

LIFESTYLE MODIFICATION

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Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Time of Observation ¹	Intervention Outcome ²	Control Outcome ³	Mean change ⁴	p-value ⁵
A Randomized Controlled Trial of Weight Reduction and Exercise for Diabetes Management in Older African-American Subjects. (Agurs-Collins, 1997) US	RCT 6 months Age range: 55-79 N = 64 Subjects had DM.	Participants in the intervention group were placed in an education program consisting of 12 weekly class sessions followed by 6 biweekly group meetings during the subsequent 3 months. In addition, participants received one individual meeting with a dietician. Class sessions included 60 minutes of nutrition education followed by 20 minutes of low impact aerobic exercise with 5 minute warm-ups and cool-downs. The education program was geared towards older adults, and included large print reading materials. Group sessions encouraged social interaction. n = 32	The control group received usual care -- one nutrition class and 2 informational mailings. n = 32	Mean Weight (kg)	Baseline	93.3 ± 18.6 (n = 32)	94.9 ± 20.1 (n = 32)	--	--
					3 months	90.8 ± 20.3 (n = 31)	96.2 ± 21.2 (n = 27)	-2.0	<0.01
					6 months	90.7 ± 20.1 (n = 30)	96.9 ± 21.6 (n = 25)	-2.4	<0.01
				Mean A1C (%)	Baseline	11.0 ± 1.7 (n = 32)	10.0 ± 1.9 (n = 32)	--	--
					3 months	9.5 ± 1.8 (n = 31)	10.3 ± 1.9 (n = 27)	-1.6	<0.01
					6 months	9.9 ± 2.0 (n = 30)	11.5 ± 4.4 (n = 25)	-2.4	<0.01
				Mean Blood pressure - systolic (mmHg)	Baseline	144 ± 17 (n = 32)	139 ± 14 (n = 32)	--	--
					3 months	144 ± 21 (n = 31)	148 ± 24 (n = 27)	-8.4	<0.10 ⁶
					6 months	146 ± 21 (n = 30)	147 ± 22 (n = 25)	-5.9	NS
				Mean Blood pressure - diastolic (mmHg)	Baseline	79 ± 10 (n = 32)	77 ± 10 (n = 32)	--	--
					3 months	78 ± 10 (n = 31)	79 ± 8 (n = 27)	-3.3	<0.10 ⁷
					6 months	79 ± 9 (n = 30)	80 ± 10 (n = 25)	-4.0	<0.05
				Mean Serum cholesterol (mg/dL)	Baseline	250.1 ± 39.6 (n = 32)	238.3 ± 48.6 (n = 32)	--	--
					3 months	226.8 ± 35.9 (n = 31)	231.2 ± 39.2 (n = 26)	-9.1	NS
					6 months	232.9 ± 44.9 (n = 30)	230.6 ± 34.1 (n = 25)	-3.7	NS
Mean Nutrition knowledge score ⁸	Baseline	12.5 ± 1.8 (n = 32)	12.4 ± 2.5 (n = 32)	--	--				
	3 months	14.8 ± 2.0 (n = 31)	13.3 ± 2.2 (n = 27)	1.4	<0.05				
	6 months	14.1 ± 2.6 (n = 30)	13.3 ± 2.3 (n = 25)	0.7	NS				
Mean dietary cholesterol (mg/day) (from food diary)	Baseline	248 ± 207 (n = 32)	197 ± 99 (n = 32)	--	--				
	3 months	177 ± 104 (n = 31)	199 ± 98 (n = 26)	-85.4	<0.10				
	6 months	198 ± 114 (n = 30)	222 ± 147 (n = 25)	-92.0	<0.10				

Subjects measures were taken at 0, 3, and 6 months.

The p-values provided in the intervention outcome column are p-values for within group comparisons. The n values in the intervention outcome column reflect the number of subjects for whom a particular outcome measure was available.

The p-values provided in the control outcome column are p-values for within group comparisons. The n values in the control outcome column reflect the number of subjects for whom a particular outcome measure was available. In this study, mean change was determined by subtracting the within-group mean change for the control group from the within-group mean change for the intervention group.

p-values in the p-value column are between group comparison values (intervention outcome versus control outcome unless otherwise noted). The p-value in this study is on mean change.

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The Nutrition Knowledge score is based on a test consisting of 20 true-false questions, adapted by the authors from Fanelli, MT: Effective nutrition education for older adults. *Topics of Clinical Nutrition* 3:65-71, 1988.

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Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Time of Observation	Intervention Outcome	Control Outcome	p-value
Patient Empowerment: Results of a randomized controlled trial. (Anderson, 1995) US	RCT 12 weeks per group Mean age: 50 N = 64 Subjects had DM	Intervention group received a six-session (one per week) "patient empowerment" education program. The program focused on managing stress, securing social support, problem-solving, and setting realistic goals. They were scored before the program, at the end, and 6 weeks later using preexisting and new indices. n = 22	The control group was placed on the "wait-list" for the program. After the intervention group completed their program, the control group was enrolled. n = 23	Mean change in impact of diabetes (DAS ¹)	post-program	+0.29	0.00	0.03
				Mean change in positive attitude (DCP ²)	post-program	+0.30	+0.12	NS
				Mean change in negative attitude (DCP)	post-program	-0.62	-0.05	0.01
				Mean change in patient autonomy (DAS)	post-program	+0.04	+0.30	NS

Diabetes Attitude Score
Diabetes Care Profile

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Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Comparison	Intervention Outcome	Control Outcome	p-value
A Comparison of Learning Activity Packages and Classroom Instruction for Diet Management of Patients with Non-Insulin-Dependent Diabetes Mellitus. (Arseneau, 1994) US	RCT 5 months Age: Mean age (intervention): 59.9 ± 8.2 (control): 58.0 ± 14.8 N = 40 Subjects had type 2 DM.	Participants in the intervention group did not attend classes but rather were asked to complete 3 Learning Activity Packages, each of which required about 1.5 hours. The packages included a pretest and posttest, a list of goals and objectives, factual information, and a set of activities aimed at meeting the goals. The foci were: Meal Plan Practice, Eating Away from Home, and Sweeteners and Combination Foods.	The control group received traditional classroom instruction of comparable duration n = 20	Mean change in fasting plasma glucose (mg/dL)	baseline vs. 2 month	-17.4 NS	-45.1 p < 0.05	na
					baseline vs. 5 month	-1.2 NS	-38.8 NS	na
					mean value at 5 months	190.1 ± 41.9	164.4 ± 70.5	< 0.05
				Mean change in A1C (%)	baseline vs. 2 month	-0.5 NS	-3.2 p < 0.05	na
					baseline vs. 5 month	-1.0 NS	-4.5 p < 0.05	na
					mean value at 5 months	10.9 ± 4.5	9.4 ± 3.2	< 0.05
				Mean change in Knowledge score ¹	baseline vs. 2 month	+0.9 NS	+0.6 NS	na
					baseline vs. 5 month	+1.6 p < 0.05	+0.4 NS	na
					mean score at 5 months	21.0 ± 2.1	19.2 ± 2.5	NS
				Mean change in Behavior score ²	baseline vs. 2 month	+0.9 p < 0.05	+1.7 p < 0.05	na
					baseline vs. 5 month	+0.3 NS	+1.3 p < 0.05	na
					mean score at 5 months	7.7 ± 1.9	7.6 ± 1.9	< 0.05
				Mean change in percent of ideal body weight	baseline vs. 2 month	-2.9 p < 0.05	-1.3 NS	na
					baseline vs. 5 month	-2.9 p < 0.05	-2.3 NS	na
					mean percent at 5 months	133.9 ± 23.2	137.4 ± 35.7	< 0.05

The Knowledge score was based on a set of 25 test questions written by the authors and derived from the behavioral objectives of each Learning Activity Package; questions included true/false, multiple choice, and matching formats.

The Behavior score was based on a 10 question test consisting of yes/no questions such as "Do you follow a meal plan at home?", "Do you weigh or measure your food portions?", "Do you skip meals?". Derived from Bloomgarden ZT e : Randomized, controlled trial of diabetic patient education: improved knowledge without improved metabolic status. *Diabetes Care* 10:263-72. 1987.

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Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Time of Observation	Intervention Outcome	Control Outcome	p-value
Culturally Competent Diabetes Education for Mexican Americans: The Starr County Study. (Brown, 1999) US	RCT 1 year Mean age: 54 N = 247 Subjects had type 2 DM.	The target of the intervention was reduction of blood glucose levels, with weight loss as a secondary target. After consultation with focus groups, an intervention plan was constructed consisting of 12 weekly education sessions, in which locally-made videotapes and demonstrations were used, and followed by 11 biweekly support group sessions, lead by a health care worker. Subjects intervention team members were local and bilingual. n = 125 ¹	The control group was wait-listed for participation in the program. n = 122	Approximate mean body weight change from baseline (lbs.)	6 months	-4	+3	preliminary findings
					12 months	0	0	
				Mean change in fasting blood glucose from baseline (mg/dL)	6 months	-27.9	+8.4	preliminary findings
					12 months	-18.9	+3.9	
				Mean change in glycosylated hemoglobin from baseline (% age points)	6 months	nr	nr	preliminary findings
					12 months	-1.7	+0.3	
A Community-Based, Culturally Sensitive Education and Group-Support Intervention for Mexican Americans with NIDDM: A Pilot Study of Efficacy. (Brown, 1995) US	Pilot Study 2.5 months Mean age: 60.8 N = 5 Subjects had type 2 DM.	PILOT STUDY FOR Brown, 1999.	--	--	--	--	--	--

¹The intervention group had some problems with attendance drop-off after the switch to support group sessions, somewhat due to change in schedule.

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Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention (s)	Control	Outcome	Time of Observation	Intervention Outcome				p-value	
						Minimal	Individual	Group	Behavior		
The Relative Effectiveness of Educational and Behavioral Instruction Programs for Patients with NIDDM: A Randomized Trial (Campbell, 1996) Australia	RCT 12 months Age < 80 N = 238 Subjects had type 2 DM for < 5 yrs.	Minimal Program. Consisted of two 1-hour sessions that were conducted within 2 weeks of referral. The first session was with a nurse educator and the second with a dietitian. Sessions less detailed topically.	na	Change in mean A1C level from baseline		Minimal	Individual	Group	Behavior		
					3 months	-3.5 ± 0.6 n = 37	-3.4 ± 0.7 n = 33	-3.8 ± 0.6 n = 29	-4.7 ± 0.6 n = 46	NS	
					6 months	-2.2 ± 0.8 (n = 17)	-5.0 ± 0.9 (n = 27)	-3.9 ± 0.6 (n = 29)	-4.7 ± 0.7 (n = 43)	NS	
		12 months			Discontinued	-3.4 ± 0.7 (n = 19)	-3.8 ± 0.6 (n = 25)	-4.7 ± 0.6 (n = 39)	NS		
		3 months			2.3 ± 0.5 (n = 48)	4.7 ± 0.5 (n = 44)	3.5 ± 0.5 (n = 41)	5.5 ± 0.5 (n = 47)	< 0.001 among all groups		
		6 months			1.4 ± 0.7 (n = 19)	4.7 ± 0.5 (n = 38)	3.5 ± 0.5 (n = 38)	5.5 ± 0.5 (n = 46)	< 0.001 among all groups		
		12 months		Discontinued	4.2 ± 0.5 (n = 26)	4.4 ± 0.6 (n = 29)	5.6 ± 0.6 (n = 35)	NS			
					Individual Education Program Consisted of two sessions that were conducted within 2 weeks of referral, then sessions scheduled approximately monthly until 12 months from the initial visit. The two initial sessions with a nurse and dietitian, respectively, were for 1 hour and subsequent sessions with the nurse were for 30 minutes. Topics were explored in more detail than for the minimal program. Patients also were given the opportunity to attend a single 2-hour lecture on diet.						
		Group Education Program. Program consisted of at least two individual sessions and a 3-day small group education course. Individual monthly sessions were continued until a course could be scheduled. The 3-day course involved lectures, small group exercises, and practical sessions and included all of the topics covered in the other programs.									
		Behavioral Program. Program consisted of a series of individual visits from a nurse educator; three were within the first month, after which session frequency was dependent upon the patient's needs. The minimal schedule was visits after 3, 6, and 12 months, supplemented with random phone calls from the educator.									
		Number of subjects participating varied widely between measures for all groups (see outcome column).									

Diabetes knowledge: this variable was assessed using the 15-item diabetes knowledge scale (DKNA).

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Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Subgroup	Intervention Outcome	Control Outcome	p-value
A Randomized Controlled Trial of the Effect of Low Fat Diet Advice on Dietary Response in Insulin Independent Diabetic Women (de Bont, 1981) UK	RCT 6 months Mean age (low fat): 56 ±7 (low CHO): 54 ±8 N = 148 Subjects had type 2 DM.	Individuals in the Low fat group received individualized diet counseling with the goal of reducing their fat intake to 30% of total energy, while increasing the portion of carbohydrates. n = 71	Individuals in the Low CHO group were given individualized diet counseling with the goal of not allowing their CHO intake to exceed 40% of total energy. n = 77	Mean change in total fats (%)	all	-10.1 ± 10.8	-1.0 ± 10.5	< 0.001
				Mean change in saturated fats (%)	all	-8.1 ± 5.8	-1.1 ± 5.7	< 0.001
				Mean change in dietary cholesterol (mg/1000 kcal)	all	-105 ± 163	24 ± 172	< 0.001
				Mean change in body weight (kg)	obese patients only	-2.7 ± 3.6 (n = 34)	-0.9 ± 3.5 (n = 35)	< 0.05

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Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention (s)	Control	Outcome	Time of Observation	Intervention Outcome	Control Outcome	p-value	
Metabolic Impact of Education in NIDDM (d'Eramo-Melkus, 1992) US	RCT 6 months Mean age: 55 ± 8.05 Age range: 21-65 N = 82 ¹	11-week diabetes education and weight-reduction intervention with one individual session by week 4 for content clarification n = 15 ²	Minimal skills educational intervention ⁴ n = 15 ⁵	Mean weight (lb)	Baseline	211.84 ± 2 7.78	200.65 ± 30.70	215.25 ± 2 5.47	nr
					3 month	199.96 ± 30.13 p < 0.01	192.42 ± 32.09 p < 0.01	209.46 ± 25.14 p < 0.01	nr
					6 month	200.72 ± 30.44 NS	191.80 ± 31.73 NS	205.14 ± 2 5.59 NS	nr
				Mean fasting blood glucose (mM)	Baseline	11.59 ± 3.67	12.21 ± 3.85	11.34 ± 3.29	nr
					3 month	8.83 ± 2.68 p < 0.05	10.08 ± 4.66 p < 0.05	10.31 ± 4.05 NS	nr
					6 month	9.45 ± 3.61 NS	9.03 ± 3.00 NS	12.18 ± 5.46 NS	nr
		Mean A1C (%)		Baseline	10.72 ± 3.16	11.15 ± 2.92	10.91 ± 2.60	nr	
				3 month	8.58 ± 2.55 p < 0.05	8.82 ± 2.77 p < 0.01	10.54 ± 3.11 p < 0.05	nr	
				6 month	9.17 ± 3.30 NS	8.26 ± 2.72 NS	10.50 ± 3.21 NS	nr	
		Mean cholesterol (mM)		Baseline	6.19 ± 0.90	6.08 ± 1.82	5.75 ± 1.19	nr	
				3 month	5.58 ± 0.72 p < 0.01	5.48 ± 1.63 p < 0.01	5.83 ± 1.23 p < 0.01	nr	
				6 month	5.71 ± 1.14	5.57 ± 0.84	5.68 ± 1.19	nr	
		11-week group education intervention (including individual session for content clarification) plus 2 individual follow-up counseling sessions n = 19 ³							

33 dropped out by the 6-month follow-up; subjects were obese.

originally 28 subjects

originally 26 subjects

food measurement, setting weight and calorie goals, self-monitored blood glucose with Chemstrip bg, and foot care

originally 28 subjects

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Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Time of Observation	Intervention Outcome		Control Outcome	p-value
Randomized Controlled Multicentre Evaluation of an Education Programme for Insulin-treated Diabetic Patients: Effects on Metabolic Control, Quality of Life, and Costs of Therapy (de Weerd, 1990) The Netherlands	RCT 6-7 months Mean age: 44.8 N = 558 Subjects had type 1 DM.	Two experimental groups were enrolled in an out-patient education program, designed to instruct patients on self-care, consisting of 4 weekly group sessions lasting 3 hours each and with ideally 10 patients each. Group one attended health care worker-led sessions n = 183 Group two attended patient-led sessions. The program included a book, a video, and practice materials. n = 172	The control group attended no sessions. n = 203	A1C(%)		health care worker-led	patient-led		
					baseline	9.1	8.9	9.2	NS
				Quality of life rating ¹	change at 6 months post- program	-0.2	-0.3	-0.1	NS
					baseline	6.8	7.0	6.9	NS
				change in hospital stays (days per 6 months)	change at 6 months post- program	-0.1	0.0	-0.1	NS
					6 months post- program	-0.7	-0.7	-0.5	NS
change in physician visits (visits per six months)	6 months post- program	-0.2	-0.1	-0.3	NS				

¹Patients were asked to rate their quality of life on a scale of 1 to 10.

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Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Subgroup	Intervention Outcome		Control Outcome	p-value
						lifestyle modification	metformin		
Reduction in the Incidence of Type 2 Diabetes with Lifestyle Intervention or Metformin. (Diabetes Prevention Program Research Group, 2002) US	RCT ~3 years Mean age: 51 N=3234 Subjects had type 2 DM.	Intervention participants received one of two interventions: one group received metformin (850 mg twice daily) as well as standard lifestyle modification advice. n = 1073 The other group was enrolled in a lifestyle modification program with the goals of at least 7% weight reduction and 150 minutes of physical activity per week. The education program consisted of 16 lessons taught one-on-one weekly plus subsequent individual sessions and group sessions to reinforce behavioral change. n = 1079	Control participants were given a placebo and standard lifestyle modification advice. n = 1082	Mean weight loss (kg)	all	5.6	2.1	0.1	< 0.001
				Mean change in physical activity (MET-hr/wk)	all	~8	~2	~2	< 0.001
					all	4.8	7.8	11.0	< 0.05
				Incidence of diabetes in case/100 person-year	age > 59	3.1	9.6	10.8	< 0.05

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Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Comparisons ¹	Intervention Outcome	Control Outcome	p-value
Problem Oriented Participatory Education in the Guidance of Adults with Non-insulin-treated Type-II Diabetes Mellitus. (Falkenberg, 1986) Sweden	RCT 3 month program, 9 month follow-up Age range: 55-73 N = 45 Subjects had type 2 DM.	Problem oriented participatory education, or POPE, is a method of education designed to include the learners (in this case, the patients) in guiding their own educational process, with the objective of dealing with a specific problem (in this case, diabetes). Staff trained by the study's educational specialists led eight 2-hour sessions in which the patients took part in planning the methods and materials of the course based on their needs. Materials were compiled at the end of the course into a book distributed to the participants. n = 27 at baseline n = 23 at conclusion	Control group participants received a one-day standard educational session on diabetes therapy, diet, and foot care, including an informative visit to a grocery store. n = 18 at baseline n = 11 at conclusion	Mean knowledge test score -- general knowledge ²	Control vs. Intervention at Test 2	nr	nr	< 0.01
					Baseline vs. Test 1	p < 0.001	nr	na
					Baseline vs. Test 2	p < 0.001	nr	na
				Mean knowledge test score -- signs of hyperglycemia	Control vs. Intervention at Test 2	nr	nr	< 0.01
					Baseline vs. Test 1	p < 0.001	nr	na
					Baseline vs. Test 2	p < 0.001	nr	na
				Mean knowledge test score -- evaluation of blood glucose	Control vs. Intervention at Test 2	nr	nr	NS
					Baseline vs. Test 1	p < 0.01	nr	na
					Baseline vs. Test 2	p < 0.05	nr	na
				Mean knowledge test score -- diet	Control vs. Intervention at Test 2	nr	nr	NS
					Baseline vs. Test 1	p < 0.01	nr	na
					Baseline vs. Test 2	p < 0.05	nr	na
				Mean A1C (%)	Control vs. intervention at Test 1	nr	nr	< 0.05
					Control vs. intervention at Test 2	nr	nr	NS
				Mean percent of fat in energy consumed at Test 1	men	34.1 ± 4.5 (n = 11)	40.0 ± 4.1 (n = 4)	< 0.05
women	34.9 ± 5.4 (n = 11)	35.1 ± 2.3 (n = 7)	NS					

Tests were given before the intervention, after the intervention (Test 1), and 6 months later (Test 2).

Subjects knowledge scores in this study were assessed using an author-developed self-administered 40-question multiple-choice test that addressed the areas listed in the outcomes. Participants used the same test paper for each exam so they were not told how they had performed on the test.

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Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Time of Observation	Intervention Outcome	Control Outcome	p-value
Dietary Advice Based on the Glycaemic Index Improves Dietary Profile and Metabolic Control in Type 2 Diabetic Patients. (Frost, 1993) UK	RCT 12 weeks Mean age (low GI): 54 ± 2 (control): 56 ± 3 N = 51 Subjects had type 2 DM.	Newly diagnosed patients were enrolled in a 12-week program in which they received dietary advice following the British Diabetic Assn. guidelines AND advice on identifying and including food with low Glycaemic Indices. n = 25	Newly diagnosed patients were enrolled in a 12-week program in which they received dietary advice following the British Diabetic Assn. guidelines only. n = 26	Mean fructosamine (mmol l ⁻¹)	baseline	3.8 ± 0.2	3.6 ± 0.2	< 0.05
					post-program	3.2 ± 0.2 NS	3.6 ± 0.2 NS	
				Mean cholesterol (mmol l ⁻¹)	baseline	6.2 ± 0.3	5.6 ± 0.1	< 0.05
					post-program	5.5 ± 0.3 NS	5.3 ± 0.1 NS	
				Mean fasting blood glucose (mmol l ⁻¹)	baseline	12.2 ± 0.7	11.1 ± 0.7	NS
					post-program	9.6 ± 0.6 p < 0.05	9.8 ± 0.6 NS	
				Mean triglycerides (mmol l ⁻¹)	baseline	1.9 ± 0.2	2.5 ± 0.4	< 0.05
					post-program	1.4 ± 0.2 p < 0.05	2.1 ± 0.2 NS	

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Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Time of Observation	Intervention Outcome		Control Outcome	p-value
						Group A	Group B		
Diabetes Support Groups Improve Health Care of Older Diabetic Patients. (Gilden, 1992) US	Partially RCT ~ 2 years Mean age: 68 ± 1.3 N = 32 Subjects had DM.	Group A received an education program (6 weekly sessions) plus enrollment in a support group for 18 months. n = 11 Group B received only the education program. n = 13 Education sessions were once a week and were led by a multi- disciplinary team consisting of a diabetologist, a nurse-educator, a dietician, a psychologist, a podiatrist, and a social worker.	Group C was a convenience sample of individuals not enrolled in either intervention. n = 8	Mean Depression Index score ¹ at 2 years	Follow-up at 2 years	43 ± 6	51 ± 3	56 ± 2	NS
				Mean A1C at 2 years	Follow-up at 2 years	6.6 ± 0.3	6.5 ± 0.2	8.4 ± 0.7	Group A p < 0.05 Group B nr
				Mean knowledge score ²	Follow-up at 2 years	38 ± 1 p < 0.05	36 ± 1 NS	nr	nr
					baseline ³	36 ± 4			
					post-program ⁴	38 ± 4 p < 0.05			
				Mean Quality of Life ⁵ (total) score	Follow-up at 2 years	78 ± 6 p < 0.01	71 ± 2 p < 0.05	nr	nr
					baseline	62 ± 13		na	na
					post-program	65 ± 9 p < 0.01			
				Mean social activity score ⁶	Follow-up at 2 years	8 ± 1 NS	10 ± 1 NS	nr	nr
					baseline	9 ± 4		na	na
					post-program	8 ± 4 NS			

Depression was assessed using Zung's Mood Scale, a 20-question test. Scores range from 25-100; 50-59=mild to moderate depression, 60-69=moderate to severe depression, 70 or greater = severe depression.

Knowledge was assessed using an author-developed test consisting of 24 true/false questions encompassing general knowledge, nutrition, and pharmacy; it was designed to cover the content of the education program. It is printed in Gilden, 1989.

Baseline of both education groups combined.

Measures immediately after the education program for both education groups combined.

Quality of Life was assessed using an author-developed test consisting of 21 true/false questions and 2 open questions ("Who prepares the meals at home?" and "What type and dose of medication are you taking?") encompassing general satisfaction, diet, exercise, medication, and self-monitoring of blood glucose. The maximum score is 100 points. It is printed in Gilden, 1989.

Social activity was assessed using 3 five-point questions. Participants indicated how frequently ("very frequently" to "very rarely") they participated in "social activities with friends," "social activities with relatives," and "community affairs".

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Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Time of Observation	Intervention Outcome	Control Outcome	Group difference	p-value
Long Term Effects and Costs of Brief Behavioural Dietary Intervention for Patients with Diabetes Delivered from the Medical Office (Glasgow, 1997) US	RCT 12 months Mean age (intervention): 61.7 ± 12.1 (control): 63.1 ± 10.5 N = 206 Subjects had DM. n = 106 -108	Brief intervention: usual care + single session that included an additional 5-10 minutes touchscreen dietary barriers assessment with immediate feedback on key barriers to dietary self-management and 20 minutes with interventionist for patient centered goal setting and problem solving and to receive dietary self-help materials. The computer feedback, personalized counseling, and self-help materials were coordinated to produce an individualized goal setting plan to lower fat intake	Usual care: high quality quarterly medical care intervention including regular assessment and follow-up of microvascular and macrovascular risk factors in addition to the touchscreen computer assessment. n = 90 - 98	Change in serum cholesterol (mg/dL)	12 months	208 – 217	226 – 223	15 ¹	0.002
				Change in A1C (%)	12 months	7.8 – 7.9	7.8 – 7.9	nr	NS
				Change in body mass index (kg/ sq. m)	12 months	30.5 – 30.4	30.4 – 30.2	nr	NS
A brief office-based intervention to facilitate diabetes dietary self-management. (Glasgow, 1995) US	RCT progress report	This article is NOT a report on a completed study. Rather, it is report on baseline data for the study fully described in Glasgow, 1997.	--	--	--	--	--	--	--

covariate adjusted difference

LIFESTYLE MODIFICATION

Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Time of Observation	Intervention Outcome	Control Outcome	p-value
Improving Self-care Among Older Patients with Type II Diabetes: The "Sixty Something..." Study. (Glasgow, 1992) US	RCT 3 month program, 3 month follow-up Mean age (intervention): 67.1±4.3 (control): 67.2 ± 5.8 Age >60 N=102 Subjects had type 2 DM. n = 52 ¹	Based on previous research, the authors found that patients with diabetes adhere less well to lifestyle modifications than to medical regimens, so the intervention group was placed in a 3-month, 10-session education program focused on diet and exercise, with limited discussion of regular blood glucose monitoring. Sessions were led by an interdisciplinary team, with emphasis on individualized plans and goal-setting. Exercise (walking) sessions were also held, during which social interaction was encouraged.	Participants in the control group were enrolled in the program after the intervention group completed it. n = 50	Mean calories per day (from 3 day food record)	0 months	1631.6 ± 494.6	1636.1 ± 412.5	Sig.
					3 months ²	1468.2 ± 474.0 Sig	1686.0 ± 426.7	
					6 months ³	1511.6 ± 432.7 Sig	1413.5 ± 355.7 Sig	
				Mean number of days/week exercised	0 months	4.4 ± 2.4	3.7 ± 2.3	NS
					3 months	4.5 ± 2.0 NS	3.7 ± 1.8	
					6 months	4.4 ± 2.1 NS	4.6 ± 1.9 Sig.	
				Average minutes of activity per day	0 months	36.3 ± 5.2	34.6 ± 2.1	NS
					3 months	36.2 ± 3.2 NS	34.5 ± 2.2	
					6 months	50.8 ± 4.7 Sig.	35.8 ± 4.6 NS	
				Mean glycosylated hemoglobin	0 months	6.8 ± 1.6	7.4 ± 1.8	NS
					3 months	6.3 ± 1.5 p < 0.05	7.0 ± 1.5	
					6 months	6.7 ± 1.7 NS	6.4 ± 1.4 p < 0.05	
Mean score on diabetes quality of life scale ⁴	0 months	37.9 ± 8.8	36.8 ± 8.0	NS				
	3 months	38.1 ± 9.2 NS	36.3 ± 8.0					
	6 months	38.2 ± 7.4 NS	37.2 ± 7.5 NS					

¹Participants attended 60% of exercise sessions on average.

²End of program for intervention group.

³Follow-up for intervention group; end of program for control group.

⁴Quality of life was assessed based on a modification of the Diabetes Control and Complications Trial Quality of Life Scale. DCCT Research Group: Reliability and validity of a diabetes quality-of-life measure for the DCCT. *Diabetes Care*. 11:725-732. 1988

LIFESTYLE MODIFICATION

Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Time of Observation	Intervention Outcome		Control Outcome	p-value	
						Nutrition + Social Learning	Nutrition			
Nutrition Education and Social Learning Interventions for Type II Diabetes. (Glasgow, 1989) US	RCT ~ 3 months Age range: 42-75 N = 78 Subjects had type 2 DM.	<p>Participants were assigned to one of two groups:</p> <p>One group received nutrition education only.</p> <p>n = 20</p> <p>One group received nutrition education plus social learning.</p> <p>n = 23</p> <p>The nutrition education component focused on: calorie reduction, fat intake reduction, and dietary fiber increase. The social learning component added individualized goal-setting and examination of barriers to adherence, and introduced a problem-solving method. The classes lasted 5 weeks.</p>	<p>A third group was a wait-listed control group.</p> <p>n = 16</p>	Mean calories consumed					no significant differences between nutrition and Nutri. + Soc.	
					baseline	1657.9 ± 508.8	1874.8 ± 582.4	1835.2 ± 643.2		
					Post-program	1657.7 ± 458.7 NS	1651.2 ± 527.8 p < 0.01	1788.9 ± 547.0 NS		
					Follow-up ¹	1519.8 ± 450.9 p < 0.05	1554.1 ± 504.8 p < 0.001	1818.1 ± 471.5 NS		
					Mean percent of calories from fat	baseline	40.6 ± 7.0	36.2 ± 8.0		38.5 ± 9.7
						Post-program	35.7 ± 9.5 p < 0.01	35.6 ± 8.2 NS		35.3 ± 10.4 NS
						Follow-up	36.8 ± 6.7 p < 0.01	38.1 ± 9.4 NS		39.2 ± 9.0 NS
					Mean grams of fiber consumed	baseline	23.3 ± 10.8	19.8 ± 8.5		26.2 ± 19.4
						Post-program	24.3 ± 10.3 NS	24.7 ± 13.1 NS		21.3 ± 15.5 NS
				Follow-up		21.9 ± 8.0 NS	19.0 ± 8.6 NS	24.2 ± 22.8 NS		
Glycemic control	There were no significant differences in glycemic control between the groups.									

¹Two months after completion of the program

LIFESTYLE MODIFICATION

Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Time of Observation	Intervention Outcome	Control Outcome	p-value
Usefulness of a Systemic Hypertension In-Hospital Educational Program. (Gonzalez-Fernandez, 1990) Puerto Rico	RCT 9 weeks Mean age (intervention): 60 ± 10 (control): 58 ± 12 N = 47	Both groups were patients admitted to a hospital. Three BPs were taken to establish baseline, then questionnaires regarding BP knowledge were given. In the intervention group, patients were then given four, 15-20 minute educational sessions on basic knowledge, diet, exercise, and medications by a multidisciplinary team. n = 25	Patients in the control group completed the questionnaire but did not receive the educational sessions. n = 22	Mean systolic BP	Baseline	151 ± 23	144 ± 13	NS
					Follow-up ¹	137 ± 16	154 ± 30	0.005
					Change	-14	+10	0.001
				Mean diastolic BP	Baseline	100 ± 13	101 ± 11	NS
					Follow-up	89 ± 10	98 ± 11	0.006
					Change	-11	-3	0.010

Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Time of Observation	Intervention Outcome	Control Outcome	p-value	
Diabetes Intervention Study: Multi-intervention Trial in Newly Diagnosed NIDDM (Hanefeld, 1991) Germany	RCT 5 year Mean age: 46 ² N=1008 Subjects had type 2 DM, newly diagnosed.	The intervention consisted of several elements: 1) instructions on low calorie diets, 2) instructions on lipid lowering diet, 3) recommendations on physical activity, 4) antismoking message, 5) anti-hypertensive drugs, if indicated by two consecutive measurements, 6) placebo or clofibrac acid for cholesterol -- non-responders were discontinued. IHE = Intensified Health Education. n = 630	n = 378			IHE	IHE plus clofibrac acid		
				Mean energy consumption (kj/day) at year 5	5 years	9073 ± 2156	8918 ± 2483	9362 ± 2621	NS
				Mean ratio of polyunsaturated fat to saturated fat at year 5	5 years	0.39 ± 0.19	0.41 ± 0.18	0.26 ± 0.14	< 0.01 for both intervention groups
				Mean cholesterol (mM) at year 5	5 years	7.24 ± 2.87	7.17 ± 2.67	7.66 ± 3.06	NS
				Mean physical activity ³	5 years	328 ± 234	326 ± 231	174 ± 191	< 0.01 for both interventions

Eight weeks after completion of the program

Mean age for control: 46.6 ± 5.6, IHE plus placebo: 46.2 ± 7.0, IHE plus clofibrac acid: 45.8 ± 8.8

Measure is unreported.

LIFESTYLE MODIFICATION

Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Time of Observation	Intervention Outcome	Control Outcome	RR	95% CI for RR	p-value
Group Education for Obese ¹ patients with Type 2 Diabetes: Greater Success at Less Cost (Heller, 1988) U.S.	RCT 12 months Age range: 30 - 75 N = 75 Subjects had type 2 DM, newly diagnosed.	Group (4-6 patients each with spouse or friend) education classes run by diabetes nurse specialists and a dietitian. Three 90-minute sessions at weekly intervals with follow-up visits (90 minutes) at 3 and 6 months. Subjects were told that the aim of treatment was to lose weight. Patients could contact nurses at any time. n = 36	Usual care n = 39	Mean A1C (%)	Baseline	12.3 (11.4 - 13.2) ²	12.7 (11.9 - 13.5)	0.4	-0.86 - 1.52	NS
					3 months	8.6 (7.9 - 9.3)	9.7 (9.0 - 10.4)	1.1	0.1 - 2.1	< 0.05
					6 months	7.5 (7.0 - 8.1)	9.5 (8.7 - 10.4)	2.0	0.9 - 3.0	< 0.001
					12 months	9.0 (8.2 - 9.8)	9.9 (8.9 - 10.9)	0.9	-0.4 - 2.2	NS
				Change in mean (CI) fasting blood glucose (mmol ⁻¹)	12 months	9.1 (7.9 - 10.3)	10.3 (8.8 - 11.8)	1.2	-0.7 - 3.1	NS
				Change in mean knowledge questionnaire score ³	12 months	24.4 (23.3 - 25.5)	18.4 (17.2 - 19.7)	6.0	2.5 - 8.7	< 0.001
				Median change in weight (kg)	3 months	6 (5 - 7)	3.5 (1.5 - 5)	nr	nr	< 0.002
					6 months	7 (5.5 - 9)	2 (1 - 5)	nr	nr	< 0.002
					12 months	5.5 (4 - 6.5)	3 (2 - 4)	nr	nr	< 0.05

BMI > 27 kg m⁻²)

95 % confidence interval

Knowledge was assessed using a author-developed multiple-choice questionnaire with a maximum 36 points, with 18 for dietary questions.

LIFESTYLE MODIFICATION

Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Time of Observation	Intervention Outcome	Control Outcome	p-value
Evaluation of a Pharmaceutical Care Model on Diabetes Management. (Jaber, 1996) US	RCT 4 months Mean age (intervention): 59 ± 12 (control): 65 ± 12 N = 39 Subjects had type 2 DM. n = 17	The intervention included the following components: 1) diabetes-specific pharmacotherapeutic evaluation and dosage adjustment, 2) comprehensive and individualized diabetes education, 3) training in recognizing hypo- and hyperglycemia, 4) medication counseling, 5) specific instructions for diet regulation and an exercise plan, and 6) training in self-monitoring blood glucose, including written instructions.	Patients in the control group continued their standard care, and reported to the clinic only for initial and final assessment. n = 22	Mean fasting plasma glucose (mmol/L)	baseline	11.1 ± 4.0	12.7 ± 4.7	na
					final	8.5 ± 2.3 p < 0.05	11.0 ± 3.9 NS	na
					change	2.6 ± 3.4	1.8 ± 3.9	< 0.05
				Mean glycated hemoglobin (%)	baseline	11.5 ± 2.9	12.2 ± 3.5	na
					final	9.2 ± 2.1 p < 0.05	12.1 ± 3.7 NS	na
					change	2.2 ± 2.6	0.1 ± 3.0	< 0.05
				Mean blood pressure -- systolic	baseline	147 ± 23	nr	NS
					change	140 ± 20 p < 0.07	nr	
				Mean blood pressure -- diastolic	baseline	88 ± 9	nr	NS
					change	82 ± 10 p < 0.07	nr	na
Quality-of-life ¹	No significant changes were seen in quality of life measures.							

¹Quality of life was assessed using the SF-36 survey.

LIFESTYLE MODIFICATION

Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Intervention Outcome	Control Outcome	OR ¹	95% CI for OR ²	p-value for OR	p-value
Reduction of Lower Extremity Clinical Abnormalities in Patients with Non-Insulin-Dependent Diabetes Mellitus: A Randomized, Controlled Trial. (Litzelman, 1993) US	RCT 1 year Mean age (intervention): 60.9 ± 9.8 (control): 59.9 ± 9.4 N = 352 ³ Subjects had type 2 DM.	Patients in the intervention group were provided with education by a nurse-clinician using slides and videos, and were asked to fill out behavioral contracts agreeing to perform self-foot care activities. They received phone and postcard reminders at 1 and 3 months. Their healthcare systems were provided with information packets and their healthcare providers were instructed to perform foot exams and remind the patient about foot care at each visit, via documents attached to the patients' charts. n = 191	n = 205	Incidence of serious foot lesions	2.9 (n = 351)	nr	0.41	0.16 - 1.00	0.05	na
				Incidence of fungal nail infection	67.0 (n = 351)	nr	0.70	0.46 - 1.07	0.10 (one-tailed) ⁴	na
				Prevalence of foot inspection by patient	61.5 (n = 352)	nr	0.23	0.12 - 0.42	< 0.01	na
				Prevalence of finding foot ulcers by doctors	23.8 (n = 185)	11.1 (n = 198)	nr	nr	nr	< 0.01
				Prevalence of finding fungal infections by doctors	3.2 (n = 185)	0.5 (n = 198)	nr	nr	nr	0.06
				Prevalence of pulse examinations by doctors	9.2 (n = 185)	3.0 (n = 198)	nr	nr	nr	0.01

Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Time of Observation	Intervention Outcome	Control Outcome	p-value
Prevention of Amputation by Diabetic Education. (Malone, 1989) US	RCT 2 years Age nr N = 182 ⁵ Subjects had DM.	Participants in the education group were given a brief education program concerning examination and care of feet. n = 90 n = 177 limbs	Control participants received no education. n = 92 n = 177 limbs	Incidence of "Success" (# of limbs)	2 years	160	128	< 0.0005
				Incidence of "Failure" -- Infection (# of limbs)	2 years	2	2	NS
				Incidence of "Failure" -- Ulcer (# of limbs)	2 years	8	26	< 0.0005
				Incidence of "Failure" -- Amputation (# of limbs)	2 years	7	21	< 0.025

The odds ratio (OR) measures the odds of an event happening in the experimental group, expressed as a proportion of the odds of an event happening in the control group. The 95% confidence interval would include 95% results from studies of the same size and design in the same population.

395 recruited

In a one-tailed test, it assumed that all risk of error is in one direction (greater or lesser than the mean).

203 recruited

LIFESTYLE MODIFICATION

Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Time of Observation	Intervention Outcome	Control Outcome	p-value
The Diabetes Education Study: A Controlled Trial of the Effects of Diabetes Patient Education. (Mazzuca, 1986) US	RCT 4 years Median age: 58.1 N = 275 ¹ Subjects had DM.	SEE ALSO Vinicor, 1987. Participants were grouped into four groups. In Group 2, patients received diabetes education. In Group 3, the patients' physicians received diabetes education, but the patients themselves did not. In Group 4, the patients and their physicians received diabetes education. For the purposes of this article, Groups 2 and 4 are the intervention group, because the article is focused on patient education. Patient education consisted of didactic instruction on diabetes, diet, hypertension, and foot care; goal setting for compliance; and phone calls for goal-setting reinforcement. n = 133	Group 1, in which neither patients nor physicians received education, and Group 3, in which only the physicians received education, serve as the controls for the purposes of this article. n = 139	Percentage of patients who can define diabetes	~13 months after intervention	41.1	38.1	NS
				Percentage of patients who can list at least two symptoms of hyperglycemia	~13 months after intervention	47.4	50.4	NS
				Percentage of patients who can list at least two causes of hyperglycemia	~13 months after intervention	51.1	30.9	0.0005
				Percentage of patients who can correctly interpret urine test result	~13 months after intervention	93.2 (n = 132)	82.3 (n = 130)	0.0058
				Mean change in A1C(%)	~13 months after intervention	-0.43 (n = 120)	+0.35 (n = 127)	< 0.05
				Mean Body weight (kg)	~13 months after intervention	83.61 (n = 119)	84.87 (n = 116)	NS

¹532 recruited.

LIFESTYLE MODIFICATION

Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Time of Observation	Intervention Outcome	Control Outcome	p-value
A Randomized Trial of Improved Weight Loss with a Prepared Meal Plan in Overweight and Obese Patients: Impact on Cardiovascular Risk Reduction. (Metz, 2000) US	RCT 13 months Mean age (intervention): 54.6 ± 9.0 (control): 54.0 ± 9.9 N = 119 ¹ Subjects had type 2 DM.	Intervention participants were placed on a dietary plan with the targets of: 22% energy from fat, 58% energy from carbohydrate, 20% energy from protein. Participants were supplied with prepared meals consisting of 7 breakfasts, 13 lunches, 12 dinners, and 8 snacks from which to select. Participants ordered meal choices every 2 weeks and the meals were delivered to their homes. n = 56	The control group was placed on the same dietary plan but was not given prepared meals. Monetary compensation for food purchases was offered. n = 63	Mean change in systolic blood pressure (mm Hg)	baseline	137.0 ± 15.3 (n = 56)	138.0 ± 12.8 (n = 63)	NS
					12 weeks	-8.5 ± 9.4 (n = 54)	-5.7 ± 8.0 (n = 56)	
					26 weeks	-7.0 ± 11.2 (n = 43)	-6.0 ± 10.7 (n = 51)	
					52 weeks	-8.8 ± 12.6 (n = 41)	-9.9 ± 13.2 (n = 51)	
				Mean change in cholesterol (mmol/L)	baseline	5.38 ± 1.0 (n = 56)	5.28 ± 0.87 (n = 63)	< 0.05 for change through time between groups
					12 weeks	-0.28 ± 0.62 (n = 54)	-0.06 ± 0.46 (n = 56)	
					26 weeks	0.39 ± 0.40 (n = 43)	0.70 ± 0.53 (n = 51)	
				Mean change in blood glucose (mmol/L)	baseline	10.5 ± 2.8 (n = 56)	11.1 ± 2.6 (n = 63)	< 0.05 for change through time between groups
					12 weeks	-2.1 ± 2.6 (n = 54)	-0.6 ± 2.3 (n = 56)	
					26 weeks	-1.7 ± 3.0 (n = 43)	-0.5 ± 2.7 (n = 51)	
					52 weeks	-0.6 ± 3.3 (n = 41)	-0.6 ± 3.4 (n = 51)	
				Mean change in glycosylated hemoglobin (%)	baseline	8.76 ± 1.43 (n = 56)	8.82 ± 1.24 (n = 63)	< 0.05 for change through time between groups
					12 weeks	-1.04 ± 1.03 (n = 54)	-0.31 ± 1.07 (n = 56)	
					26 weeks	-0.87 ± 1.29 (n = 43)	-0.22 ± 1.30 (n = 51)	
					52 weeks	-0.24 ± 1.52 (n = 41)	-0.20 ± 1.30 (n = 51)	
				Mean change in energy from carbohydrates (%)	after 52 weeks	5.9 ± 10.2 (n = 39)	1.6 ± 10.0 (n = 47)	< 0.001
				Mean change in energy from fat (%)	after 52 weeks	-7.4 ± 9.0 (n = 39)	-2.8 ± 8.3 (n = 47)	< 0.001

Patients with type 2 diabetes mellitus are a subset of this study (overall N=302). Their outcomes are presented separately in the article.

LIFESTYLE MODIFICATION

Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Time of Observation	Intervention Outcome	Control Outcome	p-value				
Nutrition Education Improves Metabolic Outcomes among Older Adults with Diabetes Mellitus: Results from a Randomized Controlled Trial. (Miller, 2002) US	RCT 10 weeks Mean age (intervention): 72.1 ± 4.2 (control): 73.0 ± 4.2 Age > 64 N = 98 Subjects had type 2 DM. n = 45	The intervention was an education developed from a range of theoretical bases. Key elements included limiting the number of topics introduced at a single session, organizing concepts into meaningful units, reinforcing previously discussed concepts, and integrating new concepts into previously existing knowledge. Sessions were weekly and lasted 1.5-2 hours, and were led by a dietician.	The control group received conventional care. n = 47	Mean total cholesterol (mg/dl)	value	185.0 ± 2.9	196.9 ± 2.8	NS				
					percent achieving clinical target	35.9	26.1	< 0.05				
				Mean fasting blood glucose (mg/dl)	value	134.4 ± 4.4	155.4 ± 4.3 (n = 46)	< 0.05				
					percent achieving clinical target	23.9	16.3 (n = 46)	NS				
				Mean A1C (%)	value	6.7 ± 0.1	7.4 ± 0.1	< 0.01				
					percent achieving clinical target	33.7	23.9	< 0.05				
				Patient Choice in Diabetes Education Curriculum: Nutritional versus standard content for Type 2 diabetes. (Noel, 1998) US	RCT 5 week program, 6 month follow-up Mean age: 50.7 ± 10.9 N = 596 Subjects had type 2 DM. n = 305 for choice group n = 291 for no-choice group	The primarily Hispanic (84.7%) participants were assigned to a choice vs. no choice condition. Patients given a choice were able to select either a standard (22%) or a nutrition-oriented (78%) program.	Participants with no choice were evenly distributed between the programs. n = 291	Percent completing all 5 classes	choice vs. no-choice	52	52	NS
										Nutrition n = 383	Standard n = 213	
Mean A1C (%)	baseline	9.0	9.1					NS				
	post-program	8.5	8.2					0.00352 ¹				
Mean serum cholesterol (mmol/l)	baseline	5.11	5.09					NS				
	post-program	5.04	5.22					0.00394 ²				

Reported as significant, but since assignment to nutrition/standard was not random in all cases, this is not a valid use of statistics.

Reported as significant, but since assignment to nutrition/standard was not random in all cases, this is not a valid use of statistics.

LIFESTYLE MODIFICATION

Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Time of Observation	Intervention Outcome	Control Outcome	p-value
Multicenter Randomized Trial of a Comprehensive Prepared Meal Program in Type 2 Diabetes. (Pi-Sunyer, 1999) US	RCT 3.5 months Age range: 25-70 N = 202 Subjects had type 2 DM. n = 100	Intervention participants were placed on a dietary plan of 55-60% carbohydrate, 15-20% protein, and 20-30% fat. They received prepared food packages that consisted of 6 breakfasts, 8 lunches, 10 dinners, and 6 snacks, provided free of charge and delivered to the participants' homes. The plan is known as the Campbell's Center for Nutrition and Wellness meal plan.	Control participants were given a similar dietary plan but were not provided with food. n = 102	Mean plasma cholesterol (mmol/L)	baseline	5.64 ± 0.85 (n = 100)	5.37 ± 0.81 (n = 102)	nr
					post-program	5.44 ± 0.88 (n = 95) p < 0.01	5.11 ± 0.77 (n = 100) p < 0.001	nr
				Mean plasma glucose (mmol/l)	baseline	10.6 ± 3.3 (n = 97)	11.4 ± 3.2 (n = 101)	nr
					post-program	8.9 ± 3.2 (n = 92) p < 0.0001	9.7 ± 3.0 (n = 100) p < 0.0001	nr
				Mean A1C (%)	baseline	8.8 ± 1.6 (n = 96)	8.9 ± 1.6 (n = 101)	nr
					post-program	7.8 ± 1.5 (n = 92) p < 0.0001	8.2 ± 1.6 (n = 100) p < 0.0001	nr
				Mean daily cholesterol intake (mg)	baseline	280 ± 141	331 ± 161	nr
					post-program	114 ± 50 NS	202 ± 86 NS	nr
Mean daily fat intake (%)	baseline	34 ± 6.8	36 ± 6.3	nr				
	post-program	18 ± 3.6 NS	27 ± 6.9 NS	nr				
A Randomized Trial Comparing Intensive and Passive Education in Patients with Diabetes Mellitus (Raji, 2002) U.S.	RCT 12 months Mean age: 60 ± .3 N = 106 ¹ Subjects had DM. n = 50	Intensive education: 3.5 days of structured curriculum in groups of 4-6 participants with core elements from the ADA diabetes education curriculum. Professionals involved in the program included a physician, nurse, nutritionist, pharmacist, exercise physiologist, and social worker.	Passive education: educational materials mailed every 3 months covering general diabetes management, nutrition, CAD, and foot care. n = 56	Change in mean A1C (%)	12 months	-2.0% p < 0.001	-1.9% p < 0.001	NS

¹Subjects had A1C levels > 8.5%

LIFESTYLE MODIFICATION

Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Time of Observation	Intervention Outcome	Control Outcome	p-value
Improved Control of Type 2 Diabetes Mellitus: A Practical Education/Behavior Modification Program in a Primary Care Clinic. (Ridgeway, 1999) US	RCT ¹ 6 month program, 6 month follow-up Mean age (intervention): 62 (control): 65 N = 38 Subjects had type 2 DM.	The intervention consisted of 1.5-hour classes one evening each month conducted by a registered nurse and a dietician at a primary care clinic. The emphasis was on diet and exercise as important means of controlling diabetes. Individual sessions with the instructors focused on diet and exercise goal-setting. At monthly sessions, weight, blood pressure, and lab results were provided to the participants in order for them to keep track of their own progress. Participants received phone calls reminding them about class meetings. 28 individuals were enrolled in the class; 18 completed it. n = 18	The control group received usual care. n = 20	Mean body weight (lbs.)	baseline	194	189	NS
					6 months	190 NS	185 p = 0.0050	NS
					12 months	186 p = 0.0166	186 NS	NS
				Mean fasting blood glucose (mg/dL)	baseline	215	210	NS
					6 months	180 p = 0.0244	195 NS	NS
					12 months	205 NS	185 NS	NS
				Mean A1C (%)	baseline	12.28	12.26	NS
					6 months	10.21 p = 0.0034	11.18 p = 0.0123	NS
					12 months	11.52 NS	11.64 NS	NS
				Mean total cholesterol (mg/dL)	baseline	259	224	NS
					6 months	221 p = 0.0129	233 NS	0.0167
					12 months	219 NS	234 NS	NS
				Mean HDL-C (mg/dL)	baseline	40	40	NS
					6 months	39 NS	37 NS	NS
					12 months	36 p = 0.0214	37 NS	NS
				Mean diabetes knowledge score (Life Skills) ²	baseline	74.2 (n = 17)	nr	NS
6 months ³	85.7 (n = 17) p = 0.0003	nr	NS					
6 months	85.0 ± 7.6 (n = 18)	76.2 ± 8.0 (n = 20)	0.0019					
12 months	85.7 (n = 15) NS	nr	NS					

Physicians were not blinded to the condition of their patients.

Diabetes Life Skills knowledge was assessed using the Life Skills cognitive knowledge of diabetes test, produced by the Diabetes Education Society and approved by the American Diabetes Association.

The two different 6 months outcomes are 1) a subset only of those for whom a baseline test was done (n=17) and 2) the complete set of those who completed the program (for comparison to the control group) (n=18).

LIFESTYLE MODIFICATION

Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Time of Observation	Intervention Outcome	Control Outcome	p-value	
The Effectiveness of Diabetes Education for Non-Insulin-Dependent Diabetic Persons. (Scott, 1984) New Zealand	RCT 4 week program, 2 month follow-up Age nr N = 60 Subjects had type 2 DM.	Participants were patients referred to a diabetes-oriented clinic. Those in the intervention group were immediately placed in a four-week education program.	Participants in the control/delay group were placed in an education program four weeks after being referred. The authors were interested both in the effects of the program itself and the effects of the delay. n=28	Mean knowledge test score ¹	baseline	22.8 ± 5.5	23.0 ± 5.3	nr	
					4 weeks	28.5 ± 4.3 p < 0.001	24.8 ± 5.8 p < 0.05	< 0.01	
				Mean plasma glucose (mmol/L)	baseline	8.7 ± 3.0	10.5 ± 3.9	nr	
					4 weeks	7.6 ± 2.5 NS	11.0 ± 4.4 NS	< 0.01	
				Mean A1C (%)	baseline	8.1 ± 1.6	8.7 ± 2.3	nr	
					4 weeks	7.6 ± 1.0 p < 0.1	8.7 ± 2.0 NS	< 0.05	
				Mean anxiety test score ²	4 weeks	32.6 ± 7.8	35.1 ± 7.9	< 0.05	
				Mean depression score ³	4 weeks	36.1 ± 7.1	37.1 ± 7.2	NS	
						Immediate (n = 30)	Delayed (n = 26)	na	na
				Mean plasma glucose (mmol/L)	baseline	9.0 ± 2.8	11.0 ± 4.4		
					post-program ⁴	7.8 ± 2.4 p < 0.01	9.7 ± 3.3 NS		
					follow-up ⁵	8.4 ± 2.7 NS	9.9 ± 3.4 NS		
Mean A1C (%)	baseline	8.4 ± 2.1	8.1 ± 1.6						
	post-program	7.6 ± 1.0 p < 0.1	7.7 ± 2.3 NS						
	follow-up	7.9 ± 2.3 NS	8.1 ± 2.9 NS						

The knowledge assessment questionnaire is not described.

Anxiety was assessed using a self-evaluation questionnaire, taken from Spielberger CD, Gorsuch RL, and Lushen ER, (Consulting Psychologists Press, Palo Alto, CA).

Depression was assessed using a self-evaluation questionnaire, taken from Spielberger CD, Gorsuch RL, and Lushen ER, (Consulting Psychologists Press, Palo Alto, CA).

At completion of the program (4 weeks for immediate intervention group, 8 weeks for delayed intervention group)

4 weeks after completion of the program (8 weeks for immediate intervention group, 8 weeks for delayed intervention group)

LIFESTYLE MODIFICATION

Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Time of Observation	Intervention Outcome	Control Outcome	p-value
Diabetes Self-Care Knowledge, Behaviors, and Metabolic Control of Older Adults -- The Effect of a Posteducational Follow-up Program. (Tu, 1993) US	RCT 4 months Mean age (intervention): 65.6 ± 7.0 (control): 62.25 ± 6.00 N = 26 Subjects had DM. n = 15	Intervention participants received a total of four phone calls. Participants had been patients in a hospital and had been given education at the hospital. The phone calls were made 1) within 48 hours of discharge, and 2) weekly for 3 weeks thereafter. The phone calls focused on reinforcing self-care education and assessing self-care deficits in knowledge and behavior.	Control patients received the in-hospital education only. n = 11	Mean A1C (%)	6 weeks	11.76 ± 3.1	11.3 ± 1.67	NS
				Mean Diabetes Knowledge Test score ¹	6 weeks	12.75 ± 2.1 (85%)	11.23 ± 1.8 (75%)	NS
				Behavioral Deficit ² -- frequency of blood glucose monitoring	6 weeks	0 out of 15	3 out of 11	< 0.05
				Behavioral Deficit -- blood glucose monitoring record keeping	6 weeks	0 out of 15	6 out of 11	< 0.01
				Behavioral Deficit -- knowledge of hypoglycemia prevention	6 weeks	1 out of 13	4 out of 11	< 0.05
				Behavioral Deficit -- reporting symptoms to health care provider	6 weeks	0 out of 15	6 out of 11	< 0.01

Knowledge was assessed using the Diabetes Knowledge Scale (DKN), with modifications to the dietary section to accommodate ethnic dietary practices. The maximum score is 15. Recorded as number who have this deficit out of the group total.

LIFESTYLE MODIFICATION

Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Time of Observation	Intervention Outcome		p-value
						Group A	Group B	
Telematic Expert System Diabeto: New Tool for Diet Self-monitoring for Diabetic Patients (Turnin, 1992) France	RCT ¹ 6 months Mean age: 45 ² N = 105 Subjects had DM.	Individuals in Group A were given access to Diabeto, a computer-assisted diet education program for diabetics which provides for self-monitoring of diets and provides personalized counseling. n = 54	none	Mean dietetic knowledge test scores ³	baseline	56	56	nr
					post-program	64 p < 0.0001	62 p < 0.0001	nr
				Mean caloric excess (kcal)	baseline	365	193	nr
					post-program	132 p < 0.05	98 p < 0.05	nr
		Percent with carbohydrate deficit (less than 45%)		baseline	39.7	38.9	nr	
				post-program	42.9 p < 0.005	41.9 p < 0.05	nr	
		Percent with fat excess (greater than 35%)		baseline	41.9	41.2	nr	
				post-program	37.4 p < 0.0005	39.4 NS	nr	
Individuals in Group B were given usual care for the first six months, then they were given access to Diabeto. n = 51								

Group B was intended to serve as a control during their six months without the intervention, however, no comparisons between Group A outcomes and Group B outcomes are evident in the article, so this study is better viewed as a before-after trial.

Mean age for Group A=44.8 ± 2.0, Group B: 45.2 ± 2.0

Knowledge was assessed using 4 author-developed tests on nutrition, including an activity in which participants corrected "unbalanced" menus. Tests were varied between baseline and post-program.

LIFESTYLE MODIFICATION

Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Time of Observation	Intervention Outcome			Control Outcome	p-value		
						Patient	Physician	Patient + Phys		Patient	Physician	Patient + Phys
Diabeds: A Randomized Trial of the Effects of Physician and/or Patient Education on Diabetes Patient Outcomes. (Vinicor, 1987) US	RCT ~ 2.5 years Mean age: 57 N = 532 Subjects had DM.	The intervention was an education program. Four groups of participants were created. In Group 2, patients received education. n = 117 In Group 3, physicians received education. n = 130 In Group 4, both patients and physicians received education. n = 133	Group 1 was the control. Physicians and patients received only routinely available information on diabetes. n = 129	Mean change in fasting plasma glucose (mg/dl)	post-program	-15.9	-13.1	-39.0	+7.7	< 0.05	0.05	< 0.01
				Mean change in glycosylated hemoglobin (%)	post-program	+0.06	+0.14	-0.92	+0.56	< 0.05	< 0.05	< 0.01
				Mean blood pressure - systolic ¹	baseline	138.9 ± 16.0	142.5 ± 21.1	140.4 ± 16.5	137.2 ± 17.5	nr	nr	nr
					post-program	138.9 ± 16.9 p<0.05	146.4 ± 20.7 NS	145.0 ± 24.8 NS	144.9 ± 18.5 NS	nr	nr	nr
				Mean blood pressure - diastolic ²	baseline	84.7 ± 9.5	83.1 ± 9.9	81.8 ± 9.6	81.4 ± 9.2	nr	nr	nr
					post-program	82.4 ± 9.6 <0.01	83.4 ± 8.8 NS	81.3 ± 8.6 p<0.05	85.2 ± 8.2 NS	nr	nr	nr

Note : data reported in text (p. 351) does NOT agree with data reported in table (p.352). This is data from table, but p-values are reported only in the text.

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LIFESTYLE MODIFICATION

Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Time of Observation	Intervention Outcome	Control Outcome	p-value
A randomized, controlled comparison of instruction by a diabetes educator versus self-instruction in self-monitoring of blood glucose. (Ward, 1985) US	RCT 30 min intervention Age nr N = nr	The intervention group read the instructions that came with a particular SMBG device and received 30 minutes of instruction on self-monitoring blood glucose using that device.	The control group was given the instructions that came with the same SMBG device and asked to practice independently for 30 minutes.	Mean percent error in SMBG measurement	immediately after instruction/ practice session	9%	22-37%	nr
A Nurse-coordinated Intervention for Primary Care Patients with Non-insulin-dependent Diabetes Mellitus: Impact on Glycemic Control and Health-related Quality of Life (Weinberger, 1995) US ¹	RCT 1 year Mean age (intervention): 63.9 ± 8.6 (control): 63.2 ± 8.3 N = 275 Subjects had type 2 DM.	Nurse-initiated monthly (more often if clinically necessary) telephone contact with patients to i) provide patient education, with special emphasis on prescribed regimens and significant signs and symptoms of hyperglycemia and hypoglycemia; ii) reinforce the importance of compliance and resolve and facilitate compliance; iii) monitor patients' health status; iv) facilitate resolution of identified problems; and v) facilitate access to primary care. Nurses spent an average of 148 minutes on the phone with each patient over the course of the study period. n = 204	Usual care n = 71	Mean A1C (%)	baseline	10.7 ± 3.4 n = 204	10.7 ± 3.3 n = 71	NS
					1 year	10.5 ± 0.2 n = 188	11.1 ± 0.3 n = 63	0.046
				Fasting blood glucose (mg/dL)	baseline	183.9 ± 75.8 n = 204	185.9 ± 75.8 n = 71	NS
					1 year	174.1 ± 4.3 n = 188	193.1 ± 7.3 n = 63	0.011
				Mean # of diabetes-related symptoms reported in previous month	1 year	1.2 ± 0.1 n = 188	1.4 ± 0.2 n = 63	NS

¹VA general clinic

LIFESTYLE MODIFICATION

Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Time of Observation	Intervention Outcome	Control Outcome	p-value				
Evaluation of Computer-based Diet Education in Persons with Diabetes Mellitus and Limited Educational Background (Wheeler, 1985) U.S.	RCT 4 weeks Age range: 21-75 N = 32 Subjects had DM.	Computer Education: The computer education group received this instruction on meal planning and the diabetic diet from computer programs, with dietitian-patient interaction time for counseling in areas such as contracting and skills demonstration. n = 16	A standard outpatient nutritional education program, which consisted of two 30-minute sessions with a dietitian. Due to scheduling problems, only 3 subjects had a second educational session n = 16	Change in weight from baseline for obese patients (lbs.)	4 weeks	-4.6 ± 5.9 (n = 15) p < 0.005	-2.0 ± 6.3 (n = 12) NS	nr				
					1 year	nr ¹ (n = 12)	3.8 ± 9.1 (n = 7) NS	nr				
								Change in exchange list score ² from baseline	4 weeks	5.7 ± 4.3 p < 0.001	0.8 ± 3.1 NS	nr
								Food portioning score ³ from baseline	4 weeks	0.1 ± 1.0 NS	0.4 ± 0.9 NS	nr
								Compliance: 24 hour recall calorie fat content (% of calories)	4 weeks	-7.8 ± 13.7 p < 0.05	-3.1 ± 12.3 NS	nr
								Compliance: 24 hour recall of protein, fat, and carbohydrate contents	4 weeks	-39.4 ± 44.7 p < 0.005	-6.4 ± 44.0 NS	nr
Management of Obese Patients with Diabetes Mellitus: Comparison of Advice Education with Group Management. (White, 1986) US	RCT 6 months Mean age (intervention): 62.4 ± 5.5 (control): 60.7 ± 6.4 N = 41 Subjects had DM. ⁴	Intervention participants were assigned to an experimental group management program, which focused on interaction and assessment among peers. n = 20 at baseline n = 16 post-program	Control participants were assigned to a standard advice education program with a lecture format, presented by a nurse or dietitian. n = 21 at baseline n = 16 post-program	Mean percent overweight	baseline	36.4 ± 21.8	40.9 ± 16.3	NS				
					post-program	36.3 ± 21.0	44.3 ± 21.0					
				Mean A1C (%)	baseline	11.0 ± 2.6	11.5 ± 3.5	NS				
					post-program	10.4 ± 2.6	11.3 ± 3.5					
				Mean serum glucose (mg/dL)	baseline	238 ± 119	279 ± 120	NS				
					post-program	221 ± 123	260 ± 117					
Mean knowledge test score ⁵	baseline	11.3 ± 3.9	14.2 ± 3.6	0.02								
	post-program	11.3 ± 3.8	14.2 ± 3.6	0.02								

Weight loss maintained

Knowledge of exchange list concepts was determined by use of a self-administered test consisting of 12 problem-solving and information-gathering exercises.

Portion control skills were determined through demonstration.

Subjects were also obese.

Knowledge was assessed using an author-developed 20-question multiple choice test regarding causes, signs, and treatment of NIDDM associated with obesity.

LIFESTYLE MODIFICATION

Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Time of Observation	Intervention Outcome			Control Outcome	p-value
						menu	buy	free		
Food provision vs. structured meal plans in the behavioral treatment of obesity (Wing 1996) US	RCT 6 month program, 12 month follow-up Mean age (menu): 41.7 ± 7.7 (buy): 40.8 ± 6.7 (free): 41.9 ± 7.1 (control): 40.5 ± 8.2 N = 123	Female subjects were recruited to one of three plans: menu = SBT plus written meal plans for 5 breakfasts and 5 dinners each week and grocery list for those meals n = 41 buy = SBT plus meal plans but groceries were distributed at meetings for \$25.00 (cost sharing with study) n = 41 free = SBT plus meal plans and box of groceries provided free n = 41	Standard behavioral treatment (SBT): weekly meetings for six months for groups of 20 women led by therapists; also assigned calorie (1000-1500) and fat intake (<20%) goals; given guidebook and asked to keep food diary; exercise (walking) with 1000 kcal/week goal. n = 40	Mean change in weight (lbs.)	6 months	12.0 ± 7.2	11.7 ± 5.4	11.4 ± 6.5	8.0 ± 6.2	covariance p < 0.03 SBT vs all p < 0.0003
				Mean change in score for difficulty having appropriate foods available ¹	6 months	-0.21	-0.64	-0.65	-0.01	F-stat p = 0.007 SBT vs all p = 0.007 menu vs buy/free p = 0.02
				Mean change in score for difficulty estimating portion size	6 months	-0.66	-1.02	-0.99	-0.39	F-stat p = 0.008 SBT vs all p = 0.004 menu vs buy/free p = 0.06
				Mean change in score for difficulty finding time to plan meals	6 months	-1.06	-1.12	-1.17	-0.25	F-stat p = 0.005 SBT vs all p = 0.0003
				Mean change in score for difficulty controlling eating when not hungry	6 months	-1.32	-1.02	-0.82	-0.34	F-stat p = 0.005 menu vs buy/ p = 0.09 SBT vs all p = 0.002

¹Participants were asked to rate the severity of various barriers to adherence, from 1 (not a problem at all) to 5 (a very important problem).

LIFESTYLE MODIFICATION

Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Time of Observation	Intervention Outcome						Control Out- come	p- value
						IDDM II n = 24	IDDM III n = 22	IDDM IV n = 20	NIDDM II n = 22	NIDDM III n = 24	NIDDM IV n = 21		
Effect of Computer-Based Learning on Diabetes Knowledge and Control. (Wise, 1986) US	RCT ~ 8 months Age range (IDDM): 17- 68 (NIDDM): 42-75 N = 172 Subjects had DM for >2 years.	Participants were divided into IDDM and NIDDM. Group II completed 2 assessments with the computer program KAP (Knowledge Assessment Program), n = 44 Group III did the same plus received feedback between the assessments, n = 46 Group IV completed 2 KAPs plus a session of Interactive Computer Teaching between assessments. n = 41	Group I, the control, did not complete any assessments or teaching programs. n = 41	Mean knowledge index score ¹ (note: only significant results; significance is baseline vs. outcome comparison)	base	NS	78 ± 2	77 ± 2	NS	64 ± 2	60 ± 3	NS	nr
						post	NS	83 ± 3 p < 0.05	83 ± 2 p < 0.001	NS	73 ± 2 p < 0.01		
					base	9.1 ± 0.2	9.3 ± 0.5	9.3 ± 0.2	9.6 ± 0.4	9.2 ± 0.4	NS	NS	nr
						post	8.4 ± 0.1 p < 0.05	8.1 ± 0.4 p < 0.02	8.6 ± 0.3 p < 0.03	8.8 ± 0.3 p < 0.05	7.9 ± 0.4 p < 0.01		

Knowledge was assessed using the Knowledge Assessment Program (KAP), a set of condition-specific (IDDM or NIDDM) multiple-choice questions. Scoring is +1 for correct answers, -1 for incorrect answers, with a maximum negative equivalent to the number of options for a "don't know" response. KAP is administered via computer.

LIFESTYLE MODIFICATION

on-Education Studies

Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome ¹	Time of Observation	Intervention Outcome	Control Outcome	p-value
Effect of a Bicultural Community Health Worker on Completion of Diabetes Education in a Hispanic Population. (Corkery, 1997) US	RCT ~ 1 year ² Mean age: 52.8 ± 11.7 N = 64 Subjects had DM.	In this study, all participants were enrolled in an education program. In the intervention group, participants also received help from a community health worker, who acted as a liaison between the patients, their families, and the health care providers. The community health worker provided Spanish translations, reinforced instructions, reminded patients about appointments, and rescheduled missed appointments. n = 30	Control participants were enrolled in the same education program but did not have further contact with the community health worker. n = 34	Percent of individuals completing the education program		80	47	< 0.007 after controlling for other factors
				Mean glycohemoglobin levels for those completing the program	baseline	11.7 ± 3.7		na
					completion	9.9 ± 2.2 p < 0.004		
				Mean knowledge score for those completing the program ³	baseline	74.4		na
completion	95.4 p < 0.001							

The purpose of the study is to show 1) that the CHW increased completion rates and 2) that completion of the education program was beneficial.

The education program in this study was one-on-one and goal-oriented, so the length of the program varied for each participant according to his/her goals. Follow-up time also varied because it was held in conjunction with next scheduled appointment. One year is an estimate (mean time to complete program: 3.4 months; mean time to follow-up after completion: 7.7 months).

Knowledge was assessed using an author-developed test consisting of 9 true-false questions.

LIFESTYLE MODIFICATION

Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome ¹	Time of Observation	Intervention Outcome	Control Outcome	Mean Change ²	95% CI for Mean Change	p-value ³
Expanding Patient Involvement in Care: Effects on Patient Outcomes. (Greenfield, 1985) US	RCT 6-8 weeks Mean age: 55 ± 12 N = 45	During a 20-minute session prior to their office visit, participants were helped in reading their medical records and were advised as to the treatment algorithm at their clinic, and coached in asking questions and negotiating medical decisions with their doctor. They were then contacted 6-8 weeks after the intervention. n = 23	Control patients were given a standard review of ulcer disease, with no reference to their own medical records. n = 22	Total number of controlling utterances by patient	after intervention	18.4 ± 11.0	9.5 ± 6.9	8.9	3.56 - 14.24	< 0.05
				Ratio of physician factual statements to controlling utterances	after intervention	0.93 ± 0.52	0.49 ± 0.34	0.44	0.18 - 0.70	< 0.001
				Mean score on physical limitation scale ⁴	6-8 weeks after intervention	0.25 ± 0.72	0.92 ± 0.85	-0.67	-1.10 - -0.26	< 0.005
				Mean score on test of knowledge of ulcer disease ⁵	after intervention	11.7 ± 4.1	16.8 ± 1.4	-5.1	-6.91 - -3.29	< 0.01

Subjects physician-patient interactions were tape-recorded and coded.

Experimental outcome minus control outcome

p-value is on mean change (calculated using a pooled t-test).

Physical limitation was assessed using 5 questions measuring illness-related limitations on physical activities (e.g. climbing stairs). Scored 1 for each answer of yes, this is a problem; 0 for no, this isn't a problem.

Knowledge was assessed using a 23 question test, scored 1 point for each correct answer, 0 for each incorrect answer.

LIFESTYLE MODIFICATION

Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Subgroup	Intervention Outcome	Control Outcome	p-value
Prompting the clinical care of non-insulin dependent (type II) diabetic patients in an inner city area: one model of community care. (Hurwitz, 1993) UK	RCT 2 years Mean age (prompt): 62.0 ± 11.2 (control): 63.1 ± 8.6 N = 181 Subjects had type 2 DM.	Participants are prompted (via mail?) for annual blood and urine exams (random plasma glucose/glycated hemoglobin, midstream urine for protein, microscopy/culture tests) based on the data in a central database. They receive records of these tests to take to their general practitioner. n = 89	Control participants receive usual annual visits at the hospital clinic, unprompted. n = 92	Compliance rate	Prompt group	prompts = 333 responses = 296 89% compliance		na
				Percent of patients without doctor diabetes review	All	3.4	15.2	0.013
				Mean number of diabetes reviews per patient per doctor		3.2	2.2	< 0.001
				Mean random plasma glucose (mmol/l)		11.2 ± 4.2 (n = 82)	11.2 ± 4.2 (n = 77)	NS
				Mean A1C (%)		10.3 ± 2.3	10.6 ± 2.5	NS

LIFESTYLE MODIFICATION

exercise Training

Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Time of Observation	Intervention Outcome	Control Outcome	p-value
Low-Intensity Exercise as a Modifier of Physical Frailty in Older Adults. (Brown, 2000) US	RCT 3 months Mean age: 83 ± 4 N = 84	Intervention participants were enrolled in a three- month program of exercise. The program included 22 exercises that were practiced with increasing levels of difficulty throughout the period. Some include modest resistance. They were designed to enhance flexibility, balance, body handling skills, speed of reaction, coordination, and, to a modest extent, strength. n = 48	Control participants were given 9 of the 22 activities that challenged range of motion for unsupervised home-based practice. n = 36	Mean score on physical performance test ¹	baseline	29 ± 4	29 ± 6	nr
					post-program	31 ± 4 NS	29 ± 6 NS	< 0.05
				Mean preferred gait velocity (m/min)	baseline	61.5 ± 12.8	58.3 ± 15.9	nr
					post-program	63.0 ± 13.2 p < 0.05	59.1 ± 15.9 p < 0.05	NS
				Mean obstacle course score (sec)	baseline	13.4 ± 3.7	14.5 ± 7.5	nr
					post-program	11.9 ± 4.0 p < 0.05	14.3 ± 7.3 NS	< 0.05

Consisted of lifting a 7 lb. book from waist level to shelf overhead, putting on and removing a lab coat, picking up a penny from the floor, walking 50 ft, turning 360 degrees, completing a timed ascent of one flight of stairs, climbing 4 flights of stairs, rising from a 16 in. chair 5 times, and completing a Progressive Romberg: eyes open condition.

LIFESTYLE MODIFICATION

Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Subgroup	Intervention Outcome			Control Outcome	p-value
						Exercise	Exercise + Supplement	Supplement		
Exercise Training and Nutritional Supplementation for Physical Frailty in Very Elderly People. (Fiatarone, 1994) US	RCT 10 weeks Mean age: 87.1 ± 0.6 N=94	Intervention participants were placed in 3 groups: exercise plus a placebo supplement (similar quantity of a low calorie beverage administered in the same fashion as the supplement). n = 22, exercise plus supplement n = 25 "placebo exercise" (walking, board games) plus supplement n=22 Exercise consisted of resistance training sessions took place 3 days/week for 10 weeks. Sessions focused on hip and knee extensors. Sessions lasted 45 minutes. The nutritional supplement added 360 kcals to participants' diets.	placebo exercise plus placebo supplement n = 25	Mean change in gait (M/sec)	n = 90	0.04 ± 0.02	0.06 ± 0.02	0.00 ± 0.02	-0.02 ± 0.02	for exercise vs. non-exercise = 0.009
				Mean change in weight (kg)	n = 88	0.02 ± 0.04	1.0 ± 0.4	0.8 ± 0.4	-0.5 ± 0.4	for supplement vs. non-supplement = 0.01
				Mean change in thigh-muscle area (cm ²)	n = 61	0.9 ± 1.7	1.7 ± 1.7	-2.7 ± 2.1	-0.4 ± 1.9	NS
				Mean percent changes in muscle strength		nr	nr	nr	nr	for exercise vs. non-exercise = 0.001
				Mean percent change in the level of spontaneous physical activity	All	nr	nr	nr	nr	for exercise vs. non-exercise = 0.03

LIFESTYLE MODIFICATION

Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Intervention Outcome			Control Outcome	p-value
					Balance	Resistance	Balance + Resistance		
Effects of Resistive and Balance Exercises on Isokinetic Strength in Older Persons. (Judge, 1994) US	RCT 3 months Mean age: 80 N = 110	Concerned with prevention of injurious falls and functional decline. Three intervention groups were created. One group engaged in resistive training sessions n = 28	The control group attended the educational sessions only. n = 27	Mean change in summary moment (joint movement score for eight movement tests)	-13 ± 82 NS	49 ± 45 p < 0.005	81 ± 60 NS	-12 ± 49 NS	< 0.005 for effect of resistive training
		one group engaged in balance training sessions n = 27 one group engaged in a combined program n = 28 The first two groups exercised 45 minutes, 3 times/week. The combined group exercised 95 minutes (two 45-minute sessions plus a 5-minute break). It is unclear how many times a week they exercised. Subjects groups attended 5 90-minute educational sessions focused on fall prevention and stress management.		Mean joint percent change from baseline mean for all 8 joint moments	3 (95% CI = -6 - 13)	19 (95% CI = 10 - 28)	26 (95% CI = 15 - 39)	3 (95% CI = -3 - 8)	nr

LIFESTYLE MODIFICATION

Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Time of Observation	Intervention Outcome	Control Outcome	p-value
A Randomized Trial of Physical Rehabilitation for Very Frail Nursing Home Residents. (Mulrow, 1994) US	RCT 4 month intervention, 4 month follow-up Mean age (intervention): 79.7 ± 8.5 (control): 81.4 ± 7.9 N = 194	Intervention participants received one-on-one physical therapy sessions 3 times/week for 30-45 minutes. Therapy addressed 2-3 movement deficits per session and could include bed mobility skills, wheelchair propulsion, transfer between surfaces, or gait training. The sessions lasted 4 months. n = 97	Control group participants received friendly visits 3 times/week during the intervention period. n = 97	Mean physical disability index score ¹	baseline	56.6 ± 10.5	58.3 ± 11.3	NS
					4 months	54.6 ± 12.0 NS	55.0 ± 13.3 NS	
				Percent of participants using assistive devices for bed mobility	baseline	93	84	NS
					4 months	85 p = 0.06 ²	84 NS	
				Percent of ambulatory participants using assistive devices	8 months	nr	nr	<0.0001
				Percent of participants using wheelchairs at baseline who could ambulate at follow-up	8 months	33	14	<0.005
Mean Geriatric Depression Scale score ³	baseline	6.3 ± 3.5	6.2 ± 3.6	NS				
	4 months	6.6 ± 3.6 NS	6.2 ± 3.8 NS					
Effects of Resistance Training on Strength, Power, and Selected Functional Abilities of Women Aged 75 and Older. (Skelton, 1995) UK	RCT 12 week program, total ~4 months Mean age: 79.5 N = 40	Intervention participants were enrolled in a 12-week exercise class. Classes met weekly and lasted 50 minutes to 1 hour. Classes were focused on strength training of major muscle groups. n = 20	Control group continued their usual activities. n = 20 Subjects participants were asked to keep an exercise diary listing any major activity events.	Mean percent change in body weight (kg)	4 months	0	0	NS
				Mean percent change in arm muscle circumference	4 months	-2	-1	NS
				Mean percent change in isometric knee extensor strength per kg weight	4 months	27	2	0.019
				Mean percent change in handgrip strength	4 months	4	-3	0.050
				Mean percent change in isometric elbow flexor strength	4 months	22	-3	0.049
				Mean percent change in leg extensor power per kg weight	4 months	18	-1	0.049

Physical disability was assessed using the Physical Disability Index, an observer-administered, performance-based, 54-item measure. Higher score indicates better function.

Recorded in article text as if it were between groups, but given the percentages reported, it could only be within group (p.523)

The short version of the Geriatric Depression Scale was used. Higher score indicates greater depression.

LIFESTYLE MODIFICATION

Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Time of Observation	Intervention Outcome	Control Outcome	p-value
A Multifactorial Intervention to Reduce the Risk of Falling among Elderly People Living in the Community. (Tinetti, 1994) US	RCT 1 year Age >69 N = 291	Participants in the intervention group were given personalized interventions according to their impairments as assessed by a nurse and a physical therapist. Impairments treated were: postural hypotension, use of a sedative-hypnotic agent, use of 4 or more prescription medications, inability to transfer safely to bathtub or toilet, environmental hazards for falling/tripping, or any impairments in gait, transfer skills/balance, or leg or arm muscle strength or motion. Interventions included behavioral recommendations, education, physical therapy and strength training, and environmental alterations. n = 147	Impairments in control group participants were also identified. Participants received visits from a social-work student at a frequency comparable to that of intervention group participants with the same impairments, during which structured interviews were conducted. n = 144	# of subjects who fell (and percent of group)	during study period	52 (35%)	68 (47%)	0.04
				Mean falls per person/week	during study period	0.012	0.018	nr
				Total number of falls	during study period	94	164	nr
				# of subjects with a fall resulting in medical care (and percent of group)	during study period	21 (14%)	26 (18%)	nr
				# of subjects with a serious injury due to a fall (and percent of group)	during study period	12 (8%)	14 (10%)	nr
				Mean change in number of risk factors	1 year	-1.1 ± 1.6	-0.6 ± 1.4	0.03

LIFESTYLE MODIFICATION

Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Time of Observation	Intervention Outcome		Control Outcome	p-value
						Tai Chi	Balance		
Reducing Frailty and Falls in Older Persons: An Investigation of Tai Chi and Computerized Balance Training. (Wolf, 1996) US	RCT 15 week program, total 8 months Mean age: 76.2 N = 200	Intervention participants were divided into 2 groups: one practiced Tai Chi. n = 72 The other used a computerized balance training program involving a moving floor. n = 64 Sessions were weekly for 15 weeks. Subjects were also encouraged to practice at home.	Those in the control group received general education only and were instructed not to change their exercise routine until the completion of the study. n = 64	Mean systolic blood pressure post-walk	baseline	172.1 ± 27.7 (n = 61)	170.5 ± 33.0 (n = 53)	164.0 ± 26.8 (n = 53)	nr
					15 weeks	158.9 ± 27.4 (n = 61) p = 0.0525	165.5 ± 25.8 (n = 53) NS	162.3 ± 27.3 (n = 53) NS	
				Fear of falling index -- % not afraid at all	baseline	43 (n = 60)	29 (n = 51)	44 (n = 54)	0.046 for Fear of falling index overall, for TC vs. Education baseline to posttest changes
					15 weeks	53 (n = 60)	27 (n = 51)	35 (n = 54)	
					8 months	47 (n = 60)	33 (n = 51)	41 (n = 54)	
				Fear of falling index -- % very afraid	baseline	10 (n = 60)	6 (n = 51)	7 (n = 54)	
					15 weeks	7 (n = 60)	12 (n = 51)	7 (n = 54)	
					8 months	8 (n = 60)	12 (n = 51)	10 (n = 54)	
Total number of falls for duration of participation (using FICSIT definition) ¹	average 164- 171 days duration	56	76	77	nr				
Fall risk ratio (using FICSIT definition)	Risk ratio significantly lower for TC group (p = 0.009)								

¹FICSIT definition of a fall is "unintentionally coming to rest on the ground, floor, or other lower level." This includes such events as a stumble in which a patient means to touch the top of a chest of drawers and instead touches the top
'awer.

LIFESTYLE MODIFICATION

on-RCT Studies

Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Time of Observation	Intervention Outcome	Control Outcome	p-value
Diabetes in Urban African-Americans. XVI. Overcoming Clinical Inertia Improves Glycemic Control in Patients with Type 2 Diabetes. (Cook, 1999) US	Non-randomized controlled trial 4 years Mean age: 57.3 ± 0.4 N = 698 Subjects had type 2 DM.	The study compares two cohorts of patients -- those admitted to a particular clinic in 1992, 1993, and 1994 versus those admitted in 1995 and 1996. In 1995, the clinic introduced a new program of intensification of therapy for those whose glycemic indices were not well controlled. n=nr	The 1992-94 cohort serves as a proxy control. n=nr			1995-1996 cohort	1992-1994 cohort	
				Mean change in average A1C	at 6 months after initial visit	7.6	8.0	0.018
					at 12 months after initial visit	7.6	8.4	< 0.0001
				Percent achieving A1C less than or equal to 7.0%	at 12 months after initial visit	46	31	nr
				Therapeutic management -- percent managed by diet alone	at 12 months after initial visit	29	32	nr
				Mean change in BMI (kg/sq. m)	at 12 months after initial visit	32.9	31.9	NS
Improvements in Diabetic Care as Measured by A1C After a Physician Education Project (Deichmann, 1999) US	Opportunistic Sample Before and After Intervention 18 month baseline, 6 month follow-up Age >64 N = 835	Nine physicians in one city were selected; billing and testing data for all diabetic patients 65 and over were analyzed for frequency of A1C testing, A1C values, and office visit frequency. This information, along with patient educational tools (brochures, etc. with an instruction to request testing) and scientific literature regarding the importance and validity of A1C testing, were delivered to the physicians. The physicians also received a visit from a "knowledgeable colleague." n = 716 at baseline n = 448 at follow-up	na	Rate of "seized opportunities" for A1C testing	before	17.7%	na	na
					after	33.9%		
				Median A1C (%)	before	7.8%	na	na
					after	8.5%		
				Percent with current A1C values and office visits	before	29.4	na	na
					after	47.6 p = 0.0001		

LIFESTYLE MODIFICATION

Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Time of Observation	Intervention Outcome	Control Outcome	p-value
Diabetes education in the elderly: a 5-year follow-up of an interactive approach. (Garcia, 1996) Cuba	Non-random non-controlled trial 5 years Mean age: 72 ± 9 Age >59 N = 148 Subjects had DM.	Subjects patients with diabetes receive a standard, one-week basic education course. The authors suggest that this is insufficient, and in this study, patients follow-up this course with monthly 1-1.5 hour meetings with health care providers and other patients to discuss self-care, issues of social support, and emotions. Meetings were informal and held in familiar, comfortable environments and included dinners and parties. Patients also acted as supports for each other (in pairs) in reaching targets between meetings. These meetings had been going on for 5 years at the time of the article.	na	Mean knowledge test score	baseline	72.7 ± 21.6	na	na
					5 year	89.3 ± 9.2 p < 0.001		
				Percent of patients reporting adherence to diet instructions	baseline	35.1	na	na
					5 year	83.1 p < 0.001		
				Percent of patients reporting adherence to exercise instructions	baseline	15.5	na	na
					5 year	86.2 p < 0.001		
				Mean A1C(%)	baseline	12.4 ± 4.7	na	na
					5 year	7.9 ± 1.9 p < 0.02		
				Percent of patients diagnosed obese	baseline	32	na	na
					5 year	6 p < 0.001		
				Percent of patients with signs of depression	baseline	69	na	na
					5 year	24 p < 0.001		

LIFESTYLE MODIFICATION

Study (Author, Year) Location	Design Duration Age # of Subjects	Intervention	Control	Outcome	Time of Observation	Intervention Outcome	Control Outcome	p-value	
The Effectiveness of Diabetes Education Programs for Older Patients and Their Spouses. (Gilden, 1989) US	Not an RCT -- Comparison of Older and Younger Males within an Intervention 3 month program, 6 month follow-up Age range: 28-82 N = 67 Subjects had DM.	Subjects participants in this study were enrolled in a six-week educational program. Sessions were once a week and were led by a multi-disciplinary team consisting of a diabetologist, a nurse-educator, a dietician, a psychologist, a podiatrist, and a social worker. Subjects study subjects were male, but 20 of the subjects' wives also participated in the educational program. The subjects were broken into two groups for analysis: Older (65-82, mean 70 ± 4.3) n = 45 Younger (28-64, mean 57 ± 8.1) n = 22	na	Mean knowledge test score ¹		Older	Spouses	Younger	
					pre-education	35.6 ± 4.3	35.9 ± 4.2	37.1 ± 4.4	NS
					post-education	38.2 ± 3.6 p < 0.05	39.2 ± 3.9 p < 0.01	38.4 ± 4.6 NS	NS
				Mean quality of life (total) score ²	6 month follow-up	38.9 ± 5.0 p < 0.01	na	39.0 ± 4.2 p < 0.01	NS
					pre-education	61.8 ± 13.4	70.7 ± 8.8	71.0 ± 6.7	NS
					post-education	65.1 ± 9.3 p < 0.01	70.5 ± 7.1 NS	66.1 ± 6.3 NS	NS
				Mean stress score ³	6 month follow-up	68.9 ± 2.3 p < 0.01	na	65.5 ± 5.7 NS	< 0.05
					pre-education	11.8 ± 3.0	12.6 ± 2.8	12.2 ± 2.3	NS
					post-education	12.3 ± 4.2 p < 0.01	12.1 ± 2.2 NS	12.1 ± 3.6 NS	NS
				Mean family involvement score ⁴	6 month follow-up	13.1 ± 2.5 NS	na	12.5 ± 2.2 NS	NS
					pre-education	27.8 ± 5.1	26.0 ± 5.7	23.5 ± 5.9	< 0.01
					post-education	27.6 ± 4.9 NS	29.5 ± 4.2 p < 0.01	23.8 ± 4.3 NS	< 0.01
				Mean A1C	6 month follow-up	24.6 ± 5.5 NS	na	25.3 ± 4.8 NS	NS
					Those with spouses attending showed significant improvement. p < 0.001				

Knowledge was assessed using an author-developed test consisting of 24 true/false questions encompassing general knowledge, nutrition, and pharmacy; it was designed to cover the content of the education program. Entire questionnaire printed in the article.

Quality of Life was assessed using an author-developed test consisting of 21 true/false questions and 2 open questions ("Who prepares the meals at home?" and "What type and dose of medication are you taking?") encompassing general satisfaction, diet, exercise, medication, and self-monitoring of blood glucose. The maximum score is 100 points. Entire questionnaire is printed in the article.

Stress was assessed using an author-developed 9 "agree-disagree-don't know" questions including statements such as "Diabetes is the worst thing that ever happened to me" and "Diabetes is not really a problem because it can be controlled." Entire questionnaire is printed in the article.

Family stress was assessed using an author-developed 8 five-point questions. Participants were asked how often ("never" to "at least once a day") a spouse or other family member criticizes, praises, or participates in issues of diabetes self-care (e.g. "How often does he/she criticize you for not exercising regularly?"). Test was derived from Schafer LC et al: Supportive and nonsupportive family behaviors: relationship to adherence and metabolic control in persons with type II diabetes. *Diabetes Care* 9:179, 1986. Entire questionnaire is printed in the article.

LIFESTYLE MODIFICATION

Meta-Analyses and Reviews

Study (Author, Year) Location	Range of Study	Major Conclusions of Interest			
Interventions to Promote Diabetes Self-Management: State of the Science. (Brown, 1999) US	This review focuses on a comparison of education-oriented studies before and after 1990, with a final section on future directions based on then-current NIH grants. This is largely a review of meta-analyses.	Before 1990: 1) Success was most frequently in glycemic control; weight loss less common. 2) Samples were heterogeneous and no separation of men/women, young/old, or ethnic groups was made, nor was separation of Type I and II. 3) Education largely occurred in groups and was out-patient. 4) Longer program produced better test scores, but metabolic control did not correlate to length of program. 5) <i>Older individuals benefited least from diabetes self-management programs, particularly in terms of improvement in metabolic control.</i>			
		Since 1990 (-1999): 1) Interventions with dietary-specific focus had greater effect on weight loss and glycosylated hemoglobin levels than general diabetes self-management programs. 2) Combined educational and behavioral strategies, particularly those that involved one-on-one or small group components, produced better compliance and effects than large, education or behavior alone programs. 3) Interventions increasingly strove to be culturally competent.			
		Future directions: 1) The drive for culturally competent interventions continues. 2) There is a growing emphasis on short, practical interventions (e.g. via telephone). 3) Dietary interventions are setting increasingly specific/narrow goals (e.g. reducing fat intake). 4) More evidence is being acquired as to the efficacy of follow-up "booster" educational sessions or contacts. 5) There are studies comparing outcomes with different providers (e.g. nurse case managers, peer counselors, etc.).			
Studies of Educational Interventions and Outcomes in Diabetic Adults: A Meta-analysis revisited. (Brown, 1990) US	An extension of Brown, 1988 (below). N=82 studies Subjects had DM.	Outcome	# of studies included in analysis	Effect size	95% CI
		Knowledge of dietary principles	12	0.49 ± 0.06	0.37 to 0.61
		Knowledge composite	25	1.05 ± 0.06	0.94 to 1.16
		Insulin injection skill	5	0.23 ± 0.09	0.05 to 0.40
		Urine testing skill	7	0.44 ± 0.06	0.32 to 0.57
		Weight	28	0.17 ± 0.05	0.08 to 0.27
		Dietary compliance	15	0.57 ± 0.07	0.44 to 0.70
		A1C	27	0.41 ± 0.05	0.31 to 0.52
		Blood sugar	28	0.34 ± 0.05	0.25 to 0.43
		Urine sugar	5	0.39 ± 0.12	0.15 to 0.63
		Insulin dose	10	0.16 ± 0.06	0.03 to 0.28
		Cholesterol	9	0.24 ± 0.07	0.09 to 0.38
		Blood pressure	3	0.34 ± 0.11	0.14 to 0.55
		Medical care	6	0.35 ± 0.07	0.21 to 0.50
		Psychological impact	14	0.27 ± 0.08	0.12 to 0.42
Recommendations: Ensure more diabetes patients have access to education, incorporate psychological elements/ coping skills, focus more attention on the needs of elderly patients, spend more time teaching insulin injection skills, do not use weight loss as sole measure of dietary compliance.					

LIFESTYLE MODIFICATION

Study (Author, Year) Location	Range of Study	Major Conclusions of Interest			
<p>Effects of Educational Interventions in Diabetes Care: A Meta-Analysis of Findings. (Brown, 1988) US</p>	<p>This meta-analysis includes random trials both with control groups and with pretest-posttest formats. N= 47 studies</p> <p>Effect size was calculated and weighted for sample size. Homogeneity of the study populations was established and outliers were removed before effect size was calculated.</p>	Outcome	# of studies included in analysis	Effect size	95% CI
		Knowledge of dietary principles	10	0.41 ± 0.07	0.28 - 0.54
		Composite knowledge	14	0.91 ± 0.07	0.83 - 1.12
		Knowledge - multiple measures	39	0.51 ± 0.03	0.45 - 0.57
		Insulin injection skill	3	0.25 ± 0.08	0.09 - 0.41
		Urine testing skill	5	0.38 ± 0.07	0.24 - 0.52
		Skills performance composite	10	0.31 ± 0.06	0.20 - 0.43
		Weight	16	0.24 ± 0.06	0.13 - 0.36
		Dietary compliance	6	1.01 ± 0.11	0.79 - 1.23
		Dietary compliance composite	7	0.99 ± 0.11	0.78 - 1.20
		A1C	13	0.84 ± 0.08	0.69 - 0.99
		Blood sugar	13	0.39 ± 0.06	0.27 - 0.51
		Metabolic control - multiple measures	53	0.34 ± 0.03	0.28 - 0.39
<p>Behavioral Science Research in the Prevention of Diabetes: Status and Opportunities. (Fisher, 2002) US</p>	<p>This review focuses on diabetes prevention research and places in the frame of an ecological or contextualized model, which focuses on the sociocultural framework in which diabetes prevention can occur. Out of this model, four areas for research are developed.</p>	<p>Risk perception and communication: This includes both the perceived risk of developing diabetes and the perceived risks associated with treatments and their potential for efficacy. Fisher et al recommend further research into the process by which those at risk of diabetes make decisions about key elements of diabetes prevention and, when applicable, treatment.</p>			
		<p>Screening: Fasting plasma glucose screening in health care rather than community settings is recommended. However, further research into the potential for psychological distress and associated social and behavioral impacts of being categorized at "at risk" or of receiving a positive notification. Research into these issues could benefit all studies of diabetes and diabetes prevention interventions with regard to issues of recruitment and retention in trials.</p>			
		<p>Lifestyle and Type II prevention: This section recounts the Diabetes Prevention Program Research Group, 1999 study summarized above. Fisher et al recommend further research into operationalizing the results of the study and emphasizes the importance of looking into organization based (e.g. schools) interventions as well as individual-focused ones.</p>			
		<p>Sociocultural disparities: Research should focus on identifying how the above phenomena are influenced by sociocultural issues, and focus on accessing disempowered groups through existing social conduits -- successful examples include interventions via literacy training programs, church groups.</p>			

LIFESTYLE MODIFICATION

Study (Author, Year) Location	Range of Study	Major Conclusions of Interest						
National Standards for Diabetes Self-Management Education Programs. (Funnell, 1995) US	This article reviews the ADA/NDAB standards for diabetes patient education programs, and provides further examination and revisions to the standards, which were developed in 1986.	Standards of Interest: Standard 4: The service area will be assessed to define the target population and determine appropriate allocation of personnel and resources to serve the educational needs of the target population. The article suggests that the use of focus groups has been an effective means of measuring these needs. Standard 12: The program will be capable of offering, based on the needs of the target population, instruction in the following content areas: 1) diabetes overview, 2) stress and psychosocial adjustment, 3) family involvement and social support, 4) nutrition, 5) exercise and activity, 6) medications, 7) monitoring and use of results, 8) monitoring and use of results, 8) relationships among nutrition, exercise, medication, and blood glucose levels, 9) prevention, detection, and treatment of acute complications, 10) prevention, detection, and treatment of chronic complications, 11) foot, skin, and dental care, 12) behavior change strategies, goal-setting, risk factor reduction, and problem solving, 13) benefits, risks, and management options for improving glucose control, 14) preconception care, pregnancy, and gestational diabetes, and 15) use of health care systems and community resources. Note especially # 3, for which there has been some support in the research, e.g. that spousal attendance of sessions improves performance. Standard 13: The program will use instructional methods and materials that are appropriate for the target population and the participants being served. The article suggests that a review of 20 studies published before 1995 indicated that diet instruction, social learning, and behavior modification had the strongest effects on knowledge gain and physical outcomes. The use of videotapes is also emphasized.						
		Positive outcomes:						
Role of Exercise Stress Testing and Safety Monitoring for Older Persons Starting an Exercise Program. (Gill, 2000) US	Meta-analysis The study looks at the benefits and risks of beginning an exercise program in persons over 75. It is NOT diabetes specific.	Study	Number of participants	minimum age	years follow-up	outcome	effect size ¹	
		Cummings et al, 1995	9516	65	6.5	hip fracture	RR 0.7	
		LaCroix et al, 1996	1645	65	4-5	hospitalization for cardiovascular	RR 0.69	
		Kaplan et al, 1987	564	70	17	all-cause mortality	HR 0.73	
		Glass et al, 1999	2761	65	13	all-cause mortality	HR 0.85	
		Bijnen et al, 1999	472	70	5	all-cause mortality	HR 0.44	
		Seeman et al, 1995	1015	70	2.5	significant decline in physical performance, based on testing	OR 0.52	
		LaCroix et al, 1993	6981	65	4	loss of mobility	RR 0.6	
		Hakim et al, 1999	2678	71	2-4	incident coronary disease from all causes	RR 2.3	
		Ferrucci et al, 1999	3319	75	1-8	active life expectancy (free from disabilities)	increased by 2.5-4 yrs	
		Leveille et al, 1999	610	72	2-8	likelihood of being non-disabled prior to death in old age	OR 1.86	
		Negative outcomes:						
		Study	number of participants	age	estimated rate of MI by level of physical exertion per 1 million person-hours			
					men -- moderate	men -- vigorous	women -- moderate	women -- vigorous
Myocardial Infarction Onset Study	nr	75-79	8.0	40.7	3.6	18.3		
	nr	80-84	8.6	43.5	3.9	19.9		
	nr	85 +	11.2	57.1	3.8	19.4		
Given these data, the authors suggest that a series of unanswered questions need to be addressed, concerning physicians current considerations in recommending exercise program for their older patients and means of measuring exercise capacity as well as cardiovascular risk. An important consideration is asymptomatic cardiac problems; the authors suggest research to determine the efficacy of screening all patients in preventing cardiac events.								

RR = risk reduction, HR = hazard ratio, OR = odds ratio

LIFESTYLE MODIFICATION

Study (Author, Year) Location	Range of Study	Major Conclusions of Interest									
Self-Management Education for Adults with Type 2 Diabetes. A meta-analysis of the effect on glycemic control. (Norris, 2002)	The study covered randomized controlled trials testing self-management education of adults with type 2 diabetes with data on A1C. Mean age: 55 N = 31	Study	Number of participants	duration of intervention (months)	Baseline A1C	First follow-up		Second follow-up		Third follow-up	
						months after	net change	months after	net change	months after	net change
		Agurs-Collins, 1997	64	6	10.0	0	-0.80	3	-2.60	--	--
		Bloomgarden, 1987	345	19	6.6	0	-0.40	--	--	--	--
		Brown, 1999	247	12	12.4	0	-2.00	--	--	--	--
		Campbell, 1996	238	12	11.9	-1	-0.50	-1	-2.30	--	--
		de Bont, 1981	148	6	9.2	0	-0.04	--	--	--	--
		de Weerd, 1989	558	1	9.2	6	-0.24	--	--	--	--
		d'Eramo-Melkus, 1992	82	3	10.9	0	-1.87	3	-1.59	--	--
		Estey, 1990	60	2.5	6.1	0	-0.40	--	--	--	--
		Falkenberg, 1986	46	3	7.3	6	0.00	--	--	--	--
		Franz, 1995	247	1.5	8.3	1.5	-0.30	4.5	-0.20	--	--
		Glasgow, 1995	206	9	7.9	3	-0.10	nr	0.00	--	--
		Glasgow, 1992	102	2.5	7.4	3	-0.10	--	--	--	--
		Hawthorne, 1997	201	nr	nr	6	-0.34	--	--	--	--
		Heller, 1988	87	6	12.7	-1	-0.70	0	-1.60	6	-0.50
		Kaplan, 1985	76	2.5	7.5	15.5	-0.24	--	--	--	--
		Korhonen, 1987	80	12	9.2	-1	-0.13	-1	-0.40	0	-0.04
		Mazzucca, 1986	532	6	9.4	12	-0.78	--	--	--	--
		McColluch, 1983	44	6	12.9	-1	-0.80	0	-1.40	--	--
		Mulrow, 1987	120	10	9.5	1	0.00	--	--	--	--
		Perry, 1997	70	6	8.7	0	-0.40	--	--	--	--
		Raz, 1988	51	12	9.6	0	-2.20	--	--	--	--
		Ridgeway, 1999	58	6	12.3	0	-0.99	6	-0.14	--	--
		Scott, 1984	60	1	8.7	0	-0.50	--	--	--	--
		Trento, 1998	120	12	7.3	0	-0.21	--	--	--	--
		Tu, 1993	31	1	nr	1.5	-0.46	--	--	--	--
		Tumin, 1992	105	6	10.8	0	-0.80	--	--	--	--
		Uusitupa, 1993	86	27	7.8	-1	-0.30	0	-0.20	--	--
		White, 1986	41	6	11.3	0	0.40	--	--	--	--
Wing, 1986	50	10	10.5	-1	0.68	3	0.51	--	--		
Wing, 1988	20	10	10.5	-1	0.49	2	1.06	--	--		
Wise, 1986	88	6	8.7	6	-0.80	--	--	--	--		
Summary statistics:											
Period of measurement			number of studies	significance level		net change in A1C (%)					
During or immediately after the intervention			20	<0.05		-0.76 (95% CI = -1.18 to -0.34)					
1-3 months after the intervention			9	NS		-0.26 (95% CI = -0.73 to 0.21)					
4 or more months after the intervention			8	NS		-0.26 (95% CI = -0.48 to -0.05)					

LIFESTYLE MODIFICATION

Study (Author, Year)	Range of Study	Major Conclusions of Interest															
		Study	number of participants	mean age	intervention ²	Significant improvement in knowledge	Significant improvement in behavior	Significant improvement in quality of life	Significant improvement in physical indicators	Study	number of participants	mean age	intervention	Significant improvement in knowledge	Significant improvement in behavior	Significant improvement in quality of life	Significant improvement in physical indicators
Effectiveness of Self-Management Training in Type 2 Diabetes. A systematic review of randomized controlled trials. (Norris, 2001)	This study examined RCTs published between 1980 and 1999 regarding self- management training and type 2 DM. ¹ Age nr N = 72	33	60	--	didactic informative	y		y	y	95	120	61	lifestyle intervention	y		n	n
		34	345	58	didactic informative	y	n		n	41	70	59	skills teaching	y	y		y
		35	77	33	didactic informative	y	n		n	45	34	37	skills teaching	y	y		
		42	30	59	didactic informative					53	50	73	skills teaching	n	n		
		47	51	53	didactic informative	n			y	58	30	55	skills teaching		y		
		51	40	60	didactic informative	y				62	395	60	skills teaching		y		y
		52	111	56	didactic informative	n				63	50	--	skills teaching	n	y		n
		57	31	65	didactic informative		y		n	64	203	--	skills teaching				y
		26	80	53	collaborative informative	y			y	85	64	50	coping skills			y	
		27	532	57	collaborative informative	y			y	86	32	68	coping skills	y			
		29	238	56	collaborative informative	y			y	65	1139	46	didactic informative		y		y
		30	46	66	collaborative informative	y	n		n	66	148	55	lifestyle intervention		y		y
		32	174	57	collaborative informative	y			y	67	206	62	lifestyle intervention		y		y
		40	558	45	collaborative informative	y	y	n	n	69	86	53	lifestyle intervention		y		y
		44	24	--	collaborative informative	y				70	75	61	lifestyle intervention		y		n
		46	471	52	collaborative informative	y	y		n	71	60	55	lifestyle intervention		y		y
		48	82	56	collaborative informative	n	n		y	72	78	--	lifestyle intervention		y		n
		50	40	57	collaborative informative	n			y	73	70	42	lifestyle intervention		y		n
		54	107	60	collaborative informative		y		n	74	102	67	lifestyle intervention		y		n
		55	41	60	collaborative informative	n			n	77	53	55	lifestyle intervention		n		y
		56	53	63	collaborative informative	n				78	79	68	lifestyle intervention				y
		59	60	55	collaborative informative		y		n	93	70	58	lifestyle intervention		y		y
		98	22	61	collaborative informative	n	y		n	106	53	55	lifestyle modification		n		
		99	56	64	collaborative informative	y			y	107	152	--	lifestyle modification		y		n
		108	280	55	collaborative informative		y			87	247	54	collaborative informative				y
		31	40	35	lifestyle intervention	y			y	96	156	58	collaborative informative				n
		36	87	56	lifestyle intervention	y			y	79	76	54	lifestyle intervention				y
		37	105	58	lifestyle intervention	n	y	y		84	163	64	lifestyle intervention				y
		38	32	53	lifestyle intervention	y	y		y	88	80	56	lifestyle intervention				n
		39	105	45	lifestyle intervention	y	y		n	90	50	54	lifestyle intervention				n
		43	201	53	lifestyle intervention	y	y		y	91	120	54	lifestyle intervention				n
		49	41	61	lifestyle intervention	n			y	92	40	54	lifestyle intervention				y
		75	66	--	lifestyle intervention		y	y	n	94	23	--	lifestyle intervention				y
76	64	62	lifestyle intervention	y	y		y	61	20	53	skills teaching				n		
80	40	59	lifestyle intervention	n	n		n	81	247	57	lifestyle intervention				n		
83	596	51	lifestyle intervention	y			y	105	55	53	coping skills				y		

Significant results listed to the right are between group significance on any measure falling under the specific heading. If "n" is listed, this indicates that all data listed for measures under that heading were not significant. Didactic informative and collaborative informative are distinguished by teaching style and the way in which the curriculum is established. Didactic programs use the traditional classroom education format while collaborative programs low participants to collaborate with educators in determining the topics covered and goals set.

LIFESTYLE MODIFICATION

Conclusions: Factors other than knowledge are needed to effect behavioral change and improvements in quality of life and physical status.

LIFESTYLE MODIFICATION

Study (Author, Year) Location	Range of Study	Major Conclusions of Interest				
Meta-analysis of the Effects of Educational and Psychosocial Interventions on Management of Diabetes Mellitus. (Padgett, 1988) US	Studies conducted from 1976-1986 with either control group or pretest-posttest. Age nr N=93 studies	Type of Intervention	Physical Outcomes ¹	Psychological Outcomes ²	Knowledge Outcomes ³	Compliance Outcomes ⁴
		Didactic education	0.60 ± 0.53 (n = 5)	(n = 0)	0.55 ± 0.91 (n = 6)	0.16 ± 0.70 (n = 4)
		Enhanced education (e.g. including any of the below)	0.36 ± 0.39 (n = 17) p < 0.05	0.41 ± 0.56 (n = 4)	0.81 ± 0.57 (n = 13) p < 0.05	0.52 ± 0.37 (n = 7) p < 0.05
		Diet Instruction alone	0.62 ± 0.62 (n=12) p < 0.05	(n = 0)	1.07 ± 0.25 (n = 3) p < 0.05	1.10 ± 1.16 (n = 5)
		Exercise instruction alone	0.31 ± 0.15 (n = 5) p < 0.05	(n = 0)	(n = 0)	(n = 0)
		Self-monitoring instruction alone	0.50 ± 0.97 (n = 10)	0.84 ± 0.50 (n = 3)	(n = 0)	0.49 ± 0.41 (n = 7) p < 0.05
		Social learning/behavior modification	0.60 ± 0.34 (n = 7) p < 0.05	0.51 ± 0.27 (n = 3)	0.77 (n = 1)	0.57 ± 0.75 (n = 3)
		Counseling	0.39 ± 0.20 (n = 5) p < 0.05	0.38 ± 0.34 (n = 3)	0.01 (n = 1)	0.23 ± 0.61 (n = 2)
		Relaxation training	0.28 ± 0.73 (n = 10)	0.61 ± 0.99 (n = 5)	(n = 0)	(n = 0)

Clinical outcomes such as change in weight or blood pressure

Psychological outcomes such as reduction in depression

Changes in knowledge test scores

Changes which indicate compliance with prescribed regimen or other evidence of compliance (e.g. refill of medications).

LIFESTYLE MODIFICATION

Study (Author, Year) Location	Range of Study	Major Conclusions of Interest											
Effectiveness of Interventions to Improve Patient Compliance: A Meta-Analysis. (Roter, 1998) US (See also Polypharmacy evidence table)	Randomized controlled trials published between 1977 and 1994 that evaluated the effectiveness of interventions to improve patient compliance with medical regimens. Age nr N=153 studies Calculations of 1) effect size (weighted for sample size of study) and 2) significance measures were made based on association between the compliance intervention and the compliance outcome.	Type of Intervention	Health Outcome ¹ (n=35)	Direct ² (n=27)	In-direct ³ (n=36)	Sub-jective ⁴ (n=45)	Util-ization ⁵ (n=68)	Type of Intervention	Health Outcome	Direct	Indirect	Sub-jective	Util-ization
		Educational (focused on information-conveyance, either written or verbal)	0.13 < 0.0001	0.23 < 0.0001	0.35 < 0.0001	0.14 < 0.0001	0.19 < 0.0001	Educational - one-on-one	0.13 < 0.01	0.21 < 0.01	0.43 < 0.0001	0.12 < 0.01	0.15 < 0.0001
		Educational - group	--	0.34 < 0.0001	--	--	0.21 < 0.01						
		Educational - written	--	--	0.12 NS	0.18 < 0.001	0.11 < 0.01						
		Educational - phone	--	--	--	--	0.35 < 0.0001						
		Educational/Behavioral	0.18 < 0.0001	0.23 < 0.001	0.83 < 0.0001	0.20 < 0.0001	0.16 < 0.0001	Educational - skill building	0.23 < 0.05	0.18 < 0.05	--	0.22 < 0.01	--
		Affective (focused on emotions/social support)	0.18 < 0.01	0.31 < 0.001	--	0.07 NS	0.18 < 0.01	Behavioral - packaging	--	0.23 < 0.01	0.21 < 0.0001	--	--
		Educational/ Affective	--	0.19 < 0.05	--	0.22 < 0.0001	0.37 < 0.0001	Behavioral - dosage	--	--	0.36 < 0.0001	--	--
		Behavioral (focused on shaping specific behaviors)	0.20 < 0.0001	0.17 < 0.001	0.27 < 0.0001	0.20 < 0.0001	0.18 < 0.0001	Behavioral - mail reminders	--	--	0.23 < 0.0001	--	0.21 < 0.0001
		Behavioral/Affective	0.20 < 0.001	--	--	0.22 < 0.0001	--	Behavioral - phone reminders	--	--	--	--	0.19 < 0.0001
		Educational/Behavioral/Affective	0.24 < 0.001	0.34 < 0.0001	--	--	0.38 < 0.0001	Behavioral - rewards	--	--	--	--	0.04 NS
		Provider Intervention	0.03 NS	--	0.46 < 0.0001	0.02 NS	0.06 < 0.0001	Affective - family support	--	--	--	0.10 < 0.01	--
		Targeted Condition n = nr	Health Outcome	Direct	Indirect	Sub-jective	Util-ization	Targeted Condition	Health Outcome	Direct	Indirect	Sub-jective	Util-ization
		Diabetes mellitus	--	0.29 < 0.0001	0.73 < 0.0001	0.17 < 0.0001	--	High blood pressure	0.16 < 0.0001	0.23 < 0.0001	0.76 < 0.0001	0.15 < 0.0001	0.31 < 0.0001
		Cardiovascular	--	--	0.02 NS	0.30 < 0.05	--	Lipids	--	--	--	--	0.13 < 0.0001

Health outcomes are such measures as blood pressure, hospitalization, pain, relapse, etc.

Direct measures are such measures as blood glucose, urine tracers, cholesterol, body weight, etc.

Indirect measures are such measures as pill counts, prescription refills, etc.

Subjective measures are such measures as patients' reports of compliance, chart review, etc.

Utilization measures are such measures as appointment making and keeping, use of preventative services, etc.