons for childhood obesity, nutrition information such as the food pyramid, food labels, food preparation, eating habits, regular meals. Recommend balanced diet of 5,021 to 8,368 KJ, a deficit of ~30% from baseline intake, or 15% less than estimated daily required intake. ***PA:*** Two 1-hour sessions/week for 14 weeks designed to mimic the type and intensity of exercise that children normally perform. Activities varied in duration and intensity, but usually included activities promoting endurance. Attention given to improving flexibility and coordination. Instructed to exercise at home for additional 30-45 minutes/week and to reduce sedentary activities. ***Beh Tx***: Information on controlling the environment to minimize over-eating, coping with situations that encourage overeating. ***Family:*** Varied with child's age. Ages 6-8: parents only for first 2 meetings, children joined thereafter. Ages 8-puberty: parents and children invited to all sessions. Puberty onward: Parents and youth attend first meeting, then alternate parents and child.

Study reference	Age range, N, Intervention hours (Intensity)	Description of intervention
Saelens et al 2002[77] Primary Care	12-16 n=44 3.8 hrs (Very low)	***Diet:*** Adaptation of Traffic Light diet, goal to reduce to ~1200-1500 kcal/day. Focus on reduction in overall quantity of food and increasing healthy eating, with no prohibition of any particular foods. Computer-based assessment used to identify eating habits, develop initial recommendation/plan. Meeting with pediatrician to confirm/modify plan, 11 10-20 minute follow-up phone calls with support staff to discuss food diaries and other behavior change issues. ***PA:*** PA also assessed via computer, goals set with pediatrician, encouraged by phone counselors. Monitored PA starting with 5th phone call, goal minimum of 60 minutes of at least moderate intensity PA 5 days/week. ***Beh Tx***: Behavioral skills covered include self-monitoring, goal setting, problem solving, stimulus control, self-reward, and preplanning. ***Family:*** Parents sent information sheets corresponding to materials received by youth, highlighting ways in which parents can be most helpful. Recommended parental skills included stimulus/environmental control, positive reinforcement, and preplanning.
Braet et al 2003[85] Residential	10-17 n=76 3,520 hrs (Very high)	***Diet:*** Fed 30% fat, 15% protein, 55% carb, 1500-1800 kcal/day. Soft drinks, sweets, high-calorie food strictly regulated. ***PA:*** Minimum 4hr/wk individual training; "stimulated to exercise 10 h/wk or more if they wanted to." ***Beh Tx***: 12-wk small group cognitive-behavioral covering self-regulation skills, such as self-observation, self-instruction, self-evaluation, self-reward; problem-solving, coping with high-risk situations, relapse prevention. Followed by weekly personalized problem-solving sessions. ***Family:*** Children saw parents every other weekend, plus holidays. Parents received leaflets on how to prepare healthy food, "stimulated" to organize aerobic exercises during weekends and holidays.
Senediak et al 1985[88] Setting NR	6-12 n=45 12 hrs (Low)	***Diet:*** Covered variety of nutritional and dietary topics, recommended diet based on Food Exchange System and Traffic Light System. ***PA:*** Children instructed to engage in at least four 30-minute aerobic exercise sessions per week. Basic conditioning exercises introduced initially, then more strenuous aerobic exercise. Also recommended other lifestyle changes (such as walking instead of riding in the car) to encourage physical activity. ***Beh Tx***: Utilized self-monitoring, self-reinforcement and parental reinforcement, stimulus control techniques (e.g., restricting food consumption to specific times and places), attempted to modify negative cognitions that may contribute to obesity. ***Family:*** Both parents and children involved in all sessions, given materials and homework.
Maintenance Outcomes		
Mellin et al1987[82] Health Care	12-18 n=66 24 hrs (Low)	***Diet:*** Sustainable, small changes in diet; very-low-calorie or restrictive diets discouraged. No specific details on recommended diet. ***PA:*** Encouraged to make sustainable, small changes in exercise habits. No further details provided. ***Beh Tx***: 14 weekly sessions; self-directed change format, encourage small, sustainable changes in relationships, lifestyle, communication, and attitudes. Details of encouraged change process not described. ***Family:*** Two parent meetings; instructed on strategies for supporting their child's weight-loss efforts, including altering family dietary and activity habits, and improving parenting and communication skills.
Flodmark et al, 1993[81] Health Care	10-11 n=93 I1: 12 hrs I2: 24 hrs (Low)	***Diet:*** Counseling by pediatrician and/or dietitian; recommend 1500 to 1700 kcal, with 30% of calories from fat. ***PA:*** No recommendations described ***Beh Tx***: None described. ***Family:*** Family therapy focused on reinforcing the resources of the family and creating and optimal emotional climate for helping the obese child. Adjustments to family hierarchy/structure, plus solution-focused therapeutic techniques.

Abbreviations: PA- physical activity; Beh TX – behavioral treatment; PE – physical education

Table 8. Characteristics of randomized clinical trials of pharmacological anti-obesity treatments among adolescents, by drug type

Source	Intervention	No. of months of drug treatment	No. of behavioral intervention sessions	Characteristics	No of study sites	Country	% Attrition	Quality[a]	Placebo Run-in Period	Funding Source
Sibutramine										
Berkowitz et al, 2003[97]	Sibutramine (5 mg/d for 1 wk, 10 mg/d for 4 wks, then 15 mg) + BI or placebo + BI	6	19	N randomized: 82 Age: 13-17 Female: 67%	1	USA	10%	Good	Yes	NIH, hospital, pharm
Berkowitz et al, 2006[98]	Sibutramine (10 mg/day for 6 mos, then 10-15 mg/d) + BI or placebo + BI	12	10	N randomized: 498 Age: 12-16 Female: 66%	33	USA	28%[b]	Good	No	Pharm
Garcia-Morales et al, 2006[100]	Sibutramine (10 mg/d) + BI or placebo + BI	6	8	N randomized: 51 Age: 14-18 Female: 56%	1	Mexico	22%	Fair	Yes	Pharm
Godoy-Matos et al, 2005[101]	Sibutramine (10 mg/d) or placebo	6	1	N randomized: 60 Age: 14-17 Female: 82%	1	Brazil	17%[b]	Fair	Yes	Pharm
Van Mil et al, 2007[103]	Sibutramine (5 mg/d for 2 wks, then 10 mg/d) + BI or placebo + BI	3[c]	16	N randomized: 24 Age: 12-17 Female: 54%	1	Nether-lands	17%[b]	Fair	No	NR
Orlistat										
Chanoine et al, 2005[99]	Orlistat (120 mg, TID) + BI or placebo + BI	12	18	N: 539 Age: 12-16 Female: 67%	32	USA & Canada	35%	Good	Yes	Pharm
Maahs et al, 2006[102]	Orlistat (120 mg, TID) + BI or placebo + BI	6	7	N: 40 Age: 14-18 Female: 67%	1	USA	15%	Fair	No	University supported

Abbreviations: BI - behavioral intervention (with or without a behavioral management program); TID - three times daily; NR - not reported; Pharm-pharmaceutical; NIH-National Institute of Health.

a: Quality criteria are described in Appendix B Table 1.

b: Attrition rate was different between the intervention and control groups.

c: Patients were treated with BT + sibutramine or placebo for 3 mos. and then BT alone for 3 mos.

Table 9. Results of randomized controlled trials of pharmacological anti-obesity treatments among adolescents, by drug type

Source	N	Baseline BMI (kg/m^2)	Treatment months	Change BMI (kg/m^2) p value	Physiological Outcomes		Adverse Events
Sibutramine							
Berkowitz et al, 2003[97]	43 39	I: 37.5 ± 4.0 C: 38.0 ± 3.6	6	-3.2[a] -1.5[a] p=0.001[b]	WC: SD LDL: NS HDL: NS TG: NS FPG: NS	Insulin: NS HOMA: NS Heart Rate: SD[e] Systolic BP: SD[e] Diastolic BP: NS	Adverse Events: NS
Berkowitz et al, 2006[98]	368 130	I: 36.1 ± 3.8 C: 35.9 ± 4.1	12	-2.9 -0.3 p < 0.001	WC: SD LDL: NS HDL: SD TG: SD FPG: NS	Insulin: SD HOMA: SD Heart Rate: SD[e] Systolic BP: SD[e] Diastolic BP: SD[e]	Adverse Events: NS SAE: NS d/c med: NS Growth: NS Maturation: NS
Garcia-Morales et al, 2006[100]	26 25	I: 35.1± 5.3 C: 36.6 ± 5.2	6	-3.4 (-2.5, -4.2) -1.8 (-0.9, -2.6) P< 0.005*	WC: NS LDL: NS HDL: NS TG: NS	FPG NS Heart Rate: SD[e] Systolic BP: NS Diastolic BP: SD[e]	Adverse Events: NS d/c med: NS Maturation: NS Growth: NS
Godoy-Matos et al, 2005[101]	30 30	I: 37.5 ± 3.8 (f) 37.6 ± 4.3 (m) C: 35.8 ± 4.2 (f) 37.4 ± 1.9 (m)	6	-3.6 ± 2.5 -0.9 ± 0.9 p < 0.001	WC: SD LDL: NS HDL: NS TG: NS FPG: NS	Insulin: NS Heart Rate: NS Systolic BP: NS Diastolic BP: NS	SAE: NS d/c med: NS Other: SD
Van Mil et al, 2007[103]	12 12	I: 30.1 ± 4.5 C: 33.3 ± 5.0	3 + 3 mos f/u[c]	-0.8[d] -1.4[d] NR	% Fat Mass: NS Heart Rate: NS	Systolic BP: NS Diastolic BP: NS	Adverse Event: NS d/c med: NS Other: SD
Orlistat							
Chanoine et al, 2005[99]	357 182	I: 35.7 ± 4.2 C: 35.4 ± 4.1	12	-0.55 +0.3 p < 0.001	WC: SD Other Adiposity: SD LDL: NS HDL: NS TG: NS	FPG: NS Insulin: NS Heart Rate: NS Systolic BP: NS Diastolic BP: SD[f]	Growth: NS Maturation: NS Other: SD
Maahs et al, 2006[102]	20 20	I: 39.2 ± 1.2 C: 41.7 ± 2.6	6	-1.3 ± 1.6 -0.8 ± 3.0 NS	% Fat Mass: NS LDL: NS HDL: NS	TG: NS FPG: NS Insulin: NS	Other: SD

a: Calculated based on average BMI at baseline and average percentage change in BMI for each group (I: -8.5% ± 6.8%, C: -4.0% ± 5.4%).
b: Based on comparison of percent change in BMI between groups
*result of ANOVA testing interaction between treatment group and time
c: Patients were treated with BT + sibutramine or placebo for 3 mos and then BT alone for 3 mos.
d: calculated based on differences reported baseline to 3 mos and 3 mos to 6 mos.
e: Relative increased rate over time in sibutramine group compared to placebo group
f: Relative reduction in rate over time in orlistat group compared to placebo group
Abbreviations: IG - Intervention group; CG - Control group; BT - Behavioral Treatment, NS - not significant; NR - not reported; WC - Waist circumference; LDL - Low-density Lipoprotein; HDL- High-density Lipoprotein; TG - triglyceride; FPG - Fasting plasma glucose; BP - Blood pressure; SD - statistically significant difference; SAE - Serious adverse events; HOMA - Homeostasis model assessment of insulin sensitivity; d/c - discontinue.

Table 10. Randomized, placebo-controlled, clinical trials evaluating pharmacological agents among special populations of obese children and adolescents and reporting weight outcomes

Source	N randomized Study design Country	Population Length of study	Intervention Drug dose	Baseline BMI	BMI results
Srinivasan et al, 2006[105]	N = 28 Cross-over RCT Australia	Obese children and adolescents ages 9-18 years with clinical suspicion of insulin resistance (fasting insulin: glucose > 4.5 or acanthosis nigricans) 12 months	A: Metformin for 6 months, then placebo for 6 months B: Placebo for 6 months, then metformin for 6 months Metformin dose: gradually increased (over 3 wks) up to 2 g/day vs. placebo	Total sample: 35.2 ± 5.1 kg/m^2 (not reported by study group)	ΔΔ BMI SDS* -0.12 p=0.005 ΔΔ BMI -1.26 kg/m^2 p=0.002
Freemark et al., 2001[104]	N =32 RCT USA	Obese adolescents ages 12 to 19 years with fasting insulin concentration > 15 µU/mL; and ≥ 1 first- or second-degree relative with type 2 DM 6 months	IG: Metformin CG: Placebo Metformin dose: 500 mg, twice per day	IG: 41.5 ± 0.9 CG: 38.7 ± 1.3 (p < 0.05)	Δ BMI SDS IG: -0.12 CG: 0.23 p< 0.02 Δ BMI IG: -0.5 kg/m^2 CG: 0.9 kg/m^2 p-value NR

Abbreviations: BMI - Body mass index; DM - Diabetes mellitus; IG - intervention group; CG - control group; RCT - randomized controlled trial

*ΔΔ BMI = Δ BMI$_{IG}$ - Δ BMI$_{CG}$

Table 11. Bariatric surgery weight outcomes

Study	Population characteristics	Baseline BMI, mean (range)	Change in BMI, kg/m^2 unless noted: Short-term 6-12 months	Medium-term 1-5 yrs	Longer-term ≥ 5 yrs
Laparoscopic Adjustable Gastric Band					
Angrisani 2005[114] Band brand NR	**N:** 58 **Age:** 17.96 ± 0.99 yr **Female:** 81%	46.1 ± 6.31 kg/m^2	1 yr 10.2 kg/m^2 (n=48/52) 9.4 kg/m^2 * (n=52/52)	3yr 8.3 kg/m^2 (n=37/42) 7.3 kg/m^2 *	5yr 11.2 kg/m^2 (n=25/33) 8.5 kg/m^2 * (n=33/33 7 yr 16.4 kg/m^2 (n=10/10)
Nadler 2007 [111] Lap-Band®	**N:** 53 **Age:** 15.9 yr (13-17) **Female:** 77.4%	47.6 ± 6.7 kg/m^2	6 mo 8.1 kg/m^2 (n=33/53) 5.0 kg/m^2 * (n=53/53)		
Dolan 2003 [115,116] Fielding[130] Lap-Band®	**N:** 17 **Age:** Median 17 yr (12-19) **Female:** 82.4%	(calculated): 43.1 kg/m^2 (30.3-70.5)	1 yr 10.1 (n=17/17)	2 yr 12.7 kg/m^2 (n=11/17) 8.2 kg/m^2 * (n=17/17)	
Abu-Abeid 2003[126] Lap-Band®	**N:** 11 **Age:** 15.7 yr (11-17) **Female:** 72.7%	46.6 kg/m^2 (38-56.6)	14.5 kg/m^2 Mean 1.9 yr (6 mo - 3 yrs)		
Silberhumer 2006[129] Widhalm 2004[117] Lap-Band® and SAGB®	**N:** 50 **Age:** 17.1 yrs (9-19) **Female:** 62%	45.2 kg/m^2 (32.5-76.7)	12.6 kg/m^2 Mean 2.9 yr (4 mo - 7 yrs)		
Yitzhak 2006[114] SAGB®	**N:** 117 total; n= 60 ≥ 36 mo follow-up **Age:** 16 yr (9-18) **Female:** 70%	43 kg/m^2 (35-61)	Self-reported weight measures		
Gastric Bypass/Other procedures					
Lawson 2006 [112] Lap RYGB	**N:** n=30 weight n=36 harms **Age:** Mean NR (13-21 yr) **Female:** NR	56.5 ± 5.2 kg/m^2 (41.9-95.5)	1 yr 20.7 ± 8.1 kg/m^2 (n=30/30)		
Collins 2007 [98] Stanford 2003[110] Lap RYGB	**N:** 11 **Age:** 16.5 ± 0.2 yrs (15-18) **Female:** NR	50.5 ± 2.0 kg/m^2 (42-66)	No valid outcomes available		

Study	Population characteristics	Baseline BMI, mean (range)	Change in BMI, kg/m^2 unless noted Short-term 6-12 months	Medium-term 1-5 yrs	Longer-term ≥ 5 yrs
Sugerman 2003[108] Gastric Bypass 91%	**N:** 33 **Age:** 16 ± 1 yr (12.4-17.9) **Female:** 57.6%	52 ± 11 kg/m^2 (38-91)	1 yr: 16 kg/m^2 (n=31/32) 15.5* kg/m^2 (n=32/32)		5 yr: 19 kg/m^2 (n=20/24) 15.8 kg/m^2 * (n=24/24) 10yr: 18 kg/m^2 (n=14/18) 14 kg/m^2 * (n=18/18) 14 yr: 14 kg/m^2 (n=6/9) 9.3 kg/m^2 * (n=9/9)
Soper 1975[120] Anderson 1980[121] Open RYGB; Horizontal gastroplasty	**N:** 18 **Age:** Median 19 yr (≤ 20 yrs) **Female:** 55.6%	**Median weight**: 147.0 kg	6 mo: % BW lost 15% (n=17/18) 14.2%* (n=18/18) 1 yr: 30% (n=14/18) 23.3%* (n=18/18)		
Mason 1995[119] VBG	**N:** 47 (2 with Prader Willi) **Age:** 18.1 ± 1.84 yr **Female:** 68%	48.4 kg/m^2			5 yr: 12.2 kg/m^2 (n=25/35) 8.7 kg/m^2 * (n=35/35) 10 yr: 9.2 kg/m^2 (n=14/19) 9.2 kg/m^2 * (n=19/19)
Capella 2003[118] Open RYGB; VBG	**N:** 19 **Age:** 15.6 yrs (calc)(13-17) **Female:** NR	49 kg/m^2 (38-67)	19 kg/m^2 Mean 5.5 yrs (1 mo -10 yrs)		
Strauss 2001[122] Open RYGB	**N:** 10 **Age:** (15-17 yr) **Female:** 70%	52.4 kg/m^2 (calc)	46.8 kg/m^2 Mean 5.75 yrs (7 mo - 13 yrs)		
Barnett 2005[113] Open RYGB; VBG; JIB	**N:** 14 **Age:** 15.7 yrs (13-17) **Female:** 57%	55.1 ± 14.8 kg/m^2	24 kg/m^2 Mean NR (9 mo - 22 yrs)		

Study	Population characteristics	Baseline BMI, mean (range)	Change in BMI, kg/m^2 unless noted Short-term 6-12 months	Medium-term 1-5 yrs	Longer-term ≥ 5 yrs
Breaux 1995[124] Open RYGB; VBG; BPD	**N:** 22 **Age:** 15.3 yr (calc)(8-18) **Female:** 59% (calc)	Without sleep apnea 56.4 kg/m^2 Sleep apnea 67.8 kg/m^2		Without Sleep Apnea 20.9 kg/m^2 Mean 4.2 yr (6 mo – 16.6 yrs) With Sleep Apnea 23.8 kg/m^2 Mean 2.7 yr (9 mo – 10.1 yrs)	
Rand 1994[125] Open RYGB; VBG	**N:** 34 of 39 possible **Age:** 17 ± 2 yrs (11-19) **Female:** 79%	47 ± 7 kg/m^2		Self reported weight	
Papadia 2007[128] BPD	**N:** 68 **Age:** 16.8 yrs **Female:** 76.5%	46 kg/m^2			78% EWL Mean 11 yrs (2 - 23 yrs)
Tsai 2007[109]	**N:** 566 procedures **Age:** 12-19 yrs (96.4% were 15-19) **Female:** 78.6%	NA		No weight outcomes reported	

*Indicates intention-to-treat calculation.

Abbreviations: BW - body weight; EWL - excess weight loss; RYGB – Roux-en-Y gastric bypass; VBG – vertical banded gastroplasty; BPD - Biliopancreatic diversion

Table 12. Other outcomes for bariatric surgical procedures

Study	Failure	Resolution of comorbidities	Adverse events	
Laparoscopic Adjustable Gastric Band				
Angrisani 2005[114] Band brand NR	≤ 25% EWL at 5 yrs: 20% (5/25)	NR	Mortality: None Laparotomic conversion: 1.7% (1/58) Overall postoperative complications: 10.3% (6/58) Band slip: 1.7% (1/58)	Gastric pouch dilation: 3.4% (2/58) Intragastric migration: 5.2% (3/58) Band removal: 10.3% (6/58) Conversion to gastric bypass or BPD: 5.2% (3/58)
Nadler 2007[111] Lap-Band®	NR	NR	Perforated appendicitis within 10 days of surgery: (1.9% 1/53) Band slip: 3.8% (2/53) Hiatal hernia: 3.8% (2/53) Wound infection: 1.9% (1/53)	Mild hair loss: 9.4% (5/53) Iron deficiency: 7.5% (4/53) Nephrolithiasis, cholelithiasis: 1.9% (1/53) Gastroesophageal reflux: 1.9% (1/53)
Dolan 2003[115,116] Fielding[130] Lap-Band®	NR	NR	Band slip: 5.9% (1/17) Leaking port: 5.9% (1/17)	
Abu-Abeid 2003[126] Lap-Band®	NR	Amenorrhea: 100% High triglycerides: 100% (2/2) Abnormal cholesterol: 0% (0/1)	Perioperative complications: 0% Late complications: 0%	
Silberhumer 2006[129] Widhalm 2004[117] Lap-Band® and SAGB®	6% (3/50) had EWL < 25% after at least 1 yr of follow-up	Diabetes mellitus II: 80% (4/5) Hypertension: 50% (6/12) Dyslipidemia: 100% (4/4) Asthma: 100% (3/3) Cholecystolithiasis: 100% (3/3)	Perioperative complications: 0% Dislocated port: 2% (1/50) Band slip: None	
Yitzhak 2006#[127] SAGB®	NR	100% resolution of all co-morbidities. Hypertension: 3/3 Diabetes Mellitus: 2/2 Asthma: 3/3 Obstructive sleep apnea: 10/10	Mortality: 0% Major post-operative complications: 0% Band slip: 10% (6/60) Band removal: 3.3% (2/60)	

Study	Failure	Resolution of comorbidities	Adverse events	
Gastric Bypass/Other procedures				
Lawson 2006[112] Lap RYGB	6.7% (2/30) in 1st year regained weight-up to 50% of weight lost. All patients were still overweight to severe obesity at 1 yr follow-up.	NR	2/36 were converted to an open procedure (5.6%) Minor complications (readmission < 7 days): 9/36 (25%) Moderate complications (readmission or sequelae for 7-30 days): 4/36 (11%)	Severe complication (sequelae for more than 30 days): 2/36 (5.6%), which includes 1 death 9 months post-operative due to complications from severe infectious colitis. Non-compliant with 12 mo. office visit: 23% (9/39)
Collins 2007[110] Stanford 2003[123] Lap RYGB	NR	Diabetes: 50% (3/6) Hypertension: 50% (3/6) Obstructive sleep apnea: 100% (2/2) no longer required constant positive airway pressure at night Polycystic ovarian syndrome: 67% (2/3) All co-morbidities: 30.1% resolved	Postoperative bleeding: 3/11 (27.3%) with 1 of these needing laparoscopic reevaluation. Marginal ulcer: 2/11 (18.2%) (1 and 18 mo postoperative) Non-compliant with vitamin regimen: 18.2% (2/11)	
Sugerman 2003[108] Gastric Bypass 91%	15% (5/33) regained all or most of weight lost at 5-10yrs	Diabetes Mellitus II: 100% (1/1) Hypertension: 80% (8/10) Sleep apnea: 100% (6/6)	<u>Late complications</u>: 21% (7/33) Incisional hernia: 18.2% (6/33) Bowel obstruction: 3% (1/33) Conversions to another type of bypass due to late weight gain or severe protein-calorie malnutrition: 6% (2/33)	<u>Early complications</u>: Pulmonary embolism: 3% (1/33) Major wound infection: 3% (1/33) Minor wound infection: 12% (4/33) Stomal stenoses: 9% (3/33) Marginal ulcers: 12% (4/33) No patients had evidence of impaired sexual or physical maturation.
Soper 1975[120] Anderson 1980[121] Open RYGB; Horizontal GP	NR	NR	Revision: 5.6% (1/18) Wound infection: 12% (3/25*) Respiratory difficulty: 12% (3/25*) Thrombophlebitis: 4% (1/25*) Upper gastrointestinal bleed: 4% (1/25*)	Urinary tract infection: 4% (1/25*) Protracted vomiting: 4%(1/25*) Incisional hernia: 16% (4/25*) *n=25, which includes 7 Prader-Willi patients
Mason 1995[119] VBG	NR	NR	Mortality: None Revisions: 8.5% (4/47)	

Study	Failure	Resolution of comorbidities	Adverse events
Capella 2003[118] Open RYGB; VBG	NR	NR	Mortality: None Revisions: 10.5% (2/19) Cholecystectomy: 5.3% (1/19)
Strauss 2001[122] Open RYGB	3 women who became pregnant regained 13-45 kg	NR	Protein-calorie malnutrition/micronutrient deficiency: 10% (1/10) Cholecystectomy: 20% (2/10) Small bowel obstruction 10 yrs postoperative: 10% (1/10) Incisional hernia: 10% (1/10)
Barnett 2005[113] Open RYGB; VBG; JIB	NR	Hypertension: 100% (5/5) Asthma: 66.7% (2/3) Sleep apnea: 100% (2/2) Diabetes: 100% (1/1) Hypothyroidism: 0% (0/1)	Mortality: None Dumping syndrome: 14.3% (2/14) Surgical site infection: 7.1% (1/14) Hypoglycemia: 7.1% (1/14)
Breaux 1995[124] Open RYGB; VBG; BPD	NR	Sleep apnea: 100% (11/11)	Mortality: 2 deaths at 15 mo and 3.5 yrs postoperative. Incisional hernia: 5% (1/22) Postoperative laryngeal edema: 5% (1/22) Gallstones: 5% (1/22) Kidney stones: 5% (1/22) Nutritional deficiencies: 23% (5/22) Revision: 4.5% (1/22)
Rand 1994[125] Open RYGB; VBG	NR	NR	2 cholecystectomies 1 abdominal panniculectomy No other AE reported. 3 had surgical revisions-2 were scheduled for revisions.
Papadia 2007[128] BPD	NR	Hypertensive: 92% (27/33) Dyslipidemic: 100% (11/11) Hyperglycemic: NR Diabetes mellitus II: 100% (2/2)	Reoperations: 19 in 14 patients (14/68=21%) Mortality long-term: 4.4% (3/68) Protein malnutriiton 1-10 yrs post surgery: 16% (11/68) Immediate complication: 1.5% (1/68)
Tsai 2007[109]	NR	NR	Mortality: None Major complications: 5.5%78.3% (119/152) of major complications were respiratory

Abbreviations: AE- adverse events; EWL – Excess weight loss; RYGB – Roux-en-Y gastric bypass; VGB – Vertical banded gastroplasty; BPD - Biliopancreatic diversion; JIB - Jejunoileal Bypass; NR – Not reported; GP – Gastroplasty

Chapter 4. Discussion

Summary of Review Findings

We evaluated 18 behavioral intervention trials conducted in a variety of settings in 1794 obese children and adolescents aged 5 to 18 years, seven trials of pharmacological treatments (sibutramine or orlistat) combined with behavioral interventions in very obese adolescents aged 12 to 18 years (and two trials of metformin in very obese high-risk adolescents), and 17 case series of surgical treatments in morbidly obese adolescents (with usable data primarily from 15 case series). As illustrated in Table 13, behavioral, pharmacological, and surgical treatments not only vary in terms of absolute weight reduction, but also in terms of potential adverse effects. While limited evidence also suggests that treatments that produce greater degrees of weight loss may also reduce comorbidities and cardiovascular risk factors, data covered in this report do not allow us to determine the precise level of weight loss required for these additional benefits.

The Expert Committee has delineated approaches that range from simple preventive messages aimed at younger children and those who are not overweight, to weight management approaches that increase in intensity as the child is more obese or has more weight-related health problems. Behavioral interventions are seen as a best first line treatment; our review found that they can be effective and are likely to be safe when delivered to children aged 5 and older who are obese. The research we reviewed is not inconsistent with this recently proposed model of a stepped-care approach to weight management treatments that increases intensity (and treatment-associated risk) according to degree of overweight (or obesity), age/maturation, health risks, and motivation.[5,11]

While all included studies primarily addressed obese children and/or adolescents (above the 95th percentile for age-and sex-specific BMI measurement and, in many cases, meeting adult criteria for obesity), the degree of obesity varied by type of treatment. Pharmacological treatments addressed very obese adolescents (adult obesity Class II) and surgeries were tested only in extremely obese adolescents (adult obesity Class III). Comparing BMIs of study participants across treatment type is critical to understanding to which participants the results of treatment trials can be applied.

Considering the BMI levels of study participants, currently studied treatments can not be clearly applied to the entire population of overweight and obese children and adolescents. Overweight and obesity are about equally prevalent among children and adolescents in the general population,[13] but almost all of the trials of behavioral interventions that we evaluated were comprised wholly or mostly of children and adolescents who were obese. Although these types of behavioral interventions should be appropriate for overweight children and adolescents as well, current studies do not clarify their use or impact. We do not know whether those who are overweight (but not obese) have as high a need for treatment nor whether they would respond similarly to weight management interventions. The adolescents in whom effective pharmacological treatments or surgeries have been studied are in the upper percentiles of the BMI range or meet criteria for Class II or III obesity in adults, and thus represent a small fraction of the 16 percent of girls aged 12 to 19 and the 18 percent of boys aged 12 to 19 that are obese. Recent data estimates that only 1 to 3 percent of 13 to 17-year-old girls and 3 to 5 percent of 13 to 17-year-old boys have BMIs that are at or above the 99th percentile for their age and sex,[10] and, based on evidence, the use of more invasive treatments would be primarily limited to these

adolescents. Clearly, a comprehensive evidence-based approach to addressing the childhood obesity epidemic will require additional treatment research on categories of overweight or obese children and adolescents that are understudied, as well as consideration of obesity prevention programs that address the entire population. We return to these themes later in the discussion.

Behavioral Interventions

Based on our review, there are effective behavioral interventions that can improve weight measures, at least over the short-term, in obese children and adolescents aged 5 to 18 years. We found no evidence addressing weight management approaches in overweight or obese children under 5 years old. Evidence-based treatments for obese children aged 5 to 12 years are limited to behavioral interventions (without pharmacological adjuncts).

Behavioral interventions for obese children and adolescents aged 5 to 18 years in either schools or in specialty health care settings can effectively produce short-term improvements in weight. Very limited evidence suggests that these improvements can be maintained (completely or somewhat) over the 12 months following the end of treatment. The amount of absolute or relative weight change associated with behavioral interventions in these settings is generally modest and varies by intervention intensity and setting.

In school setting interventions, trials reported 0.4 to 2.07 kg/m^2 difference in mean BMI change between those that were treated and controls at 6 to 12 months, with a pooled estimate of -0.82 kg/m^2 (CI: -1.18, -0.46) lower BMI in those treated. For an 8-year-old boy or girl, this BMI difference would translate to about a 3 pound difference (assuming growth of 2 inches or less), and for a 12-year old boy or girl this would translate to about a four pound difference under the same growth assumptions. In girls aged 16, this BMI difference would translate to between 4.5 and 5 pounds, depending on growth. For 16-year-old boys the difference would be between 5 and 6 pounds.

Interventions in specialty health care settings (such as pediatric obesity referral clinics) resulted in a 1.9 to 3.3 kg/m^2 difference in mean BMI change 6-12 months following treatment, compared with controls. For an 8-year-old boy or girl, the largest BMI difference (3.3 kg/m^2) would translate to about 12 to 13 pounds (with up to 2 inches of growth). For a 12-year old boy or girl this would translate to 16.6 to 17.75 pounds difference under the same growth assumptions. In girls aged 16, this BMI difference would translate to about 20 pounds, while for boys aged 16, the difference would be between 22 and 23 pounds for two inches of growth or less.

The intervention effects possible with behavioral interventions, particularly those in specialty health care settings, appear adequate to improve adiposity, as measured by significant reductions in skin fold thickness measures or bioelectric impedance. Effects on blood pressure, lipids, or blood glucose levels have not been as well reported in those undergoing exclusively behavioral interventions as they have been for those combining pharmacological treatments with behavioral approaches. Limited evidence suggests that reductions in these measurements do not routinely occur, but are possible with the larger treatment effects seen in effective specialty health care treatments. As illustrated in Table 13, however, children and adolescents included in behavioral interventions tended to be less obese than those in pharmacological or surgical treatment trials, which would make them less likely to have elevated cardiovascular or diabetes risk factors.

Psychological outcomes were assessed in several trials, suggesting that interventions potentially improve depression, eating disorder pathology, and shape concern. These results, however, are based on minimal data and should be considered tentative. One included trial

examined self-esteem and found no differences in change in self-esteem (both groups improved). Data were also mixed in a recent review[131] on self-esteem in overweight children and adolescents.

We found no evidence of adverse effects on growth, on eating disorder pathology, or on mental health. Effects on growth found in this review are consistent with data from several noncomparative studies, including one that followed 158 children for 10 years and found that weight loss was not related to growth in height in a multivariate model controlling for child age, sex, baseline height, baseline percent overweight, and midparent height.[132] We found little risk of exercise-induced injuries from behavioral interventions. Although these findings are reassuring, they are limited by incomplete reporting, given that fewer than half of behavioral intervention trials in children and adolescents specifically reported on any potential adverse effects. Only four trials of adolescents and two trials with both children and adolescents (representing relatively few total participants, since most trials enrolled fewer than 100 participants) reported results for any single type of adverse event. None of these found any adverse effects of treatment. The data on potential adverse effects are also further limited for children under 12 years of age. Only two studies[83,84] reported potential harms in participants in this age group, indicating no adverse impact on height gains in 111 children at 1 year[83] or on body satisfaction or appearance at 1 year in 163 children.[84] One bone fracture was reported among 107 children under aged 12 years participating in supervised exercise.[93,94]

Most treatment programs focused on supporting healthy lifestyle changes through establishing healthful eating habits and increasing regular physical activity. While some trials in adolescents had the explicit goal of weight reduction, trials with younger children generally aimed to reduce participants' relative level of overweight through limiting weight gain as the child grew. Many trials utilized behavioral management techniques, such as teaching parents and/or children about goal-setting, relapse prevention, problem-solving, and managing their environment to encourage healthy lifestyle. Teaching behavior management techniques and providing organized physical activity sessions seem to improve the chances of a program's success.

Physical activity is clearly an important factor in altering the balance between caloric intake and expenditure, and therefore has in important role to play in weight loss interventions. All but two interventions in the 18 main trials included either actual exercise sessions or instruction in behavioral management principles targeting exercise. It appears that organized exercise sessions increase the likelihood of treatment success, but this could not be determined conclusively since programs with organized exercise as also tended to be more intensive programs with considerably more hours of contact. Regardless of whether children and adolescents exercise under the supervision of interventionists or on their own time, improved physical fitness is likely beneficial even if it does not increase weight loss.[133,134]

Observational data show a relationship between sedentary behavior, such as television and electronic games, and obesity in children.[135-137] Interventions targeting sedentary behavior have reduced weight gain in trials of obesity prevention.[138] However, the relative importance of targeting sedentary behavior in treatment of obesity could not be determined from the primary trials included in this review. In addition, Epstein and colleagues conducted three studies[139-141] examining the relative benefits of encouraging obese participants to decrease sedentary behavior, increase physical activity, or both. Taken as a whole, these trials did not demonstrate that any of these three approaches were clearly superior. One trial[139] found that focusing on sedentary behavior was more effective than focusing on increasing physical activity, but neither of these

groups differed from the group that encouraged both approaches. Neither of the remaining two trials found that the approach to physical activity had an impact on the effectiveness of weight-loss interventions.

All programs targeting younger children involved parents, and since parents usually control most of younger children's food intake, the necessity of parental involvement is self-evident. However, since all of the trials in younger children included parents, we have no empirical basis for quantifying the importance of parental involvement in this age group. The few trials in adolescents that included parental involvement were effective. Since these interventions included many components, however, it was impossible to isolate the specific effect of parental involvement in interventions targeting adolescents.

It is difficult to determine how well the results of these trials would generalize to patients in real-world treatment settings. Several studies relied at least in part on media advertisements for recruitment, and may therefore have enrolled participants who are more motivated to lose weight than a typical obese young person. Trials that recruited via screening, actively seeking participants rather than relying on potential participants to contact them, saw only a minority of overweight or obese children actually participate in the research trial. For example, only 38 percent in Graf's study[86,142] and 32 percent in McCallum's trial[78,84] who met weight criteria actually enrolled in the trials. There may be unmeasured differences between children who did and children who did not participate that influence how well they respond to the intervention. Children and adolescents who participate may have higher levels of motivation, more free time, more concerned parents, more failed attempts at weight loss, or any number of factors that may moderate the effectiveness of the intervention.

Pharmacological Plus Behavioral Interventions

Pharmacological adjuncts to behavioral interventions have been studied only in obese adolescents aged 12 to 18 years that meet adult criteria for class II obesity (mean BMI of 35 to 40 kg/m^2 at trial entry), but not in less obese adolescents or in children younger than 12. Treatments with pharmacological agents (sibutramine and orlistat) delivered in combination with behavioral interventions over 6 to 12 months have been studied, but longer term results after treatment discontinuation are not available in any of the pharmacological treatment trials. This is an important limitation in our overall knowledge about their beneficial effects. Two small trials in very obese adolescents at high risk for type 2 diabetes mellitus examined the impact of metformin on glucose tolerance, insulin sensitivity, and BMI. These results are preliminary and are not directly applicable to the general population of obese adolescents.

The most informative data on sibutramine comes from a large (n=498) multicenter trial testing 12 months of sibutramine plus a behavioral intervention, compared with the behavioral intervention plus placebo. Participants receiving 10 to15 mg per day of sibutramine treatment plus a behavioral intervention decreased their BMI 2.9 kg/m^2 at the conclusion of treatment, corresponding to an average weight reduction of 6.5 kg (14 pounds). Trial participants receiving a behavioral intervention (plus placebo) reduced their BMI 0.3 kg/m^2, which correspond to a weight gain of 1.9 kg (4.2 pounds). The weight reduction possible at 12 months with effective behavioral intervention in specialty health care is similar in magnitude to the benefits achieved with 12 months of sibutramine plus some level of behavioral intervention. Direct head-to-head comparisons would allow us to confirm this impression.

Available data do not allow us to clearly determine whether behavioral interventions that produce similar effects on BMI as sibutramine also produce similar effects on other potentially

beneficial outcomes. In most of the sibutramine trials, waist circumference in those receiving sibutramine was significantly reduced, on average 7 to 8 cm compared with 2 to 3 cm reductions in controls. Significant improvements in HDL cholesterol, *triglycerides*, and glucose tolerance measures (serum insulin and HOMA) were reported in the sibutramine treatment group in the largest multicenter trial (n=498). Trial participants receiving sibutramine were consistently more likely to develop elevated heart rates than placebo-treated participants, but had similar rates of discontinuation due to this side effect. Systolic or diastolic blood pressure (or both) were significantly elevated in about half of trials. These differences, however, were small in magnitude and are of unknown clinical significance. Few other adverse effects with sibutramine treatment were noted, except for one report of increased constipation. Limited evidence suggests no adverse effects on growth or maturation. One trial testing only three months of sibutramine (10 mg/day) plus six months of a behavioral intervention (compared with placebo and a behavioral intervention) showed modest BMI reductions at 6 months (-0.8 and -1.4 kg/m^2) in both arms favoring placebo, but these were not statistically significantly different. No adverse effects were reported.

The most informative data on orlistat come from a large multicenter trial (n=539) testing 12 months of orlistat (360 mg/day) treatment plus a behavioral intervention. Mean BMI in this trial was significantly different (-0.55 kg/m^2) after treatment, compared with those receiving the behavioral intervention only (who increased their mean BMI 0.3 kg/m^2). This difference reflected weight gain in both groups, which was relatively attenuated in the orlistat group. From these results, it appears that the behavioral intervention component of the orlistat trials was ineffective. This could reflect the freedom at each of the 32 centers to use its own approach to the behavioral intervention aspect of the trial with no assessment of delivery.[99] Therefore, the quality or intensity of the behavioral interventions may have been lacking at some sites. Participants receiving orlistat significantly reduced their waist and hip circumference (2.7 and 1.5 cm respectively), compared with controls (0.9 and 0.1 cm reductions). Serious adverse effects were uncommon. However, mild-moderate gastrointestinal side effects (most commonly oily spotting, evacuation, abdominal pain, fecal urgency, or flatus with discharge) occurred in 20 to 30 percent of patients taking orlistat and 9 percent reported fecal incontinence. Few participants (2 percent) discontinued treatment due to these side effects, although 35 percent overall dropped out before the trial ended. The impact gastrointestinal effects would have on treatment adherences outside a trial setting is unclear. Orlistat treatment did not reduce vitamin A, D, or E levels or affect growth, bone mineral density, or sexual maturation.

Sibutramine appears to have a larger effect on weight than orlistat, although the two drugs have not been compared directly. Only orlistat has been approved for use in pediatric populations (aged 12 years or older) by the FDA. Both drugs have side effects that must be taken into account when considering treatment for an individual patient. While orlistat has a higher rate of adverse effects, the nature of these effects may be less clinically significant than those seen with sibutramine. Both drugs lack evidence of persistence of weight reduction after active treatment ends.

As with the interventions that were limited to behavioral approaches, these trials involving the addition of pharmacological agents may also be subject to limitations in how well they apply to real-world treatment. That is, adolescents participating in these trials may be more or less likely than the average overweight or obese adolescent to respond to the intervention provided. For example, they may have higher levels of motivation to lose weight and therefore do better than the average adolescent, or they may have a greater number of failed weight loss attempts,

which may make them less likely to succeed than the typical overweight or obese teen in the community. The supports provided in a typical trial may also exceed those provided in a usual treatment setting.

Surgical Treatments

Some adolescents reach extremely high levels of obesity and experience substantial health problems due to increased weight. For morbidly obese adolescents with obesity-related health problems who have failed intensive efforts at medical management, surgery may offer a treatment of last resort. Case series of laparoscopic adjustable gastric banding, Roux-en-Y gastric bypass, and other bariatric surgery techniques have been reported in a relatively small number of severely obese adolescents. Surgical case series have been based primarily on retrospective medical chart reviews of patients who have received clinical care. Followup in these series can be incomplete and data collection inconsistent. Thus, both data on weight outcomes as well as other beneficial outcomes from surgery are quite limited. Adverse effect documentation may be somewhat better, particularly for serious adverse effects, since these would reflect issues requiring clinical diagnosis and/or treatment.

Although adolescents undergoing obesity surgery have generally been required to meet NIH criteria for surgery in obese adults (BMI greater than 40 kg/m^2 or greater than 35 kg/m^2 with co-morbidities), adolescents included in surgical series were much more severely obese (Table 11). Those undergoing gastric bypass and other bariatric surgeries requiring laparotomy were more severely obese than patients undergoing LAGB.

LAGB is logically the surgical treatment of choice in morbidly obese adolescents who are candidates for bariatric surgery, since it should be completely reversible and potentially less risky than other bariatric procedures. LAGB is done via laparoscopic rather than open surgery (laparotomy). Both absolute weight loss and risks related to the surgery, however, appear to be lower after laparoscopic adjustable gastric banding than after more invasive procedures, including gastric bypass procedures. In one LAGB series (n=53),[111]estimates of mean reduction in BMI at 6 months ranged from 5.0 to 8.1 kg/m^2 in intention-to-treat and in complete case analyses respectively. We focus on intention-to-treat analyses as the more realistic measure of overall treatment efficacy. In two studies (n=69), estimates for mean BMI reduction at 12 months ranged from 9.4 to 10.1 kg/m^2. Based on limited longer term followup from the same two studies.[114,115] BMI reductions somewhat reversed between one and three years after surgery (from 10.1 kg/m^2 at 1 year to 8.2 kg/m^2 at 2 years and from 9.4 kg/m^2 at 1 year to 7.3 kg/m^2 at 3 years). Little data are available to estimate the proportion achieving clinically significant thresholds of weight reduction after surgery or the proportion that fail bariatric surgeries. One small study[115,116,130] (n=17) reported that three-quarters of patients at 12 months and 82 percent at 24 months achieved a BMI less than 35. Similarly, a single case series[117,129] of 50 patients reported that only 3/50 (6 percent) did not achieve at least 25 percent body weight loss at one-year post-surgery. No perioperative mortality or major morbidity after LABG has been reported. Limited data suggested 10 to 13 percent of adolescents undergoing LABG require reoperations for band repositioning or removal. Around 10 percent may also have nutrition-related complications (mild hair loss or iron deficiency). Other miscellaneous complications were rarely noted. Very little data are available on whether comorbidities resolved after surgery. It seems clear, however, that those with sleep apnea and probably weight-associated asthma experience resolution, given the degree of weight loss induced by surgery.

A greater reduction in BMI has been seen in adolescents undergoing Roux-en-Y gastric bypass (RYGB) or vertical banded gastroplasty (VBG) procedures. In one small case series[120,121] of 18 adolescents whose median preoperative weight was 147 kg, median percentage of body weight lost at 10 to 15 months was 23 percent. At 12 months after RYGB surgery (performed laparoscopically or requiring a laparotomy) in two studies (n=63 adolescents), mean reductions in BMI ranged from 15.5 to 20.7 kg/m^2. Among 24 patients with ongoing followup,[108] mean BMI appeared to be maintained at 5-year followup. Followup data beyond five years are very limited (less than 20 persons eligible and fewer with measured weights). Most studies that report data on followup longer than one year after surgery are uninformative due to averaging weight measurements taken from individuals at markedly different points of time after surgery (often over 10 years apart). Further, only small numbers of patients are eligible for longer term post-surgical followup, given the rarity of performing bariatric surgery in adolescents during this time period. Treatment failures, however, have been reported even among these limited data. In one series,[112] two of 30 patients regained up to 50 percent of the weight lost within the first year. Five of 33 patients regained most or all of their weight 5 to 10 years after RYGB.[108] In both of these cases, patients met NIH inclusion criteria for adults. In a large nationally representative study of inpatient data from 566 RYGB or gastroplasty surgeries in adolescents, no in-hospital deaths were recorded, but major complications occurred in 5.5 percent of patients (two-thirds of which were respiratory). Longer-term adverse events were not captured. Other data suggest, however, that complications occur in at least 30 percent of patients during the first year after open RYGB, and in at least 39 percent in the first 12 months after laparoscopically performed RYGB. After laparoscopically performed RYGB, severe complications (death or severed organ failure) were reported in 2/36 patients and 5/36 patients experienced reoperation, unanticipated intensive care unit admission, or hospital readmission for more than seven days. About one-quarter of patients (13/47) required some special test, treatment, endoscopy, or hospital readmission for seven days or less.

At five years after VBG surgery, three-quarters of patients achieved over 25 percent excess weight loss, although this estimate was lower (61 percent) at "last followup." [119] This procedure is not currently in widespread use due to higher recidivism than other surgeries and the advent of gastric banding. Although biliopancreatic diversion surgeries (with or without duodenal switching) are not currently in widespread use, it is worth noting that significant harms, including long-term mortality, were reported in 4.4 percent and protein-calorie malnutrition in 16 percent of patients within one to 10 years after surgery.[128] These data suggest this procedure may be too risky to be considered in obese adolescents.

Even more so than the children and adolescents participating in behaviorally based treatments (with pharmacological adjuncts or those without), adolescents receiving bariatric surgeries were a highly selected group of extremely obese primarily older adolescent patients (with average pre-surgical weights ranging from 284 to 297 pounds) that were often accrued over many years of practice. Many if not most had obesity-related co-morbidities. While bariatric surgeries may provide life-saving treatments for some morbidly obese adolescents, the very limited data currently available on treatment efficacy, along with the known short-term risks and unknown long-term implications of bariatric surgery, demand the utmost care and consideration before choosing these types of treatments and conducting prospective collection of long-term outcomes.[45,143]

Long-term Maintenance

It is unfortunate, although not surprising, that evidence of treatment maintenance is quite limited in behavioral intervention trials and surgery studies, and nonexistent in trials of pharmacological treatments. Long-term outcomes are particularly important for surgical treatments, especially in younger adolescents, in whom continuing growth and maturation are complicating factors. The effects of mechanically restricting absorption or the size of the stomach in these children, and of potentially substantial weight loss, cannot be ascertained from the adult literature.

Although this review focused on controlled trials, we searched for additional evidence that may shed light on long-term effectiveness of behavioral intervention programs. An observational study of a behavioral intervention by Epstein and colleagues reported on 10-year followup of four comparative effectiveness treatment trials in children 6 to 12 years of age that were conducted between 1981 and 1986.[144] It did not meet our inclusion criteria because it had no control group for comparison purposes, and it is unclear what proportion of the original participants provided 10-year followup data. Epstein and colleagues report that 30 percent of their participants were not obese at 10-year followup. It is difficult to determine, however, whether this is a higher rate of change than would be seen in a general population of obese children, many of whom likely seek assistance naturalistically in various forms. Freedman and colleagues' large scale observational study of children in Bogalusa, Louisiana[27] found that 22.8 percent of 9 to 11 year olds who were at or above the 95th percentile were no longer obese an average of 16 years later, which is lower than the 30 percent found by Epstein and colleagues. On the other hand, a retrospective observational study from the UK found that 39.3 percent of obese 16-year-olds were no longer obese at age 30, which is a higher rate of remission than that reported by the Epstein study. Several differences between the populations and settings of these studies limit drawing definitive conclusions about whether children undergoing treatment programs are more or less likely to be obese at long-term follow-up. Limited as it is, the best evidence remains that described for KQ2 addressing maintenance effects after treatment, in which control groups were comparable to the treated participants and outcomes were measured consistently between the groups. Even longer-term followup of participants in these trials could be very informative.

Applicability to Vulnerable Populations

As discussed, research on treating obesity must be considered in terms of its applicability to the general population of obese children and adolescents and, in particular, those bearing the greatest burden due to higher prevalence of obesity. These vulnerable groups include racial and ethnic minorities[13,15] and those within lowest income groups,[19] who disproportionately bear the brunt of the obesity epidemic.

Minority involvement in addressing the obesity epidemic will be essential, and as such, their involvement in obesity research is critical. Five[71,74,75,77,89] of the behavioral intervention trials with short-term outcomes had 10 percent or more of the children and adolescents in their samples classified as Hispanic, including two trials that comprised only Mexican-American participants.[71,75] The remaining three reported 24.7 percent,[74] 15.9 percent,[77] and 12.5 percent[89] Hispanic samples. All of these, except the trial with the least-intensive intervention[89] found that the intervention programs improved weight outcomes. The highest-intensity trial[74] of these five reported that there were no differences in any outcome measure between ethnic groups. This,

coupled with the fact that both of the trials with 100 percent Mexican-American participants were successful, indicates that behavioral interventions can have an impact in Hispanic young people. Two of the trials had more than 10 percent of their samples classified as Black,[74,76] one of which included 38.5 percent Black children. This trial successfully promoted weight loss[74] and reported no ethnic differences on any outcomes. The other [89] did not improve weight loss outcomes, included 26.3 percent Black youth, and did not report on the impact of ethnicity on treatment outcome. None of the trials with maintenance outcomes reported more than minimal inclusion of Black or Hispanic children and adolescents.

We found no evidence to suggest that medication treatment is more or less effective in Black or Hispanic than in White youth. Black and Hispanic youth were present in the samples of most of the medication trials, although only three[98,99,104] examined differential impact of treatment by ethnicity: large-scale trials of sibutramine,[98] orlistat,[99] and a small trial of metformin.[104] None of these trials found that race had an effect on response to treatment. Data on minority youth in surgical case series were reported in only two trials,[108,111] which involved a total of nine Black and seven Hispanic youth between the two trials. No results were reported specifically on the minority youth in either study.

Little was reported about the socioeconomic status of participants in any of the studies. Given the lack of universal access to health care, however, programs delivered through health care settings could be out of reach of many. Public school programs, however, could be available to most if not all children.

Applicability to Real-world Settings

While behavioral interventions are all ostensibly applicable to real-world settings, three of the trials[69,71,75] conducted in schools involved programs that would likely be truly feasible for schools to offer during school hours as alternative health and physical education classes without extensive financial investment. All three of these programs were conducted all or mostly during school hours, and could be included in a school curriculum with some additional resources to support teacher training and planning, the acquisition of materials, and consultation with experts such as dietitians and behavioral specialists. Research on dissemination of programs such as these would be extremely valuable.

Higher intensity programs that were conducted in specialty care settings may also be feasible for many health care settings, perhaps at little extra cost. It may be possible to adapt the detailed protocols developed for use in the trials included in this review. For example, the comprehensive and effective Bright Bodies weight management program developed by Savoye and colleagues,[74] was facilitated by a registered dietitian or social worker and an exercise physiologist. A team of professionals in these or related fields would likely have the requisite training to conduct this type of program without extensive additional training. Third-party payment for these types of programs or indication of their cost-effectiveness would assist in their uptake in the real world.

Two of the behavioral intervention programs specifically addressed the use of very-low-intensity interventions (approximately four hours of total intervention time) that could be integrated into primary care.[77,78,84] Only one of these improved short-term weight loss,[77] and could be feasible for implementation in some primary care practices, if it is proven to be beneficial through replication. This program relied on bachelors-level support staff to provide adjunctive care via mail and phone counseling, thus relieving the primary care provider of some of the burden of conducting the intervention. Dissemination research would be needed to truly determine the wide-spread feasibility of this and other ostensibly feasible programs.

While pharmacological treatments have been studied in multi-site clinical trials, which enhances their applicability, treatment adherence outside of the trial setting and longer term weight impacts remain unclear. And, as recommended by experts, surgical treatments should probably be delivered in centers of excellence for bariatric surgery, with adaptation to the nutritional, psychological, and medical needs of adolescents.[45]

Contextual Issues

Factors Contributing to the Recent Increase in Childhood Obesity

While many experts have speculated on the causes of the recent increases in childhood obesity,[145,146] data are not available to conclusively determine causality. Evidence does support, however, a relationship between childhood obesity and several factors, such as overall physical activity, sedentary behaviors (e.g., watching television, playing video games, and spending time on computers), and intake of sweetened beverages.[11] Children (ages 2 to 17) average 4.7 hours per day "screen time" (covering cluster of activities involving television and computer screens, such as TV viewing, DVDs/videotapes, video games, computer games, e-mail and other computer activities).[147] Cross-sectional data show that higher prevalence of obesity is associated with more hours per day watching television.[136,137] Also, an obesity prevention program that reduced screen time by an average of almost ten hours per week also resulted in a BMI reduction of 0.45 kg/m^2 in sample of 3rd and 4th grade school children.[138] Environmental factors have likely reduced the amount of physical activity children get currently. For example, in 1969, 42 percent of children walked to or rode their bikes to school, while only 16 percent of children did so in 2001.[148] Also, enrollment in physical education classed declined from 41.6 percent in 1991 to 28.4 percent in 2003 in high school students.[149] Longitudinal and cross-sectional observational data have demonstrated that higher levels of physical activity tend to be associated with lower BMIs in children.[136,150] In one study, an increase in one hour/day of physical activity was associated with a BMI decrement of 0.22 kg/m^2 in boys and 0.16 kg/m^2 in girls after one year.[150]

Similarly, intake of sweetened beverages has also increased and appears to contribute to childhood obesity.[11,151-153] Between the late 1970s and the late 1990s, average daily intake of sweetened beverages increased from 5 ounces to 12 ounces in 6 to 17 year-olds.[153] BMI increases by an estimated 0.01 kg/m^2 with every 100 grams of regular soda consumed daily in adolescent girls, but this is not true of other beverages.[151] The odds of obesity increases by 60 percent with each additional serving of sugar-sweetened soda consumed in children.[154]

Preventing Childhood Obesity and Overweight

While this report focuses on the effectiveness and benefits of treatments in children and adolescents who are already overweight or obese, the challenge of achieving significant weight loss (and the uncertainty as to how well any weight reduction can be maintained) reaffirms the importance of obesity prevention. Obesity prevention is a critical component of the full breadth of a public health approach to overweight and obesity among American children and adolescents. Preventive approaches address some of the factors discussed above and emphasize helping children and adolescents develop lifelong healthy habits, in order to prevent the development of overweight or obesity during childhood and into adulthood. Obesity prevention should be conceptualized broadly, to include ecological interventions as well as health promotion campaigns in schools, communities, and health care settings.

Calling for public health action at its broadest and most inclusive level, the Institute of Medicine (IOM) created a set of 10 integrated recommendations for families, schools, communities, the public sector, and the private sector to prevent the development of obesity in the majority of children and adolescents in the United States[1] (see Table 14). In addition to their recommendations to parents for creating a home environment conducive to a healthy lifestyle, they recommend that schools provide regular physical activity and an environment that facilitates eating healthy foods, with the support of federal and state departments of education and health and professional organizations. The IOM recommends that local governments, private developers, and community groups work together to expand opportunities for physical activity through recreational facilities, parks, sidewalks, and urban planning that encourages alternative forms of transportation. The IOM recommends that the advertising and marketing industry develop and strictly adhere to guidelines that minimize the risk of obesity in children and adolescents, and that the Federal Trade Commission monitor compliance with these standards. Policymakers and other leaders would do well to consider evidence on the full range of programs that constitute a broad scale approach to childhood obesity.

To support the broad public health recommendations called for in the recent IOM report, international experts are engaged in ongoing activities, including summarizing available research to inform best strategies for health promotion and primary prevention of childhood obesity through policies and programs in healthcare and other community settings. The CDC is undertaking a series of reports on evidence to support obesity interventions in schools, community-settings, and health systems, which are made publicly available as they are completed.[155] The CDC also provides statistics on the prevalence of childhood obesity by state and year, data from the School Health Policies and Programs Study and from the Youth Behavioral Risk Factor Surveillance System, and information about state and local programs.[156] The National Institute for Clinical Excellence (NICE) in the United Kingdom made its comprehensive evidence-based clinical guideline on both obesity prevention and treatment in adults and children available in December, 2006.[2] Other systematic reviewers have published reports recently examining the effectiveness of preventive interventions and factors associated with etiology and risks. The Robert Wood Johnson Foundation's Active Living by Design Program has sponsored considerable research that has supported a link between the built environment and physical activity. Reviews of the impact of urban planning and obesity have concluded that "(1) areas with mixed land use, greater residential and commercial densities, grid street networks, and sidewalks are associated with more walking, biking, and pubic transportation usage; and (2) children with access to parks, recreation facilities, and programs are more physically active than children without access" .[157] Given the relatively small effects seen in most behavioral interventions, and the fact that more invasive interventions are only appropriate for a small portion of the population, prevention programs are likely to be the most effective agents in slowing the growth of childhood obesity.

Review Limitations

Limitations in the Body of Evidence

The quality of research on treating child and adolescent obesity has improved substantially since the 2003 Cochrane review and our 2005 review which both enumerated concerns about the childhood obesity treatment literature, specifically regarding behavioral interventions. These concerns included small sample sizes, high attrition (among other quality issues), less than ideal

outcome measures, and highly heterogeneous treatment approaches.[51] Most (15/18) of the behavioral interventions included in our review were published since the end of the search window for these prior reviews, including seven published in 2007 and three in 2006. Several of the newly published trials have over 100 participants, although larger trials can be quite expensive. While retention remains somewhat problematic, eight of the 15 newer trials reported overall retention of 89 percent or higher. Outcome measurement has improved as well—almost all of the newer trials reported raw BMI scores or BMI SDS and all directly measured their participants rather than relying on self-report (though some did fill in missing data with self-report measures). A lingering quality issue, however, is that the blinding procedures for treatment allocation and outcomes assessment were often not described. And, research would be improved with more explicit reporting of intervention fidelity and of impacts on other outcomes (both harms and benefits, such as comorbidities), in addition to weight. Finally, while treatment trials remain quite heterogeneous, it is hoped that better reporting and growth in the research base will eventually allow determination of effective components of behavioral interventions.

While methods and reporting have improved, and the number of studies has increased, the large amount of heterogeneity in the behavioral intervention literature (e.g., populations, intervention intensity, settings, treatment components, types of outcomes assessed) makes providing summary measures of expected treatment effects still very difficult. Thus, our findings and meta-analysis should be interpreted with caution. While it appears that treatment settings were the major factor differentiating size of treatment effect, other factors such as treatment intensity and age also appear to be important and may have been inappropriately combined in our meta-analysis. Because change in BMI has a different meaning for children of different ages, it would have been preferable to analyze change in BMI SDS, which is adjusted for age and sex. However, many authors did not report BMI SDS, and because special software or look-up data are needed to calculate BMI SDS, it was not feasible to expect authors to provide this data upon request.

While larger trials of pharmacological treatments are quite recent (2005 and 2006), as are better quality surgical case series (2005 to 2007), the available treatment data for these approaches remains limited. There are only two weight-loss medications studied (sibutramine, orlistat), with few randomized trials overall, and only one large-scale trial of each of the medications. No trials were conducted among children age 11 years or younger, so no conclusions can be drawn regarding efficacy or safety for that age group. We found no data on long-term maintenance of treatment effect or safety. The longest treatment period studied was 12 months, and the only followup reported for either medication was 3 months after medication use terminated. Medication use may have either a positive or negative effect on long-term maintenance of weight changes, compared with exclusively behavioral approaches, so longer follow-up is very important. While we found sibutramine and orlistat each had one large-sample trial, these trials were not large enough to detect more rare but serious adverse effects. The high variability across trials in intensity and possibly of intervention fidelity for behavioral interventions hampered our ability to determine both the combined and independent effect of the medication.

Surgical case series are not considered to be strong evidence as these are non-comparative studies. Without a good understanding of the natural history of weight in severely obese children, it is difficult to determine if the case series are giving an accurate estimate of the effect of surgery compared with no treatment. Lack of prospective, research-designed data collection also limits the results.

The research on all types of obesity treatments remains limited for its focus on obese (or highly obese) children and adolescents. While focus on more obese adolescents is appropriate for pharmaceutical and surgical treatments, future researchers evaluating all three types of weight management approaches should address current limitations by ensuring that their studies enroll the range of obese (or overweight) children and adolescents who might benefit, and for whom the level of treatment-associated risk is appropriate. Future researchers should also address limitations in research on children under aged 6 and ensure that treatment studies enroll and evaluate race-specific effects among adequate numbers of racial and ethnic minority participants. Further data on long-term maintenance of treatment effects (benefits and harms), and better reporting of the effect of treatment on co-morbidities will address these important limitations in the currently available evidence.

Limitations in our Approach

We conducted comprehensive searches of multiple electronic databases (including those with dissertation abstracts), reviewed bibliographies, and contacted experts, but did not hand-search or otherwise review gray literature. We may not have located all relevant studies through this approach. We also did not formally assess for publication bias, given the heterogeneity of outcomes reported in included studies. Thus, it is possible that our review overestimates overweight treatment efficacy due to the "file drawer" problem whereby ineffective treatment studies are more likely to be unpublished. Finally, our review did not include all studies that others might consider relevant. We did not do a comprehensive assessment of comparative effectiveness trials, as our primary goal was to determine whether treatment worked and the size of the effects compared with no treatment. The comparative effectiveness literature was fairly extensive, and included considerable older work completed by Epstein and colleagues as well as other researchers, which represents the majority of research available for earlier reviews. We could not be confident that comparative effectiveness results would tell us about the overall effectiveness of either treatment approach tested because good, recent data could not be found on the natural history of childhood obesity. Also, there was a great deal of variability in the basic weight management approach and in the reporting of the programs, so we did not believe that effectiveness of individual components could be accurately isolated. After consultation with our Technical Expert Panel, we chose to limit our use of comparative effectiveness trials to further explore approaches (e.g., physical activity components, behavioral management techniques, and parent involvement) that seemed to be important components in those interventions that were shown to be effective when tested against minimally treated control groups.

Our examination of other beneficial outcomes was limited to studies that met our general inclusion criteria, including reporting some measure of weight change six months or more after the baseline assessment. Given the primary purpose of this review (focus on weight management) and with support of our Technical Expert Panel, we did not include trials that reported other beneficial outcomes without some measure of weight change, and therefore may have missed some reports of other beneficial outcomes.

We did not address the impact of population-based prevention programs on weight reduction in overweight or obese children. These programs are primarily targeted at preventing obesity, but since some children participating in these programs are already overweight or obese when they begin, it would be useful to know the degree to which overweight and obese children benefit. It would also be useful to know whether overweight and obese children suffer deleterious effects of such programs, such as increased dieting, increased teasing, or poorer self-esteem.

Emerging Issues/Next Steps

In order to have a real impact on childhood obesity, a broader approach to obesity care may be required within the health care system and in connecting the health care system with efforts in the broader community. Dietz and colleagues[158] have proposed a model of care in which self-management by the patient or parent is considered central. The health care system supports self-management by making decision support tools available to office-based providers, teaching providers to help children and adolescents with excess weight and their families to make changes and access helpful resources, help increase patient confidence in their ability to make changes. Barlow and colleagues[5] have recommended a complementary office-based system that relies on a network of health system resources (such as pediatric dietitians or behavioralists) and referral resources (including community resources and specialty treatment settings with access to a multidisciplinary team experienced with childhood obesity). Both groups recognize that health plans also have a role to play in changing the environment, particularly to support obesity prevention, through partnerships with schools and community organizations.[158,159]

Given the importance of child and adolescent obesity worldwide, this is an extremely active area for ongoing research, for clinical and public health guideline development, and for development of policies that affect all aspects of society. Federal agencies and private foundations, such as the Robert Wood Johnson Foundation,[160] have put very high priority on funding obesity research as well as disseminating findings once research is completed. Thus, this issue will require frequent revisiting for those intending to make policy and clinical decisions based on the most up-to-date thinking and evidence available.

We identified over 20 ongoing clinical studies that investigate the broad spectrum of issues related to obesity in children and adolescents.[161] About half focus on adolescents (12 to 18 years) while the other half enroll children 7 to 11 years. The only trial focusing on the very young (3 to 5 years) is a primary prevention trial. Almost all of these studies include behavioral interventions to improve healthy diet and/or physical activity among already overweight or obese young people in order to reduce BMI or body fat. However, a few focus on environmental interventions such as integrating activities at home and in schools to reduce sugar-sweetened beverage consumption or on primary prevention through engaging children and caregivers in a home-based or community recreation center program to improve healthy eating and physical activity. A range of settings, including primary care, specialty outpatient treatment settings, and schools are involved. A few focus on high-risk groups, including those in special education classes, Latinos or Blacks, or those at high-risk for diabetes. Several focus on surgical outcomes in obese adolescents. The results of these studies are expected beginning in 2008 and continuing through 2018. We expect that many more trials will be added to this roster, given the ongoing importance of obesity research.

Future Research

Based on this review, we have several recommendations for priorities for funding additional research in obesity treatment. These recommendations also reflect input from our Technical Expert Panel. The relative importance of funding treatment studies (as compared to prevention studies) is beyond the scope of this report, but bears consideration.

Childhood overweight has been the focus of considerable research in recent years, and certainty in the short-term effectiveness of behavioral intervention programs in school and

specialty healthcare treatment settings (and perhaps primary care) is emerging. Replication of behavioral intervention trials (particularly given their heterogeneity of treatment components) is needed to confirm the benefits of these programs, to estimate their likely effects in real-world settings, to determine their feasibility and sustainability, and to report on cost-effectiveness. Understanding important components of behavioral interventions is an ongoing need. To help clarify which components of these programs are most important, researchers should provide consistent and detailed descriptions of treatment components, including information on intensity and duration of treatment components. In addition, trials should report on program adherence, including receipt of treatment, quality of delivery, participant responsiveness, and whether any of these factors varied by subgroups. This would enable reviewers to distinguish small group differences due to difficulty in adhering to the treatment program from ineffectiveness of the program as designed for that subgroup. Consistency in reporting of weight-related outcomes is also crucial for being able to analyze the literature as a body and to allow statistical pooling, as well as potentially exploring the importance of treatment components statistically. Future meta-analyses would be facilitated by all studies consistently reporting at least these weight-related measures: BMI, change in BMI, BMI SDS, and change in BMI SDS. Similarly, all studies and trials of weight management treatments should systematically assess and report on possible harms, on changes in weight-related co-morbidities, on changes in psychosocial and related outcomes, and should monitor and report other unanticipated effects, particularly associated with more invasive treatments. And, once it is established the degree to which multi-factorial treatments can resolve weight-related co-morbidities, it will be critical to establish whether certain intervention components (e.g., increased physical activity, fat-mass reduction, modification of dietary macronutrient or micronutrient intakes) are the key drivers of health benefits.

Longer-term followup is needed to confirm maintenance of treatment and other health effects and to assess longer term risks or harms, preferably with outcomes measured at the end of treatment and at fixed follow-up points, such as 1, 2, and 5 years from baseline. As further research elucidates both short- and long-term health benefits, more appropriate clinical treatment planning will be possible, particularly for children and adolescents who are not experiencing immediate weight-related health consequences. There is a particular need for more information on the maintenance of treatment effect in youth taking sibutramine and orlistat for weight loss or undergoing bariatric surgery. Followup data at least one and ideally up to 3 years after pharmaceutical treatment has ended and for at least 2 to 5 years (and ideally through mid-adulthood) after surgery will be very important for determining the impact of these treatments on the ability of adolescents to maintain their weight loss. Given our limited certainty about the quality of the behavioral interventions delivered within current pharmaceutical trials, exploring whether greater treatment effects are possible when pharmacotherapies are combined with proven, effectively delivered behavioral interventions could be important. And, as effective treatment data accrue, it would also be useful to explore whether different subgroups of patients respond better to different types of treatments within a single modality (e.g., different medications or behavioral approaches), different treatment modalities, (behavioral interventions as opposed to pharmacotherapies), or different treatment combinations (e.g., behavioral only vs. behavioral with pharmacotherapy). Similarly, longer term monitoring for harms, treatment failures, or reversals after bariatric surgeries is important to understand their desirability in adolescents who still face growth and maturation issues as well as future reproductive issues. And, as the use of medications to treat obesity increases in adolescents, it will be important to

monitor and publish safety information. Large comparative cohort studies could examine real world adverse events and adherence, while case-control studies of obese adolescents taking these medications with age-, weight- and sex-matched controls could help explore rare but serious side-effects. Health care systems with electronic medical records that track BMI, medications, diagnoses, and procedures would be well-placed to conduct such studies.

Ideally, randomized controlled trials comparing bariatric surgeries would provide data to more rigorously evaluate the efficacy of surgical procedures in adolescents. For safety monitoring, and to monitor outcomes in real-world settings, a national prospective registry of bariatric surgery procedures in adolescents with funded data collection and extended followup (outside of clinical care requirements) would be of enormous value. Also, since bariatric surgery is associated with very high costs, linked to both admission and followup by a multidisciplinary team, cost-effectiveness analyses would be very useful.

More studies are needed in understudied populations: in minority children and adolescents for types of treatments; in younger children (5 years and under) for behavioral interventions; and in children who are overweight but not obese, behavioral interventions. Future studies should also evaluate specific approaches that have been advocated by experts for treating excess weight in childhood and adolescence. For example, the Expert Committee [5] has recently advocated a stepped care approach that is pragmatic and evidence-informed, but has never been tested through formal research. Also, we found no controlled trials on more aggressive dietary treatments, such as protein-modified fasts, which may be of use in very obese children for whom more invasive treatments would be considered. It could be beneficial to compare aggressive dietary treatments to both standard weight management approaches such as the stop light diet, and to pharmacological and surgical approaches. Finally, recent data suggest health benefits in adults with physical activity increases (without weight loss); determining whether exercise has a positive effect on health independent of weight loss in children and adolescents could provide an important opportunity for health improvement.

The health effects of childhood obesity (particularly independent of the long-term increased risk of adult obesity and its attendant morbidity) are still not well enough understood. Researchers must ask themselves, “What are the best ways to improve the current and future health of obese, as well as overweight, children and adolescents?” In addition to the research recommendations above, a broader understanding of the prevalence and implications of obesity-related disorders in childhood, and of the natural history of overweight and obesity are needed to answer this question. Documentation of changes in BMI (growth trajectories) and their determinants---in those who are underweight, normal weight, overweight, and obese, beginning at various time points in childhood and adolescence, and considering males and females and different racial/ethnic subgroups separately---would be very useful. A better understanding of the natural history of this condition will be important to complement the immediate efforts at prevention and intervention, and will help inform what is considered desirable outcomes from these efforts.

The causes of the dramatic increases in obesity are not well understood, although many potential causes have been hypothesized. Population-based prevention trials targeting factors that have changed in recent decades and that are related to obesity may help determine some causes of the increases in childhood obesity.

Finally, just as the portability of research-tested interventions into the real world must be tested in dissemination trials, it is also important for researchers to make efforts to describe results and implications in real-world terms that can be understand and used by policy makers

and the general public. Being clear about how much weight loss a child may be expected to experience, or how much weight gain is prevented, is crucial. It is very useful to lay readers if researchers provide illustrative examples and ranges of outcomes in terms that the public understands, such as pounds (in the United States) or kilograms, since valid research measures, such as BMI and BMI SDS, have little intuitive meaning for most lay people. To the extent possible, it is important for researchers to translate clinical outcomes such as changes in blood pressure and fitness levels into terms that demonstrate whether these changes are likely to have any real impact on a child's health. Ongoing epidemiologic research within children and adolescents who have made favorable weight-related changes to help establish the health impact of various degrees of weight change on short-term and longer term health outcomes will be critical in this regard.

Conclusions

Much headway has been made in the past several years in determining the effectiveness of treatments for obese children and adolescents. Behavioral interventions have been studied in children and adolescents aged 5-18 years, while adjunctive pharmacological treatments or bariatric surgeries have been studied only in highly obese adolescents. Across treatment settings (schools, specialty health care treatment settings, and perhaps primary care) and ages, behavioral interventions have demonstrated beneficial effects on weight compared with no or minimal treatment. Effects are small to moderate after 6 to 12 months of treatment. Some evidence supports more robust effects on weight in specialty treatment settings, with weight changes in some instances similar to those achieved through pharmacological treatments combined with behavioral interventions. Limited evidence supports maintenance of behavioral treatment effects for at least 12 months after treatment ends. Effective behavioral interventions address healthy lifestyle, utilize behavioral management techniques, provide physical activity as part of treatment, and involve parents (particularly in children under aged 12 years). Sibutramine plus a behavioral intervention can lead to moderate weight loss over 12 months of treatment in very obese adolescents, with smaller treatment effects from Orlistat treatment. The evidence base for pharmacological treatments is limited to a one large multicenter study for each type of medication, along with a small number of other trials. No trials provide follow-up after treatment has been discontinued. The research on surgical interventions is limited to fair- or poor-quality case series, which are noncomparative studies, conducted in highly selected morbidly obese adolescents. Few data are available to assess either beneficial or harmful consequences more than 12 months after surgery. Based on incomplete follow up of a limited number of patients, available data suggests that surgical interventions in highly selected morbidly obese adolescents can lead to moderate to substantial weight loss in the short to medium term and to resolution of co-morbidities, such as sleep apnea and asthma. Short-term adverse effects or complications occur in 10 to more than 30 percent and vary with the type of surgery, while longer term risks and maintenance of weight loss is hard to establish with currently available data.

Clarifying the contribution of various treatment approaches in achieving short-term and long-term health benefits (as well as weight loss) is imperative in all ages of children and adolescents and across all levels of overweight and obesity. Given safety concerns and possibly growing use, bariatric surgeries and pharmaceutical approaches require careful monitoring and ongoing research. Since most children and adolescents who are overweight or obese will likely be best-served by behavioral interventions since they appear to have relatively few associated risks,

further research in this area is imperative. Thoughtful planning by funding agencies to fund studies that elucidate the role of common behavioral treatment components across a range of overweight subjects and settings would be very beneficial. And, given how difficult it is to lose weight, as evidenced by the generally modest effect sizes for all but the most invasive interventions, efforts to prevent childhood overweight and obesity through obesity prevention strategies and programs offer very important complements to treatment approaches in addressing the current obesity epidemic.

Table 13. Main findings of weight reduction programs in children and adolescents

# of trials	Age	Mean BMI at entry	Trial reported outcomes (trials with significant effects noted with *and bolding)	Range of BMI reduction in effective treatments	Adverse effects
Behavioral interventions					
8	5-12 yr (n=900)	20-24 kg/m^2 Obesity category: >95th percentile	**Short-term**: Effective: 2 of 6 Golley[83]; Graf[70,86]; **Kalavainen**[72]*; McCallum[78,84]; Rooney[80]; **Senediak**[88]* **Maintenance**: Effective: 3 of 4 McCallum[78,84]; **Nemet**[79]*, **Flodmark**[81]*, **Kalavainen**[72]*	**Short-term**: *School:* 0.8 kg/m^2 group difference *Setting NR:* 7 to 13 percentage points greater reduction in percent overweight **Maintenance**: *School:* 0.7 kg/m^2 group difference *Specialty Care*: 1.7 to 3.2 kg/m^2 group difference	Programs showed no effects on growth No effect on eating disorders or body image Very minimal injury documented during exercise programs
4	12-18 yr (n=246)	31-35 kg/m^2 Obesity category: >>95th percentile; Class I adult obesity	**Short-term**: Effective 2 of 3 **Carrel**[69]*; Celio[76]; **Saelens**[77]* **Maintenance**: Effective: 1 of 1 **Mellin**[82]*	**Short-term**: *School:* 1.06 kg/m^2 group difference *Primary Care:* 1.3 kg/m^2 group difference **Maintenance**: *Specialty Care*: 10 percentage points greater decrease in percent overweight	
6	Mixed children and adolescents (n=648)	25-36 kg/m^2 Obesity category: >>95th percentile; Class I adult obesity	**Short-term**: Effective: 6 of 6 **Braet**[85]*; **Gillis**[87]*; **Johnston**(a)[75]*; **Johnston**(b)[71]*; **Reinehr**[73]*; **Savoye**[74]* **Maintenance**: Effective 1 of 1 **Reinehr**[73]*	**Short-term**: *School:* 0.8 to 2.07 kg/m^2 group difference *Specialty Care*: 1.9 to 3.3 kg/m^2 group difference; 0.12 BMI SDS group difference; *Residential Treatment*: 57 percentage points greater reduction in percent overweight **Maintenance**: *Specialty Care*: 1.7 kg/m^2 group difference	

# of trials	Age	Mean BMI at entry	Trial reported outcomes (trials with significant effects noted with *and bolding)	Range of BMI reduction in effective treatments	Adverse effects
Pharmacological treatment (sibutramine, orlistat) + behavioral intervention (BI) †					
6‡	12-18 yr (n=1271)	35-40 kg/m^2 Obesity category: >>95th percentile; Class II adult obesity	**Short-term**: Sibutramine: Effective: 4 of 4 **Berkowitz**(a)[97]*; **Berkowitz**(b)[98]*; **Garcia-Morales**[100]*; **Godoy-Matos**[101]* Orlistat: Effective: 1 of 2 **Chanoine**[99]*; Maahs[102] **Maintenance**: None	**Short-term**: *Sibutramine+BI vs Placebo+BI*: *6 mo* -3.2 to -3.6 kg/m^2 vs -0.9 to -1.8 kg/m^2 Group difference: 1.6 to 2.7 kg/m^2 *12 mo* -2.9 vs -0.3 kg/m^2 Group difference: 2.6 kg/m^2 *Orlistat + BI:* *12 mo* -0.55 kg/m^2 vs 0.3 kg/m^2 Group difference: 0.85 kg/m^2 **Maintenance**: Not available	Sibutramine: Serious adverse effects: 2.7% (sibutramine) vs 1% (placebo) Sibutramine had significantly increased HR, SBP, abdominal complaints, and constipation No effects on growth seen Orlistat: Serious adverse effect 3% in both drug and placebo Significantly greater GI side effects (>30% on drug) No effects on growth

Case series with usable weight outcomes	Age	Mean BMI at entry	Case series with reported weight outcomes	Range of BMI reduction after surgery	Adverse effects
Surgical treatments (based on non-comparative case series)					
Banding surgical technique					
3	12-18 (n=128)	43-48 kg/m^2	**Short-term (trials with distinct time point)**: Angrisani[114]; Dolan[115,116]; Nadler[111]	**Short-term**: 5.0 to 10.2 kg/m^2 (n=122)	**Laparoscopic (all studies)** Band slip or removal: 10-13% Nutritional-related: 17%
		Obesity category: Class II adult obesity or morbid obesity	**Maintenance (trials with distinct time point)**: Angrisani[114]; Dolan[115,116]	**Maintenance**: (1-5 years) 7.3 to 12.7 kg/m^2 (n=59)	
Gastric bypass					
12	12-18 (n=81)	46-57 kg/m^2	**Short-term (trials with distinct time point)**: Lawson[112]; Soper[120]; Sugerman[108]	**Short-term**: 15.1 to 20.7 kg/m^2 23 to 30% body weight lost (n=81)	**Laparoscopic + open (all studies)** Major post-operation complications: 5.5% Any complications first year after surgery: 30-39% Severe complications or death: 6% Re-operation, hospital or ICU admission: 14%
		Obesity category: Morbid to super obese	**Maintenance (trials with distinct time point)**: Sugerman[108]	**Maintenance**: (1-5 years) 15.8 to 19 kg/m^2 (n=33)	

*Statistically significant effect
† Metformin trials not included as these address only obese adolescents selected as high-risk for type 2 diabetes mellitus
‡ Excludes one trial of sibutramine with only 3 months of treatment and lower BMI entry criterion (30-33 kg/m^2) VanMil[103]
Abbreviations: NR – not reported; GI – gastrointestinal; HR- heart rate; SBP- systolic blood pressure; BI – behavioral intervention

Table 14. National public health priority recommendations from IOM for childhood and adolescent obesity prevention

Recommendation 1. National Priority. Government at all levels provides coordinated leadership for the prevention of obesity in youth and children, with coordinated budgets, policies, and program requirements and with an increased and sustained commitment of federal and state funds and resources.

Recommendation 2. Industry. Industry should develop and promote products, opportunities, and information that will encourage healthful eating behaviors and regular physical activity.

Recommendation 3. Nutrition labeling. FDA should revise nutrition labeling and health claims approaches so that parents and youth can make informed product comparisons and decisions to achieve and maintain energy balance at a health weight.

Recommendation 4. Advertising and Marketing. Industry should develop and strictly adhere to marketing and advertising guidelines that minimize the risk of obesity in children and youth, and the FTC should be the monitoring agency for compliance with these standards.

Recommendation 5. Multi-Media and Public Relations Campaign. DHHS should develop and evaluate a long-term national multi-media public relations campaign focused on obesity prevention in children and youth.

Recommendation 6. Community Programs. Local governments, public health agencies, schools, and community organizations should collaboratively develop and promote program to encourage healthful eating behaviors and regular physical activity, particularly for high-risk populations in order to eliminate health disparities.

Recommendation 7. Built Environment. Local governments, private developers, and community groups should expand opportunities for physical activity through recreational facilities, parks, playgrounds, sidewalks, bike paths, routes for walking or biking to school, and safe streets and neighborhoods, particularly for populations at high-risk of childhood obesity.

Recommendation 8. Healthcare. Pediatricians, family physicians, nurses, and other clinicians should engage in the prevention of childhood obesity, with support from professional organizations, insurers, and accrediting groups for individual and population-based obesity prevention efforts.

Recommendation 9. Schools. Schools should provide a consistent environment conducive to healthful eating behaviors and regular physical activity, supported by federal and state departments of education and health and professional organizations.

Recommendation 10. Home. Parents should promote healthful eating behaviors and regular physical activity for their children through breast-feeding, providing health food and beverage choices, teaching children to make healthful food and beverage choices, supporting regular physical activity, limiting recreational screen time to under 2 hours per day, monitoring and discussing weight status with the child's healthcare clinician, and serving as positive role models.

Adapted from Preventing Childhood Obesity: Health in the Balance. IOM 2005.

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Appendix A: Exact Search String

Database: MEDLINE, Database of Abstracts of Reviews of Effectiveness, Education Resource Information Center, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, NICE, PsycInfo
<2003 to December 2007>
Search Strategy:
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1 exp "Obesity"/
2 "Weight-Gain"/
3 "Weight-Loss"/
4 (obesity or obese).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
5 (weight gain or weight loss).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
6 (overweight or over weight or overeat$ or over eat$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
7 weight change$.mp.
8 ((bmi or body mass index) adj2 (gain or loss or change)).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
9 weight maintenance.mp.
10 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9
11 limit 10 to child <6 to 12 years>
12 limit 10 to adolescent <13 to 18 years>
13 limit 10 to preschool child <2 to 5 years>
14 (child$ or adolescen$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
15 (teenage$ or young people or young person or young adult$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
16 (schoolchildren or school children).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
17 (pediatr$ or paediatr$).ti,ab.
18 (boys or girls or youth or youths).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
19 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18
20 exp "Behavior-Therapy"/
21 Social Support/
22 Family-Therapy/
23 exp "Psychotherapy-Group"/
24 ((psychological or behavio?r$) adj (therapy or modif$ or strateg$ or intervention$)).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
25 (group therapy or family therapy or cognitive therapy).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
26 ((lifestyle or life style) adj (chang$ or intervention$)).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
27 counsel?ing.mp.

28 social support.mp.
29 (peer adj2 support).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
30 ((children adj3 parent$) and therapy).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
31 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30
32 exp OBESITY/dt [Drug Therapy]
33 exp Anti-Obesity Agents/
34 lipase inhibitor$.mp.
35 (orlistat or xenical or tetrahydrolipstatin).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
36 (appetite adj (suppressant$ or depressant$)).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
37 sibutramine.mp. or meridia.ti,ab. [mp=title, original title, abstract, name of substance word, subject heading word]
38 (dexfenfluramine or fenfluramine or phentermine).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
39 bulking agent$.mp.
40 (methylcellulose or celevac).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
41 ((antiobesity or anti obesity) adj (drug$ or agent$)).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
42 guar gum.mp.
43 (metformin or glucophage).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
44 (fluoxetine or prozac).mp.
45 (Sertraline or zoloft).mp.
46 Diethylpropion.mp.
47 zonisamide.mp.
48 topiramate.mp.
49 (Octreotide or somatostatin or sandostatin).mp.
50 (Amantadine or symmetrel).mp.
51 (Glucagon-Like Peptide 1 or glp-1).mp.
52 (rimonabant or acomplia).mp.
53 (SLV 319 or SLV319).mp.
54 exenatide.mp.
55 liraglutide.mp.
56 vildagliptin.mp.
57 sitagliptin.mp.
58 (qnexa or contrave or excalia).mp.
59 exp OBESITY/dh [Diet Therapy]
60 "Diet-Fat-Restricted"/
61 "Diet-Reducing"/
62 "Diet-Therapy"/
63 "Fasting"/

64 (diet or diets or dieting).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
65 (diet$ adj (modif$ or therapy or intervention$ or strateg$)).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
66 (low calorie or calorie control$ or healthy eating).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
67 (fasting or modified fast$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
68 exp "Dietary-Fats"/
69 (fruit or vegetable$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
70 (high fat$ or low fat$ or fatty food$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
71 formula diet$.mp.
72 59 or 60 or 61 or 62 or 63 or 64 or 65 or 66 or 67 or 68 or 69 or 70 or 71
73 "Exercise"/
74 "Exercise-Therapy"/
75 exercis$.mp.
76 (aerobics or physical therapy or physical activity or physical inactivity).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
77 (fitness adj (class$ or regime$ or program$)).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
78 (physical training or physical education).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
79 dance therapy.mp.
80 sedentary behavio?r reduction.mp.
81 73 or 74 or 75 or 76 or 77 or 78 or 79 or 80
82 exp OBESITY/su [Surgery]
83 "Surgical-Staplers"/
84 "Surgical-Stapling"/
85 "Lipectomy"/
86 "Gastric-Bypass"/
87 "Gastroplasty"/
88 (dental splinting or jaw wiring).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
89 (gastroplasty or gastric band$ or gastric bypass).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
90 (intragastric balloon$ or vertical band$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
91 (stomach adj (stapl$ or band$ or bypass)).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
92 biliopancreatic diversion$.mp.
93 liposuction.mp.
94 82 or 83 or 84 or 85 or 86 or 87 or 88 or 89 or 90 or 91 or 92 or 93
95 exp "Alternative-Medicine"/

96 (alternative medicine or complementary therap$ or complementary medicine).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
97 (hypnotism or hypnosis or hypnotherapy).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
98 (acupuncture or homeopathy).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
99 (chinese medicine or indian medicine or herbal medicine or ayurvedic).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
100 95 or 96 or 97 or 98 or 99
101 ((diet or dieting or slim$) adj (club$ or organi?ation$)).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
102 (weightwatcheR$ or weight watcher$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
103 (correspondence adj (course$ or program$)).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
104 (fat camp$ or diet$ camp$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
105 101 or 102 or 103 or 104
106 (family intervention$ or parent$ intervention$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
107 (parent$ adj2 (behavio?r or involve$ or control$ or attitude$ or educat$)).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
108 106 or 107
109 (systematic$ review$ or systematic$ overview$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
110 (quantitative$ review$ or quantitative$ overview$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
111 Evidence-Based Medicine/
112 evidence based review$.mp.
113 exp "Controlled-Clinical-Trials"/
114 exp "Research-Design"/
115 ((singl$ or doubl$ or trebl$ or tripl$) adj5 (blind$ or mask$)).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
116 (CONTROLLED-CLINICAL-TRIAL or RANDOMIZED CONTROLLED TRIAL or META-ANALYSIS).pt.
117 (control$ and (trial$ or stud$ or evaluation$ or experiment$)).ti,ab.
118 (comparison group$ or control group$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
119 random$.ti,ab.
120 matched pairs.mp.
121 (outcome study or outcome studies).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
122 (quasiexperimental or quasi experimental or pseudo experimental).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
123 (nonrandomi?ed or non randomi?ed or pseudo randomi?ed).mp. [mp=title, original title, abstract, name of substance word, subject heading word]

124 cohort studies/
125 (cohort adj (study or studies)).ti,ab.
126 cohort analys$.ti,ab.
127 case series.ti,ab.
128 longitudinal studies/
129 longitudinal$.ti,ab.
130 follow-up studies/
131 (follow up adj (study or studies)).ti,ab.
132 prospective studies/
133 prospective$.ti,ab.
134 109 or 110 or 111 or 112 or 113 or 114 or 115 or 116 or 117 or 118 or 119 or 120 or 121 or 122 or 123 or 124 or 125 or 126 or 127 or 128 or 129 or 130 or 131 or 132 or 133
135 10 and 19
136 32 or 33 or 34 or 36 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58
137 134 and 135 and 136
138 limit 137 to yr="2003 - 2007"
139 31 or 35 or 37 or 72 or 81 or 94 or 100 or 105 or 108
140 134 and 135 and 139
141 limit 140 to yr="2005 - 2007"
142 138 or 141
143 limit 142 to animals
144 limit 142 to humans
145 143 not 144
146 142 not 145
147 limit 146 to english language

Appendix B Table 1. Sample Data Abstraction Items for Behavioral Intervention Trials

Study Reference	Study characteristics	Patient characteristics	CONSORT Numbers, Retention	Inclusion/Exclusion Criteria
Description of Intervention Groups	Intervention Components	Components Score	Treatment Target Individual vs. Group Treatment	Treatment Intensity
Mean Entry Weight	Intervention phase 2-11 mo	Intervention phase 12-23 mo	Intervention phase 24+ mo	Post-Intervention
BMI Change Mean (SD)	Physiological Outcomes	Other anthropomorphic Outcomes (list)	Other Beneficial Outcomes	Adverse Effects (report findings)
Study Quality	Comment (mention which other outcomes significant), other outcomes reported that are not captured in previous columns			

Appendix B Table 2. Sample abstraction items for supplementary behavioral trials for key questions 2 & 5

Study Reference	Study Characteristics	Patient Characteristics	CONSORT Numbers, Retention	Inclusion/ Exclusion Criteria
Description of Intervention Groups	Treatment Target Individual vs. Group Treatment	Treatment Intensity	Mean Entry Weight	Intervention phase 2-11 mo
Intervention phase 12-23 mo	Intervention phase 24+ mo	Post-Intervention	Other anthropomorphic Outcomes	Study Quality
Comment, other outcomes reported that are not captured in previous columns				

Appendix B Table 3. Sample abstraction items for pharmacological intervention trials

Study Reference	Study Characteristics	Patient Characteristics	CONSORT Numbers Retention	Inclusion/Exclusion
Description of Intervention Groups	Dose/ Duration	Mean Entry Weight	Intervention phase 6-11 mo	Intervention phase 12-23 mo
Intervention phase 24+ mo	Post-Intervention	Physiological Outcomes Reported	Other anthropomorphic Outcomes	Adverse Effects
Study Quality	Comment (mention which other outcomes significant			

Appendix B Table 4. Sample abstraction items for surgical intervention trials

Study Reference	Country Setting Recruitment Source Years	Surgical Encounter Characteristics	Inclusion/Exclusion	Patient Characteristics (% with DM, IGT, hypertension, hyperlipidemia)
Duration of follow-up	Mean Entry Weight	Change in Weight	Resolution of co-morbidities post surgery	Other positive outcomes
Adverse effects	Study Quality			

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Study characteristics	Patient characteristics	CONSORT Numbers, Retention	Inclusion/Exclusion Criteria	Description of Intervention Groups
Braet et al 2003	CCT 76 children Residential obesity treatment center Belgium Physician referral Weight loss	Age: 10-17 (Mean=13) 60.5% Female (calc) % White: 93.4% (c) 93.4% White (calc) SES: NR Co-morb: NR	190 enrolled in residential program (est) 38 selected for study enrollment 38 age-sex-matched controls selected from wait list <u>Retention:</u> I: 31/38 (81.6%) C: 35/38 (92.1%)	<u>Incl:</u> Enrolled in treatment program <u>Excl:</u> Dx of Prader Willi syndrome or mental retardation	I: 10-month residential treatment, covering diet, physical activity, nutrition education, behavioral management/psychological intervention C: Waiting list
Carrel et al 2005	RCT 53 adolescents PE class USA One school Improved body composition, cardiovascular fitness, and insulin sensitivity in OW children	Age: 12-13 (Mean=12.5) 48% Female Race/Eth: NR SES: NR Co-morb: NR	55 invited 53 baseline eval 53 randomized: I: 27 C: 26 <u>Retention, published:</u> I: 27/27 (100%) C: 23/26 (88.5%) Retention, personal communication: I: 30 C: 23 denom unknown	<u>Incl:</u> age 12-13; BMI>95th %ile (norms not specified)	I: PE class emphasizing non-competative movement activities (e.g. walking, cycline, snow shoeing), maximizing minutes of movement (average 42 min/class), small nutritional component. Class size 12-14 C: PE class, typical competative, team sports emphasis (average 25 min/class, with opportunities for less athletic youth to hold back). Class size 35-40

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

			Treatment Target		
Study Reference	**Intervention Components**	**Components Score**	**Individual vs. Group Tx**	**Treatment Intensity**	**Mean Entry Wt**
Braet et al 2003	D, PA, BT	D=2; PA=2; Tx=2 Total=6	Child Individual and Group	I: 10 months residential (est 16 hrs/day * 5 days/wk * 44 wks = 3520 hrs) C: None (0 hrs)	BMI (Median): I: 33 (SD NR), C: 33 (SD NR) % OW: I: 75% C: 73%
Carrel et al 2005	D, PA	D=0; PA=2; Tx=0 Total=2	Child Group	I: 90 sessions (calc) 45 min/session 39 weeks (est) (90*45/60 = 67.5 hrs) C: 90 sessions (calc) 25 min/session 39 wks (est) (90*25/60=37.5 hrs)	BMI I: 32 ± 6 C: 30 ± 4

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Interv phase 2-11 mo	Interv phase 12-23 mo	Interv phase 24+ mo	Post-Intervention	BMI Change Mean (SD)	Physiological Outcomes
Braet et al 2003	10-mo % OW: I: 24% C: 79% p<0.001 Wt change: I: -19 kg (-41.8 lbs) C: +4kg (+8.8 lbs)	NA	NA	NA		Lipids: No Glucose tol: No BP: No Phys fitness: No
Carrel et al 2005	9-mo BMI: I: 33 ± 10 C: 30 ± 5 p=0.10	NA	NA	NA	Post-tx (9-mo) I: +1 (NR) C: 0 (NR) Follow-up: NR	Lipids: No Glucose tol: Yes BP: No Phys fitness: Yes

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Other anthropo-morphic Outcomes (list)	Other Beneficial Outcomes	Adverse Effects (report findings)	Study Quality	Comment (mention which other outcomes significant), other outcomes reported that are not captured in previous columns
Braet et al 2003	None	NR	No differences in change in height	Fair	Also measured eating psychopathology and child's self-perception in treatment group (but not control)
Carrel et al 2005	% body fat, fat-free body mass	NR	Among treatment participants, measures of "drive for thinness" and "external eating" declined, self-reported ratings of physical appearance, athletic competence, and social acceptance improved.	Fair	Significant improvement in intervention group relative to control group: % body fat, VO2max, oxygen consumption at heart rate of 170 beat/min, fasting insuling level, 1/insulin ration, glucose-insulin ratio

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Study characteristics	Patient characteristics	CONSORT Numbers, Retention	Inclusion/Exclusion Criteria	Description of Intervention Groups
Doyle et al, in press; Celio et al 2006	RCT 83 adolescents Setting for enrollment/assessment NR, Internet-based intervention USA (CA and MO) Media adverstisements; flyers in schools, medical facilities, and weight-loss organizations; referrals from pediatricians and school nurses Weight Loss and improved eating disorders attitudes/behaviors	Age: 12-18 (Mean 14.5) 62.5% Female 50% White 12.5% Hispanic 26.3% Black 11.3% Other SES: 43.1% parent college graduate or higher Co-morb: NR	155 assessed for eligibility 72 excluded: 14 did not meet criteria 25 not interested 33 did not attend/complete screening 83 randomized I: 42 C: 41 <u>Retention, in-person (personal communication):</u> I: 28/42 (66.7%) C: 29/41 (70.3%) Retention, incl self-report (published): I: 33/42 (78.6%) C: 33/41 (80.5%) ITT/baseline substitution analysis (published): I: 40/42 (92.2%) C: 40/41 (97.6%)	<u>Incl:</u> Age 12-18; ≥85th %ile for age and sex per CDC 2000 growth charts; Internet access at home or where regular use was possible <u>Excl:</u> Medical condition (e.g. endocrinologic diseases); use of prescription medication assoc with significant weight changes; complications of OW that contraindicated moderate physical activity (e.g. orthopedic disorders); reading ability <6th grade; curr/past eating disorder dx	I: Student Bodies 2 (SB2), Internet-delivered moderated cognitive-behavioral program; basic educational material; guided behavioral modification for wt loss; cognitive exercises for body image issues; gender-specific interfaces and content; on-line journal for recording food intake, physical activity, weight, triggers for body dissatisfaction; individual e-mail contact with moderator; discussion group; monthly newletter to parents C: Basic information on nutrition and physical activity

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

		Treatment Target			
Study Reference	**Intervention Components**	**Components Score**	**Individual vs. Group Tx**	**Treatment Intensity**	**Mean Entry Wt**
Doyle et al, in press; Celio et al 2006	I: D, PA, BT, PT C: D, PA	D=1; PA=1; Tx=1 Total=3	Child Individual and on-line Group	I: # sessions varied 60-120 min/wk encouraged 16-wks (est 1 hr/wk*16wks=16 hrs) (est 1 hr rather than 1.5 because partic read avg of 30% of material, and 35% of partic read <10% of material) C: 0 sessions (0 hrs)	BMI SDS: I: 2.19 ± 0.50 C: 2.19 ± 0.44 per CDC 2000 Growth Charts BMI: I: 34.6 ± 7.8 C: 33.9 ± 6.9

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Interv phase 2-11 mo	Interv phase 12-23 mo	Interv phase 24+ mo	Post-Intervention	BMI Change Mean (SD)	Physiological Outcomes
Doyle et al, in press; Celio et al 2006	4-mo, BMI SDS: I: 2.11 ± 0.51 C: 2.20 ± 0.43 p=0.03 BMI: I: 34.0 ± 7.6 C: 34.1 ± 6.6 n.s.			8-mo (4-mo post intervention), BMI SDS: I: 2.10 ± 0.51 C: 2.15 ± 0.48 p=.29 BMI: I: 34.4 ± 7.6 C: 34.3 ± 6.9 n.s.	Post-tx (4-mo) I: -0.6 (NR) C: +0.2 (NR) Follow-up (4-mo post-tx) I: -0.2 (NR) C: +0.4 (NR)	Lipids: No Glucose tol: No BP: No Phys fitness: No

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Other anthropo-morphic Outcomes (list)	Other Beneficial Outcomes	Adverse Effects (report findings)	Study Quality	Comment (mention which other outcomes significant), other outcomes reported that are not captured in previous columns
Doyle et al, in press; Celio et al 2006	None	Self-image (Shape Concern)	C group showed greater decline in Shape Concern than I group; no other differences in eating disorder pathology	Good	

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Study characteristics	Patient characteristics	CONSORT Numbers, Retention	Inclusion/Exclusion Criteria	Description of Intervention Groups
Flodmark et al 1993	CCT 43 children (plus 50 matched controls) Outpatient referral clinical setting Sweden Screening program in schools Prevention of progression to severe obesity	Age: 10-11 (Mean NR) 52% Female (c) Race/Eth: NR SES: NR Comorb: clinically euthyroid, blood pressures less than 140/90, none with signs of endocrine d/o	Tx groups: 1,906 screened, age 10-11 1,774 parents consent to study partic 49 BMI >23.0 43 randomized: I1 (conventional tx): 19 I2 (I1 + family therapy): 24 C (matched controls): 50 Unclear if controls pulled from same screening population as randomized <u>Retention:</u> I1: 19/19 (100%) i2: 20/24 (83%) C: 48/50 (96%)	<u>Incl:</u> BMI > 23.0 kg/m^2	I1: Conventional treatment: dietary counseling with dietitian, monthly visits to experienced pediatrician w interest in wt problems, low fat, 1500-1700 kcal diet prescribed, exercise encouraged I2: Same as above + family therapy C: Matched controls, no treatment

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

		Treatment Target			
Study Reference	**Intervention Components**	**Components Score**	**Individual vs. Group Tx**	**Treatment Intensity**	**Mean Entry Wt**
Flodmark et al 1993	I1: D, PA I2: D, PA, FC C: None	D=0; PA=0; Tx=2 Total=2 (for I2)	I1: Child, parent Individual I2: Family Individual	I1: 0-1 session w dietitian, 5 sessions w/ pediatrician minutes NR 14-18 mos (est 6 * 1 hr *2 family member= 12 hrs) I2: 0-1 session w dietitian, 5 sessions w/ pediatrician, 6 family therapy sessions minutes NR 14-18 mos (est 12 * 1 hr *2 family member = 24 hrs) C: None (0 hrs)	BMI: (Mean ± SE) I1: 25.5 ± 0.53* I2: 24.7 ± 0.36* C: 25.1 ± 0.35* (similar to 40-50% overweight range) *calculated SD (SE*sqrt(n)): I1: 0.53*sqrt(19)=2.3 I2: 0.36*sqrt(24)=1.8 C: 0.35*sqrt(50)=2.5

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference		Interv phase 2-11 mo	Interv phase 12-23 mo	Interv phase 24+ mo	Post-Intervention	BMI Change Mean (SD)	Physiological Outcomes
Flodmark et al 1993	NA		Post-tx (14-18 mos): BMI (Mean ± SE) I1=26.1 ± 0.72* I2=25.0 ± 0.53* C: (data not collected) *calculated SD (SE*sqrt(n)): I1: 0.72*sqrt(19)=3.1 I2: 0.53*sqrt(24)=2.6		~48-mo (30-34 mos post-intervention) BMI: (Mean ± SE) I1=27.1 ± 0.88* I2: 25.8 ± 0.73* C: 27.9 ± 0.61* p=.15 *calculated SD (SE*sqrt(n)): I1: 0.88*sqrt(19)=3.8 I2: 0.73*sqrt(24)=3.6 C: 0.61*sqrt(50)=4.3	Post-tx (14-18 mos): NA Follow-up (30-34 mo post-tx): I1: +1.6 (NR) I2: +1.1 (NR) C: +2.8 (NR)	Lipids: No Glucose tol: No BP: No Phys fitness: Yes

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Other anthropo-morphic Outcomes (list)	Other Beneficial Outcomes	Adverse Effects (report findings)	Study Quality	Comment (mention which other outcomes significant), other outcomes reported that are not captured in previous columns
Flodmark et al 1993	Triceps, Subscapular, Suprailiac skinfolds	None	NR	Fair	Skinfold measures all showed significantly greater decreases in family therapy group than conventional treatment group.

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Study characteristics	Patient characteristics	CONSORT Numbers, Retention	Inclusion/Exclusion Criteria	Description of Intervention Groups
Gillis et al 2007	RCT 27 children Primary care clinics in urban Jewish ultra-orthodox neighborhoods Israel 2 primary care clinics Weight loss, improvement in adverse metabolic consequences of obesity and obesity-related attitudes	Age: 7-16 (10.6 (calc)) %Male NR Race/Eth: 100% Jewish SES: NR Co-morb: NR	27 recruited 27 randomized I: 14 C: 13 <u>Retention:</u> 18/27 (66.7%) overall I: 11/14 (78.6%) C: 7/13 (53.8%)	<u>Incl:</u> Age 7-16; BMI>90th %ile; refered to author (endocrinologist) for eval of obesity	I: Basic discussion on health diet and exercise (at baseline and 3-months); asked to record food/exercise one day/week; weekly phone call to review food/exercise diary and encourage adherence to prescribed plan C: Basic discussion on health diet and exercise (at baseline and 3-months)

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Intervention Components	Components Score	Treatment Target: Individual vs. Group Tx	Treatment Target: Treatment Intensity	Mean Entry Wt
Gillis et al 2007	D, PA	D=0; PA=0; Tx=0 Total=0	Child Individual	I: 2 1/2 hr clinic visits + 24 weekly calls (est) # Min/session NR 26 weeks (est) (est 2*.5*hr*2(parent+child) + 24*.25 hr = 8 hrs) C: 2 clinic visits # minutes NR (est 2 hrs)	BMI SDS= I: 1.98 ± 0.21 C: 2.16 ± 0.34

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Interv phase 2-11 mo	Interv phase 12-23 mo	Interv phase 24+ mo	Post-Intervention	BMI Change Mean (SD)	Physiological Outcomes
Gillis et al 2007	6-mo BMI SDS: I: 1.93 ± 0.37 C: 2.23 ± 0.29 p=0.40 BMI SDS change: I: -0.045 ± 0.19 C: 0.075 ± 0.08 p=0.10	NA	NA	NA		Lipids: Yes Glucose tol: Yes BP: No Phys fitness: Yes

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Other anthropo-morphic Outcomes (list)	Other Beneficial Outcomes	Adverse Effects (report findings)	Study Quality	Comment (mention which other outcomes significant), other outcomes reported that are not captured in previous columns
Gillis et al 2007	None	Diet (self-report of change), PA (self-report of change)	NR	Fair	No significant group differences.

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Study characteristics	Patient characteristics	CONSORT Numbers, Retention	Inclusion/Exclusion Criteria	Description of Intervention Groups
Golley et al 2007	RCT 111 children teaching hospitals Australia media publicity and school newsletters Weight management in prepubertal children	Age: 6-9 (Mean 8.2) 64% Female (calc) 98% White SES: Index of relative socioeconomic advantage slightly above South Australian average Co-morb: NR	262 Initial phone screening completed 126 eligibility confirmed at medical screening 115 consented 111 completed baseline assessment 111 randomized: I1 (Parenting group): 37 I2 (Parenting + lifestyle): 38 C:(Wait list): 36 Retention: I1: 29/37 (78.4%) I2: 31/38 (81.6%) C: 31/36 (86.1%)	Incl: Age 6-9; OW, per International Obesity Task Force defn); Tanner Stage 1; caregiver willing to attend sessions and able to read and understand English Excl: BMI z-score >3.5; syndromal cause of obesity; medication use that may influence weight; dx of physical or developmental disability; sibling enrolled in study	I1 Parenting skills training, aims to promote parental competence to manage child's behavior with emphasis on dietary and activity behaviors in program examples, pamphlet covering eating and activity behaviors, I2: Parenting + Intensive lifestyle education covering wide variety of topics related to healthy eating, activity, and emotional sequalae of overweight such as self-esteem and teasing. C: Wait-list Control, 3-4 brief phone calls for encourage retention in study

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Intervention Components	Components Score	Treatment Target: Individual vs. Group Tx	Treatment Intensity	Mean Entry Wt
Golley et al 2007	I1: D (minimal), PA (minimal), PT I2: D, PA, PT C: None	D=1; PA=2; Tx=2 Total=5 (for I2)	Parent Group and Individual	I1: 4 group, 7 individual group=120 min indiv=15-20 min 21 wks (calc) (4*2 hrs + 7*.33 hrs =10.33 hrs) I2: 11 group 120 min # wks NR (22 hrs) C: 3-4 5-minute phone calls (0.33 hrs)	BMI: 24.3 ± 2.6 (overall) BMI z-score: I1: 2.76 ± 0.58 I2: 2.74 ± 0.58 C: 2.75 ± 0.39

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Interv phase 2-11 mo	Interv phase 12-23 mo	Interv phase 24+ mo	Post-Intervention	BMI Change Mean (SD)	Physiological Outcomes
Golley et al 2007	6-mo (1-mo post-intervention): BMI z-score: I1: 2.63 ± 0.53 I2: 2.52 ± 0.53 C: (NR)		NA	12-mo (7-mos post-intervention): BMI SDS: I1: 2.56 ± 0.79 I2: 2.43 ± 0.68 C: 2.60 ± 0.57 group*time effect p=0.76 BMI SDS reduction I1: 6% I2: 9% C: 5% (p=0.76, same analysis as above) % increased BMI SDS: I1: 24% I2: 19% C: 45% p<0.03		Lipids: Yes Glucose tol: Yes BP: Yes Phys fitness: No

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Other anthropo-morphic Outcomes (list)	Other Beneficial Outcomes	Adverse Effects (report findings)	Study Quality	Comment (mention which other outcomes significant), other outcomes reported that are not captured in previous columns
Golley et al 2007	Waist circumference	None	Height change did not differ between treatment and control conditions	Good	Waist circumference showed time*group interaction: intervention groups showed decline in waist circumference while control group did not. Also measured satisfaction with care

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Study characteristics	Patient characteristics	CONSORT Numbers, Retention	Inclusion/Exclusion Criteria	Description of Intervention Groups
Graf et al 2006 Graf et al 2005	Cluster-randomized RCT 276 children School Gemany 7 schools Weight loss	Age: 6-11 (Mean 8.4 (calc)) Sex: NR Race/Eth: NR SES: NR Co-morb: NR	1678 screened 276 screened OW or obese, randomized at school level I: 121 (46 (38%) agreed to participte in intervention) C: 155 <u>Retention:</u> I: 40/46 (87.0%) (among participants) 75/75 (100%) (among non-participants) C: 144/155 (93.5%)	<u>Incl:</u> Grade 1-4, attending one of randomly selected schools, Overweight or obese (>90th %ile per German percentile graphs of Kromeyer-Hauschild)	I: information on nutrition, health, and behavioral principles of weight management; physical activity; healthy meals; parent meetings to provide information and encourage family activities that support weight management C: Usual school health and P.E. activities
Johnston et al, 2007a	RCT 71 adolescents School Invitations sent to homes of all children in 6th and 7th grade in single school Weight loss	Age: 10-14 (Mean 12.5) 55% Female 100% Mexican American SES: NR	173 Consent forms distributed 102 not randomized (66 did not return consent form, 36 not OW) 71 randomized: I: 46 C: 25 <u>Retention:</u> I: 44/46 (95.6%) C: 22/25 (88.0%)	<u>Incl:</u> 6th or 7th grade at study school; BMI ≥ 85th %ile for age and gender, per 2000 CDC guidelines	I: Intensive Intervention: One class period five days/week, covering nutrition education; structured physical activity; cognitive-behavioral strategies; parent meeting to facilitate family adoption of healthy habits C: Self-Help: Instructed youth and their parents to use a book, Trim Kids; provided 12 weekly activities and maintenance activities

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

		Treatment Target			
Study Reference	**Intervention Components**	**Components Score**	**Individual vs. Group Tx**	**Treatment Intensity**	**Mean Entry Wt**
Graf et al 2006 Graf et al 2005	I: D, PA, SA, BT, PT C: None	D=1; PA=2; Tx=1 Total=4	Child, Parent Group, option for single-family consultations	I: 60 165-min (est) child sessions, 6 105 min parent session 30 weeks (60*2.75 hrs + 6*1.75 hrs = 175.5 hrs) C: No treatment (0 hrs)	BMI I (participants): 22.8 ± 3.6 I (non-partic): 21.1 ± 2.4 C: 21.7 ± 2.7 BMI SDS: I (participants): 1.99 ± 0.52 I (non-partic): 1.81 ± 0.44 C: 1.87 ± 0.41
Johnston et al, 2007a	I: D, PA, BT, PT C: D, PA, BT, PT	D=1; PA=2; Tx=1 Total=4	I: Child, parent Group C: Child, parent Individual	I: 4x/wk exercise for 12 wks, 30-35 min 1x/wk nutrition for 12 weeks, 35-40 min 3 monthly parent meetings 6 (calc) bi-weekly child meetings (5*.58hr*12 wks=35 hrs + 3 + (6*.58) = 41.5 hrs total) C: None (0 hrs)	BMI: I: 27.7 ± 5.0 C: 25.6 ± 3.4 BMI SDS: I: 1.86 ± 0.48 C: 1.64 ± 0.44 Weight, kg: I: 64.9 ± 16.9 C: 58.7 ± 9.1

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Interv phase 2-11 mo	Interv phase 12-23 mo	Interv phase 24+ mo	Post-Intervention	BMI Change Mean (SD)	Physiological Outcomes
Graf et al 2006 Graf et al 2005	9-mo change in BMI: I (participants): 0.3 ± 1.3 I (non-partic): 0.5 ± 1.3 C: 0.7 ± 1.2 n.s. Change in BMI SDS: I (participants): -0.15 ± 0.26 I (non-partic): -0.09 ± 0.31 C: -0.05 ± 0.27 p=0.03	NA	NA	NA	Post-tx (9-mo) I (participants): +0.3 (1.3) I (non-partic): +0.5 (1.3) C: +0.7 (1.2) Follow-up: NR	Lipids: No Glucose tol: No BP: Yes Phys fitness: No
Johnston et al, 2007a	6-mo Change in BMI: I: -0.16 ± 1.05 C: +0.64 ± 0.90 p<0.001 Change in BMI %ile: I: -1.50 ±3.61 C: +0.53 ± 2.12 p<0.01 Change in weight (kg): I: 1.90 ± 2.70 C: 3.49 ± 2.74 p<0.05	NA	NA	NA	Post-tx (6-mo) I: -0.16 (1.05) C: +0.64 (0.90) Follow-up: NR	Lipids: Yes Glucose tol: Yes BP: Yes Phys fitness: No

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Other anthropo-morphic Outcomes (list)	Other Beneficial Outcomes	Adverse Effects (report findings)	Study Quality	Comment (mention which other outcomes significant), other outcomes reported that are not captured in previous columns
Graf et al 2006 Graf et al 2005	Waist circumference	None	None	Fair	Children in both intervention groups (participants and non-partic) showed greated reduction in systolic BP than control group children
Johnston et al, 2007a	% Body fat	None	NR	Good	Children in the I group reduced their % body fat more than those in the C group

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Study characteristics	Patient characteristics	CONSORT Numbers, Retention	Inclusion/Exclusion Criteria	Description of Intervention Groups
Johnston et al, 2007b	RCT 60 adolescents School Invitations sent to homes of all children in 6th and 7th grade in single school Weight loss	Age: 10-14 (Mean 12.4 calc) 45% Female 100% Mexican American SES: NR	181 Consent forms distributed 121 not randomized (55 did not return consent form, 66 not OW) 60 randomized: I: 40 C: 20 <u>Retention:</u> I: 38/40 (95.0%) C: 19/20 (95.0%)	<u>Incl:</u> 6th or 7th grade at study school; BMI ≥ 85th %ile for age and gender, per 2000 CDC guidelines	I: Intensive Intervention: One class period five days/week, covering nutrition education; structured physical activity; cognitive-behavioral strategies; parent meeting to facilitate family adoption of healthy habits C: Self-Help: Instructed youth and their parents to use a book, Trim Kids; provided 12 weekly activities and maintenance activities
Kalavainen et al 2007	RCT 70 children School for CG, IC setting NR School nurses and newspaper articles Weight loss	Age: 6-9 (Mean 8.1) 60% Female 99% Causcian/Finnish 1% Mixed African/Caucasian 4.3% low SES 54.3% high SES Co-morb: NR	83 families interviewed 70 randomized I: 35 C: 35 <u>Retention:</u> Post-tx: I: 34/35 (97.1%) C: 34/35 (97.1%) 6-mo fup: I: 35/35 (100%) C: 34/35 (97.1%)	<u>Incl:</u> Family with child aged 6-9 20-100% OW <u>Excl</u>: disease or medication causing obesity, obvious movement disturbance, major mental problems in child or parent, any family member participating in weight loss program	I: Family-centered group program based on behavioral and solution-focused therapy for healthy lifestyle; parent and child sessions, child sessions usually involved PA C: Two meetings with school nurse plus booklets for families

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

			Treatment Target		
Study Reference	**Intervention Components**	**Components Score**	**Individual vs. Group Tx**	**Treatment Intensity**	**Mean Entry Wt**
Johnston et al, 2007b	I: D, PA, BT, PT C: D, PA, BT, PT	D=1; PA=2; Tx=1 Total=4	I: Child, parent Group C: Child, parent Individual	I: 4x/wk exercise for 12 wks, 30-35 min 1x/wk nutrition for 12 weeks, 35-40 min 3 monthly parent meetings 6 (calc) bi-weekly child meetings (5*.58hr*12 wks=35 hrs + 3 + (6*.58) = 41.5 hrs total) C: None (0 hrs)	BMI: I: 25.4 ± 4.7 C: 26.7 ± 5.5 BMI SDS: I: 1.6 ± 0.6 C: 1.7 ± 0.6 Weight, kg: I: 59.0 ± 11.8 C: 62.5 ± 16.3
Kalavainen et al 2007	D, PA, BT, PT	D=1; PA=2; Tx=1 Total=4	I: Parent, Child Group C: Parent Child/ Individual	I: 15 90-minute session for parent and child (15*1.5*2=45 hrs total) 6 months C: 2 meetings (est 2 hrs)	BMI I: 23.4 ± 2.6 C: 22.9 ± 2.5 BMI SDS I: 2.6 ± 0.6 C: 2.5 ± 0.6 (per UK 1990 Growth Reference) %OW I: 43 ± 14 C: 41 ± 15

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Interv phase 2-11 mo	Interv phase 12-23 mo	Interv phase 24+ mo	Post-Intervention	BMI Change Mean (SD)	Physiological Outcomes
Johnston et al, 2007b	6-mo (ITT analysis) Change in BMI: I: -0.99 ± 3.79 C: +1.08 ± 1.0 p<0.001 Change in BMI %ile: I: -3.13 ± 5.35 C: +0.19 ± 1.41 p<0.01 Change in weight (kg): I: -0.29 ± 9.26 C: 4.54 ± 2.82 p<0.05	NA	NA	NA	NA	Lipids: Yes Glucose tol: Yes BP: Yes Phys fitness: No
Kalavainen et al 2007	6-mo Change in BMI: I: -0.8 ± 1.0 C: 0.0 ± 1.1 p<0.003 Change in BMI SDS: I: -0.3 ± 0.3 C: -0.2 ± 0.3 p<0.022 Change in %OW: I: -6.8 ± 6.2 C: -1.8 ± 6.2 p<0.001			12-mo (6-mo post-intervention) Change in BMI: I: 0.1 ± 1.2 C: 0.8 ± 1.3 p<0.016 Change in BMI SDS: I: -0.2 ± 0.3 C: -0.1 ± 0.3 p<0.081 Change in %OW: I: -3.4 ± 7.7 C: 1.8 ± 7.8 p<0.008	Post-tx (6-mo) I: -0.8 ± 1.0 C: 0.0 ± 1.1 Follow-up: I: 0.1 ± 1.2 C: 0.8 ± 1.3	Lipids: No Glucose tol: No BP: No Phys fitness: No

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Other anthropo-morphic Outcomes (list)	Other Beneficial Outcomes	Adverse Effects (report findings)	Study Quality	Comment (mention which other outcomes significant), other outcomes reported that are not captured in previous columns
Johnston et al, 2007b	% Body fat (bioelectrical impedance)	None	NR	Good	Children in the I showed smaller increased in total cholesterol and greater decreases in LDL cholesterol
Kalavainen et al 2007	None	NR	NR	Good	No other target outcomes examined

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Study characteristics	Patient characteristics	CONSORT Numbers, Retention	Inclusion/Exclusion Criteria	Description of Intervention Groups
McCallum et al, 2007 McCallum et al, 2005	RCT 163 children Oupatient medical clinic Australia GPs recruited from sociodemographically diverse practices Weight loss in moderately overweight children	Age: 5-9 (Mean 7.4) 52% Female Race/Eth: NR SES: practices range from <10th to >90th %ile; median practice close to 50th %ile Comorb: NR	2112 screened 505 OW or mildly obese 342 excluded or refused, 163 randomized: I: 82 C: 81 Retention: 9-mo fup I: 73 (89%) C: 80 (99%) 12-mo fup I: 70 (85%) C: 76 (94%)	Incl: Age 5-9; attending participating medical practice; classified as OW or mildly obese per International Obesity Task Force definition; not receiving ongoing wt management in secondary or tertiary care program Excl: SDS ≥ 3.0, chromosomal, endocrine, or medical condition/ disability/ medication which could have an impact on wt or growth	I: GP given folder prior to appointment containing child's individualized intervention materials, BMI, and 2-page summary of parent responses from baseline qx. Brief solution-focused intervention to set and record appropriate, healthy lifestyle goals with the family; personalized 20-page "Family Folder" containing topic sheets targeting different areas of behavior change C: Usual care

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

		Treatment Target			
Study Reference	**Intervention Components**	**Components Score**	**Individual vs. Group Tx**	**Treatment Intensity**	**Mean Entry Wt**
McCallum et al, 2007 McCallum et al, 2005	D, PA	D=1; PA=1; Tx=0 Total=2	Child, parent Individual	I: 4 sessions minutes NR 12-weeks (assume .5 hrs appointments, 4*.5 hrs*2 fam members=4 hrs total) C: NR (0 hrs)	BMI I: 20.5 ± 2.2 C: 20.0 ± 1.8 BMI SDS I: 2.0 ± 0.5 C: 1.9 ± 0.5 (per UK 1990 Growth Reference) BMI %ile I: 80.8 C: 85.6

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Interv phase 2-11 mo	Interv phase 12-23 mo	Interv phase 24+ mo	Post-Intervention	BMI Change Mean (SD)	Physiological Outcomes
McCallum et al, 2007 McCallum et al, 2005	NA	NA	NA	<u>9-mo (6-mo post-intervention)</u> BMI: I: 21.0 ± 2.6 C: 20.8 ± 2.2 adjusted p=0.25 BMI SDS: I: 1.96 ± 0.64 C: 1.93 ± 0.57 adjusted p=0.12 (per CDC 2000 Growth Charts) <u>15-mo (12-mo post-intervention)</u> BMI: I: 21.7 ± 3.1 C: 21.2 ± 2.4 adjusted p=1.0 BMI SDS: I: 2.0 ± 0.68 C: 1.92 ± 0.59 adjusted p=0.62 (per CDC 2000 Growth Charts)	Post-tx: NR Follow-up (9 mo post-tx) I: +0.5 (NR) C: +0.8 (NR) Follow-up (12 mo post-tx) I: +1.2 (NR) C: +1.2 (NR)	Lipids: No Glucose tol: No BP: No Phys fitness: No

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Other anthropo-morphic Outcomes (list)	Other Beneficial Outcomes	Adverse Effects (report findings)	Study Quality	Comment (mention which other outcomes significant), other outcomes reported that are not captured in previous columns
McCallum et al, 2007 McCallum et al, 2005	None	Diet (4-day food diary) PA (4-day activity diary)	"Little evidence of either harm or benefit of the intervention with respect to parent- and child-reported child health status and child-reported body satisfaction and appearance/self-worth."	Good	% of activity time spent in moderate-vigorous activity and daily nutrition scores better in intervention group than control group at 9 months (nutrition score improved due to substitution of low-fat milk and water for whole milk) Daily nutrition scores better in intervention group than control group at 15 months (nutrition score improved due to substitution of low-fat milk and water for whole milk)

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Study characteristics	Patient characteristics	CONSORT Numbers, Retention	Inclusion/Exclusion Criteria	Description of Intervention Groups
Mellin et al 1987	design NR (RCT or CCT) 66 adolescents Rural health dept; rural nutrition private practice, suburban medical clinic; urban outpatient clinic USA newspaper announcements, notices to physicians and school personnel Weight loss	Age 12-18 (Mean 15.6) 21% Male 87.9% White 7.6% Hispanic 4.5% Asian or Black (calc) SES: NR Co-morb: NR	66 sought to enroll 66 randomized I: 37 C: 29 Retention: I: 92% C: 100%	NR	I: SHAPEDOWN program; cognitive, behavioral, affective treatment encouraging successive, sustainable, small modification in diet, exercies, relationship, lifestyle, communicatins, and attitudes. C: no treatment controls

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

		Treatment Target			
Study Reference	**Intervention Components**	**Components Score**	**Individual vs. Group Tx**	**Treatment Intensity**	**Mean Entry Wt**
Mellin et al 1987	D, PA, BT, PT	D=1; PA=2; Tx=1 Total=4	Child, Parent Group	I: 14 sessions with adolescents 2 parent sessions 90 min/session 14 weeks (16*1.5 hrs =24 hrs) C: None (0 hrs)	% OW I: 36.5% C: 29.5% per 1973 US Natl Ctr for Health Statistics

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Interv phase 2-11 mo	Interv phase 12-23 mo	Interv phase 24+ mo	Post-Intervention	BMI Change Mean (SD)	Physiological Outcomes
Mellin et al 1987	3-mo change in % OW I: -5.9 ± 6.8 C: -0.3 ± 6.6 dependent t-test I: p<0.001 C: n.s.	NA	NA	15-mo (12-mo post-intervention) change in % OW I: -9.9 ± 15.0 C: -0.1 ± 13.2 dependent t-test I: p<0.01 C: n.s.		Lipids: No Glucose tol: No BP: No Phys fitness: No

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Other anthropo-morphic Outcomes (list)	Other Beneficial Outcomes	Adverse Effects (report findings)	Study Quality	Comment (mention which other outcomes significant), other outcomes reported that are not captured in previous columns
Mellin et al 1987	None	depression; self-esteem	Depression improved in treatment group, did not change in control group.	Fair	Treatment group showed improvement on a scale measuring behaviors associated with wt loss or normal wt while control group did not show improvement

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Study characteristics	Patient characteristics	CONSORT Numbers, Retention	Inclusion/Exclusion Criteria	Description of Intervention Groups
Nemet et al 2005	RCT 54 children Child Health and Sports Center Isreal Self-referral Weight Loss	Age: range 6-16 (Mean 11.1) 43.5% Female Race/Eth: NR (Isreali) SES: NR Co-morb: NR	54 self-referred to center, randomized: I: 30 C: 24 Retention: 3-mo: I: 24/30 (80.0%) C: 22/24 (91.7%) 12-mo: I:20/30 (66.7%) C: 20/24 (83.3%)	NR, but reported that none of the children had an organic cause for obesity, none received any medication that might interfere with growth or weight control. Unclear if these were exclusion criteria.	I: Twice weekly exercise sessions plus expectation of at least one exercise session at home, 6 semi-monthly parent and/or child meetings with dietician primarily for nutritional counseling, 4 general interest lectures for parents and children on topics related to childhood obesity. C: At least one nutritional counseling session, encouraged to exercise 3 times/week on their own.

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Treatment Target: Intervention Components	Components Score	Individual vs. Group Tx	Treatment Intensity	Mean Entry Wt
Nemet et al 2005	I: D, PA, PT C: D	D=1; PA=2; Tx=0 Total=3	I: Child, Parent Individual C: Child, Parent Individual	I: 28 1-hr exercise sessions 6 30-45 min nutrition counseling 4 lecture, minutes NR 14 wks (calc) (28*1 + 1 hr + .75hr + 4*.75*2)=28+1.75 +6=35.75 hrs C: 1 or more nutrition counseling sessions, minute NR (Est 1 hr)	Analyzed sample: BMI: I: 27.7 ± 3.6 C: 28.0 ± 5.2 All randomized: BMI: I: 28.5 ± 4.1 C: 27.8 ± 5.0 BMI percentile: I: 98.2 ± 0.3 C: 97.2 ± 0.7 Weight, kg: I: 63.8 ± 19.1 C: 63.4 ± 22.8

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Interv phase 2-11 mo	Interv phase 12-23 mo	Interv phase 24+ mo	Post-Intervention	BMI Change Mean (SD)	Physiological Outcomes
Nemet et al 2005	3-mo BMI: I: 26.8 ± 3.9 C: 27.6 ± 5.6 p<0.05 Weight, kg: I: 61.0 ± 18.3 C: 64.5 ± 24.1 p<0.05			15-mo (12-mos post-intervention): BMI: I: 26.1 ± 4.7 C: 28.6 ± 5.8 p<0.05 BMI percentile: I: 92.3 ± 3.0 C: 96.1 ± 1.4 p<0.05 Weight, kg: I: 59.7 ± 17.7 C: 68.6 ± 24.8 p<0.05	Follow-up (12-mo post-tx): I: -1.5 (NR) C: +0.6 (NR)	Lipids: Yes Glucose tol: No BP: No Phys fitness: Yes

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Other anthropo-morphic Outcomes (list)	Other Beneficial Outcomes	Adverse Effects (report findings)	Study Quality	Comment (mention which other outcomes significant), other outcomes reported that are not captured in previous columns
Nemet et al 2005	triceps, Subscapular skinfolds	Diet, Physical activity, Sedentary behavior	NR	Fair	At post-intervention (3-mo) I group reported greater increases in the amount of habitual activity, greater reductions in overall and LDL cholesteral. At 1-year followup, I group had greater reductions in body fat, greater amount of habitual activity, and greater improvements in endurance time.

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Study characteristics	Patient characteristics	CONSORT Numbers, Retention	Inclusion/Exclusion Criteria	Description of Intervention Groups
Reinehr et al 2006	CCT 240 children OW specialty treatment unit in medical facility Germany Recruitment NR Weight loss and cardiovascular disease risk profile improvement	Age: 6-14 (Mean 10.4) 46.5% Female Race/Eth: NR SES: NR Co-morb: 0% endocrine disorders	240 analyzed: I: 203 C: 37 Retention: I: 174/203 (86%) C: 37/37 (100%)	Incl: Age 6-14; BMI >97th %ile per 2001 German norms; participate in local exercise group for ≥ 8 wks to prove motivation Excl: endocrine disorders, familial hyperlipidemia, or syndromal obesity	I: Multidisciplinary treatment team, program includes physical exercise, nutrition education, behavioral therapy, individual and/or family therapy C: No treatment; Comprised of children who met all criteria but did not participate due to travel distance to the treatment facility

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

		Treatment Target			
Study Reference	**Intervention Components**	**Components Score**	**Individual vs. Group Tx**	**Treatment Intensity**	**Mean Entry Wt**
Reinehr et al 2006	I: D, PA, BT, FC, PT C: None	D=1; PA=2; Tx=2 Total=5	I: Child, parent, family Individual, group C: None	I: 6 1.5-hr parent group sessions 6 1.5-hr child group sessions 3 1-hr parent sessions 52 exercise session (minutes NR) variable number (est 6) 30-minute individual and/or family therapy sessions (12*1.5hr + 3 + 52*1 hr + 6*.5hr = 76.0 hrs) 1 yr C: None (0 hrs)	BMI: I: 27.0 (26.4, 27.6) C: 26.1 (25.2, 27.8) BMI SDS: I: 2.4 (2.3, 2.4) C: 2.3 (2.2, 2.4)

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference		Interv phase 2-11 mo	Interv phase 12-23 mo	Interv phase 24+ mo	Post-Intervention	BMI Change Mean (SD)	Physiological Outcomes
Reinehr et al 2006	NA		12-mo BMI: I: 27.1 (26.4, 27.6) C: 28.1 (27.0, 29.2) p=0.013 (treatment x time effect) BMI SDS: I: 2.1 (2.1, 2.2) C: 2.3 (2.1, 2.4) p=0.007 (treatment x time effect)		24-mo (12-mos post-intervention) BMI: I: 28.2 (27.4, 29.0) C: 29.0 (28.0, 30.8) p=0.013 (treatment x time effect) BMI SDS: I: 2.1 (2.1, 2.2) C: 2.3 (2.1, 2.4) p=0.007 (treatment x time effect)	Post-tx (12-mo) I: +0.1 (NR) C: +2.0 (NR) Follow-up (12-mo post-tx): I: +1.2 (NR) C: +2.9 (NR)	Lipids: Yes Glucose tol: Yes BP: Yes Phys fitness: No

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Other anthropo-morphic Outcomes (list)	Other Beneficial Outcomes	Adverse Effects (report findings)	Study Quality	Comment (mention which other outcomes significant), other outcomes reported that are not captured in previous columns
Reinehr et al 2006	None	None	NR	Fair	Intervention group showed greater improvement than control group in systolic blood pressure, fasting insulin, homeostatis model assessment of insuline resistance

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Study characteristics	Patient characteristics	CONSORT Numbers, Retention	Inclusion/Exclusion Criteria	Description of Intervention Groups
Rooney et al 2005	RCT 98 families (353 people, adults and children combined) NR USA NR Increased physical activity	Age: 5-12 (Mean 9.7) 51% Female Race/Eth: NR SES: NR Co-morb: NR	98 families randomized 87 families analyzed: I1: 28 families I2: 30 families C: 29 families <u>Retention:</u> 87 families (88.8%) 316 people (89.5%) Individual children (personal communication): I1: 21 I2: 24 C: 27 (denominators unknown)	<u>Incl:</u> At least one child aged 5-12 with BMI over 84th %ile; at least one adult willing to participate. (Siblings also invited to participate)	I1: Pedometer group given a pedometer, instructed in its use and told to walk 10,000 steps daily for 12 weeks; biweekly newsletters containing informative articles and fun activity tips. I2: Pedometer + education group; above, plus education sessions covering nutrition, physical activity, other parenting issues. C: Not described

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Intervention Components	Components Score	Individual vs. Group Tx	Treatment Intensity	Mean Entry Wt
			Treatment Target		
Rooney et al 2005	I1: PA I2: D, PA, PT C: Not described	D=1; PA=1; Tx=0 Total=2 (for I2)	Family NR	I1: #session, min NR 12 wks (est 1 hr pedometer instruction*3 fam members=3 hrs) I2: 1 session pedometer instruction (est 1 hr) 6 1-hr wt loss education sessions (est (1hr+7 hrs)*3 fam members=21 hrs) 12 wks C: NR (est 0 hrs)	BMI %ile: I1&I2: 80.8 C: 85.6 (per CDC growth charts, year not specified)

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Interv phase 2-11 mo	Interv phase 12-23 mo	Interv phase 24+ mo	Post-Intervention	BMI Change Mean (SD)	Physiological Outcomes
Rooney et al 2005	3-mo BMI %ile: I1&I2: 82.3 C: 85.0 p=0.42	NA	NA	9-mo (6 mos post-intervention) BMI %ile: I1&I2: 80.9 (SD NR) C: 84.3 (SD NR) p=0.33 Change in BMI %ile: I1&I2: +0.31 (SD NR) C: -1.32 (SD NR) p=0.28	9-mo (personal communication): I: -0.87 ± 1.27 C: -0.43 ± 1.09	Lipids: No Glucose tol: No BP: No Phys fitness: No

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Other anthropo-morphic Outcomes (list)	Other Beneficial Outcomes	Adverse Effects (report findings)	Study Quality	Comment (mention which other outcomes significant), other outcomes reported that are not captured in previous columns
Rooney et al 2005	None	Physical activity	NR	Fair	No significant group differences at 9 months

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Study characteristics	Patient characteristics	CONSORT Numbers, Retention	Inclusion/Exclusion Criteria	Description of Intervention Groups
Saelens et al 2002	RCT 44 adolescents Primary care clinical setting USA Flyers in pediatric clinic waiting room, pediatrician encouragement to participate Weight loss	Age: 12-16 Mean 14.2 ± 1.2 40.9% Female 70.5% White 15.9% Hispanic 4.5% Black 2.3% Asian 6.8% Multi-ethnic SES: Median household income $60K-69K Co-morb: NR	59 scheduled baseline assmt 47 complete baseline assmt 44 met wt criteria and were randomized I: 23 C: 21 Retention: I: 18/23 (78%) complete fup C: 19/21 (90%) fup	Incl: Age 12-16; 20-100% above median (50%ile) for BMI for sex and age per CDC 2000 growth charts; interested in weight control, but not currently engaged in another wt control program; otherwise healthy as determined by pediatrician	I: Healthy habits intervention: computerized assessment; meeting with pediatritian to discuss results of assessment, develop action plan; 10-20 minutes counseling calls; mailed participant manual in three different mailings (part of manual mailed each time); encouraged self-monitoring of food intake and physical activity C: Typical care intervention: 5-10 minute meeting with pediatrician assessing motivation and providing (non-tailored) information on healthy eating and physical activity

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

		Treatment Target			
Study Reference	**Intervention Components**	**Components Score**	**Individual vs. Group Tx**	**Treatment Intensity**	**Mean Entry Wt**
Saelens et al 2002	I: D, PA, SA, BT C: D, PA (brief)	D=1; PA=1; Tx=0 Total=2	Child Individual	I: 1 pediatrician session, 11 phone calls Pediatrician visit 5-10 minutes, phone calls 10-20 minutes 14-16 wks total (10 min + 11*20 min = 230 min = 3.8 hrs) C: 1 pediatrician session 5-10 minutes 1 day (.2 hrs)	BMI I: 31.0 ± 3.5 C: 30.7 ± 3.1 % OW I: 62.0 ± 20.5 C: 62.3 ± 17.4 (per 2000 CDC growth charts)

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Interv phase 2-11 mo	Interv phase 12-23 mo	Interv phase 24+ mo	Post-Intervention	BMI Change Mean (SD)	Physiological Outcomes
Saelens et al 2002	4-mo BMI z-score: I: 2.15 (SD NR) C: 2.02 (SD NR) (est from graph) p=<0.03 for overall time*treatment effect BMI: I: 30.9 ± 3.8 C: 31.8 ± 3.4 p=NR % OW: I: 59.8 ± 21.8 C: 66.2 ± 18.6 p=NR	NA	NA	7-mo (3-mo post intervention) BMI z-score: I: 2.15 (SD NR) C: 2.01 (SD NR) (est from graph) p=<0.03 for overall time*treatment effect BMI: I: 31.1 ± 4.5 C: 32.1 ± 3.8 p=NR % OW: I: 59.6 ± 24.6 C: 66.4 ± 20.1 p=NR	Post-tx (4-mo): I: -0.1 (NR) C: +1.1 (NR) Follow-up (3 mo post-tx): I: +0.1 (NR) C: +1.4 (NR)	Lipids: No Glucose tol: No BP: No Phys fitness: No

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Other anthropo-morphic Outcomes (list)	Other Beneficial Outcomes	Adverse Effects (report findings)	Study Quality	Comment (mention which other outcomes significant), other outcomes reported that are not captured in previous columns
Saelens et al 2002	None	Diet, Physical activity, Sedentary behavior, problematic eating/eating disorder psychopathology	problematic eating/eating disorder psychopathology did not differ between treatment and control groups	Good	No significant group differences at 7 months in secondary outcomes

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Study characteristics	Patient characteristics	CONSORT Numbers, Retention	Inclusion/Exclusion Criteria	Description of Intervention Groups
Savoye et al 2007	RCT 174 children and adolescents pediatric obesity clinic USA NR Changes in BMI, body composition, insulin sensitivity, blood pressure, and lipid profiles	Age: 8-16 (Mean 12.1 (calc)) 60.9% Female (calc) 36.8% White 24.7% Hispanic 38.5% Black (all calc) SES: NR Co-morb: 0% Diabetes	284 assessed 271 met inclusion criteria 209 consented and randomized I: 105 C: 69 <u>Retention:</u> I: 86/105 (81.9%) 6-mo intervtn/assessmt C: 49/69 (71.0%) 6-mo intervtn/assessmt I: 75/105 (71.4%) 12-mo intervtn/assessmt C: 44/69 (63.8%) 12-mo intervtn/assessmt	Incl: BMI >95th %ile; age 8-16; English-speaking; caregiver willing to participate. Excl: diabetes; severe psychiatric disorder or cognitive deficits; serious medical condition that would preclude them from participation; taking medications that could cause significant wt gain; using medications for wt loss; involved in wt management program	I: Bright Bodies Weight Management, twice weekly exercise program; weekly nutrition education and behavior modification class. C: pediatric obesity clinic visit every 6 months for diet and exercise counseling and brief pschosocial counseling with social worker.
Senediak et al 1985	45 children Setting NR USA Media ads + publicity to medical professionals Weight loss	Age: 6-12 (calc) (Mean 10.3) 34% Female (est) Race/Eth: NR SES: NR Co-morb: NR	45 randomized: I1 (rapid schedule): 12 I2 (standard schedule): 12 C1 (attention control): 11 C2 (wait-list): 10 (not reported here) Retention: I1: 66.7% fup I2: 83.3% fup C1: 63.6% fup	Incl: At least 20% overweight for height, age, and sex Excl: Height not below 20th %ile for age; no hx of psychiatric contact; no hx of endocrine or metabolic disorders; not in special education	I1: rapid schedule BT I2: gradually decreasing schedule BT C1: relaxaion, mood management control C2: wait list (not reported here)

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

		Treatment Target			
Study Reference	**Intervention Components**	**Components Score**	**Individual vs. Group Tx**	**Treatment Intensity**	**Mean Entry Wt**
Savoye et al 2007	I: D, PA, BT, PT	D=1; PA=2; Tx=2 Total=5	Child, Parent Group	I: 65 sessions (calc) 90 min/session 52 weeks (65*1.5=97.5 hrs) C: 2 sessions (calc) min/sessin NR 52 weeks (est) (2*1 hr=2 hrs)	BMI I: 35.8 ± 7.6 C: 36.2 ± 6.2 Wt, kg I: 87.0 ± 25.1 C: 91.2 ± 23.3
Senediak et al 1985	I1&I2: D, PA, BT, PT C: PT	D=1; PA=1; Tx=1 Total=3	Child, parent Group	All: 8 90-minute sessions (12 hrs) I1&C1: 4 wks I2: 15 wks	BMI I: 20.5 ± 2.2 C: 20.0 ± 1.8 BMI SDS I: 2.0 ± 0.5 C: 1.9 ± 0.5 (per UK 1990 Growth Reference) BMI %ile I: 80.8 C: 85.6

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Interv phase 2-11 mo	Interv phase 12-23 mo	Interv phase 24+ mo	Post-Intervention	BMI Change Mean (SD)	Physiological Outcomes
Savoye et al 2007	6-mo Change in BMI I: -2.1 (-2.6, -1.5)* C: 1.1 (0.4, 1.8)* p<0.001 *SD calc: I: 1.1*2.61=2.87 C: 1.4*2.1=2.97 Change in Wt, kg I: -2.6 (-4.2, -0.9) C: 5.0 (2.9, 7.2) p<0.001	12-mo Change in BMI I: -1.7 (-2.3, -1.1)* C: 1.6 (0.8, 2.3)* p<0.001 *SD calculated: I: 1.2*[sqrt(105)/(2*1.96)]=3.13 C: 1.5*[sqrt(69)/(2*1.96)]=3.18 Change in Wt, kg I: 0.3 (-1.4, 2.0) C: 7.7 (5.3, 10.0) p<0.001	NA	NA	Post-tx (12-mo): I: -1.7 ± 3.14 C: +1.6 ± 3.17 Follow-up: NR	Lipids: Yes Glucose tol: Yes BP: Yes Phys fitness: No
Senediak et al 1985	NA (report post-treatment, but since post-tx point different (1 mo vs 3.5-mo), will only report post-intervention follow-up			%OW I1: 19.9 ± 14.2 I2: 16.6 ± 11.5 C1: 30.8 ± 10.4 p<0.05 Wt, kg I1: 49.5 ± 7.4 I2: 48.6 ± 11.1 C1: 44.8 ± 4.9 p<0.05		Lipids: No Glucose tol: No BP: No Phys fitness: No

Appendix C Evidence Table 1. Behavioral intervention trials-key question 1

Study Reference	Other anthropo-morphic Outcomes (list)	Other Beneficial Outcomes	Adverse Effects (report findings)	Study Quality	Comment (mention which other outcomes significant), other outcomes reported that are not captured in previous columns
Savoye et al 2007	% Body fat, Body fat mass		Found no difference between treatment and control group in changes in height at 6 months or 12 months	Good	Also significant were: % body fat at 6-mo & 12-mo; body fat mass at 6-mo & 12-mo; total cholesterol at 6-mo & 12-mo; fasting insulin at 6-mo & 12-mo; homeostatsis model assessment of insulin resistance, 6-mo & 12-mo
Senediak et al 1985	Subscapular skinfold	NR	NR	Fair	I groups showed greater reductions in skinfold than C1

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Appendix C Evidence Table 2. Supplementary behavioral trials for key question 2 and 5

Study Reference	Study Characteristics	Patient Characteristics	CONSORT Numbers, Retention	Inclusion/ Exclusion Criteria
	Effect of Additional Maintenance support (KQ2)			
Deforche et al 2005	20 adolescents Phone and mail follow-up after residential treatment Australia Youth who had completed residential OW treatment recruited Increase physical activity, decrease sedentary behaviors	Age: 11-18 (Mean 16.3) 50% Female Race/Eth: NR SES: NR Co-morb: NR	20 recruited 20 randomized Retention: Unclear, but appears from degrees of freedom in analyses that there was 100% fup	Incl: Completed 10-mo residential treatment programme; not involved in another study

Appendix C Evidence Table 2. Supplementary behavioral trials for key question 2 and 5

Study Reference	Description of Intervention Groups	Treatment Target Individual vs. Group Tx	Treatment Intensity	Mean Entry Wt	Interv phase 2-11 mo
	Effect of Additional Maintenance support (KQ2)				
Deforche et al 2005	I: Bi-weekly calls initially, then every 3 wks; youth sent weekly diary of physical and sedentary behaviors; goal-setting and problem solving; reward system for physical activity C: Monthly check-ups	Child Individual	I: 10 calls (calc) 5-10 min/call 21 wks C: 3 check-ups # minutes NR 13 wks (calc)	% OW I: 31% C: 31% (est from graph, per 2000 Flemish growth charts (ref 10))	NA

Appendix C Evidence Table 2. Supplementary behavioral trials for key question 2 and 5

Study Reference	Interv phase 12-23 mo	Interv phase 24+ mo	Post-Intervention	Other anthropo-morphic Outcomes	Study Quality
	Effect of Additional Maintenance support (KQ2)				
Deforche et al 2005	16.5 mos (calc, 6.5 mos after end of residential treatment, at end of maintenance trial) %OW I: 40% C: 45% p<0.05 (est from graph)	NA	NA	None	Fair

Appendix C Evidence Table 2. Supplementary behavioral trials for key question 2 and 5

Study Reference	Comment, other outcomes reported that are not captured in previous columns
	Effect of Additional Maintenance support (K
Deforche et al 2005	I group showed greater increases in total activity and moderate-to-high intensity activites compared with C group; No diffs in change in low-intesity activities; I group played computer games less often than C group; No diffs in change in TV viewing

Appendix C Evidence Table 2. Supplementary behavioral trials for key question 2 and 5

Study Reference	Study Characteristics	Patient Characteristics	CONSORT Numbers, Retention	Inclusion/ Exclusion Criteria
Wilfley et al, 2007	RCT 150 children University USA media announcements/ ads, physician referral Weight loss	Age: 7-12 (Mean 9.9 (calc)) 69.3% Female (calc) 7.3% Black (calc) 70.7% White (calc) 18.7% Hispanic (calc) 3.3% Other (calc) 50.7% Maternal education college or higher (calc) Co-morb: NR	1,028 Contacted clinic 325 Attended orientation 236 Interviewed 32 Excluded (18 not interested; 14 did not meet inclusion crit) 204 Began wt loss treatment 54 not randomized due to dropped out of wt loss program (44), not interested/available for maintenence trial (10) 150 randomized to maintenance strategy: I1 (behavioral): 51 I2: (social facilitation): 50 C: 49 Retention: 1-yr fup: I1: 86.2% I2: 86.0% C: 85.7% 2-yr fup: I1: 84.3% I2: 86.0% C: 77.6%	Incl: Age 7-12; 20% to 100% OW per CDC 2000 growth charts; parent with BMI >25 Excl: child or parent currently in psychological or wt loss treatment; child/parent using appetite or weight-affecting medications; child/parent had psychiatric disorder that would interfere with participation (e.g., eating disorder, psychosis)

Appendix C Evidence Table 2. Supplementary behavioral trials for key question 2 and 5

Study Reference	Description of Intervention Groups	Treatment Target Individual vs. Group Tx	Treatment Intensity	Mean Entry Wt	Interv phase 2-11 mo
Wilfley et al, 2007	I1: Behavioral Self Management, including problem solving, goal-setting, and relapse prevention I2: Social facilitation, including social support skills (e.g. facilitating physical activities with friends, friendships with active children), coping with teasing, body esteem C: Usual care (discontinued contact after wt loss program)	Child, parent Group and individual (parent and child together)	I1&I2: 16 1-hr maintenance sessions over 16 wks + 20 hrs over 5 months from initial wt loss program 32 hrs total C: 20 hrs over 5 months from initial wt loss program 20 hrs total	BMI SDS (at tx baseline) I1: 2.17 ± 0.28 I2: 2.26 ± 0.27 C: 2.17 ± 0.34 %OW (at tx baseline) I1: 61.8 ± 17.4 I2: 68.1 ± 17.6 C: 63.3 ± 20.8 BMI SDS (at randomization to maintenance program) I1: 1.99 ± 0.39 I2: 2.03 ± 0.51 C: 2.07 ± 0.38 %OW (at randomization to maintenance program) I1: 49.7 ± 16.2 I2: 56.5 ± 20.1 C: 54.2 ± 20.3 (all per CDC 2000 growth charts)	NA

Appendix C Evidence Table 2. Supplementary behavioral trials for key question 2 and 5

Study Reference	Interv phase 12-23 mo	Interv phase 24+ mo	Post-Intervention	Other anthropo-morphic Outcomes	Study Quality
Wilfley et al, 2007	9-mo from start of wt loss tx (immediately after maintenance intervention) BMI SDS: I1: 1.90 ± 0.35 I2: 1.99 ± 0.48 C: 2.04 ± 0.37 I1 vs. C, p=0.01 I2 vs. C, p=0.009 I1&I2 vs. C p=0.003 % OW: I1: 49.1 ± 16.9 I2: 56.2 ± 21.8 C: 57.9 ± 21.2 I1 vs. C, p=0.003 I2 vs. C, p=0.006 I1&I2 vs. C p=0.001		17-mo from start of wt loss tx (8 mos after end of intervention) BMI SDS: I1: 1.99 ± 0.39 I2: 2.03 ± 0.51 C: 2.07 ± 0.38 I1 vs. C, p=0.19 I2 vs. C, p=0.06 I1&I2 vs. C p=0.07 % OW: I1: 57.0 ± 21.5 I2: 61.2 ± 24.5 C: 61.6 ± 23.3 I1 vs. C, p=0.19 I2 vs. C, p=0.08 I1&I2 vs. C p=0.08 29-mo from start of wt loss tx (20 mos after end of intervention) BMI SDS: I1: 1.98 ± 0.48 I2: 2.02 ± 0.50 C: 2.11 ± 0.36 I1 vs. C, p=0.51 I2 vs. C, p=0.17 1&I2 vs. C p=0.25 % OW: I1: 59.6 ± 24.1 I2: 62.6 ± 25.9 C: 64.8 ± 22.9 I1 vs. C, p=0.97 I2 vs. C, p=0.25 I1&I2 vs. C p=0.50	None	Good

Appendix C Evidence Table 2. Supplementary behavioral trials for key question 2 and 5

Study Reference	Comment, other outcomes reported that are not captured in previous columns
Wilfley et al, 2007	No other significant findings in outcomes listed here

Appendix C Evidence Table 2. Supplementary behavioral trials for key question 2 and 5

Study Reference	Study Characteristics	Patient Characteristics	CONSORT Numbers, Retention	Inclusion/ Exclusion Criteria
	Importance of Organized Physical Activity Session (KQ5)			
Epstein et al 1985a	RCT 23 girls Setting NR USA Physician and school nurse referal, response to media coverage Weight Loss	Age: 8-12 (Avg NR) 100% Female Race/Eth: NR SES: NR Co-morb: NR	22 families enrolled, one with 2 children Group assignment NR	at least 20% overweight for height and age; no medical problems that would contra-indicate weight loss, exercise, or fitness testing; parent willing to participate
Gutin et al 2002 Kang et al 2002	RCT 80 adolscents Research clinic USA Flyers sent to parents of children attending nearby schools, community and hospital newspaper ads improve cardiovascular fitness, body fat, visceral adipose tissue	Age: 13-16 (Mean 14.8) 67.5% Female 68.8% Black 31.2% White SES: NR Co-morb: NR	80 Randomized (N in each group NR) Retention (overall): 59/80 (73.8%) fup	Incl: Age 13-16; triceps skinfold thickness > 85%ile for sex, ethnicity, and age; not involved in any other weight control or exercise program; not restricted as to physical activity

Appendix C Evidence Table 2. Supplementary behavioral trials for key question 2 and 5

Study Reference	Description of Intervention Groups	Treatment Target Individual vs. Group Tx	Treatment Intensity	Mean Entry Wt	Interv phase 2-11 mo
	Importance of Organized Physical Activity Session (KQ5)				
Epstein et al 1985a	I1: Behavioral wt loss program + organized PA sessions I2: Behavioral wt loss program without organized PA sessions	Child, Parent Group	I1: 18 beh tx sessions over 12 mos + exercise 3x/wk (1.5 hrs est) for 6 wks + 10 monthly exercise sessions assume 1-hr sessions=18*2fam memb+ 3*1.5*6wks+10=36 + 27 + 10 = 65 hrs total I2: 18 beh tx sessions over 12 mos 18*2 fam members=36 hrs total	%OW: I1: 48.0 ± 23.2 I2: 48.1 ± 17.6	6-mo %OW: I1: 20.5 ± 22.6 I2: 29.3 ± 22.3 p<0.05 Weight, kg: I1: 47.0 ± 17.0 I2: 50.1 ± 19.4 p<0.05
Gutin et al 2002 Kang et al 2002	I1: lifestyle education only (LSE), information on diet, physical activity, psychosocial skills, problem-solving, coping skills I2: LSE + moderate PA I3: LSE + high intensity PA	Child Group	I1: 19 (est) 1-hour sessions I2: I1 + 171 (est) 43-min PA sessions 19 + 171*.75 = 147.25 hr total I3: I1 + 171 (est) 29-min PA sessions 19 + 171*.30 = 104.5 hr total	Overall 44.5% body fat (group means NR)	8-mo Change in % body fat per DXA I1: -0.11 ± 0.57 I2: -1.42 ± 0.84 I3: -2.85 ± 1.25 p=0.11

Appendix C Evidence Table 2. Supplementary behavioral trials for key question 2 and 5

Study Reference	Interv phase 12-23 mo	Interv phase 24+ mo	Post-Intervention	Other anthropo-morphic Outcomes	Study Quality
	Importance of Organized Physical Activity Session (KQ5)				
Epstein et al 1985a	12-mo %OW: I1: 22.6 ± 29.3 I2: 29.4 ± 22.5 n.s. Weight, kg: I1: 49.9 ± 19.1 I2: 52.6 ± 19.0 n.s.	NR	NA	None	Fair
Gutin et al 2002 Kang et al 2002	NA	NA		Visceral Adipose Tissue (VAT); Triacylglycerol; Apolipoprotein levels	Fair

Appendix C Evidence Table 2. Supplementary behavioral trials for key question 2 and 5

Study Reference	Comment, other outcomes reported that are not captured in previous columns
	Importance of Organized Physical Activity S
Epstein et al 1985a	I1 greater physical work capacity at 12-mo than I2.
Gutin et al 2002 Kang et al 2002	Significant group differences in cardiovascular fitness, triacylglycerol, ratio of total cholesteral to HDLC, LDL size, and diastolic blood pressure.

Appendix C Evidence Table 2. Supplementary behavioral trials for key question 2 and 5

Study Reference	Study Characteristics	Patient Characteristics	CONSORT Numbers, Retention	Inclusion/ Exclusion Criteria	
Woo et al, 2004	RCT 82 children Setting NR Hong Kong School teachers To improve obesity-related vascular abnormalities	Age: 9-12 (Mean 9.9) 34% Female Race/Eth: NR SES: NR Co-morb: 0% DM	170 children and parents indicated interest in study 151 evaluated and found eligible 82 randomized: I1 (diet only): 41 I2 (diet + exercise): 41 Retention: NR	Incl: Age 9-12; no known medical illness; no alternative cause for obesity; resting brachial artery diameter >2.5 mm Excl: family hx of premature cardivascular disease; taking regular medications or vitamin supplementation; hx of diabetes, renal disease, cardiovascular disease; sexual maturity > Tanner stage 2	
	Importance of Cognitive-Behavioral Techniques				
Epstein 1985b	RCT 24 children Setting NR USA Physician referral, school nurse, media advertisements Weight loss	Age: 5-8 (NR) 100% Female Race/Eth: NR SES: NR Co-morb: NR	24 accepted into program and randomized 5 dropped out after preliminary meeting. I1: 8 I2: 11		NR

Appendix C Evidence Table 2. Supplementary behavioral trials for key question 2 and 5

Study Reference	Description of Intervention Groups	Treatment Target Individual vs. Group Tx	Treatment Intensity	Mean Entry Wt	Interv phase 2-11 mo
Woo et al, 2004	I1: Diet I2: Diet + Exercise training	I1&I2: Child, parent NR	I1: 32 sessions (calc), minutes NR 1-year est 32 hrs total I2: Above, + 58 75-min workout sessions est 32 + 58*1.25 = 104.5 hrs total	BMI I1:24.5 ± 2.9 I2: 25.4 ± 3.1 Weight, kg I1: 50.3 ± 8.5 I2: 54.6 ± 9.5	
	Importance of Cognitive-Behavioral Techniques				
Epstein 1985b	I1: Education + BT (PA-) I2: Education only	Child, parent NR	I1&I2: Child: 3x/wk for 5 wks + preliminary session + 9 monthly maintenance session Parent 5 weekly meetings + same preliminary and maintenance session as child assume all session 1 hr, 15 + 1+ 9 + 5 + 1 + 9 = 40 hrs total	BMI I1: 22.8 ± 2.6 I2: 22.7 ± 3.0 %OW I1: 41.9 ± 13.6 I2: 39.2 ± 17.1	8-mo (during maintenance phase) BMI I1: 19.2 ± 2.7 I2: 21.2 ± 3.3 p<0.05 %OW I1: 18.2 ± 16.2 I2: 27.6 ± 17.1 p<0.05

Appendix C Evidence Table 2. Supplementary behavioral trials for key question 2 and 5

Study Reference	Interv phase 12-23 mo	Interv phase 24+ mo	Post-Intervention	Other anthropo-morphic Outcomes	Study Quality
Woo et al, 2004			12-mo (10.5 mo post-intervention) BMI I1:24.5 ± 3.3 I2-discontinued exercise program: 26.1 ± 4.2 I2-continued exercise program: 25.4 ± 2.4 (all changes from baseline n.s.)	%body fat, hip-waist ratio	Fair
	Importance of Cognitive-Behavioral Techniques				
Epstein 1985b	12-mo (after maintenance phase) BMI I1: 19.1 ± 2.8 I2: 21.4 ± 3.3 p<0.05 %OW I1: 15.6 ± 15.2 I2: 28.0 ± 16.7 p<0.05	NR	NA	None	Fair

Study Reference	Comment, other outcomes reported that are not captured in previous columns
Woo et al, 2004	No direct comparisons made between the 3 groups, interpretation of pattern of differences from baseline hampered by lack of randomized (or unbiased) assignment between those continuing and not continuing exercise--instead self-selected.

	Importance of Cognitive-Behavioral Techniq
Epstein 1985b	I1 showed greater improvement in eating habits (not defined) compared with I2

Appendix C Evidence Table 2. Supplementary behavioral trials for key question 2 and 5

Study Reference	Study Characteristics	Patient Characteristics	CONSORT Numbers, Retention	Inclusion/ Exclusion Criteria
Williamson et al 2005 Williamson et al 2006 White et al, 2004	RCT 57 adolescents research clinic USA Media stories and advertisements Weight Loss	Age: 11-15 (Mean 13.2) 100% Female 100% Black SES: NR Co-morbidities: NR	230 expressed interest 116 met BMI crit, scheduled for full screening 96 completed screening interview 61 met criteria and were randomized 57 completed full baseline assessment at began intervention: I1: 29 I2: 28 Retention 6-mo: I1: 93.1% fup I2: 82.1% fup 24-mo: I1: 75.9% fup I2: 64.3% fup	Incl: Age 11-15; African American; Female; BMI > 85th %ile for age and gender per 1999 NHANES norms; at least one biological parent BMI >30; one parent with BMI >27 willing to participate in study; family willing to pay $300 out-of-pocket (plus use study-provider coupon) to purchase computer; electricity and functional telephone line in the home Excl: adolescent or parent have insulin-dependent diabetes, eating disorder, significant mental health problem, or serious health proble; adolescent or parent pregnant; other problems that might interfere with family's participation

Appendix C Evidence Table 2. Supplementary behavioral trials for key question 2 and 5

Study Reference	Description of Intervention Groups	Treatment Target Individual vs. Group Tx	Treatment Intensity	Mean Entry Wt	Interv phase 2-11 mo
Williamson et al 2005	I1: Education only, passive face-to-face and internet education	Child, parent	I1&I2: 4 face-to-face sessions	BMI I1: 37.3 ± 8.2	-1.12%; -0.19 kg/m2
Williamson et al 2006	I2: Behavioral, interactive face-to-face and internet behavioral counseling programs	Individual nutrition couseling, e-mail contact	(minutes NR) variable time on internet, e-mail contact with counselor 12 weeks	I2: 35.3 ± 7.6 % body fat: I1: 46.2 ± 6.4	
White et al, 2004			est 4 hrs face-to-face + 12 hrs internet = 16 hrs total	I2: 45.5 ± 8.3	

Appendix C Evidence Table 2. Supplementary behavioral trials for key question 2 and 5

Study Reference	Interv phase 12-23 mo	Interv phase 24+ mo	Post-Intervention	Other anthropo-morphic Outcomes	Study Quality
Williamson et al 2005 Williamson et al 2006 White et al, 2004	NR	NR	6-mo (3-mo post intervention) Change (±SE) in BMI: I1: +0.65 ± 0.23 I2: -0.19 ± 0.24 p<0.05 Change (±SE) in % body fat: I1: +0.43 ± 0.47 I2: -1.12 ± 0.47 p<0.05 Change (±SE) in weight, kg: I1: +2.29 ± 0.56 I2: +0.70 ± 0.59 n.s. 24-mo (21-mo post intervention) Change (±SE) in BMI: I1: +1.2 ± 0.65 I2: +0.7 ± 0.66 n.s. Change (±SE) in % body fat: I1: +0.84 ± 0.72 I2: -0.08 ± 0.71 n.s. Change (±SE) in weight, kg: I1: +6.3 ± 1.6 I2: +4.4 ± 1.7 n.s.	None	Good

Appendix C Evidence Table 2. Supplementary behavioral trials for key question 2 and 5

Study Reference	Comment, other outcomes reported that are not captured in previous columns
Williamson et al 2005	
Williamson et al 2006	
White et al, 2004	

Appendix C Evidence Table 2. Supplementary behavioral trials for key question 2 and 5

Study Reference	Study Characteristics	Patient Characteristics	CONSORT Numbers, Retention	Inclusion/ Exclusion Criteria
	Varying degrees of family involvement			
Golan et al, 2006	RCT 37 children (32 families) Setting NR Isreal Newspaper advertisement Weight loss	Age: 6-11 (Mean 8.7) 54% Female Race/Eth: NR SES: NR Co-morb: NR	102 families responded to advertisement 32 families met inclusion criteria 32 families randomized: I1 (Parent only): 14 I2: (Parent + Child): 18 Retention: 100% attended follow-up meeting, presume this means they all had at least 12 month fup data Retention in tx program: I1: 76.5% I2: 95%	Incl: Age 6-11; >20% OW (per Cole et al, 2000); parents agree to attend meetings Excl: Current participation of any family member in wt-loss program; restrictions on physical activitiy for children or parents; dx of psychiatric or major endocrine pathology
Israel et al 1985	RCT 33 children Setting: NR USA Recruitment through letters to pediatricians and school nurses and newspaper ads Weight loss	Age 8-12 (Mean 10.6) 30.3% Male Race/Eth: NR SES: NR Co-morb: NR	33 randomized I1: 12 I2: 12 C: 9 (not reported here) Retention at 1-yr fup: Unclear if controls later assigned to I1 or I2 were added in, if this really represents retention as originally assigned I1: 9/12 (75.0%) I2: 11/12 (91.7%)	Age 8-12; at least 20% overweight for height per NCHS 1977 norms; able to obtain medical clearance from doctor

Appendix C Evidence Table 2. Supplementary behavioral trials for key question 2 and 5

Study Reference	Description of Intervention Groups	Treatment Target Individual vs. Group Tx	Treatment Intensity	Mean Entry Wt	Interv phase 2-11 mo
	Varying degrees of family involvement				
Golan et al, 2006	I1: Only attended by parents: family-based, encouraging health eating patterns, encreased physical activity, reduced sedentary activity; coping techniques for parents to foster authoritative feeding style, de-emphasize thinness, and nurture children emotionally I2: Same content, classes attended by children and parents	I1: Parent I2: Parent, Child I1&I2: Group	I1&I2: 16 sessions 40-50 min/session 6 months est 16*.75=12 hrs total	BMI I1: 24.2 ± 3.0 I2: 24.3 ± 3.6 % OW: I1: 44.0 ± 22.1 I2: 48.5 ± 18.1 BMI SDS: I1: 2.0 (SD NR) I2: 2.1 (SD NR)	6-mo %OW: I1: 37.5 ± 22.0 I2: 46.1 ± 17.8 p<0.02
Israel et al 1985	I1: BT only, covering diet, physical activity, problem solving, stimulus control/cues, rewards I2: BT + parent training in child management C: Wait list controls	Child, parent Group, individual phone calls	I1: 9 90-min session over 9 weeks, phone calls between session and monthly from mos 4-12 (# and minutes NR) 6 "brief" ploblem-solving discussions + weigh-in 9*1.5*2 + 8*.25 + 8*.25 + 6*.5*2 = 27+4+4+6 =41 hr total I2: above + 2 60-min parent training session est 43 hrs total	% OW I1: 53.13% I2: 45.88% C: 56.02%	NR

Appendix C Evidence Table 2. Supplementary behavioral trials for key question 2 and 5

Study Reference	Interv phase 12-23 mo	Interv phase 24+ mo	Post-Intervention	Other anthropo-morphic Outcomes	Study Quality
	Varying degrees of family involvement				
Golan et al, 2006			12-mo (6-mo post intervention) %OW: I1: 34.4 (SD NR) I2: 48.9 (NS NR) p<0.05	None	Good
Israel et al 1985	12-mo % OW I1: 45.5 ± 21.2 I2: 40.4 ± 32.9 p<0.045 for treatment*time, including 9-week assessment (I1 showed continued improvement, I2 showed relapse)	NR		None	Fair

Appendix C Evidence Table 2. Supplementary behavioral trials for key question 2 and 5

Study Reference	Comment, other outcomes reported that are not captured in previous columns
	Varying degrees of family involvement
Golan et al, 2006	No others listed here were significant
Israel et al 1985	

Appendix C Evidence Table 2. Supplementary behavioral trials for key question 2 and 5

Study Reference	Study Characteristics	Patient Characteristics	CONSORT Numbers, Retention	Inclusion/ Exclusion Criteria
Wadden et al 1990	RCT	Age 12-16 (Mean 13.8)	58 interviewed 47 randomized:	Incl: Age 12-16; ≥10 kg overweight for age, sex, and height; free of medical conditions that would affect body weight; mothers agree to participate
	47 adolescent girls	0% Male	I1 (child only): 19 I2 (mother child together): 14	
	Setting NR	100% Black	13 (mother child separately): 14	
	USA	SES: 64% single-parent homes		
	newspaper ads, school nurses referral, physician referral	economically "lower- to lower-middle class"	Retention: 31/36 (86%) fup overall, no group differences in retention	
		Co-morb: NR		
	Weight loss			
Israel et al 1994	RCT	8-13 (Mean NR)	34 randomized I1 (Standard Tx): 18	Incl: Age 8-13; at least 20% overweight for weight, height, and sex; parent willing to participate; medical clearance from physician
	34 families	Sex: NR	I2 (Enhanded Child Involvement: 16	
	Setting NR	Race/Eth: NR		
	USA	SES: NR	Retention: I1: 11/18 (61.1%) I2: 9/16 (56.2%)	Excl: Physical or psychological difficulties suggesting that the program would be inappropriate
	Media articles, letters to pediatricians and school nurses	Co-morb: NR		
	Weight loss			

Appendix C Evidence Table 2. Supplementary behavioral trials for key question 2 and 5

Study Reference	Description of Intervention Groups	Treatment Target Individual vs. Group Tx	Treatment Intensity	Mean Entry Wt	Interv phase 2-11 mo
Wadden et al 1990	I1: Child alone, information on diet, physical activity, eating process, behavior modification I2: Mother and child seen together, same program as above I3: Mother and child seen separately, same program as above	I1: Child I2&I3: Child, parent All: Group	All: 22 1-hr sessions 10 months	BMI I1: 35.1 ± 5.4 I2: 32.8 ± 3.8 I3: 36.7 ± 3.7 % body fat: I1: 41.6 ± 3.5 I2: 39.5 ± 5.2 I3: 40.4 ± 5.6	10-mo Overall mean BMI 35.4, not different from baseline, no group differences
Israel et al 1994	I1: Standard treatment (parents primarily responsible) I2: Enhanced Child Involvement (children encouraged to take more active role)	I1: Parent I2: Parent, Child I1&I2: Group	I1&I2: 17 1.5-hr sessions, parent + child 26 weeks	I1: 46.0% OW I2: 48.1% OW	6-mo %OW: I1:33.4 ± 17.0 I2: 32.6 ± 17.3 n.s.

Appendix C Evidence Table 2. Supplementary behavioral trials for key question 2 and 5

Study Reference	Interv phase 12-23 mo	Interv phase 24+ mo	Post-Intervention	Other anthropo-morphic Outcomes	Study Quality
Wadden et al 1990	NA	NA	NA	None	Fair
Israel et al 1994	-0.8%	6.4%	12-mo (6-mo post intervention) %OW: I1: 45.2 ± 23.9 I2: 42.3 ± 22.5 n.s. 36-mo (30-mo post intervention) %OW: I1: 52.3 ± 24.4 I2: 43.3 ± 21.2 n.s.	Triceps skinfold	Fair

Appendix C Evidence Table 2. Supplementary behavioral trials for key question 2 and 5

Study Reference	Comment, other outcomes reported that are not captured in previous columns
Wadden et al 1990	
Israel et al 1994	No other outcomes listed here were significant

Appendix C Evidence Table 2. Supplementary behavioral trials for key question 2 and 5

Study Reference	Study Characteristics	Patient Characteristics	CONSORT Numbers, Retention	Inclusion/ Exclusion Criteria
Golan et al 1998	RCT	Age 6-11 (Mean 9.0)	160 identified as obese 140 met inclusion criteria	Incl: Age 6-11; > 20 % overweight for age, height and gender; both parents living at home
	60 children	38.3% Male	60 agree to participate 60 randomized:	
	Setting NR	Race/Eth: NR (Israeli)	I1 (parent target): 30 I2: (child target): 30	Excl: Hx of psychiatric disorder
	Israel	SES: "Middle class"		
	Schools	Co-morb: NR	Retention: I1 29/30 (96.7%) fup I2 21/30 (70.0%) fup	
	Weight loss		p<0.02 for group difference	

Appendix C Evidence Table 2. Supplementary behavioral trials for key question 2 and 5

Study Reference	Description of Intervention Groups	Treatment Target Individual vs. Group Tx	Treatment Intensity	Mean Entry Wt	Interv phase 2-11 mo
Golan et al 1998	I1: conventional: children responsible for own wt loss, counseling regarding diet, physical activity, behavior modification I2: parents exclusive agents of change, counseling regarding diet, physical activity, behavior modification	I1: Child I2: Parent, family I1&I2: Group	I1: 30 60-min session 12 months total 30 hrs total I2: 14 60-min group sessions for parents; 5 15-min individual session for families 12 months total 15.25 hrs total	%OW: I1: 39.1 ± 3.8 I2: 39.6 ± 3.0	NA

Appendix C Evidence Table 2. Supplementary behavioral trials for key question 2 and 5

Study Reference	Interv phase 12-23 mo	Interv phase 24+ mo	Post-Intervention	Other anthropo-morphic Outcomes	Study Quality
Golan et al 1998	12-mo %OW: I1: 31.5 (SD NR) I2: 25.1 (SD NR) p<0.01 Change in %OW I1: -8.1 (SD NR) I2:-14.7 (SD NR) p<0.03	NR	18-mo (6-mo post-intervention): % of weight loss maintained: I1: 40% I2: 85% p<0.05 24-mo (12 mos post-intervention): %OW: I1: 26.0 I2: 39.8 p<0.01 Change in %OW: I1: 0% I2: -13.6% p<0.05 36-mo (24-mos post-intervention): %OW: I1: 42.0 I2: 24.6 p<0.01 Change in %OW: I1: +2.9% I2: -15.0% p<0.01 7-yr (6-yrs post-intervention): %OW: I1: 18.9 I2: 10.4 p<0.05 Change in %OW: I1: -20.2% I2: -29.0% p<0.05	None	Fair

Appendix C Evidence Table 2. Supplementary behavioral trials for key question 2 and 5

Study Reference	Comment, other outcomes reported that are not captured in previous columns
Golan et al 1998	

Appendix C Evidence Table 3. Pharmacological intervention trials

Study Reference	Study Characteristics	Patient Characteristics	CONSORT Numbers Retention	Inclusion/Exclusion	Description of Intervention Groups	Dose/ Duration
	Sibutramine					
Berkowitz et al 2003 Budd et al 2007	RCT 82 adolescents University-based specialty research clinic USA Source NR Weight loss March 1999- August 2002 Funding: NIH; Hospital; Pharmaceutical	Age: 13-17 (Mean 14.1) 67.1% Female 54.9% White 41.5% Black 3.6% Other SES: NR Co-Morb: 0% DM	146 Evaluated 64 Excluded due to: psychiatric condition (24), not interested (21) Unable to attend group meetings (12), medical conditions (2), other (7) 82 randomized: I: 43 C: 39 Retention: I: 93% follow-up C:87.2% follow-up	Inclusion: Age 13-17; BMI 32-44 Exclusion: cardiovascular disease; Type 1 or 2 diabetes; major psychiatric disorder; pregnancy; use of wt-loss medication; weight loss of ≥ 5kg in past 6 mos; use of medication associated with wt gain; use of medication contraindicated with use of sibutramine; cigarette smoking	I: Sibutramine + Behavior Therapy C: Placebo + Behavior Therapy	Week 1: placebo Week 2: 5 mg/day Wks 3-6: 10 mg/day Wks 7-6 mos: 15 mg/day (decreased dose if systolic or diastolic BP increased by ≥10 mm Hg or pulse rate increased by ≥15% from baseline for 2 consecutive visits

Appendix C Evidence Table 3. Pharmacological intervention trials

Study Reference	Mean Entry Wt	Interv phase 6-11 mo	Interv phase 12-23 mo	Interv phase 24+ mo	Post-Intervention	Physiological Outcomes Reported	Other anthropo-morphic Outcomes
	Sibutramine						
Berkowitz et al 2003 Budd et al 2007	BMI: I: 37.5 ± 4.0 C: 38.0 ± 3.6 BMI SDS: I: 2.4 ± 0.2 C: 2.5 ± 0.2	6-mo % change in BMI: I: -8.5% ± 6.8% C: -4.0% ± 5.4% p=0.001 change in BMI SDS: I: -0.2 ± 0.2 C: -0.1 ± 0.1 p=0.003	NA	NA	NA	Lipids: Yes Glucose tol: Yes BP: Yes Phys fitness: No Pulse: pulse rate higher in IG compared to CG by 5-6 bpm at 3 mos (P < 0.001) and 6 mos (p=0.007) SBP: at 3 mos, mean SBP was increased in IG (1.8 (10.7)mmHG) and decreased in CG (-3.6(8.6); ES 0.55 (95% CI 0.10-1.00);p=0.02) at 6 mos, IG: 0.4 (9.0)mmHg CG: -4.0 (8.9)mmHg ES: 0.45 (-0.02, 0.92)p=0.06 DBP: no differences between groups Elevated BP: I: 3/43 (7.0%) C: 0/39 (0%) p=0.06 No statistically significant difference between groups at 6 mos for lipids, TG, serum insulin, serum glucose, HOMA	Waist Circumference Waist Circ(cm) IG: -8.2(6.9) CG: -2.8 (5.6) p<0.001

Appendix C Evidence Table 3. Pharmacological intervention trials

Study Reference	Adverse Effects	Study Quality	Comment (mention which other outcomes significant
	Sibutramine		
Berkowitz et al 2003 Budd et al 2007	Any A.E.: I: 6/43 (13.9%) C: 3/39 (7.8%) NS See cardiovascular effects reported in physiological outcomes column Total rate of discontinuation due to A.E. among those taking sibutramine (I group in months 0-6 and 7-12, C group in months 7-12): 10/82 (12.2%); due to increased BP or HR 5/82 (6%), ecchymoses, VPCs or rash of unclear etiology Sexual maturity: NR Height change: NR	Good	Results of physiological, anthropometric, and adverse outcomes are reported in those columns.

Appendix C Evidence Table 3. Pharmacological intervention trials

Study Reference	Study Characteristics	Patient Characteristics	CONSORT Numbers Retention	Inclusion/Exclusion	Description of Intervention Groups	Dose/ Duration
Berkowitz et al 2006 Daniels et al 2007	RCT 498 adolescents 33 weight-loss clinics USA Databases of weight-loss clinics; advertisements Weight loss July 2000-February 2002 Funding: Pharmaceutical	Age: 12-16 (Mean 13.7) 65.7% Female White: 56.6% Black: 21.1% Hispanic: 15.7% Other: 6.6% SES: NR Co-morb: 0% DM BP > 130/85 I: 5 (1.4%) C: 3 (2.3%)	498 randomized I: 368 C: 130 Retention: I: 281 (76%) follow-up C: 80 (62%) follow-up	Inclusion: Age 12-16; BMI ≥ 2 SD more than U.S. weighted mean of the 95th %ile based on age/sex per 1998 Rosner norms (ref 17); BMI ≤ 44 Exclusion: cardiovascular disease; Type 1 or 2 diabetes; major psychiatric disorder; pregnancy; use of wt-loss medication or participation in weight loss program for >2 wks; use of medication associated with wt gain; use of medication contraindicated with use of sibutramine; cigarette smoking; SBP >130 mm HG; DBP >85 mm Hg; pulse rate > 95 beats/min	I: Sibutramine + Behavior Therapy C: Placebo + Behavior Therapy	10 mg daily, increase to 15 mg daily at 6 mos if have not lost 10% of initial BMI or more. Total of 12 mos. At 6 mos increased to 15 mg dose N=174 (47.9%) of the Sibutramine group

Appendix C Evidence Table 3. Pharmacological intervention trials

Study Reference	Mean Entry Wt	Interv phase 6-11 mo	Interv phase 12-23 mo	Interv phase 24+ mo	Post-Intervention	Physiological Outcomes Reported	Other anthropo-morphic Outcomes
Berkowitz et al 2006 Daniels et al 2007	BMI: I: 36.1 ± 3.8 C: 35.9 ± 4.1 NS	NA	<u>12-mo</u> % change in BMI: I: -9.4 ± 0.51 C: -1.2 ± 0.90 p<0.001 Absolute change in BMI: I: -2.9 C:-0.3 p<0.001 (using LOCF)	NA	NA	Lipids: Yes Glucose tol: Yes BP: Yes Phys fitness: No <u>Mean difference between groups:</u> Systolic BP: 1.0 mm HG (95% CI 0.1 – 1.9) p=0.03 Diastolic BP: 1.7 mmHG (95% CI 1.0-2.5) p<0.001 Pulse rate: 2.5 beats per minute (95%CI 1.6-3.3) p<0.001 (For the BP parameters, the differences between groups were a reflection of a reduction in BP in the control group and slight (or no) reduction on average in the sibutramine group.)	Waist circumference WC (cm): IG: -8.2 ± 0.49 CG: -1.8 ± 0.86 p<0.001

Appendix C Evidence Table 3. Pharmacological intervention trials

Study Reference	Adverse Effects	Study Quality	Comment (mention which other outcomes significant
Berkowitz et al 2006 Daniels et al 2007	Any A.E.: I: 327/368 (89%) C: 111/130 (85%) NS Serious A.E.: I: 2.7% (10/368) 0.8% (1/130) p=0.30 Discontinuation due to A.E. I: 23/368 (6%) C: 7/130 (5%) p=0.83 Tachycardia: I: 46/368 (13%) C: 8/130 (6%) p=0.05 ECG: No clinically significant QTc prolongation or other mean changes from baseline. Also see additional relevant results in physiological outcomes and comments columns Growth and Maturation were not detectably different Other A.E. with >1 percentage point differences	Good	I group showed more improvement than C group in: waist circumference, fasting triglycerides, HDL, fasting insulin, homeostasis model assessment of insulin sensitivity. No difference between groups for serum total cholesterol, LDL, and glucose. C group showed more improvement than I group in systolic BP, diastolic BP Withdrawals due to tachycardia I: 2.4% C: 1.5% (p=0.74) Withdrawal due to hypertension I: 5/368 (1.4%) C: 0/ 130 (0%) (difference, 1.4% (95% CI 0.4% - 3.1%)) No significant differences between groups for suicide attempts (1/368 (0.3%) in the sibutramine group vs. 1/130 (0.8%) in the CG. The two suicide attempts were considered unlikely related to the study drug, but treatment was discontinued for both patients. Reported syncope, chest pain, arrhythmia, or extra systoles was ≤ 1.5% for each in both groups.

Appendix C Evidence Table 3. Pharmacological intervention trials

Study Reference	Study Characteristics	Patient Characteristics	CONSORT Numbers Retention	Inclusion/Exclusion	Description of Intervention Groups	Dose/ Duration
Van Mil et al, 2007	RCT 24 adolescents Obesity research center The Netherlands Regional public health department, pediatric outpatient clinic of teaching hospital Weight Loss Time period NR Funding NR	Age: 12-17 yrs (Mean 14.0 (calc)) 54.2% Female Race/Eth: NR SES: NR Co-morb: NR	24 randomized Retention: I: 11/12 (91.7%) C: 9/12 (75.0%)	Inclusion: Age 12-18; BMI ≥ 97th %ile for age and sex; triceps skinfold thickness ≥ 97th %ile for age and sex per 1996 Dutch norms (ref 9); persisting obesity despite professionally supervised wt loss attempts. Exclusion: Endocrine or other secondary causes of overweight; significant physical or medical illness.	I: Sibutramine + Behavior Therapy C: Placebo + Behavior Therapy	Wks 1-2: 5 mg/day Wks 3-12: 10 mg/day

Appendix C Evidence Table 3. Pharmacological intervention trials

Study Reference	Mean Entry Wt	Interv phase 6-11 mo	Interv phase 12-23 mo	Interv phase 24+ mo	Post-Intervention	Physiological Outcomes Reported	Other anthropo-morphic Outcomes
Van Mil et al, 2007	BMI: I: 30.1 ± 4.5 C: 33.3 ± 5.0 BMI SDS: I: 2.60 ± 0.55 C: 2.97 ± 0.47	NA	NA	NA	6-mo (3-mo post-intervention): BMI change: I: -0.8 (calc) C: -1.4 (calc) (could not calculate SD) BMI SDS change: I: -0.14 (calc) C: -0.13 (calc) (could not calculate SD) Compliance NR	Lipids: No Glucose tol: No BP: Yes Phys fitness: No	Fat mass, free fat mass

Appendix C Evidence Table 3. Pharmacological intervention trials

Study Reference	Adverse Effects	Study Quality	Comment (mention which other outcomes significant
Van Mil et al, 2007	Any A.E. # events/# partic I: 41/12 C: 22/12 # partic with A.E I: 12/12 (100%) C: 9/12 (75.0%) NS Abdominal complaints I: 7/12 (58.3%) C: 0/12 (0.0%) p<0.01 No differences between groups in heart rate, BP, ECG changes	Fair	No other outcomes showed significant group differences

Appendix C Evidence Table 3. Pharmacological intervention trials

Study Reference	Study Characteristics	Patient Characteristics	CONSORT Numbers Retention	Inclusion/Exclusion	Description of Intervention Groups	Dose/ Duration
Garcia-Morales et al, 2006	RCT 52 adolescents Primary care pediatric obesity clinic Mexico Outpatients attending endocrinology department of children's hospital. Weight loss August 2001-August 2003 Funding: Pharmaceutical	Age: 14-18 yrs (Mean 15.0 (c)) 56.5% Female(c) Race/Eth NR SES: NR Co-morb: NR	70 screened 52 randomized I: 26 C: 25 Drop-out before 1 mo of treatment I: 3 C: 2 Completed 6 mo I: 21 (81%) C: 19 (76%) Analyzed I: 23 C: 23	Inclusion: Living in the Mexico City metropolitan area; 14-18 yrs; BMI > 95 percentile for age and sex. Exclusion: Lactating or pregnant females; females sexually active without contraception; SBP ≥ 140 mmHg or DBP ≥ 90 mmHg; history of anorexia nervosa or bulimia; no treatment within 30 days with corticosteroids, MAOIs, antidepressants, lithium, weight loss drugs, nasal or respiratory anticongestives, migraine treatment, gastrointestinal prokinetics, or antihistamines; using alcohol or recreational drugs; history of depression or weight loss treatment in last 6 mo; genetic disease associated with obesity; hypothyroidism; cancer; blood disease; gastrointestinal surgery; psychiatric disease; history of work or school problems; weight loss ≥ 3 kg in last 3 mo; unable to follow protocol.	I: Sibutramine + diet/exercise counseling C: Placebo + diet/exercise counseling	10 mg/day 6 month

Appendix C Evidence Table 3. Pharmacological intervention trials

Study Reference	Mean Entry Wt	Interv phase 6-11 mo	Interv phase 12-23 mo	Interv phase 24+ mo	Post-Intervention	Physiological Outcomes Reported	Other anthropo-morphic Outcomes
Garcia-Morales et al, 2006	BMI I: 35.1 ± 5.3 C: 36.6 ± 5.2 Weight I: 92.6 ± 14.6 C: 98.9 ± 22.7	BMI I: -3.4 (-2.5, -4.2) C: -1.8 (-0.9, -2.6) p< 0.005 (ANOVA testing interaction between treatment and time) Weight I: -7.7 (-5.2, -10.2) C: -3.8 (-1.6, -5.9) p< 0.005 (ANOVA testing interaction between treatment and time)	NA	NA	NA	Lipids: Yes Glucose tol: Yes BP: Yes Phys fitness: No	Waist Circumference WC and % change in WC: NS between groups

Appendix C Evidence Table 3. Pharmacological intervention trials

Study Reference	Adverse Effects	Study Quality	Comment (mention which other outcomes significant
Garcia-Morales et al, 2006	Mild AE: IG: 3/23 patients (headache, dry mouth; HA w/ nausea; HA w/ weakness and paleness) CG: 3/23 patients (HA, HA w somlolence, HA w/ dry mouth) P > 0.05 between groups Withdrawl due to AE: none in either group Sexual maturity: All patients were in Tanner stage IV at baseline and end of study Height: not different between groups	Fair	No other outcomes showed significant group differences

Appendix C Evidence Table 3. Pharmacological intervention trials

Study Reference	Study Characteristics	Patient Characteristics	CONSORT Numbers Retention	Inclusion/Exclusion	Description of Intervention Groups	Dose/ Duration
Godoy-Matos, 2005	RCT 60 adolescents Research setting designed to reflect clinical practice Turkey Recruitment NR Weight loss January 2002-April 2003 Funding: Pharmaceutical	Age: 14-17 yrs 82% Female Race: NR SES: NR Co-morb: None	68 patients recruited 8 subjects were lost after run-in period 60 randomized I: 30 C: 30 Completed I: 28 C: 22	Inclusion: 14-17 yrs; BMI 30-45. Exclusion: Diabetes mellitus; endocrine diseases predisposing to obesity; severe hyperlipidemia; systemic or major psychiatric disorders; history of bulimia or anorexia; uncontrolled hypertension (DBP > 110 mmHg) or other cardiac diseases; weight loss of 3 kg or more within 2 mo or use of weight loss/gain drugs within 3 mo; drug or alcohol abuse; recent tobacco cessation or intention to quit during study period; pregnancy or lactation.	I: Sibutramine + diet/exercise counseling C: Placebo + diet/exercise counseling	1 mo run-in: placebo 6 mo: 10 mg/day

Appendix C Evidence Table 3. Pharmacological intervention trials

Study Reference	Mean Entry Wt	Interv phase 6-11 mo	Interv phase 12-23 mo	Interv phase 24+ mo	Post-Intervention	Physiological Outcomes Reported	Other anthropo-morphic Outcomes
Godoy-Matos, 2005	BMI, at wk -4 I: female 37.5 ± 3.8 male 37.6 ± 4.3 C: female 35.8 ± 4.2 male 37.4 ± 1.9 NS Weight, kg at wk 0 I: female 97.7 ± 14.9 male 115.2 ± 14.7 C: female 91.9 ± 13.1	BMI change I: -3.6 ± 2.5 C: -0.9 ± 0.9 p<0.001 Weight loss, kg I: -10.3 ± 6.6 C: -2.4 ± 2.5 p<0.001	NA	NA	NA	Lipids: Yes Glucose tol: Yes BP: Yes Phys fitness: No	Waist Circumference; waist to hip ratio

Appendix C Evidence Table 3. Pharmacological intervention trials

Study Reference	Adverse Effects	Study Quality	Comment (mention which other outcomes significant
Godoy-Matos, 2005	Constipation I: 40% C: 13.3% p=0.039 All others NS: dry mouth, heache, constipation, abdominal pain, cold dizzy. No one withdrew due to AE	Fair	

Appendix C Evidence Table 3. Pharmacological intervention trials

Study Reference	Study Characteristics	Patient Characteristics	CONSORT Numbers Retention	Inclusion/Exclusion	Description of Intervention Groups	Dose/ Duration
	Orlistat					
Chanoine et al, 2005	RCT 539 adolescents 32 institutions with established pediatric obesity treatment programs Canada and USA Advertisements in participant clinics and media, referrals from family physicians Weight loss August 2000-October 2002 Funding: Pharmaceutical	Age: 12-16 (Mean 13.6 (c)) 67% Female (c) 76.0% White (c) 16.9% Black (c) 7.1% Other (c) SES: NR 25.3% metabolic syndrome 1% DM	588 Evaluated 49 Excluded (did not meet incl crit (42), other (7)) 539 Randomized I: 357 C: 182 Retention: I: 232/257 (65.0%) C: 117/180 (64.3%)	Inclusion: Age 12-16; BMI ≥ 2 SD more than U.S. weighted mean of the 95th %ile based on age/sex per Rosner 1998 norms (ref 1); parent/guardian willing to attend study visits with them; willing to be actively involved in behavioral modification Exclusion: BMI ≥ 44; body wt ≥ 130 kg or <55 kg; wt loss of ≥ 3 kg in past 3 mos; diabetes requiring antidiabetic meds; obesity associated with genetic disorders; psychiatric disorder; use of dexamphetamine or methylphenidate; active GI tract disorder; bulimia or laxative abuse; use of anorexiants or weight-loss treatment in past 3 mos	I: Orlistat + Behavior Therapy C: Placebo + Behavior Therapy	Wks 1-2: placebo Wks 3-54: 360 mg/day Compliance I: 73% C:72%

Appendix C Evidence Table 3. Pharmacological intervention trials

Study Reference	Mean Entry Wt	Interv phase 6-11 mo	Interv phase 12-23 mo	Interv phase 24+ mo	Post-Intervention	Physiological Outcomes Reported	Other anthropo-morphic Outcomes
	Orlistat						
Chanoine et al, 2005	BMI: I: 35.7 ± 4.2 C: 35.4 ± 4.1	NA	12-mo: Adjusted Mean change in BMI: I: -0.55 C: +0.31 p<.001	NA	NA	Lipids: Yes Glucose tol: Yes BP: Yes Phys fitness: No	Waist & Hip Circumference, fat mass

Appendix C Evidence Table 3. Pharmacological intervention trials

Study Reference	Adverse Effects	Study Quality	Comment (mention which other outcomes significant
	Orlistat		
Chanoine et al, 2005	Any A.E. I: 97% C: 94% Serious A.E. I: 11/352 (3.1%) C: 5/181 (2.8%) discontinued tx due to A.E.: I: 12/352 (3.4%) C: 3/181 (1.7%) Also assessed and found no group differences: levels of vit. A, D, E, & beta carotene; levels of estradiol; change in height; sexual maturation, bone mineral density	Good	I group showed greater improvements than C group in waist circumference, hip circumference, fat mass, and diastolic BP

Appendix C Evidence Table 3. Pharmacological intervention trials

Study Reference	Study Characteristics	Patient Characteristics	CONSORT Numbers Retention	Inclusion/Exclusion	Description of Intervention Groups	Dose/ Duration
Maahs et al 2006	RCT 40 adolescents Research clinic USA Physician referal and newpaper advertisement Weight loss December 2002-February 2003 Funding: University supported	Age: 14-18 (Mean 15.8) 67.5% Female(c) 62.5% Hispanic (c) SES: NR Co-morb: NR	43 evaluated 3 excluded (parent refusal, not interested, psychological issues) 40 randomized I: 20 C: 20 Retention: I: 16/20 (80%) C: 18/20 (90%) p=0.68	Inclusion: Age 14-18; BMI >85th %ile of age and sex (norms NR) Exclusion: known secondary cause for obesity (e.g., hypothyroidism, daily corticosteroid exposure, genetic disorder); pregnancy	I: Orlistat + monthly diet/exercise counseling C: Placebo + monthly diet/exercise counseling	360 mg/day, 6 mos

Appendix C Evidence Table 3. Pharmacological intervention trials

Study Reference	Mean Entry Wt	Interv phase 6-11 mo	Interv phase 12-23 mo	Interv phase 24+ mo	Post-Intervention	Physiological Outcomes Reported	Other anthropo-morphic Outcomes
Maahs et al 2006	BMI: I: 39.2 ± 1.2 C: 41.7 ± 2.6 Weight I: 111.1 ± 5.1 C: 114.3 ± 8.6	<u>6-mo:</u> BMI: I: 37.9 ± 1.6 C: 40.9 ± 3.0 p=0.70, for time-by-group effect (including 3-mo values) Weight I: 105.6 ± 6.2 C: 112.7 ± 9.5 p=0.76	NA	NA	NA	Lipids: Yes Glucose tol: Yes BP: No Phys fitness: No	% body fat by bioelectrical impedance analysis

Appendix C Evidence Table 3. Pharmacological intervention trials

Study Reference	Adverse Effects	Study Quality	Comment (mention which other outcomes significant
Maahs et al 2006	Discontinue due to A.E.: I: 2/20 (10%) C: 0/20 (0%) p-value NR I group reported higher levels of: soft stools (p=0.002); oily spotting (p<0.001); fatty or oily stools (p<0.001); oily evacuation (p<0.001); liquid stools (p=0.02); cramping (p=0.02); flatus w discharge (p<0.001); fecal incontinence (p<0.001)	Fair	No other outcomes listed here showed significant group differences

Appendix C Evidence Table 3. Pharmacological intervention trials

Study Reference	Study Characteristics	Patient Characteristics	CONSORT Numbers Retention	Inclusion/Exclusion	Description of Intervention Groups	Dose/ Duration
	Metformin-in special population					
Srinivasan et al, 2006	Cross-over RCT 28 children and adolescents Pediatric endocrine clinic Australia Physician referal to endocrine clinic of pediatric hospital Change in body composition	Age: 9-18 (Mean 12.5) 53.6% Female (c) 64% Pacific Islands or Indian subcontinent 25% Northern European 11% Mixed heritage SES: NR Co-morb: 0% DM	34 assessed for eligibility 28 randomized: Group A (metformin first): 13 Group B (placebo first): 15 Retention: A: 10/13 (76.9%) B: 12/15 (80.0%) follow-up	Inclusion: Age 9-18; referred to endocrine clinic with obesity per International Obesity Task Force definition; clinical suspicion of insulin resistance as defined by either a fasting insuline to glucose ratio >4.5 OR the presence of acanthosis nigricans. Exclusion: Known type 1 or 2 DM; contraindications to metformin; contraindications to MRI; weight >120 kg	A: Metformin, then placebo B: Placebo, then metformin	6 months metformin, gradually increased (over 3 wks) up to 2 g/day, 6 months placebo Compliance I: 78% (15-99%) C: 78% (35-98%) p=0.689
Freemark et al., 2001	RCT 32 adolescents University research clinic USA Recruitment strategy: NR Funding: Pharmaceutical and General Clinical Research Center Grant	Age: 12 - 19 years (Mean for CG: 15.4 ± 0.5; IG: 14.4 ± 0.6) 62% Female (c*) 55%White(calc*) 45% Black (calc*) SES: NR % Co-morbid:NR 8 pts had acanthosis nigricans (all were black) *=data were reported only for 29/32 who completed trial	#assessed for eligibility: NR 32 randomized I: 15 C: 17 %retention: I: 93% C: 88% analyzed completers only	Inclusion: Age 12 - 19 who had reached Tanner stage III puberty; BMI > 30 kg/m2; fasting insulin concentration > 15 µU/mL; at least 1 first- or second-degree relative with type 2 diabetes; normal fasting glucose concentration (< 110 mg%) and HbA1c concentration (≤ 6.0%). Exclusion: NR	IG: Metformin CG: Placebo No attempt was made to control the caloric intake or food selection of the patients	Metformin 500 mg or Placebo, twice per day (1 at breakfast; 1 at dinner) x 6 months

Appendix C Evidence Table 3. Pharmacological intervention trials

Study Reference	Mean Entry Wt	Interv phase 6-11 mo	Interv phase 12-23 mo	Interv phase 24+ mo	Post-Intervention	Physiological Outcomes Reported	Other anthropo-morphic Outcomes
	Metformin-in special population						
Srinivasan et al, 2006	BMI, overall: 35.2 ± 5.1 BMI SDS, overall: 2.43 ± 0.28 Weight, kg, overall: 89.9 ± 17.6	Metformin treatment effect size: Weight, kg: -4.35 p=0.02 BMI -1.26 p=0.002 BMI SDS: -0.12 p=0.005				Lipids: Yes Glucose tol: Yes BP: Yes Phys fitness: No	Waist circumference, subcutaneous abdominal adipose tissue, visceral abdomnial adipose tissue, % total body fat.
Freemark et al., 2001	BMI: IG: 41.5 ± 0.9 CG: 38.7 ± 1.3 (p < 0.05)	6 mos: BMI SDS IG: -0.12 CG: 0.23 p< 0.02 BMI IG: -0.5 kg/m2 CG: 0.9 kg/m2 p-value NR	N/A	N/A	N/A	Glucose tol=yes lipids=yes	No

Appendix C Evidence Table 3. Pharmacological intervention trials

Study Reference	Adverse Effects	Study Quality	Comment (mention which other outcomes significant
	Metformin-in special population		
Srinivasan et al, 2006	Any A.E. 2/28 (7%) nausea prevented full dose (both 9-year-olds, youngest age in study) They tolerated 750 mg x2/day Serious A.E. 0/28 (0%) Discontinued treatment due to A.E.: NR	Fair	Fasting insulin and fasting glucose improved with metformin use; sc abdominal adipose tissue reduced with metformin use.
Freemark et al., 2001	No patients discontinued due to adverse events; no episodes of vomiting or lactic acidosis; serum lactate, liver and renal function parameters remained normal IG: 1 pt intermittent nausea in mos 3-4 until metforming dose was reduced by 50%; 3 abdominal discomfort during first 1-2 wks CG: 1 had abdominal discomfort	Fair	Fasting glucose improved more in IG than CG ($p<0.01$); No other statistically significant differences between groups for insulin levels or various measures of insulin sensitivity; nodifference in serum lipids between groups

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Country Setting Recruitment Source Years	Surgical Encounter Characteristics	Inclusion/Exclusion	Patient Characteristics (% with DM, IGT, hypertension, hyperlipidemia)
Laproscopic adjustable gastric banding trials				
Abu-Abeid 2003	Israel Multidisciplinary obesity center with pre-operative evaluation and post-surgical follow-up Patients were referred after failing diet management through dietician. Years NR	Laparoscopic adjustable gastric banding (Lap-Band®) Surgeon characteristics NR Procedure time: NR Hospital stay: 24 hours (1 patient 48 hours)	**Inclusion:** Fulfilled the NIH criteria for morbid obesity; failed weight reduction after 1 yr under supervision of a dietician. **Exclusion:** NR	**N:** 11 **Age:** 15.7 y (11-17) **Female:** 72.7% **Race/Eth:** NR **SES:** NR **Co-morbidities** Heart failure and pulmonary hypertension: 9% (1/11) Amenorrhea: 18% (2/11) Gallstones: 9% (1/11) High triglycerides: 18% (2/11) Abnormal cholesterol: 9% (1/11)

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Duration of follow-up	Mean Entry Weight	Change in Weight	Resolution of co-morbidities post surgery	Other positive outcomes
Laproscopic adj		**Laproscopic adjustable gastric banding trials**			
Abu-Abeid 2003	23 mo (6-36) n=11/11	**BMI:** 46.6 kg/m^2 (38-56.6)	**Mean decrease in BMI (calculated)**: 14.5 kg/m^2 **Mean BMI at follow-up**: 32.1 kg/m^2	Amenorrhea: 100% High triglycerides: 100% (2/2) Abnormal cholesterol: 0% (0/1)	None

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Adverse effects	Study Quality
Laproscopic adj		
Abu-Abeid 2003	Perioperative complications: 0% Late complications: 0%	Fair/poor Data collection: NR

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Country Setting Recruitment Source Years	Surgical Encounter Characteristics	Inclusion/Exclusion	Patient Characteristics (% with DM, IGT, hypertension, hyperlipidemia)
Angrisani 2005	Italy Cases were collected from the electronic database of the Italian Collaborative Study Group for Lap-Band. Multidisciplinary team completed pre-operative evaluation. January 1996-December 2003	Laparoscopic adjustable gastric banding (Brand NR) Surgeon characteristics NR Procedure time: NR Hospital stay: NR	**Inclusion:** ≤ 19 yrs; BMI ≥ 40 or ≥ 35 with comorbities; supportive family environment; failure to obtain weight loss after ≥ 1 yr of conservative medical treatment; psychologic maturity with decisional capacity; willingness to be operated on and follow post-op guidelines. **Exclusion:** Psychiatric or genetic disorders.	**N:** 58 **Age:** 17.96 ± 0.99 y **Female:** 81% **Race/Eth:** NR **SES:** NR **Co-morbidities** Any co-morbidty: 46.5% (27/58) Anxiety/depression: 19% (11/58) Hypertension: 14% (8/58) Dyslipidemia: 10% (6/58) Diabetes: 14% (8/58) Osteoarthropathy: 21% (12/58) Sleep apnea: 17% (10/58) Amenorrhea: 7% (4/58)
Dolan 2003 Dolan 2004 Fielding 2005	Australia Surgical department, community hospital. Multi-disciiplinary team completed pre-operative evaluation. Recruitment source NR Years NR	Laparoscopic adjustable gastric banding (Lap-Band®) Single surgeon Procedure time: NR Hospital stay: NR	**Inclusion:** < 20 yrs, other criteria NR **Exclusion:** NR	**N:** 17 **Age:** Median 17 (12-19) **Female:** 82.4% **Race/Eth:** NR **SES:** NR **Co-morbidities:** NR

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Duration of follow-up	Mean Entry Weight	Change in Weight	Resolution of co-morbidities post surgery	Other positive outcomes
Angrisani 2005	Range 0-7 yrs 1 yr: 48/52 (92.3%) 3 yr: 37/42 (88.1%) 5 yr: 25/33 (75.7%) 7 yr: 10/10 (100%)	**BMI**: 46.1 ± 6.31 kg/m^2 16% had BMI ≥ 50 kg/m^2	**Mean decrease in BMI (calculated)**: ***1 yr*** Completed: 10.2 kg/m^2 Intention-to-treat (ITT): 9.4 kg/m^2 ***3 yr*** Completed: 8.3 kg/m^2 ITT: 7.3 kg/m^2 ***5 yr*** Completed: 11.2 kg/m^2 ITT: 8.5 kg/m^2 ***7 yr*** Completed: 16.4 kg/m^2 ITT: 16.4 kg/m^2 **Failures:** ≤ 25% EWL at 5 yrs: 20% (5/25)	NR	None
Dolan 2003 Dolan 2004 Fielding 2005	Median 25 mo (12-46) <u>Follow-up</u> 12 mo: 17/17 24 mo: 11/17	**BMI** (calculated): 43.1 kg/m^2 (30.3-70.5) **Weight** (calculated): 129.19 kg (82.9-218.8)	**Mean decrease in BMI (calculated)** 12 mo: 10.1 kg/m^2 24 mo: Reported 12.7 kg/m^2 ITT 8.2 kg/m^2 **Mean decrease in weight (calculated)** 12 mo: 29.9 kg 24 mo: Reported 38.7 kg ITT 25.0 kg **BMI < 35**: 76.5% at 12 mo;	NR	None

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Adverse effects	Study Quality
Angrisani 2005	Mortality: None Laparotomic conversion: 1.7% (1/58) Overall postoperative complications: 10.3% (6/58) Band slip: 1.7% (1/58) Gastric pouch dilation: 3.4% (2/58) Intragastric migration: 5.2% (3/58) Band removal: 10.3% (6/58) Conversion to gastric bypass or BPD: 5.2% (3/58)	Fair Small numbers, one with Prader-Willi syndrome; Data collection: Retrospective review of electronic database of the Italian Collaborative Study Group for Lap-Band.
Dolan 2003 Dolan 2004 Fielding 2005	Band slip: 5.9% (1/17) Leaking port: 5.9% (1/17)	Fair/poor Small numbers; inclusion/exclusion criteria not stated Data collection: Prospective

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Country Setting Recruitment Source Years	Surgical Encounter Characteristics	Inclusion/Exclusion	Patient Characteristics (% with DM, IGT, hypertension, hyperlipidemia)
Nadler 2007	NY University center with comprehensive bariatric surgery program Recruitment NR September 2001-February 2006	Laparoscopic adjustable gastric banding (Lap-Band®) 3 surgeons Procedure time: 38 ± 20 min (19-134) Hospital stay: 24 hrs	**Inclusion:** Met NIH criteria for bariatric surgery **Exclusion:** NR	**N:** 53 **Age:** 15.9 y (13-17) **Female:** 77.4% **Race/Eth:** African American 6%; Hispanic 13%; White 81% **SES:** NR **Co-morbidities:** NR

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Duration of follow-up	Mean Entry Weight	Change in Weight	Resolution of co-morbidities post surgery	Other positive outcomes
Nadler 2007	Up to 24 mo Results available for 33/53 (62%) at 6 mo	**BMI**: 47.6 ± 6.7 kg/m^2 **Weight**: 297 ± 53 lbs	**Mean decrease in BMI** (calculated): Completed follow-up 8.1 kg/m^2 ITT 5.0 kg/m^2	NR	None

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Adverse effects	Study Quality
Nadler 2007	Perforated appendicitis within 10 days of surgery: (1.9% 1/53) Band slip 3.8% (2/53) Hiatal hernia 3.8% (2/53) Wound infection 1.9% (1/53) Mild hair loss 9.4% (5/53) Iron deficiency 7.5% (4/53) Nephrolithiasis, cholelithiasis 1.9% (1/53) Gastroesophageal reflux 1.9% (1/53)	Fair Clearly stated "all" adolescents Data collection: All patients prospectively entered into database.

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Country Setting Recruitment Source Years	Surgical Encounter Characteristics	Inclusion/Exclusion	Patient Characteristics (% with DM, IGT, hypertension, hyperlipidemia)
Silberhumer 2006 Widhalm 2004	Austria 3 bariatric surgery centers, Multi-disciplinary team support before and after surgery Referral source NR Years 1998-2004	Laparoscopic adjustable gastric banding ((Lap-Band® n=13; SAGB® n=37) Multiple surgeons Procedure time: 55 ± 35.5 min Hospital stay: 4.0 ± 4.4 days	**Inclusion**: Unsuccessful weight loss through behavioral or drug therapy; above 99.5th percentile for age and gender; those < 14 yrs also had to have at least one co-morbidity. **Exclusion**: NR	**N:** 50 **Age:** 17.1 yrs (9-19) **Female:** 62% **Race/Eth:** NR **SES:** NR **Co-morbidities** Atleast 1 co-morbidty 62% DM II: 10% (5/50) Hypertension: 24% (12/50) Dyslipidemia: 8% (4/50) Asthma: 6% (3/50) Cholecystolithiasis: 6% (3/50)

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Duration of follow-up	Mean Entry Weight	Change in Weight	Resolution of co-morbidities post surgery	Other positive outcomes
Silberhumer 2006 Widhalm 2004	Mean follow-up: 34.7 ± 17.5 mo. (3.6-85.4) n=50/50	**BMI**: 45.2 kg/m^2(32.5-76.7)	**Mean decrease in BMI** (calc): 12.6 kg/m^2 **Mean decrease in weight**: 35.2 ± 23.0 kg (4-120 kg) **Failures**: 6% (3/50) had EWL < 25% after at least 1 yr of follow-up	Resolution DM II: 80% (4/5) Hypertension: 50% (6/12) Dyslipidemia: 100% (4/4) Asthma: 100% (3/3) Cholecystolithiasis: 100% (3/3)	***At last follow-up*** QOL (Moorehead-Ardelt): 0.8 ± 03 to 2.1 ± 0.8 Body image-BAROS: significantly improved Agility-BAROS: increased Psychosocial outcome-BAROS: Excellent 24% (12/50) Very good 40% (20/50) Good 24% (12/50) Fair 10% 5/50) Failure 2% (1/50)

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Adverse effects	Study Quality
Silberhumer 2006 Widhalm 2004	Perioperative complications: 0% Dislocated port: 2% (1/50) Band slip: None	Fair Data collection: Clinic follow-up

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Country Setting Recruitment Source Years	Surgical Encounter Characteristics	Inclusion/Exclusion	Patient Characteristics (% with DM, IGT, hypertension, hyperlipidemia)
Yitzhak 2006	Israel Surgical department of university hospital. Psychological assessment prior to surgery. Recruitment NR 2000-2006	Laparoscopic adjustable gastric banding (SAGB®) Single surgeon Procedure time: NR Hospital stay: NR	**Inclusion:** ≤ 18 yrs; NIH criteria for bariatric surgery; failed conservative weight loss methods. **Exclusion:** NR	**N:** 117 total; n= 60 ≥ 36 mo follow-up **Age:** 16 (9-18) **Female:** 70% **Race/Eth:** NR **SES:** NR **Co-morbidities** Any co-morbidity: 23% Hypertension: 5% Diabetes: 3.3% Asthma: 5% Sleep apnea: 16.7%
Gastric Bypass				
Lawson 2006	Multi-site US 3 pediatric surgical centers Recruitment NR May 2001-October 2003	Laparoscopic Roux-En-Y Gastric Bypass (n=3 open procedure) Surgeons at 3 centers Procedure time: NR Hospital stay: NR	**Inclusion:** BMI ≥ 40 kg/m^2 with serious comorbidities or BMI ≥ 50 kg/m^2 with less severe comorbidities; unsuccessful medical weight loss previously. **Exclusion:** NR	**N:** n=30 weight n=36 harms **Age:** Mean NR (13-21) **Female:** NR **Race/Eth:** NR **SES:** NR **Co-morbidities:** NR

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Duration of follow-up	Mean Entry Weight	Change in Weight	Resolution of co-morbidities post surgery	Other positive outcomes
Yitzhak 2006	Mean follow-up for those with ≥ 36 mo: 39.5 mo n=60/60	**BMI:** 43 kg/m^2 (35-61)	Self-reported measures-Not used	100% resolution of all co-morbidities. Hypertension: 3/3 Diabetes Mellitus: 2/2 Asthma: 3/3 Obstructive sleep apnea: 10/10	Improvement in physical activity: 93% (56/60) Improvement in social self-esteem 72% (43/60) Would you undergo the operation again? Yes-93% (56/60)
Gastric Bypass		**Gastric**			
Lawson 2006	12 mo (10-14) n=30 Harms data reported for patients that were not seen in the 10-14 mo window. N=36	**BMI**: 56.5 ± 5.2 kg/m^2 (41.9-95.5)	**Mean decrease in BMI**: 20.7 ± 8.1 kg/m^2 (3.3-43.5) **Failures**: 6.7% (2/30) in 1st year regained weight-up to 50% of weight lost. All patients were still overweight to severe obesity at 1 yr follow-up.	NR	1 successful and healthy pregnancy within the 1st year.

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Adverse effects	Study Quality
Yitzhak 2006	Mortality: 0% Major post-operative complications: 0% Band slip: 10% (6/60) Band removal: 3.3% (2/60)	Fair/poor Data collection: Review of medical and clinic records; telephone questionnaire.
Gastric Bypass		
Lawson 2006	2/36 were converted to an open procedure (5.6%) Minor complications (readmission < 7 days): 9/36 (25%) Moderate complications (readmission or sequelae for 7-30 days): 4/36 (11%) Severe complication (sequelae for more than 30 days): 2/36 (5.6%), which includes 1 death 9 months post-operative due to complications from severe infectious colitis. Non-compliant with 12 mo. office visit: 23% (9/39)	Fair Patient population not well described. Data collection: retrospective medical record review. Loss to follow-up with physician: 8% (3/36)

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Country Setting Recruitment Source Years	Surgical Encounter Characteristics	Inclusion/Exclusion	Patient Characteristics (% with DM, IGT, hypertension, hyperlipidemia)
Collins 2007 Stanford 2003	Pennsylvania Hospital surgical center with multidisciplinary specialists from affiliated Children's Hospital evaluating before and after surgery. Recruitment NR Years NR	Laparoscopic Roux-En-Y Gastric Bypass Surgeons NR Procedure time: NR Hospital stay: Mean 2.1 days	**Inclusion:** BMI ≥ 35 kg/m^2 with comorbid conditions or ≥ 40 kg/m^2 without comorbid conditions who have failed attempts at traditional methods of weight loss. Carefully selected after multi-disciplinary evaluation of patient with families. **Exclusion: NR**	**N:** 11 **Age:** 16.5 ± 0.2 yrs (15-18) **Female:** NR **Race/Eth:** NR **SES:** NR **Co-morbidities** Diabetes: 54.5% (6/11) Hypertension: 54.5% (6/11) Sleep apnea: 18.2% (2/11) Hypercholesterolemia: 45.5% (5/11) Hypercholesterolemia: 18.2% (2/11) Fatty liver/steatosis: 45.5% (5/11) Polycystic ovarian syndrome: 27.3% (3/11)
Soper 1975 Anderson 1980	USA-Iowa Pediatric surgery department of university hospital Recruitment NR 1969-1973	Open gastric bypass (n=NR); Horizontal gastroplasty (n=NR) Multiple surgeons at single center Procedure time: NR Hospital stay: NR	**Inclusion:** Twice ideal body weight; good health except for obesity-related disorders; potential for normal physical activity; endocrine disorder not cause of obesity. **Exclusion:** NR	**N:** 18 **Age:** Median 19 (≤ 20 yrs) **Female:** 55.6% **Race/Eth:** NR **SES:** NR **Co-morbidities:** NR

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Duration of follow-up	Mean Entry Weight	Change in Weight	Resolution of co-morbidities post surgery	Other positive outcomes
Collins 2007 Stanford 2003	Mean 11.5 ± 2.8 mo (3-32) n=11/11 < 6 mo 6/11	**BMI**: 50.5 ± 2.0 kg/m^2 (42-66) **Weight**: 329.7 ± 15.7 lbs (242-418)	No valid reported outcomes available.	Diabetes: 50% (3/6) Hypertension: 50% (3/6) Obstructive sleep apnea: 100% (2/2) no longer required constant positive airway pressure at night Polycystic ovarian syndrome: 67% (2/3) All co-morbidities: 30.1% resolved.	All patients described self-esteem, physical function, social interactions, and function at work as either "improved" or "greatly improved"
Soper 1975 Anderson 1980	6 mo: 94.4% (17/18 estimated) 10-15 mo: 77.8% (14/18 estimated)	**Median weight**: 147.0 kg	**Median weight loss, % body weight**: 6 mo: Reported 15% ITT 14.2% 10-15 mo: Reported 30% ITT 23.3%	NR	None

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Adverse effects	Study Quality
Collins 2007 Stanford 2003	Postoperative bleeding: 3/11 (27.3%) with 1 of these needing laporoscopic reevaluation. Marginal ulcer: 2/11 (18.2%) (1 and 18 mo postoperative) Non-compliant with vitamin regimen: 18.2% (2/11)	Fair/poor Data collection: Retrospective medical chart review.
Soper 1975 Anderson 1980	Revision: 5.6% (1/18) Wound infection: 12% (3/25*) Respiratory difficulty: 12% (3/25*) Thrombophlebitis: 4% (1/25*) Upper gastrointestinal bleed: 4% (1/25*) Urinary tract infection: 4% (1/25*) Protracted vomiting: 4%(1/25*) Incisional hernia: 16% (4/25*) *n=25, which includes 7 Prader-Willi patients	Fair/poor Data collection: NR

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Country Setting Recruitment Source Years	Surgical Encounter Characteristics	Inclusion/Exclusion	Patient Characteristics (% with DM, IGT, hypertension, hyperlipidemia)
Sugerman 2003	USA-Virginia Surgical department of university hospital Recruitment NR 1981- January 2002	Laparoscopic gastric bypass (n=2); Open gastric bypass (n=15); Long-limb gastric bypass (n=10); Distal gastric bypass (n=3); Horizontal gastroplasty (n=1); Vertical banded gastroplasties (n=2) Surgeon characteristics NR Procedure time: NR Hospital stay: NR	**Inclusion:** 12 to < 18 yrs; eligible for bariatric surgery according to the NIH adult criteria. **Exclusion:** NR	**N:** 33 **Age:** 16 ± 1 yr (12.4-17.9) **Female:** 57.6% **Race/Eth:** White 81.8%; Black 18.2% **SES:** NR **Co-morbidities** Diabetes Mellitus II 3% (1/33) Hypertension 30.3% (10/33) Pseudotumor cerebri 6.1% (2/33) Sleep apnea 18.2% (6/33)

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Duration of follow-up	Mean Entry Weight	Change in Weight	Resolution of co-morbidities post surgery	Other positive outcomes
Sugerman 2003	1 yr n=31/32 5 yr n=20/24 10 yr n=14/18 14 yr n=6/9	**BMI**: 52 ± 11 kg/m^2 (38-91) **Weight**: 150 ± 40 kg (100-303)	**Mean decrease in BMI** 1 yr: Reported 16 kg/m^2 (calc) ITT 15.5 kg/m^2 (calc) 5 yr: Reported 19 kg/m^2 (calc) ITT 15.8 kg/m^2 (calc) 10 yr: Reported 18 kg/m^2 (calc) ITT 14 kg/m^2 (calc) 14 yr: Reported 14 kg/m^2 (calc) ITT 9.3kg/m^2 (calc) **Failures:** 15% (5/33) regained all or most of weight lost at 5-10yrs	Diabetes Mellitus II 100% (1/1) Hypertension 80% (8/10) Sleep apnea 100% (6/6)	None

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Adverse effects	Study Quality
Sugerman 2003	**Late complications**: 21% (7/33) Incisional hernia: 18.2% (6/33) Bowel obstruction: 3% (1/33) Conversions to another type of bypass due to late weight gain or severe protein-calorie malnutrition: 6% (2/33) **Early complications**: Pulmonary embolism 3% (1/33) Major wound infection 3% (1/33) Minor wound infection 12% (4/33) Stomal stenoses 9% (3/33) Marginal ulcers 12% (4/33) No patients had evidence of impaired sexual or physical maturation.	Fair Data collection: Retrospective medical record review.

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Country Setting Recruitment Source Years	Surgical Encounter Characteristics	Inclusion/Exclusion	Patient Characteristics (% with DM, IGT, hypertension, hyperlipidemia)
Capella 2003	USA-New Jersey University Medical Center Recruitment NR May 1990-August 2001	Vertical banded gastroplasty-Roux-en-Y gastric bypass-open procedure Surgeon information NR Procedure time: NR Hospital stay: NR	**Inclusion:** NR **Exclusion:** NR	**N:** 19 **Age:** 15.6 yrs (calc)(13-17) **Female:** NR **Race/Eth:** NR **SES:** NR **Co-morbidities** Dyslipidemia: 15.8% (3/19) Sleep apnea: 15.8% (3/19) Pulmonary hypertension 5.3% (1/19) Hypertension: 15.8% (3/19) Liver steatosis: 21% (4/19) Diabetes: 10.5% (2/19) Peptic esophagitis: 15.8% (3/19) Cholelithiasis: 10.5% (2/19)
Strauss 2001	USA-New Jersey University Hospital Identified in database of those undergoing bariatric surgery at Medical School. Three patients without co-morbidities had psychological evaluation prior to surgery. April 1985- May 1999	Open Roux-en-Y gastric bypass Single surgeon Procedure time: NR Hospital stay: NR	**Inclusion:** Developmentally and genetically normal; > 100% above ideal body weight; at least 100 lbs over ideal body weight; previously unsuccessful at weight loss, typically for > 3 yrs. **Exclusion:** NR	**N:** 10 **Age:** (15-17) **Female:** 70% **Race/Eth:** NR **SES:** NR **Co-morbidities** Hypertension: 30% (3/10) Sleep Apnea: 20% (2/10)

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Duration of follow-up	Mean Entry Weight	Change in Weight	Resolution of co-morbidities post surgery	Other positive outcomes
Capella 2003	Mean 5.5 yrs (1-10) (n=19/19)	**BMI**: 49 kg/m^2 (38-67) **Weight**: 133 kg (91-201)	**Mean decrease in BMI**: 19 kg/m^2	NR	None
Strauss 2001	Mean 5.75 yrs (0.67-13 yr) (n=10/10) > 1 yr in 90 % (9/10)	**Weight:** 148 ± 37 kg **BMI**: 52.4 kg/m^2 (calc)	**Mean decrease in weight**: 46.8 kg (calc) Satisfactory weight loss in 90% (9/10) **Failures**: 3 women who became pregnant regained 13-45 kg	NR	Three uneventful pregnancies occurred.

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Adverse effects	Study Quality
Capella 2003	Mortality: None Revisions: 10.5% (2/19) Cholecystectomy: 5.3% (1/19)	Fair Data collection: "contact with patients was made through office visits, their personal physicians and by phone or mail."
Strauss 2001	Protein-calorie malnutrition/micronutrient deficiency: 10% (1/10) Cholecystectomy: 20% (2/10) Small bowel obstruction 10 yrs postoperative: 10% (1/10) Incisional hernia: 10% (1/10)	Poor Data collection: Medical record review on 5 patients; Self-report weight was by phone interview in 4 patients. 1 patient was lost-to-follow-up.

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Country Setting Recruitment Source Years	Surgical Encounter Characteristics	Inclusion/Exclusion	Patient Characteristics (% with DM, IGT, hypertension, hyperlipidemia)
Barnett 2005	USA-Minnesota Department of surgery-university hospital Recruitment 1971-2001	Open Roux-en-Y gastric bypass (n=5); Vertical banded gastroplasty (n=7); Jejunoileal bypass (n=3) Single surgeon Procedure time: NR Hospital stay: Mean 7 days (4-11)	**Inclusion:** NIH criteria for bariatric surgery **Exclusion:** NR	**N:** 14 **Age:** 15.7 yrs (13-17) **Female:** 57% **Race/Eth:** NR **SES:** NR **Co-morbidities** Hypertension: 35.7% (5/14) Asthma: 21.4% (3/14) Sleep apnea 14.3% (2/14) Diabetes 7.1% (1/14) Hypothyroidism 7.1% (1/14)

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Duration of follow-up	Mean Entry Weight	Change in Weight	Resolution of co-morbidities post surgery	Other positive outcomes
Barnett 2005	9/14 had follow-up > 9 mo (9 mo to 22 yrs)	**BMI**: 55.1 ± 14.8 kg/m^2	**Mean decrease in BMI**: Reported: 24 ± 13.8 kg/m^2 ITT: 15.4 kg/m^2 (calc) **> 50% EWL with > 9 mo follow-up**: 77.8% (7/9)	Hypertension: 100% (5/5) Asthma: 66.7% (2/3) Sleep apnea 100% (2/2) Diabetes 100% (1/1) Hypothyroidism 0% (0/1)	All patients contacted by phone rated their experience as excellent.

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Adverse effects	Study Quality
Barnett 2005	Mortality: None Dumping syndrome: 14.3% (2/14) Surgical site infection: 7.1% (1/14) Hypoglycemia: 7.1% (1/14)	Fair/poor Data collection: Retrospective medical record review of patients in clinical bariatric surgery database.

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Country Setting Recruitment Source Years	Surgical Encounter Characteristics	Inclusion/Exclusion	Patient Characteristics (% with DM, IGT, hypertension, hyperlipidemia)
Breaux 1995	USA-Alabama Surgical unit in community hospital Recruitment NR 1983-1995	Roux-en-Y gastric bypass (n=14); Vertical banded gastroplasty (n=5); Biliopancreatic diversion (n=4) Single surgeon Procedure time: NR Hospital stay: Mean 4.6 (4-5) days non-sleep apnea patients; 6.3 (4-22) days with sleep apnea	**Inclusion:** NR **Exclusion:** NR	**N:** 22 **Age:** 15.3 yr (calc)(8-18) **Female:** 59% (calc) **Race/Eth:** NR **SES:** NR **Co-morbidities** Sleep apnea: 50% (11/22)
Rand 1994	USA-Florida Community hospital Recruitment NR January 1979-December 1990	Open Roux-en-Y gastric bypass (n=30); Vertical banded gastroplasty (n=4) Single surgeon Procedure time: NR Hospital stay: 5 or 6 days	**Inclusion:** NR **Exclusion:** NR	**N:** 34 of 39 possible **Age:** 17 ± 2 yrs (11-19) **Female:** 79% **Race/Eth:** NR **SES:** NR **Co-morbidities:** NR

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Duration of follow-up	Mean Entry Weight	Change in Weight	Resolution of co-morbidities post surgery	Other positive outcomes
Breaux 1995	***Without Sleep apnea*** Mean 50 mo (6-131); 100% follow-up (11/11) ***Sleep apnea*** Mean 32 mo (9-105) ; 81.8% (9/11)	**BMI**: Without sleep apnea 56.4 kg/m^2 Sleep apnea 67.8 kg/m^2 **Weight**: Without sleep apnea 148.6 kg Sleep apnea 169 kg	**Mean decrease in BMI** Without sleep apnea: 20.9 kg/m^2 (calc) Sleep apnea: Reported 23.8 kg/m^2 (calc) ITT 19.5 kg/m^2 (calc) **Mean decrease in Weight** Without sleep apnea: 52 kg (calc) Sleep apnea: Reported 74 kg (calc) ITT 60.5 kg (calc)	Sleep apnea: 100% (11/1	None
Rand 1994	Mean 6 yrs (2-13) (n=34/34)	**BMI**: 47 ± 7 kg/m^2 **Weight**: 131 ± 26 kg (96-189)	Self-reported measures-Not used	NR	85% said they would definitely elect to do surgery if they had it to do over again.

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Adverse effects	Study Quality
Breaux 1995	Mortality: 2 deaths at 15 mo and 3.5 yrs postoperative. 1 had brain tumor and was admitted with protein malnutrition and a seizure disorder. She developed multisystem organ failure and family refused autopsy. The second did not have autopsy but cause of death was listed as "complications arising out of morbid obesity." Incisional hernia: 5% (1/22) Postoperative laryngeal edema: 5% (1/22) Gallstones: 5% (1/22) Kidney stones: 5% (1/22) Nutritional deficiences: 23% (5/22) Revision: 4.5% (1/22)	Fair Data collection: NR
Rand 1994	2 cholecystectomies 1 abdominal panniculectomy No other AE reported. 3 had surgical revisions-2 were scheduled for revisions.	Fair/poor

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Country Setting Recruitment Source Years	Surgical Encounter Characteristics	Inclusion/Exclusion	Patient Characteristics (% with DM, IGT, hypertension, hyperlipidemia)
Mason 1995	USA-Iowa Surgical department of university hospital Recruitment NR 1980-1994	Vertical banded gastroplasty Multiple surgeons Procedure time: Hospital stay: Mean 5.6 days-males; 5.1 days-females.	**Inclusion:** 14 yrs to < 21 yrs; other criteria NR. **Exclusion:** NR	**N:** 47 (2 with Prader Willi) **Age:** 18.1 ± 1.84 **Female:** 68% **Race/Eth:** NR **SES:** NR **Co-morbidities:** NR
Papadia 2007	Italy Surgical department of university hospital Recruitment NR May 1976-December 2005	Biliopancreatic diversion Surgeon characteristics Procedure time: NR Hospital stay: NR	**Inclusion:** <18 yrs **Exclusion:** Prader-Willi syndrome; Turner syndrome.	**N:** 68 **Age:** 16.8 yrs **Female:** 76.5% **Race/Eth:** NR **SES:** NR **Co-morbidities** Hypertensive: 49% (33/68) Dyslipidemic: 16% (11/68) Hyperglycemic: 4% (3/68) Diabetes mellitus II: 3% (2/68)

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Duration of follow-up	Mean Entry Weight	Change in Weight	Resolution of co-morbidities post surgery	Other positive outcomes
Mason 1995	At 5 yrs, data was available for 25/35 patients (71.4%). At 10 yrs, data was available for 14/19 patients (73.7%).	**BMI:** 48.4 kg/m^2 **Weight**: 138.7 kg	**Mean decrease in BMI**: 5 yr Reported: 12.2 kg/m^2 (calc) ITT: 8.7 kg/m^2 (calc) 10yr Reported : 9.2 kg/m^2 (calc) ITT: 6.8 kg/m^2 (calc) **≥ 25% EWL and no revision**: At 5 yrs 74% At last follow-up 61%	NR	None
Papadia 2007	Mean follow up: 11 yrs (2-23) 98.5% (67/68)	**BMI**: 46 kg/m^2 **Weight**: 125 kg	Mean percentage of excess weight lost at last follow-up: 78%	Hypertensive: 92% (27/33) Dyslipidemic: 100% (11/11) Hyperglycemic: NR Diabetes mellitus II: 100% (2/2)	18 women had 28 healthy pregnancies; 3 women had complicated pregnancies.

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Adverse effects	Study Quality
Mason 1995	Mortality: None Revisions: 8.5% (4/47)	Fair/poor Data collection: Medical record review, physician letters, self-report.
Papadia 2007	Reoperations: 19 in 14 patients (14/68=21%) Mortality long-term: 4.4% (3/68) Protein malnutriiton 1-10 yrs post surgery: 16% (11/68) Immediate complication: 1.5% (1/68)	Fair Data collection: Retrospective medical record review

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Country Setting Recruitment Source Years	Surgical Encounter Characteristics	Inclusion/Exclusion	Patient Characteristics (% with DM, IGT, hypertension, hyperlipidemia)
Tsai 2007	USA Healthcare Cost and Utilization Project Nationwide Inpatient Sample Sample contains a representative 20% sample of US community hospitals 1996-2003	Procedures coded as gastric bypass (90%) or gastroplasty (10%) Surgeon characteristics NR Hospital stay: Mean in 2003 of 3.1 ± 0.2 days	**Inclusion:** 10-19 yrs; ICD9 code for obesity and procedure code for gastric bypass or gastroplasty. **Exclusion:** Diagnosis code for abdominal tumors.	**N:** 566 procedures **Age:** 12-19 yrs (96.4% were 15-19) **Female:** 78.6% **Race/Eth:** NR **SES:** NR **Co-morbidities:** NR

NIH criteria for bariatric surgery: BMI ≥ 40 or 35-40 BMI with high-risk co-morbidities.
BAROS: Bariatric Analysis and Reporting Outcome System
NR-not reported

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Duration of follow-up	Mean Entry Weight	Change in Weight	Resolution of co-morbidities post surgery	Other positive outcomes
Tsai 2007	Length of hospital stay post surgery which was 4.1 ± 0.2 days in 1996 and declined to 3.1 ± 0.2 in 2003 p<0.001	NA	NA	NA	None

Appendix C Evidence Table 4. Surgical intervention trials

Study Reference	Adverse effects	Study Quality
Tsai 2007	Mortality: none Major complications: 5.5% 78.3% (119/152) of major complications were respiratory	Fair Laparoscopic procedures became increasingly used throughout the study period. Did not capture any longer-term adverse events Data collection: Inhospital experience use medical record

Appendix D. List of Excluded Studies

Behavioral interventions

References	Reason for Exclusion
Alexy U, Reinehr T, Sichert-Hellert W, Wollenhaupt A, Kersting M, Andler W. Positive changes of dietary habits after an outpatient training program for overweight children. *Nutrition Research* 26 (5):202-208, 2006.	Not a weight loss trial
Amador M, Ramos LT, Morono M, Hermelo MP. Growth rate reduction during energy restriction in obese adolescents. *Exp Clin Endocrinol.* 1990;96:73-82.	Setting
Ambler C, Eliakim A, Brasel JA, Lee WN, Burke G, Cooper DM. Fitness and the effect of exercise training on the dietary intake of healthy adolescents. *Int J Obes Relat Metab Disord.* 1998;22:354-362.	Relevance
Arnold, Linda L. The effects of a program of exercise and nutrition on body composition in adolescents and young adults with moderate cognitive disabilities: A descriptive study. Dissertation Abstracts International: Section B: The Sciences and Engineering 65[11-B], 6062. 2005.	Population
Ask AS, Hernes S, Aarek I, Johannessen G, Haugen M. Changes in dietary pattern in 15 year old adolescents following a 4 month dietary intervention with school breakfast--a pilot study. *Nutrition Journal 5:33.* 2006.	Did not report relevant outcomes
Atlantis E, Barnes EH, Singh MA. Efficacy of exercise for treating overweight in children and adolescents: a systematic review. *Int J Obes (Lond).* 2006;30:1027-1040.	Design
Balagopal P, George D, Patton N et al. Lifestyle-only intervention attenuates the inflammatory state associated with obesity: a randomized controlled study in adolescents. *Journal of Pediatrics 146(3):342 -8.* 2005.	Design
Balagopal P, George D, Yarandi H, Funanage V, Bayne E. Reversal of obesity-related hypoadiponectinemia by lifestyle intervention: a controlled, randomized study in obese adolescents. *Journal of Clinical Endocrinology & Metabolism 90(11):6192 -7.* 2005.	Design
Bauer C, Fischer A, Keller U. Effect of sibutramine and of cognitive-behavioural weight loss therapy in obesity and subclinical binge eating disorder. *Diabetes, Obesity & Metabolism 8(3):289 -95 .* 2006.	Design
Baumer JH. Obesity and overweight: its prevention, identification, assessment and management. *Archives of Disease in Childhood Education & Practice 92(3):ep92 -6.* 2007.	Design
Becque MD, Katch VL, Rocchini AP, Marks CR, Moorehead C. Coronary risk incidence of obese adolescents: reduction by exercise plus diet intervention. *Am J Clin Nutr.* 1988;81:605-612.	Design
Beech BM, Klesges RC, Kumanyika SK et al. Child- and parent-targeted interventions: the Memphis GEMS pilot study. *Ethn Dis.* 2003;13:S40-S53.	Design
Berry D, Savoye M, Melkus G, Grey M. An intervention for multiethnic obese parents and overweight children. *Applied Nursing*	Design

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Behavioral interventions

References	Reason for Exclusion
Research. 2007;63-71, 2007.	
Berry D, Sheehan R, Heschel R, Knafl K, Melkus G, Grey M. Family-based interventions for childhood obesity: a review (Structured abstract). *SO: Journal of Family Nursing.* 2004;10:429-449.	Design
Braet C, Van WM, Van LK. Follow-up results of different treatment programs for obese children. *Acta Paediatr.* 1997;86:397-402.	Design
Braet, C. and Winckel, M. V. Long-Term Follow-Up of a Cognitive Behavioral Treatment Program for Obese Children. Behavior Therapy 31, 55-74. 2000.	Design
Brown R, Sothern M, Suskind R, Udall J, Blecker U. Racial differences in the lipid profiles of obese children and adolescents before and after significant weight loss. *Clin Pediatr (Phila).* 2000;39:427-431.	Design
Brownell KD, Kaye FS. A school-based behavior modification, nutrition education, and physical activity program for obese children. *Am J Clin Nutr.* 1982;35:277-283.	Design
Butryn ML, Wadden TA. Treatment of overweight in children and adolescents: does dieting increase the risk of eating disorders? (Structured abstract). *SO: International Journal of Eating Disorders.* 2005;37:285-293.	Design
Campbell KJ, Hesketh KD. Strategies which aim to positively impact on weight, physical activity, diet and sedentary behaviours in children from zero to five years. A systematic review of the literature. *Obesity Reviews 8(4):327-38.* 2007.	Did not report relevant outcomes
Chang FT, Hu SH, Wang RS. The effectiveness of dietary instruction in obese school children of southern Taiwan. *Kaohsiung J Med Sci.* 1998;14:528-535.	Setting
Chen W, Chen SC, Hsu HS, Lee C. Counseling clinic for pediatric weight reduction: program formulation and follow-up. *J Formos Med Assoc.* 1997;96:59-62.	Setting
Clemmens D, Hayman LL. Increasing activity to reduce obesity in adolescent girls: a research review (Provisional record). *SO: Journal of Obstetric, Gynecologic and Neonatal Nursing.* 2004;33:801-808.	Design
Cliff DP, Wilson A, Okely AD, Mickle KJ, Steele JR. Feasibility of SHARK: A physical activity skill-development program for overweight and obese children. *Journal of Science & Medicine in Sport 10(4):263-7.* 2007.	Design
Cole K, Waldrop J, D'Auria J, Garner H. An integrative research review: effective school-based childhood overweight interventions. *J Spec Pediatr Nurs.* 2006;11:166-177.	Design
Coleman KJ, Tiller CL, Sanchez J et al. Prevention of the epidemic increase in child risk of overweight in low-income schools: the El Paso coordinated approach to child health. *Archives of Pediatrics & Adolescent Medicine 159(3):217 -24.* 2005.	Relevance

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Behavioral interventions

References	Reason for Exclusion
Collins CE, Warren J, Neve M, McCoy P, Stokes BJ. Measuring effectiveness of dietetic interventions in child obesity: a systematic review of randomized trials. *Arch Pediatr Adolesc Med.* 2006;160:906-922.	Design
Collins CE, Warren JM, Neve M, McCoy P, Stokes B. Systematic review of interventions in the management of overweight and obese children which include a dietary component (Provisional record). *SO: International Journal of Evidence Based Healthcare.* 2007;5:2-53.	Design
Daley AJ, Copeland RJ, Wright NP, Roalfe A, Wales JK. Exercise therapy as a treatment for psychopathologic conditions in obese and morbidly obese adolescents: a randomized, controlled trial. *Pediatrics 118 (5):2126 -34.* 2006.	Relevance
Daley AJ, Copeland RJ, Wright NP, Wales JK. Protocol for: Sheffield Obesity Trial (SHOT): a randomised controlled trial of exercise therapy and mental health outcomes in obese adolescents [ISRCNT83888112]. *BMC Public Health 5:113.* 2005.	Relevance
Danielzik, S., Pust, S., Landsberg, B., and Muller, M. J. First lessons from the Kiel Obesity Prevention Study (KOPS). International Journal of Obesity 29[Suppl2], S78-S83. 2005.	Relevance
Davee AM, Blum JE, Devore RL et al. The vending and a la carte policy intervention in Maine public high schools. *Preventing Chronic Disease 2 Spec no:A14 .* 2005.	Design
Davis CE, Hunsberger S, Murray DM et al. Design and statistical analysis for the Pathways study. *Am J Clin Nutr.* 1999;69:760S-763S.	Relevance
DeJongh ED, Binkley TL, Specker BL. Fat mass gain is lower in calcium-supplemented than in unsupplemented preschool children with low dietary calcium intakes. *American Journal of Clinical Nutrition 84(5):1123 -7.* 2006.	Relevance
DeMattia L, Lemont L, Meurer L. Do interventions to limit sedentary behaviours change behaviour and reduce childhood obesity? A critical review of the literature. *Obesity Reviews 8(1):69 -81 .* 2007.	Design
Dennison BA, Russo TJ, Burdick PA, Jenkins PL. An intervention to reduce television viewing by preschool children. *Arch Pediatr Adolesc Med.* 2004;158:170-176.	Relevance
Dicken KR, Bell MM. Pedometers as a means to increase walking and achieve weight loss. *SO: Journal of the American Board of Family Medicine : JABFM.* 2006;19:524-525.	Population
Donnelly JE, Jacobsen DJ, Whatley JE, Hill JO, Swift LL, Cherrington A, Polk B, Tran ZV, Reed G. Nutrition and physical activity program to attenuate obesity and promote physical and metabolic fitness in elementary school children. *Obes Res* 4 (3):229-243, 1996.	Prevention trial
Dreimane D, Safani D, MacKenzie M et al. Feasibility of a hospital-based, family-centered intervention to reduce weight gain in overweight children and adolescents. *Diabetes Research & Clinical*	Design

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Behavioral interventions

References	Reason for Exclusion
Practice 75(2):159-68 . 2007.	
Ebbeling CB, Feldman HA, Osganian SK, Chomitz VR, Ellenbogen SJ, Ludwig DS. Effects of decreasing sugar-sweetened beverage consumption on body weight in adolescents: a randomized, controlled pilot study. *Pediatrics 117 (3):673 -80 .* 2006.	Relevance
Ebbeling CB, Garcia-Lago E, Leidig MM, Seger-Shippee LG, Feldman HA, Ludwig DS. Altering portion sizes and eating rate to attenuate gorging during a fast food meal: effects on energy intake. *Pediatrics 119 (5):869 -75.* 2007.	Relevance
Ebbeling CB, Leidig MM, Feldman HA, Lovesky MM, Ludwig DS. Effects of a low-glycemic load vs low-fat diet in obese young adults: a randomized trial. *JAMA 297 (19):2092 -102 .* 2007.	Population
Ebbeling CB, Leidig MM, Sinclair KB, Hangen JP, Ludwig DS. A reduced-glycemic load diet in the treatment of adolescent obesity. *Archives of Pediatrics & Adolescent Medicine.* 2003;157:773-779.	Design
Economos CD, Hyatt RR, Goldberg JP et al. A community intervention reduces BMI z-score in children: Shape Up Somerville first year results. *Obesity 15(5):1325 -36.* 2007.	Relevance
Edwards B. Childhood obesity: a school-based approach to increase nutritional knowledge and activity levels. *Nurs Clin North Am.* 2005;40:661-6ix.	Did not report relevant outcomes
Eliakim A, Kaven G, Berger I, Friedland O, Wolach B, Nemet D. The effect of a combined intervention on body mass index and fitness in obese children and adolescents - a clinical experience. *Eur J Pediatr.* 2002;161:449-454.	Did not report relevant outcomes
Epstein LH, Kuller LH, Wing RR, Valoski A, McCurley J. The effect of weight control on lipid changes in obese children. *Am J Dis Child.* 1989;143:454-457.	Precedes search period
Epstein LH, McCurley J, Wing RR, Valoski A. Five-year follow-up of family-based behavioral treatments for childhood obesity. *J Consult Clin Psychol.* 1990;58:661-664.	Design
Epstein LH, McKenzie SJ, Valoski A, Klein KR, Wing RR. Effects of mastery criteria and contingent reinforcement for family-based child weight control 3838. *Addictive Behaviors.* 1994;19:135-145.	Design
Epstein LH, Paluch RA, Raynor HA. Sex differences in obese children and siblings in family-based obesity treatment. *Obesity Research.* 2001;9:746-753.	Design
Epstein LH, Saelens BE, O'Brien JG. Effects of reinforcing increases in active behavior versus decreases in sedentary behavior for obese children. *Int J Behav Med.* 1995;2:41-50.	Did not report relevant outcomes
Epstein LH, Valoski A, McCurley J. Effect of weight loss by obese children on long-term growth. *Am J Dis Child.* 1993;147:1076-1080.	Design
Epstein LH, Valoski A, Wing RR, McCurley J. Ten-year outcomes of behavioral family-based treatment for childhood obesity. *Health*	Design

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Behavioral interventions

References	Reason for Exclusion
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Epstein LH, Valosk Ai, Wing RR, McCurley J. Ten-year follow-up of behavioral, family-based treatment for obese children. *JAMA* 264 (19):2519-2523, 1990.	Precedes search period
Epstein LH, Valoski AM, Kalarchian MA, McCurley J. Do children lose and maintain weight easier than adults: a comparison of child and parent weight changes from six months to ten years. *Obes Res.* 1995;3:411-417.	Did not report relevant outcomes
Epstein LH, Wing RR, Koeske R, Andrasik F, Ossip DJ. Child and parent weight loss in family-based behavior modification programs. *J Consult Clin Psychol.* 1981;49:674-685.	Design
Epstein LH, Wing RR, Koeske R, Valoski A. Effect of parent weight on weight loss in obese children. *J Consult Clin Psychol.* 1986;54:400-401.	Did not report relevant outcomes
Epstein LH, Wing RR, Koeske R, Valoski A. Effects of diet plus exercise on weight change in parents and children. *J Consult Clin Psychol.* 1984;52:429-437.	Precedes search period
Epstein LH, Wing RR, Koeske R, Valoski A. Long-term effects of family-based treatment of childhood obesity. *J Consult Clin Psychol.* 1987;55:91-95.	Precedes search period
Epstein LH, Valoski A, Koeske R, Wing RR. Family-based behavioral weight control in obese young children. *J Am Diet Assoc* 86 (4):481-484, 1986.	Design
Epstein LH, Valoski AM, Vara LS, McCurley J, Wisniewski L, Kalarchian MA, Klein KR, Shrager LR. Effects of decreasing sedentary behavior and increasing activity on weight change in obese children 3814. *Health Psychology.* 14 (2):109-115, 1995	Design
Epstein LH, R. Paluch RA, Gordy CC, Dorn J. Decreasing sedentary behaviors in treating pediatric obesity. *Arch Pediatr Adolesc Med* 154 (3):220-226, 2000.	Design
Epstein LH, Paluch RA, Saelens BE, Ernst MM, Wilfley DE. Changes in eating disorder symptoms with pediatric obesity treatment. *J Pediatr* 139 (1):58-65, 2001	Design
Epstein LH, Paluch RA, Kilanowski CK, Raynor HA. The effect of reinforcement or stimulus control to reduce sedentary behavior in the treatment of pediatric obesity. *Health Psychol* 23 (4):371-380, 2004.	Design
Epstein LH, Paluch RA, Roemmich JN, Beecher MD. Family-based obesity treatment, then and now: Twenty-five years of pediatric	Design

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References	Reason for Exclusion
obesity treatment. *Health Psychol.* 26(4):381-391, 2007.	
Epstein LH, Wing RR, Valoski A, Penner BC. Stability of food preferences during weight control. A study with 8- to 12-year-old children and their parents. *Behav Modif.* 1987;11:87-101.	Did not report relevant outcomes
Figueroa-Colon R, von Almen TK, Franklin FA, Schuftan C, Suskind RM. Comparison of two hypocaloric diets in obese children. *Am J Dis Child.* 1993;147:160-166.	Design
Figueroa-Colon R, Franklin FA, Lee JR, von Almen TK, Suskind RM. Feasibility of a clinic-based hypocaloric dietary intervention implemented in a school setting for obese children. *Obes Res* 4 (5):419-429, 1996.	Design
Flodmark, C.-E., Marcus, C., and Britton, M. Interventions to prevent obesity in children and adolescents: A systematic literature review. International Journal of Obesity 30[4], 579-589. 2006.	Relevance
Flores R. Dance for health: improving fitness in African American and Hispanic adolescents. *Public Health Rep* 110 (2):189-193, 1995.	Outcomes < 6 months
Foster GD, Wadden TA, Brownell KD. Peer-led program for the treatment and prevention of obesity in the schools. *J Consult Clin Psychol.* 1985;53:538-540.	Design
Gately PJ, Cooke CB, Barth JH, Bewick BM, Radley D, Hill AJ. Children's residential weight-loss programs can work: a prospective cohort study of short-term outcomes for overweight and obese children. *Pediatrics 116(1):73-7.* 2005.	Design
Gately PJ, King NA, Greatwood HC et al. Does a High-protein Diet Improve Weight Loss in Overweight and Obese Children? *Obesity 15(6):1527 -34.* 2007.	Design
Gibson LJ, Peto J, Warren JM, dos SS, I. Lack of evidence on diets for obesity for children: a systematic review. *International Journal of Epidemiology 35(6):1544 -52.* 2006.	Design
Golan M, Crow S. Targeting parents exclusively in the treatment of childhood obesity: long-term results. *Obes Res.* 2004;12:357-361.	Information provided in another publication
Goldfield GS, Mallory R, Parker T et al. Effects of modifying physical activity and sedentary behavior on psychosocial adjustment in overweight/obese children. *Journal of Pediatric Psychology 32(7):783-93.* 2007.	Design
Goldfield GS, Epstein LH, Kilanowski CK, Paluch RA, Kogut-Bossler B. Cost-effectiveness of group and mixed family-based treatment for childhood obesity. *Int J Obes Relat Metab Disord* 25 (12):1843-1849, 2001.	Design
Gortmaker SL, Peterson K, Wiecha J et al. Reducing obesity via a school-based interdisciplinary intervention among youth: Planet	Relevance

Appendix D. List of Excluded Studies

Behavioral interventions

References	Reason for Exclusion
Health. *Arch Pediatr Adolesc Med.* 1999;153:409-418.	
Graf C, Koch B, Bjarnason-Wehrens B et al. Who benefits from intervention in, as opposed to screening of, overweight and obese children? *Cardiology in the Young 16(5):474 -80 .* 2006.	Did not report relevant outcomes
Graves T, Meyers AW, Clark L. An evaluation of parental problem-solving training in the behavioral treatment of childhood obesity. *J Consult Clin Psychol.* 1988;56:246-250.	Design
Grey M, Berry D, Davidson M, Galasso P, Gustafson E, Melkus G. Preliminary testing of a program to prevent type 2 diabetes among high-risk youth. *J Sch Health* 74 (1):10-15, 2004.	Design
Harrell JS, Gansky SA, McMurray RG, Bangdiwala SI, Frauman AC, Bradley CB. School-based interventions improve heart health in children with multiple cardiovascular disease risk factors. *Am J Clin Nutr.* 1998;102:371-380.	Relevance
Harvey-Berino J, Rourke J. Obesity prevention in preschool native-american children: a pilot study using home visiting. *Obes Res.* 2003;11:606-611.	Relevance
Heymsfield SB, van-Mierlo CA, van-der-Knaap HC, Heo M, Frier H, I. Weight management using a meal replacement strategy: meta and pooling analysis from six studies (Structured abstract). *SO: International Journal of Obesity.* 2003;27:537-549.	Population
Hills AP, Parker AW. Obesity management via diet and exercise intervention. *Child Care Health Dev.* 1988;14:409-416.	Design
Huang JS, Norman GJ, Zabinski MF, Calfas K, Patrick K. Body image and self-esteem among adolescents undergoing an intervention targeting dietary and physical activity behaviors. *Journal of Adolescent Health 40(3):245 -51.* 2007.	Relevance
Ildiko V, Zsofia M, Janos M et al. Activity-related changes of body fat and motor performance in obese seven-year-old boys. *Journal of Physiological Anthropology 26(3):333-7.* 2007.	Setting
Intense diet, behavior, and physical activity intervention effective for obese children. *J Fam Pract.* 2005;54:579.	Design
Israel A, Solotar LC, Zimand E. An Investigation of Two Parental Involvement Roles in the Treatment of Obese Children. *Int.J.Eat.Disord.* 9(5):557-564, 1990.	Design
Jago R, Jonker ML, Missaghian M, Baranowski T. Effect of 4 weeks of Pilates on the body composition of young girls. *Preventive Medicine 42(3):177-80 .* 2006.	Relevance
Jago R, Baranowski T, Baranowski JC, Thompson D, Cullen KW, Watson K, Liu Y. Fit for Life Boy Scout badge: outcome evaluation of a troop and Internet intervention. *SO: Preventive medicine* 42 (3):181-187, 2006.	Prevention Trial

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Behavioral interventions

References	Reason for Exclusion
Jelalian E, Mehlenbeck R, Lloyd-Richardson EE, Birmaher V, Wing RR. 'Adventure therapy' combined with cognitive-behavioral treatment for overweight adolescents. *International Journal of Obesity 30(1):31-9.* 2006.	Design
Jelalian E, Wember YM, Bungeroth H, Birmaher V. Practitioner review: bridging the gap between research and clinical practice in pediatric obesity. *Journal of Child Psychology & Psychiatry & Allied Disciplines 48 (2):115-27.* 2007.	Design
Jiang JX, Xia XL, Greiner T, Lian GL, Rosenqvist U. A two year family based behaviour treatment for obese children. *Archives of Disease in Childhood 90(12):1235 -8.* 2005.	Setting
Johnston, Craig A. and Steele, Ric G. Treatment of Pediatric Overweight: An Examination of Feasibility and Effectiveness in an Applied Clinical Setting. Journal of Pediatric Psychology 32[1], 106-110. 2007.	Design
Jones RA, Okely AD, Collins CE et al. The HIKCUPS trial: a multi-site randomized controlled trial of a combined physical activity skill-development and dietary modification program in overweight and obese children. *BMC Public Health 7:15.* 2007.	Did not report relevant outcomes
Kelly AS, Steinberger J, Olson TP, Dengel DR. In the absence of weight loss, exercise training does not improve adipokines or oxidative stress in overweight children. *Metabolism: Clinical & Experimental 56(7):1005 -9.* 2007.	Design
Kitzmann, Katherine M. and Beech, Bettina M. Family-Based Interventions for Pediatric Obesity: Methodological and Conceptual Challenges From Family Psychology. Journal of Family Psychology 20[2], 175-189. 2006.	Design
Klijn PH, van der Baan-Slootweg OH, van Stel HF. Aerobic exercise in adolescents with obesity: preliminary evaluation of a modular training program and the modified shuttle test. *BMC Pediatrics 7:19.* 2007.	Design
Korsten-Reck U, Kromeyer-Hauschild K, Wolfarth B, Dickhuth HH, Berg A. Freiburg Intervention Trial for Obese Children (FITOC): results of a clinical observation study. *International Journal of Obesity 29(4):356 -61.* 2005.	Did not report relevant outcomes
Lansky D, Vance MA. School-based intervention for adolescent obesity: analysis of treatment, randomly selected control, and self-selected control subjects. *J Consult Clin Psychol.* 1983;51:147-148.	Design
Lauer RM, Obarzanek E, Hunsberger SA, Van Horn L, Hartmuller VW, Barton BA, Stevens VJ, Kwiterovich Jr. PO, Franklin, Jr. FA, Kimm SY, Lasser CL, Simons-MortonDG. Efficacy and safety of lowering dietary intake of total fat, saturated fat, and cholesterol in children with elevated LDL cholesterol: the Dietary Intervention Study in Children. *Am J Clin Nutr* 72 (5 Suppl):1332S-1342S, 2000.	Not a weight loss trial
Levine MD, Ringham RM, Kalarchian MA, Wisniewski L, Marcus MD. Is family-based behavioral weight control appropriate for severe	Design

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Behavioral interventions

References	Reason for Exclusion
pediatric obesity? *Int J Eat Disord.* 2001;30:318-328.	
Lytle LA, Stone EJ, Nichaman MZ et al. Changes in nutrient intakes of elementary school children following a school-based intervention: results from the CATCH Study. *Prev Med.* 1996;25:465-477.	Relevance
Maffeis C, Castellani M. Physical activity: an effective way to control weight in children? *Nutrition Metabolism & Cardiovascular Diseases 17(5):394 -408 .* 2007.	Design
Manios Y, Moschandreas J, Hatzis C, Kafatos A. Evaluation of a health and nutrition education program in primary school children of Crete over a three-year period. *Prev Med.* 1999;28:149-159.	Relevance
McLean N, Griffin S, Toney K, Hardeman W. Family involvement in weight control, weight maintenance and weight-loss interventions: a systematic review of randomised trials (Provisional record). *SO: International Journal of Obesity.* 2003;27:987-1005.	Design
Meyer AA, Kundt G, Lenschow U, Schuff-Werner P, Kienast W. Improvement of early vascular changes and cardiovascular risk factors in obese children after a six-month exercise program. *Journal of the American College of Cardiology 48 (9):1865 -70.* 2006.	Did not report relevant outcomes
Moore, Brie A. and O'Donohue, William T. 225-270. 2005.	Design
Moreno LA. Interventions to improve cardiovascular risk factors in obese children. *Journal of Pediatric Gastroenterology & Nutrition 43(4):433 -5.* 2006.	Design
Mo-suwan L, Pongprapai S, Junjana C, Puetpaiboon A. Effects of a controlled trial of a school-based exercise program on the obesity indexes of preschool children. *Am J Clin Nutr.* 1998;68:1006-1011.	Setting
Muller MJ, Asbeck I, Mast M, Langnase K, Grund A. Prevention of obesity--more than an intention. Concept and first results of the Kiel Obesity Prevention Study (KOPS). *Int J Obes Relat Metab Disord* 25 Suppl 1:S66-S74, 2001.	Prevention trial
Nemet D, Berger-Shemesh E, Wolach B, Eliakim A. A combined dietary-physical activity intervention affects bone strength in obese children and adolescents. *International Journal of Sports Medicine 27(8):666 -71.* 2006.	Design
Nova E, Varela P, Lopez-Vidriero I, Toro O, Cena MJ, Casas J, Marcos A. A one-year follow-up study in anorexia nervosa. Dietary pattern and anthropometrical evolution. *Eur J Clin Nutr* 55 (7):547-554, 2001.	Population
Nuutinen O, Knip M. Long-term weight control in obese children: persistence of treatment outcome and metabolic changes. *Int J Obes Relat Metab Disord.* 1992;16:279-287.	Relevance
O'Dea JA, Abraham S. Improving the body image, eating attitudes, and behaviors of young male and female adolescents: a new educational approach that focuses on self-esteem. *Int J Eat Disord.*	Relevance

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Behavioral interventions

References	Reason for Exclusion
2000;28:43-57.	
Owens S, Gutin B, Allison J et al. Effect of physical training on total and visceral fat in obese children. *Med Sci Sports Exerc.* 1999;31:143-148.	Design
Patrick K, Calfas KJ, Norman GJ et al. Randomized controlled trial of a primary care and home-based intervention for physical activity and nutrition behaviors: PACE+ for adolescents. *SO: Archives of pediatrics & adolescent medicine.* 2006;160:128-136.	Relevance
Peterson KE, Fox MK. Addressing the epidemic of childhood obesity through school-based interventions: what has been done and where do we go from here? *Journal of Law, Medicine & Ethics 35(1):113-30.* 2007.	Design
Poland BD. Learning to 'walk our talk': the implications of sociological theory for research methodologies in health promotion. *Can J Public Health.* 1992;83 Suppl 1:S31-S46.	Relevance
Ray R, Lim LH , Ling SL. Obesity in preschool children: an intervention programme in primary health care in Singapore. *Ann Acad Med Singapore* 23 (3):335-341, 1994.	Design
Reinehr T, Kersting M, Alexy U, Andler W. Long-term follow-up of overweight children: after training, after a single consultation session, and without treatment. *J Pediatr Gastroenterol Nutr* 37 (1):72-74, 2003.	Quality
Reinehr T, de SG, Toschke AM, Andler W. Long-term follow-up of cardiovascular disease risk factors in children after an obesity intervention. *American Journal of Clinical Nutrition 84(3):490 -6.* 2006.	Did not report relevant outcomes
Reinehr T, de SG, Wabitsch M. Changes of cardiovascular risk factors in obese children effects of inpatient and outpatient intervention. *Journal of Pediatric Gastroenterology & Nutrition 43(4):506-11.* 2006.	Information provided in another publication
Resnicow K, Davis R, Rollnick S. Motivational interviewing for pediatric obesity: Conceptual issues and evidence review. *Journal of the American Dietetic Association 106(12):2024-33.* 2006.	Design
Resnicow K, Yaroch AL, Davis A et al. GO GIRLS!: results from a nutrition and physical activity program for low-income, overweight African American adolescent females. *Health Educ Behav.* 2000;27:616-631.	Design
Reybrouck T, Vinckx J, Van den BG, Vanderschueren-Lodeweyckx M. Exercise therapy and hypocaloric diet in the treatment of obese children and adolescents. *Acta Paediatr Scand.* 1990;79:84-89.	Did not report relevant outcomes
Robbins LB, Gretebeck KA, Kazanis AS, Pender NJ. Girls on the move program to increase physical activity participation. *Nursing Research 55(3):206 -16.* 2006;-Jun.	Design

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Behavioral interventions

References	Reason for Exclusion
Robinson TN. Reducing children's television viewing to prevent obesity: a randomized controlled trial. *JAMA.* 1999;282:1561-1567.	Relevance
Rocchini AP, Katch V, Anderson J et al. Blood pressure in obese adolescents: effect of weight loss. *Am J Clin Nutr.* 1988;82:16-23.	Design
Rocchini AP, Katch V, Schork A, Kelch RP. Insulin and blood pressure during weight loss in obese adolescents. *Hypertension.* 1987;10:267-273.	Design
Rodearmel SJ, Wyatt HR, Barry MJ et al. A family-based approach to preventing excessive weight gain. *Obesity 14(8):1392 -401 .* 2006.	Design
Rolland-Cachera MF, Thibault H, Souberbielle JC, Soulie D, Carbonel P, Deheeger M, Roinsol D, Longueville E, Bellisle F, Serog P. Massive obesity in adolescents: dietary interventions and behaviours associated with weight regain at 2 y follow-up. *Int J Obes Relat Metab Disord* 28 (4):514-519, 2004.	Design
Rosenbaum M, Nonas C, Weil R et al. School-based intervention acutely improves insulin sensitivity and decreases inflammatory markers and body fatness in junior high school students. *Journal of Clinical Endocrinology & Metabolism 92(2):504 -8.* 2007.	Design
Salmon J, Booth ML, Phongsavan P, Murphy N, Timperio A. Promoting Physical Activity Participation among Children and Adolescents. *Epidemiologic Reviews 29:144 -59.* 2007.	Design
Sasaki J, Shindo M, Tanaka H, Ando M, Arakawa K. A long-term aerobic exercise program decreases the obesity index and increases the high density lipoprotein cholesterol concentration in obese children. *Int J Obes.* 1987;11:339-345.	Design
Schwartz RP, Hamre R, Dietz WH et al. Office-based motivational interviewing to prevent childhood obesity: a feasibility study. *Archives of Pediatrics & Adolescent Medicine 161(5):495 -501 .* 2007.	Did not meet quality criteria
Schwingshandl J, Sudi K, Eibl B, Wallner S, Borkenstein M. Effect of an individualised training programme during weight reduction on body composition: a randomised trial. *Arch Dis Child.* 1999;81:426-428.	Design
Shaibi GQ, Cruz ML, Ball GD et al. Effects of resistance training on insulin sensitivity in overweight Latino adolescent males. *Medicine & Science in Sports & Exercise 38(7):1208 -15.* 2006.	Design
Sharma M. School-based interventions for childhood and adolescent obesity. *Obesity Reviews 7(3):261 -9.* 2006.	Design
Sherry B. Food behaviors and other strategies to prevent and treat pediatric overweight. *International Journal of Obesity 29 Suppl 2:S116 -26.* 2005.	Design
Singh AS, Paw MJ, Brug J, van MW. Short-term effects of school-based weight gain prevention among adolescents. *Archives of Pediatrics & Adolescent Medicine 161(6):565 -71.* 2007.	Relevance

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References	Reason for Exclusion
Snethen JA, Broome ME, Cashin SE. Effective weight loss for overweight children: a meta-analysis of intervention studies. *Journal of Pediatric Nursing 21(1):45-56.* 2006.	Design
Sondike SB, Copperman N, Jacobson MS. Effects of a low-carbohydrate diet on weight loss and cardiovascular risk factor in overweight adolescents. *J Pediatr.* 2003;142:253-258.	Design
Sothern MS, Despinasse B, Brown R, Suskind RM, Udall JN, Jr., Blecker U. Lipid profiles of obese children and adolescents before and after significant weight loss: differences according to sex. *South Med J.* 2000;93:278-282.	Design
Sothern MS, Hunter S, Suskind RM, Brown R, Udall JN, Jr., Blecker U. Motivating the obese child to move: the role of structured exercise in pediatric weight management. *South Med J.* 1999;92:577-584.	Design
Sothern MS, Loftin JM, Udall JN et al. Safety, feasibility, and efficacy of a resistance training program in preadolescent obese children. *Am J Med Sci.* 2000;319:370-375.	Design
Sothern MS, Schumacher H, von Almen TK, Carlisle LK, Udall JN. Committed to kids: an integrated, 4-level team approach to weight management in adolescents. *J Am Diet Assoc.* 2002;102:S81-S85.	Design
Sothern, Udall JN, Jr., Suskind RM, Vargas A, Blecker U. Weight loss and growth velocity in obese children after very low calorie diet, exercise, and behavior modification. *Acta Paediatr.* 2000;89:1036-1043.	Design
Southard DR, Southard BH. Promoting physical activity in children with MetaKenkoh. *Clinical & Investigative Medicine - Medecine Clinique et Experimentale 29(5):293 -7.* 2006.	Design
Spieth LE, Harnish JD, Lenders CM et al. A low-glycemic index diet in the treatment of pediatric obesity. *Arch Pediatr Adolesc Med.* 2000;154:947-951.	Design
Sung RY, Yu CW, Chang SK, Mo SW, Woo KS, Lam CW. Effects of dietary intervention and strength training on blood lipid level in obese children. *Arch Dis Child.* 2002;86:407-410.	Design
Tanas R, Marcolongo R, Pedretti S, Gilli G. A family-based education program for obesity: a three-year study. *BMC Pediatr* 7 (1):33, 2007.	Design
Temple JL, Wrotniak BH, Paluch RA, Roemmich JN, Epstein LH. Relationship between sex of parent and child on weight loss and maintenance in a family-based obesity treatment program. *International Journal of Obesity 30(8):1260 -4.* 2006.	Design
Vido L, Facchin P, Antonello I, Gobber D, Rigon F. Childhood obesity treatment: double blinded trial on dietary fibres (glucomannan) versus placebo. *Padiatr Padol.* 1993;28:133-136.	Design
Viner R, Nicholls D. Managing obesity in secondary care: a personal practice. *Arch Dis Child.* 2005;90:385-390.	Design

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Behavioral interventions

References	Reason for Exclusion
Viski-Stalec N, Stalec J, Kati R, Podvorac D, Katovi D. The impact of dance-aerobics training on the morpho-motor status in female high-schoolers. *Collegium Antropologicum 31(1):259-66.* 2007.	Setting
Warschburger P, Fromme C, Petermann F, Wojtalla N, Oepen J. Conceptualisation and evaluation of a cognitive-behavioural training programme for children and adolescents with obesity. *Int J Obes Relat Metab Disord.* 2001;25 Suppl 1:S93-S95.	Design
Williams CL, Strobino BA, Bollella M, Brotanek J. Cardiovascular risk reduction in preschool children: the "Healthy Start" project. *J Am Coll Nutr.* 2004;23:117-123.	Relevance
Williams CL, Strobino BA, Brotanek J. Weight control among obese adolescents: A pilot study. *International Journal of Food Sciences & Nutrition 58 (3):217 -30.* 2007.	Design
Young KM, Northern JJ, Lister KM, Drummond JA, O'Brien WH. A meta-analysis of family-behavioral weight-loss treatments for children. *Clinical Psychology Review 27(2):240 -9.* 2007.	Design
Young-Hyman D, Schlundt DG, Herman L, De LF, Counts D. Evaluation of the insulin resistance syndrome in 5- to 10-year-old overweight/obese African-American children. *Diabetes Care.* 2001;24:1359-1364.	Relevance
Zemel MB, Richards J, Mathis S, Milstead A, Gebhardt L, Silva E. Dairy augmentation of total and central fat loss in obese subjects.[see comment]. *International Journal of Obesity 29(4):391 -7.* 2005.	Relevance

Appendix D. List of excluded studies

Pharmacological interventions

Reference	Reason for Exclusion
Appolinario JC, Bacaltchuk J, Sichieri R et al. A randomized, double-blind, placebo-controlled study of sibutramine in the treatment of binge-eating disorder. *Archives of General Psychiatry 60(11):1109 -16.* 2003.	Population
Bauer C, Fischer A, Keller U. Effect of sibutramine and of cognitive-behavioural weight loss therapy in obesity and subclinical binge eating disorder. *Diabetes, Obesity & Metabolism 8(3):289 -95 .* 2006.	Design
Birkenfeld AL, Schroeder C, Pischon T et al. Paradoxical effect of sibutramine on autonomic cardiovascular regulation in obese hypertensive patients--sibutramine and blood pressure. *Clinical Autonomic Research 15(3):200 -6.* 2005.	Population
Cuellar GE, Ruiz AM, Monsalve MC, Berber A. Six-month treatment of obesity with sibutramine 15 mg; a double-blind, placebo-controlled monocenter clinical trial in a Hispanic population. *Obes Res.* 2000;8:71-82.	Population
Curran MP, Scott LJ. Orlistat: a review of its use in the management of patients with obesity. *Drugs 64(24):2845 - 64.* 2004.	Design
Danielsson P, Janson A, Norgren S, Marcus C. Impact sibutramine therapy in children with hypothalamic obesity or obesity with aggravating syndromes. *J Clin Endocrinol Metab.* 2007.	Population
Dastjerdi, M. Siavash, Kazemi, F., Najafian, A., Mohammady, M., Aminorroaya, A., and Amini, M. An open-label pilot study of the combination therapy of metformin and fluoxetine for weight reduction. International Journal of Obesity 31[4], 713-717. 2007.	Population
Erdmann J, Lippl F, Klose G, Schusdziarra V. Cholesterol lowering effect of dietary weight loss and orlistat treatment--efficacy and limitations. *Alimentary Pharmacology & Therapeutics.* 2004;1173-1179.	Population
Fanghanel G, Cortinas L, Sanchez-Reyes L, Berber A. A clinical trial of the use of sibutramine for the treatment of patients suffering essential obesity. *Int J Obes Relat Metab Disord.* 2000;24:144-150.	Population
Freemark M. Pharmacotherapy of childhood obesity: an evidence-based, conceptual approach. *Diabetes Care.* 2007;30:395-402.	Design
Gilliam FG, Veloso F, Bomhof MA et al. A dose-comparison trial of topiramate as monotherapy in recently diagnosed partial epilepsy. *Neurology 60(2):196-202 .* 2003.	Relevance
Greenway FL, De JL, Blanchard D, Frisard M, Smith SR. Effect of a dietary herbal supplement containing caffeine and ephedra on weight, metabolic rate, and body composition. *Obesity Research 12(7):1152 -7.* 2004.	Population

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Pharmacological interventions

Hamilton J, Cummings E, Zdravkovic V, Finegood D, Daneman D. Metformin as an adjunct therapy in adolescents with type 1 diabetes and insulin resistance: a randomized controlled trial. *Diabetes Care 26(1):138-43.* 2003.	Population
Henness S, Perry CM. Orlistat: a review of its use in the management of obesity. *Drugs 66(12):1625 -56.* 2006.	Design
Ioannides-Demos LL, Proietto J, Tonkin AM, McNeil JJ. Safety of drug therapies used for weight loss and treatment of obesity. *Drug Safety 29(4):277 -302 .* 2006.	Design
James WP, Astrup A, Finer N et al. Effect of sibutramine on weight maintenance after weight loss: a randomised trial. STORM Study Group. Sibutramine Trial of Obesity Reduction and Maintenance. *Lancet.* 2000;356:2119-2125.	Population
Jordan J, Scholze J, Matiba B, Wirth A, Hauner H, Sharma AM. Influence of Sibutramine on blood pressure: evidence from placebo-controlled trials. *International Journal of Obesity 29(5):509 -16.* 2005.	Population
Junior AC, Savassi-Rocha PR, Coelho LG et al. Botulinum A toxin injected into the gastric wall for the treatment of class III obesity: a pilot study. *Obesity Surgery 16(3):335 -43.* 2006.	Population
Kay JP, Alemzadeh R, Langley G, D'Angelo L, Smith P, Holshouser S. Beneficial effects of metformin in normoglycemic morbidly obese adolescents. *Metabolism.* 2001;50:1457-1461.	Did not meet quality criteria
Larsen TM, Toubro S, Gudmundsen O, Astrup A. Conjugated linoleic acid supplementation for 1 y does not prevent weight or body fat regain. *American Journal of Clinical Nutrition 83 (3):606 -12.* 2006.	Population
Li Z, Maglione M, Tu W et al. Meta-analysis: pharmacologic treatment of obesity. *Ann Intern Med.* 2005;142:532-546.	Population
McDuffie JR, Calis KA, Booth SL, Uwaifo GI, Yanovski JA. Effects of orlistat on fat-soluble vitamins in obese adolescents. *Pharmacotherapy.* 2002;22:814-822.	Design
McDuffie JR, Calis KA, Uwaifo GI et al. Efficacy of orlistat as an adjunct to behavioral treatment in overweight African American and Caucasian adolescents with obesity-related co-morbid conditions. *Journal of Pediatric Endocrinology 17(3):307-19.* 2004.	Design
McDuffie JR, Calis KA, Uwaifo GI et al. Three-month tolerability of orlistat in adolescents with obesity-related comorbid conditions. *Obes Res.* 2002;10:642-650.	Design
McElroy SL, Shapira NA, Arnold LM et al. Topiramate in the long-term treatment of binge-eating disorder associated with obesity. *Journal of Clinical Psychiatry 65(11):1463 -9.* 2004.	Population
Norgren S, Danielsson P, Jurold R, Lotborn M, Marcus C. Orlistat treatment in obese prepubertal children: a pilot study. *Acta Paediatrica 92(6):666 -70.* 2003.	Design

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Pharmacological interventions

Ozkan B, Bereket A, Turan S, Keskin S. Addition of orlistat to conventional treatment in adolescents with severe obesity. *Eur.J.Pediatr.* 163 (12):738-741, 2004	Design
Reith D, Burke C, Appleton DB, Wallace G, Pelekanos J. Tolerability of topiramate in children and adolescents.[see comment]. *Journal of Paediatrics & Child Health 39(6):416 -9.* 2003.	Relevance
Reisler G, Tauber T, Afriat R, Bortnik O, Goldman M. Sibutramine as an adjuvant therapy in adolescents suffering from morbid obesity. *Isr.Med Assoc J* 8 (1):30-32, 2006.	Design
Scheen AJ, Finer N, Hollander P, Jensen MD, Van Gaal LF, and RIO-Diabetes Study Group. Efficacy and tolerability of rimonabant in overweight or obese patients with type 2 diabetes: a randomised controlled study. *Lancet.368.(9548.):1660-72,* 2006.	Population
Summaries for patients. Effects of drug treatment for obesity in adolescence.[original report in Ann Intern Med. 2006 Jul 18;145(2):81-90; PMID: 16847290]. *Annals of Internal Medicine 145 (2):I16.* 2006.	Design
Zhi J, Moore R, Kanitra L. The effect of short-term (21-day) orlistat treatment on the physiologic balance of six selected macrominerals and microminerals in obese adolescents. *Journal of the American College of Nutrition 22(5):357 -62.* 2003.	Not relevant outcomes
Zilberstein B, Pajecki D, Garcia de Brito AC, Gallafrio ST, Eshkenazy R, Andrade CG. Topiramate after adjustable gastric banding in patients with binge eating and difficulty losing weight. *Obesity Surgery 14(6):802 -5.* 2004;-Jul.	Population

Appendix D. List of excluded studies

Surgical interventions

Reference	Reason for exclusion
Abu-Abeid S, Szold A. Results and complications of laparoscopic adjustable gastric banding: an early and intermediate experience. *Obes Surg.* 1999;9:188-190.	Population
Alden JF. Gastric and jejunoileal bypass. A comparison in the treatment of morbid obesity. *Arch Surg.* 1977;112:799-806.	Population
Alper D, Ramadan E, Vishne T et al. Silastic ring vertical gastroplasty- long-term results and complications. *Obes Surg.* 2000;10:250-254.	Population
Angrisani L, Lorenzo M, Borrelli V, Giuffre M, Fonderico C, Capece G. Is bariatric surgery necessary after intragastric balloon treatment? *Obesity Surgery 16(9):1135 -7.* 2006.	Population
Baltasar A, Bou R, Arlandis F et al. Vertical banded gastroplasty at more than 5 years. *Obes Surg.* 1998;8:29-34.	Population
Benotti P, Wood GC, Still C, Petrick A, Strodel W. Obesity disease burden and surgical risk. *Surgery for Obesity & Related Diseases 2(6):600 -6.* 2006;-Dec.	Population
Biertho L, Steffen R, Branson R et al. Management of failed adjustable gastric banding. *Surgery 137 (1):33-41.* 2005.	Population
Boschi S, Fogli L, Berta RD et al. Avoiding complications after laparoscopic esophago-gastric banding: experience with 400 consecutive patients. *Obesity Surgery 16(9):1166 -70.* 2006.	Population
Bowne WB, Julliard K, Castro AE, Shah P, Morgenthal CB, Ferzli GS. Laparoscopic gastric bypass is superior to adjustable gastric band in super morbidly obese patients: A prospective, comparative analysis. *Archives of Surgery 141(7):683 -9.* 2006.	Population
Carbajo M, Garcia-Caballero M, Toledano M, Osorio D, Garcia-Lanza C, Carmona JA. One-anastomosis gastric bypass by laparoscopy: results of the first 209 patients. *Obesity Surgery 15(3):398 -404.* 2005.	Population
Carmody BJ, Sugerman HJ, Kellum JM et al. Pulmonary embolism complicating bariatric surgery: detailed analysis of a single institution's 24-year experience. *Journal of the American College of Surgeons.* 2006;831-7.	Population
Csendes A, Burdiles P, Burgos AM, Maluenda F, Diaz JC. Conservative management of anastomotic leaks after 557 open gastric bypasses. *Obesity Surgery 15(9):1252 -6.* 2005.	Population
Dallal RM, Bailey LA. Omental infarction: a cause of acute abdominal pain after antecolic gastric bypass. *Surgery for Obesity & Related Diseases 2(4):451 -4.* 2006;-Aug.	Population
Dargent J. Laparoscopic adjustable gastric banding: lessons from the first 500 patients in a single institution. *Obes Surg.* 1999;9:446-452.	Population
de ZM, Lancaster KL, Mitchell JE et al. Health-related quality of life in morbidly obese patients: effect of gastric bypass surgery. *Obes Surg.* 2002;12:773-780.	Population

Appendix D. List of excluded studies

Surgical interventions

Reference	Reason for exclusion
Field RJ, Jr., Field RJ, III, Park SY. Vertical banded gastroplasty: is obesity worth it? *J Miss State Med Assoc.* 1992;33:423-432.	Population
Fielding GA, Duncombe JE. Clinical and radiological follow-up of laparoscopic adjustable gastric bands, 1998 and 2000: a comparison of two techniques. *Obesity Surgery 15(5):634 -40.* 2005.	Population
Fobi MA, Lee H, Felahy B, Che-Senge K, Fields CB, Sanguinette MC. Fifty consecutive patients with the GaBP ring system used in the banded gastric bypass operation for obesity with follow up of at least 1 year. *Surgery for Obesity & Related Diseases 1(6):569-72.* 2005;-Dec.	Population
Forestieri P, Meucci L De Luca M et al. Two years of practice in adjustable silicone gastric banding (LAP-BAND): evaluation of variations in body mass index, percentage ideal body weight and percentage excess body fat. 1. Obes Surg 8, 49-52. 1998.	Population
Freeman JB, Kotlarewsky M, Phoenix C. Weight loss after extended gastric bypass. *Obes Surg.* 1997;7:337-344.	Population
Goulding ST, Hovell BC. Anaesthetic experience of vertical banded gastroplasty. *Br J Anaesth.* 1995;75:301-306.	Population
Greenstein RJ, Rabner JG. Is Adolescent Gastric-Restrictive Antiobesity Surgery Warranted? *Obes Surg.* 1995;5:138-144.	Only self-reported outcomes
Haynes B. Creation of a bariatric surgery program for adolescents at a major teaching hospital. *Pediatric Nursing 31(1):21-2, 59.* 2005;-Feb.	Design
Helmrath MA, Brandt ML, Inge TH. Adolescent obesity and bariatric surgery. *Surg Clin North Am.* 2006;86:441-454.	Design
Herve J, Wahlen CH, Schaeken A et al. What becomes of patients one year after the intragastric balloon has been removed? *Obesity Surgery 15(6):864 -70.* 2005;-Jul.	Population
Higa KD, Boone KB, Ho T, Davies OG. Laparoscopic Roux-en-Y gastric bypass for morbid obesity: technique and preliminary results of our first 400 patients. *Arch Surg.* 2000;135:1029-1033.	Population
Higa KD, Boone KB, Ho T. Complications of the laparoscopic Roux-en-Y gastric bypass: 1,040 patients--what have we learned? *Obes Surg.* 2000;10:509-513.	Population
Inge TH, Xanthakos SA, Zeller MH. Bariatric surgery for pediatric extreme obesity: now or later?. *International Journal of Obesity 31(1):1-14.* 2007.	Design
Inge TH, Zeller MH, Lawson ML, Daniels SR. A critical appraisal of evidence supporting a bariatric surgical approach to weight management for adolescents. *Journal of Pediatrics 147 (1):10-9.* 2005.	Design
Jones DB. Laparoscopic surgery for obesity. *Asian Journal of Surgery 29(4):217 -22.* 2006.	Design

Appendix D. List of excluded studies

Surgical interventions

Reference	Reason for exclusion
Kalfarentzos F, Dimakopoulos A, Kehagias I, Loukidi A, Mead N. Vertical banded gastroplasty versus standard or distal Roux-en-Y gastric bypass based on specific selection criteria in the morbidly obese: preliminary results. *Obes Surg.* 1999;9:433-442.	Population
Keidar A, Carmon E, Szold A, bu-Abeid S. Port complications following laparoscopic adjustable gastric banding for morbid obesity.[see comment]. *Obesity Surgery 15(3):361 -5.* 2005.	Population
Kinzl JF, Schrattenecker M, Traweger C, Mattesich M, Fiala M, Biebl W. Psychosocial predictors of weight loss after bariatric surgery. *Obesity Surgery 16(12):1609 -14.* 2006.	Population
Lee WJ, Wang W, Wei PL, Huang MT. Weight loss and improvement of obesity-related illness following laparoscopic adjustable gastric banding procedure for morbidly obese patients in Taiwan. *J Formos Med Assoc.* 2006;105:887-94.	Population
Leifsson BG, Gislason HG. Laparoscopic Roux-en-Y gastric bypass with 2-metre long biliopancreatic limb for morbid obesity: technique and experience with the first 150 patients. *Obesity Surgery 15(1):35-42.* 2005.	Population
Madan AK, Orth WS, Ternovits CA, Tichansky DS. Preoperative carbohydrate "addiction" does not predict weight loss after laparoscopic gastric bypass. *Obesity Surgery 16(7):879 -82 .* 2006.	Population
Madan AK, Speck KE, Ternovits CA, Tichansky DS. Outcome of a clinical pathway for discharge within 48 hours after laparoscopic gastric bypass. *American Journal of Surgery.* 2006;399-402.	Population
Maggard MA, Shugarman LR, Suttorp M et al. Meta-analysis: surgical treatment of obesity. *Ann Intern Med.* 2005;142:547-559.	Population
Marinari GM, Papadia FS, Briatore L, Adami G, Scopinaro N. Type 2 diabetes and weight loss following biliopancreatic diversion for obesity. *Obesity Surgery 16(11):1440 -4.* 2006.	Population
McCarty TM, Arnold DT, Lamont JP, Fisher TL, Kuhn JA. Optimizing outcomes in bariatric surgery: outpatient laparoscopic gastric bypass. *Annals of Surgery 242 (4):494 -8; discussion 498 -501 .* 2005.	Population
Melissas J, Mouzas J, Filis D et al. The intragastric balloon - smoothing the path to bariatric surgery. *Obesity Surgery 16(7):897 - 902 .* 2006.	Population
Miller K, Hell E. Laparoscopic adjustable gastric banding: a prospective 4-year follow-up study. *Obes Surg.* 1999;9:183-187.	Population
Moon HS, Kim WW, Oh JH. Results of laparoscopic sleeve gastrectomy (LSG) at 1 year in morbidly obese Korean patients. *Obesity Surgery 15(10):1469 -75.* 2005;-Dec.	Population
Nocca D, Frering V, Gallix B et al. Migration of adjustable gastric banding from a cohort study of 4236 patients. *Surgical Endoscopy.* 2005;947-950.	Population

Appendix D. List of excluded studies

Surgical interventions

Reference	Reason for exclusion
O'Brien PE, Brown WA, Smith A, McMurrick PJ, Stephens M. Prospective study of a laparoscopically placed, adjustable gastric band in the treatment of morbid obesity. *Br J Surg.* 1999;86:113-118.	Population
O'Brien PE, Dixon JB, Brown W et al. The laparoscopic adjustable gastric band (Lap-Band): a prospective study of medium-term effects on weight, health and quality of life. *Obes Surg.* 2002;12:652-660.	Population
Oh CH, Kim HJ, Oh S. Weight loss following transected gastric bypass with proximal Roux-en-Y. *Obes Surg.* 1997;7:142-147.	Population
Organ CH, Jr., Kessler E, Lane M. Long-term results of jejunoileal bypass in the young. *Am Surg.* 1984;50:589-593.	Study not one of the specified interventions
Parikh M, Duncombe J, Fielding GA. Laparoscopic adjustable gastric banding for patients with body mass index of <or=35 kg/m2. *Surgery for Obesity & Related Diseases 2(5):518 -22.* 2006;-Oct.	Population
Parikh MS, Laker S, Weiner M, Hajiseyedjavadi O, Ren CJ. Objective comparison of complications resulting from laparoscopic bariatric procedures. *Journal of the American College of Surgeons.* 2006;252-61, 2006.	Population
Paroz A, Calmes JM, Giusti V, Suter M. Internal hernia after laparoscopic Roux-en-Y gastric bypass for morbid obesity: a continuous challenge in bariatric surgery. *Obesity Surgery 16(11):1482 -7.* 2006.	Population
Prachand VN, Davee RT, Alverdy JC. Duodenal switch provides superior weight loss in the super-obese (BMI > or =50 kg/m2) compared with gastric bypass. *Annals of Surgery 244 (4):611 -9.* 2006.	Population
Randolph JG, Weintraub WH, Rigg A. Jejunoileal bypass for morbid obesity in adolescents. *J Pediatr Surg.* 1974;9:341-345.	Study not one of the specified interventions
Rigg CA. Proceedings: Jejunoileal bypass by morbidly obese adolescent. *Acta Paediatr Scand Suppl.* 1975;62-64.	Study not one of the specified interventions
Rutledge R, Walsh TR. Continued excellent results with the mini-gastric bypass: six-year study in 2,410 patients. *Obesity Surgery 15(9):1304 -8.* 2005.	Population
Salinas A, Santiago E, Yeguez J, Antor M, Salinas H. Silastic ring vertical gastric bypass: evolution of an open surgical technique, and review of 1,588 cases. *Obesity Surgery 15(10):1403 -7.* 2005;-Dec.	Population
Schauer PR, Ikramuddin S, Gourash W, Ramanathan R, Luketich J. Outcomes after laparoscopic Roux-en-Y gastric bypass for morbid obesity. *Ann Surg.* 2000;232:515-529.	Population
Scopinaro N, Gianetta E, Adami GF et al. Biliopancreatic diversion for obesity at eighteen years. *Surgery.* 1996;119:261-268.	Population
Shargorodsky M, Fleed A, Boaz M, Gavish D, Zimlichman R. The effect of a rapid weight loss induced by laparoscopic adjustable gastric banding on arterial stiffness, metabolic and inflammatory parameters in patients with morbid obesity. *International Journal of Obesity 30(11):1632 -8.* 2006.	Population

Appendix D. List of excluded studies

Surgical interventions

Reference	Reason for exclusion
Silber T, Randolph J, Robbins S. Long-term morbidity and mortality in morbidly obese adolescents after jejunoileal bypass. *J Pediatr.* 1986;108:318-322.	Study not one of the specified interventions
Suter M, Paroz A, Calmes JM, Giusti V. European experience with laparoscopic Roux-en-Y gastric bypass in 466 obese patients. *British Journal of Surgery 93(6):726 -32.* 2006.	Population
Szold A, bu-Abeid S. Laparoscopic adjustable silicone gastric banding for morbid obesity: results and complications in 715 patients. *Surg Endosc.* 2002;16:230-233.	Population
Szomstein S, Whipple OC, Zundel N, Cal P, Rosenthal R. Laparoscopic Roux-en-Y gastric bypass with linear cutter technique: comparison of four-row versus six-row cartridge in creation of anastomosis. *Surgery for Obesity & Related Diseases 2(4):431 -4.* 2006;-Aug.	Population
Thomusch O, Keck T, Dobschutz EV, Wagner C, Ruckauer KD, Hopt UT. Risk factors for the intermediate outcome of morbid obesity after laparoscopically placed adjustable gastric banding. *American Journal of Surgery 189 (2):214 -8.* 2005.	Population
Wang HH, Lee WJ, Liew PL et al. The influence of Helicobacter pylori infection and corpus gastritis on the postoperative outcomes of laparoscopic vertical banded gastroplasty. *Obesity Surgery 16(3):297 -307.* 2006.	Population
Weller WE, Rosati C, Hannan EL. Relationship between surgeon and hospital volume and readmission after bariatric operation. *Journal of the American College of Surgeons.* 2007;383-91.	Population
White JJ, Cheek D, Haller JA, Jr. Small bowel bypass is applicable for adolescents with morbid obesity. *Am Surg.* 1974;40:704-708.	Design
White S, Brooks E, Jurikova L, Stubbs RS. Long-term outcomes after gastric bypass. *Obesity Surgery 15(2):155 -63.* 2005.	Population
Yale CE, Weiler SJ. Weight control after vertical banded gastroplasty for morbid obesity. *Am J Surg.* 1991;162:13-18.	Population
Zappa MA, Micheletto G, Lattuada E et al. Prevention of pouch dilatation after laparoscopic adjustable gastric banding. *Obesity Surgery 16(2):132-6.* 2006.	Population
Zehetner J, Holzinger F, Triaca H, Klaiber C. A 6-year experience with the Swedish adjustable gastric band Prospective long-term audit of laparoscopic gastric banding. *Surgical Endoscopy.* 2005;21-28.	Population
Zilberstein B, Pajecki D, Garcia de Brito AC, Gallafrio ST, Eshkenazy R, Andrade CG. Topiramate after adjustable gastric banding in patients with binge eating and difficulty losing weight. *Obesity Surgery 14(6):802 -5.* 2004;-Jul.	Population

Appendix E. Technical Expert Panel/Peer Reviewers

Carolyn Summerbell, PhD
Professor of Human Nutrition
Assistant Dean (Research), School of Health & Social Care.
University of Teesside

Laurie Anderson PhD, MPH
Lead Health Scientist
Centers for Disease Control and Prevention
Guide to Community Preventive Services

Jean Pierre Chanoine, MD, MPH
Clinical Professor, Department of Pediatrics, University of British Columbia
Head of Endocrinology and Diabetes Unit, Children's and Women's Health Centre of BC

Amy Fine, BSN, MPH
Health Policy/Program Consultant
The Association of Maternal and Child Health Programs

Laura L Hayman, PhD, RN, FAAN
Associate Dean for Research
Professor of Nursing
College of Nursing and Health Sciences
University of Massachusetts-Boston

William Dietz, MD, MPH
Division of Nutrition and Physical Activity,
National Center for Chronic Disease Prevention and Health Promotion,
Centers for Disease Control and Prevention,

Virginia A. Moyer, M.D., M.P.H. *(AAP fellow, Editorial Board AAP Grand Rounds)*
Section Head, Academic General Pediatrics
Baylor College of Medicine

Paul Shekelle, MD, MPH
Director, Southern California Evidence-based Practice Center
RAND Corporation

Appendix F. Pending Assessment

1. Ahrens W, Bammann K, de HS et al. Understanding and preventing childhood obesity and related disorders--IDEFICS: a European multilevel epidemiological approach. *Nutrition Metabolism & Cardiovascular Diseases* 16(4):302 -8. 2006.

2. Wen LM, Baur LA, Rissel C, Wardle K, Alperstein G, Simpson JM. Early intervention of multiple home visits to prevent childhood obesity in a disadvantaged population: a home-based randomised controlled trial (Healthy Beginnings Trial). *BMC Public Health* 7:76. 2007.

3. Inge, T. H., Garcia, V. K., Kirk, S., and et al. Body composition changes after gastric bypass in morbidly obese adolescents. Obes Res 12, A53. 2004.

Appendix G. Study eligibility criteria

1. Populations. The following apply to all Key Questions:
    a. Age 2-18. If study substantially overlaps our age range (e.g., 14-65), include article if results for younger participants reported separately. For study of "young adult" or "college-aged", exclude unless average age is <19 or "college freshmen" is specified.
    b. Either (a) entire sample is ≥overweight or obese (85th percentile for age and sex-specific BMI, or who meet previously accepted criteria for overweight based on ideal body weight) or (b) ≥50% of the sample are overweight or obese AND ≥80% of the sample have one of the following risk factors for overweight or obesity-related medical problems: Children of overweight parents; Hispanic, Black, or American Indian/Alaska Native; children with the following medical conditions: diabetes, metabolic syndrome, hypertension, lipid abnormalities, or other cardiovascular-related disorders.
    c. Exclude trials in which the sample is limited to youth: (1) with eating disorders, (2) pregnant/ post-partum, (3) overweight/obesity secondary to genetic or medical condition, including Polycystic ovarian syndrome, hypothyroid, Cushings, GH deficiency, insulinoma, hypothalamic disorders (e.g. Froehlich's syndrome), Laurence-Moon-Biedl syndrome, Prader-Willi syndrome, weight gain secondary to medications (e.g., antipsychotics), or (4) other idiosyncratic weight-loss issues.

2. Study Design.
    a. All studies for KQ1, KQ2, KQ4, and KQ5 must have an outcomes assessment at 6 months or later post-baseline. No minimum follow-up is required for serious (i.e., requiring urgent medical care) adverse events, KQ3.
    b. Behavioral interventions: limit to RCT or CCT with minimal intervention or placebo control, with a minimum of 10 subjects per treatment arm
    c. Pharmacological interventions: RCT with placebo pill control, with a minimum of 10 subjects per treatment arm
    d. Surgical interventions: RCT, CCT, systematically selected large case-series, large comparative cohort studies.

3. Setting. For Behavioral interventions: all KQ except *serious* (i.e., requiring urgent medical care) adverse effects (KQ3): limit to countries listed as "high" human development on Human Development Index (over .90): Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Hong Kong, Iceland, Ireland, Israel, Italy, Japan, Korea, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Singapore, Slovenia, Spain, Sweden, Switzerland, United Kingdom, United States.

4. Intervention.
    a. Include behavioral (published ≥1985), pharmacological, complimentary/alternative, surgical, or health care system interventions, singly or combined, designed to promote weight control/loss or weight maintenance, or an important components of weight loss (e.g., physical activity).
    b. Exclude trials in which intervention focuses primary prevention, changes in the build environment, jejunal ileal bypass surgery, mazindol.

Appendix H. Quality rating criteria

Design	United States Preventive Services Task Force quality rating criteria[1]	National Institute for Health and Clinical Excellence methodology checklists[2]
Systematic reviews and meta-analyses	• Comprehensiveness of sources considered/search strategy used • Standard appraisal of included studies • Validity of conclusions • Recency and relevance are especially important for systematic reviews	• The study addresses an appropriate and clearly focused question • A description of the methodology used is included • The literature search is sufficiently rigorous to identify all the relevant studies • Study quality is assessed and taken into account • There are enough similarities between the studies selected to make combining them reasonable
Case-control studies	• Accurate ascertainment of cases • Nonbiased selection of cases/controls with exclusion criteria applied equally to both • Response rate • Diagnostic testing procedures applied equally to each group • Measurement of exposure accurate and applied equally to each group • Appropriate attention to potential confounding variables	• The study addresses an appropriate and clearly focused question • The cases and controls are taken from comparable populations • The same exclusion criteria are used for both cases and controls • What percentage of each group (cases and controls) participated in the study? • Comparison is made between participants and non-participants to establish their similarities or differences • Cases are clearly defined and differentiated from controls • Is it clearly established that controls are non-cases? • Measures have been taken to prevent knowledge of primary exposure influencing case ascertainment • Exposure status is measured in a standard, valid and reliable way • The main potential confounders are identified and taken into account in the design and analysis • Have confidence intervals been provided?
Randomized controlled trials (RCTs)	• Initial assembly of comparable groups employs adequate randomization, including first concealment and whether potential confounders were distributed equally among groups. • Maintenance of comparable groups (includes attrition, crossovers, adherence, contamination) • Important differential loss to follow-up or overall high loss to follow-up • Measurements: equal, reliable, and valid (includes masking of outcome assessment) • Clear definition of the interventions • All important outcomes considered	• The study addresses an appropriate and clearly focused question • The assignment of subjects to treatment groups is randomized • An adequate concealment method is used • Subjects and investigators are kept 'blind' about treatment allocation • The treatment and control groups are similar at the start of the trial • The only difference between groups is the treatment under investigation • All relevant outcomes are measured in a standard, valid and reliable way • What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed? • All the subjects are analyzed in the groups to which they were randomly allocated (often referred to as intention-to-treat analysis) • Where the study is carried out at more than one site, results are comparable for all sites

Appendix H. Quality rating criteria

Design	United States Preventive Services Task Force quality rating criteria[1]	National Institute for Health and Clinical Excellence methodology checklists[2]
Cohort studies	• Initial assembly of comparable groups employs consideration of potential confounders with either restriction or measurement for adjustment in the analysis; consideration of inception cohorts • Maintenance of comparable groups (includes attrition, crossovers, adherence, contamination) • Important differential loss to follow-up or overall high loss to follow-up • Measurements: equal, reliable, and valid (includes masking of outcome assessment) • Clear definition of the interventions • All important outcomes considered	• The study addresses an appropriate and clearly focused question • The two groups being studied are selected from source populations that are comparable in all respects other than the factor under investigation • The study indicates how many of the people asked to take part did so, in each of the groups being studied • The likelihood that some eligible subjects might have the outcome at the time of enrollment is assessed and taken into account in the analysis • What percentage of individuals or clusters recruited into each arm of the study dropped out before the study was completed? • Comparison is made between full participants and those lost to follow-up, by exposure status • The outcomes are clearly defined • The assessment of outcome is made blind to exposure status • Where blinding was not possible, there is some recognition that knowledge of exposure status could have influenced the assessment of outcome • The measure of assessment of exposure is reliable • Evidence from other sources is used to demonstrate that the method of outcome assessment is valid and reliable • Exposure level or prognostic factor is assessed more than once • The main potential confounders are identified and taken into account in the design and analysis • Have confidence intervals been provided?
Diagnostic accuracy studies	• Screening test relevant, available for primary care, adequately described • Study uses a credible reference standard, performed regardless of test results • Reference standard interpreted independently of screening test • Handles indeterminate result in a reasonable manner • Spectrum of patients included in study • Sample size • Administration of reliable screening test	• The nature of the test being studied is clearly specified • The test is compared with an appropriate gold standard • Where no gold standard exists, a validated reference standard is used as a comparator • Patients for testing are selected either as a consecutive series or randomly, from a clearly defined study population • The test and gold standard are measured independently (blind) of each other • The test and gold standard are applied as close together in time as possible • Results are reported for all patients that are entered into the study • A pre-diagnosis is made and reported

Appendix H. Quality rating criteria

Hierarchy of research design[1]

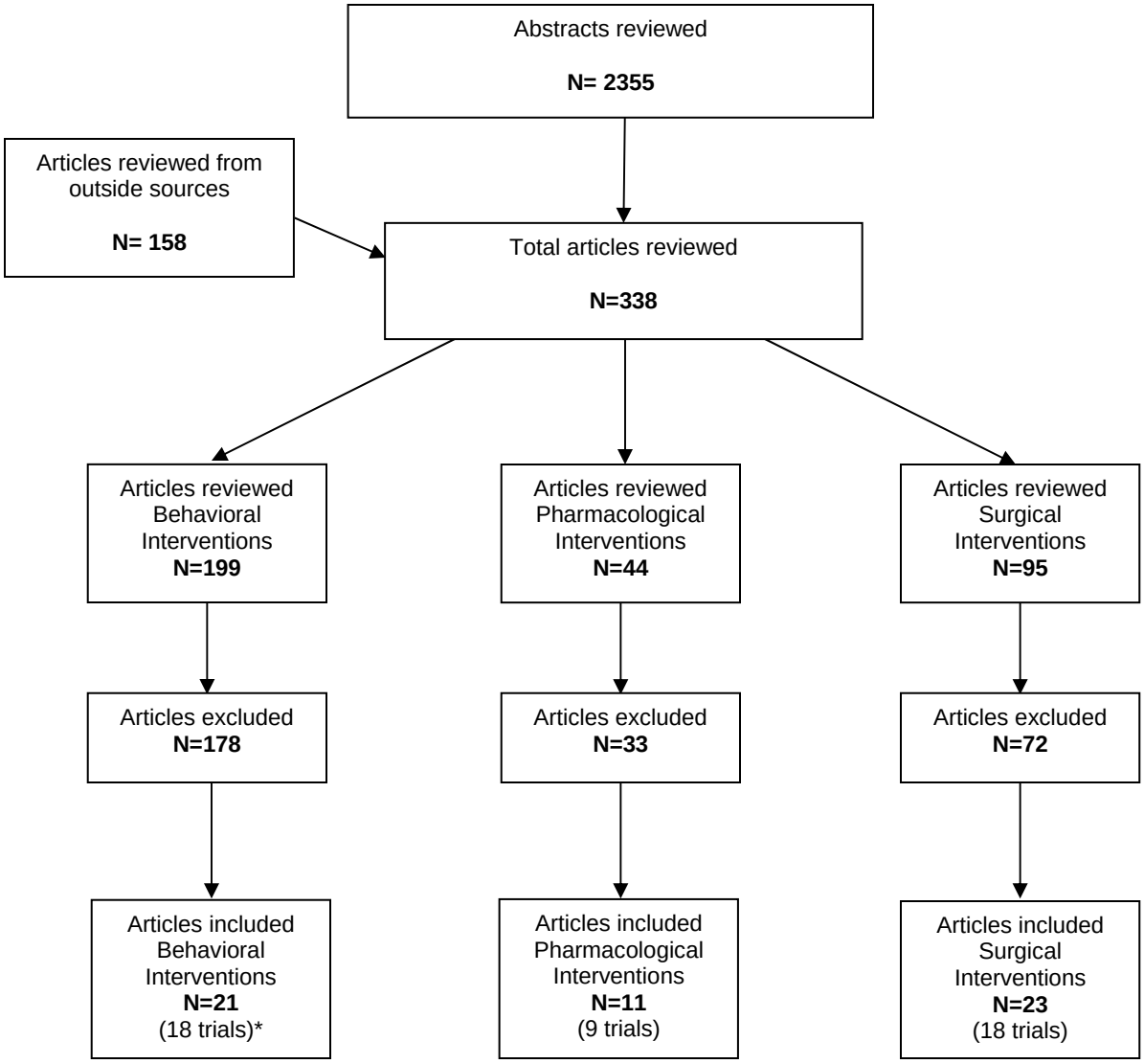
I	Properly conducted randomized controlled trial (RCT)
II-1:	Well-designed controlled trial without randomization
II-2:	Well-designed cohort or case-control analytic study
II-3:	Multiple time series with or without the intervention; dramatic results from uncontrolled experiments
III:	Opinions of respected authorities, based on clinical experience; descriptive studies or case reports; reports of expert committees

References

1. Harris RP, Helfand M, Woolf SH, Lohr KN, Mulrow CD, Teutsch SM et al. Current methods of the US Preventive Services Task Force: a review of the process. *Am J Prev Med* 2001; 20(3 Suppl):21-35.

2. National Institute for Health and Clinical Excellence. (April 2006). *'The guidelines manual'.* London: National Institute for Health and Clinical Excellence. Available from: www.nice.org.uk.

Appendix I. Search results and article flow



* Does not include supplemental behavioral trials discussed in key questions 2, 3 and 5.

Appendix J Table 1. Behavioral intervention trials, sorted by the presence of organized physical activity

Study Reference	Age Range (Mean) N	Treatment Hours	PA	Fam	Age Grp	Beh Mod
Braet et al 2003[1]	10-17 (13) n=76	3,520	1	0	A	1
Graf et al 2006 [2,3]	6-11 (8.4) n=276	175.5	1	2	C	1
Savoye et al 2007[4]	8-16 (12.1) n=174	97.5	1	2	B	1
Reinehr et al 2006[5]	6-14 (10.4) n=240	76	1	2	B	1
Carrel et al 2005[6]	12-13 (12.5) n=53	67.5	1	0	A	0
Kalavainen 2007[7]	6-9 (8.1) n=70	45	1	2	C	1
Johnston 2007a[8]	10-14 (12.5) n=71	41.5	1	1	A	1
Johnston 2007b[9]	10-14 (12.4) n=60	41.5	1	1	A	1
Nemet et al 2005[10]	Avg age 11.1 n=54	35.75	1	2	C	1
Mellin et al1987[11]	12-18 (15.6) n=66	24	1	1	A	1
Golley 2007[12]	6-9 (8.2) n=111	22	1	2	C	1
Flodmark et al, 1993[13]	10-11 (Avg NR) n=93	24	0	2	C	0
Rooney 2005[14]	5-12 (9.7) n=98	21	0	2	C	0
Celio/Doyle et al 2007[15]	12-18 (14.5) n=43	16	0	0	A	1
Senediak et al 1985[16]	6-12 (10.3) n=45	12	0	2	C	1
Gillis 2007[17]	7-16 (10.6) n=27	8	0	1	B	0
McCallum et al, 2007[18,19]	5-9 (7.4) n=163	4	0	2	C	1
Saelens et al 2002[20]	12-16 (14.2) n=44	3.8	0	0	A	1

Note: Grayed interventions did not show statistically significant weight benefits compared with controls.
PA=Physical Activity (1=included organized PA sessions, 0=no organized PA session)
Fam=Family Involvement (2=parent a primary participant, 1=parent invited to 1-3 treatment sessions, 0=minimal parental involvement)
Age Grp=Age Group (A=adolescent, exclusively aged 10 and older; B=age spans younger children and adolescents; C=exclusively aged 12 and younger)
Beh Mod=Behavior Modification (1=Behavior modification employed, 0=not employed)

Appendix J. Table 2. Behavioral intervention trials, sorted by family involvement, within age group

Study Reference	Age Range (Mean) N	Treatment Hours	PA	Fam	Age Grp	Beh Mod
Johnston 2007a[8]	10-14 (12.5) n=71	41.5	1	1	A	1
Johnston 2007b[9]	10-14 (12.4) n=60	41.5	1	1	A	1
Mellin et al1987[11]	12-18 (15.6) n=66	24	1	1	A	1
Braet et al 2003[1]	10-17 (13) n=76	3,520	1	0	A	1
Carrel et al 2005[6]	12-13 (12.5) n=53	67.5	1	0	A	0
Celio/Doyle et al 2007[15]	12-18 (14.5) n=43	16	0	0	A	1
Saelens et al 2002[20]	12-16 (14.2) n=44	3.8	0	0	A	1
Savoye et al 2007[4]	8-16 (12.1) n=174	97.5	1	2	B	1
Reinehr et al 2006[5]	6-14 (10.4) n=240	76	1	2	B	1
Gillis 2007[17]	7-16 (10.6) n=27	8	0	1	B	0
Graf et al 2006[2,3]	6-11 (8.4) n=276	175.5	1	2	C	1
Kalavainen 2007[7]	6-9 (8.1) n=70	45	1	2	C	1
Nemet et al 2005[10]	Avg age 11.1 n=54	35.75	1	2	C	1
Golley 2007[12]	6-9 (8.2) n=111	22	1	2	C	1
Flodmark et al, 1993[13]	10-11 (Avg NR) n=93	24	0	2	C	0
Rooney 2005[14]	5-12 (9.7) n=98	21	0	2	C	0
Senediak et al 1985[16]	6-12 (10.3) n=45	12	0	2	C	1
McCallum et al, 2007[18,19]	5-9 (7.4) n=163	4	0	2	C	1

Note: Grayed interventions did not show statistically significant weight benefits compared with controls.
PA=Physical Activity (1=included organized PA sessions, 0=no organized PA session)
Fam=Family Involvement (2=parent a primary participant, 1=parent invited to 1-3 treatment sessions, 0=minimal parental involvement)
Age Grp=Age Group (A=adolescent, exclusively aged 10 and older; B=age spans younger children and adolescents; C=exclusively aged 12 and younger)
Beh Mod=Behavior Modification (1=Behavior modification employed, 0=not employed)

Appendix J. Table 3. Behavioral intervention trials, sorted by the presence of behavioral management techniques

Study Reference	Age Range (Mean) N	Treatment Hours	PA	Fam	Age Grp	Beh Mod
Braet et al 2003[1]	10-17 (13) n=76	3,520	1	0	A	1
Graf et al 2006[2,3]	6-11 (8.4) n=276	175.5	1	2	C	1
Savoye et al 2007[4]	8-16 (12.1) n=174	97.5	1	2	B	1
Reinehr et al 2006[5]	6-14 (10.4) n=240	76	1	2	B	1
Kalavainen 2007[7]	6-9 (8.1) n=70	45	1	2	C	1
Johnston 2007a[8]	10-14 (12.5) n=71	41.5	1	1	A	1
Johnston 2007b[9]	10-14 (12.4) n=60	41.5	1	1	A	1
Nemet et al 2005[10]	Avg age 11.1 n=54	35.75	1	2	C	1
Mellin et al1987[11]	12-18 (15.6) n=66	24	1	1	A	1
Golley 2007[12]	6-9 (8.2) n=111	22	1	2	C	1
Celio/Doyle et al 2007[15]	12-18 (14.5) n=43	16	0	0	A	1
Senediak et al 1985[16]	6-12 (10.3) n=45	12	0	2	C	1
McCallum et al, 2007[18,19]	5-9 (7.4) n=163	4	0	2	C	1
Saelens et al 2002[20]	12-16 (14.2) n=44	3.8	0	0	A	1
Carrel et al 2005[6]	12-13 (12.5) n=53	67.5	1	0	A	0
Flodmark et al, 1993[13]	10-11 (Avg NR) n=93	24	0	2	C	0
Rooney 2005[14]	5-12 (9.7) n=98	21	0	2	C	0
Gillis 2007[21]	7-16 (10.6) n=27	8	0	1	B	0

Note: Grayed interventions did not show statistically significant weight benefits compared with controls.
PA=Physical Activity (1=included organized PA sessions, 0=no organized PA session)
Fam=Family Involvement (2=parent a primary participant, 1=parent invited to 1-3 treatment sessions, 0=minimal parental involvement)
Age Grp=Age Group (A=adolescent, exclusively aged 10 and older; B=age spans younger children and adolescents; C=exclusively aged 12 and younger)
Beh Mod=Behavior Modification (1=Behavior modification employed, 0=not employed)

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Glossary

Adipose Tissue: Fat tissue in the body

Bariatric Surgery: Surgery on the stomach and/or intestines to help patients with extreme obesity to lose weight. Bariatric surgery is a weight-loss method used for people who have a body mass index (BMI) above 40. Surgery may also be an option for people with BMI between 35 and 40 who have health problems like heart disease or type 2 diabetes.

Behavioral Treatment: Behavioral treatment (or behavior therapy) draws on the principles of learning theory (stimulus–behavior contingencies or behavior–reward contingencies). Consists of assessment (identifying and specifying problem behaviors and the circumstances in which they are elicited), treatment (including setting specific, measurable and modest goals that are continually revised) and monitoring. Behavior change processes include stimulus control, graded exposure, extinction and reward

Behavioral Counseling Interventions: Brief counseling in which the primary goal is usually to provide information and make recommendations, with minimal discussion of behavioral management principles. May be delivered in primary care or other settings and primarily involve office staff. Is analogous to the Prevention Plus activities recommended as the first step for those that are overweight in the Expert Panel.

Behavioral Management Interventions: Interventions that include at least some behavioral management principles, such as those used in behavioral treatment. May be less intensive than behavioral treatment.

Behavioral Interventions: A generic term encompassing behavioral counseling, behavioral management interventions, and behavioral treatment.

Bio-electrical Impendence (BIA): A way to estimate the amount of body weight that is fat and nonfat. Nonfat weight comes from bone, muscle, body water, organs and other tissues. BIA works by measuring how difficult it is for a harmless electrical current to move through the body. The more fat a person has the harder it is for electricity to flow through the body. The less fat a person has, the easier it is for electricity to flow through the body. By measuring the flow of electricity, one can estimate body fat percent.

Body Mass Index (BMI): A measure of body weight relative to height. BMI is a tool that is often used to determine if a person is at a healthy weight, overweight, or obese, and whether a persons' health is at risk due to his or her weight. To calculate BMI, use the following formula: weight in kilograms/ height in meters^2

Body Mass Index Standard Deviation Score (BMI SDS): This is also known as a BMI z-score. A standard deviation score quanitifies the distance of a BMI from the average BMI of a population or sample. In a normally distributed population, 84% of the population have a BMI SDS at or below 1.0 and 97.5% of the population have a BMI SDS at or below 2.0. The Center for Disease Control and Prevention provides a computer program that converts BMI scores (combined with age and sex of the child) to BMI SDSs. They also provide tables for select BMI scores.

Body Mass Index Z-score (BMI z-score): See Body Mass Index Standard Deviation Score.

Dual Energy X-ray Absorptiometry (DEXA): is an enhanced form of x-ray technology that is used to measure bone loss. DEXA is today's established standard for measuring bone mineral density (BMD).An x-ray (radiograph) is a painless medical test that helps physicians diagnose and treat medical conditions. Radiography involves exposing a part of the body to a small dose of ionizing radiation to produce pictures of the inside of the body. X-rays are the oldest and most frequently used form of medical imaging. DEXA is most often performed on the lower spine and hips. Portable DEXA devices, including some that use ultrasound waves rather than x-rays, measure the wrist, fingers or heel and are sometimes used for screening purposes.

Dyslipidemia: An abnormal profile of blood lipids. The characteristic dyslipidemia associated with insulin resistance and poorly controlled diabetes includes high levels of triglycerides, low levels of HDL-C, and partitioning of LDL-C into relatively small and dense particles.

Glucose: A building block for most carbohydrates. Digestion causes some carbohydrates to break down into glucose. After digestion, glucose is carried in the blood and goes to the body cells where it is used for energy or stored.

High-density Lipoprotein (HDL): A unit made up of proteins and fats that carry cholesterol to the liver. The liver removes cholesterol from the body. HDL is commonly called “good “ cholesterol. High levels of HDL cholesterol lower the risk of heart disease. An HDL level of 60 mg/dl or greater is considered high and is protective against heart disease. An HDL level less than 40 mg/dl is considered low and increases the risk for developing heart disease.

Homeostasis Model Assessment of Insulin Resistance (HOMA): An empirical mathematical formula based on fasting plasma glucose and fasting plasma insulin levels that was developed as a surrogate measurement of in vivo insulin sensitivity

$$\text{HOMA-IR} = \frac{\text{fasting plasma insulin (μIU/mL) x fasting plasma glucose (mmol/L)}}{22.5}$$

Hypertension/High Blood Pressure: Blood pressure rises and falls throughout the day. An optimal blood pressure is less than 120/80 mmHg. When blood pressure stays high—greater than or equal to 140/90 mmHg—you have high blood pressure. With high blood pressure, the heart works harder, your arteries take a beating, and your chances of a stroke, heart attack and kidney problems are greater.

Insulin Resistance: Reduced effectiveness of insulin to mediate its metabolic effects. Insulin resistance generally refers to glucose metabolism, but can be used to describe reductions in other aspects of insulin action. Insulin resistance is a primary abnormality that places people at risk for type 2 diabetes. Additional conditions may be associated with insulin resistance, including cardiovascular disease, hyperinsulinemia, dyslipidemia, hypertension, abdominal obesity, and clotting abnormalities, among others

Insulin: A hormone made by the pancreas that helps moves glucose (sugar) from the blood to muscles and other tissues. Insulin controls blood sugar levels.

Intention-to-Treat: A strategy for analyzing data from a randomized controlled trial. All participants are included in the arm to which they were allocated, whether or not they received (or completed) the intervention given to that arm. Intention-to-treat analysis prevents bias caused by the loss of participants, which may disrupt the baseline equivalence established by

randomization and which may reflect non-adherence to the protocol. The term is often misused in trial publications when some participants were excluded.[3]

LOCF (Last observation carried forward): An imputation that substitutes the last data collected for a time point with missing data.

Laparoscopic Surgery: Surgical approach using a laparoscope and limited incisions to indirectly visualize and perform surgery.

Laparotomy: Surgical incision of the abdomen to allow direct visualization during surgery.

Least Squares Mean (LSM): The method of least squares is a criterion for fitting a specified model to observed data. The LSM is the estimated mean after controlling for potentially confounding variables using the least squares method.

Low-density Lipoprotein (LDL): A unit made up of proteins and fats that carry cholesterol in the body. High levels of LDL cholesterol cause a buildup of cholesterol in the arteries. Commonly called "bad" cholesterol High levels of LDL increase the risk of heart disease. An LDL level less than 100 mg/dl is considered optimal, 100 to 129 mg/dl is considered near or above optimal, 130 to 159 mg/dl is considered borderline high, 160 to 189 mg/dl is considered high, and 190 mg/dl or greater is considered very high.

Metformin: is an oral anti-diabetic drug from the biguanide class.

Obesity: In children aged 2-17, overweight is defined as having a BMI at or above the 95th percentile, compared with other children of the same age and sex, *or* having a BMI of 30 or more, whichever is lower.

Overweight: In children aged 2-17, overweight is defined as having a BMI in the 85th to 94th percentile, compared with other children of the same age and sex.

Percentile: The percentile indicates the relative position of the child's BMI among children of the same sex and age. Specifically, a percentile tells the proportion of a population or sample that are at or below a given percentile value. For example, 95% of the population are at or below the 95th percentile. To determine a child's BMI percentile score, his or her BMI is compared with published BMI percentile scores based on large, representative samples of children. In the U.S., norms developed by the Center for Disease Control and Prevention are most widely use. Several other countries have developed their own BMI norms.

Physical Activity: Any form of exercise or movement. Physical activity may include planned activities such as walking, running, strength training, basketball, or other sports. Physical activity may also include daily activities such as household chores, yard work, walking the dog, etc. It is recommended that adults get at least 30 minutes of moderate-intensity physical activity for general health benefits. Adults who wish to lose weight may need 60 minutes of physical activity on most days and adults who wish to maintain lost weight may require 60 to 90 minutes of physical activity. Children should get at least 60 minutes of moderate-intensity physical activity most days of the week. Moderate-intensity physical activity is any activity that requires about as much energy as walking 2 miles in 30 minutes.

Skinfold Thickness: A measure of the amount of fat under the skin; the measurement is made with a calliper. Measurements at several sites are normally required as the per cent of fat at each site varies with age, sex and ethnicity. Skinfold measurements are usually taken at the triceps, subscapular and supra-iliac sites

Triglycerides: Triglycerides are the chemical form in which most fat exists in food as well as in the body. They're also present in blood plasma and, in association with cholesterol, form the plasma lipids

Type 2 Diabetes: Diabetes that results from insulin resistance and inadequate insulin secretion (Formerly known as non–insulin-dependent diabetes mellitus or NIDDM). Insulin resistance is generally present before diabetes develops and insulin secretion declines progressively, leading to progressive hyperglycemia. Patients require treatments to reduce insulin resistance and/or increase insulin levels to regulate blood glucose levels. Type 2 diabetes accounts for ~90% of all diabetes cases

Waist Circumference: A measurement of the waist. Fat around the waist increases the risk of obesity related health problems. Women with a waist measurement of more than 35 inches or men with a waist measurement of more than 40 inches have a higher risk of developing obesity-related health problems, such as diabetes, high blood pressure, and heart disease.