

Technology Assessment



**Technology
Assessment Program**

Use of Behavioral Therapies for Treatment of Medical Disorders: Part 1 – Impact on Management of Patients with Diabetes Mellitus

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**Technology Assessment on the
Use of Behavioral Therapies for Treatment of Medical Disorders:
Part 1 – Impact on Management of Patients with Diabetes Mellitus**

David B. Matchar, MD
Francis J. Keefe, PhD
Douglas C. McCrory, MD, MHS
Cindy D. Scipio, BA
Karen Cooper, BA
Jane T. Kolimaga, MA
Ayn C. Huntington, BA

Duke Evidence-based Practice Center
Center for Clinical Health Policy Research
2200 W. Main St., Suite 220
Durham, NC 27705

Phone: 919/286-3399
Fax: 919/286-5601
E-mail: match001@mc.duke.edu

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CONTENTS

Introduction.....	5
Framework of the Technology Assessment: Efficacy in Terms of Clinical Outcomes.....	5
Policy Considerations Guiding the Current Technology Assessment	5
Methods.....	6
Definitions.....	6
Search Strategy	7
Literature Screening.....	7
Data Abstraction	8
Results.....	9
Characteristics of the Studies Included in the Detailed Review	9
Overall Efficacy of Treatment	10
Efficacy of Treatment by Treatment Characteristics	15
Discussion.....	23
 Bibliography	 24

Appendixes

Appendix A. Description of Health and Behavior Assessment/Intervention	
CPT codes	25
Appendix B. Search Strategies	26
Appendix C. Key to Figures Illustrating Effect Size	27
Appendix D. Evidence Tables	54

INTRODUCTION

In 2002, new Current Procedural Terminology (CPT) codes were established to allow providers to indicate when behavioral therapies were employed specifically for treatment of general medical disorders. In response, regional Centers for Medicare & Medicaid Services (CMS) carriers expressed interest in developing appropriate coverage decisions, accounting for available scientific evidence. CMS, through the Agency for Healthcare Research and Quality (AHRQ), requested the Duke Evidence-based Practice Center (EPC) to perform an evaluation of the evidence regarding a limited group of potential circumstances for the use of behavioral therapies for general medical disorders.

The new health and behavior codes (Appendix A) concentrate on assessments and interventions aimed at improving physical health. The focus of the current analysis is thus on physical health status. Potential intervention targets cover a wide range of possibilities including patient adherence to general medical treatment, symptom expression, health-promoting behaviors, health-related risk-taking behaviors, and overall adjustment to general medical illness. In conjunction with the CMS regional carrier medical directors, three medical conditions were selected for systematic review, based on their clinical importance and their representativeness of the variety conditions for which behavioral therapies are commonly considered. This technology assessment focuses on the first condition selected: diabetes mellitus.

Framework of the Technology Assessment: Efficacy in Terms of Clinical Outcomes

The current review was designed to answer the following analytic question: Do behavioral interventions for individuals with diabetes result in improved physical health outcome(s), compared with control interventions? The specific effort focused on behavioral therapies presumed to improve health outcomes by improving adherence by patients with diabetes mellitus (e.g., in recommended use of insulin and other medications, diet, exercise, and so on). The specific clinical outcomes of interest included the following categories: glycemic control, control of risk factors especially important to individuals with diabetes (e.g., obesity, hyperlipidemia, hypertension) and health events (e.g., hospitalization related to diabetes).

Policy Considerations Guiding the Current Technology Assessment

To make the current technology assessment relevant to the decision needs of the CMS regional medical directors, three policy considerations guided the review process.

First, interventions currently covered by CMS under preexisting codes are not included in this assessment. Most salient are:

- Diabetes self-management training
- Medical nutrition therapy

- Institutional and home care education programs already covered for home health agencies, skilled nursing facilities, hospitals, and outpatient physical therapy providers
- Behavioral therapies provided for individuals with related psychiatric diagnoses

Second, while behavioral therapies may be deemed generally reimbursable, it is potentially valuable to regional carriers to specify the conditions under which reimbursement will be provided, based on considerations such as patient, provider, and therapy characteristics. Thus, in this assessment, we sought to identify the circumstances in which behavioral therapies might be especially effective or not. Examples of potentially relevant patient characteristics are age, comorbid conditions, and previous or concurrent therapies. Provider characteristics could include education/licensure and training in the specific behavioral intervention. Therapy could be characterized by type and intensity. As potential guides to targeted reimbursement, we also considered behavioral outcomes in addition to health outcomes.

Third, an evidence-based reimbursement strategy is most useful if the evidence is scientifically credible. Given the real and perceived potential for bias in studies of behavioral therapies, this technology assessment is restricted to assessing randomized controlled trials.

METHODS

Definitions

The analytic question of whether behavioral therapies for individuals with diabetes mellitus improve glycemic control or other health outcome measures requires definition of several terms.

Diabetes. The criteria developed by the American Diabetes Association (Diabetes Care 2003; 26:S33-50) were used to determine a diagnosis of diabetes mellitus. Basically, these are: symptoms of diabetes and a casual plasma glucose ≥ 200 mg/dl, OR fasting plasma glucose ≥ 126 mg/dl, OR 2-hour plasma glucose ≥ 200 mg/dl during an oral glucose tolerance test (OGTT).

Behavioral therapy or intervention. Behavioral therapy or intervention was defined to include four categories of interventions:

1. Cognitive behavioral therapy—using one or more interventions derived from the cognitive behavioral model of behavior change, including techniques such as cognitive restructuring, motivational interviewing, positive reinforcement, contingency management, problem-solving, goal setting, self-monitoring, skills training, and modeling.
2. Relaxation-based interventions—interventions whose primary focus is on teaching patients to relax including progressive relaxation training, electromyographic, or thermal biofeedback.
3. Behavioral diet/exercise interventions—interventions whose goal was to influence health outcomes through behavioral changes in diet or exercise using techniques such as caloric monitoring, portion control, exercise regimens, and individualized dietary prescriptions.
4. Blood glucose awareness training—interventions whose goal was to teach patients how to interpret physical symptoms, moods, feelings, and external cues to estimate blood glucose level.

Behavioral therapies or interventions would not include: educational programs that provide didactic education or information to the patient on how to manage diabetes with minimal (e.g., 10 minutes or less) or no interactive behavioral training, traditional multifamily therapy; education only; traditional group therapy; peer group counseling; and traditional family-oriented support.

Health outcomes. Three categories of health outcomes were included:

- Glycemic control as measured by glycosylated hemoglobin (either as hemoglobin A1C (HbA1C), hemoglobin A1 (HbA1) or glycosylated hemoglobin (GHb) or glucose measurements (e.g., fasting blood glucose or area under the serum glucose curve)
- Diabetes related health events, such as foot infection, amputation, or diabetic ketoacidosis
- Control of risk factors that can enhance the potential for poor health outcomes in diabetic patients, including obesity, hypertension, and hyperlipidemia

Among studies that included health outcomes in at least one of the above categories, we also reviewed data provided on subjective outcomes, including health-related quality of life, adjustment to disease, self-efficacy, stress/hassles, distress, and mood.

Search Strategy

There were two basic search strategies developed for the systematic literature review. The first of these combined the MeSH term “diabetes mellitus” with a behavioral therapy concept (implemented using MeSH terms “behavioral disciplines and activities’/or cognitive therapy”). The second search strategy focused on patient education using MeSH terms “diabetes mellitus” and “patient education.” Both searches employed a standard search strategy for randomized control trials. The strategies were conducted in MEDLINE®, PsychINFO, and Web of Science (1966 through June 2003) and were limited to articles pertaining to humans and published in the English language. The exact texts of the search strategies are provided in Appendix B.

Supplemental searches were conducted in Web of Science and the National Guideline Clearinghouse. References lists of relevant systematic reviews and meta-analyses were also checked.

Additional articles were included at the suggestion of peer reviewers and as a result of ongoing secondary searches of the literature such as articles cited in other recent systematic reviews and meta-analyses. A recent systematic review of randomized controlled trials on the effectiveness of self-management training in type 2 diabetes by Norris, Engelgau, and Narayan (2001) was particularly useful.

Literature Screening

Abstracts and the full-text versions of articles identified in the MEDLINE and other searches were screened by the investigators against six exclusion criteria:

- Study subjects are not diabetic or hyperglycemic

- Majority of study subjects are not adults
- Study design is not a randomized controlled trial
- No medical outcome is reported
- No behavioral intervention is reported
- “Other” reason (e.g., editorial, review article)

Overall, there were 736 potentially relevant articles reviewed for this study. After an initial screening of their titles and abstracts, 209 (28 percent) were reviewed in their full-text versions. Of these, 61 (29 percent) met our inclusion criteria, and 148 (71 percent) were excluded.

Data Abstraction

For each of the 61 included articles, basic study parameters were abstracted into an evidence table. These included: study identification (authors, publication year); inclusion and exclusion criteria (for the study being abstracted); description of study design; description of patient population (number in each study group, number of drop-outs, baseline measures such as HbA1C); description of interventions, treatment duration; outcomes or results (see below); and quality assessment (see below).

The “Outcomes/Results” column of the table reported three basic categories of findings: metabolic control (e.g., HbA1C); significant health events (e.g., hospitalization, physician or emergency department visits), and measures of risk (e.g., specific measure of weight, body mass index, blood pressure).

The last column of the evidence table indicates the presence or absence of specific criteria used to assess each article’s internal and external validity. Criteria used to determine internal validity are: randomization; clear description of the randomization method; concealment of allocation (e.g., through the use of sealed envelopes); details of the study’s blinding method (patient, investigators, outcome assessors); and the number of withdrawals in each study group. Factors affecting external validity are: the presence or absence of clear description of the patient population; description of the intervention(s) that are detailed enough to reproduce; codification of intervention in manual; description of provider training; and patient assessment for a Diagnostic and Statistical Manual for Mental Disorders (DSM) diagnosis.

Study biases, study limitations, and other comments are noted at the bottom of the last column of the evidence table.

A psychology graduate student and a research assistant with a bachelor’s degree in psychology completed the initial data abstraction for each included article. Each data abstraction was over-read by a physician and a psychologist.

In addition to the evidence table, we summarized the results of the reviewed studies in two ways. First, we tabulated the proportion of studies that indicated a statistically positive effect in any of the primary clinical outcomes of interest. Since statistically significant results would only be expected in 5 percent of studies by chance alone, this provides a general-purpose, albeit crude, assessment of the presence of a treatment effect in a pool of diverse studies. Second, we focused

on studies in which the outcome measure was glycemic control in terms of GHb, HbA1, or HbA1c and for which mean and variance could be estimated. For these studies, we calculated effect sizes (means and confidence intervals) using the Comprehensive Meta Analysis software (Englewood, NJ).

RESULTS

Details of each study are provided in the evidence tables (Appendix D). Below, we provide a summary of the characteristics of these studies and a tabulation of study data. Study results are tabulated in terms of proportion reporting statistically positive results (with regard to either glycemic control or risk factor status) and in terms of effect size (for studies of glycemic control and weight reduction). Note that because health events such as hospitalization were rarely described, these were excluded from the tables summarizing proportion of studies reporting statistically significant intervention effects.

Characteristics of the Studies Included in the Detailed Review

Design characteristics. Of the 61 included studies, 48 (79 percent) compared a behavioral therapy group to a non-behavioral therapy control group. The remaining 13 studies (21 percent) conducted head-to-head comparisons of different behavioral interventions, treatment intensities, or other aspects of treatment that might modify the effectiveness of behavioral therapies. These latter studies are described in a separate section on effect modifiers.

Types of patients. While all included studies selected patients based on diagnostic criteria for diabetes mellitus (both insulin dependent and non-insulin dependent), there was no evidence that trials sought to systematically include patients whose glycemic control was more or less difficult to manage.

Types of treatment. Of the 48 studies reviewed in detail, the majority (56 percent) evaluated the efficacy of cognitive-behavioral treatment. Of the remainder, six studies (13 percent) examined relaxation-based interventions, 14 studies (29 percent) tested behavioral interventions aimed specifically at diet and/or exercise, and two studies (4 percent) examined blood glucose awareness training.

Intensity of treatment. Thirty-four of the 48 studies (71 percent) reported on the frequency of treatment sessions. Of these 34 studies, the majority (24, 62 percent) reported that treatment sessions were conducted at least weekly, 1 (3 percent) reported treatment sessions were conducted biweekly, 2 (6 percent) reported treatment sessions were conducted monthly, 4 (12 percent) reported treatment sessions were conducted bi-monthly, and 3 (9 percent) reported that that treatment sessions were conducted every three months.

Forty-seven of the 48 articles (98 percent) reported on the duration of the treatment phase of the study. The mean duration of treatment was 33.2 weeks, with the length of treatment varying from 1 to 260 weeks. The mean duration is high due to several studies that had long treatment

phases (treatments that lasted 208 weeks to 260 weeks). The duration of treatment for most studies was in the 10 to 20 week range.

Outcomes reported. Per the inclusion criteria, health outcomes were reported in all of the studies. Further, all studies included some measure of metabolic control. Of the 48 articles included, 19 (40 percent) used HbA1c as the primary measure of metabolic control, 7 (15 percent) used HbA1, 16 (33 percent) used GHb, and the remaining 6 studies used fasting blood glucose as the primary metabolic outcome measure.

Thirty of the articles (63 percent) measured weight as an additional health outcome. Of risk factor status measures, 21 (44 percent) reported cholesterol and 9 (19 percent) report blood pressure. Smoking was reported uncommonly (in 2 studies, 4 percent). Other health events were also rarely reported, including health care utilization (reported in 3 studies, 6 percent), and morbidity and mortality (reported in 2 studies, 4 percent).

Quality of life/general health, adjustment, self-efficacy, stress/hassles, distress, and mood measures were also reported in a number of the studies. Of the 48 studies, 6 (12 percent) reported on quality of life and general health, 1 (2 percent) reported on adjustment to diabetes, 1 (2 percent) reported on self-efficacy, 4 (8 percent) reported on stress and hassles, and 2 (4 percent) reported on distress. Regarding mood, 3 (6 percent) reported on anxiety and 3 (6 percent) reported on depression.

Quality of studies. The majority of included studies provided details of the patient characteristics (93 percent), the number of withdrawals and dropouts (83 percent), and described the intervention well enough to allow replication of the study (78 percent). Fewer studies (17, 35 percent) relied on a manual-based treatment protocol or described the methods used to train the individuals administering the intervention (10, 21 percent).

Overall Efficacy of Treatment

Proportion of positive studies (Table 1). Studies were defined as positive when the behavioral intervention group(s) showed significant improvements on a specific measure in comparison to a non-behavioral control group. Of the 48 randomized trials of behavioral interventions compared to a control, 22 (46 percent) indicated statistically significant improvements in glycemic control. Studies which examined the effect of treatment on risk factors (i.e., weight, cholesterol, blood pressure) were somewhat less often positive, but still positive more often than would be expected by chance alone.

Subjective outcomes were reported for the minority of studies. Proportion of statistically positive studies for subjective measures are as follows: three of six studies measuring quality of life, one of one studies of adjustment, one of one studies of self-efficacy, two of four studies of stress/hassles, zero of two studies of distress, and one of six studies of mood. Thus, overall, subjective measures do not appear to be more likely to be improved than are health outcomes, and, at least for mood, may be somewhat less affected.

Table 1. Overall results: proportion of non-behavioral control studies with statistically positive results (positive studies)

Outcome	Number of Studies	Number of Positive Studies (%)
Glycemic control	48	22 (46)
Risk factor reduction		
○ Weight	30	6 (20)
○ Cholesterol	21	8 (38)
○ Blood pressure	9	4 (33)

Proportion of positive studies by study sample size. Treatment outcome was examined as a function of how many patients were randomized to each of the group conditions (Table 2). Studies were grouped into two categories: smaller—those that included fewer than 25 participants per group, and larger—those that include 25 participants per group or more. For glycemic control, larger studies appear to be more commonly positive than smaller studies, whereas the opposite is suggested by the data on risk factor status.

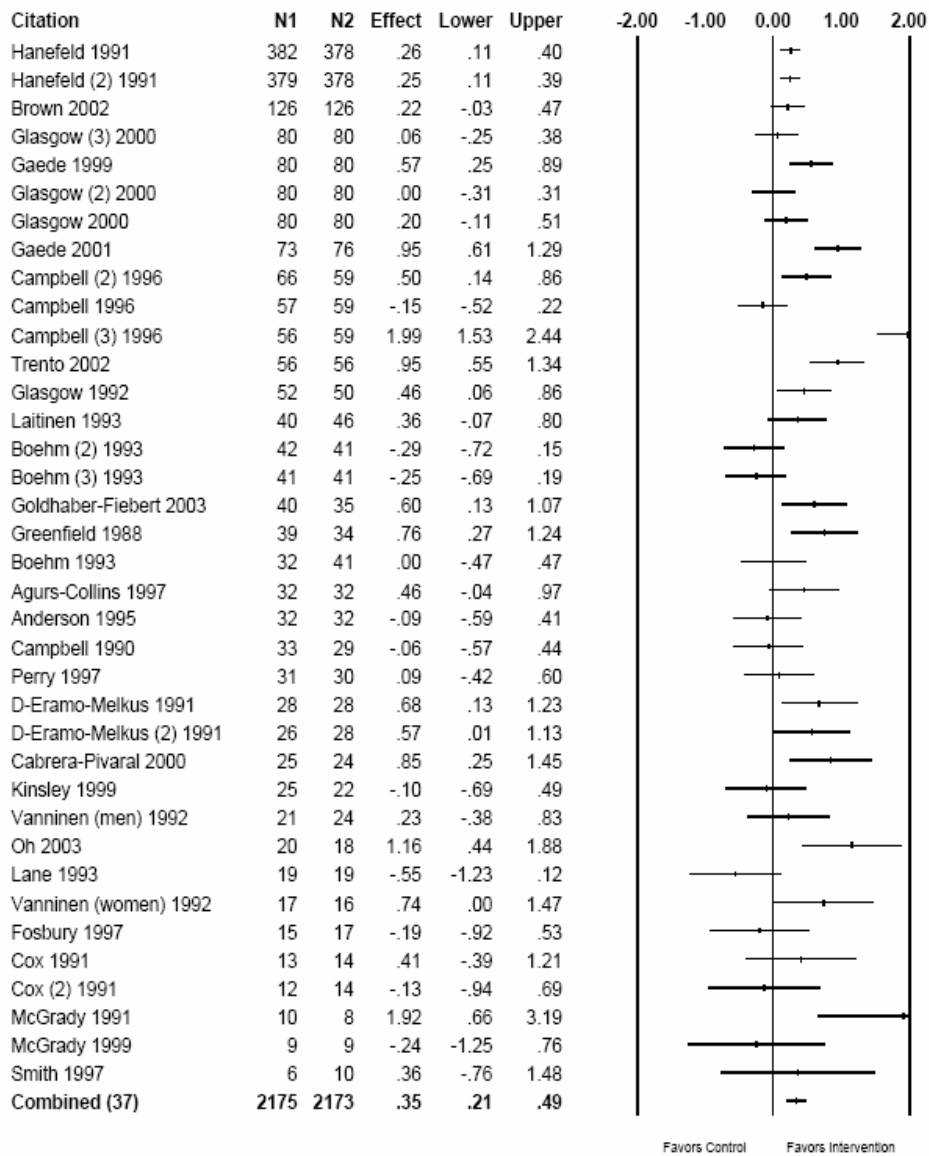
Table 2. Outcome by study size: proportion of studies with statistically positive results (positive studies)

Outcome	> 25 per treatment group		< 25 per treatment group	
	Number of Studies	Number of Positive Studies (%)	Number of Studies	Number of Positive Studies (%)
Glycemic control	28	14 (50)	20	8 (40)
Risk factor status				
○ Weight	20	4 (20)	10	2 (20)
○ Cholesterol	16	5 (31)	5	3 (60)
○ Blood pressure	9	3 (33)	–	–

Efficacy of treatment on glycemic control. Of the 48 studies, 29 (60 percent) provided sufficient data to calculate effect size post-treatment (time points less than or equal to 3 months after the end of treatment), corresponding to 37 active interventions evaluated (Figure 1). The mean effect size post-treatment was 0.35 (CI, 0.21 to 0.49) which translates into an absolute decrease in HbA1c of approximately 0.62 percent (CI, 0.32 percent to 0.88 percent). Thirteen of the 48 studies (27 percent) provided sufficient data to calculate effect size at a follow-up point beyond 3 months, corresponding to 19 active interventions evaluated (Figure 2). The mean effect size at follow-up was 0.24 (CI, 0.09 to 0.40), which translates into an absolute decrease in HbA1c of approximately 0.47 percent (CI, 0.18 percent to 0.78 percent). Again, it appears that larger studies tend more often to indicate a positive effect for behavioral therapy on glycemic control.

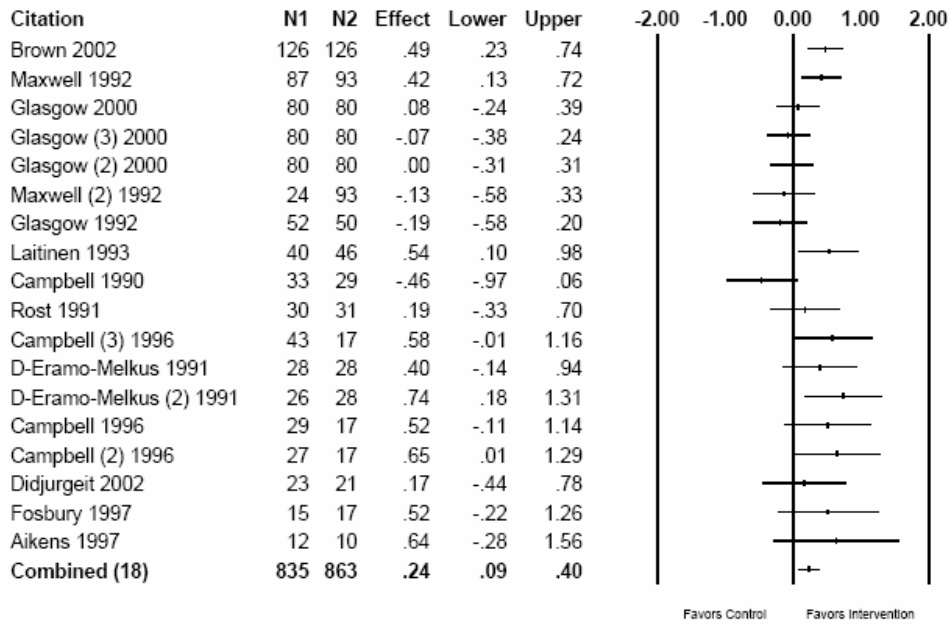
Efficacy of treatment on weight control. Twenty-six studies (54 percent) included data sufficient to estimate effect size for weight control. As seen in Figure 3, no effect was seen overall or by sample size for this outcome measure.

Figure 1. Impact of treatment on effect size for glycemic control (within 3 months of completing treatment)



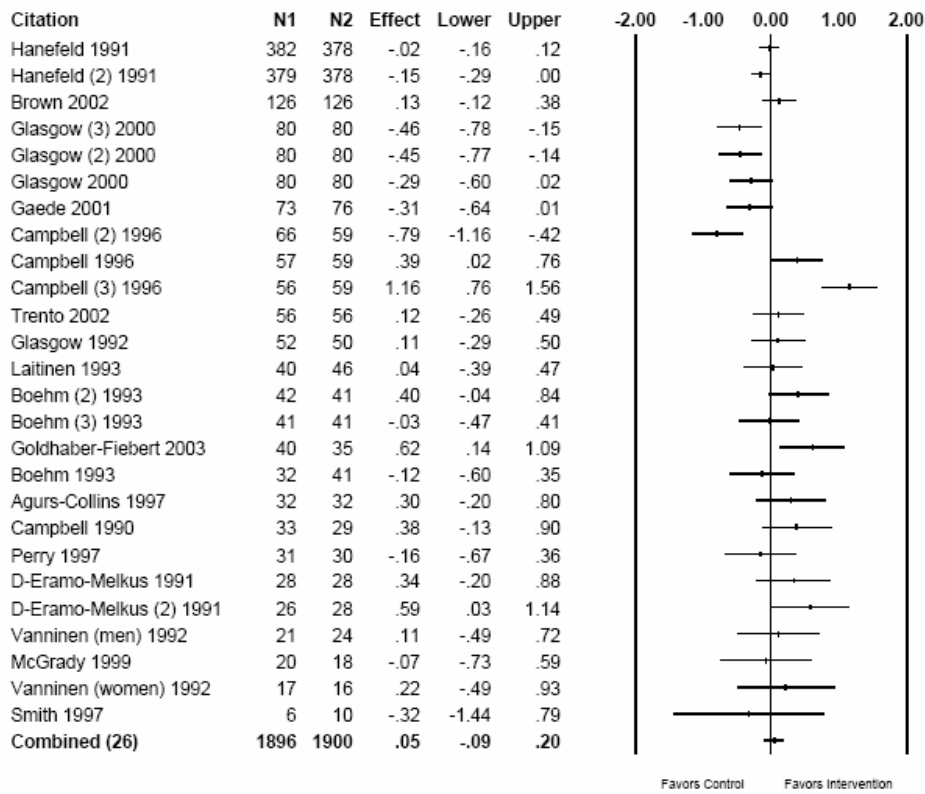
* Studies are ordered by decreasing sample size. For key to individual studies, see Appendix C.

Figure 2. Impact of treatment on effect size for glycemic control (at followup beyond 3 months following completion of treatment)



* Studies are ordered by decreasing sample size. For key to individual studies, see Appendix C.

Figure 3. Impact of treatment on effect size for weight control (within 3 months of completing treatment)



* Studies are ordered by decreasing sample size. For key to individual studies, see Appendix C.

Effectiveness vs. time since completion of therapy. To further examine the durability of behavioral therapy in effecting a change in health outcome, we plotted glycemic effect size vs. time since completion of therapy (Figure 4), and weight control effect size vs. time (Figure 5). In both cases there was an unimpressive trend; for glycemic effect there was a negligible trend towards a decay in effectiveness and for weight control a negligible increase in effectiveness over time.

Figure 4. Glycemic Control effect size vs. time since completion of therapy

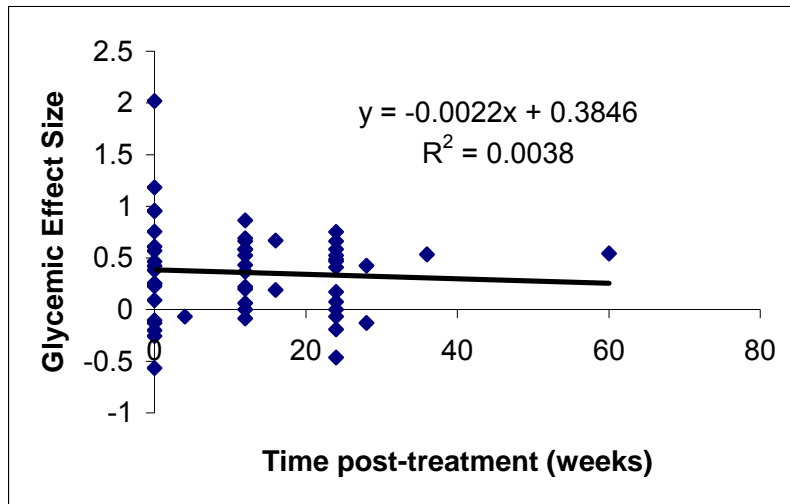
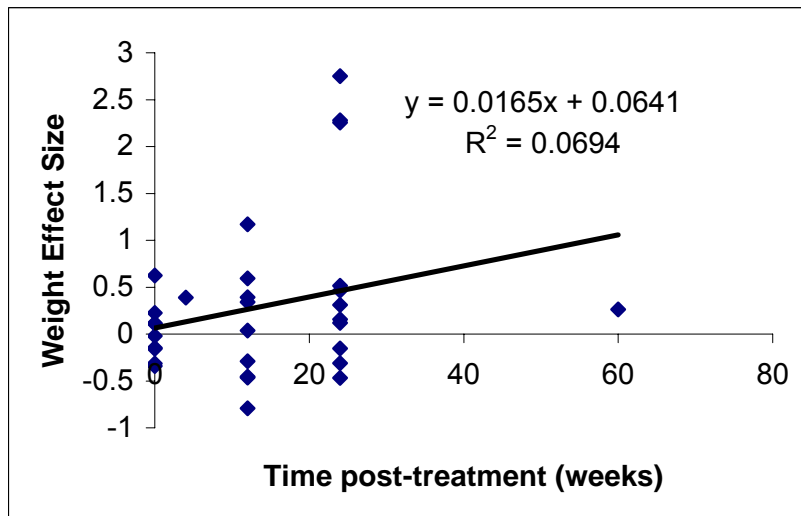


Figure 5. Weight Control effect size vs. time since completion of therapy



Efficacy of Treatment by Treatment Characteristics

Efficacy by type of behavioral intervention. Treatment outcome was examined for the four different categories of behavioral intervention: cognitive-behavioral therapy, relaxation-based interventions, diet/exercise interventions, and blood glucose awareness training (Table 3).

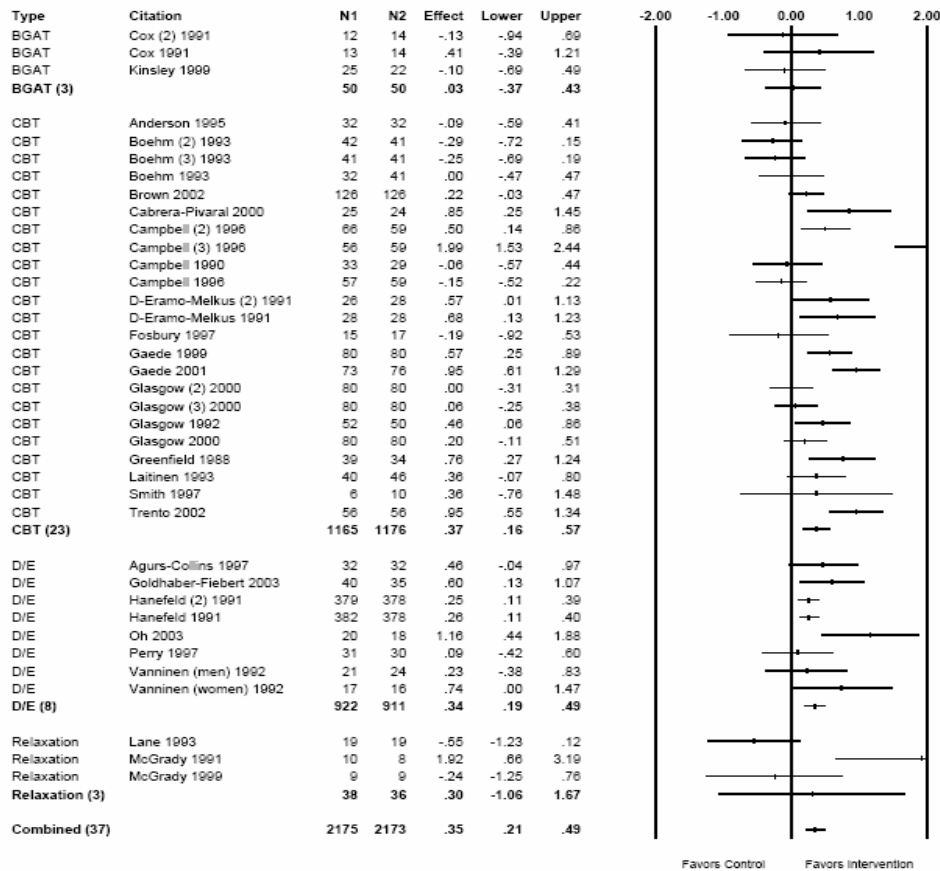
Proportion of positive studies was similar to the overall results for cognitive-behavioral therapy and behavioral exercise/diet interventions. However, studies of relaxation therapy are less likely to report positive results, and information on blood glucose awareness vs. control intervention are limited.

Table 3. Outcome by treatment type proportion of studies with statistically positive results (positive studies)

Outcome	Cognitive-behavioral		Relaxation		Diet/exercise		Blood Glucose Awareness	
	# of Studies	# of Positive Studies (%)	# of Studies	# of Positive Studies (%)	# of Studies	# of Positive Studies (%)	# of Studies	# of Positive Studies (%)
Glycemic control	26	11 (42)	6	2 (33)	14	8 (57)	2	1 (50)
Risk factor reduction								
o Weight	17	3 (18)	1	0 (0)	12	3 (25)	–	–
o Cholesterol	12	4 (33)	–	–	9	4 (44)	–	–
o Blood pressure	4	2 (50)	–	–	5	1 (20)	–	–

Figure 6 illustrates the effect sizes ordered by type of treatment. Here we see that both cognitive-behavioral therapy and behavioral diet/exercise programs tend to be more effective than control in improving glycemic control, whereas no clear trend is demonstrated in the more limited studies of relaxation therapy and blood glucose awareness training.

Figure 6. Impact of treatment on effect size for glycemic control within 3 months of completing therapy



* Studies are organized by treatment type (BGAT, Blood Glucose Awareness Therapy; CBT, cognitive-behavioral therapy; D/E, behavioral diet/exercise therapy; relaxation, relaxation therapy). For key to individual studies, see Appendix C.

Efficacy by intensity of treatment. Only one study was identified in which different intensities of therapy were compared head-to-head (Hendricks, 2000). In this study, the investigator compared cognitive-behavioral interventions at monthly and once every 3 month intervals. No significant differences in glycemic control or health care utilization were reported.

For trials in which behavioral therapy was compared to a non-behavioral control, studies were grouped into two intensity categories based on number of sessions: low intensity, those that included less than 14 weekly sessions; and high intensity, those that included 14 or more weekly sessions. The mean number of sessions for the low intensity group was 7.9 and the mean for the high intensity group was 22.8. As seen in Table 4, there was a trend toward a benefit from a greater number of sessions for both glycemic control and risk factor status.

Table 4. Outcomes by treatment intensity: proportion of studies with statistically positive results (positive studies)

Outcome	Low Intensity (<14 Sessions)		High Intensity (≥ 14 Sessions)	
	Number of Studies	Number of Positive Studies (%)	Number of Studies	Number of Positive Studies (%)
Glycemic control	27	13 (48)	12	8 (67)
Risk factor status				
○ Weight	14	3 (21)	8	3 (37)
○ Cholesterol	11	6 (54)	6	1 (17)
○ Blood pressure	1	0 (0)	4	2 (50)

In Figures 7 and 8, effect size for glycemic control within 3 months of completing therapy and beyond 3 months of completing therapy is plotted against numbers of interventions. (Note that the results were similar for glycemic control vs. duration of therapy or frequency of therapy (data not shown).) A negligible negative correlation between number of interventions and effect of treatment is noted in the short-term outcomes and a negligible positive correlation is noted in the longer-term outcomes.

Figure 7. Glycemic effect size within 3 months of completing treatment vs. number of interventions

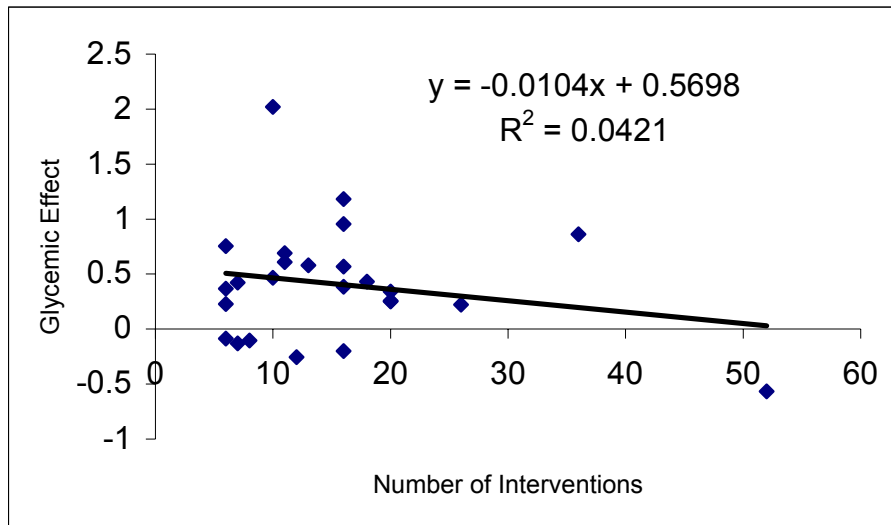
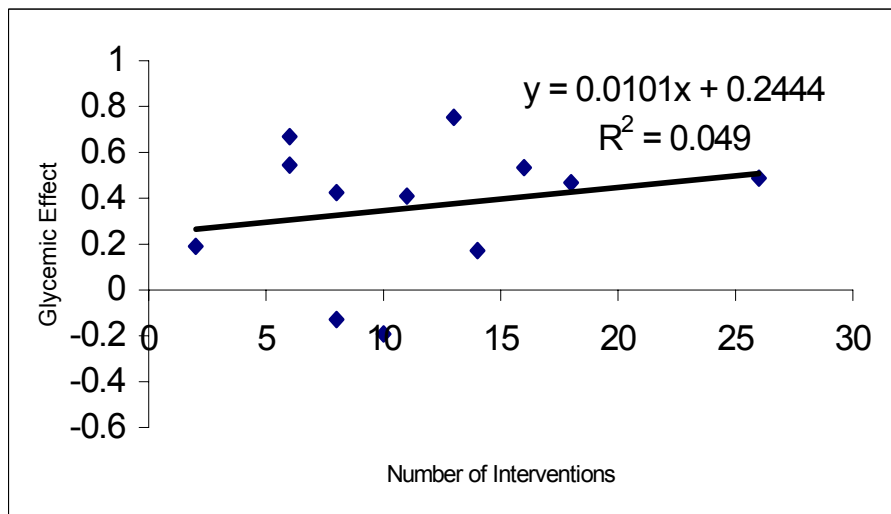
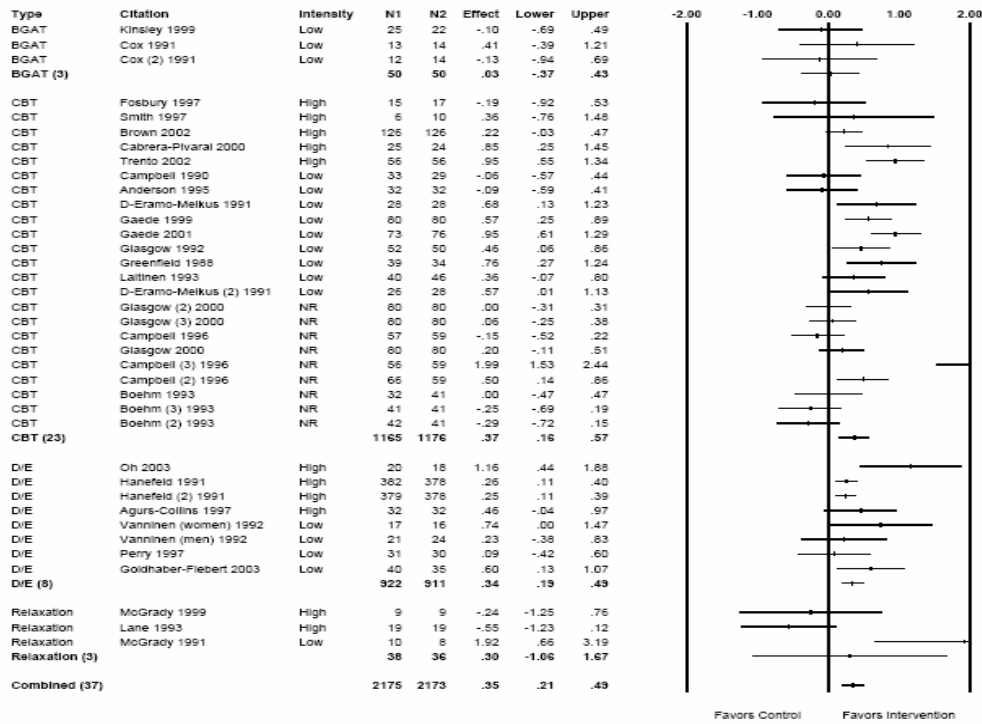


Figure 8. Glycemic effect size beyond 3 months of completing treatment vs. number of interventions



Since type of therapy appeared to influence efficacy, in Figure 9 we examine intensity level within therapy type. There is no evidence that specific therapies are more or less likely to be effective at higher levels of intensity. (Note: a similar plot for effectiveness by intensity and treatment type for glycemic control beyond 3 months of completing therapy also showed no trend (data not shown).)

Figure 9. Impact of treatment on effect size for glycemic control (within 3 months of completing therapy) by intensity (High, more than 14 interventions; Low, 14 or fewer interventions) and treatment type



* For key to individual studies, see Appendix C.

Interaction of glycemic effect and weight effect. Weight control was measured as a risk factor in 30 of the 48 non-behavioral control studies. To examine whether interventions that were more effective in controlling glycemic control were associated with improvements in metabolic control, we plotted the effect size of both, for outcomes within 3 months of completing therapy (Figure 10) and beyond 3 months of completing therapy (Figure 11). A modest positive correlation suggests that the two effects tended to be related.

Figure 10. Weight control effect size as a function of glycemic control effect size within 3 months of completing therapy

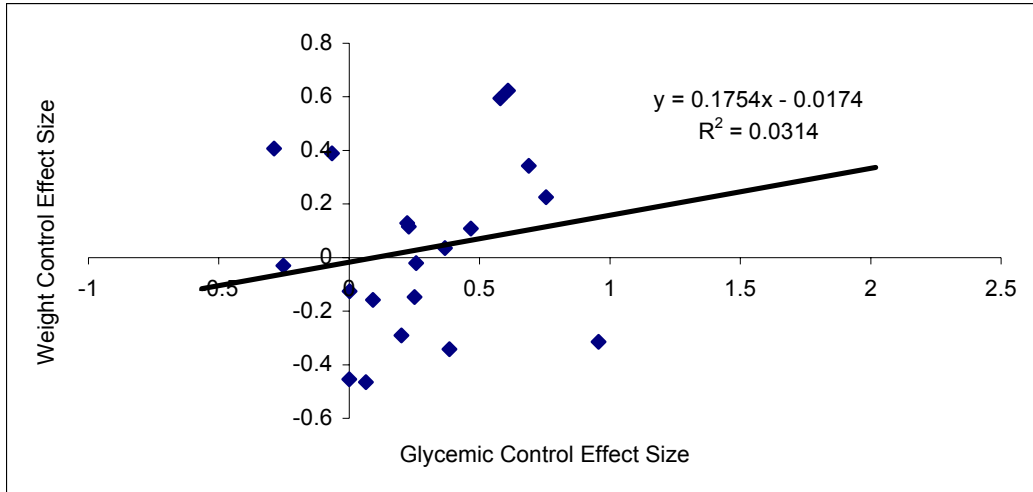
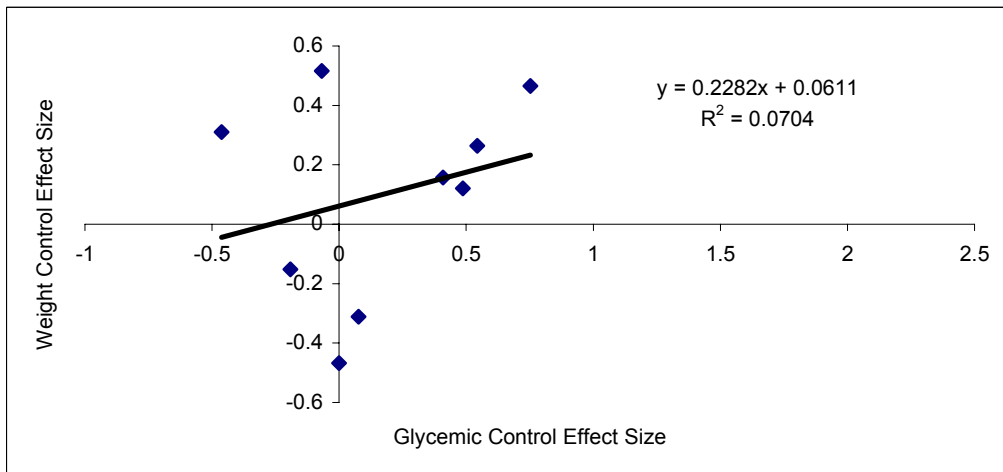


Figure 11. Weight control effect size as a function of glycemic control effect size beyond 3 months of completing therapy



Mode of calorie restriction. Five studies conducted head-to-head comparisons of modes of calorie restriction. Wing, Blair, Bononi et al. (1994) showed a significant decrease in fasting glucose means for very low calorie diet (VLCD) when compared to low-calorie diet (LCD) at the end of the 12-week treatment period, but followup data at 15 weeks post-treatment showed no

significant differences between the two intervention groups. A similar study, Wing, Blair, Marcus et al. (1994) conducted over a 50-week intervention period showed no significant differences at the end of treatment between VLCD and LCD groups in glycemic or weight control.

Williams (1998) compared standard behavioral therapy to interventions of 1-day and 5-day VLCD over a 20-week period, with no significant differences in HbA1c change means or cholesterol means after treatment.

Both Williams (1999) and Wing (1996) compared varying intensities of VLCDs with weekly meetings over 12- and 20-week periods respectively, neither reporting significant results in metabolic or weight control.

Other potential effect modifiers. Seven studies investigated other modifiers of effect on glycemic control and risk factors, with only one study, Glasgow (2002), reporting significant effect differences between treatment groups.

Large studies of other effect modifiers. Glasgow (2002) compared 4 treatment conditions—basic goal setting, community resources, telephone follow-up and combined condition—on a group of 320 patients over a period of 12 months. Telephone followup showed significant effect when compared to other groups for both glycemic control and lipid ratio ($p < 0.05$).

Glasgow (2003) conducted a large study ($N=320$) comparing three online interventions—tailored self-management, peer support and information only—over a period of 10 months. No significant differences were reported in glycemic control or lipids ratios between the three groups.

Rickheim (2002) evaluated 170 patients, comparing group vs. individual education, with 4 intervention sessions constituting 5–7 hours of education. There were no significant differences in effect on metabolic or weight control between the groups.

Wing (1985) compared a standard behavioral weight control program to a weight control plus glucose monitoring program, each set of interventions conducted weekly on 25 patients. There were no significant differences between the intervention groups on glycemic or weight control.

Small studies of other effect modifiers. The effect of treatment alone vs. treatment together with a spouse was investigated in Wing (1994) using a 20-week cognitive-behavioral therapy intervention on a total of 49 patients and 49 spouses. No significant differences of effect were reported between the groups for glycemic or weight control.

Lamparski (1989) looked at the effect of current vs. non-current feedback in a blood glucose awareness training (BGAT) program. Interventions were conducted on two 18-patient groups over a period of 4 weeks, with no significant differences in effect between the two groups (current vs. non-current feedback).

Mayer-Davis (2001) conducted a small study (N=33) comparing intensive lifestyle interventions with and without formal evaluation. The 8-week study did not report comparative data between the two groups.

DISCUSSION

This assessment identified 61 randomized controlled trials of behavioral therapies for the treatment of apparently typical patients with diabetes mellitus. Forty-eight of these trials compared behavioral therapies to non-behavioral control groups. The preponderance of evidence supports the contention that behavioral therapies tend to be modestly effective. Overall, the mean absolute effect on glycemic control at post-treatment (less than or equal to 3 months after completion of intervention) of such behavioral therapies is on the order of an absolute decrease in HbA1c of 0.62 percent (e.g., from 10 percent to 9.38 percent). At followup (greater than 3 months after completion of intervention), the mean absolute effect is on the order of a decrease in HbA1c of 0.47 percent (e.g., from 10 percent to 9.53 percent).

Among the types of interventions, cognitive-behavioral and behavioral diet/exercise interventions appear more effective than relaxation or blood glucose awareness therapy. Evidence for the two latter approaches is especially limited; what is available does not suggest a trend towards efficacy compared to control. Although not conclusive, it appears that therapies that affect weight loss tend to be more successful in improving glycemic control.

Of note, intensity of therapy in terms of numbers of sessions does not seem to relate to effectiveness. Specifically, more than 14 sessions does not appear to impart a greater clinical benefit than regimens of lesser intensity. Though it was not possible to sort out the possible benefit in the long-term of more sessions, it is plausible that more intensive therapy may provide more long-lasting benefits.

Studies not including a non-behavioral control were analyzed qualitatively, and the results were in concordance with the overall conclusions regarding the effectiveness of type and intensity of treatments.

Finally, we did not discern patterns in the available trials that would suggest that other patient, provider, or intervention characteristics influence the effectiveness of behavioral therapies.

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Appendixes

Appendix A

Description of Health and Behavior Assessment/Intervention CPT codes (Excerpted from American Medical Association's Current Procedural Terminology, CPT 2004, Chicago, IL: AMA)

Code	Description
96150	Health and behavior assessment (e.g., health-focused clinical interview, behavioral observations, psychophysiological monitoring, health-oriented questionnaires), each 15 minutes face-to-face with the patient; initial assessment
96151	Re-assessment
96152	Health and behavior intervention, each 15 minutes, face-to-face; individual
96153	Group (2 or more patients)
96154	Family (with the patient present)
96155	Family (without the patient present)

APPENDIX B

Search Strategy 1: Behavioral Therapy for Diabetes Mellitus

1. exp "behavioral disciplines and activities"/ or cognitive therapy/
2. exp Diabetes Mellitus/
3. 1 and 2
4. randomized controlled trials/
5. random allocation/
6. double-blind method/
7. single-blind method/
8. randomized controlled trial.pt.
9. 4 or 5 or 6 or 7 or 8
10. animal/
11. human/
12. 10 and 11
13. 10 not 12
14. 9 not 13
15. clinical trial.pt.
16. exp clinical trials/
17. (clin\$ adj trial\$.tw.
18. ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj (blind\$ or mask\$)).tw.
19. placebos/
20. placebo\$.tw.
21. random\$.tw.
22. research design/
23. 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22
24. 23 not 13
25. comparative-study/
26. exp evaluation studies/
27. follow-up studies/
28. prospective-studies/
29. (control\$ or prospectiv\$ or volunteer\$).tw.
30. 25 or 26 or 27 or 28 or 29
31. 30 not 13
32. 24 not 14
33. 31 not (24 or 14)
34. 3 and 14
35. 3 and 32
36. 3 and 33
37. limit 3 to (human and english language)
38. 37 and 14
39. 37 and 32
40. 37 and 33

Search Strategy 2: Patient Education and Diabetes Mellitus

Database: MEDLINE <1966 to June Week 3 2003>

- 1 randomized controlled trial.pt. (176910)
- 2 controlled clinical trial.pt. (63666)
- 3 Randomized Controlled Trials/ (29246)
- 4 Random Allocation/ (48831)
- 5 Double-Blind Method/ (74469)
- 6 Single-Blind Method/ (7355)
- 7 or/1-6 (300346)
- 8 Animal/ not Human/ (2682706)
- 9 7 not 8 (285640)
- 10 clinical trial.pt. (360658)
- 11 exp Clinical Trials/ (147492)
- 12 (clinic\$ adj25 trial\$.tw. (91610)
- 13 ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj (mask\$ or blind\$)).tw. (71153)
- 14 Placebos/ (23020)
- 15 placebo\$.tw. (79266)
- 16 random\$.tw. (263309)
- 17 Research Design/ (37382)
- 18 (latin adj square).tw. (1990)
- 19 or/10-18 (629578)
- 20 19 not 8 (584818)
- 21 20 not 9 (308889)
- 22 Comparative Study/ (1052532)
- 23 exp Evaluation Studies/ (462029)
- 24 Follow-Up Studies/ (269186)
- 25 Prospective Studies/ (162165)
- 26 (control\$ or prospectiv\$ or volunteer\$).tw. (1344071)
- 27 Cross-Over Studies/ (12786)
- 28 or/22-27 (2712604)
- 29 28 not 8 (2074987)
- 30 29 not (9 or 21) (1663527)
- 31 9 or 21 or 30 (2258056)
- 32 Patient Education/ (36623)
- 33 31 and 32 (8854)
- 34 exp Diabetes Mellitus/ (161644)
- 35 33 and 34 (1243)
- 36 limit 35 to english language (1046)
- 37 36 and (9 or 21) (366)
- 38 from 37 keep 1-366 (366)

APPENDIX C

Key to Figures Illustrating Effect Size

Rec #	Study	Metabolic Control	Intervention	Intervention Category	Size	Intensity	Control	N (total) Subjects	Treatment Length (weeks)	Number of sessions	Sessions/Week
5220	Agurs-Collins, 1997	HbA1c	Group and individual diet and exercise counseling	D/E	Large	High	Usual care	64	24	18	0.750
460	Aikens, 1997	GHb	Theory, guidelines and in-session therapist-guided instruction on relaxation	Relaxation	Small	Low	Usual care	22	8	6	0.750
2920	Anderson, 1995	GHb	Patient empowerment: goal-setting, problem-solving, coping strategies	CBT	Large	Low	Wait list	64	6	6	1.000
840	Boehm, 1993	GHb	Compliance—behaviors related to regimen	CBT	Large	NR	Usual care	73	NS	NS	NS
840	Boehm, 1993 (2)	GHb	Behavioral strategies—analysis sessions with nurse, focused on one strategy	CBT	Large	NR	Usual care	83	NS	NS	NS
840	Boehm, 1993 (3)	GHb	Behavioral strategies with instruction—patient received instruction on strategies	CBT	Large	NR	Usual care	82	NS	NS	NS
3830	Brown, 2002	HbA1c	Bilingual health behavior—focused on realistic health recommendations	CBT	Large	High	Usual care/ Wait list	252	28	26	0.929
1440	Cabrera-Pivaral, 2000	Glucose means	Behavior modification—changing thoughts, behaviors and feelings through participation techniques	CBT	Small	High	Standard education	49	36	36	1.000
3400	Campbell, 1990	FBG	Intensive group education including visualization	CBT	Large	Low	Conventional education program	62	11	NS	NS
620	Campbell, 1996	HbA1c	Individual sessions plus 3 day small group course focused on diet, exercise, diabetes education	CBT	Large	NR	Minimal intervention	116	NS	NS	NS
620	Campbell, 1996 (2)	HbA1c	Group sessions with information on diet, exercise, diabetes education	CBT	Large	NR	Minimal intervention	125	NS	NS	NS
620	Campbell, 1996 (3)	HbA1c	CBT strategies taught by nurse, focused on eating, exercise and smoking—individual	CBT	Large	NR	Minimal intervention	115	NS	NS	NS
6360	Cox, 1991	HbA1c	BGAT (standard)—classes with readings and homework and daily recordings of BG cues	BGAT	Small	Low	Control—attended meetings and kept diaries	27	7	7	1.000

Rec #	Study	Metabolic Control	Intervention	Intervention Category	Size	Intensity	Control	N (total) Subjects	Treatment Length (weeks)	Number of sessions	Sessions/Week
6360	Cox, 1991 (2)	HbA1c	BGAT (intensive)—immediate feedback during hospitalization	BGAT	Small	Low	Control—attended meetings and kept diaries	16	7	7	1.000
6250	D'Eramo-Melkus, 1991	HbA1c	Group behavioral intervention—lecture sessions on general skills and nutrition, goal-setting	CBT	Large	Low	Minimal skills intervention	56	11	11	1.000
6250	D'Eramo-Melkus, 1992 (2)	HbA1c	Group behavioral intervention plus individual followup sessions	CBT	Large	Low	Minimal skills intervention	54	18	13	.7220
20	Didjurgeit, 2002	HbA1c	Psycho-therapeutic intervention by one therapist	CBT	Small	High	Wait list	44	14	14	1.000
510	Fosbury, 1997	HbA1	Cognitive Analytic Therapy (CAT)	CBT	Small	High	Diabetes specialist nurse education	32	16	16	1.000
330	Gaede, 1999	HbA1c	Intensified treatment—standard treatment plus behavior modification and introduction to pharmacological therapy	CBT	Large	High	Standard information	160	208	16	0.077
210	Gaede, 2001	HbA1c	Intensive multifactorial intervention—goal-setting and information on diet, exercise, smoking cessation, self-monitoring	CBT	Large	Low	Standard information	149	24	NS	NS
6180	Glasgow, 1992	GHb	Focused education on dietary and self-care behaviors, problem-solving and coping strategies	CBT	Large	Low	Delayed intervention	102	12	10	0.833
240	Glasgow, 2000	HbA1	Basic intervention plus telephone follow-up to provide support and reinforcement, personalized problem-solving training	CBT	Large	NR	Basic intervention—interactive multimedia touch-screen assessment	160	NS	NS	NS
240	Glasgow, 2000 (2)	HbA1	Basic intervention plus community resources—newsletters, goal feedback, food-frequency questionnaire	CBT	Large	NR	Basic intervention—interactive multimedia touch-screen assessment	160	NS	NS	NS
240	Glasgow, 2000 (3)	HbA1	Combined condition—combination of basic, telephone and community resource follow-up	CBT	Large	NR	Basic intervention—interactive multimedia touch-screen assessment	160	NS	NS	NS
3440	Goldhaber-Fiebert, 2003	GHb	Lifestyle intervention (in Spanish) focusing on nutrition	D/E	Large	Low	Standard diabetes lecture	75	12	11	0.917
3220	Hanefeld, 1991	FBG	IHE + placebo—patients seen at 3-month intervals	D/E	Large	High	Regular clinical checkups	760	260	20	0.077

Rec #	Study	Metabolic Control	Intervention	Intervention Category	Size	Intensity	Control	N (total) Subjects	Treatment Length (weeks)	Number of sessions	Sessions/Week
3220	Hanefeld, 1991 (2)	FBG	IHE + calofibric acid—patients seen at 3-month intervals	D/E	Large	High	Regular clinical checkups	757	260	20	0.077
4650	Kinsley, 1999	HbA1c	BGAT—group training sessions	BGAT	Small	Low	Cholesterol awareness	47	16	8	0.500
6110	Laitinen, 1993	GHb	In-clinic education and goal-setting focusing on nutrition	CBT	Large	Low	Usual care	86	52	6	0.115
2050	Lane, 1993	GHb	Intensive diabetes education plus weekly biofeedback-assisted relaxation training	Relaxation	Small	High	Intensive diabetes education	38	48	52	1.083
3180	Maxwell, 1992	GHb	5-day training program plus behavioral group therapy—0–3 group meetings	CBT	Large	Low	5-day small group training program	180	8	8	1.000
3180	Maxwell, 1992 (2)	GHb	5-day training program plus behavioral group therapy—4–8 group meetings	CBT	Large	Low	5-day small group training program	117	8	8	1.000
2970	McGrady, 1991	Blood glucose means	Biofeedback-assisted relaxation	Relax	Small	Low	Group counseling	18	10	10	1.000
350	McGrady, 1999	GHb	45-minute sessions of biofeedback assisted relaxation	Relaxation	Small	High	Usual care/ glucose monitoring	18	8 to 15	12	NS
2370	Oh, 2003	HbA1c	Telephone intervention—continuous education reinforcement	D/E	Small	High	Usual care	38	12	16	1.333
2910	Perry, 1997	HbA1c	Monthly meetings, individualized diet and exercise prescriptions, fitness appraisal	D/E	Large	Low	Standard care once every 3 months	61	NS	NS	NS
3200	Rost, 1991	GHb	Patient activation intervention—focusing on decision making and information seeking	CBT	Large	Low	Standard evaluation and education	61	0.14	2	14.286
550	Smith, 1997	GHb	Behavioral weight control (group) plus three individualized motivational interviews	CBT	Small	High	Behavioral weight control (group)	16	16	16	1.000
2360	Trento, 2002	HbA1c	Group education sessions focusing on multiple factors	CBT	Large	High	Individual diabetes education	112	208	16	0.077
6240	Vanninen, 1992 (men)	HbA1c	Physician distributed information on exercise	D/E	Small	Low	Basic information sessions	45	52	6	0.115
6240	Vanninen, 1992 (women)	HbA1c	Physician distributed information on exercise	D/E	Small	Low	Basic information sessions	32	52	6	0.115

APPENDIX D

Evidence Tables

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 5220 Agurs-Collins, Kumanyika, Ten Have & Adams-Campbell, 1997.	<p>Include: African-American, diagnosed NIDDM, ≥ 55 years old, $\geq 120\%$ of Metropolitan weight standards, HbA1c $\geq 8\%$.</p> <p>Exclude: non-ambulatory, medical contraindications to program participation.</p>	RCT with 2 treatment conditions: 1) Usual care 2) Intervention	<p>N = 64 n uc = 32 n int = 32</p> <p>*9 did not complete the program (7 from control, 2 from intervention).</p> <p>Age means (SD): uc = 61(5.7) int = 62.4(5.9)</p> <p>Age range: 55-79</p> <p>% Female: uc: 88 int: 66</p> <p>Race % not given</p> <p>Baseline HbA1c means (SD): Intention to treat: uc: 10.0 (1.9) int: 11.0 (1.7)</p>	<p>1) Usual care 2) Intervention— program was age and culture appropriate for pop. Encouraged adherence to a healthy diet, moderate physical activity at least 3 times a week. In the first 3 months, 12 weekly group sessions were held for an hour with a 30 min discussion on nutrition education and then a 30 min exercise session in the physical therapy area of the clinic. One individual diet counseling session during this pd. The next 3 months consisted of 6 bi-weekly (90 min) group sessions providing additional information and support, with sharing, problem solving. Each participant also received an individualized</p>	6 months. Assessments made at 0, 3, and 6 mos.	<p>COMPLETER RESULTS: 1) Metabolic control a) HbA1c % means (SD): uc: 10.0 (1.9) base 10.3 (1.9) 3 mo 11.5 (4.4) 6 mo int: 11.0 (1.7) base 9.5 (1.8) 3 mo 9.9 (2.0) 6 mo</p> <p>* Reported a significant between group difference in HbA1c at 3- and 6-months ($p < 0.01$). Statistical test not given.</p> <p>2) Measures of risk: a) Weight (kg) means (SD): uc: 94.9 (20.1) base 96.2 (21.2) 3 mo 96.9 (21.6) 6 mo int: 93.3 (18.6) base 90.8 (20.3) 3 mo 90.7 (20.1) 6 mo</p> <p>* Reported a significant between group difference in weight at 3- and 6-months ($p < 0.01$). Statistical test not given.</p> <p>b) Systolic blood pressure-SBP means (SD): uc: 139 (14) base 148 (24) 3 mo 147 (22) 6 mo int: 144 (17) base 144 (21) 3 mo 146 (21) 6 mo</p> <p>*Reported no significant differences in SBP between groups at 3 and 6 mo. Statistical test not given.</p>	<p>QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? Yes Concealment of allocation? No</p> <p>Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? Yes</p> <p>EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? Yes Provider training described? Yes Patients assessed for DSM dx? No</p> <p>Biases, etc: None Noted</p>

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 5220				weight reduction diet. The behavioral component included topics such as relapse prevention and weight maintenance, goal setting, controlling triggers to eat and portion control. Participants were asked to keep food and exercise diaries. Spouses were encouraged to come to the interventions as well.		<p>c) Diastolic blood pressure-DBP means (SD):</p> <p>uc: 77 (10) base 79 (8) 3 mo 80 (10) 6 mo</p> <p>int: 79 (10) base 78 (10) 3 mo 79 (9) 6 mo</p> <p>*Reported no significant differences in DBP between groups at 3 and 6 mo. Statistical test not given. ($p < 0.05$ at 6-months)</p> <p>d) HDL Cholesterol means (SD):</p> <p>uc: 52.6 (15) base 50.9 (12.9) 3 mo 51.9 (14.2) 6 mo</p> <p>int: 49.2 (9.9) base 46.1 (8.1) 3 mo 46.8 (10.8) 6 mo</p> <p>*Reported no significant decrease in HDL for both groups at 3 and 6 mo. Statistical test not given.</p> <p>e) LDL Cholesterol means (SD):</p> <p>uc: 156.0 (47.9) base 150.1 (27.8) 3 mo 154.6 (30.7) 6 mo</p> <p>int: 171.9 (37) base 156.1 (32.8) 3 mo 162.4 (39.2) 6 mo</p> <p>*Reported no significant decrease in LDL for both groups at 3 and 6 mo. Statistical test not given.</p>	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 5220	Agurs-Collins, Kumanyika, Ten Have & Adams- Campbell, 1997.					Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 460 Aikens, Kiolbasa, Sobel 1997	Include: NIDDM ≥ 1 year Exclude: comorbid medical conditions affecting metabolic or neuroendocrine function; gross medical noncompliance	RCT- single-center design with 2 groups: 1) control 2) relaxation training (tx)	N=22 n control=10 n tx=12 *No drop-outs Age mean (SD): 61 (10.2) Age range=33-83 59% Female Race %: 59- African Amer. 32- Caucasian 5- Hispanic 5- Asian Baseline GHb % means (SD): Completers: control: 12.0 (1.7) tx: 10.2 (1.9)	Relaxation group attended group sessions consisting of: 1) rationale for the practice of relaxation 2) general guidelines for encouraging relaxation and discussion of role of stress. 3) in-session therapist-guided instruction emphasizing progressive muscle relaxation 4) brief relaxing imagery component	8-week intervention with follow-up at week 16 (f/u).	COMPLETER RESULTS: 1) Metabolic control: a) GHb % means (SD): control: 12.0 (1.7) base 11.3 (1.7) f/u tx: 10.2 (1.9) base 10.2 (1.6) f/u * ANCOVA indicated no significant effect of group on Week 16GHb. b) Area under 2-hour oral- glucose-tolerance curve (AUC) means (SD): control: 32,110 (9,002) base 33,965 (8,212) post 32,167 (7,212) f/u tx: 33,493 (7,335) base 35,271 (6,286) post 35,408 (7,008) f/u *ANOVA indicated no significant effect of group on Post and Week 16 AUC 2) Measures of risk: Not given 3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given	QUALITY ASSESSMENT: INTERNAL VALIDITY Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. withdrawals stated? Yes, none. EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? Yes Provider training described? No Patients assessed for DSM dx? No Biases, etc: Investigators state that baseline GHb significantly different between groups, but did not use baseline measures as covariate; very small sample

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 460						<p>4) Psychological Measures:</p> <p>a) Generalized distress (General Severity Index-GSI†) means (SD):</p> <p>con: 53.8 (11) base 55.6 (8.7) post 56.1(7.9) f/u</p> <p>tx: 57.5 (10) base 51.4 (8.9) post 54.1 (12) f/u</p> <p>*Significance not given</p> <p>b) Anxiety Symptoms (Symptoms Checklist- 90 Revised- SCL-90R†) means (SD):</p> <p>con: 46.6 (13.3) base 50.0 (11.2) post 52.1(11.1) f/u</p> <p>tx: 52.5 (11.9) base 47.4 (8) post 49.8 (13.5) f/u</p> <p>*Significance not given</p> <p>c) Daily Stress (Daily Hassles†) means (SD):</p> <p>con: 24.3 (13.3) base 28.3 (16) post 29 (11) f/u</p> <p>tx: 37.4(18.8) base 29.5(15.1) post 28.4(15.8) f/u</p> <p>*Significance not given</p>	<p>†Higher scores on the GSI, SCL-90R, and Hassles scales indicate more generalized distress, anxiety symptoms and hassles respectively</p>

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 2920 Anderson, Funnell, Butler, Arnold, Fitzgerald, & Feste, 1995.	Include: type II diabetes Exclude: not stated	RCT with 2 treatment conditions: 1) Intervention group (int) 2) Wait-list control group (wl)	N = 64 *18 subjects were not randomized, 10 subjects dropped out (does not specify from which groups). Age mean: 50 % Female: 70 Race % not given Baseline GHb % means (sd): Completers: int: 11.75 (3.01) wl: 10.82 (2.94)	1) Intervention—6 weekly session patient empowerment education program: designed to enhance the ability of patients to identify and set realistic goals, to apply problem-solving processes to eliminated barriers, help cope with circumstances that cannot be changed, manage the stress caused by living with diabetes, obtain social support, and improve self-motivation. 2) Wait-list control—after the first six weeks, the control group completed the six-session empowerment program.	6-weeks, follow-up completed by both groups after 12-weeks.	COMPLETER RESULTS 1) Metabolic control a) GHb % means (SD): int: 11.75 (3.01) base 11.02 (2.89) post wl: 10.82 (2.94) base 10.78 (2.59) post *t-tests indicated a significantly greater reduction in int group compared to wl (p=0.05). 2) Measures of risk: Not given 3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given 4) Psychological Measures: a) Self Efficacy mean Change Scores t: -Assessing satisfaction: int: 0.29 base-post wl: -0.04 base-post *t-tests indicated no significant difference. Statistical test not given. -Setting goals: int: 0.69 base-post wl: -0.12 base-post *t-tests indicated a significant difference (p<0.001). Statistical test not given. -Solving problems: int: 0.32 base-post wl: -0.02 base-post *t-tests indicated no significant difference. Statistical test not given.	QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? Yes EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? No Provider training described? No Patients assessed for DSM dx? No Biases, etc: No measures of risk assessed; no statistical analyses reported

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 2920						<p>-Emotional coping: int: 0.41 base-post wl: 0.12 base-post *Analysis indicated no significant difference. Statistical test not given.</p> <p>-Managing stress: int: 0.29 base-post wl: 0.01 base-post *Analysis indicated a significant difference (p=0.05). Statistical test not given.</p> <p>-Obtaining support: int: 0.36 base-post wl: -0.11 base-post *Analysis indicated a significant difference (p=0.002). Statistical test not given.</p> <p>-Motivating oneself: int: 0.29 base-post wl: -0.09 base-post *Analysis indicated no significant difference. Statistical test not given.</p> <p>-Making decisions: int: 0.47 base-post wl: 0.05 base-post *Analysis indicated a significant difference (p=0.02). Statistical test not given.</p>	
							<p>‡ Higher scores on the Self Efficacy scales indicated higher self efficacy</p>

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 840 Boehm, Schlenk, Raleigh, Ronis 1993	Include: Under physician care for Type II Diabetes, Age ≥ 18 years Exclude: non-English literate	RCT-multi center design with 4 groups: 1) attention control (attention) 2) compliance 3) behavioral strategies (beh. strat.) 4) behavioral strategies with instruction (beh. strat. w/ inst.)	N=156 n attention=41 n compliance=32 n beh.strat.=42 n beh.strat w/ inst.= 41 *does not state # of drop-outs mean age (SD): 58 (11.3) 60% Female Race % not given Baseline GHb %: Not given	1) attention - received routine care & consistent follow-up by clinical nurse 2) compliance- focused on behaviors directly related to regimen 3) beh. strat.- behavioral analyses sessions with nurse that focused on one of 4 strategies: self-monitoring, stimulus control, changing behaviors in small steps and self-resourcefulness 4) beh. strat. w/ inst.- behavioral analyses with nurse & received instruction about strategies and behavioral analysis	Ranged from 1.5- 29 months. mean treatment period= 12.8 months	COMPLETER RESULTS: 1) Metabolic control: GHb (% change mean (SD)): attention: -4.98 (26.08) compliance: -5.02 (20.37) beh. strat.: 1.73 (20.27) beh. strat. w/ inst.: 1.6 (25.93) * t-tests indicated no significant between-group differences 2) Measures of risk: Weight (% change mean (SD)): attention: 1.3 (6.97) compliance: 0.47 (6.08) beh. strat.: -1.52 (6.89) beh. strat. w/ inst.: 1.54(8.71) * t-tests indicated no significant between-group differences 3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given	QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized: Yes Method of randomization clearly described? No Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. withdrawals stated? No EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? No Provider training described? No Patients assessed for DSM dx? No Biases, etc: Large range in treatment duration

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 3830 Brown, Garcia, Kouzekanani & Hanis, 2002	Include: type II diabetes, 35-70 years old Exclude: pregnant women, medical contraindications *recruited from Mexican-American community in Texas.	RCT with 2 treatment conditions: 1) Experimental (exp) 2) 1-yr. Waitlisted control group receiving usual care (wl)	N = 256 n exp = 126 n wl = 126 *4 patients did not complete study Age means (SD): n exp = 54.7(8.2) n wl = 53.3 (8.3) Age range: 35-71 % Female: exp = 60 wl = 68 Race % not given Baseline HbA1c % means (SD) exp : 11.81 (3) wl : 11.8 (3.02)	1) 1-yr wait list condition has usual care 2) Intervention— employed bilingual Mexican American nurses/dietitians. Focused on realistic health recommendations and showed videos of community leaders discussing their experiences with diabetes. Focused on improving blood glucose levels rather than on weight loss: provided rapid, frequent feedback; promoted group problem solving; involved support from family and friends. Taught self-monitoring of blood glucose, exercise, problem-solving and food preparation demonstrations.	52 contact hours, over 12 months. Longitudinal follow-up for up to 3 years	1) Metabolic control: a) HbA1c % means (SD): exp: 11.81 (3.0) base 10.6 (2.64) 3 mo 10.8 (2.8) 6 mo 10.89 (2.56) 12 mo wl: 11.80 (3.02) base 11.22 (2.77) 3 mo 12.2 (2.95) 6 mo 11.64 (2.85) 12 mo *ANCOVA indicated significant effect of group on HbA1c at 6 mo (p<0.001) and 12 mo (p=0.011) b) Fasting Blood Glucose-FBG means (SD): exp: 213.01 (64.06) base 189.62 (66.97) 3 mo 185.24 (60.90) 6 mo 194.95 (63.27) 12 mo wl: 207.12 (71.41) base 201.01 (62.16) 3 mo 215.04 (66.81) 6 mo 210.51 (66.55) 12 mo *ANCOVA indicated significant effect of group on FBG at 3 mo (p=0.038), 6 mo (p<0.001) and 12 mo (p=0.019) 2) Measures of risk: a) BMI means (SD): exp: 32.33 (5.97) base 31.9 (6.05) 3 mo 31.7 (5.84) 6 mo 32.17 (6.45) 12 mo wl: 32.12 (6.35) base 32.73 (6.84) 3 mo 32.47 (6.83) 6 mo 32.28 (6.52) 12 mo *ANCOVA indicated no significant effect of group on BMI.	QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? Yes EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? No Provider training described? Yes Patients assessed for DSM dx? No Biases, etc: F/u continued for 3 years, yet did not report any longitudinal findings beyond one year.

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 3830						b) Cholesterol means (SD): exp: 211.83 (45.34) base 191.39 (41.12) 3 mo 192.46 (40.34) 6 mo 189.88 (36.35) 12 mo wl: 203.57 (6.35) base 187.93 (40.84) 3 mo 185.88 (40.53) 6 mo 187.64 (42.66) 12 mo *ANCOVA indicated no significant effect of group on Cholesterol at 3 6 and 12 mo. 3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 1440 Cabrer Pivara Gondale Perez, Vega Lopez et al 2000	Include: Type II diabetes Exclude: Insulin treatment	RCT with 2 groups: 1) diabetes education (con) 2) behavior modification (tx)	N= 49 n con=24 n tx= 25 Age means (SD): con: 57.8 (8.7) tx: 58.1 (12.4) % Female: con: 54.2 tx: 48 Race % not given Baseline Glucose (mg/dl) means(SD): Completers: con: 221 (83) tx: 210 (43)	Behavior modifying program consisted of the development of the patients' natural skills and abilities, encouraging communication and the exchange of ideas, and the use of various participation techniques. Program focused on changing thoughts, behaviors and feelings. Educational control patients received information about nutrients, calories, and metabolic control.	Weekly sessions over 9 mo. period.	COMPLETER RESULTS: 1) Metabolic control: -Glucose (mg/dl) means (SD): con: 221 (83) base 182 (48) final 3 mos. mean tx: 210 (43) base 147 (32) final 3 mos. mean *Between group differences not given. Statistical test not given. 2) Measures of risk: -Total Cholesterol means (SD): con: 225 (39) base 222 (27) final 3 mos. mean tx: 230 (41) base 199 (21) final 3 mos. mean* *Between group differences not given. Statistical test not given. 3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given	QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? No EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? No Provider training described? No Patients assessed for DSM dx? No BIASES, ETC: Statistical analyses not clearly explained; between-group results not reported

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 620 Campbell, Redman, Moffitt, et al. 1996	Include: diagnosed with NIDDM <5 years; age<80 Exclude: previous formal instruction in diabetes care; taking over 75% of maximum oral hypoglycemic dosage; terminal illness diagnosis	RCT-single-center design with 4 groups: 1) minimal(min), 2) individual education (ind), 3) group education (grp), & 4) behavioral (beh)	N=238 n min=59 n ind=57 n grp=66 n beh=56 *56 patients did not complete study- ind: 23; grp: 28; beh: 5 Age means (SD): min=58.2 (1.3) ind=56.8 (1.5) gr=58.4 (1.4) beh=60.9 (1.4) % Female: min=63 ind=42 grp=47 beh=57 Race % not given Baseline HbA1 means (SD): Intended to treat: min=11.9 (0.6) ind=12.2 (0.5) grp=12.1 (0.6) beh=13.3 (0.6)	1) min-2 sessions: received minimal information about diet, exercise & diabetic education 2) ind-individual sessions plus 3 day small group course: focused on diet, exercise & diabetic education 3) grp- group education sessions with information about diet, exercise & diabetic education 4) beh- nurse-taught cognitive-behavioral strategies focused on eating, exercise & smoking in individual visits ≥ 3	Ranged from 2 weeks to 12 months.	COMPLETER RESULTS: 1) Metabolic control: HbA1 (% change mean (SD)): min= -3.5 (0.6) 3 mo -2.2 (0.8) 6 mo ind= -3.4 (0.7) 3 mo -3.9 (0.6) 6 mo -3.3 (0.9) 12 mo grp= -3.8 (0.6) 3 mo -5 (0.9) 6 mo -3 (1.1) 12 mo beh= -4.7 (0.6) 3 mo -4.7 (0.7) 6 mo -4.8 (0.7) 12 mo * ANCOVA indicated no significant effect of group on HbA1c at 6 mo and 12 mo 2) Measures of risk: a) BMI (% change mean (SD)): min= -1.8 (0.3) 3 mo -1.4 (0.4) 6 mo ind= -1.9 (0.2) 3 mo -2.2 (0.3) 6 mo -2 (0.4) 12 mo grp= -1.6 (0.2) 3 mo -2.2 (0.3) 6 mo -1.4 (0.5) 12 mo beh= -2.1(0.2) 3 mo -2.5 (0.4) 6 mo -2.6 (0.5) 12 mo * ANCOVA indicated no significant effect of group on BMI at 6 mo and 12 mo	QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized: Yes Method of randomization clearly described? No Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? No No. withdrawals stated? Yes External Validity: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? No Provider training described? No Patients assessed for DSM dx? No Biases, etc: Different attrition rates across groups: min=0%, ind=40% by mo, grp=42% by 12 mo, beh=9% by 12 mo; investigators note no control for provider

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 620						b) Systolic blood pressure (% change mean (SD)): min= -3.4(3.5) 3 mo -1.6(5.2) 6 mo ind= -3.2(3.5) 3 mo -7.5(4.8) 6 mo -6.8(5.8) 12 mo grp= -6.1(3.31) 3 mo -4.0(4.9) 6 mo -12.4(6.8) 12 mo beh= -9.0(2.4) 3 mo -11.2(3.2) 6 mo -16.9(3.8) 12 mo c) Diastolic blood pressure (% change mean (SD)): min= -4.9(1.4) 3 mo 1.1(2.2) 6 mo ind= -4.1(1.8) 3 mo -4.2(1.8) 6 mo -5.3(3) 12 mo* grp= -5.5(1.9) 3 mo -3.3(2.4) 6 mo -5.0(4) 12 mo* beh= -9.1(1.8) 3 mo -11.6(1.9) 6 mo -7.9(2.6) 12 mo*	
Campbell, Redman, Moffitt, et al. 1996						* ANCOVA indicated a significant effect of group on Diastolic blood pressure at 12 mo: p= .022	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 620						3) Events: a) Health care utilization: -Consulted Ophthalmologist (%) min= 63 3 mo 79 6 mo ind= 67 3 mo 85 6 mo 97 12 mo grp= 50 3 mo 82 6 mo 95 12 mo beh= 57 3 mo 78 6 mo 89 12 mo * Chi square indicated no significant effect of group at 6 mo and 12 mo -Consulted Podiatrist (%) min= 12 3 mo 27 6 mo ind= 10 3 mo 33 6 mo 55 12 mo grp= 21 3 mo 53 6 mo 73 12 mo beh= 43 3 mo 65 6 mo 74 12 mo * Chi square indicated a significant effect of group at 3 mo (p=.003) and 6 mo (p=.005)	
	Campbell, Redman, Moffitt, et al. 1996					b) Morbidity/mortality: Not given	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 3400 Campbell, Barth, Gosper, Jupp, Simons, & Chisolm, 1990.	Include: Randomized educational approach to dietary change in NIDDM.	RCT with 2 treatment conditions: 1) Conventional Intervention (con) 2) Intensive intervention (int)	N = 70 n con = 29 n del = 33 *8 subjects dropped out. Age mean(SD): con = 59(9) del = 58(9) % Female: con = 41.4 int = 45.5 Race % not given Baseline Fasting Blood Glucose (mM) means (SD): con: 8.9 (2.1) del: 9.7 (2.8)	1) Conventional Program—covered topics of explaining diabetes, diabetes complications, and diet, exercise, and food composition. 2) Intensive program— included longer, more in-depth sessions on diet, podiatry, cognitive-motivation components, unconscious and conscious mental processes affecting the desire to achieve goals or take action. Participants established adequate reasons for behavioral change. Subjects were asked to visualize the adverse effects of diabetic complications.	Convention—3 consecutive days. Intensive—11 weeks (total 22 hrs) Both had 1 month and 3 month follow-up	1) Metabolic control -Fasting Blood Glucose (mM) means (SD): con: 8.9 (2.1) base 9.2 (3.4) 1 mo 9.5 (3.4) 3 mo 8.3 (2.7) 6 mo del: 9.7 (2.8) base 9.4 (2.7) 1 mo 9.1 (3.0) 3 mo 9.6 (2.9) 6 mo * RM-ANCOVA indicated no significant differences in fasting blood glucose between groups over time (=0.7). 2) Measures of risk: a) Body Mass Index-BMI means (SD): con: 32.0 (5.5) base 31.5 (5.6) 1 mo 31.2 (5.4) 3 mo 31.1 (5.1) 6 mo del: 30.4 (4.8) base 29.5 (4.7) 1 mo 29.6 (4.5) 3 mo 29.6 (4.6) 6 mo *RM-ANCOVA indicated no significant differences between groups over time (p=0.28). b) Total Cholesterol means (SD): con: 6.5 (1.1) base 6.5 (1.4) 1 mo 6.3 (1.2) 3 mo 6.5 (1.0) 6 mo del: 7.4 (1.2) base 6.6 (1.1) 1 mo 6.8 (1.1) 3 mo 6.6 (1.0) 6 mo *RM-ANCOVA indicated a significant difference between groups over time (p=0.007).	QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? Yes EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? No Provider training described? No Patients assessed for DSM dx? No Biases, etc: None noted

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 3400							
Campbell, Barth, Gosper, Jupp, Simons, & Chisolm, 1990.						b) HDL-Cholesterol means (SD): con: 1.2 (0.2) base 1.1 (0.2) 1 mo 1.2 (0.2) 3 mo 1.1 (0.2) 6 mo del: 1.1 (0.2) base 1.1 (0.2) 1 mo 1.2 (0.2) 3 mo 1.1 (0.3) 6 mo *RM-ANCOVA indicated no significant differences between groups over time (p=0.27). 3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 6360 Cox, Gonder-Frederick, Julian, Cryer, Herrman, Richards & Clarke, 1991.	<p>Include: IDDM ≥ 2 years since diagnosis; insulin usage since diagnosis; using self-measurement of blood glucose</p> <p>Exclude: history of heart disease, hypertension, seizure activity, or severe psychiatric disturbance; chronic medication other than insulin</p>	RCT with 3 treatment conditions: 1) Control (con) 2) Standard BGAT (sta) 3) Intensive BGAT (int)	<p>N = 39 n con = 14 n sta = 13 n int = 12 *withdrawals not stated</p> <p>Age means: Intended to treat: con = 33.8 sta = 33.7 int = 31.1</p> <p>% Female: Intended to treat: con = 57.1 sta = 61.5 int = 66.7</p> <p>Race % not given</p> <p>Baseline HbA1 means: Intended to treat: Con = 11.4 Sta = 10.4 Int = 12.8</p>	<p>1) Standard BGAT—7 weekly classes with readings and BGAT with homework exercises having to do with BGAT manual, BG symptoms, how insulin, food, and exercise effects BG. Daily systematic recordings of internal and external cues of BG.</p> <p>2) Intensive BGAT—during hospitalization, subjects were provided with immediate BG feedback while hyper and hypoglycemic. At these times, subjects described their experiences on audio tape, rated perceived symptoms on a checklist, estimated BG level and then were told actual BG level. Patients were later given</p>	7-week intervention following hospitalizations	<p>COMPLETER RESULTS:</p> <p>1) Metabolic control: - HbA1 % means (SD): con: 11.1 (2.2) base 11.7 (2.6) post 11.3 (2.6) f/u sta: 10.5 (2.4) base 10.6 (2.6) post 10.1 (2.4) f/u int: 12.8 (4.1) base 12.1 (3.6) post 10.3 (2.7) f/u</p> <p>*ANOVA indicated int significantly different from con (p<0.02)</p> <p>2) Measures of risk: Not given</p> <p>3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given</p>	<p>QUALITY ASSESSMENT:</p> <p>INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No</p> <p>Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No</p> <p>No. of withdrawals in each group stated? No</p> <p>EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? Yes Provider training described? No Patients assessed for DSM dx? No</p> <p>Biases, etc: None noted</p>

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 6360	Cox, Gonder-Frederick, Julian, Cryer, Herrman, Richards & Clarke, 1991.			...the audio tape and were allowed to recall how they felt when hyper- and hypoglycemic. 3) Placebo control group also attended group meetings and kept diaries recording daily stress factors and diabetic self-care behaviors.			

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 6250 D'Eramo-Melkus, Wylie-Rosett, Hagen, 1991.	Include: NIDDM, 21-65 years old, 20-75% over desirable body weight. Exclude: Insulin dependence, or serious illness.	RCT with 3 treatment conditions: 1) Single individual session (con) 2) 12-wk behavior oriented diabetes education and weight control group 3) Group intervention plus six individual follow-up sessions (int + fu)	N = 82 n con = 28 n int = 28 n int+fu = 26 *33 drop-outs (13 in control, 13 in int, 7 in int+fu) Age mean (SD): 55.6 (8.05) % Female: 58.5 Race % not given Baseline HbA1 % means (SD): Completers: con = 10.91(2.6) int = 10.72(3.16) int+fu = 11.15(2.92)	1) all participants received minimal skills educational intervention, including food measurement, setting weight and calorie goals, self-monitoring blood glucose, and foot care 2) Intervention—11 wk group intervention of 2 hr session consisting of lecture and slide presentation on general diabetes principals and skills and nutrition principals. Goals for changing eating behavior, increasing physical activity, and blood glucose control were set. Societal pressures, internal resistance to change and lack of self-reinforcement 3) Intervention + Follow-up counseling—participants	11 weeks, 12 and 18 week followup	COMPLETER RESULTS: 1) Metabolic control: a) HbA1 % means (SD): con: 10.91 (2.6) base 10.54 (3.11) 3 mo 10.5 (3.21) 6 mo int: 10.72 (3.16) base 8.58 (2.55) 3 mo 9.17 (3.3) 6 mo int+fu: 11.15 (2.9) base 8.82 (2.8) 3 mo 8.26 (2.7) 6 mo *RM-ANOVA indicated a significant decrease in HbA1 for int (p<0.05) and int+fu (p<0.01) at 3 mo on HbA1c over time. Between groups not reported. b) Fasting Blood Glucose (mM) means (SD): con: 11.34 (3.29) base 10.31 (4.05) 3 mo 12.18 (5.46) 6 mo int: 11.59 (3.67) base 8.83 (2.68) 3 mo 9.45 (3.61) 6 mo int+fu: 12.21 (3.85) base 10.08 (4.66) 3 mo 9.03 (3.0) 6 mo *RM-ANOVA indicated a significant decrease in fasting blood glucose for int and int+fu at 3 and 6 mo on HbA1c over time (p<.05 for all). Between groups not reported.	QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? Yes Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? Yes EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? No Provider training described? No Patients assessed for DSM dx? No Biases, etc: Large number of participants did not complete study

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 6250				received intervention plus 2 follow-up sessions.		<p>2) Measures of risk:</p> <p>a) Weight (lbs) means (SD): con: 215.25 (25.47) base 209.46 (25.14) 3 mo 205.14 (25.59) 6 mo int: 211.84 (27.78) base 199.96 (30.13) 3 mo 200.72 (30.44) 6 mo int+fu: 200.65 (30.7) base 192.42 (32.09) 3 mo 191.8 (31.73) 6 mo *RM-ANOVA indicated a significant decrease in weight for all groups at 3 mo (p<0.05 for all)</p> <p>b) Cholesterol means (SD): con: 5.75 (1.19) base 5.83 (1.23) 3 mo 5.77 (1.61) 6 mo int: 6.19 (0.9) base 5.58 (0.72) 3 mo 5.71 (1.14) 6 mo int+fu: 6.08 (1.82) base 5.48 (1.63) 3 mo 5.57 (0.84) 6 mo *RM-ANOVA indicated a significant decrease in weight for all groups at 3 mo (p<0.05 for all)</p> <p>3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given</p>	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 20 Didjurgeit, Kruse, Schmitz, et al, 2002	<p>Include: Type I diabetes, presence of self-reported persistent psychological problem, presence of at least one microvascular diabetic complications.</p> <p>Exclude: not given</p>	Randomized wait-list controlled trial for patients indicating psychological problems- single-center design	<p>N=46 n con= 21 n tx= 23</p> <p>*2 patients died during study- con: 1, tx: 1</p> <p>Age means (SD): con= 41(10) tx= 36 (9)</p> <p>61% Female</p> <p>Race % not given</p> <p>Baseline HbA1c means (SD): Completers: tx: 9.1(2.0) con: 8.7 (1.7)</p>	<p>Psycho-therapeutic intervention:</p> <ol style="list-style-type: none"> 1) definition of the patient-therapist relationship 2) detailed description of a problematic situation of the patient 3) analysis of components of the problem 4) definition of the problem 5) handling the problem 6) conclusion of therapy <p>Plus: Diverse psychotherapeutic interventions to foster awareness, modify thoughts, modify behavior, emotionality, awareness of body's ability to rely and support.</p> <p>*all patients treated by one therapist</p>	Weekly sessions- 14 session maximum, 55-min sessions	<p>COMPLETER RESULTS:</p> <ol style="list-style-type: none"> 1) Metabolic control: -HbA1c mean (SD): total con: 8.7 (1.7) base 8.8 (1.9) f/u tx: 9.1 (2) base 8.5 (1.6) f/u <p>*ANOVA indicated a significant effect of group on f/u HbA1c (p=0.016)</p> <ol style="list-style-type: none"> 2) Measures of risk: Not given 3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Deaths=2; con: 1, tx: 1 4) Psychological Measures: a) Top 3 patient-indicated problems & severity (10- point scale) means (SD): con: #1: 8.3 (1.72) base 6.8 (3) f/u #2: 7.61(1.79) base 5.83(2.75) f/u #3: 7.36(2.65) base 6.79(2.42) f/u tx: #1: 7.78(1.98) base 4.3 (2.87) f/u #2: 7.67(2.31) base 3.86(2.41) f/u #3: 7.71(2.33) 4.71(2.43) f/u <p>*ANOVA indicated a significant effect of group on problem severity</p>	<p>QUALITY ASSESSMENT:</p> <p>INTERNAL VALIDITY: Described as randomized: Yes Method of randomization clearly described? No Concealment of allocation? No</p> <p>Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No withdrawals stated? Yes</p> <p>External Validity: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? Not sure Provider training described? No</p> <p>Biases, etc: 4 participants in intervention group did not complete therapeutic sessions, yet still completed f/u; Investigators note that therapy not easily replicated since not strictly structured; No objective measures of self-care used; Investigators note that no distinction made between how closely tied "problems" were to disease</p>

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 20	Didjurgeit, Kruse, Schmitz, et al, 2002 (cont'd)					<p>b) Severity of psychological distress symptoms related to disease (Symptoms Checklist 90 Revised-SCL-90R†) means (SD): control: 0.99(0.47) base 0.75(0.49) f/u tx: 1.1(0.71) base .93 (0.81) f/u *ANOVA indicated no significant group by time interaction for SCL-90 (p= .49)</p> <p>c) Depression Score (ZERSSSEN†) means (SD): control: 13.8(8.9) base 11.7(9.8) f/u tx: 16.3(9.6) base 11.8(10.9) f/u *ANOVA indicated no significant group by time interaction for ZERSSSEN (p= .39).</p> <p>d) Quality of Life (IRES†) means (SD): control: 4.7(2) base 4.3(1.6) f/u tx: 4(2.2) base 4.4(1.7) f/u *ANOVA indicated no significant group by time interaction for IRES (p= .21)</p> <p>†Higher scores on the SCL-90R, ZERSSSEN, and IRES indicate more disease related distress and quality of life respectively</p>	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
#5140 Dyson, Hammersley, Morris, Holman & Turner, 1997	Include: Patients with increased fasting glucose (5.5 to 7.7 mmol/L on 2 occasions. Exclude: diabetes diagnosis	RCT with 2 x 2 factorial design. Four conditions: 1) Sulfonylurea + reinforced healthy-living advice (S+RA) 2) Sulfonylurea + basic healthy-living advice (S+BA) 3) Control(placebo/no tablets) + reinforced healthy-living advice (con+RA) 4) Control(placebo/no tablets) + basic healthy-living advice (con+BA) *groups 1 and 3 considered treatment (tx) and 2 and 4 considered control (con)	N = 227 n S+RA = 56 n S+BA = 56 n con+RA = 55 n con+BA = 60 *26 drop-outs by 1-yr. f/u. (18 in RA, 8 in BA) Age mean (SD): 50(9) 59% Female ace % not given Baseline HbA1c % mean: Completers: 5.7	1) sulfonylurea— an anti-hyperglycemic— helps body better respond to insulin and reduces the amount of sugar produced by liver 2) Basic healthy-living advice— given written dietary information and seen by a physician who advised weight loss and increased physical activity. Patients seen every 3 months for assessment of glycemia, but basic advice was only given once at the initial visit. 3) Reinforced healthy-living advice—patients seen by dietitian and advised to change their diet, limit fat intake and increase consumption of unrefined carbs and dietary fiber. Individual energy requirements were	3 months, 1 yr followup	COMPLETER RESULTS: 1) Metabolic control - HbA1c % means: RA: 5.7 base 5.6 1 year BA: 5.7 base 5.6 1 year *Reported no significant effect of group on HbA1c. Statistical test not given. No change in findings when medicated Ss eliminated from analysis. 2) Measures of risk: a) Weight (kg) means: RA: 81.3 base 80.8 1 year BA: 82.0 base 81.8 1 year *Reported no significant effect of group on weight loss. Statistical test not given. No change in findings when medicated Ss eliminated from analysis. b) Systolic blood pressure-SBP means: RA: 122 base 120 1 year BA: 121 base 121 1 year *Reported no significant effect of group on SBP. Statistical test not given. c) Diastolic blood pressure- DBP means: RA: 78 base 77 1 year BA: 76 base 76 1 year *Reported no significant effect of group on DBP. Statistical test not given.	QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? Yes EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? Yes Provider training described? No Patients assessed for DSM dx? No Biases, etc: Statistical analyses not clearly explained; differential attrition—more in treatment group (RA)

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
#5140 Dyson, Hammersley, Morris, Holman & Turner, 1997				calculated and caloric consumption. Saw a fitness Instructor every 3 months and were encouraged to increase physical activity gradually. Subjects filled out food and exercise diaries. 4) Placebo—half of the control group received a placebo tablet, the other half received no tablets.		d) HDL Cholesterol means: RA: 1.1 base 1.1 1 year BA: 1.1 base 1.1 1 year *Reported no significant effect of group on HDL-C. Statistical test not given. e) LDL-Cholesterol means: RA: 3.2 base 3.1 1 year BA: 3.2 base 3.01 year *Reported no significant effect of group on LDL-C. Statistical test not given. 3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 510 Fosbury, Bosley, Ryle, Sonksen, Judd 1997	Include: type I diabetes, 18-55 years old, poor diabetes control, HbA1c > 9%. Exclude: pregnant, in other clinical trials, or those living a considerable distance from the hospital.	RCT with 2 treatment conditions: 1) CAT treatment—cognitive analytic therapy (cat) 2) DSNE Control—diabetes specialist nurse education (dsne)	N = 32 n.cat = 15 n.dsne = 17 *6 drop-outs (5 from CAT, 1 from dsne) Age means (SD): cat = 30.5(10.6) dsne = 32(9.2) % Female: cat = 70 dsne = 69 Race %: 88- Caucasian 8- African Amer. 4- Asian Baseline HbA1 % means (SD): Completers: cat = 12.12(1.37) dsne = 11.76(1.88)	1) CAT—a time limited (16-20 sessions) focused psychotherapy, using psychosomatic and CBT methods, where self-care and relationships with others are understood as sequences of mental and behavioral processes. CAT therapist makes links between the patients' past and present experiences and their use of procedures that are ineffective and harmful. 2) DSNE—involved teaching, counseling, and advice about diabetes management in relation to the personal needs and lifestyle of the patient.	16 (50 min) sessions, approx. once a week, 3 and 6 month follow-up	COMPLETER RESULTS: 1) Metabolic control - HbA1 % means (SD): cat: 12.1 (1.4) base 11.0 (2.0) post 10.6 (1.3) 3 mo 10.1 (1.5) 9 mo dsne: 11.8 (1.9) base 10.6 (2.0) post 10.5 (2.2) 3 mo 10.9 (1.5) 9 mo *t-tests indicated no significant differences between groups. Both groups showed significant within group improvements at 3- and 6-months 2) Measures of risk: Not given 3) Events a) Health care utilization: Not given b) Morbidity/mortality: Not given	QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? Yes Concealment of allocation? Yes Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? Yes EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? Yes Provider training described? No Patients assessed for DSM dx? No Biases, etc: No measures of risk assessed ; disproportionate attrition in the intervention and control group.

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 210 Gaede, Beck, Vedel & Pederson 2001	Include: Type 2 diabetes mellitus, age 45-65 Exclude: not stated	RCT-single center with 2 groups: 1) standard intervention (con) 2) intensive multifactorial intervention (tx)	N= 160 n con=76 n tx= 73 *5 drop-outs- tx: 3, con: 2) and 6 died Age mean (SD): 55.1 (7.2) 25% Female Race % not given Baseline HbA1c % means (SD): Intended to treat: con: 8.8 (1.7) tx: 8.4 (1.5)	Both groups received information on diet, exercise, and smoking cessation. Tx group was taught to set individual goals for diet, smoking and exercise, received spouse-assisted training to help retain their goals, engaged in self-monitoring, and were both encouraged to exercise more and was offered smoking cessation programs	6 months	COMPLETER RESULTS: 1) Metabolic control: -HbA1c % means (SD): con: 8.8 (1.7) base 9.0 (1.8) post tx: 8.4 (1.5) base 7.6 (1.0) post* *Reported a significant decrease in HbA1c for tx group (p<0.01), and a significant difference between groups at post (p<0.000001). Statistical tests not given. 2) Measures of risk: a) Weight (kg) means (SD): con: 89.9 (17.3) base 90.4 (16.4) post tx: 91.4 (13.6) base 95.1 (13.2) post* *Reported a significant increase in weight for tx group (p<0.001), and a significant difference between groups at post (p=0.001). Statistical test not given. b) Current Smokers: con: 26 base 21 post tx: 28 base 22 post *Reported a significant decrease in smokers for both con and tx groups (p<0.05), yet no significant difference between groups. Statistical test not given.	QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? Yes EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? No Intervention codified in manual? No Provider training described? No Patients assessed for DSM dx? No Biases, etc: Behavioral intervention not explained clearly; statistical analyses not stated.

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 210							
Gaede, Beck, Vedel & Pederson 2001						<p>c) Fasting Total Cholesterol means (SD): con: 5.8 (1.3) base 5.5 (1.2) post tx : 5.4 (1) base 4.8 (0.7) post</p> <p>Reported a significant decrease in total cholesterol for tx group (p<0.001), and a significant difference between groups (p=0.00003). Statistical test not given.</p> <p>d) Fasting HDL Cholesterol means (SD): con: 1.01 (0.3) base 1.04 (0.3) post tx : 1.03 (0.2) base 1.05 (0.3) post</p> <p>*Reported no significant differences between groups at post. Statistical tests not given.</p> <p>3) Events: a) Health care utilization: Not given b) Morbidity/mortality: 6 patients died during f/u</p>	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 330 Gaede, Vedel, Hans-Henrik et al 1999	<p>Include: type 2 diabetes, albumin excretion rates (AER) of 30-300 mg in a 24-hr urine sample.</p> <p>Exclude: older than 65 or younger than 40, alcohol abuse, non-diabetic kidney disease, malignancy or life-threatening disease with death probable within 4 years.</p>	RCT- single-center design with 2 groups: 1) standard (st) and 2) intensified (in)	<p>N=160 n st= 80 n in=80</p> <p>*4 drop-outs in ST (2 withdrew, 2 died), 7 drop-outs in IN (3 withdrew, 4 died)</p> <p>Age means (SD): st: 55.2(7.2) in: 54.9(7.2)</p> <p>% Female: st: 30 in: 21.25</p> <p>Race % not given</p> <p>Baseline HbA1c % means (SD): Intended to treat: st: 8.8 (1.7) in: 8.4 (1.6)</p>	<p>St and In groups both received individualized diabetic advice. In received additional multifactorial intervention with behavior modification (i.e.,: lowering intake of fat, moderate exercise, spouse-assisted smoking cessation), and stepwise introduction of pharmacological therapy.</p>	4 years with monitoring every 3 months.	<p>COMPLETER RESULTS:</p> <p>1) Metabolic control: a) HbA1c % mean change (SD): st: 0.2 (1.9) in: -0.8 (1.6)</p> <p>* Indicated a significant difference between groups (p<0.0001). Statistical test not given.</p> <p>b) Fasting glucose (mmol/L) mean change (SD): st: -0.3 (4.2) in: -2.7 (3.5)</p> <p>*Indicated a significant difference between groups (p<0.0001). Statistical test not given.</p> <p>2) Measures of risk: a) BMI mean Change (SD): st: 0.0 (1.8) men 0.6 (3.1) women in: 1.1 (1.8) men 1.8 (2.1) women</p> <p>*ANCOVA indicates significant differences between groups (by sex) in BMI change (men p=0.004; women p=0.06)</p> <p>b) Systolic blood pressure mean change (SD): st: -4(17) in: -8(18)</p> <p>* Indicated a significant difference between groups (p<0.01). Statistical test not given.</p>	<p>QUALITY ASSESSMENT:</p> <p>INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No</p> <p>Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. withdrawals stated? Yes</p> <p>EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? No Intervention codified in manual? No Provider training described? No Patients assessed for DSM dx? No</p> <p>Biases, etc: Behavior modification not clearly defined/ described; statistical methods not clearly explained</p>

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 330						<p>c) Diastolic blood pressure mean change (SD): st: -5 (10) in: -7 (10)</p> <p>*Indicated no significant difference between groups (p=0.21). Statistical test not given.</p> <p>d) Currently Smokes Change: st: -5 in: -7</p> <p>*Indicated no significant difference between groups (p=0.50). Statistical test not given.</p> <p>e) Cholesterol mean change (SD): st: -15(176) in: -79(147)</p> <p>*Indicated a significant difference between groups (p=0.005). Statistical test not given.</p> <p>3) Events: a) Health care utilization: Not given b) Morbidity/mortality: st: 2 deaths (cardio-vascular) 42 total health events in: 4 deaths (3 cardio-vascular, 1 cancer) 26 total health events</p> <p>*Indicated a significant difference between groups (p=0.03). Statistical test not given.</p>	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 9120 Glasgow, Boles, McKay, Feil, Barrera, 2003	<p>Include: adult type-II diabetes for at least 1 year, are living independently, had a telephone, were literate in English, not planning to move.</p> <p>Exclude: none given</p>	<p>RCT with 2 groups:</p> <p>1) Tailored Self Management (TSM) with basic nutrition information</p> <p>2) Peer support (PS) with basic nutrition information</p> <p>3) Information only (con)</p> <p>*other groups used in outcome/results were: - no peer support (NPS) - no tailored self management (NTSM) *participants were not randomized into these groups, with grouping system unclear.</p>	<p>N= 320</p> <p>*#'s per group not given</p> <p>Intended to treat: 18% of pts dropped out before 1-yr f/u</p> <p>Age mean (SD): 59 (9.2)</p> <p>53.13% Female</p> <p>Race %: not given</p> <p>Baseline HbA1c mean (SD): 7.44 (1.62)</p>	<p>1) Tailored Self-Management—pts work with computer mediated access to a professional “coach” who provides dietary advice to reach their dietary goals negotiated with the online coaches whom they accessed twice a week. The coach suggested strategies to overcome barriers and provide encouragement. Participants could enter information of their daily intake of foods on a personal database. Dietician Q & A conference. Blood glucose and dietary databases and graphical feedback</p> <p>2) Peer Support—patients participated in activities, like structured support conferences, where they could interact with one another and discuss diabetes-related information, coping strategies, support concerns, and</p>	10 months, with quarterly online assessments.	<p>COMPLETER RESULTS:</p> <p>1) Metabolic control: HbA1c % means (SD): NPS: 7.35 (1.56) base 7.68 (1.10) 10 mo PS: 7.54 (1.68) base 7.42 (1.10) 10 mo NTSM: 7.43 (1.71) base 7.67 (1.10) 10 mo TSM: 7.45 (1.53) base 7.42 (1.10) 10 mo</p> <p>* MANCOVA reported to be not significant.</p> <p>2) Measures of risk: a) Lipid Ratio: NPS: 5.44 (1.79) base 5.13 (1.16) 10 mo PS: 5.43 (1.59) base 5.02 (1.16) 10 mo NTSM: 5.18 (1.44) base 5.02 (1.17) 10 mo TSM: 5.70 (1.89) base 5.13 (1.16) 10 mo</p> <p>* MANCOVA reported to be not significant.</p> <p>3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given</p>	<p>QUALITY ASSESSMENT:</p> <p>INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No</p> <p>Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. withdrawals stated? Yes</p> <p>EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? No Intervention codified in manual? No Provider training described? No Patients assessed for DSM dx? No</p> <p>Biases, etc: Not many measures of risk reported. Actual interventions not explained clearly. Education group never directly compared to intervention groups, group assignment not explained clearly, participant #'s per group not given.</p>

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 9120 Glasgow, Boles, McKay, Feil, Barrera, 2003				stressors. Participants could also participate in live chat discussions. Pts. Electronic newsletters (5) containing information on local restaurants that provide low-fat menu options, strategies for talking with doctors, media, and real-life success stories 3) Information only—pts had computer access to articles on topics of medical, nutritional, and lifestyle aspects of diabetes. They also completed assessments online and received automated dietary change goals. Quarterly online assessments.		COMPLETER RESULTS: 4) Psychological outcomes†: a) CES-D means (SD): NPS: 17.8 (10.08) base 14.06 (9.12) 10 mo PS: 18.1 (10.51) base 12.59 (9.13) 10 mo NTSM: 17.9 (10.56) base 12.93 (9.11) 10 mo TSM: 18.0 (10.02) base 13.72 (9.12) 10 mo * MANCOVA reported to be not significant. b) Total Support Scale means (SD): NPS: 4.23 (1.23) base 4.71 (1.12) 10 mo PS: 4.05 (1.28) base 5.22 (1.11) 10 mo NTSM: 4.14 (1.32) base 4.96 (1.12) 10 mo TSM: 4.14 (1.20) base 4.97 (1.12) 10 mo * MANCOVA reported to be significant for NPS and PS comparison (p=0.001), but significant for NTSM and TSM comparison. † Higher scores on Center for Epidemiologic Studies-Depression (CES-D) and Total Support Scale indicate more depressive symptoms and support respectively.	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 240 Glasgow & Toobert, 2000	Include: Type II diabetes Exclude: planning to move within 1 year	2 x 2 RCT: 1) Basic condition (BC) 2) Basic & telephone follow-up (BCT) 3) Basic & Community Resources (BCC) 4) Combined Condition (CC)	N= 320 n BC=80 n BCT= 80 n BCC= 80 n CC=80 * 43 patients did not complete study (BC=13, BCT= 13, BCC=5, CC=12) % Female not given Race % not given Baseline HbA1c % means (sd): Completers: BC: 7.6 (1.2) BCT: 7.3 (1.5) BCC: 7.5 (1.9) CC: 7.6 (1.8)	Intervention consisted of 3 parts: 1) interactive multimedia touch-screen assessment of patient's dietary patterns, a tailored fat reduction goal completed at baseline and 3 month follow-up (BC) 2) Telephone follow-up (3-4 follow-up calls before the 6 mo. Follow-up) to provide support and reinforcement and personalized problem-solving training for barriers on their dietary self-care (BCT, CC) 3) Community resources were given to participants—newsletters for obtaining support for their eating patterns and goal feedback on ways to decrease	Treatment duration not stated. F/u at 3 and 6 mo	COMPLETER RESULTS: 1) Metabolic control a) HbA1c % means (SD): BC: 7.6 (1.2) base 7.6 (1.4) 3 mo 7.4 (1.2) 6 mo BCT: 7.3 (1.5) base 7.3 (1.6) 3 mo 7.3 (1.4) 6 mo BCC: 7.5 (1.9) base 7.6 (2.1) 3 mo 7.4 (1.4) 6 mo CC: 7.6 (1.8) base 7.5 (1.7) 3 mo 7.5 (1.7) 6 mo *ANCOVA indicated no significant effect of group on HbA1c 2) Measures of risk: a) Weight (lbs) means (SD): BC: 199 (36) base 198 (37) 3 mo 197 (37) 6 mo BCT: 212 (49) base 210 (46) 3 mo 210 (46) 6 mo BCC: 219 (49) base 217 (47) 3 mo 217 (48) 6 mo CC: 221 (52) base 218 (49) 3 mo 219 (51) 6 mo *ANCOVA indicated no significant effect of group on weight loss.	QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? Yes EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? No Intervention codified in manual? No Provider training described? No Patients assessed for DSM dx? No Biases, etc: Treatment duration not stated

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 240 Glasgow & Toobert, 2000				setting for community nutrition. Participants had to return a postcard stating which CR they used. A Food-frequency questionnaire was mailed with personally tailored Fat intake (BCC, CC)		<p>b) Total Cholesterol means (SD):</p> <p>BC: 210 (40) base 201 (34) 3 mo 206 (39) 6 mo</p> <p>BCT: 203 (39) base 202 (34) 3 mo 194 (30) 6 mo</p> <p>BCC: 202 (38) base 198 (37) 3 mo 202 (39) 6 mo</p> <p>CC: 205 (35) base 201 (31) 3 mo 201 (30) 6 mo</p> <p>*ANCOVA indicated no significant effect of group on Total Cholesterol.</p> <p>3) Events:</p> <p>a) Health care utilization: Not given</p> <p>b) Morbidity/mortality: Not given</p> <p>4) Psychological Measures: -Quality of Life: Illness Intrusiveness Scale- IIS means (SD):</p> <p>BC: 25.7 (11.1) base 31.0 (15.6) 3 mo 26.0 (12.7) 6 mo</p> <p>BCT: 29.2 (15.2) base 30.6 (15) 3 mo 29.6 (14.9) 6 mo</p> <p>BCC: 28.6 (12) base 32.4 (13) 3 mo 28.2 (12.4) 6 mo</p> <p>CC: 30.8 (15.7) base 31.4 (13.3) 3 mo 29.2 (14.0) 6 mo</p> <p>*ANCOVA indicated no significant effect of group on Quality of Life.</p>	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 3090 Glasgow, La Chance, Toobert, Brown, Hampson, Riddle, 1997.	Include: type 1 or type 2 diabetes, older than 40 years, being primarily responsible for one's own diabetes dietary self-management Exclude: not stated	RCT with 2 treatment conditions: 1) Usual Care (con) 2) Brief intervention (int)	N = 206 n con = 98 n int = 108 *33 drop-outs Age means (SD): con = 63.1(10.5) int = 61.7(12.1) % Female: con: 60 int: 63 Baseline HbA1c % means: Completers: con: 7.9 int: 7.9	1) Usual care—a high quality quarterly medical care intervention—did not focus on behavioral interventions 2) 5-10 min touch-screen dietary barriers assessment that generated feedback forms including problem situations to plan for. 20 min patient centered goal setting and problem solving session, plan to lower fat intake.	2 30 min interventions (1 at time of tx and one at 3 month follow-up), 6 month phone follow-up, 12 month follow-up	COMPLETER RESULTS: 1) Metabolic control a) HbA1c % means: con: 7.9 base 7.8 f/u int: 7.9 base 7.8 f/u *MANCOVA indicated no significant effect of group on HbA1c at f/u (p=0.42). 2) Measures of risk: a) Body Mass Index-BMI means: con: 30.2 base 30.4 f/u int: 30.4 base 30.5 f/u *MANCOVA indicated no significant effect of group on BMI at f/u (p=0.33). b) Serum Cholesterol means (SD): con: 223 base 226 f/u int: 217 base 208 f/u *MANCOVA indicated a significant effect of group on serum cholesterol at f/u (p=0.002). 3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given	QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? Yes Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? Yes EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? No Provider training described? No Patients assessed for DSM dx? No Biases, etc: None noted

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 3110 Glasgow, Toobert, & Hampson, 1996.	<p>Include: Type I or II diabetes; age ≥40 years; primarily responsible for one's own diabetes self-management</p> <p>Exclude: None noted</p>	RCT with 2 treatment conditions: 1) Usual Care (con) 2) Brief intervention (int)	<p>N = 206 n con = 98 n int = 108 *26 drop-outs- int: 13; con: 13</p> <p>Age means (SD): Intended to treat: con = 63.1(10.5) int = 61.7(12.1)</p> <p>% Female: Intended to treat: con = 60 int = 63</p> <p>Race % not given</p> <p>Baseline HbA1c % means: Intended to treat: con: 7.9 int: 7.8</p>	<p>1) Usual care— complete the 15— 20 minute computerized assessment, then saw their physician as scheduled and were re-assessed at their scheduled 3 month follow-up</p> <p>2) Intervention— completed one additional touch-screen dietary barriers assessment that generated feedback forms then gave recommendations for personalized strategies to help patients reduce fat intake. Patients were also given a video on frequent barriers (30 min). Patients received follow-up phone calls at 1 and 3 weeks after the visit. Intervention was repeated 3 months later.</p>	2 separate 20- min sessions and 2 follow-up phone calls at 1 and 3 weeks.	<p>COMPLETER RESULTS:</p> <p>1) Metabolic control a) HbA1c % means: con: 7.9 base 7.7 f/u int: 7.8 base 7.6 f/u *ANCOVA indicated no significant effect of group on HbA1c at f/u (p=0.20).</p> <p>2) Measures of risk: a) Serum Cholesterol means: con: 223 base 231 f/u int: 216 base 207 f/u *ANCOVA indicated a significant effect of group on serum cholesterol at f/u (p=0.0001).</p> <p>3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given</p>	<p>QUALITY ASSESSMENT:</p> <p>INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No</p> <p>Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? Yes</p> <p>EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? Yes Provider training described? No Patients assessed for DSM dx? No</p> <p>Biases, etc: Not many measures of risk assessed</p>

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 6180 Glasgow, Toobert, Hampson, Brown, Lewinsohn & Donnelly, 1992	Include: type II diabetes, age ≥ 60 years Exclude: Positive submaximal exercise test	RCT with 2 treatment conditions: 1) Immediate intervention 2) Delayed intervention	N = 102 n imm = 52 n del = 50 *1 subject dropped out before the post-test assessment. Age means (SD): imm = 67.1(4.3) del = 67.2 (5.8) % Female: imm = 63.5 del = 62.0 Race % not given Baseline GHb % means (SD): Completers: imm: 6.8 (1.6) del: 7.4 (1.8)	1) Focused on dietary and exercise self-care behaviors and regular blood glucose monitoring. Dietary targets were reducing caloric intake, decreasing consumption of fats and increasing fiber intake. Exercise: regular participation in low level aerobic activity. Also focused on problem-solving and coping strategies. 2) Delayed intervention-received intervention following post-treatment.	8 Weekly meetings followed by 2 bi-weekly meetings = 12 weeks total	COMPLETER RESULTS: 1) Metabolic control a) GHb % means (SD): imm: 6.8 (1.6) base 6.3 (1.5) post 6.7 (1.7) 6 mo del: 7.4 (1.8) base 7.0 (1.5) post 6.4 (1.4) post replication *ANCOVA indicated no significant differences between groups. 2) Measures of risk: - Weight (lbs) means (SD): imm: 188.0 (34.2) base 182.2 (33.9) post 186.1 (32.6) 6 mo del: 184.5 (34.4) base 185.9 (34.6) post 181.0 (34.7) post replication *ANCOVA indicated no significant differences between groups. 3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given 4) Psychological Measures: - Diabetes Quality of Life Scale † means (SD): imm: 37.9 (8.8) base 38.2 (7.4) post 38.1 (9.2) 6 mo del: 36.8 (8.0) base 36.3 (8.0) post 37.2 (7.5) post replication *paired t-tests indicated no significant differences. † Higher scores on the Diabetes Quality of Life Scale indicated higher quality of life.	QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? Yes Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? Yes EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? No Provider training described? Yes Patients assessed for DSM dx? No Biases, etc: Not many measures of risk assessed

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 9140 Glasgow, Toobert, Hampson, Stryker, 2002	<p>Include: type II diabetes, lived independently, had a telephone, were not planning to move</p> <p>Exclude: none noted</p>	<p>RCT with 4 groups:</p> <p>1) Basic goal setting (BGS)</p> <p>2) Community Resources (CR)</p> <p>3) Telephone Follow-up (TF)</p> <p>4) Combined Condition (COM)</p>	<p>N= 320</p> <p>n BGS=80</p> <p>n CR=80</p> <p>n TF=80</p> <p>n COM= 80</p> <p>* 15 participants withdrew before the 1-yr f/u</p> <p>Age mean: 59.7</p> <p>56% Female</p> <p>Race (%Caucasian): BGS = 90 CR = 90.9 TF = 88.6 COM = 91.4</p> <p>Baseline HbA1c mean (SD): BGS: 7.63 (1.3) CR: 7.38 (1.6) TF: 7.55 (1.9) COM: 7.54 (1.7)</p>	<p>1) Basic Goal Setting—attended baseline assessment with other participants where completed interactive assessment with feedback and brief session with an interventionist. Assessed dietary patterns, barriers, and gave one-page printout summarizing this information. Were given a general pamphlet about low-fat eating.</p> <p>2) Telephone follow-up—7 (15-20 min) brief structured calls providing support and reinforcement, personalized problem-solving training</p> <p>3) Community Resources—binder of indexed community re-</p>	<p>12 months f/u, 6 months of face-to-face interaction</p> <p>Visits at BL, 3 and 6 mos. (1-2 hrs)</p>	<p>COMPLETER RESULTS:</p> <p>1) Metabolic control: HbA1c % means (SD): BGS: 7.63 (1.3) base 7.43 (1.3) 12 mo CR: 7.38 (1.6) base 6.99 (1.0) 12 mo TF: 7.55 (1.9) base 7.39 (1.3) 12 mo COM: 7.54 (1.7) base 7.23 (1.2) 12 mo</p> <p>* MANCOVA indicated TF group significantly different than other groups at 12 mo (p<0.05) on all biological measures combined (HbA1c and lipid ratio).</p> <p>2) Measures of risk: a) Lipid Ratio: BGS: 5.1 (1.7) base 4.8 (1.6) 12 mo CR: 4.8 (1.4) base 4.5 (1.2) 12 mo TF: 5.2 (3.8) base 4.3 (1.0) 12 mo COM: 4.9 (1.3) base 4.4 (1.1) 12 mo</p> <p>3) Event: a) Health care utilization: Not given b) Morbidity/mortality: Not given</p>	<p>QUALITY ASSESSMENT:</p> <p>INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No</p> <p>Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. withdrawals stated? Yes</p> <p>EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? No Provider training described? No Patients assessed for DSM dx? No</p> <p>Biases, etc: Statistical analyses not differentiated on measure, but type of outcome (biological, behavioral, or psychosocial)</p>

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 9140 Glasgow, Toobert, Hampson, Stryker, 2002				sources, 8 newsletters focused on identifying opportunities for participants to obtain support for their eating patterns. Goal setting for community support activities was included in each face-to-face meeting. 4) combined condition received everything mentioned for BGS, TF, and CR.		<p>COMPLETER RESULTS: 4) Psychological outcomes†: a) Illness Intrusiveness means (SD): BGS: 27.1 (14.2) base 27.8 (12.4) 12 mo CR: 28.2 (15.0) base 32.8 (17.0) 12 mo TF: 30.0 (13.6) base 31.6 (12.7) 12 mo COM: 30.8 (15.6) base 29.5 (12.7) 12 mo</p> <p>* MANCOVA indicated TF group significantly different than other groups at 12 mo (p<0.05) on all psychological measures combined (illness intrusiveness, illness resources, and self efficacy).</p> <p>b) Self Efficacy means (SD): BGS: 3.9 (0.8) base 3.9 (0.7) 12 mo CR: 3.9 (0.6) base 4.1 (0.7) 12 mo TF: 3.8 (0.7) base 4.0 (0.6) 12 mo COM: 3.9 (0.6) base 4.1 (0.7) 12 mo</p> <p>† Higher scores on Center for Epidemiologic Studies-Depression (CES-D) and Total Support Scale indicate more depressive symptoms and support respectively.</p>	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 6620 Glasgow, Toobert, Mitchell, Donnelly, & Calder, 1989.	Include: type II diabetes, GHb > 9% or physician judgment of poor control. Exclude: not stated	RCT with 3 treatment conditions: 1) Nutrition education (NE) 2) Nutrition education + social learning (NE +SL) 3) Wait-list control (WL)	N = 78 n NE = 20 n NE + SL = 23 n WL = 16 *4 in NE did not complete study Age range: 42-75 73% Female Race % not given Baseline GHb %: Intend to treat: mean = 9.7	1) NE—3 targets: reduction in calorie intake, reduction in fat intake, and increases in dietary fiber. Weight loss was deemphasized, but presented as a possible bonus 2) NE + SL—NE as above, plus other components including goal setting based on individual barriers to adherence and modeling of strategies used successfully by other individuals with type II diabetes, problem solving method called STOP(specify the problem, think of the options, opt for the best solution, put the solution into practice). 3) Wait-list	5 Weekly meetings, 2-month follow-up	COMPLETER RESULTS: 1) Metabolic control: a) GHb % Not given *Comparisons of groups on GHb said to be not significant. Statistical tests not given. 2) Measures of risk: -Not Given 3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given	QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? Yes EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? Yes Provider training described? No Patients assessed for DSM dx? No Biases, etc: Results not given for metabolic control; no measures weight, blood pressure, or cholesterol assessed. All 4 drop-outs were in the control (NE) condition.

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
#3440 Goldhaber-Fiebert, Goldhaber-Feibert, Tristan & Nathan, 2003.	Include: Type II diabetes Exclude: none	RCT with 2 conditions: 1) Control group (con) 2) Intervention Group (int)	N = 75 n con = 35 n int = 40 *14 drop-outs (7 intervention, 7 control) Age mean (SD): n con = 57(9) n int = 60(10) % Female: con = 74.3 int = 82.5 Race % not given Baseline GHb% means (SD): Intention to treat: con = 8.6 (3.9) int = 8.6 (3.7)	1) Control— standard diabetes educational lecture 2) Intervention— 12-week lifestyle intervention (in Spanish), including 11 weekly nutrition classes (90 min) focusing on portion control and healthy food substitutes. Taught of the basic food groups. Subjects set weekly goals for eating behavior changes. Emphasis put on health for all family members. Recorded food diaries. 20 of 40 subjects in this group also participated in a 60-min walking group 3 times a week for 12 weeks.	12 weeks	COMPLETER RESULTS: 1) Metabolic control a) GHb % Change means (SD): con: -0.4 (2.3) base-post int: -1.8 (2.3) base-post *t-tests indicated significant differences between groups on GHb change (p=0.028) b) Fasting Plasma Glucose (mg/dl) Change means (SD): con: 16 (78) base-post int: -19 (55) base-post *t-tests indicated significant differences between groups on Fasting Plasma Glucose change (p=0.048) 2) Measures of risk: a) Weight (kg) Change means (SD): con: 0.4 (2.3) base-post int: -1.0 (2.2) base-post *t-tests indicated significant differences between groups on weight change (p=0.028) b) Systolic blood pressure-SBP Change means (SD): con: -4 (16) base-post int: -5 (23) base-post *t-tests indicated no significant differences between groups on SBP (p=0.95). c) Diastolic blood pressure- DBP Change means (SD): con: -3 (8) base-post int: -7 (9) base-post *t-tests indicated no significant differences between groups on DBP (p=0.06).	QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? Yes Outcome assessors blinded? No No. of withdrawals in each group stated? Yes EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? No Provider training described? Yes Patients assessed for DSM dx? No Biases, etc: None noted

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
#3440	Goldhaber-Fiebert, Goldhaber-Feibert, Tristan & Nathan, 2003.					<p>d) Total Cholesterol Change means (SD): con: 1 (33) base-post int: -8 (36) base-post *t-tests indicated no significant differences between groups on total cholesterol (p=0.31).</p> <p>e) HDL Cholesterol Change means (SD): con: -3 (6) base-post int: -5 (5) base-post *t-tests indicated no significant differences between groups on HDL-C (p=0.49).</p> <p>f) LDL-Cholesterol Change means (SD): con: -1 (29) base-post int: 5 (36) base-post *t-tests indicated no significant differences between groups on LDL-C (p=0.53).</p> <p>3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given</p>	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 6710 Greenfield, Kaplan, Ware, Yano, Frank 1988	<p>Include: diabetic patients</p> <p>Exclude: non-continuing patients, >75 years old, blind, could not speak English, on insulin pump, had cancer or any other major health concern.</p>	RCT with 2 groups: 1) Experimental (exp) 2) Control (con)	<p>N= 73 n con= 34 n exp= 39</p> <p>*14 drop-outs: 8 con, 6 exp</p> <p>Age means (SD): con: 49.5 (13.0) exp: 49.8 (14.7)</p> <p>% Female: con: 52 exp: 48</p> <p>Race %: not given</p> <p>Baseline HbA1 % means (SD): con: 10.26 (1.96) exp: 10.59 (2.11)</p>	<p>1) In a 20-minute intervention the exp group patients were taught to identify relevant medical issues about which they can question their doctors. The patients were also taught which options were available in the event of some common medical issues, and the skills to negotiate with their doctors as to which options was chosen. Obstacles to information-seeking such as embarrassment, forgetfulness, and intimidation were addressed, and the patients were taught skills to deal with them such obstacles.</p> <p>2) The con group were similarly seen for 20 minutes, but only received educational material.</p>	20 minutes prior to doctor's visit	<p>COMPLETER RESULTS:</p> <p>1) Metabolic control: HbA1 % means (SD): con: 10.26 (1.96) base 10.61 (2.15) post exp: 10.59 (2.11) base 9.06 (1.92) post</p> <p>* t-tests indicate significant differences between groups at post (p<0.01).</p> <p>2) Measures of risk: Not given</p> <p>3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given</p> <p>4) Psychological Outcomes: a) Health Related Quality of Life Variables†: i) Mobility means (SD): con: 1.11 (0.96) base 0.39 (1.09) post exp: 0.85 (0.95) base 0.19 (0.48) post</p> <p>* ANCOVA indicated that the groups were significantly different at post (p<.0.01).</p> <p>ii) Role means (SD): con: 0.50 (0.62) base 0.60 (0.77) post exp: 0.37 (0.49) base 0.11 (0.32) post</p> <p>* ANCOVA indicated that the groups were significantly different at post (p<.0.01).</p>	<p>QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No</p> <p>Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. withdrawals stated? Yes</p> <p>EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? Yes Provider training described? No Patients assessed for DSM dx? No</p> <p>Biases, etc: No measures of risk reported.</p>

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 6710						<p>iii) Physical means (SD): con: 1.89 (1.38) base 2.25 (1.40) post exp: 1.41 (1.02) base 0.98 (1.15) post</p> <p>* ANCOVA indicated that the groups were significantly different at post ($p < 0.01$).</p> <p>iii) Self Care means (SD): con: 0.07 (0.12) base 0.06 (0.13) post exp: 0.06 (0.18) base 0.03 (0.09) post</p> <p>* ANCOVA indicated no significant differences between groups.</p> <p>b) Perceived Health Status Variables‡:</p> <p>i) Overall Health means (SD): con: 2.17 (0.88) base 2.82 (0.86) post exp: 2.38 (0.78) base 2.04 (0.77) post</p> <p>* ANCOVA indicated that the groups were significantly different at post ($p < 0.001$).</p> <p>li) Health Concern means (SD): con: 4.22 (0.81) base 4.44 (1.38) post exp: 4.30 (0.91) base 3.26 (1.38) post</p> <p>* ANCOVA indicated that the groups were significantly different at post ($p < 0.01$).</p>	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 6710						iii) Number of Health Concerns means (SD): con: 2.68 (1.73) base 2.73 (1.49) post exp: 2.94 (1.69) base 2.35 (1.82) post * ANCOVA indicated no significant differences between groups.	
Greenfield, Kaplan, Ware, Yano, Frank 1988						† Higher scores for health related quality of life variables signify higher ability to perform as usual in mobility, role, physically, and self-care respectively. ‡ Higher scores on the perceived health status variables indicate poorer health, more concern and more problems respectively.	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 3220 Hanefeld, Fischer, Schmechel, Rothe, Schulze, Dude, Schwanebeck, Julius 1991	Include: NIDDM patients, 30-55 years old, Exclude: myocardial infarction, stroke, gangrene, cancer, or other severe life-limiting illness	RCT with 3 treatment conditions: 1) Control group (con) 2) IHE + placebo (ihe) 3) IHE + calofibric acid (ihe+ca)	N = 1139 n con = 378 n ihe = 382 n ihe+ca = 379 *131 drop-outs (32 control, 54 ihe, 45 ihe+ca) Age means (SD): Con: 46.6(5.6) ihe: 46.2(7.0) ihe+ca: 45.8(8.8) % Female: con: 45.5 ihe: 39.5 ihe+ca: 47.8 Race % not given Baseline Fasting Blood Glucose (mM) means (SD): Intention to treat: con = 7.54(2.11) ihe = 7.04(1.8) ihe+ca = 7.21(2.1)	1) control—regular clinical checkups with 3 to 4 monthly visits. Traditional diet was encouraged. Only had a complete check up in the clinic at entry and after 5 years. 2) Both IHE groups were seen at 3-month intervals. Adherence to diet and physical activity recommendations was annually recorded by questionnaires. Recommendations for lowering weight, lipid-lowering diet, recommendations for physical activity were incorporated to improve metabolic control and reduce the level of coronary risk factors and incidence of ischemic heart disease.	5-years	COMPLETER RESULTS: 1) Metabolic control: - Fasting Blood Glucose (mM) means (SD): con: 7.55 (2.11) base 9.38 (3.33) 5 yr ihe: 7.1 (1.83) base 8.6 (2.72) 5 yr ihe+ca: 7.27 (2.22) base 8.6 (2.89) 5 yr *Reported significant differences between con and both ihe and ihe-ca at 5 yr, with base as covariate. t-test for proportion 2) Measures of risk: a) Body Mass Index-BMI means (SD): con: 28.8 (5.0) base 28.5 (4.9) 5 yr ihe: 29.0 (4.5) base 28.6 (4.6) 5 yr ihe+ca: 29.6 (4.6) base 29.2 (4.6) 5 yr *Reported no significant differences between groups in BMI. T-test for proportion b) Systolic blood pressure- SBP means (SD): con: 150 (20.8) base 154.3 (22.6) 5 yr ihe: 148.6 (19.9) base 143 (18.2) 5 yr ihe+ca: 150.9 (19.4) base 145.4 (18.1) 5 yr *Reported significant differences between con and both ihe and ihe+ca in SBP (both p<0.01). t-test for proportion	QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? Yes EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? No Provider training described? No Patients assessed for DSM dx? No Biases, etc: Statistical analyses not reported

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 3220							
Hanefeld, Fischer, Schmechel, Rothe, Schulze, Dude, Schwanebeck, Julius 1991						<p>c) Diastolic blood pressure-DBP means (SD): con: 90.4 (10.2) base 91.8 (10.7) 5 yr ihe: 89.9 (10.2) base 86.9 (8.5) 5 yr ihe+ca: 90.7 (10.4) base 87.8 (8.9) 5 yr</p> <p>*Reported significant differences between con and both ihe and ihe+ca in DBP (both p<0.01). t-test for proportion</p> <p>d) Cholesterol means (SD): con: 5.75 (1.23) base 6.22 (1.59) 5 yr ihe: 5.71 (1.2) base 6.06 (1.4) 5 yr ihe+ca: 5.62 (1.37) base 5.96 (1.41) 5 yr</p> <p>*Reported no significant differences between groups at 5 yr. Within group improvements for all groups. T-test for proportion</p> <p>3) Events: a) Health care utilization: Not given b) Morbidity/mortality: i) Myocardial Infarction-MI and Ischemic Heart Disease-IHD: MI: con: 10; ihe: 17; ihe+ca: 18 IDH: con: 30; ihe: 31; ihe+ca: 32</p>	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 3220	Hanefeld, Fischer, Schmechel, Rothe, Schulze, Dude, Schwanebeck , Julius 1991					ii) Death: Cardiac death: con: 5; ihe: 1; ihe+ca: 1 Stroke: con: 1; ihe: 1; ihe+ca: 3 Malignant neoplasia: con: 2; ihe: 3; ihe+ca: 2 Liver cirrhosis: con: 5; ihe: 4; ihe+ca: 1 Infectious disease: ihe+ca: 2, others=0 Coma diabeticum: con: 1, others=0 Suicide: con: 1; ihe: 1, ihe+ca=0 Others: con:1, others=0	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 2860 Hartwell, Kaplan, & Wallace 1986	Include: Type II diabetes mellitus, non-insulin dependent Exclude: not stated	RCT-single center with 4 groups: 1) diet (diet) 2) exercise (exer) 3) diet plus exercise (di-ex) 4) education control (con)	N= 78 *2 patients did not complete study Age means (SD): Not Given 57.9% Female Race % not given Baseline GHb % mean (SD): Intention to treat: 8.66 (2.74)	1) Diet group participated in goal setting exercises, and monitored eating behavior; also instructed in self-administration of positive reinforcement 2) Exer group were instructed in goal setting, planning for exercise, and self-monitoring strategies. 3) Di-ex group received diet instruction for first five sessions, then were instructed on exercise practices 4) Con group received traditional diabetes education including information on glucose monitoring, podiatry, & ophthalmology.	10 weekly sessions with f/u at 3 and 6 mo.	COMPLETER RESULTS: 1) Metabolic control: -Blood Glucose (mg/dl) Change means: diet: -44.63 6 mo exer: 15.65 6 mo di-ex: -5.38 6 mo con: -16 6 mo *ANOVA indicated diet group had a significantly different from the con group (p<0.037) 2) Measures of risk: a) Weight (lbs) Change means Estimated from Graph: diet: -5.5 3 mo -7.72 6 mo exer: -1.4 3 mo -3.15 6 mo di-ex: -0.6 3 mo -0.54 6 mo con: 0.6 3 mo 2.5 6 mo *Reported significant differences between diet and con groups (p<0.02) at 6 mo. b) HDL-Cholesterol Change means Estimated from Graph: diet: 5.0 3 mo 4.0 6 mo exer: 0.5 3 mo -1.0 6 mo di-ex: 1.0 3 mo 5.0 6 mo con: -3.5 3 mo 2.0 6 mo *ANOVA indicated significant difference between diet and con groups (p<0.001), exercise and con (p<0.02) and di-ex and con (p<0.02) at 3 mo.	QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? Yes EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? Yes Provider training described? No Patients assessed for DSM dx? No Biases, etc:

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 2860	Hartwell, Kaplan, &Wallace 1986					c) LDL-Cholesterol Change means Estimated from Graph: diet: -1.0 6 mo exer: 12.0 6 mo di-ex: -9.5 6 mo con: 26.0 6 mo *ANOVA indicated both di-ex and con (p<0.01) and diet and con (p<0.05) were significantly different. 3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 1010 Heitzman, Kaplan, Wilson et al. 1987	<p>Include: type II diabetes, fasting blood glucose higher than 140 mg/dl, or normal fasting blood sugar but oral glucose tolerance tests that indicated blood glucose levels exceeding 200 mg/dl at 2-hrs after administration of a 75-g carbohydrate dose</p> <p>Exclude: not given</p>	RCT with 4 groups: 1) relaxation control (con) 2) behavior modification (bm) 3) cognitive modification (cm) 4) cognitive-behavioral modification (cbm)	<p>N= 55 n con=14 n bm= 13 n cm= 13 n cbm= 15 * 9 patients withdrew by 18 mo</p> <p>Age mean (SD): 52.94(12.08) Age range: 29- 79</p> <p>52.17% Female</p> <p>Race %: 95.7- Caucasian 4.3 African Amer.</p> <p>Baseline HbA1 % means (SD): Intended to treat: con: 10.99(2.2) bm: 9.99(3.04) cm: 10.17(2.3) cbm:11.52 (2.4)</p>	<p>1) Con exposed to brief progressive muscle relaxation</p> <p>2) Bm focused on self-control and self-monitoring procedures</p> <p>3) Cm discussed importance of change in cognitions</p> <p>4) Cbm received training in both behavioral and cognitive techniques.</p>	Seven weekly sessions with f/u at 3,6,12 & 18 mo	<p>COMPLETER RESULTS:</p> <p>1) Metabolic control: -HbA1 % at f/u not given, but said to be not significant</p> <p>2) Measures of risk: a) Weight Loss: -Weight change at f/u not given</p> <p>3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given</p>	<p>QUALITY ASSESSMENT:</p> <p>INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? Yes</p> <p>Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. withdrawals stated? Yes</p> <p>EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? Yes Provider training described? Yes Patients assessed for DSM dx? No</p> <p>Biases, etc: Results not clearly stated, with no actual quantitative results given for any main findings; study focused on sex, differences.</p>

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 4330 Hendricks & Hendricks, 2000.	Include: African American men, type II diabetes Exclude: not stated	RCT with 2 treatment conditions: 1) Monthly follow-up intervals 2) 3 month follow-up intervals	N = 30 n 1 mo = 15 n 3 mo = 15 *no attrition Age mean(SD): 1 mo = 58.9(10.5) 3 mo = 57.4(13.0) 0% Female Race %: 100- African Amer. Baseline HbA1c% means (SD): Completers: 1 mo: 7.8 (1.9) 3 mo: 8.3 (2.0)	1) Diabetes self-management education— provides comprehensive instruction in 15 content areas—2 hrs a week for 4 weeks. Audiovisual presentations, lectures provide information that would empower the participants, encourage them to take charge of their diabetes, learn to problem solve. Instructors were positive, open and honest. Altruistic reasons were identified as reasons to adhere to a diabetes regimen. Two randomly assigned telephone follow-up conditions 1) monthly follow-up, 2) every 3-month follow-up. Goals of follow up: to evaluate progress towards set goals,.	4 week education prgm. Group 1 = monthly follow-up for six months Group 2 = follow-up at month 3 and month 6	COMPLETER RESULTS: 1) Metabolic control a) HbA1c % means (SD): 1 mo: 7.8 (1.9) base 6.6 (1.6) post 3 mo: 8.3 (2.0) base 7.8 (2.3) post *paired t-tests indicated no significant differences. 2) Measures of risk: Not Given 3) Events: a) Health care utilization: - Patients reported having no hospitalizations or emergency room visits during 6 mo period b) Morbidity/mortality: Not given	QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? Yes, none. EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? Yes Provider training described? No Patients assessed for DSM dx? No Biases, etc: Not many measures of risk assessed at post.

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 4330	Hendricks & Hendricks, 2000.			identify self- management problems, track selected outcomes, give instruction/skills training & advice			

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
#6800 Kaplan, Hartwell, Wilson & Wallace, 1987	Include: Non-insulin-dependent type II diabetes Exclude: None stated	RCT with 4 conditions: 1) Diet (diet) 2) Exercise (exer) 3) Diet + exercise (di-ex) 4) Education (con)	N = 76 * 6 subjects were lost before the 18 month follow-up—did not specify from which groups. Age means (SD): diet= 54.87(12.32) exer= 53.81(8.04) di-ex = 56.96(8.95) con = 54.5(8.83) Race % not given Baseline HbA1c % means (SD): Intention to treat: diet= 8.97(2.82) exer= 8.16(3.44) di-ex= 9.18(2.46) con= 8.21(1.54)	1) Diet - subjects identified goals, monitored eating through use of diaries, learned to identify cues that led to overeating or inappropriate eating patterns, positive reinforcement, and environment alterations, and changes in cognitions that can be made to change eating habits. Relaxation exercises also used. 2) Exercise—goal setting, planning for exercise, self-monitoring strategies, weekly diaries, foot care, graded exercise test, stretching, walking, reinforcers, negative/positive self talk, distractors, scheduling for holidays and vacations. Used exercise leaders to provide a	Treatment sessions lasted 10 weeks, f/u at 3, 6, 12 and 18 mos	COMPLETER RESULTS: 1) Metabolic control - HbA1c % Change means: diet: -0.46 base- 18 mo exer: 1.30 base- 18 mo di-ex: -1.48 base- 18 mo con: 0.36 base- 18 mo *ANOVA indicated significant differences between groups di-ex and con on GHb (p<0.05). 2) Measures of risk: a) Weight-kg Change means: *ANOVA indicated no significant effect of group on weight loss at 18 mo. Values not reported. 3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given 4) Psychological Measures: -Quality of Well Being-QWB† Change means: diet: 0.03 base- 18 mo exer: 0.00 base- 18 mo di-ex: 0.06 base- 18 mo con: -0.04 base- 18 mo *ANOVA indicated significant differences between both groups di-ex and con (p<0.01) and groups diet and con (p<0.05). † Higher scores on the QWB indicated higher Quality of Life	QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? Yes EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? Yes Provider training described? No Patients assessed for DSM dx? No Biases, etc: Post-tx means not clearly reported in table form for all outcomes

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
#6800	Kaplan, Hartwell, Wilson & Wallace, 1987			<p>model, positive feedback. 20 min stretch, 45-60 min walking, 5-10 min stretching, 30 min of group discussion.</p> <p>3) Diet and Exercise—modified dietary intervention for the first 5 weeks. The 6th meeting focused on exercise prescription, self-monitoring, foot care, and stretching. Remaining four meetings were conducted as: 20 min stretching, 45-60 min walking/jogging, and 30 min behavior modification</p> <p>4) Education (control group)—10 two-hr. presentations over a 10 wk pd. From health care professionals. Provided no instructions, only information.</p>			

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 4650 Kinsley, Weinger, Bajaj, Levy, Simonson, Quigley, Cox, Jacobson 1999	Include: type I diabetes, no evidence of diabetic complications Exclude: If evidence of diabetic complications	RCT with 2 treatment conditions: 1) BGAT group (BGAT) 2) Cholesterol awareness control group (con)	N = 60 n int = 25 n con = 22 *13 drop-outs (5 in int, 8 in con) Age mean (SD): 34(8) Age range: 19-50 % Female: 51.1 Race % not given Baseline HbA1c % mean (SD): Completers: 9.0 (1.1)	1) Intervention—8 4 months session group education program in blood glucose awareness training (BGAT) 2) control—8 session cholesterol education group	4 months	COMPLETER RESULTS: 1) Metabolic control a) HbA1c % means (SD): con: 9.0 (1.1) base 7.8 (0.8) f/u int: 9.1 (1.4) base 7.9 (1.1) f/u *ANOVA indicated no significant effect of group on HbA1c at f/u. Both group showed significant within group changes. 2) Measures of risk: Not given 3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given	QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? Yes EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? No Intervention codified in manual? Yes Provider training described? No Patients assessed for DSM dx? No Biases, etc: No measures of risk assessed; intervention not described clearly

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 6110 Laitinen, Aloha, Sarkkinen, Winberg, Harmaakorpi- Iivonen, Uusitupa 1993	Include: NIDDM, fasting blood glucose levels of 6.7 mmol/L or greater, 40-64 years old Exclude: not stated	RCT with 2 treatment conditions: 1) conventional treatment (con) 2) intervention (int)	N = 86 n con = 46 n int = 40 *0 drop-out Age means (SD): con : men = 54.0(6.6) women = 54.4(6.4) int : men = 50.7(7.7) women = 53.7(6.3) % Female: con = 39.1% int = 47.5% Race % not given Baseline HbA1c % means (SD): Completers: con: 9.0 (2.6) int: 8.4 (2.2)	1) conventional treatment— received usual education given at local health centers (visited at 2- to 3-month intervals) and visited the outpatient clinic at 9 and 15 months 2) intervention— visited outpatient clinic every second month for 12 months (6 sessions). Received intensified dietary education, tailored diet plans for each individual behavior modification. Each visit, patient and nutritionist set two clear goals for dietary change and weight loss. Patients also completed food records that were used for diet counseling.	12 months—15 month follow up.	COMPLETER RESULTS: 1) Metabolic control a) HbA1c % means (SD): con: 9.0 (2.6) base 7.8 (2.0) 3 mo 7.5 (1.7) 15 mo int: 8.4 (2.2) base 7.1 (1.8) 3 mo 6.6 (1.6) 15 mo *RM-MANOVA indicated a significant decrease in GHb for both groups at 3 mo (p<0.001 for both). Int group had significantly lower Ghb at 15 mo compared to con group (p<0.05). b) Fasting Blood Glucose-FBG (mmol/L) means (SD): con: 8.9 (3.3) base 7.5 (2.9) 3 mo 7.5 (2.2) 15 mo int: 7.6 (2.4) base 6.6 (1.9) 3 mo 6.2 (1.8) 15 mo *RM-MANOVA indicated a significant decrease in FBG for both groups at 3 mo (p<0.001 for both) Int group had significantly lower FBG at 15 mo compared to con group (p<0.05). 2) Measures of risk: a) Weight (kg) means (SD): con: 92.2 (14.7) base 88.8 (14.0) 3 mo 90.2 (14.3) 15 mo int: 91.6 (14.5) base 88.3 (14.1) 3 mo 86.5 (13.7) 15 mo *RM-MANOVA indicated a significant decrease in FBG for both groups at 3 mo (con p<0.001; int p<0.01)	QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? No EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? No Intervention codified in manual? No Provider training described? No Patients assessed for DSM dx? No Biases, etc: None noted

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 6110	Laitinen, Aloha, Sarkkinen, Winberg, Harmaakorpilivonen, Uusitupa 1993					<p>b) Serum Cholesterol means (SD): con: 6.5 (1.1) base 6.3 (1.0) 3 mo 6.4 (1.0) 15 mo int: 6.3 (1.4) base 6.1 (1.2) 3 mo 6.0 (1.0) 15 mo</p> <p>*RM-MANOVA indicated no significant decrease in serum cholesterol for either group.</p> <p>c) Serum HDL-Cholesterol means (SD): con: 1.12 (0.26) base 1.17 (0.29) 3 mo 1.21 (0.28) 15 mo int: 1.07 (0.32) base 1.07 (0.25) 3 mo 1.20 (0.29) 15 mo</p> <p>*RM-MANOVA indicated a significant within-group increase in HDL-C for int group at 15 mo (p<0.001)</p> <p>3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given</p>	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 8950 Lamparski & Wing, 1989	<p>Include: adult-onset diabetics, receiving treatment with insulin or oral hypoglycemic medication, little or no experience with home blood glucose monitoring, adequate eyesight</p> <p>Exclude: those with food allergies, those using beta-blocker medications</p>	RCT with 2 groups: 1) current feedback (cur) 2) noncurrent feedback (non)	<p>N= 36 n cur = 18 n non = 18</p> <p>Age mean (SD): 56.4 (7.1) Age range: 35-69</p> <p>% Female not given</p> <p>Race not given</p> <p>Baseline Fasting Blood Glucose (mg %) Estimated from Graph: cur: 205 non: 168</p>	<p>Sessions included discrimination training in estimating blood glucose levels. Participants in the cur group received immediate actual glycemic control, then re-estimated blood glucose levels. Participants in the non group only received feedback for the previous session, and were not given individualized help in estimating blood glucose levels.</p>	Six training sessions conducted twice a week for four weeks, plus a pretest session and a posttest session.	<p>1) Metabolic control: -Fasting Blood Glucose means (mg %) Estimated from graph: cur: 205 base 165 post non: 168 base 142 post</p> <p>* Statistical significance of differences between groups not given.</p> <p>2) Measures of risk: Not given</p> <p>3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given</p>	<p>QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No</p> <p>Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. withdrawals stated? No</p> <p>EXTERNAL VALIDITY: Pop. Described? No Intervention described well enough to reproduce? Yes Intervention codified in manual? Yes Provider training described? No Patients assessed for DSM dx? No</p> <p>Biases, etc: Results not clearly reported, no measures of risk assessed, statistical analyses not reported for actual reduction in blood glucose</p>

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 2050 Lane, McCaskill, Ross et al. 1993	Include: NIDDM, type RCT-single center II, poor clinical control with 2 groups: (2-hr post-prandial glucose > 200 mg/dl. Exclude: Insulin	1) control (con) 2) relaxation intervention (tx)	N= 38 n con= 19 n tx= 19 *6 drop-outs (4 -tx, 2-conl) Race % not given Week 1 GHb % means (SD): Completers: con: 10.1 (0.5) tx: 10.5 (0.6)	Both con and tx received intensive diabetes education. Tx group also received weekly biofeedback-assisted relaxation training sessions which included progressive muscle relaxation training, plus 4 follow-up relaxation sessions at 3, 4, 5 and 6 months.	48 weeks	COMPLETER RESULTS: 1) Metabolic control: a) GHb% means (SD): con: 10.1 (0.5) Week 1 8.5 (0.4) Week 48 tx: 10.5 (0.6) Week 1 8.7 (0.3) Week 48 *RM-ANOVA did not show significant difference between con and tx at Week 48. 2) Measures of risk: Not given 3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given	QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? Yes EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? No Provider training described? No Patients assessed for DSM dx? No Biases, etc: Patient baseline characteristics not clearly stated; Although some measures taken at baseline, not monitored throughout treatment (e.g. Weight)

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 380 Lustman, Griffith, Freeland, et al 1998	<p>Include: Type II diabetes; age 21-70; major depression; score ≥ 14 on Beck Depression Inventory (BDI)</p> <p>Exclude: suicidal ideation or past suicide attempt; psychiatric comorbid illness</p>	RCT- single-center design with 2 groups: 1) control and 2) CBT	<p>N=51 n control=26 n CBT=25 *10 participants did not complete study</p> <p>Age means (SD): CBT= 53.1(10.5) control=56.4 (9.7)</p> <p>% Female: CBT: 60 control: 59.1</p> <p>Race %: CBT: 85- White 15-non-White control: 77.3- White 22.7-non-White</p> <p>Baseline GHb % means (SD): CBT: 10.2(3.6) control: 10.4 (3.1)</p>	<p>Control and CBT groups both attended individual diabetes education sessions. CBT received additional weekly 1-hour therapy for treating depression including 1)behavioral strategies to involve participants in activities 2) problem-solving procedures to resolve stressful circumstances and 3) cognitive techniques to identify distorted or maladaptive thought patterns</p>	10-week intervention with follow-up at 6 mo.	<p>1) Metabolic control: a) GHb % change: control: -0.5 pre-post 0.9 post-f/u CBT: 0.1 pre-post -0.7 post-f/u</p> <p>* t-tests indicate significant difference of GHb between groups at f/u (p=0.04).</p> <p>2) Measures of risk: Not given</p> <p>3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given</p> <p>4) Psychological Measures: -Depression (Beck Depression Inventory-BDI) % remitted (r) or improved (i): control: 27.3 r post 33.3 r f/u 36.6 i post 31.9 i f/u CBT: 85.0 r post 70.0 r f/u 70.0 i post 70.0 i f/u</p> <p>* ANCOVA indicated significant effects of group on BDI p<.04</p> <p>†Higher scores on the BDI indicate more depressive symptoms.</p>	<p>QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No</p> <p>Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? Yes No. withdrawals stated? Yes</p> <p>EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? Yes Provider training described? Yes Patients assessed for DSM dx? Yes</p> <p>Biases, etc: Investigators state that baseline GHb significantly different between groups, but did use baseline measures as covariate; subjects in neither group received anti-depressants during treatment but were referred at end of 10 weeks for anti-depressants if BDI ≥ 10.</p>

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 690 Manning, Jung, Leese, & Newton 1995	<p>Include: insulin-dependent, non-insulin-dependent, BMI between 28-45, ages 16-70</p> <p>Exclude: anyone who had lost more than 3 kg of weight in the previous year, pregnant women, thyroid, those on oral corticosteroids.</p>	<p>RCT with 5 groups:</p> <p>1) individual diet consultation in clinic (clin)</p> <p>2) individual diet consultation with dexfenfluramine (dex)</p> <p>3) individual diet consultation in clinic and home (home)</p> <p>4) behavioral group therapy (beh)</p> <p>5) control (con)</p>	<p>N= 205</p> <p>n clin= 37</p> <p>n dex= 37</p> <p>n home= 35</p> <p>n beh= 38</p> <p>n con= 58</p> <p>* 44 patients did not complete study</p> <p>Age means:</p> <p>Intended to treat:</p> <p>clin: 57.3</p> <p>dex: 54.4</p> <p>home: 55.2</p> <p>beh: 58.8</p> <p>con: 53.7</p> <p>Completers:</p> <p>clin: 58.4</p> <p>dex: 54.7</p> <p>home: 58.4</p> <p>beh: 58.6</p> <p>con: not given</p> <p>Age range: 16-70</p> <p>% Female:</p> <p>Intended to treat:</p> <p>clin: 56.7</p> <p>dex: 62.2</p> <p>home: 42.9</p> <p>beh: 47.4</p> <p>con: 41.4</p> <p>Completers:</p> <p>clin: 50.0</p> <p>dex: 63.3</p> <p>home: 35.7</p> <p>beh: 42.9</p> <p>con: not given</p> <p>Race % not given</p>	<p>1) Clin patients received individual diet consultations in clinic at 6-weekly intervals for first 6 months, then 2-monthly for remainder of the year; dietary advice based on 1992 dietary recommendations</p> <p>2) Dex patients received the same dietary advice as clin, but were additionally given dexfenfluramine twice a day for first 3 mo.</p> <p>3) Home patients received the same dietary advice as clin, but were seen in both the clinic and at home.</p> <p>4) Beh therapy involved a physiotherapist, a clinical psychologist, and a dietician</p> <p>5) Con received no routine advice</p>	1 year	<p>1) Metabolic control:</p> <p>- HbA1c % means:</p> <p>Intended to treat:</p> <p>clin: 7.6 base</p> <p>7.59 12 mo</p> <p>dex: 6.59 base</p> <p>7.1 12 mo</p> <p>home: 6.52 base</p> <p>6.86 12 mo</p> <p>beh: 6.04 base</p> <p>5.72 12 mo</p> <p>Completers:</p> <p>clin: 7.6 base</p> <p>7.46 12 mo</p> <p>dex: 6.79 base</p> <p>7.07 12 mo</p> <p>home: 6.56 base</p> <p>6.96 12 mo</p> <p>beh: 5.9 base</p> <p>5.69 12 mo</p> <p>* ANOVA indicated that the groups were not significantly different from each other nor were they significantly different from control. Difference between intention to treat and completers not given.</p> <p>2) Measures of risk:</p> <p>- Weight (kg) means:</p> <p>Intended to treat:</p> <p>Not given</p> <p>Completers:</p> <p>clin: 85.8 base</p> <p>83.8 12 mo</p> <p>dex: 88.9 base</p> <p>85.85 12 mo</p> <p>home: 92.4 base</p> <p>91.4 12 mo</p> <p>beh: 89.5 base</p> <p>86.4 12 mo</p>	<p>QUALITY ASSESSMENT:</p> <p>INTERNAL VALIDITY:</p> <p>Described as randomized? Yes</p> <p>Method of randomization clearly described? No</p> <p>Concealment of allocation? Yes</p> <p>Described as double-blind? No</p> <p>Patient blinded? No</p> <p>Investigators blinded? No</p> <p>Outcome assessors blinded? No</p> <p>No. of withdrawals in each group stated? Yes</p> <p>EXTERNAL VALIDITY:</p> <p>Pop. Described? Yes</p> <p>Intervention described well enough to reproduce? No</p> <p>Intervention codified in manual? No</p> <p>Provider training described? No</p> <p>Patients assessed for DSM dx? No</p> <p>Biases, etc:</p> <p>Patient baseline characteristics not clearly stated; Control group statistics not displayed with intervention groups for any time assessments</p>

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 690	Manning, Jung, Leese, &Newton 1995		Baseline HbA1c means: Intended to treat: clin: 7.6 dex: 6.59 home: 6.52 beh: 6.04 *con not given Completers: clin: 7.6 dex: 6.79 home: 6.56 beh: 5.9 *con not given			* ANOVA indicated that the groups were not significantly different from each other, but all were significantly different from control at 12 mo (p<0.01) 3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 410 Manning, Jung, Leese, & Newton 1998	Include: Type I or II diabetes; age 16-70; BMI 28-45 Exclude: weight loss of ≥3 kg in previous year	RCT with 5 groups: 1) individual diet consultation in clinic (clin) 2) individual diet consultation with dexfenfluramine (dex) 3) individual diet consultation in clinic and home (home) 4) behavioral group therapy (beh) 5) control (con)	N= 205 n clin= 37 n dex= 37 n home= 35 n beh= 38 n con= 58 * 44 patients did not complete study- clin: 12; dex: 7; home: 6; beh: 16; Age means: Intended to treat: clin: 56.4 dex: 54.5 home: 55 beh: 58.2 con: 53.3 Completers: clin: 57.6 dex: 54.9 home: 53.4 beh: 58.0 con: not given Age range: 16-70 % Female: Intended to treat: clin: 59.4 dex: 65.8 home: 79.3 beh: 47.2 con: 38.9 Completers: clin: 55.0 dex: 64.3 home: 34.8 beh: 45.0 con: not given	1) Clin patients received individual diet consultations in clinic at 6-weekly intervals for first 6 months, then 2-monthly for remainder of the year; dietary advice based on 1992 dietary recommendations 2) Dex patients received the same dietary advice as clin, but were additionally given dexfenfluramine twice a day for first 3 mo. 3) Home patients received the same dietary advice as clin, but were seen in both the clinic and at home. 4) Beh therapy involved a physiotherapist, a clinical psychologist, and a dietician 5) Con received no routine advice	Treatment for 1 year with post at 1 year and f/u at 4 years	1) Metabolic control: - HbA1c % means: Intended to treat: clin: 7.7 base 7.99 4 years dex: 6.28 base 7.55 4 years home: 6.72 base 7.89 4 years beh: 5.97 base 6.79 4 years con: 7.02 base 7.74 4 years * Reported no significant reduction in HbA1c for any group. Statistical test not given. Completers: clin: 7.77 base 8.01 4 years dex: 6.43 base 7.67 4 years home: 6.68 base 7.72 4 years beh: 6.02 base 6.92 4 years con: not given 2) Measures of risk: - Weight (kg) Change means: Intended to treat: clin: -0.99 at 1 year 0.24 at 4 years dex: -2.51 at 1 year -2.6 at 4 years home: -1.59 at 1 year -1.0 at 4 years beh: -1.76 at 1 year -0.76 at 4 years con: 1.0 at 1 year 0.35 at 4 years	QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? Yes EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? No Provider training described? No Patients assessed for DSM dx? No Biases, etc: Large number of patients did not complete study, with different attrition numbers for groups

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 410 Manning, Jung, Leese, &Newton 1998			Race % not given Baseline HbA1c % means: Intended to treat: clin: 7.77 dex: 6.28 home: 6.72 beh: 5.97 con: 7.02 Completers: clin: 7.77 dex: 6.43 home: 6.68 beh: 6.02 con: not given			* Reported dex group significantly reduced weight compared to control (p<.05). Statistical test not given Completers: clin: -1.88 at 1 year -0.48 at 4 years dex: -3.01 at 1 year -2.46 at 4 years home: -1.71 at 1 year -1.92 at 4 years beh: -2.76 at 1 year -0.95 at 4 years con: not given *Reported no significant differences between groups at 4 years. Statistical test not given. 3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Intended to treat: Deceased: clin: 4 dex: 1 home: 4 beh: 0 con: 3 Completers: Deceased: clin: 3 dex: 1 home: 4 beh: 0 con: not given	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 3180 Maxwell, Hunt, Bush, 1992	Include: Type I or II diabetes	RCT with 2 treatment conditions: 1) Control group 2) Experimental: a) 1-3 Support Group Meetings-SGM b) 4-8 Support Group Meetings-SGM	N = 204 n con = 93 n exp = 111 *70 subjects were lost by 7-month follow up due to attrition- con: 29; 0-3 SGM: 38; 4-8 SGM: 3 Age range 20-81 % Female: con = 55 exp = 57 Race %: con: 74- Caucasian 17- African Amer. 4- Hispanic exp: 70- Caucasian 22- African Amer. 5- Hispanic Baseline HbA1 % means (SD): Intended to treat: con = 11.3 (2.8) exp = 1-3 SGM = 11.2(2.6) 4-8 SGM = 11.3(3.2) *SGM—support group meeting	1) Control group received 5-day training program only—consisted of small groups (5-12 patients) emphasizing patient self-management, monitoring of blood glucose, and adjusting insulin dosage. Blood samples were taken and patients were tested on their knowledge of diabetes, and given a questionnaire about demographics, diabetes management behaviors, emotion adjustment, health locus of control, and perceived need for support. Patients were randomized on the 5 th day of the training program. 2) Experimental group—were asked to attend 8 support group	5-day training session for all subjects. Experimental group had 8 weeks of support group sessions. 7-month follow-up.	COMPLETER RESULTS: 1) Metabolic control a) HbA1% means (SD): con: 11.3 (2.8) base 9.1 (2.3) 7 mo 1-3 SGM: 11.2 (2.6) base 8.2 (1.9) 7 mo 4-8 SGM: 11.3 (3.2) base 9.4 (2.4) 7 mo *ANOVA indicated no significant between-group differences. b) Fasting Serum Glucose- means (SD): con: 10.4 (3.8) base 8.6 (3.1) 7 mo 1-3 SGM: 10.5 (3.9) base 8.4 (2.4) 7 mo 4-8 SGM: 10.4 (3.8) base 10.0 (3.1) 7 mo *ANOVA indicated no significant between-group differences. 2) Measures of risk: a) Total Cholesterol means (SD): con: 213 (56) base 213 (58) 7 mo 1-3 SGM: 206 (41) base 212 (42) 7 mo 4-8 SGM: 210 (43) base 200 (40) 7 mo *ANOVA indicated no significant between-group differences.	QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? No EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? No Provider training described? No Patients assessed for DSM dx? No Biases, etc: Large number of subjects did not complete study

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 3180 Maxwell, Hunt, Bush, 1992				meetings. After the 5 day training and education session.		<p>b) HDL-Cholesterol means (SD): con: 49 (17) base 49 (15) 7 mo 1-3 SGM: 47 (18) base 46 (14) 7 mo 4-8 SGM: 41 (9) base 41 (11) 7 mo *ANOVA indicated no significant between-group differences.</p> <p>3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given</p> <p>4) Psychological Measures: a) Emotional Adjustment- ATT39 Revised †. con: 2.9 (0.3) base 3.1 (0.4) 7 mo 1-3 SGM: 2.9 (0.4) base 3.0 (0.3) 7 mo 4-8 SGM: 2.9 (0.3) base 3.0 (0.4) 7 mo *ANOVA indicated no significant between-group differences.</p> <p>† Higher scores on the ATT39 indicated better emotional adjustment to diabetes.</p>	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 170 Mayer-Davis, D'Antonio, Martin et al 2001	<p>Include: Type II Diabetes, ≥ 50 years old, BMI ≥ 25</p> <p>Exclude: those with significant comorbidities that would prevent safe or appropriate weight loss</p>	<p>RCT-single center with 2 groups:</p> <p>1) intensive lifestyle intervention (con)</p> <p>2) intensive lifestyle intervention plus formal evaluation (tx)</p>	<p>N= 33</p> <p>* 5 patients did not complete study and 2 others were not computed in the data analysis</p> <p>Age mean (SD): 64.03 (11.06)</p> <p>82.1% Female</p> <p>Race %: 96- African Amer. 4- Amer. Indian</p> <p>Baseline Fasting Blood Glucose-FBG (mg/dl) mean (SD): Completers: 158.41 (60.38)</p>	<p>Both con and tx received 8-week intensive lifestyle management intervention—low calorie and low-fat diet, moderate physical activity, self-monitoring of eating and physical activity, therapist monitoring and support and problem solving. Tx group received formal continuous quality improvement evaluations to address adherence, and generate appropriate solutions.</p>	8 weeks—2 individual and 6 group sessions	<p>COMPLETER RESULTS</p> <p>1) Metabolic control: - FBG (mg/dl) means (SD): 158.41 (60.38) base 132.35 (36.2) post *Significant difference in FBG ($p < 0.03$)- test not given</p> <p>2) Measures of risk: - Weight * Weight loss did not differ between groups. Statistical test not given.</p> <p>3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given</p>	<p>QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No</p> <p>Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? Yes</p> <p>EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? Yes Provider training described? No Patients assessed for DSM dx? No</p> <p>Biases, etc: Results not analyzed by group</p>

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 6920 Mazzuca, Moorman, Wheeler et al. 1986	<p>Include: diabetes diagnosis based on 2 FBS > 130 mg/dl or 1 FBS > 150 mg/dl or 2-hr post-prandial BS > 250 mg/dl; ability to perform ≥ 2 self-care tasks</p> <p>Exclude: psychiatric comorbidity; terminal illness</p>	<p>RCT-single center with 4 groups:</p> <p>1) control (con) 2) patient education (pat) 3) physician education (phy) 4) patient & physician education (patphy)</p> <p>* groups 1 and 3 were considered control & groups 2 and 4 were considered treatment</p>	<p>N= 532 n con=135 n pat= 125 n phy= 134 n patphy=138 * 257 patients did not complete study-withdrawals-by-group not given</p> <p>Age Median: 58.1 Intended to treat: 79 % Female: 79 Race %: 72- African Amer. Baseline HbA1 mean (SD): 10.7 (3.1) Intended to treat:</p>	<p>Education treatment intervention consisted of three parts: 1) didactic instruction using lecture, discussion, demonstration and feedback 2) goal setting exercises where patients set compliance goals and signed contracts with instructors 3) reinforcement schedule where patients were contacted by phone 2 and 6 weeks after instruction</p>	4 years	<p>COMPLETER RESULTS: 1) Metabolic control a) HbA1 means: con: 10.19 base 10.74 post pat: 10.17 base 10.23 post phy: 10.51 base 10.65 post patphy: 11.34 base 10.42 post *ANOVA indicated pat and patphy significantly different from other groups (p<0.05) b) Fasting Blood Glucose (FBG) (mg/dl) means: con: 201.1 base 208.7 post pat: 213.8 base 197.7 post phy: 209.6 base 196.5 post patphy: 229.2 base 190.2 post *t-test (con + phy vs. pat Vs patphy) indicated significant differences on FBG (p<0.05) 2) Measures of risk: a) Weight (kg) means: con: 84.04 base 84.54 post pat: 84.63 base 83.02 post phy: 85.65 base 84.08 post patphy: 87.89 base 85.77 post *ANCOVA indicated no significant effect of group on weight loss.</p>	<p>QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? Yes Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? No EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? No Provider training described? No Patients assessed for DSM dx? No Biases, etc: Large number of withdrawals from study: death: 30; physical/psychological incapacitation: 43; physician transfer: 32; relocation: 13; work conflict: 24; personal reasons: 45; failure to keep appointments: 11; lost contact by phone and mail: 58</p>

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 6920						<p>b) Systolic blood pressure-SBP means: con: 137.2 base 144.9 post pat: 139.9 base 138.9 post phy: 142.5 base 146.4 post patphy: 140.4 base 145.0 post</p> <p>*ANCOVA indicated no significant effect of group on SBP.</p> <p>c) Diastolic blood pressure-DBP means: con: 81.4 base 85.2 post pat: 84.7 base 82.4 post phy: 83.1 base 83.4 post patphy: 81.8 base 81.3 post</p> <p>*ANCOVA indicated no significant effect of group on DBP.</p> <p>3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given</p>	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 2970 McGrady, Bailey & Good 1991	Include: type I diabetes for at least a year, at least 21, written permission from physician. Exclude: pregnant women	RCT-single center with 2 groups: 1) control (con) 2) biofeedback-assisted relaxation (tx)	N= 19 n con= 8 n tx= 10 * 1 patient in the control group did not complete study Age mean (SD): 42 (9.5) age range: 26-55 72% Female Race %: 100- Caucasian Baseline Blood Glucose (mM) means (SD): Completers: con: 9.62 (1.13) tx: 9.14 (2.69)	Con group was counseled in the management of glycemic problems. TX group sessions consisted of biofeedback-assisted relaxation along with taped instructions for autogenic training and progressive relaxation.	10 weekly sessions (20-30 minutes)	COMPLETER RESULTS: 1) Metabolic control: - Blood Glucose (mM) means (SD): con: 9.62 (1.13) pre 9.67 (1.2) post tx: 9.14 (2.69) pre 7.19 (1.25) post *ANOVA indicated post test values were significantly different between groups (p=0.0009) 2) Measures of risk: Not given 3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given	QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? Yes EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? No Provider training described? No Patients assessed for DSM dx? No Biases, etc: Small sample; no additional measures of risk assessed; results not displayed clearly; control subjects later received tx and showed significant statistical improvements

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 350 McGrady & Horner 1999	Include: IDDM > 1 year duration; Exclude: severe diabetic complications; severe psychiatric disorders; other chronic non-diabetes-related illnesses	RCT- single-center design with 2 groups: 1) control 2) biofeedback	N=25 n control=9 n biofeedback=9 *7 dropped before randomization Age mean: 41 Age range=21-64 % Female: 44 Completer Race %: 88.9- Caucasian 11.1-African Amer. Baseline GHb mean: 7.1 range=4.5-9.2	Both control and treatment groups monitored blood glucose and reviewed logs biweekly with nurse. Biofeedback group participated in twelve 45-minute sessions of biofeedback assisted relaxation. Focused on autogenic phrases and diaphragmatic breathing.	8-15 weeks for twelve-session completion. Follow up at 1 mo and 3 mo.	COMPLETER RESULTS: 1) Metabolic control: a) GHb means (SD): control: 6.9 (1.5) base 6.9 (1.5) post 7.1 (2) 1 mo biofeedback: 7.3 (1.2) base 7.2 (0.7) post 6.9 (1.1) 1 mo 7.3 (1.1) 3 mo * ANOVA indicated no significant effect of group on GHb at post, 1 mo, 3 mo. 2) Measures of risk: Not given 3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given 4) Psychological Measures a) State Anxiety (State Trait Anxiety Inventory-STAI†) means (SD): control: 35.0 (10.6) base 37.2 (11.0) 1 mo biofeedback: 36.0 (15.0) base 31.6 (7.1) 1 mo *ANOVA indicated no significant effect of group on 1 mo State Anxiety	QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized: Yes Method of randomization clearly described? No Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. withdrawals stated? Yes EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? Yes Provider training described? No Patients assessed for DSM dx? No Biases, etc: Participants received treatment for varied lengths of time; investigators note small sample size; drop-outs all women, younger, and had poorer glucose control

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 2370 Oh, Kim, Yon & Choi 2003	<p>Include: diabetes; ability to perform self-care tasks</p> <p>Exclude: HbA1c<7%; psychiatric comorbidity; severe medical illness</p>	RCT with 2 groups: 1) routine care (con) 2) telephone-delivered intervention group (tx)	<p>N= 50 n con=18 n tx= 20 * 12 patients did not complete study- con: 7 ; tx: 5</p> <p>Age means (SD): con: 62 (5.7) tx: 59.2 (7.2)</p> <p>%Female Intended to treat: 64</p> <p>Race % not given</p> <p>Baseline HbA1c means (SD): Intended to treat: con: 8.3(0.9) tx: 8.8(1.1)</p>	Intervention group received telephone within 12-week sessions consisting of continuous education and reinforcement of diet, exercise, and medication adjustment, as well as frequent self-monitoring of blood glucose levels.	16 sessions	<p>COMPLETER RESULTS:</p> <p>1) Metabolic control: a) HbA1c means (SD) con: 8.4 (1) base 9.0 (1.2) post tx: 8.9 (1.2) base 7.7 (1) post *t-tests indicated significantly greater decreases in HbA1c in the tx group than con (p=0.000).</p> <p>b) Fasting blood glucose- FBG (mg/dl) means (SD): con: 180.2 (62.4) base 173.3 (53.4) post tx: 176.6 (56) base 160.9 (56.8) post *t-tests indicated no significant difference between groups at post</p> <p>c) 2-hour postprandial blood glucose- PP2h (mg/dl) means (SD) con: 278 (71.7) base 297.6 (89.1) post tx: 302.8 (94) base 260.2 (76.6) post *t-test indicate no significant differences between groups at post</p> <p>2) Measures of risk: - BMI means (SD): con: 24.5 (2.6) base 24.7 (2.6) post tx: 24.6 (2.8) base 24.9 (2.8) post *t-tests indicated no significant differences between groups at post</p> <p>3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given</p>	<p>QUALITY ASSESSMENT:</p> <p>INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? Yes Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? Yes</p> <p>EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? No Intervention codified in manual? No Provider training described? No Patients assessed for DSM dx? No</p> <p>Biases, etc: Treatment not described in detail; large number of patients (n=12) dropped out before post: 2 moved, 10 withdrew</p>

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 2910 Perry, Mann, Lewis-Barned, Duncan, Waldron & Thompson, 1997.	Include: IDDM > 1 year duration; age 20-69 years old Exclude: severe comorbid illness or disability	RCT with 2 treatment conditions: 1) intensive (Group 1) 2) standard (Group 2) -Participants switched conditions for the second six months of the study	N = 61 n Grp1 = 31 n Grp2 = 30 * no withdrawals Age means (SD): Completers: Grp 1: 41.5(11.6) Grp 2: 42.8(12.6) % Female: Completers: Grp 1: 51.6 Grp 2: 33.3 Race % not given Baseline HbA1 % means (SD): Completers: Grp 1: 9.3 (2.8) Grp 2: 9.5 (1.6)	1) Intensive— participants met with research team monthly to achieve dietary goals balanced with insulin regimens, and to increase physical activity— translated into individualized dietary and exercise prescriptions. Participants were provided with a resource booklet and were asked to record food, exercise and lab results. Physical fitness appraisal and training program was administered to those participants deemed eligible 2) Standard care—consisted of usual diabetes care from GP or Diabetes clinic once every 3 months.	6 months. A second six month pd. occurred as group 2 was administered the intensive education program that group one received in the first six months; and group 1 received the standard program.	COMPLETER RESULTS: 1) Metabolic control a) HbA1 % means (SD): Grp1: 8.9 (2.6) base 8.6 (2.1) 6 mo 8.4 (1.8) 12 mo Grp2: 8.7 (2.0) base 8.8 (2.3) 6 mo 7.9 (1.5) 12 mo *RM-ANOVA indicates significant difference between groups in change in HbA1c from 6 to 12 mo (p=0.017) 2) Measures of risk: a) Weight-kg means (SD): Grp1: 75.4 (11.2) base 75.7 (10.9) 6 mo 75.8 (11.1) 12 mo Grp2: 73.5 (9.6) base 74.1 (9.3) 6 mo 73.6 (9.2) 12 mo *RM-ANOVA indicates no significant decrease in weight over 12 mo. for either group b) Total Cholesterol means (SD): Grp1: 4.9 (1.0) base 5.0 (1.1) 6 mo 5.1 (1.1) 12 mo Grp2: 5.5 (1.1) base 5.6 (1.1) 6 mo 5.3 (1.0) 12 mo *RM-ANOVA indicates significant difference between groups (p=0.048)	QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? Yes EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? No Provider training described? No Patients assessed for DSM dx? No Biases, etc: Overall, Grp2 showed significant change on many outcomes after switched to treatment.

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 2910						<p>c) HDL-Cholesterol means (SD):</p> <p>Grp1: 1.2 (0.2) base 1.3 (0.3) 6 mo 1.3 (0.3) 12 mo</p> <p>Grp2: 1.3 (0.3) base 1.3 (0.4) 6 mo 1.3 (0.3) 12 mo</p> <p>*RM-ANOVA indicates no significant between group differences.</p> <p>d) LDL-Cholesterol means (SD):</p> <p>Grp1: 3.1 (0.9) base 3.1 (0.9) 6 mo 3.1 (0.9) 12 mo</p> <p>Grp2: 3.5 (0.9) base 3.7 (1.0) 6 mo 3.4 (0.9) 12 mo</p> <p>*RM-ANOVA indicated significant difference between groups at 6 mo (p=0.022)</p> <p>e) Systolic blood pressure-SBP means (SD):</p> <p>Grp1: 127 (21) base 128 (17) 6 mo 127 (18) 12 mo</p> <p>Grp2: 131 (18) base 134 (17) 6 mo 129 (15) 12 mo</p> <p>*RM-ANOVA indicates significant decrease in SBP in Grp2 from 6 to 12 mo (p=0.002)</p>	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 1090 Rabkin, Boyko, Wilson, Streja 1983	<p>Include: NIDDM, younger than 65, not receiving insulin, fasting serum glucose levels over 135 mg/dl, and physician assessment of diabetes being "stable"</p> <p>Exclude: not stated</p>	<p>RCT with 2 treatment conditions:</p> <p>1) Individualized dietary review and recommendation program (ind)</p> <p>2) Behavioral Program (beh)</p>	<p>N = 40 n.beh = 20 n ind = 20</p> <p>*2 subjects excluded due to illness, and disinterest (both in ind)</p> <p>Age means (SD): beh = 52.7(1.7) ind = 55.0(2.2)</p> <p>% Female: Beh = 65% Ind = 50%</p> <p>Race % not given</p> <p>Baseline Fasting Serum Glucose (mg/dl) means (SD): Intention to treat: ind = 221(12) beh = 221(16)</p>	<p>1) Individual—One 6 weeks - hour-long session reviewing patients and 12 weeks eating habits and discussion of diabetes and its complications. Taught meal planning and given a tailored meal plan. Counseled on the necessity of losing weight. Follow up 6 and 12 weeks later.</p> <p>2) Behavioral—6 1.5 hour weekly group meetings aimed at behavioral strategies for controlling the signals leading to overeating and noncompliance with a dietary regimen. Intensive discussion, stressing calorie counting, calorie restriction, management of one's thoughts and influences from the environment that lead to overeating, coping</p>	<p>Follow-up at 6 weeks and 12 weeks</p>	<p>COMPLETER RESULTS:</p> <p>1) Metabolic control</p> <p>a) Fasting Serum Glucose (mg/dl) Change means (SD):</p> <p>ind: -18 (9) base-6 weeks -26 (10) base-12 weeks beh: : -22 (10) base-6 weeks -15 (10) base-12 weeks</p> <p>*t-tests indicated no significant differences in fasting serum glucose between groups, but there were significant reductions within group for beh at 6-weeks.</p> <p>2) Measures of risk:</p> <p>a) Weight (kg) Change means (SD):</p> <p>ind: -1.7 (0.05) base-6 weeks -3.0 (0.5) base-12 weeks beh: : -0.4 (0.6) base-6 weeks -0.9 (0.4) base-12 weeks</p> <p>*t-tests indicated a significant difference in weight change, with ind group losing significantly more than beh group at 12 weeks (p<0.01)</p> <p>b) LDL-Cholesterol Change means Estimated from Graph:</p> <p>ind: 5.0 base-6 weeks 2.0 base-12 weeks beh: : 5.0 base-6 weeks 1.0 base-12 weeks</p> <p>*t-tests indicated no significant differences between groups in LDL-C.</p> <p>c) HDL-Cholesterol Change means Estimated from Graph:</p> <p>ind: -3.0 base-6 weeks 1.0 base-12 weeks beh: : -5.0 base-6 weeks -5.0 base-12 weeks</p>	<p>QUALITY ASSESSMENT:</p> <p>INTERNAL VALIDITY:</p> <p>Described as randomized? Yes</p> <p>Method of randomization clearly described? No</p> <p>Concealment of allocation? No</p> <p>Described as double-blind? No</p> <p>Patient blinded? No</p> <p>Investigators blinded? No</p> <p>Outcome assessors blinded? No</p> <p>No. of withdrawals in each group stated? Yes</p> <p>EXTERNAL VALIDITY:</p> <p>Pop. Described? Yes</p> <p>Intervention described well enough to reproduce? Yes</p> <p>Intervention codified in manual? Yes</p> <p>Provider training described? Yes</p> <p>Patients assessed for DSM dx? No</p> <p>Biases, etc: means (SD) not reported for all measures;</p>

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 1090	Rabkin, Boyko, Wilson, Streja 1983			with emotions, and encouraging self-observation with daily eating records.		*t-tests indicated no significant differences between groups in HDL-C. 3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 3820 Rickheim, Weaver, Flader, Kendall 2002	<p>Include: Type II diabetes; either newly diagnosed with diabetes or no history of prior systematic diabetes education; age 30-80</p> <p>Exclude: Mental disability</p>	RCT with 2 treatment conditions: 1) Group education setting (grp) 2) Individual education (ind)	<p>N = 170 n grp= 87 n ind = 83 *78 patients did not complete 6 month follow-up- grp: 44; ind: 34</p> <p>Age means (SD): grp = 51.6 (9.2) ind = 52.9 (12.8)</p> <p>% Female: grp = 64.4 ind = 67.5</p> <p>Race % not given</p> <p>Baseline HbA1c means (SD): Intended to treat: grp = 8.9 (1.9) ind = 8.0 (1.7) Completers: grp: 9.0 (1.6) ind: 8.2 (1.7)</p>	<p>Both group and individual educational sessions received same curriculum with ind group receiving individual sessions, while grp group had groups sessions occurred four separate times for a total of about 5-7 hrs of education. Topics discussed were: carb counting, portion control, meal spacing, self-monitoring for blood glucose, physical activity, heart-healthy eating, foot care, sick day management, complications, problem solving, and progression of type II diabetes. Patients kept food and bg records.</p>	<p>Four sessions (5-7 hrs) 3 and 6 month follow-up</p>	<p>5-COMPLETER RESULTS: 1) Metabolic control: - HbA1c means (SD): grp: 9.0 (1.6) base 6.5 (0.7) 6 mo ind: 8.2 (1.7) base 6.5 (0.9) 6 mo *t-tests indicated both groups significantly decreased HbA1c (p<0.01 for both), with grp showing greater improvement than ind, but groups were not significantly different from each other at 6 mo.</p> <p>2) Measures of risk: a) BMI means (SD): grp: 34.1 (5.9) base 33.3 (6.1) 6 mo ind: 33.6 (7.1) base 32.1 (7.0) 6 mo *t-tests indicated ind group significantly decreased BMI (p<0.01), but the groups were not significantly different from each other at 6 mo.</p> <p>3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given</p>	<p>QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? Yes Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? Yes</p> <p>EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? Yes Provider training described? Yes Patients assessed for DSM dx? No</p> <p>Biases, etc: Not many measures of risk assessed; Large number of drop-outs (41%) with differential attrition between groups</p>

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 310 Ridgeway, Harvill, Harvill et al. 1999	<p>Include: Type II diabetes ; $\geq 20\%$ ideal weight; inadequately controlled diabetes</p> <p>Exclude: history of diabetic ketoacidosis; age of diabetes onset >40 years</p>	RCT-single center with 2 groups:	<p>N= 56 n con=20 n tx= 18 * 18 patients withdrew from study: con: 8; tx: 10</p> <p>Age means: con: 65 tx: 62</p> <p>%Female: con: 67 tx: 75</p> <p>Race % not given</p> <p>Baseline GHb % means (SD): con: 12.3 (3) tx: 12.3 (2.2)</p>	<p>Tx group received both education and behavior modification components: education: designed to help patients understand diabetes, its treatments and its consequences behavior modification: patients given individualized diet and exercise instructions, contracts to emphasize personal responsibility, and feedback and social reinforcement was given. Control group completed assessments but received no behavior modification</p>	Sessions held 1.5 hours a month for six months. F/u at 12 mo.	<p>COMPLETER RESULTS:</p> <p>1) Metabolic control a) GHb % means: con: 12.26 base 11.18 6 mo 11.64 12 mo tx: 12.28 base 10.21 6 mo 11.52 12 mo</p> <p>*t-tests indicated no significant differences between groups at 6 mo ($p=0.17$) and 12 mo ($p=0.87$).</p> <p>b) Fasting Blood Glucose-FBG means: con: 210 base 195 6 mo 185 12 mo tx: 215 base 180 6 mo 205 12 mo</p> <p>*t-tests indicated no significant differences between groups at 6 mo ($p=0.32$) and 12 mo ($p=0.51$).</p> <p>2) Measures of risk: a) Weight (lbs) means: con: 189 base 185 6 mo 186 12 mo tx: 194 base 190 6 mo 186 12 mo</p> <p>*t-tests indicated no significant differences between groups at 6 mo ($p=0.94$) and 12 mo ($p=0.20$).</p>	<p>QUALITY ASSESSMENT:</p> <p>INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No</p> <p>Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? Yes</p> <p>EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? Yes Provider training described? Yes Patients assessed for DSM dx? No</p> <p>Biases, etc: Results not presented clearly Small sample with high number of withdrawals (n=18)</p>

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 310						<p>b) Total Cholesterol means: con: 224 base 233 6 mo 234 12 mo tx: 259 base 221 6 mo 219 12 mo *t-tests indicated a significant differences between groups at 6 mo (p=0.167) but not at 12 mo (p=0.09).</p> <p>c) HDL-Cholesterol means: con: 40 base 37 6 mo 37 12 mo tx: 40 base 39 6 mo 36 12 mo *t-tests indicated no significant differences between groups at 6 mo (p=0.26) and 12 mo (p=0.64).</p> <p>d) LDL-Cholesterol means: con: 119 base 116 6 mo 125 12 mo tx: 133 base 113 6 mo* 130 12 mo *t-tests indicated no significant differences between groups at 6 mo (p=0.08) and 12 mo (p=0.17).</p>	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 3200 Rost, Flavin, Cole & McGill, 1991.	Include: adults with type I or II diabetes; GHb >8% Exclude: acute psychiatric illness; life-threatening medical illness; on insulin pump; non-literate	RCT with 2 treatment conditions: 1) control group 2) experimental group	N = 61 n con = 31 n exp = 30 *11 patients did not complete follow up; numbers by group not given Age mean (SD): Intended to treat: n con = 40.6(13.6) n exp = 40.0(16.2) % Female: Intended to treat: con = 63.3 exp = 56.7 Race % not given Baseline GHb % means (SD): Intended to treat: con = 13.6 (3.6) exp = 13.1 (3.4)	1) control patients received comprehensive 3-day evaluation and educational program 2) experimental intervention involved a 45-min patient activation intervention including the discussion of information seeking and decision making, and introduction a decision tree, taking active roles, past difficulties in communication with physicians, common obstacles/strategies to overcome them, and writing down questions the patient wants to ask the physician. A 1-hr self-administered booster was completed by those in the experimental group in addition to the program	Control—3 day eval. Experimental—45 min session and 1-hr take home instructional package 4 month post-discharge follow-up.	COMPLETER RESULTS: 1) Metabolic control: -GHb % means (SD): con: 13.5 (3.6 base 12.4 (3.3) f/u exp: 13.0 (3.5) base 11.8 (3.0) f/u *ANCOVA indicated the groups were not significantly different at f/u. 2) Measures of risk: Not given 3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given	QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? Yes Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? No EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? Yes Provider training described? No Patients assessed for DSM dx? No Biases, etc: No measures of weight, cholesterol, or blood pressure assessed

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 3200	Rost, Flavin, Cole & McGill, 1991.			consisting of tips on question asking, question construction, question introduction and clarification, with a simulated medical visit and a role play exercise.			

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 4880 Sadur, Moline, Costa, et al., 1999.	<p>Include: Type I or II diabetes; 16-75 years old; recent HbA1c>8.5%; no HbA1c evaluation in last year</p> <p>Exclude: Current pregnancy; current dementia; inability to speak English</p>	RCT with 2 treatment conditions: 1) Diabetes Cooperative Care Clinic Intervention (int) 2) Control (con)	<p>N = 185 n int = 97 n con = 88 *29 drop-outs: con: 14; tx: 15</p> <p>Age means (SD): int = 55.7(9.1) con = 56.4(9.1)</p> <p>% Female: int = 41.2 con = 44.3</p> <p>Race %: Intended to Treat: con: 79.0- Caucasian 8.1- Asian Amer. 4.8- Hispanic 4.8- African Amer.</p> <p>int: 71.2- Caucasian 6.3- Asian Amer. 15.0- Hispanic 5.0- African Amer.</p> <p>Baseline HbA1c % means (SD): Intended to treat: int = 9.7(1.8) con = 9.6(1.5) Completers: int: 9.48 con: 9.55</p>	<p>1) 2-hr monthly visit for 6 month— education let by a dietitian, a behaviorist and a pharmacist and two nurse educators and two diabetologists and services were administered in cluster visits.</p> <p>2) control group continued to receive all diabetes care from their primary care physician throughout the 6-month study period</p>	6 month intervention	<p>COMPLETER RESULTS: 1) Metabolic control: - HbA1c % means: int: 9.48 base 8.18 post con: 9.55 base 9.33 post</p> <p>* ANOVA indicated a significant difference in HbA1c between groups at post (p<0.0001).</p> <p>2) Measures of risk: Not given</p> <p>3) Events: a) Health care utilization: i) Hospitalization Rates Estimated from Graph: int: 18 pre-randomization 16 post-randomization con: 17 pre-randomization 26 post-randomization</p> <p>* ANOVA indicated a significant difference in hospitalizations at post-randomization (p=0.04)</p> <p>ii) Nutritionist visited in last 2 years int: 50 base 85 post con: 40 base 39 post</p> <p>* ANOVA indicated a significant difference in number indicating having visited a nutritionist between groups at post (p<0.001).</p>	<p>QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? Yes Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? Yes</p> <p>EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? No Provider training described? No Patients assessed for DSM dx? No</p> <p>Biases, etc: No measures of risk assessed; first cohort so small all assigned to int (non-randomly)</p>

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 4880	Sadur, Moline, Costa, et al., 1999.					iii) Physician visits Estimated from Graph : int: 310 base 250 during 270 post con: 360 base 340 during 370 post *ANOVA indicated no significant differences between groups in physician visits. b) Morbidity/mortality: Not given	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 550 Smith, Heckemeyer, Kratt, & Mason, 1997	<p>Include: NIDDM; women; weight 120-200% ideal body weight; age>50 years old</p> <p>Exclude: insulin treatment; cardiovascular disease; inability to walk for exercise</p>	<p>RCT with 2 treatment conditions:</p> <p>1) Standard behavior weight control (standard)</p> <p>2) Behavioral weight control with motivational interviewing (motivational)</p>	<p>N = 22 n st = 10 n mot = 6 *5 were lost to attrition (2 schedule reasons) and 1 one omitted for beginning insulin treatment; group numbers not given</p> <p>Age mean (SD): Intended to treat: 62.4(7.0)</p> <p>% Female Intended to treat: 100</p> <p>Race % not given</p> <p>Baseline GHb % Intended to treat: mean (SD): 10.25(2.2)</p>	<p>1) Standard behavior weight control (standard) group behavioral weight-control program incorporating moderate calorie restriction, fat gram recommendations, physical activity, and home monitoring of blood glucose. Meetings provided nutritional information and training in behavior modification of eating and exercise. Participants recorded daily calorie consumption and physical activity in diaries. Fasting blood glucose was recorded 3 times a week. Diaries were collected at each meeting and then were returned to the participant with feedback.</p>	<p>16-week group program (1 session a week). 4-month post-treatment assessment</p>	<p>COMPLETER RESULTS:</p> <p>1) Metabolic control a) GHb % means (SD): st: 10.8 (3.1) post mot: 9.8 (1.3) post</p> <p>*ANCOVA indicated significant effect of group on GHb at post (p=0.05):</p> <p>2) Measures of risk: a) Weight (kg) Change means (SD): st: 4.5 (2.2) base-post mot: 5.5 (3.9) base-post</p> <p>*ANCOVA indicated no significant effect of group on weight loss.</p> <p>3) Events a) Health care utilization: Not given b) Morbidity/mortality: Not given</p>	<p>QUALITY ASSESSMENT:</p> <p>INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No</p> <p>Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No</p> <p>No. of withdrawals in each group stated? No</p> <p>EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? No Provider training described? Yes Patients assessed for DSM dx? No</p> <p>Biases, etc: Small sample with 23% attrition; non-completers tended to be younger with poorer glycemic control</p> <p>Positive feature: included an analysis of adherence; it was higher in the motivational group</p>

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 550	Smith, Heckemeyer, Kratt, & Mason, 1997			2) Same as standard with three individualized motivational interviewing session added (one at the beginning and two at mid-treatment). Interviews explored ambivalence about behavior change, elicited personal goals and self-motivational statements, formulated personal goals, and identified barriers to change. Therapist uses open-ended questions and reflective listening.			

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 130 Surwit, van Tilburg, Zucker et al. 2002	<p>Include: Type II diabetes; ≥30 years old; diabetes currently managed by diet, exercise, and/or oral medication</p> <p>Exclude: Prior training in relaxation or stress management; current use of psychoactive drugs; current psychiatric treatment; use of insulin; pregnancy or lactation</p>	RCT with 2 groups: 1) diabetes education (con) 2) stress management* (tx)	<p>N= 108 n con=34 n tx= 38 * 36 patients did not complete study: con :9; tx: 17</p> <p>Age means (SD): con: 58.33(11.33) tx: 56.53</p> <p>% Female: con: 43.8 tx: 40</p> <p>Race %: con: 87.5- Caucasian 10.4- African Amer. 2.1- Asian Amer. int: 85- Caucasian 15- African Amer.</p> <p>Baseline HbA1c % means (SD): con: 7.54 (1.34) tx: 8.14 (2.11)</p>	<p>Stress management intervention not included: 1) progressive muscle relaxation (consecutively tensing and relaxing a prescribed set of muscles) 2) instruction in the use of cognitive behavioral skills to recognize and reduce physiological stress levels 3) education on the health consequences of stress; Diabetes education focused on diabetes facts, complications, healthy eating, and generic information.</p>	Five 30-minute weekly sessions with f/u at 2, 4, 6 and 12 mo for tx group	<p>COMPLETER RESULTS: 1) Metabolic control: -HbA1c % means Estimated from Graph: con: 7.54 base 7.56 2 mo 7.5 4 mo 7.4 6 mo 7.68 12 mo tx: 8.14 base 7.52 2 mo 7.6 4 mo 7.48 6 mo 7.16 12 mo</p> <p>* Chi-squared indicated significant differences between con and tx at 12 mo (p=0.04)</p> <p>2) Measures of risk: Not given</p> <p>3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given</p> <p>4) Psychological Measures: a) Perceived Stress Scale- PSS * f/u scores not given, but said to not be significantly different between groups</p> <p>b) General Health Questionnaire- GHQ * f/u scores not given, but said to not be significantly different between groups c) State-Trait Anxiety Inventory-STAI * f/u scores not given, but said to not be significantly different between groups</p>	<p>QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No</p> <p>Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? Yes</p> <p>EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? No Provider training described? No Patients assessed for DSM dx? No</p> <p>BIASES, ETC: Large number of withdrawals from study (n=36) with differential drop-out between groups; f/u results not presented in table; results for some measures taken at baseline not reported for f/u</p>

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 2360 Trento, Passera, Bajardi, et al., 2002	Include: Type II diabetes; age <80 years; followed ≥ 1 year Exclude: insulin-treated	RCT with 2 treatment conditions: 1) group care (grp) 2) individual education* control (ind)	N = 112 n grp = 56 n ind = 56 *32 participants did not complete study- grp: 11; con: 21 Age mean: Intended to treat: grp = 62.0 ind = 61.0 % Female: Intended to treat: grp = 51.8 Ind = 39.3 Race % not given Baseline HbA1c % means (SD): Completers: grp = 7.4 (1.4) ind = 7.4 (1.4)	1) Group care— educational sessions held every 3 months discussion food choices, meal planning, physical exercise, metabolic control, smoke cessation, medication and complications 2) individual (control)—3-monthly visits in general diabetes clinic. Info on diabetes self-care and educational reinforcement were offered with special reference to eating habits home monitoring of blood glucose and preventing complications plus one-to-one educational reinforcement yearly	4 years	COMPLETER RESULTS: 1) Metabolic control a) HbA1c % means (SD): grp = 7.4 (1.4) base 7.0 (1.1) 4 yr ind = 7.4 (1.4) base 8.6 (2.1) 4 yr * Reported a significant difference in HbA1c at 4 yr. Statistical test and p value not given. b) Fasting Blood Glucose means (SD): grp = 9.8 (2.6) base 9.3 (2.6) 4 yr ind = 10.2 (3.2) base 11.0 (4.6) 4 yr * Reported no significant differences in fasting blood glucose between groups at 4 yr. Statistical test and p value not given. 2) Measures of risk: a) Weight (kg) means (SD): grp = 77.8 (13.6) base 75.2 (13.0) 4 yr ind = 77.8 (15) base 76.9 (16.1) 4 yr * Reported no significant differences in weight between groups at 4 yr. Statistical test and p value not given. b) Systolic blood pressure-SBP means (SD): grp = 160 (26) base 154 (21) 4 yr ind = 151 (19) base 149 (15) 4 yr * Reported no significant differences in SBP between groups at 4 yr. Statistical test and p value not given.	QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? Yes Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? Yes EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? No Provider training described? No Patients assessed for DSM dx? No Biases, etc: Statistical analyses not reported clearly

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 2360						<p>c) Diastolic blood pressure-DBP means (SD): grp = 95 (11) base 88 (7) 4 yr ind = 92 (10) base 86 (9) 4 yr</p> <p>* Reported no significant differences in DBP between groups at 4 yr. Statistical test and p value not given.</p> <p>d) Total Cholesterol means (SD): grp = 5.84 (1.11) base 5.77 (1.34) 4 yr ind = 5.46 (0.93) base 5.59 (1.29) 4 yr</p> <p>* Reported no significant differences in total cholesterol between groups at 4 yr. Statistical test and p value not given.</p> <p>e) HDL-Cholesterol means (SD): grp = 1.27 (0.31) base 1.42 (0.31) 4 yr ind = 1.32 (0.31) base 1.37 (0.28) 4 yr</p> <p>* Reported no significant differences in HDL-C between groups at 4 yr. Statistical test and p value not given.</p> <p>3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given</p>	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 6240 Vanninen, Uusitupa, Siitonen, Laitinen, & Lansimies, 1992.	<p>Include: Newly diagnosed type II diabetes patients; 40-64 years old; blood glucose >6.7 mmol/l</p> <p>Exclude: comorbid chronic diseases affecting glucose tolerance</p>	RCT with 2 treatment conditions: 1) Conventional treatment (con) 2) Intervention (int)	<p>N = 78 n con = 40 n int = 38 *4 participants did not complete study.</p> <p>Age means (SD): Men: 53 (7) Women: 54 (6)</p> <p>% Female: 42.3 con: 40 int = 44.7</p> <p>Race % not given</p> <p>Baseline HbA1c % means (SD): Intended to treat: con: men = 7.3 (1.7) women = 8.1 (2.4) int: men = 7.1 (1.5) women = 7.1 (1.5)</p>	<p>1) Intervention—physician gave printed and oral instructions for effective exercise training. Physical activity was regularly monitored by daily exercise records. Participants were encouraged to increase their physical activity level over the course of bi-monthly visits to the outpatient clinic for the 12 month treatment pd.</p> <p>2) basic information session attended by all subjects—two sessions (at baseline and 6 weeks) where participants received information concerning the benefits of diet and exercise.</p>	12 month with 6 bi-monthly visits	<p>COMPLETER RESULTS:</p> <p>1) Metabolic control: a) HbA1c means % (SD): con: men: 7.3 (1.7) base 7.4 (1.6) 12 mo women: 8.1 (2.4) base 7.2 (1.6) 12 mo int: men: 7.1 (1.5) base 7.0 (1.9) 12 mo women: 7.1 (1.5) base 6.2 (1.0) 12 mo</p> <p>*RM-ANOVA indicated a significant difference in HbA1c for women between groups at 12 mo (p<0.05).</p> <p>b) Fasting Blood Glucose (mmol/l) means (SD): con: men: 6.7 (2.2) base 7.3 (2.2) 12 mo women: 8.5 (3.5) base 7.2 (1.9) 12 mo int: men: 6.6 (2.1) base 6.7 (2.1) 12 mo women: 6.3 (1.2) base 5.7 (1.4) 12 mo</p> <p>*RM-ANOVA indicated a significant difference in fasting blood glucose for women between groups at 12 mo (p<0.05).</p>	<p>QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No</p> <p>Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? No</p> <p>EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? No Provider training described? No Patients assessed for DSM dx? No</p> <p>Biases, etc: Change by gender was a secondary analysis</p>

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 6240	Vanninen, Uusitupa, Siitonen, Laitinen, & Lansimies, 1992.					<p>2) Measures of risk:</p> <p>a) Body Mass Index-BMI means (SD):</p> <p>con: men: 30.1 (3.1) base 30.9 (3.3) 12 mo women: 34.2 (6.2) base 34.0 (5.9) 12 mo</p> <p>int: men: 31.1 (3.7) base 30.5 (3.6) 12 mo women: 33.4 (6.7) base 32.6 (6.5) 12 mo</p> <p>*RM-ANOVA indicated a significant difference in BMI for men over time for both con (p<0.01) and int (p<0.05).</p> <p>b) Serum Cholesterol means- mmol/l (SD):</p> <p>con: men: 6.1 (1.0) base 6.2 (1.0) 12 mo women: 6.5 (0.8) base 6.7 (0.7) 12 mo</p> <p>int: men: 6.3 (1.2) base 6.0 (1.0) 12 mo women: 6.0 (1.2) base 6.0 (1.0) 12 mo</p> <p>*RM-ANOVA indicated a significant difference in serum cholesterol for women across groups at 12 mo (p<0.05).</p>	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 6240						<p>c) HDL-Cholesterol means- mmol/l (SD):</p> <p>con: men: 1.1 (0.24) base 1.15 (0.27) 12 mo women: 1.25 (0.36) base 1.29 (0.29) 12 mo</p> <p>int: men: 1.0 (0.28) base 1.11 (0.28) 12 mo women: 1.13 (0.18) base 1.25 (0.22) 12 mo</p> <p>*RM-ANOVA indicated a significant difference in HDL-C for both men (p<0.05) and women (p<0.01) in int group over time.</p> <p>3) Events:</p> <p>a) Health care utilization: Not given</p> <p>b) Morbidity/mortality: Not given</p>	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 1030 White, Carnahan, Nugent et al. 1986	<p>Include: men with NIDDM; less than satisfactory control of glucose; infrequent hypoglycemic reactions; body weight >15% above mean value for height</p> <p>Exclude: history of alcohol abuse; history of severe personality disorder; current use of glucocorticoids</p>	RCT with 2 groups: 1) advice education (con) 2) group management (tx)	<p>N= 41 n con=16 n tx= 16 *9 participants did not complete study: con: 5; tx: 4</p> <p>Age means (SD): Intended to Treat: con: 60.7 (6.9) tx: 62.4 (6.1) Completers: con: 60.7 (6.4) tx: 62.4 (5.5)</p> <p>% Female: 0</p> <p>Race % not given</p> <p>Baseline GHb % means (SD): Intended to Treat: con: 11.5 (3.5) tx: 11.0 (2.6) Completers: con: 11.3 (3.5) tx: 10.4 (2.6)</p>	<p>The treatment group was divided into smaller groups in which they were encouraged to interact and assess each other's progress and to offer advice and support, using problem solving format.</p> <p>The advice-education group minimized patient interaction, with instructors lecturing on the disease and its management.</p>	10 sessions over 6 mo. period	<p>COMPLETER RESULTS</p> <p>1) Metabolic control: - GHb % means Estimated from graph: con: 11.3 base 9.7 post tx: 10.4 base 9.4 post</p> <p>No significant effect of group on percent overweight reduction. Statistical test, p value not given.</p> <p>2) Measures of risk: - % Overweight means Estimated from graph: con: 45 base 46 6 mo tx: 37 base 36 6 mo</p> <p>* No significant effect of group on percent overweight reduction. Statistical test, p value not given.</p> <p>3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given</p>	<p>QUALITY ASSESSMENT:</p> <p>INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No</p> <p>Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? Yes</p> <p>EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? No Provider training described? No Patients assessed for DSM dx? No</p> <p>Biases, etc: Results not reported in table-form; statistical analyses not reported clearly; small sample with large number of drop-outs (21%)</p>

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 8640 Williams, Mullen, Lang, Considine, and Wing, 1999.	<p>Include: type 2 diabetes diagnosed less than or equal to 8 years ago, were at least 120% of ideal body weight, were not receiving insulin</p> <p>Exclude: those with history of cardiovascular, renal or hepatic disease, those with a fasting plasma glucose (FPG) over 16.7 mmol/L</p>	<p>RCT with 3 groups:</p> <p>1) 1500-1800 kcal/day diet (control)</p> <p>2) VLCD for 5 consecutive days in weeks 2,7, 12, 17. (Treatment 1).</p> <p>3) VLCD for 5 consecutive days in week 2, then 1 day a week for weeks 3-17 (Treatment 2).</p>	<p>N= 54</p> <p>*7 subjects withdrew after 3 weeks and their data were analyzed separately</p> <p>Age mean (SD): 52.0 (7.9)</p> <p>57.4% Female</p> <p>Race: 79.6- Caucasian 18.5- African Amer. 1.9- Hispanic</p> <p>Baseline HbA1c % mean (SD): 8.1(1.7) *all participants combined</p>	<p>1) All participants attended weekly meetings focused on achieving dietary goals, recognizing, and overcoming behavioral impediments of weight loss. Subjects also received written feedback based on diary content.</p> <p>2) control group was assigned to a moderately caloric restricted diet of 1500 to 1800 kcal/day</p> <p>3) VLCD for 5 consecutive days in weeks 2, 7, 12, 17. For the other weeks the participant was assigned the moderate caloric restriction diet of 1500 to 1800 kcal/day.</p>	<p>Measures were obtained at baseline, week 3, 10 and 20.</p>	<p>COMPLETER RESULTS:</p> <p>1) Metabolic control: HbA1c % means and significance not reported by intervention group.</p> <p>2) Measures of risk: a) Weight-kg means and significance not reported by intervention group.</p> <p>3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given</p>	<p>QUALITY ASSESSMENT:</p> <p>INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No</p> <p>Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. withdrawals stated? Yes</p> <p>EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? Yes Provider training described? Yes Patients assessed for DSM dx? No</p> <p>Biases, etc: No results reported by intervention group, but by gender</p>

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 8640	Williams, Mullen, Lang, Considine, and Wing, 1999.			4) VLCD for 5 consecutive days in week 2 then for one day a week for weeks 3 through 17. In the remaining days the participant was assigned a moderate caloric restriction of 1500 to 1800 kcal/day			

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 430 Williams, Kelley, Mullen, & Wing, 1998.	<p>Include: Type II diabetes; age 30-70; >20% above ideal body weight based on established norms</p> <p>Exclude: history of liver, renal, or heart disease that would contradict the use of a very low calorie diet</p>	<p>RCT with 3 treatment conditions:</p> <p>1) Standard behavior therapy (sbt)</p> <p>2) 1-day very low-calorie diet- (1vlcd)</p> <p>3) 5-day very low-calorie diet- (5vlcd)</p>	<p>N = 54</p> <p>n sbt = 18</p> <p>n 1vlcd = 18</p> <p>n 5vlcd = 18</p> <p>*7 drop-outs</p> <p>Age means (SD):</p> <p>sbt = 54.1(7)</p> <p>1vlcd = 51.4 (7.9)</p> <p>5vlcd = 50.3 (8.6)</p> <p>% Female:</p> <p>sbt = 61.6</p> <p>1vlcd = 50</p> <p>5vlcd = 61.6</p> <p>Race %:</p> <p>sbt:</p> <p>88.9- Caucasian</p> <p>11.1- African Amer.</p> <p>1vlcd:</p> <p>83.3- Caucasian</p> <p>11.1- African Amer.</p> <p>5.6- Hispanic</p> <p>5vlcd:</p> <p>66.7- Caucasian</p> <p>33.3- African Amer.</p> <p>Baseline HbA1c % means (SD):</p> <p>Intended to treat:</p> <p>sbt = 8.4 (1.9)</p> <p>1vlcd = 7.9 (1.3)</p> <p>5vlcd = 8.0 (1.7)</p>	<p>1) All three groups participated in a 20-wk behavioral treatment prgm with weekly meetings including instruction on behavioral modification exercise and diet</p> <p>2) 1- and 5-day VLCD groups had a total of 20 days of VLCD (400-600 calories). All food was provided—to increase compliance to the diet.</p> <p>1-day: VLCD for 5 consecutive days in week two, followed by intermittent VLCD for 1 day/week for the next 15 weeks</p> <p>5-day: VLCD for 5 consecutive days every five weeks</p>	20 weeks	<p>COMPLETER RESULTS:</p> <p>1) Metabolic control</p> <p>a) HbA1c Change means (SD):</p> <p>sbt: -0.03 (1.03) base-10 wk</p> <p>1vlcd: -0.65 (1.35) base-10 wk</p> <p>5vlcd: -0.40 (1.14) base-10 wk</p> <p>* ANOVA indicated no significant differences in HbA1c changes between groups (p=0.38).</p> <p>2) Measures of risk:</p> <p>a) Total Cholesterol means (SD):</p> <p>sbt: 5.46 (1.17) base</p> <p>5.03 (0.95) 10 wk</p> <p>5.21 (1.06) 20 wk</p> <p>1vlcd: 5.6 (1.01) base</p> <p>5.1 (1.39) 10 wk</p> <p>5.29 (1.33) 20 wk</p> <p>5vlcd: 5.26 (0.91) base</p> <p>5.01 (0.85) 10 wk</p> <p>4.96 (0.76) 20 wk</p> <p>* ANOVA indicated no significant differences in total cholesterol between groups.</p> <p>b) LDL-Cholesterol means (SD):</p> <p>sbt: 3.31 (1.01) base</p> <p>3.08 (0.66) 10 wk</p> <p>3.12 (0.71) 20 wk</p> <p>1vlcd: 3.48 (0.87) base</p> <p>3.15 (1.08) 10 wk</p> <p>3.33 (1.08) 20 wk</p> <p>5vlcd: 3.36 (0.69) base</p> <p>3.21 (0.63) 10 wk</p> <p>3.17 (0.56) 20 wk</p> <p>* ANOVA indicated no significant differences in total cholesterol between groups.</p>	<p>QUALITY ASSESSMENT:</p> <p>INTERNAL VALIDITY:</p> <p>Described as randomized? Yes</p> <p>Method of randomization clearly described? No</p> <p>Concealment of allocation? No</p> <p>Described as double-blind? No</p> <p>Patient blinded? No</p> <p>Investigators blinded? No</p> <p>Outcome assessors blinded? No</p> <p>No. of withdrawals in each group stated? Yes</p> <p>EXTERNAL VALIDITY:</p> <p>Pop. Described? Yes</p> <p>Intervention described well enough to reproduce? Yes</p> <p>Intervention codified in manual? No</p> <p>Provider training described? No</p> <p>Patients assessed for DSM dx? No</p> <p>Biases, etc: None noted</p>

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 430						c) HDL-Cholesterol means (SD): sbt: 1.20 (0.30) base 1.07 (0.24) 10 wk 1.05 (0.30) 20 wk 1vlcd: 1.10 (0.20) base 1.03 (0.19) 10 wk 1.13 (0.23) 20 wk 5vlcd: 1.09 (0.17) base 1.06 (0.21) 10 wk 1.08 (0.22) 20 wk * ANOVA indicated no significant differences in total cholesterol between groups. 3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 640 Wing & Anglin, 1996	<p>Include: >30% or >18 kg above ideal weight, NIDDM, 30-70 years old,</p> <p>Exclude: those with health problems that would interfere with use VLCD</p>	RCT with 2 groups: 1) LCD throughout + behavior therapy 2) LCD + 12 week periods of VLCD + behavior therapy	<p>N= 93 n LCD=14 n VLCD= 13</p> <p>Intend to treat: * 16 patients withdrew before the end of treatment</p> <p>Age means (SD): Blacks: 49.4(9.0) Whites: 52.4(9.4)</p> <p>68% female</p> <p>Race %: 80.6- Caucasian 17.2- African Amer. 2.2- Other (not analyzed)</p> <p>Baseline HbA1 means (SD): African Amer.: 11.0 (1.6) Caucasian: 10.2 (2.0)</p>	<p>All participants attended weekly session for a full year that consisted of a lecture/discussion on nutritional, behavioral techniques, or exercise. Also, all pts were encouraged to increase activity gradually until they were walking 2 mi. a day/ 5 days a week. Participants learned techniques such as stimulus control, goal setting, self-monitoring.</p> <p>1)LCD—given a goal of 1000-1200 kcal/day. 2)VLCD—VLCD for weeks 1-12 and 24-36 (~500 kcal/day) and a LCD for the remaining weeks.</p>	12 months, weekly sessions	<p>COMPLETER RESULTS:</p> <p>1) Metabolic control: a) HbA1 % means (SD): Caucasian: 10.3 (2.0) base 8.4 (1.9) 6 mo 8.9 (2.4) 1 year African Amer.: 11.2 (1.5) base 9.8 (2.0) 6 mo 9.8 (2.0) 1 year</p> <p>*Differences between intervention groups not reported.</p> <p>b) Fasting Glucose (mmol/l) means (SD): Caucasian: 12.3 (3.8) base 8.9 (3.3) 6 mo 9.7 (3.6) 1 year African Amer.: 12.5 (3.8) base 8.7 (2.9) 6 mo 10.4 (3.3) 1 year</p> <p>*Differences between intervention groups not reported.</p> <p>2) Measures of risk: a) Weight (kg) Loss means estimated from graph:: LCD: Caucasian: -14.0 6 mo -12.0 1 year African Amer.: -10.5 6 mo -7.0 1 year VLCD: Caucasian: -17.5 6 mo -17.0 1 year African Amer.: -14.0 6 mo - 7.5 1 year</p> <p>*Differences between intervention groups not reported.</p>	<p>QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No</p> <p>Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. withdrawals stated? Yes</p> <p>EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? Yes Provider training described? Yes Patients assessed for DSM dx? No</p> <p>Biases, etc: No results reported by intervention group, but by race</p>

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 640	Wing & Anglin, 1996					COMPLETE RESULTS: 3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 750 Wing, Blair, Marcus, Epstein, Harvey, 1994.	Include: Type II diabetes; weight >30% or 18 kg above ideal body weight; age 30-70 years old Exclude: inability to follow very low calorie diet	RCT with 2 treatment conditions: 1) Balanced low-calorie diet (LCD) 2) Low-calorie diet with periods of a very-low-calorie diet (VLCD)	N = 93 n LCD = 48 n VLCD = 45 *14 dropped out by the end of the 50-week treatment numbers by group not given Age means (SD): LCD = 51.3(8.7) VLCD = 52.3(10.7) % Female: Intended to treat: LCD = 62.5% VLCD = 66.7% Race % not given Baseline HbA1c means (SD): Intended to treat: LCD = 10.5(2.0) VLCD = 10.3(2.0)	1) LCD—group was assigned a calorie intake goal of 1,000—1,200. Weekly group meetings were held for 50 weeks consisting of a weigh-in, review of the self-monitoring records, lecture and discussion on nutrition, exercise, or behavior modification. 2) VLCD—same as the LCD but were prescribed a diet of 400-500 calories a day for weeks 1-12 and 24-36 of the 50 week treatment period.	50-week treatment, 2-year follow-up	COMPLETER RESULTS: 1) Metabolic control a) HbA1c % means (SD): LCD: 10.5 (2.0) base 8.8 (1.8) 6 mo 9.2 (2.0) 12 mo VLCD: 10.4 (2.0) base 8.4 (2.2) 6 mo 8.9 (2.5) 12 mo *RM-ANOVA indicated no significant effect of group on HbA1c over time (P=0.08). b) Fasting Plasma Glucose means (SD): LCD: 12.8 (3.17) base 9.01 (3.0) 6 mo 9.78 (3.28) 12 mo VLCD: 12.29 (4.39) base 8.67 (3.56) 6 mo 9.28 (3.67) 12 mo *RM-ANOVA indicated no significant effect of group on fasting plasma glucose over time. However, fasting glucose levels remained <240 mg/dl for a longer time in VLCD than LCD (p<0.05) 2) Measures of risk: a) Weight (kg) Change means (SD): LCD: -5.7 (7.9) base-2 years VLCD: 7.2 (8.0) base-2 years *No significant differences between groups in weight loss.	QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? Yes EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? No Provider training described? No Patients assessed for DSM dx? No Biases, etc: Majority of measures not reported for 2 year f/u

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 750						<p>b) Systolic blood pressure- SBP means (SD): LCD: 140 (15) base 134 (17) 6 mo 137 (14) 12 mo VLCD: 139 (15) base 130 (15) 6 mo 133 (14) 12 mo</p> <p>*RM-ANOVA indicated no significant effect of group on SBP over time.</p> <p>c) Diastolic blood pressure- DBP means (SD): LCD: 87 (11) base 84 (13) 6 mo 84 (11) 12 mo VLCD: 87 (9) base 81 (9) 6 mo 79 (9) 12 mo</p> <p>*RM-ANOVA indicated a significant effect of group on DBP at 12 mo (p=0.03).</p> <p>d) Cholesterol means (SD): LCD: 5.3 (0.81) base 4.73 (0.81) 6 mo 4.99 (0.91) 12 mo VLCD: 5.41 (1.01) base 5.10 (1.22) 6 mo 5.43 (1.14) 12 mo</p> <p>*RM-ANOVA indicated no significant effect of group on cholesterol over time (p=0.058).</p>	

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# 750						e) LDL-Cholesterol means (SD): LCD: 3.22 (0.78) base 2.91 (0.73) 6 mo 3.09 (0.91) 12 mo VLCD: 3.3 (0.73) base 3.22 (0.99) 6 mo 3.43 (0.96) 12 mo *RM-ANOVA indicated no significant effect of group on LDL-C over time (p=0.14). f) HDL-Cholesterol means (SD): LCD: 1.09 (0.23) base 1.14 (0.21) 6 mo 1.17 (0.91) 12 mo VLCD: 1.12 (0.21) base 1.17 (0.23) 6 mo 1.25 (0.23) 12 mo *RM-ANOVA indicated no significant effect of group on HDL-C over time. 3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given	

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# 8770 Wing, Marcus, Blair, Watanabe, Bononi, Bergman, 1994	Include: type II diabetes, 30-70 years old, at least 30% above ideal body weight Exclude: liver disease, renal disease, cancer, or recent myocardial infarction	RCT with 2 groups: 1) 400 kcal diet (VLCD) 2) 1000 kcal diet (LCD) Post-tx, 2 groups aboveAge means (SD): groups divided into 4: 1) VLCD that achieved 11% weight loss goal (VLCDN) 2) VLCD that did not achieve 11% weight loss goal (VLCDN) 3) LCD that achieved 11% weight loss goal (LCDA) 4) LCD that did not achieve 11% weight loss goal (LCDN)	N= 93 n VLCD=45 n LCD= 48 Age means (SD): VLCDA= 53.5 (1.6) VLCDN= 47.8 (4.5) LCDA= 55.2 (1.9) LCDN= 49.2 (1.5) % Female: VLCDA= 69.4 VLCDN= 55.6 LCDA= 58.8 LCDN= 64.5 Race %: not given Baseline HbA1 % means (SD): VLCDA= 10.3 (0.3) VLCDN= 10.3 (0.7) LCDA= 10.2 (0.5) LCDN= 10.7 (0.4)	Both groups attended weekly meetings in which they were taught behavior modification techniques to promote diet adherence and to increase daily activity. VLCD group was restricted to 400 kcal per day. For first 12 weeks. LCD group restricted to 1000 kcal per day for 12 weeks. Both groups were encouraged to gradually increase caloric intake for next 15 weeks.	12 weeks with weekly sessions	COMPLETER RESULTS: 1) Metabolic control: Fasting Glucose means (mmol/l) Estimated from Graph: VLCDA: 13.5 base 7.5 12 week 8.0 27 week LCDN: 13.5 base 10.0 12 week 8.0 27 week * Reported a significant difference between groups at 12 week, but not at 27 weeks. Statistical test not given. 2) Measures of risk: a) Weight-kg means Estimated from Graph: VLCDA: 104 base 92 12 week 85 27 week LCDA: 100 base 88 12 week 83 27 week *Reported similar reductions in weight for both groups. Statistical analyses not reported. 3) Event: a) Health care utilization: Not given b) Morbidity/mortality: Not given	QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. withdrawals stated? No EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? Yes Provider training described? Yes Patients assessed for DSM dx? No Biases, etc: Statistical analyses not explained clearly, actual behavior modification intervention not explained, results not presented in concise format

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# 1070 Wing, Epstein, Nowalk et al. 1985	<p>Include: patients with type II diabetes, between the ages of 30-70, 20% or more above ideal weight, diabetes being treated by diet only or by oral hypoglycemic medication, permission from physician.</p> <p>Exclude: not given</p>	<p>RCT with 3 groups: 1) standard care (con) 2) nutrition education (edu) 3) behavior modification (beh)</p>	<p>N= 53 *no drop-outs Age mean (SD): 55.1(1) % Female: 62 Race % not given Baseline HbA1% mean (SD): 9.3 (0.3) Completers: 9.3 (0.3)</p>	<p>con- patients attended monthly meetings where nutritional information was given edu- patients attended 16 weekly sessions that provided basic diabetes, exercise, & nutrition information beh- patients attended 16 weekly sessions in which they were given diabetes information along with behavior strategies that would help change behavior, i.e., diet, exercise, cognitions, environment and eating behaviors</p>	<p>16 weeks with follow-up at 2, 4 10 and 16 mo.</p>	<p>COMPLETER RESULTS 1) Metabolic control a) HbA1 %: *RM-ANOVA indicated no significant differences in HbA1c between groups over the 16 mo period. b) Fasting Blood Sugar-FBS mean (SD): *RM-ANOVA indicated no significant differences between groups on FBS over the 16 mo period. 2) Measures of risk: a) Approximate Weight (kg) means: con: 97.4 base 94.6 4 mo 94.3 16 mo edu: 96.8 base 93.2 4 mo 94.2 16 mo beh: 96.8 base 90.5 4 mo 95.0 16 mo *simple effects showed weight loss for beh group was significantly greater than con or edu groups (p<0.01) 3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given</p>	<p>QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? Yes, none EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? Yes Provider training described? Yes Patients assessed for DSM dx? No Biases, etc: Investigators did not separate majority of findings by group since there were no group differences</p>

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# 1020 Wing, Epstein, Nowalk, Scott, Koeske, & Hagg, 1985	<p>Include: NIDDM; age 35-65; ≥20% above ideal body weight based on norms; development of diabetes after the age of 30</p> <p>Exclude: prior experience with home monitoring of blood glucose</p>	<p>RCT with 2 treatment conditions:</p> <p>1) Weight Control - standard behavioral weight control program (WC)</p> <p>2) Glucose monitoring - weight control program including self-monitoring of blood glucose levels and focuses on the weight-blood glucose relationship (GM)</p>	<p>N = 50 n WC = 25 n GM = 25 *5 dropouts during study- WC: 3; GM: 2</p> <p>Age means: WC = 54.0 GM = 53.5 Age range: 35-65</p> <p>78% Female</p> <p>Race % not given</p> <p>Baseline GHb % mean: Intended to treat: 10.5</p>	<p>1) Behavioral weight control program, incl daily wks, monthly for calorie goal based on individual weight, calorie books, self-monitoring diaries. Encouraged walking. Behavior modification involving reducing stimuli associated with eating, slowing the act of eating, preplanning for holidays and vacations, and eliciting social support. Focused on weight reduction as the goal of therapy.</p> <p>2) Included above aspects of weight control therapy but focused more on the relationship btwn. Weight loss and blood glucose control. Patients taught to monitor blood glucose with chemstrips and took five fasting and two pre- and postprandial BG measurements</p>	<p>Treatment weekly for 12 program, incl daily wks, monthly for 6 mo. Post at 6 mo, f/u at 9 mo.</p>	<p>COMPLETER RESULTS:</p> <p>1) Metabolic control: a) GHb % means (SD): WC: 10.86 (2.0) base 10.0 (2.08) post 10.44 (2.16) f/u GM: 10.19 (2.51) base 9.68 (1.95) post 10.19 (2.29) f/u</p> <p>*RM-ANOVA indicated no significant effect of group on GHb, but a significant effect of time on weight loss for both groups at post (p<0.001).</p> <p>b) Fasting Blood Glucose- FBG (mg/dl) means (SD): WC: 207.5 (70.5) base 190.7 (65.0) post 210.2 (73.1) f/u GM: 209.2 (69.7) base 197.3 (50.0) post 216.2 (58.7) f/u</p> <p>*RM-ANOVA indicated no significant effect of group on FBS, and no significant effect of time on FBS for both groups.</p> <p>2) Measures of risk: a) Weight (kg) means (SD): WC: 96.35 (23.57) base 89.53 (21.75) post 88.11 (17.79) f/u GM: 99.02 (16.13) base 93.19 (15.25) post 94.92 (16.5) f/u</p> <p>*RM-ANOVA indicated no significant effect of group on weight loss, but a significant effect of time on weight loss for both groups (p<0.001)</p>	<p>QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No</p> <p>Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? Yes</p> <p>EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? No Provider training described? No Patients assessed for DSM dx? No</p> <p>Biases, etc: None noted</p> <p>Positive points: Also assessed effects of treatment on medications, eating and exercise behaviors, mood, and compliance with glucose self-monitoring</p>

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# 1020	Wing, Epstein, Nowalk, Scott, Koeske, & Hagg, 1985			Per week. Values were recorded and self-monitored. Patients were encouraged to keep BG levels w/in normal range by adjusting caloric intake/expenditure and to observe relationship between their eating, exercise behavior, weight, and blood glucose level—and make appropriate adjustments if BG levels were elevated		3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given	

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# 900 Wing, Marcus, Epstein, and Jawad, 1991	<p>Include: Type II diabetes; weight ≥ 20% above ideal body weight; spouse >15% above ideal body weight; age 30-70</p> <p>Exclude: None noted</p>	<p>RCT with 2 treatment conditions:</p> <p>1) together—subjects and spouses treated together in behavioral weight control</p> <p>2) alone—subject treated alone</p>	<p>N = 49 patients and 49 spouses</p> <p>pt.alone = 23 sp.alone = 22 pt.tog = 20 sp.tog = 20</p> <p>*6 patients (pt. alone: 1; pt. tog: 5) and 7 spouses (group numbers not given) withdrew by 1 year follow up</p> <p>Age means (SD): Completers: pt.alone = 51.2(7.3) sp.alone = 51.6(9.9) pt.tog = 53.6(7.7) sp.tog = 53.4(8.3)</p> <p>% Female: Completers: atients: 58</p> <p>Race % not given</p> <p>Baseline HbA1 means (SD): Completers: pt.alone = 10.3(2) sp.alone = 7.3(1.4) pt.tog = 9.5(2.4) ap.tog = 7.1(1.4)</p>	<p>1) Alone condition—behavioral weight loss program. 1 hr at 20 weeks and sessions. Glucose levels monitored & medication adjusted accordingly. Subjects self-monitored caloric intake. Subjects given step-wise goals for a walking program. Trained in behavior strategies such as, stimulus control techniques, problem solving, assertion, goal setting and other cog. Techniques. Spouses in alone condition participated in assessment session after 20 week weight control program and at 1-yr. Follow-up.</p> <p>2) Together condition—patient and spouse completed program</p>	<p>20 week treatment session with post 1 hr at 20 weeks and f/u at 1 year.</p>	<p>COMPLETER RESULTS:</p> <p>1) Metabolic control</p> <p>a) HbA1 Change means (SD): pt. alone: -2.1 (2.1) pre-post -0.7 (2.7) pre-1 year pt. tog: -1.2 (1.9) pre-post -0.1 (1.9) pre- 1 year *ANOVA indicated no significant effect of group on GHb.</p> <p>b) Fasting Blood Sugar-FBS</p> <p>Change means (SD): pt. alone: -64 (83) pre-post -36 (85) pre-1 year pt. tog: -50 (52) pre-post -11 (61) pre- 1 year *ANOVA indicated no significant effect of group on FBS</p> <p>2) Measures of risk: a) Weight Change means (SD): pt. alone: -19.9 (18.2) pre-post -11.6 (22.9) pre-1 year pt. tog: -19.1 (11.2) pre-post -7.0 (11.7) pre- 1 year *ANOVA indicated no significant effect of group on weight loss.</p> <p>3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given</p>	<p>QUALITY ASSESSMENT:</p> <p>INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No Concealment of allocation? No</p> <p>Described as double-blind? No Patient blinded? No Investigators blinded? No Outcome assessors blinded? No No. of withdrawals in each group stated? Yes</p> <p>EXTERNAL VALIDITY: Pop. Described? Yes Intervention described well enough to reproduce? Yes Intervention codified in manual? Yes Provider training described? No Patients assessed for DSM dx? No</p> <p>Biases, etc: None noted</p>

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# 900	Wing, Marcus, Epstein, and Jawad, 1991			described above. This program also emphasized the importance of spousal support in modifying diet and exercise and were taught positive reinforcement and support skills.			