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.**	Include: African-American, diagnosed NIDDM, ≥ 55 years old, ≥ 120% of Metropolitan weight standards, HbA1c ≥ 8%. Exclude: non-ambulatory, medical contraindications to program participation.	RCT with 2 treatment conditions: 1) Usual care 2) Intervention	N = 64 n uc = 32 n int = 32 *9 did not complete the program (7 from control, 2 from intervention). Age means (SD): uc = 61(5.7) int = 62.4(5.9) Age range: 55-79 % Female: uc: 88 int: 66 Race % not given Baseline HbA1c means (SD): Intention to treat: uc: 10.0 (1.9) int: 11.0 (1.7)	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	6 months. Assessments made at 0, 3, and 6 mos.	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 * Reported a significant between group difference in HbA1c at 3- and 6-months (p<0.01). Statistical test not given. 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 * Reported a significant between group difference in weight at 3- and 6-months (p<0.01). Statistical test not given. 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 *Reported no significant differences in SBP between groups at 3 and 6 mo. Statistical test 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? Yes 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
# 5220 **Agurs-Collins, Kumanyika, Ten Have & Adams-Campbell, 1997.**				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.		c) Diastolic blood pressure-DBP means (SD): uc: 77 (10) base 79 (8) 3 mo 80 (10) 6 mo int: 79 (10) base 78 (10) 3 mo 79 (9) 6 mo *Reported no significant differences in DBP between groups at 3 and 6 mo. Statistical test not given. (p<0.05 at 6-months) d) HDL Cholesterol means (SD): uc: 52.6 (15) base 50.9 (12.9) 3 mo 51.9 (14.2) 6 mo int: 49.2 (9.9) base 46.1 (8.1) 3 mo 46.8 (10.8) 6 mo *Reported no significant decrease in HDL for both groups at 3 and 6 mo. Statistical test not given. e) LDL Cholesterol means (SD): uc: 156.0 (47.9) base 150.1 (27.8) 3 mo 154.6 (30.7) 6 mo int: 171.9 (37) base 156.1 (32.8) 3 mo 162.4 (39.2) 6 mo *Reported no significant decrease in LDL for both groups at 3 and 6 mo. Statistical test not given.	

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 **Aikens, Kiolbasa, Sobel 1997**						4) Psychological Measures: a) Generalized distress (General Severity Index-GSI†) means (SD): con: 53.8 (11) base 55.6 (8.7) post 56.1(7.9) f/u tx: 57.5 (10) base 51.4 (8.9) post 54.1 (12) f/u *Significance not given b) Anxiety Symptoms (Symptoms Checklist- 90 Revised- SCL-90R†) means (SD): con: 46.6 (13.3) base 50.0 (11.2) post 52.1(11.1) f/u tx: 52.5 (11.9) base 47.4 (8) post 49.8 (13.5) f/u *Significance not given c) Daily Stress (Daily Hassles†) means (SD): con: 24.3 (13.3) base 28.3 (16) post 29 (11) f/u tx: 37.4(18.8) base 29.5(15.1) post 28.4(15.8) f/u *Significance not given	†Higher scores on the GSI, SCL-90R, and Hassles scales indicate more generalized distress, anxiety symptoms and hassles respectively

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 **Anderson, Funnell, Butler, Arnold, Fitzgerald, & Feste, 1995.**						-Emotional coping: int: 0.41 base-post wl: 0.12 base-post *Analysis indicated no significant difference. Statistical test not given. -Managing stress: int: 0.29 base-post wl: 0.01 base-post *Analysis indicated a significant difference (p=0.05). Statistical test not given. -Obtaining support: int: 0.36 base-post wl: -0.11 base-post *Analysis indicated a significant difference (p=0.002). Statistical test not given. -Motivating oneself: int: 0.29 base-post wl: -0.09 base-post *Analysis indicated no significant difference. Statistical test not given. -Making decisions: int: 0.47 base-post wl: 0.05 base-post *Analysis indicated a significant difference (p=0.02). Statistical test not given. ŧ Higher scores on the Self Efficacy scales indicated higher self efficacy	

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 **Brown, Garcia, Kouzekanani & Hanis, 2002.**						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 **Cabrera-Pivaral, Gondalez-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 **Campbell, Redman, Moffitt, et al. 1996**						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* * 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 **Campbell, Redman, Moffitt, et al. 1996**						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) 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 effects of an intensive 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.**	Include: IDDM ≥ 2 years since diagnosis; insulin usage since diagnosis; using self-measurement of blood glucose Exclude: history of heart disease, hypertension, seizure activity, or severe psychiatric disturbance; chronic medication other than insulin	RCT with 3 treatment conditions: 1) Control (con) 2) Standard BGAT (sta) 3) Intensive BGAT (int)	N = 39 n con = 14 n sta = 13 n int = 12 *withdrawals not stated Age means: Intended to treat: con = 33.8 sta = 33.7 int = 31.1 % Female: Intended to treat: con = 57.1 sta = 61.5 int = 66.7 Race % not given Baseline HbA1 means: Intended to treat: Con = 11.4 Sta = 10.4 Int = 12.8	1) Standard BGAT—7 weekly classes with readings and BGAT with readings and 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. 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	7-week intervention following hospitalizations	COMPLETER RESULTS: 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 *ANOVA indicated int significantly different from con ($p<0.02$) 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? 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: None noted

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 intervention (int.) 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 **D'Eramo-Melkus, Wylie-Rosett, Hagen, 1991.**				received intervention plus 2 follow-up sessions.		2) Measures of risk: 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) 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) 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
# 20 **Didjurgeit, Kruse, Schmitz, et al, 2002**	Include: Type I diabetes, presence of self-reported persistent psychological problem, presence of at least one microvascular diabetic complications. Exclude: not given	Randomized wait-list controlled trial for patients indicating psychological problems- single-center design	N=46 n con= 21 n tx= 23 *2 patients died during study- con: 1, tx: 1 Age means (SD): con= 41(10) tx= 36 (9) 61% Female Race % not given Baseline HbA1c means (SD): Completers: tx: 9.1(2.0) con: 8.7 (1.7)	Psycho-therapeutic intervention: 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 Plus: Diverse psychotherapeutic interventions to foster awareness, modify thoughts, modify behavior, emotionality, awareness of body's ability to rely and support. *all patients treated by one therapist	Weekly sessions- 14 session maximum, 55-min sessions	COMPLETER RESULTS: 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 *ANOVA indicated a significant effect of group on f/u HbA1c (p=0.016) 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 *ANOVA indicated a significant effect of group on problem severity	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? Not sure Provider training described? No 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

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 20 **Didjurgeit, Kruse, Schmitz, et al, 2002 (cont'd)**						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) c) Depression Score (ZERSSEN†) 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 ZERSSEN (p= .39).** 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) †Higher scores on the SCL-90R, ZERSSEN, and IRES indicate more disease related distress and quality of life respectively	

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 se 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**						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 **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.** 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 ***Reported no significant differences between groups at post. Statistical tests not given.** 3) Events: a) Health care utilization: Not given b) Morbidity/mortality: 6 patients died during f/u	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 330 **Gaede, Vedel, Hans-Henrik et al 1999**	Include: type 2 diabetes, albumin excretion rates (AER) of 30-300 mg in a 24-hr urine sample. 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.	RCT- single-center design with 2 groups: 1) standard (st) and 2) intensified (in)	N=160 n st= 80 n in=80 *4 drop-outs in ST (2 withdrew, 2 died), 7 drop-outs in IN (3 withdrew, 4 died) Age means (SD): st: 55.2(7.2) in: 54.9(7.2) % Female: st: 30 in: 21.25 Race % not given Baseline HbA1c % means (SD): Intended to treat: st: 8.8 (1.7) in: 8.4 (1.6)	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.	4 years with monitoring every 3 months.	COMPLETER RESULTS: 1) Metabolic control: a) HbA1c % mean change (SD): st: 0.2 (1.9) in: -0.8 (1.6) * Indicated a significant difference between groups (p<0.0001). Statistical test not given. b) Fasting glucose (mmol/L) mean change (SD): st: -0.3 (4.2) in: -2.7 (3.5) *Indicated a significant difference between groups (p<0.0001). Statistical test not given. 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 *****ANCOVA indicates significant differences between groups (by sex) in BMI change (men p=0.004; women p=0.06) b) Systolic blood pressure mean change (SD): st: -4(17) in: -8(18) * Indicated a significant difference between groups (p<0.01). 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. withdrawals 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: Behavior modification not clearly defined/ described; statistical methods not clearly explained

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 330 **Gaede, Vedel, Hans-Henrik et al 1999**						c) Diastolic blood pressure mean change (SD): st: -5 (10) in: -7 (10) *Indicated no significant difference between groups (p=0.21). Statistical test not given. d) Currently Smokes Change: st: -5 in: -7 *Indicated no significant difference between groups (p=0.50). Statistical test not given. e) Cholesterol mean change (SD): st: -15(176) in: -79(147) *Indicated a significant difference between groups (p=0.005). Statistical test not given. 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 *Indicated a significant difference between groups (p=0.03). Statistical test not given.	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 9120 **Glasgow, Boles, McKay, Feil, Barrera, 2003**	Include: adult type-II diabetes for at least 1 year, are living independently, had a telephone, were literate in English, not planning to move. Exclude: none given	RCT with 2 groups: 1) Tailored Self Management (TSM) with basic nutrition information 2) Peer support (PS) with basic nutrition information 3) Information only (con) *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.	N= 320 *#'s per group not given Intended to treat: 18% of pts dropped out before 1-yr f/u Age mean (SD): 59 (9.2) 53.13% Female Race %: not given Baseline HbA1c mean (SD): 7.44 (1.62)	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 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	10 months, with quarterly online assessments.	COMPLETER RESULTS: 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 * MANCOVA reported to be not significant. 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 * MANCOVA reported to be not significant. 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 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: 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.

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 & Tooobert, 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)		b) Total Cholesterol means (SD): BC: 210 (40) base 201 (34) 3 mo 206 (39) 6 mo BCT: 203 (39) base 202 (34) 3 mo 194 (30) 6 mo BCC: 202 (38) base 198 (37) 3 mo 202 (39) 6 mo CC: 205 (35) base 201 (31) 3 mo 201 (30) 6 mo *ANCOVA indicated no significant effect of group on Total Cholesterol. 3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given 4) Psychological Measures: -Quality of Life: Illness Intrusiveness Scale- IIS means (SD): BC: 25.7 (11.1) base 31.0 (15.6) 3 mo 26.0 (12.7) 6 mo BCT: 29.2 (15.2) base 30.6 (15) 3 mo 29.6 (14.9) 6 mo BCC: 28.6 (12) base 32.4 (13) 3 mo 28.2 (12.4) 6 mo CC: 30.8 (15.7) base 31.4 (13.3) 3 mo 29.2 (14.0) 6 mo *ANCOVA indicated no significant effect of group on Quality of Life.	

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.**	Include: Type I or II diabetes; age ≥40 years; primarily responsible for one's own diabetes self-management Exclude: None noted	RCT with 2 treatment conditions: 1) Usual Care (con) 2) Brief intervention (int)	N = 206 n con = 98 n int = 108 *26 drop-outs- int: 13; con: 13 Age means (SD): Intended to treat: con = 63.1(10.5) int = 61.7(12.1) % Female: Intended to treat: con = 60 int = 63 Race % not given Baseline HbA1c % means: Intended to treat: con: 7.9 int: 7.8	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 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.	2 separate 20-min sessions and 2 follow-up phone calls at 1 and 3 weeks.	COMPLETER RESULTS: 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). 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). 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: Not many measures of risk assessed

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 ŧ 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. ŧ 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**	Include: type II diabetes, lived independently, had a telephone, were not planning to move Exclude: none noted	RCT with 4 groups: 1) Basic goal setting (BGS) 2) Community Resources (CR) 3) Telephone Follow-up (TF) 4) Combined Condition (COM)	N= 320 n BGS=80 n CR=80 n TF=80 n COM= 80 * 15 participants withdrew before the 1-yr f/u Age mean: 59.7 56% Female Race (%Caucasian): BGS = 90 CR = 90.9 TF = 88.6 COM = 91.4 Baseline HbA1c mean (SD): BGS: 7.63 (1.3) CR: 7.38 (1.6) TF: 7.55 (1.9) COM: 7.54 (1.7)	1) Basic Goal Setting—attended baseline assessment with all other participants where completed interactive computer 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. 2) Telephone follow-up—7 (15-20 min) brief structured calls providing support and reinforcement, personalized problem-solving training 3) Community Resources—binder of indexed community re-	12 months f/u, 6 months of face-to-face interaction Visits at BL, 3 and 6 mos. (1-2 hrs)	COMPLETER RESULTS: 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 * MANCOVA indicated TF group significantly different than other groups at 12 mo ($p<0.05$) on all biological measures combined (HbA1c and lipid ratio). 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 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? 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 differentiated on measure, but type of outcome (biological, behavioral, or psychosocial)

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.		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 * 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). 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 † 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
# 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(**s**pecify the problem, **t**hink of the options, **o**pt for the best solution, **p**ut 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.**						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). 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). 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). 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
# 6710 **Greenfield, Kaplan, Ware, Yano, Frank 1988**	Include: diabetic patients Exclude: non-continuing patients, >75 years old, blind, could not speak English, on insulin pump, had cancer or any other major health concern.	RCT with 2 groups: 1) Experimental (exp) 2) Control (con)	N= 73 n con= 34 n exp= 39 *14 drop-outs: 8 con, 6 exp Age means (SD): con: 49.5 (13.0) exp: 49.8 (14.7) % Female: con: 52 exp: 48 Race %: not given Baseline HbA1 % means (SD): con: 10.26 (1.96) exp: 10.59 (2.11)	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. 2) The con group were similarly seen for 20 minutes, but only received educational material.	20 minutes prior to doctor's visit	COMPLETER RESULTS: 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 * t-tests indicate significant differences between groups at post (p<0.01). 2) Measures of risk: Not given 3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given 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 * ANCOVA indicated that the groups were significantly different at post (p<.0.01). 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 * ANCOVA indicated that the groups were significantly different at post (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. 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: No measures of risk reported.

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 6710 **Greenfield, Kaplan, Ware, Yano, Frank 1988**						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 * ANCOVA indicated that the groups were significantly different at post (p<.0.01). 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 * ANCOVA indicated no significant differences between groups. b) Perceived Health Status Variables‡: 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 * ANCOVA indicated that the groups were significantly different at post (p<.0.001). Ii) 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 * ANCOVA indicated that the groups were significantly different at post (p<.0.01).	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 6710 **Greenfield, Kaplan, Ware, Yano, Frank 1988**						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. † 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**						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 *Reported significant differences between con and both ihe and ihe+ca in DBP (both p<0.01). t-test for proportion 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 *Reported no significant differences between groups at 5 yr. Within group improvements for all groups. T-test for proportion 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	

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**	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 Exclude: not given	RCT with 4 groups: 1) relaxation control (con) 2) behavior modification (bm) 3) cognitive modification (cm) 4) cognitive-behavioral modification (cbm)	N= 55 n con=14 n bm= 13 n cm= 13 n cbm= 15 * 9 patients withdrew by 18 mo Age mean (SD): 52.94(12.08) Age range: 29- 79 52.17% Female Race %: 95.7- Caucasian 4.3 African Amer. 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)	1) Con exposed to brief progressive muscle relaxation 2) Bm focused on self-control and self-monitoring procedures 3) Cm discussed importance of cognitions and change in cognitions 4) Cbm received training in both behavioral and cognitive techniques.	Seven weekly sessions with f/u at 3,6,12 & 18 mo	COMPLETER RESULTS: 1) Metabolic control: -HbA1 % at f/u not given, but said to be not significant 2) Measures of risk: a) Weight Loss: -Weight change at f/u 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? **Yes** 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? Yes Patients assessed for DSM dx? No Biases, etc: Results not clearly stated, with no actual quantitative results given for any main findings; study focused on sex, differences.

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 diabetes 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-QWBŧ 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 ($p<0.05$). ŧ 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**				model, positive feedback. 20 min stretch, 45-60 min walking, 5-10 min stretching, 30 min of group discussion. 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 4)Education (control group)—10 two-hr. presentations over a 10 wk pd. From health care professionals. Provided no instructions, only information.			

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 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-livonen, 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, Harmaakorpi-livonen, Uusitupa 1993**						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 *RM-MANOVA indicated no significant decrease in serum cholesterol for either group. 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 *RM-MANOVA indicated a significant within-group increase in HDL-C for int group at 15 mo ($p<0.001$) 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
# 8950 **Lamparski & Wing, 1989**	Include: adult-onset diabetics, receiving treatment with insulin or oral hypoglycemic medication, little or no experience with home blood glucose monitoring, adequate eyesight Exclude: those with food allergies, those using beta-blocker medications	RCT with 2 groups: 1) current feedback (cur) 2) noncurrent feedback (non)	N= 36 n cur = 18 n non = 18 Age mean (SD): 56.4 (7.1) Age range: 35-69 % Female not given Race not given Baseline Fasting Blood Glucose (mg %) Estimated from Graph: cur: 205 non: 168	Sessions included discrimination training in estimating blood glucose levels. Participants in the cur group received immediate actual glycemic feedback after estimating 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.	Six training sessions conducted twice a week for four weeks, plus a pretest session and a posttest session.	1) Metabolic control: -Fasting Blood Glucose means (mg %) Estimated from graph: cur: 205 base 165 post non: 168 base 142 post * Statistical significance of differences between groups 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. withdrawals stated? No 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 Biases, etc: Results not clearly reported, no measures of risk assessed, statistical analyses not reported for actual reduction in blood glucose

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 2050 **Lane, McCaskill, Ross et al. 1993**	Include: NIDDM, type II, poor clinical control (2-hr post-prandial glucose > 200 mg/dl. Exclude: Insulin	RCT-single center with 2 groups: 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**	Include: Type II diabetes; age 21-70; major depression; score ≥14 on Beck Depression Inventory (BDI) Exclude: suicidal ideation or past suicide attempt; psychiatric comorbid illness	RCT- single-center design with 2 groups: 1) control and 2) CBT	N=51 n control=26 n CBT=25 *10 participants did not complete study Age means (SD): CBT= 53.1(10.5) control=56.4 (9.7) % Female: CBT: 60 control: 59.1 Race %: CBT: 85- White 15-non-White control: 77.3- White 22.7-non-White Baseline GHb % means (SD): CBT: 10.2(3.6) control: 10.4 (3.1)	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	10-week intervention with follow-up at 6 mo.	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 * t-tests indicate significant difference of GHb between groups at f/u (p=0.04). 2) Measures of risk: Not given 3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given 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 * ANCOVA indicated significant effects of group on BDI p<.04 †Higher scores on the BDI indicate more depressive symptoms.	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? Yes No. withdrawals stated? Yes 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 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.

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 690 **Manning, Jung, Leese, & Newton 1995**	Include: insulin-dependent, non-insulin-dependent, BMI between 28-45, ages 16-70 Exclude: anyone who had lost more that 3 kg of weight in the previous year, pregnant women, patients with unstable thyroid, those on oral corticosteroids.	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 Age means: Intended to treat: clin: 57.3 dex: 54.4 home: 55.2 beh: 58.8 con: 53.7 Completers: clin: 58.4 dex: 54.7 home: 58.4 beh: 58.6 con: not given Age range: 16-70 % Female: Intended to treat: clin: 56.7 dex: 62.2 home: 42.9 beh: 47.4 con: 41.4 Completers: clin: 50.0 dex: 63.3 home: 35.7 beh: 42.9 con: not given Race % 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	1 year	1) Metabolic control: - HbA1c % means: Intended to treat: clin: 7.6 base 7.59 12 mo dex: 6.59 base 7.1 12 mo home: 6.52 base 6.86 12 mo beh: 6.04 base 5.72 12 mo Completers: clin: 7.6 base 7.46 12 mo dex: 6.79 base 7.07 12 mo home: 6.56 base 6.96 12 mo beh: 5.9 base 5.69 12 mo * 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. 2) Measures of risk: - Weight (kg) means: Intended to treat: Not given Completers: clin: 85.8 base 83.8 12 mo dex: 88.9 base 85.85 12 mo home: 92.4 base 91.4 12 mo beh: 89.5 base 86.4 12 mo	QUALITY ASSESSMENT: INTERNAL VALIDITY: Described as randomized? Yes Method of randomization clearly described? No 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? No Intervention codified in manual? No Provider training described? No Patients assessed for DSM dx? No Biases, etc: Patient baseline characteristics not clearly stated; Control group statistics not displayed with intervention groups for any time assessments

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 5th 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.		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. 3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given 4) Psychological Measures: a) Emotional Adjustment- ATT39 Revised ŧ. 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. ŧ Higher scores on the ATT39 indicated better emotional adjustment to diabetes.	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 170 **Mayer-Davis, D'Antonio, Martin et al 2001**	Include: Type II Diabetes, ≥ 50 years old, BMI ≥ 25 Exclude: those with significant comorbidities that would prevent safe or appropriate weight loss	RCT-single center with 2 groups: 1) intensive lifestyle intervention (con) 2) intensive lifestyle intervention plus formal evaluation (tx)	N= 33 * 5 patients did not complete study and 2 others were not computed in the data analysis Age mean (SD): 64.03 (11.06) 82.1% Female Race %: 96- African Amer. 4- Amer. Indian Baseline Fasting Blood Glucose-FBG (mg/dl) mean (SD): Completers: 158.41 (60.38)	Both con and tx received 8-week intensive lifestyle weight 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.	8 weeks—2 individual and 6 group sessions	COMPLETER RESULTS 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 2) Measures of risk: - Weight * Weight loss did not differ between groups. 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? 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 analyzed by group

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 6920 **Mazzuca, Moorman, Wheeler et al. 1986**	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 Exclude: psychiatric comorbidity; terminal illness	RCT-single center with 4 groups: 1) control (con) 2) patient education (pat) 3) physician education (phy) 4) patient & physician education (patphy) * groups 1 and 3 were considered control & groups 2 and 4 were considered treatment	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 Age Median: Intended to treat: 58.1 % Female: Intended to treat: 79 Race %: 72- African Amer. Baseline HbA1 mean (SD): Intended to treat: 10.7 (3.1)	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	4 years	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.	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

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 6920 **Mazzuca, Moorman, Wheeler et al 1986**						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 *ANCOVA indicated no significant effect of group on SBP. 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 *ANCOVA indicated no significant effect of group on DBP. 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
# 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**	Include: diabetes; ability to perform self-care tasks Exclude: HbA1c<7%; psychiatric comorbidity; severe medical illness	RCT with 2 groups: 1) routine care (con) 2) telephone-delivered intervention group (tx)	N= 50 n con=18 n tx= 20 *** 12 patients did not complete study- con: 7 ; tx: 5** Age means (SD): con: 62 (5.7) tx: 59.2 (7.2) %Female Intended to treat: 64 Race % not given Baseline HbA1c means (SD): Intended to treat: con: 8.3(0.9) tx: 8.8(1.1)	Intervention group received telephone 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 within 12-week time period	COMPLETER RESULTS: 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). 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 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 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 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? No Intervention codified in manual? No Provider training described? No Patients assessed for DSM dx? No Biases, etc: Treatment not described in detail; large number of patients (n=12) dropped out before post: 2 moved, 10 withdrew

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 **Perry, Mann, Lewis-Barned, Duncan, Waldron & Thompson, 1997.**						c) HDL-Cholesterol means (SD): Grp1: 1.2 (0.2) base 1.3 (0.3) 6 mo 1.3 (0.3) 12 mo Grp2: 1.3 (0.3) base 1.3 (0.4) 6 mo 1.3 (0.3) 12 mo *RM-ANOVA indicates no significant between group differences. d) LDL-Cholesterol means (SD): Grp1: 3.1 (0.9) base 3.1 (0.9) 6 mo 3.1 (0.9) 12 mo Grp2: 3.5 (0.9) base 3.7 (1.0) 6 mo 3.4 (0.9) 12 mo *RM-ANOVA indicated significant difference between groups at 6 mo (p=0.022) e) Systolic blood pressure-SBP means (SD): Grp1: 127 (21) base 128 (17) 6 mo 127 (18) 12 mo Grp2: 131 (18) base 134 (17) 6 mo 129 (15) 12 mo *RM-ANOVA indicates significant decrease in SBP in Grp2 from 6 to 12 mo (p=0.002)	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 1090 **Rabkin, Boyko, Wilson, Streja 1983**	Include: NIDDM, younger than 65, not receiving insulin, fasting serum glucose levels over 135 mg/dl, and physician assessment of diabetes being "stable" Exclude: not stated	RCT with 2 treatment conditions: 1) Individualized dietary review and recommendation program (ind) 2) Behavioral Program (beh)	N = 40 n.beh = 20 n ind = 20 *2 subjects excluded due to illness, and disinterest (both in ind) Age means (SD): beh = 52.7(1.7) ind = 55.0(2.2) % Female: Beh = 65% Ind = 50% Race % not given Baseline Fasting Serum Glucose (mg/dl) means (SD): Intention to treat: ind = 221(12) beh = 221(16)	1) Individual—One hour-long session reviewing patients 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. 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 ones thoughts and influences from the environment that lead to overeating, coping	6 weeks - Follow-up at 6 and 12 weeks	COMPLETER RESULTS: 1) Metabolic control a) Fasting Serum Glucose (mg/dl) Change means (SD): ind: -18 (9) base-6 weeks -26 (10) base-12 weeks beh: : -22 (10) base-6 weeks -15 (10) base-12 weeks *t-tests indicated no significant differences in fasting serum glucose between groups, but there were significant reductions within group for beh at 6-weeks. 2) Measures of risk: a) Weight (kg) Change means (SD): 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 *t-tests indicated a significant difference in weight change, with ind group losing significantly more than beh group at 12 weeks (p<0.01) b) LDL-Cholesterol Change means Estimated from Graph: ind: 5.0 base-6 weeks 2.0 base-12 weeks beh: : 5.0 base-6 weeks 1.0 base-12 weeks *t-tests indicated no significant differences between groups in LDL-C. c) HDL-Cholesterol Change means Estimated from Graph: ind: -3.0 base-6 weeks 1.0 base-12 weeks beh: : -5.0 base-6 weeks -5.0 base-12 weeks	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? Yes Patients assessed for DSM dx? No Biases, etc: means (SD) not reported for all measures;

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**	Include: Type II diabetes; either newly diagnosed with diabetes or no history of prior systematic diabetes education; age 30-80 Exclude: Mental disability	RCT with 2 treatment conditions: 1) Group education setting (grp) 2) Individual education (ind)	N = 170 n grp= 87 n ind = 83 *78 patients did not complete 6 month follow-up- grp: 44; ind: 34 Age means (SD): grp = 51.6 (9.2) ind = 52.9 (12.8) % Female: grp = 64.4 ind = 67.5 Race % not given 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)	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.	Four sessions (5-7 hrs) 3 and 6 month follow-up	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. 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. 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? Yes Provider training described? Yes Patients assessed for DSM dx? No Biases, etc: Not many measures of risk assessed; Large number of drop-outs (41%) with differential attrition between groups

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 310 **Ridgeway, Harvill, Harvill et al. 1999**	Include: Type II diabetes ; ≥20% ideal weight; inadequately controlled diabetes Exclude: history of diabetic ketoacidosis; age of diabetes onset >40 years	RCT-single center with 2 groups: 1) control (con) 2) behavior modification (tx)	N= 56 n con=20 n tx= 18 * 18 patients withdrew from study: con: 8; tx: 10 Age means: con: 65 tx: 62 %Female: con: 67 tx: 75 Race % not given Baseline GHb % means (SD): con: 12.3 (3) tx: 12.3 (2.2)	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	Sessions held 1.5 hours a month for six months. F/u at 12 mo.	COMPLETER RESULTS: 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 *t-tests indicated no significant differences between groups at 6 mo (p=0.17) and 12 mo (p=0.87). b) Fasting Blood Glucose-FBG means: con: 210 base 195 6 mo 185 12 mo tx: 215 base 180 6 mo 205 12 mo *t-tests indicated no significant differences between groups at 6 mo (p=0.32) and 12 mo (p=0.51). 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 *t-tests indicated no significant differences between groups at 6 mo (p=0.94) and 12 mo (p=0.20).	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? Yes Patients assessed for DSM dx? No Biases, etc: Results not presented clearly Small sample with high number of withdrawals (n=18)

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 310 **Ridgeway, Harvill, Harvill et al 1999**						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). 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). 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).	

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.**	Include: Type I or II diabetes; 16-75 years old; recent HbA1c>8.5%; no HbA1c evaluation in last year Exclude: Current pregnancy; current dementia; inability to speak English	RCT with 2 treatment conditions: 1) Diabetes Cooperative Care Clinic Intervention (int) 2) Control (con)	N = 185 n int = 97 n con = 88 *29 drop-outs: con: 14; tx: 15 Age means (SD): int = 55.7(9.1) con = 56.4(9.1) % Female: int = 41.2 con = 44.3 Race %: Intended to Treat: con: 79.0- Caucasian 8.1- Asian Amer. 4.8- Hispanic 4.8- African Amer. int: 71.2- Caucasian 6.3- Asian Amer. 15.0- Hispanic 5.0- African Amer. Baseline HbA1c % means (SD): Intended to treat: int = 9.7(1.8) con = 9.6(1.5) Completers: int: 9.48 con: 9.55	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. 2) control group continued to receive all diabetes care from their primary care physician throughout the 6-month study period	6 month intervention	COMPLETER RESULTS: 1) Metabolic control: - HbA1c % means: int: 9.48 base 8.18 post con: 9.55 base 9.33 post * ANOVA indicated a significant difference in HbA1c between groups at post (p<0.0001). 2) Measures of risk: Not given 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 * ANOVA indicated a significant difference in hospitalizations at post-randomization (p=0.04) ii) Nutritionist visited in last 2 years int: 50 base 85 post con: 40 base 39 post * ANOVA indicated a significant difference in number indicating having visited a nutritionist between groups at post (p<0.001).	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: No measures of risk assessed; first cohort so small all assigned to int (non-randomly)

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**	Include: NIDDM; women; weight 120-200% ideal body weight; age>50 years old Exclude: insulin treatment; cardiovascular disease; inability to walk for exercise	RCT with 2 treatment conditions: 1) Standard behavior weight control (standard) 2) Behavioral weight control with motivational interviewing (motivational)	N = 22 n st = 10 n mot = 6 *5 were lost to attrition (2 schedule conflicts, 3 personal reasons) and 1 one omitted for beginning insulin treatment; group numbers not given Age mean (SD): Intended to treat: 62.4(7.0) % Female Intended to treat: 100 Race % not given Baseline GHb % Intended to treat: mean (SD): 10.25(2.2)	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.	16-week group program (1 session a week). 4-month post-treatment assessment	COMPLETER RESULTS: 1) Metabolic control a) GHb % means (SD): st: 10.8 (3.1) post mot: 9.8 (1.3) post *ANCOVA indicated significant effect of group on GHb at post (p=0.05): 2) Measures of risk: a) Weight (kg) Change means (SD): st: 4.5 (2.2) base-post mot: 5.5 (3.9) base-post *ANCOVA indicated no significant effect of group on weight loss. 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? Yes Patients assessed for DSM dx? No Biases, etc: Small sample with 23% attrition; non-completers tended to be younger with poorer glycemic control Positive feature: included an analysis of adherence; it was higher in the motivational group

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**	Include: Type II diabetes; ≥30 years old; diabetes currently managed by diet, exercise, and/or oral medication Exclude: Prior training in relaxation or stress management; current use of psychoactive drugs; current psychiatric treatment; use of insulin; pregnancy or lactation	RCT with 2 groups: 1) diabetes education (con) 2) stress management (tx)	**N= 108** n con=34 n tx= 38 * 36 patients did not complete study: con :9; tx: 17 Age means (SD): con: 58.33(11.33) tx: 56.53 % Female: con: 43.8 tx: 40 Race %: con: 87.5- Caucasian 10.4- African Amer 2.1- Asian Amer. int: 85- Caucasian 15- African Amer. Baseline HbA1c % means (SD): con: 7.54 (1.34) tx: 8.14 (2.11)	Stress management intervention 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.	Five 30-minute weekly sessions with f/u at 2, 4, 6 and 12 mo for tx group	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 * Chi-squared indicated significant differences between con and tx at 12 mo (p=0.04) 2) Measures of risk: Not given 3) Events: a) Health care utilization: Not given b) Morbidity/mortality: Not given 4) Psychological Measures: a) Perceived Stress Scale- PSS *** f/u scores not given, but said to not be significantly different between groups** 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	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 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

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 **Trento, Passera, Bajardi, et al., 2002**						c) Diastolic blood pressure-DBP means (SD): grp = 95 (11) base 88 (7) 4 yr ind = 92 (10) base 86 (9) 4 yr * Reported no significant differences in DBP between groups at 4 yr. Statistical test and p value not given. 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 * Reported no significant differences in total cholesterol between groups at 4 yr. Statistical test and p value not given. 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 * Reported no significant differences in HDL-C between groups at 4 yr. Statistical test and p value 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
# 6240 **Vanninen, Uusitupa, Siitonen, Laitinen, & Lansimies, 1992.**	Include: Newly diagnosed type II diabetes patients; 40-64 years old; blood glucose >6.7 mmol/l Exclude: comorbid chronic diseases affecting glucose tolerance	RCT with 2 treatment conditions: 1) Conventional treatment (con) 2) Intervention (int)	N = 78 n con = 40 n int = 38 *4 participants did not complete study. Age means (SD): Men: 53 (7) Women: 54 (6) % Female: 42.3 con: 40 int = 44.7 Race % not given 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)	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. 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.	12 month with 6 bi-monthly visits	COMPLETER RESULTS: 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 *RM-ANOVA indicated a significant difference in HbA1c for women between groups at 12 mo ($p<0.05$). 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 *RM-ANOVA indicated a significant difference in fasting blood glucose for women between groups at 12 mo ($p<0.05$).	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: Change by gender was a secondary analysis

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 6240 **Vanninen, Uusitupa, Siitonen, Laitinen, & Lansimies, 1992.**						2) Measures of risk: a) Body Mass Index-BMI means (SD): 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 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 *RM-ANOVA indicated a significant difference in BMI for men over time for both con ($p<0.01$) and int ($p<0.05$). b) Serum Cholesterol means-mmol/l (SD): 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 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 *RM-ANOVA indicated a significant difference in serum cholesterol for women across groups at 12 mo ($p<0.05$).	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 6240 **Vanninen, Uusitupa, Siitonen, Laitinen, & Lansimies, 1992.**						c) HDL-Cholesterol means- mmol/l (SD): 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 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 *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. 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
# 1030 **White, Carnahan, Nugent et al. 1986**	Include: men with NIDDM; less than satisfactory control of glucose; infrequent hypoglycemic reactions; body weight >15% above mean value for height Exclude: history of alcohol abuse; history of severe personality disorder; current use of glucocorticoids	RCT with 2 groups: 1) advice education (con) 2) group management (tx)	**N= 41** n con=16 n tx= 16 ***9 participants did not complete study: con: 5; tx: 4** 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) % Female: 0 Race % not given 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)	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. The advice-education group minimized patient interaction, with instructors lecturing on the disease and its management.	10 sessions over 6 mo. period	COMPLETER RESULTS 1) Metabolic control: - GHb % means Estimated from graph: con: 11.3 base 9.7 post tx: 10.4 base 9.4 post No significant effect of group on percent overweight reduction. Statistical test, p value not given. 2) Measures of risk: - % Overweight means Estimated from graph: con: 45 base 46 6 mo tx: 37 base 36 6 mo * No significant effect of group on percent overweight reduction. Statistical test, p value 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: Results not reported in table-form; statistical analyses not reported clearly; small sample with large number of drop-outs (21%)

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 8640 **Williams, Mullen, Lang, Considine, and Wing, 1999.**	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 Exclude: those with history of cardiovascular, renal or hepatic disease, those with a fasting plasma glucose (FPG) over 16.7 mmol/L	RCT with 3 groups: 1) 1500-1800 kcal/day diet (control) 2) VLCD for 5 consecutive days in weeks 2,7, 12, 17. (Treatment 1). 3) VLCD for 5 consecutive days in week 2, then 1 day a week for weeks 3-17 (Treatment 2).	N= 54 *7 subjects withdrew after 3 weeks and their data were analyzed separately Age mean (SD): 52.0 (7.9) 57.4% Female Race: 79.6- Caucasian 18.5- African Amer. 1.9- Hispanic Baseline HbA1c % mean (SD): 8.1(1.7) *all participants combined	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. 2) control group was assigned to a moderately caloric restricted diet of 1500 to 1800 kcal/day 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.	Measures were obtained at baseline, week 3, 10 and 20.	COMPLETER RESULTS: 1) Metabolic control: HbA1c % means and significance not reported by intervention group. 2) Measures of risk: a) Weight-kg means and significance not reported by intervention group. 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 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: No results reported by intervention group, but by gender

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.**	Include: Type II diabetes; age 30-70; >20% above ideal body weight based on established norms Exclude: history of liver, renal, or heart disease that would contradict the use of a very low calorie diet	RCT with 3 treatment conditions: 1) Standard behavior therapy (sbt) 2) 1-day very low-calorie diet- (1vlcd) 3) 5-day very low-calorie diet- (5vlcd)	N = 54 n sbt = 18 n 1vlcd = 18 n 5vlcd = 18 *7 drop-outs Age means (SD): sbt = 54.1(7) 1vlcd = 51.4 (7.9) 5vlcd = 50.3 (8.6) % Female: sbt = 61.6 1vlcd = 50 5vlcd = 61.6 Race %: sbt: 88.9- Caucasian 11.1- African Amer. 1vlcd: 83.3- Caucasian 11.1- African Amer. 5.6- Hispanic 5vlcd: 66.7- Caucasian 33.3- African Amer. Baseline HbA1c % means (SD): Intended to treat: sbt = 8.4 (1.9) 1vlcd = 7.9 (1.3) 5vlcd = 8.0 (1.7)	1) All three groups participated in a 20-wk behavioral treatment prgm with weekly meetings including instruction on behavioral modification exercise and diet 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. 1-day: VLCD for 5 consecutive days in week two, followed by intermittent VLCD for 1 day/week for the next 15 weeks 5-day: VLCD for 5 consecutive days every five weeks	20 weeks	COMPLETER RESULTS: 1) Metabolic control a) HbA1c Change means (SD): sbt: -0.03 (1.03) base-10 wk 1vlcd: -0.65 (1.35) base-10 wk 5vlcd: -0.40 (1.14) base-10 wk * ANOVA indicated no significant differences in HbA1c changes between groups (p=0.38). 2) Measures of risk: a) Total Cholesterol means (SD): sbt: 5.46 (1.17) base 5.03 (0.95) 10 wk 5.21 (1.06) 20 wk 1vlcd: 5.6 (1.01) base 5.1 (1.39) 10 wk 5.29 (1.33) 20 wk 5vlcd: 5.26 (0.91) base 5.01 (0.85) 10 wk 4.96 (0.76) 20 wk * ANOVA indicated no significant differences in total cholesterol between groups. b) LDL-Cholesterol means (SD): sbt: 3.31 (1.01) base 3.08 (0.66) 10 wk 3.12 (0.71) 20 wk 1vlcd: 3.48 (0.87) base 3.15 (1.08) 10 wk 3.33 (1.08) 20 wk 5vlcd: 3.36 (0.69) base 3.21 (0.63) 10 wk 3.17 (0.56) 20 wk * ANOVA indicated no significant differences in total cholesterol between groups.	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
# 430 **Williams, Kelley, Mullen, & Wing, 1998.**						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**	Include: >30% or >18 kg above ideal weight, NIDDM, 30-70 years old, Exclude: those with health problems that would interfere with use VLCD	RCT with 2 groups: 1) LCD throughout + behavior therapy 2) LCD + 12 week periods of VLCD + behavior therapy	N= 93 n LCD=14 n VLCD= 13 Intend to treat: * 16 patients withdrew before the end of treatment Age means (SD): Blacks: 49.4(9.0) Whites: 52.4(9.4) 68% female Race %: 80.6- Caucasian 17.2- African Amer. 2.2- Other (not analyzed) Baseline HbA1 means (SD): African Amer.: 11.0 (1.6) Caucasian: 10.2 (2.0)	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. 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.	12 months, weekly sessions	COMPLETER RESULTS: 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 *Differences between intervention groups not reported. 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 *Differences between intervention groups not reported. 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 *Differences between intervention groups not reported.	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? Yes Patients assessed for DSM dx? No Biases, etc: No results reported by intervention group, but by race

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 640 **Wing & Anglin, 1996**						COMPLETER 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 HbA1 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) HbA1 % 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 **Wing, Blair, Marcus, Epstein, Harvey, 1994.**						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 *RM-ANOVA indicated no significant effect of group on SBP over time. 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 *RM-ANOVA indicated a significant effect of group on DBP at 12 mo (p=0.03). 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 *RM-ANOVA indicated no significant effect of group on cholesterol over time (p=0.058).	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 750 **Wing, Blair, Marcus, Epstein, Harvey, 1994.**						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	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 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 above groups divided into 4: 1) VLCD that achieved 11% weight loss goal (VLCDA) 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 LCDA: 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

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 1070 Wing, Epstein, **Nowalk et al. 1985**	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. Exclude: not given	RCT with 3 groups: 1) standard care (con) 2) nutrition education (edu) **3) behavior modification (beh)**	N= 53 *no drop-outs Age mean (SD): 55.1(1) % Female: 62 Race % not given Baseline HbA1% mean (SD): Completers: 9.3 (0.3)	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	16 weeks with follow-up at 2, 4 10 and 16 mo.	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	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

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 1020 **Wing, Epstein, Nowalk, Scott, Koeske, & Hagg, 1985**	Include: NIDDM; age 35-65; ≥20% above ideal body weight based on norms; development of diabetes after the age of 30 Exclude: prior experience with home monitoring of blood glucose	RCT with 2 treatment conditions: 1) Weight Control - standard behavioral weight control program (WC) 2) Glucose monitoring - weight control program including self-monitoring of blood glucose levels and focuses on the weight-blood glucose relationship (GM)	N = 50 n WC = 25 n GM = 25 *5 dropouts during study- WC: 3; GM: 2 Age means: WC = 54.0 GM = 53.5 Age range: 35-65 78% Female Race % not given Baseline GHb % mean: Intended to treat: 10.5	1) Behavioral weight control program, incl daily 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. 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	Treatment weekly for 12 wks, monthly for 6 mo. Post at 6 mo, f/u at 9 mo.	COMPLETER RESULTS: 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 *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). 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 *RM-ANOVA indicated no significant effect of group on FBS, and no significant effect of time on FBS for both groups. 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 *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)	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 Positive points: Also assessed effects of treatment on medications, eating and exercise behaviors, mood, and compliance with glucose self-monitoring

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 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	

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 900 **Wing, Marcus, Epstein, and Jawad, 1991**	Include: Type II diabetes; weight ≥ 20% above ideal body weight; spouse >15% above ideal body weight; age 30-70 Exclude: None noted	RCT with 2 treatment conditions: 1) together—subjects and spouses treated together in behavioral weight control 2) alone—subject treated alone	N = 49 patients and 49 spouses pt.alone = 23 sp.alone = 22 pt.tog = 20 sp.tog = 20 *6 patients (pt. alone: 1; pt. tog: 5) and 7 spouses (group numbers not given) withdrew by 1 year follow up 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) % Female: Completers: atients: 58 Race % not given 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)	1) Alone condition—behavioral weight loss program. 1 hr at 20 weeks and f/u at 1 year. 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. 2) Together condition—patient and spouse completed program	20 week treatment session with post	COMPLETER RESULTS: 1) Metabolic control 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. **b) Fasting Blood Sugar-FBS** **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 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. 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:** None noted

Study	Selected Inclusion/ Exclusion Criteria	Study Design	Patients	Interventions	Treatment Duration	Outcomes/Results	Comments
# 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.			