

Effectiveness of Self-Management Training in Type 2 Diabetes

A systematic review of randomized controlled trials

SUSAN L. NORRIS, MD, MPH
MICHAEL M. ENGELGAU, MD, MSC
K.M. VENKAT NARAYAN, MD, MPH

OBJECTIVE — To systematically review the effectiveness of self-management training in type 2 diabetes.

RESEARCH DESIGN AND METHODS — MEDLINE, Educational Resources Information Center (ERIC), and Nursing and Allied Health databases were searched for English-language articles published between 1980 and 1999. Studies were original articles reporting the results of randomized controlled trials of the effectiveness of self-management training in people with type 2 diabetes. Relevant data on study design, population demographics, interventions, outcomes, methodological quality, and external validity were tabulated. Interventions were categorized based on educational focus (information, lifestyle behaviors, mechanical skills, and coping skills), and outcomes were classified as knowledge, attitudes, and self-care skills; lifestyle behaviors, psychological outcomes, and quality of life; glycemic control; cardiovascular disease risk factors; and economic measures and health service utilization.

RESULTS — A total of 72 studies described in 84 articles were identified for this review. Positive effects of self-management training on knowledge, frequency and accuracy of self-monitoring of blood glucose, self-reported dietary habits, and glycemic control were demonstrated in studies with short follow-up (<6 months). Effects of interventions on lipids, physical activity, weight, and blood pressure were variable. With longer follow-up, interventions that used regular reinforcement throughout follow-up were sometimes effective in improving glycemic control. Educational interventions that involved patient collaboration may be more effective than didactic interventions in improving glycemic control, weight, and lipid profiles. No studies demonstrated the effectiveness of self-management training on cardiovascular disease-related events or mortality; no economic analyses included indirect costs; few studies examined health-care utilization. Performance, selection, attrition, and detection bias were common in studies reviewed, and external generalizability was often limited.

CONCLUSIONS — Evidence supports the effectiveness of self-management training in type 2 diabetes, particularly in the short term. Further research is needed to assess the effectiveness of self-management interventions on sustained glycemic control, cardiovascular disease risk factors, and ultimately, microvascular and cardiovascular disease and quality of life.

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Diabetes self-management training, the process of teaching individuals to manage their diabetes (1), has been considered an important part of clinical management since the 1930s (2). The goals of diabetes education are to optimize metabolic control, prevent acute and chronic complications, and optimize

quality of life while keeping costs acceptable (3). One of the goals of Healthy People 2010 is to increase to 60% (from the 1998 baseline of 40%) the proportion of individuals with diabetes who receive formal diabetes education (4). There are significant knowledge and skill deficits in 50–80% of individuals with diabetes (5), and ideal glycemic control ($HbA_{1c} < 7.0\%$) (6) is achieved in less than half of persons with type 2 diabetes (7). The direct and indirect costs of diabetes and its complications were estimated to be \$98 billion in 1997 (8), although the cost of diabetes education as a discrete component of care has not been defined.

A large body of literature exists on diabetes education and its effectiveness, including several important quantitative reviews showing positive effects. However, these reviews aggregated studies of heterogeneous quality (9–11) and types of interventions (9,10) and do not identify the most effective form of diabetes education for specific populations or outcomes. Moreover, educational techniques have evolved since these reviews (9–11) and have shifted from didactic presentations to interventions involving patient “empowerment” (12).

The objective of this study was to systematically review reports of published randomized controlled trials to ascertain the effectiveness of self-management training in type 2 diabetes, to provide summary information to guide diabetes self-management programs and future quantitative analyses, and to identify further research needs.

RESEARCH DESIGN AND METHODS

Search methods

The English-language medical literature published between January 1980 and December 1999 was searched using the MEDLINE database of the National Library of Medicine, the Educational Resources Information Center (ERIC) database, and the Nursing and Allied

From the Division of Diabetes Translation, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, Atlanta, Georgia.

Address correspondence and reprint requests to Susan L. Norris, MD, Centers for Disease Control and Prevention, MS K-10, 4770 Buford Highway NE, Atlanta, GA 30341. E-mail: scn5@cdc.gov.

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Abbreviations: SMBG, self-monitoring of blood glucose.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

Health database (commenced in 1982). The medical subject headings (MeSH) searched were “Health Education” combined with “Diabetes Mellitus,” including all subheadings. Abstracts were not included because they generally contain insufficient information to assess the validity of the study by the criteria described below. Dissertations were also excluded because the available abstracts contained insufficient information for evaluation and the full text was frequently unavailable. Titles of articles extracted by the search were reviewed for their relevance to the effectiveness of diabetes education, and if potentially relevant, the full-text article was retrieved. Because automated databases are incomplete (13–15), the following journals, believed to have the highest relevance, were searched manually: *Diabetes Care*, *Diabetes Educator*, *Diabetes Research and Clinical Practice*, *Diabetologia*, and *Diabetic Medicine*.

Study selection

Only randomized, controlled trial reports were selected because this type of study design generally supports maximum validity and causal inference (16). We reviewed only studies in which all or most subjects had type 2 diabetes. If the type of diabetes was unclear, then the study was included when the mean age was >30 years. It was believed that the educational techniques and social influences (especially family and peers) relevant to children and adolescents with either type 1 or type 2 diabetes were sufficiently different to warrant a separate review. To examine as broadly as possible the effectiveness of diabetes education, we included studies of subjects with type 2 diabetes >18 years of age, with any degree of disease severity and with any comorbidity. Interventions in all settings were included. Education could be delivered by any provider type, could involve any medium (written, oral, video, computer), could be individual- or group-based, and could be of any duration and intensity. Studies with multi-component interventions were included only if the effects of the educational component could be examined separately.

Self-management training interventions were classified into one of the following categories by primary educational focus: knowledge or information; lifestyle behaviors, including diet and physical activity; skill development, including skills to improve glycemic control such as self-

Table 1—Assessment of internal validity based on Cochrane Collaboration Criteria (20)

Type of bias	Definition
Selection bias	Systematic differences in control and intervention groups at baseline To avoid requires randomization and no significant differences between baseline variables in control and intervention groups, or adequate statistical consideration of potential confounders if baseline differences exist
Performance bias	Systematic differences in care provided to control and intervention groups, apart from the intervention being evaluated To avoid requires no evidence of contamination or cointervention, including no additional contacts with researcher or providers for the intervention group compared with the control group
Attrition bias	Systematic differences between study groups in withdrawals from the study To avoid requires attrition <20% of total n, or dropouts must resemble completers in baseline characteristics
Detection bias	Systematic differences in outcomes assessment between study groups To avoid requires blinding for any outcome subject to assessor interpretation

monitoring of blood glucose (SMBG), as well as skills to prevent and identify complications (e.g., foot care); and coping skills (to improve psychosocial function), including interventions using empowerment techniques or promoting relaxation or self-efficacy. Studies with a focus on knowledge or information were subclassified by primary type of educational approach: didactic or collaborative. Didactic education occurred when the patient attended to the information but did not interact with the instructor or participate actively in teaching sessions. Collaborative education occurred when the patient participated actively in the learning process, including group discussions or hands-on practice, or when teaching techniques included empowerment (17), individualized goal-setting, biofeedback, or modeling. The other three categories of lifestyle, skill development, and coping skills education were generally all collaborative to some extent; therefore, these types of interventions were not subclassified.

Data extraction

Data extracted from eligible studies included descriptive information, analysis methods, and results. Extraction was not blinded, because there is no evidence that blinding results in a decrease in bias in the conduct of systematic reviews and meta-analyses (18,19).

Validity assessment

Quality assessment was determined by what was reported in each article, and internal validity was assessed using Cochrane methodology (20) for four types of bias (Table 1). These biases are believed to have significant effects on measured outcomes in intervention studies (21), and if present in an article, note was made in the tables.

These criteria for bias were modified from those used in Cochrane methodologies, because not one study in the literature reviewed fulfilled all definitions for the absence of bias. To avoid selection bias, ideally one requires concealment of the allocation schedule so that neither patient nor researcher can influence assignment sequence (22). However, because most studies in this review did not comment on method of allocation, beyond stating that subjects were randomized, allocation concealment was not used as a necessary criteria for the absence of selection bias. To avoid performance bias, blinding of patients to the intervention is required, which is impossible in diabetes education studies; therefore, patient blinding was not used as a validity criterion. Attrition was noted as a potential bias when more than 20% of initially enrolled subjects dropped out before data collection, and dropouts were not compared or were not found equivalent to completers at baseline.

External validity was also assessed

and was considered adequate if the accessible population reasonably represented the target population and study subjects were either a random sample of the accessible population or consecutively referred patients, or if no significant differences between participants and nonparticipants were demonstrated at baseline. Studies with populations that consisted of volunteers, that were convenience samples, or were otherwise selected by the researchers may not be generalizable to target populations; therefore, the nature of these study populations is indicated in the tables.

Outcomes

Outcomes are summarized in a qualitative fashion to 1) aid in generating hypotheses, 2) detail the categorization of variables for future quantitative syntheses (23), and 3) portray the heterogeneity of the populations, interventions, methodology, study quality, and outcomes in this literature. It was believed that derivation of a single summary statistic would not be meaningful in determining what interventions are effective in what populations. The power of statistical tests of homogeneity is low, and failure to reject a hypothesis of homogeneity does not prove that studies are sufficiently similar to be aggregated (24).

We classified outcomes as 1) process measures including knowledge, attitudes, and self-care skills; 2) lifestyle behaviors, psychological outcomes, and quality of life; 3) glycemic control; 4) cardiovascular disease risk factors; and 5) economic measures and health service utilization. Because a study can have multiple outcomes, each study can be listed one or more times in the results tables, which are classified by outcome. Glycated hemoglobin measures are presented as percentage change in the text and the figure, due to the measurement of different glycated components of hemoglobin in different studies as well as the variability of measurement between laboratories and over time (25).

RESULTS— A total of 72 discrete studies, published in 84 articles, were identified. These studies are heterogeneous with respect to patient population, educational intervention, outcomes assessed, study quality, and generalizability (Tables 2–6). Review of this literature reveals a number of important generaliza-

tions concerning the components and determinants of effective interventions and the outcomes most conducive to improvement.

Process measures

Knowledge. Most studies measuring changes in diabetes knowledge demonstrate improvement with education (Table 2) (26–46), including those with follow-up of 6–12 months after the last intervention contact (28–30,36,40,43). Seven studies demonstrated improved knowledge for both the intervention and control groups (47–53), suggesting possible contamination due to the infeasibility of blinding participants. A number of studies demonstrated that regular reinforcement or repetition of the intervention seemed to improve knowledge levels at variable lengths of follow-up: Bloomgarden et al. (34) (nine visits in 18 months), Korhonen et al. (35) (one visit every 3 months for 12 months), Campbell et al. (29) (regular reinforcement with visits and telephone calls over 12 months), and Rettig et al. (46) (12 visits in 12 months). Knowledge was measured using a variety of instruments, often specifically developed for the study and lacking in documented reliability and validity (26,30,32,33,35,39,44,47,52,54–56).

Self-care. Several studies observed increased frequency of, or more accurate SMBG, demonstrated by a decreased discrepancy between measurement by the patient and health-care personnel (40,45,57–59) (Table 2). Several studies examined the relationship between skills teaching and glycemic control. Although three of these studies (40,57,60) noted an increase in frequency of SMBG, no corresponding improvement in HbA_{1c} was found. Wing et al. (61) taught adjustment of diet and physical activity in conjunction with SMBG, but the patients in this study failed to show improved glycemic control at 1 year.

Several studies examined interventions focusing on foot lesions with mixed results. Litzelman et al. (62) noted a decrease in serious foot lesions at 1 year after an intervention consisting of group education, with three follow-up visits, provider guidelines, and chart reminders. Other studies failed to demonstrate improvements with interventions (41,46,63). Malone et al. (64) found a significant decrease in foot ulcer and ampu-

tation rates, although this study had significant methodological inadequacies.

Lifestyle behaviors

Most studies that examined dietary changes were positive for self-reported changes, including improvements in dietary carbohydrate or fat intake (38,39,65–70) (Table 3), a decrease in caloric intake (39,67), and an increase in consumption of lower glycemic-index foods (71). A few studies demonstrating improved dietary changes found corresponding improvements in weight (38,66,72) or glycemic control (31). Only two studies failed to show improvement in diet: one had an 18-month follow-up and an intervention delivered every 3 months (35), and the other (73) noted improved dietary habits during the intervention but no significant difference at 6 months.

Studies measuring physical activity outcomes had variable results. Hanefeld et al. (65) demonstrated an increase in activity at 5 years with a didactic intervention. Among studies with shorter follow-up duration, Wood (54) noted an increase in physical activity at 4 months, Glasgow et al. (74) found an increase in the number of minutes of activity 3 months after an intensive intervention, and Wierenga (75) found improved physical activity after five intervention sessions at 4 months. Five studies found no changes in physical activity compared with control groups (30,40,69,76,77). It is unclear what factors might account for success in some studies and not in others.

Psychological and quality-of-life outcomes

Four studies examined psychological outcomes (Table 3) (33,40,74,78); improvements were noted in problem solving (74) and anxiety levels (33). Quality of life was examined in three studies. Kaplan et al. (79) noted an increase in quality of life at 18 months for an intervention subgroup that received intensive counseling on both diet and physical activity. Two studies of brief interventions failed to demonstrate improved quality of life (60,67).

Glycemic control

Studies that focused on glycemic control are described in Table 4 and Fig. 1. Both control and intervention study groups tended to have improved glycated hemoglobin measures (29,31,32,36,48,49,60,

Table 2—Effect of self-management training on knowledge, attitudes, and self-care skills

Reference	n, F/U interval, and mean age	Interventions	Outcomes	Comments
1. Didactic, knowledge, and information interventions				
33	n = 60; F/U immediate, 4 weeks; ?age	I: Four weekly group sessions; individual as needed C: Started same education 4 weeks later	Increased knowledge I vs. C at 4 weeks, P < 0.01	No BL statistics; I more visits than C Attrition 29%, dropouts not equal to completers at BL Low participation rate, but NSD participants and nonparticipants
34	n = 345; F/U immediate; 58 years	I: Nine multimedia education classes over 1.5 years C: Usual care	Increased knowledge I vs. C, P = 0.0073 NSD behavior score; NSD foot lesions	No mention blinding assessor Low participation rate; nonparticipants older, more males
35	n = 77; F/U 6–18 months from BL; 33 years	I: 5-day IP teaching: didactic, individual F/U q3 months, phone access; instruction in self-adjustment insulin C: 5-day IP “traditional” education + written information; 3 × 1.5-h sessions; q3 months F/U	Increased knowledge both C and I, I > C, P < 0.01 at 12 months Increased urine testing I and C (NSD between groups) Knowledge not correlated with BS control	No BL comparison statistics No attrition information No blinding for diet history Low recruitment rate and no information on nonparticipants
42	n = 30; F/U immediate; 59 years	I: 15-min video featuring local HCW in Spanish C: Pretest only, then viewed video	Increased knowledge in I, effect size moderate (0.61)	No BL comparison of demographics Unclear if assessor blinded Convenience sample I had no pretest to avoid bias from retesting
47	n = 51; F/U 12 months from BL; 53 years	I: Three weekly didactic, small group sessions q4 months + q2 months visit with doctor C: Visit with doctor q2 months	NSD knowledge between groups	I more visits than C No information on participation rates
51	n = 40; F/U immediate; 60 years	I: 1-h individual education based on patient’s priorities C: 1 h individual education based on educator’s priorities	Increased knowledge both groups, P < 0.0001, NSD between groups	Unclear if assessor blinded Consecutively referred patients Type of DM unclear
52	n = 111; F/U 2–3 months; 56 years	I: One-page drug information sheet given to patients attending clinic C: Usual care	Both groups increased knowledge; NSD between groups	
57	n = 31; F/U 1 week; HbA _{1c} F/U 2 months; 65 years	I: Four weekly TC after hospital discharge: identify deficits and teach C: No TC or other contact	I more frequent SMBG and increased hypoglycemic prevention, P < 0.05	I more contact than C Unclear if assessor blinded No information on nonparticipants
2. Collaborative, knowledge, and information interventions				
26	n = 80; F/U 6 months from BL; 53 years	I: Group sessions: didactic and discussions; no details of duration or frequency; F/U every 3 months C: Care at general medical clinic every 3 months	Increased knowledge in I vs. C, P < 0.01	Attrition 25%, no comparison dropouts to completers
27, 28	n = 532; F/U 12–14 months; 57 years	I: Average 2.4 sessions × 1.5 h over 2 months + home visit, TC F/U, contracting, skill exercises, goal-setting; over 26 months C: Usual care	Achievement of some knowledge, skill, and self-care objectives in I vs. C, P < 0.05	I more visits than C Attrition 51%, differences dropouts and completers No blinding assessor Low participation rate
29	n = 238; F/U 3, 6, 12 months from BL; 56 years	I-1: 13 individual sessions in 12 months I-2: Three-day interactive course + F/U 3 and 9 months + two individual sessions I-3: Six or more individual sessions based on cognitive behavior theory, TC F/U over 12 months C: 2 × 1-hour group education	Increased knowledge I-3 at 3 and 6 months, P < 0.05	BL differences: I-2 better educated, I-1 longer duration DM I more visits than C Dropouts longer duration DM than completers Unclear if study population represents target population
30	n = 46; F/U immediate, 6 months; 66 years	I: 8 × 2-hour small group sessions over 3 months; problem- and participant-focused C: One-day didactic teaching	Increased knowledge at 6 months I vs. C, P < 0.05	I more visits than C More C excluded due to poor control No mention blinding assessor Nonparticipants older and heavier
32	n = 174; F/U 4–6 months; 57 years	I-1: Computer knowledge assessment program (KAP) + interactive computer teaching (60 min) I-2: KAP (20–40 min) + feedback I-3: KAP only C: No intervention	Increased knowledge all I, P < 0.05 (within group)	Randomization by year and birth month (no details given) I more contact than C NIDDM results reported here (49% of total study population IDDM)

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Table 2—Continued

Reference	n, F/U interval, and mean age	Interventions	Outcomes	Comments
40, 60	n = 558; F/U 6 months; 45 years	I-1: Collaborative education by HCW, 3 h/week × 4 weeks I-2: Same education, led by fellow patient C: No intervention I based on Fishbein and Ajzen Health Belief Model	Increased knowledge both I, $P < 0.001$; Increased DM locus of control, $P < 0.001$ Improved attitude and frequency SMBG both I, $P < 0.05$ Increased self-adjustment of insulin both I, $P < 0.01$	Hospitals randomized I more visits than C Uncertain blinding assessor
44	n = 24; F/U immediate; 35–65 years	I: 1-h computer-based drill with feedback including explanation of correct answer C: As for I, but right/wrong feedback only I and C received 14-min instructive video before computer drill	Increased knowledge in I vs. C, $P = 0.005$ NSD attitudes toward the drill	No BL comparisons Volunteer study population
46	n = 471; F/U 6, 12 months from BL; 52 years	I: Home visits, teaching based on needs assessment, maximum 12 visits C: Usual care	Increased knowledge at 6 months, $P = 0.001$ NSD foot appearance score at 6 months Increased medication skills at 6 months, $P = 0.04$ and urine testing, $P = 0.01$	Attrition 20%, no comparison dropouts to completers 70% of eligible participated
48	n = 82; F/U 6 months from BL; 56 years	I-1: 11 × 2-h didactic weekly course + 1 individual session I-2: 11-week course + three individual sessions: barriers and support C: Usual care	Increased knowledge for all three groups; NSD between groups NSD health locus of control	No BL statistics comparing groups I more visits than C Attrition 40%, no comparison dropouts to completers Volunteer study population
50	n = 40; F/U 3 months; 57 years	I: CAI, 4 × 1-h sessions: didactic, some feedback and testing C: Didactic group teaching; 4 × 3-h	Increased knowledge both groups; NSD between groups	No BL group comparison statistics Low participation rate, no information on nonparticipants or dropouts
54	n = 107; F/U 1, 4 months; 60 years	I: 2 × 2-h group didactic + practice + feedback + usual care C: Usual care: individual education based on perceived patient need Both in IP setting	Increased compliance to insulin injection time for I at 4 months, $P = 0.05$	Randomized by hospital number No blinding assessor No information on participation rates
55	n = 41; F/U 2 months; 60 years	I-1: Three-day program + group session with pharmacist I-2: Three-day program + individual session with pharmacist; TC F/U C: Standard center 3-day education program	NSD change in knowledge between I and C or between I-1 and I-2 Improved attitudes/perceptions towards medications in I vs. C, $P < 0.05$ NSD attitudes to SMBG	No BL comparison I more contact than C 23% had unusable data for SMBG
56	n = 53; F/U 3–5 weeks; 63 years	I: 2 × 5-min TC in 5 weeks; focus knowledge and skills C: 2 × 15-min individual visits in 5 weeks, same content Both groups individual education immediately before intervention	NSD overall knowledge	Attrition 25%, no comparison dropouts to completers
59	n = 60; F/U 3 months from BL; 55 years	I: Three-day group education, with F/U of four TC and one home visit; reinforce knowledge and skills C: Three-day group education	Frequency SMBG I > C, $P < 0.0001$	I more contact than C Unclear if study population represents target population
98	n = 22; F/U 32 weeks from BL; 61 years	I: Weekly to biweekly home visits: nutrition, exercise, foot care, SMBG; by nursing students C: Usual care	NSD knowledge between groups Increased self-care competency in I vs. C, $P = 0.003$	Attrition 24%, no comparison dropouts to completers No mention blinding assessor Unclear if study population represents target population
99	n = 56; F/U 6 months; 64 years	I: Monthly × 6 group sessions: behavior modification (contracts, feedback), and general knowledge C: Usual care	Increased knowledge at 6 months, $P = 0.0003$	I more contact than C Attrition 32%, no comparison dropouts to completers Participation rate 37%, no comparison participants to nonparticipants
108	n = 280; F/U 6 months; 55 years	I: Education on importance of eye examination: booklet, video; one interactive TC C: Usual care	Increased rate of retinal examination in I (OR = 4.3, 95% CI 2.4–7.8)	

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Table 2—Continued

Reference	n, F/U interval, mean age	Interventions	Outcomes	Comments
3. Lifestyle interventions				
31	n = 40; F/U 6 months from BL; 35 years	I-1: Lunch demonstrations I-2: Videotape education C: Dietitian instruction and written information Three visits total for all groups over 6 months	Increased knowledge in I-1 and I-2, P < 0.001	No mention blinding assessor Study population selected by researchers; low participation rate Type of diabetes unclear ("insulin dependent")
36	n = 87; F/U 12 months from BL; 56 years	I: Five group sessions over 6 months, focus on weight loss C: Individual education on weight loss by dietitian; 3 or more visits in 12 months	Increased knowledge I > C, P < 0.001	
37	n = 105; F/U 6 months; 58 years	I: Diet guide: guidelines, nutrition goals, food logs C: Traditional exchange list teaching Both groups taught at 3 × 2.25-h weekly sessions	NSD diet principals; Increased applied nutrition knowledge I > C, P < 0.01 Attitude to life and diet, and diet knowledge improved I and C, P < 0.05	Attrition 21%, no information on dropouts Unclear how patients recruited
38	n = 32; F/U immediate; 53 years	I: Two sessions: dietitian and CAI C: 2 × 30-min sessions: dietitian only Teaching for both over ~1 month	Increased exchange list knowledge for I, P < 0.05; NSD C	No BL statistics Unclear if blinding assessor Type of DM unclear
39	n = 105; F/U immediate, 12 months; 45 years	I: Interactive computer program on diet; 90 min/month over 6 months C: Wait listed for I Both groups received 5 days of teaching	Increased knowledge for I, P < 0.0001; NSD for C	I more contact than C Attrition appears to be 76% at 12 months F/U No comparison dropouts to completers No mention blinding assessor No information on patient recruitment Crossover design
43	n = 201; F/U 6 months; 53 years	I: Culturally appropriate flashcards: diet, SMBG; delivered by lay HCW C: Usual care	Increased knowledge, self-care in I vs. C, P < 0.05	I more contact than C Intensity of intervention unclear
49	n = 41; F/U 6 months; 61 years	I: Psychologist-led group sessions on PA and diet C: Didactic lectures on diet and DM Both groups 10 × 1-h sessions over 6 months	Increased knowledge for both groups, P < 0.05, NSD between groups	Dropouts (22%) had higher mean BS; equal number dropouts I and C Low participation rate, no information on nonparticipants
75	n = 66; F/U 4 months; 30–86 years	I: 5 × 90-min weekly sessions by nurse: diet, PA, barriers, social and group support C: No information on care received	Improved health attitudes I vs. C, P = 0.015 NSD perceptions of health relating to DM	No BL statistics Volunteer study population Number of visits uncertain
76	n = 64; F/U 3, 6 months from BL; 62 years	I: 12 × 1.5-h weekly (didactic) sessions, then 6 × 1.5-h biweekly participatory sessions; based on social action theory C: One didactic class and two mailings	Increased nutrition knowledge at 3 months; NSD from BL at 6 months	I more visits than C More C dropouts, no comparison dropouts to completers Volunteer study population
80	n = 40; F/U 2, 5 months from BL; 59 years	I: 3 × 1.5-h individual learning activity packages with diet information, goals, activities C: 3 × 1.5-h didactic lectures	Increased knowledge for I at 5 months, P < 0.05	Attrition 23%, no comparison dropouts to completers Volunteer study population from DM education program
83	n = 596; F/U immediate, 6 months; 51 years	I: More nutrition content, follow food pyramid C: Usual education, given meal plan Both I and C: 5 × 2-h weekly group sessions	NSD attrition, knowledge, self-care between choice/no choice groups NSD knowledge, self-care between I and C	Randomized into choice/no choice of program, then I and C Attrition 28%, dropouts younger, more male No mention blinding assessor Physician-referred patients or volunteers
95	n = 120; 12 months from BL; 61 years	I: Group education (diet, PA, BS control) q3 months × 4 C: Usual care	Increased knowledge in I, P < 0.001	I more contact than C Unclear if study population represents target population

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Table 2—Continued

Reference	n, F/U interval, and mean age	Interventions	Outcomes	Comments
4. Skills teaching interventions				
41	n = 70; F/U 6 months; 59 years	I: 9 h over 4 weeks: participatory foot care based on cognitive motivation theory C: Usual DM teaching: 14 h didactic/3 days, including 1 h foot care	Increased knowledge both groups at 6 months, I > C, P < 0.001 Increased compliance foot care routines at 6 months, I > C, P = 0.012 Compliance correlates with decreased foot problems, P = 0.002 Decreased foot problems both I and C, NSD between groups at 6 months Compliance correlates with decreased foot problems, P = 0.002	Volunteer study population
45	n = 34; F/U 8 weeks; 37 years	I: Self-study course on self-control and self-management SMBG, over 4 weeks C: Usual care	Increased knowledge and skills for I > C, P < 0.01 Increased SMBG goal adherence rate more for I than C, P < 0.01	No BL statistics Attrition 26%, no comparison dropouts to completers Community recruitment; participants self-selected Type of DM unclear No mention blinding assessor
53	n = 50; F/U 1 month; 73 years	I: 24-min instructional video on technique SMBG C: Group didactic instruction on technique SMBG	Increased knowledge both groups, NSD between groups No improvement SMBG technique I or C	
58	n = 30; F/U immediate; 55 years	I: SMBG instruction for 30 min by educator C: Self-instruction SMBG for 30 min	Decreased error BS measurement in I, P < 0.01	
62	n = 395; F/U 12 months from BL; 60 years	I: Group foot education with F/U ×3 over 3 months; chart reminders for providers, provider guidelines C: Usual care	Decreased serious foot lesions in I at 1 year, P = 0.05 I had more appropriate foot care behaviors, P < 0.05 Physicians examined I feet more often at office visits, P < 0.001	Randomized by practice team I more contact than C Low participation rate; no information on nonparticipants
63	n = 50; F/U 6 months; adult	I: Additional participatory teaching on foot care C: Usual education, with routine, didactic foot education Both groups: 5 days of OP DM education	Self-care practices increased both groups, no statistics Increased knowledge foot care for C only, P = 0.02 NSD physical assessment feet I or C	Randomized by week entering program; no BL comparisons Attrition 35% I, 44% C, no comparison dropouts to completers No mention blinding assessor No demographic data; type of DM unclear
64	n = 203; F/U 13 months I, 9 months C; ?age	I: 1-h didactic group education on foot care C: No education	Decreased foot ulcer rate, P < 0.005 Decreased amputation rate, P < 0.025 NSD infection rate	Randomized on SSN No information on dropouts No mention blinding assessor No information on nonparticipants Type of DM unclear
5. Coping skills interventions				
85	n = 64; F/U 6 weeks; 50 years	I: 6 × 2-h weekly group sessions: patient empowerment, goal-setting, problem solving, stress management C: Wait listed	Increased 4/8 self-efficacy subscales, between group difference, P < 0.02	No BL comparisons; 18 patients not randomly assigned I more contact than C Volunteer study population 64% DM2 HbA _{1c} measured immediately after program for C, 6 weeks after for I
86	n = 32; F/U 2 years; 68 years	I-1: Six weekly sessions + 18 monthly support group sessions: coping, discussion, education I-2: Six-week sessions only; wait list for support group C: Usual care	Increased knowledge maintained for I-1 at 2 years, P < 0.05	C is nonrandomized comparison group More visits for I-1 > I-2 > C No information on attrition Unclear if study population represents target population Type of DM unclear

BL, baseline; BS, blood sugar; BP, blood pressure; C, C-1, C-2, control groups; CAI, computer-assisted instruction; CHO, carbohydrate; D/SBP, diastolic/systolic blood pressure; DM, diabetes mellitus; DM2, type 2 diabetes; FBS, fasting blood sugar; F/U, follow-up; HCW, health-care worker; I, I-1, I-2, I-3, intervention groups; IP, inpatient; NSD, no significant difference; OP, outpatient; PA, physical activity; q, every; RN, registered nurse; SD, significant difference; TC, telephone call.

66,68,74,78,80–83) (Fig. 1). All studies were unblinded. In 14 studies, an improvement was noted in glycemic control in the intervention group compared with the control group (26,28,32,33,47,48,50,

65,71,76,79,84–87). Percentage change in glycosylated hemoglobin ranged from –26 to +4% in the intervention groups and from –33 to +15% in the control groups. In three studies, glycosylated hemoglobin de-

creased more in the control group (61,80,83), although the difference was significant in only one study (80).

Length of follow-up after completion of an intervention seemed to have a major

Table 3—Effect of self-management training on lifestyle behaviors, psychological outcomes, and quality of life

Reference	n, F/U interval, and mean age	Interventions	Outcomes	Comments
1. Didactic, knowledge, and information interventions				
33	n = 60; F/U immediate, 4 weeks; ?age	I: Four weekly group sessions: individual as needed C: Started same education 4 weeks later	Decreased anxiety at 4 weeks I vs. C, $P < 0.05$ NSD depression score	No BL statistics I more visits than C Attrition 29%, dropouts not equal completers at BL Low participation rate, but NSD participants and nonparticipants
35	n = 77; F/U 6 to 18 months from BL; 33 years	I: Five days IP teaching: didactic, individual F/U q3 months, phone access; instruction in self-adjustment insulin C: Five days IP “traditional” education + written information; 3 × 1.5-h sessions; q3 months F/U	NSD diet adherence at 18 months	No BL comparison statistics No attrition information No blinding for diet history Low recruitment rate and no information on nonparticipants
65, 109	n = 1,139; F/U 5 years; 46 years	I-1: Didactic individual and group sessions q3 months: focus on diet, PA, smoking, BP, and BS control I-2: I-1 + clofibrac acid C: Usual care at DM clinics; q3–4 months	Increased polyunsaturated fats in I vs. C, $P < 0.01$ Increased PA in I vs. C, $P < 0.01$	No mention blinding assessor Low participation rate, no information on nonparticipants Clofibrac acid arm double-blinded
2. Collaborative, knowledge, and information interventions				
30	n = 46; F/U immediate, 6 months; 66 years	I: 8 × 2-h small group sessions over 3 months; problem- and participant-focused C: One day didactic teaching	NSD exercise	I more visits than C More C excluded due to poor control No mention blinding assessor Nonparticipants older and heavier
40, 60	n = 558; F/U 6 months; 45 years	I-1: Collaborative education by HCW, 3 h/week × 4 weeks I-2: Same education, led by fellow patient C: No intervention I based on Fishbein and Ajzen Health Belief Model	NSD hypoglycemic reactions, anxiety, PA	Hospitals randomized I more visits than C Uncertain blinding assessor
54	n = 107; F/U 1, 4 months; 60 years	I: 2 × 2-h group didactic + practice + feedback + usual care C: Usual care: individual education based on perceived patient need Both in IP setting	Increased exercise I vs. C at 1 and 4 months, $P = 0.05$	Randomized by hospital number No binding assessor No information on participation rates
98	n = 22; F/U 32 weeks from baseline; 61 years	I: Weekly to biweekly home visits: nutrition, exercise, foot care, SMBG; by nursing students C: Usual care	NSD food assessment, 3-day dietary recall, functional health status between groups	Attrition 24%, no comparison dropouts to completers No mention blinding assessor Unclear if study population represents target population
3. Lifestyle interventions				
31	n = 40; F/U 6 months from BL; 35 years	I-1: Lunch demonstrations I-2: Videotape education C: Dietitian instruction and written information Three visits total for all groups over 6 months	Decreased CHO variation in I-1 and I-2, $P < 0.01$	No mention blinding assessor Study population selected by researchers; low participation rate Type of diabetes unclear (“insulin dependent”)
38	n = 32; F/U immediate; 53 years	I: Two sessions: dietitian and CAI C: 2 × 30-min sessions: only dietitian Teaching for both over approximately 1 month	Decreased % fat intake I, $P < 0.005$; NSD C	No BL statistics Unclear if blinding assessor Type of DM unclear
39	n = 105; F/U immediate, 12 months; 45 years	I: Interactive computer program on diet; 90 min/month over 6 months C: Wait listed for I Both groups received 5 days teaching	Decreased caloric and fat intake for those in I with initial high intake, $P < 0.05$	I more contact than C Attrition appears to be 76% at 12 months F/U, no comparison dropouts to completers No mention blinding assessor No information on patient recruitment Crossover design
66	n = 148; F/U 6 months from BL; 55 years	I: Advice to decrease fat to <30% total calorie intake C: Advice to decreased CHO to <40% total calorie intake Both individual counseling by dietitian, three home visits	Decreased fat and cholesterol intake, increased CHO for I, between group difference, $P < 0.001$	

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Table 3—Continued

Reference	n, F/U interval, and mean age	Interventions	Outcomes	Comments
67, 68, 104	n = 206; F/U 12 months from BL; 62 years	I: Single visit: focus on diet; goal-setting, interactive video on barriers; F/U q3 months C: Usual care q3 months	Improvement in I vs. C at 12 months for food habits, 4-day food record, kcal/day, % calories from fat, P < 0.05	Unclear if food record reviewers blinded Low participation rate; participants differ from nonparticipants
69, 82, 89, 103	n = 86; F/U 15, 27 months from BL; 53 years	I: Six individual visits at 2-month intervals: intensive therapy for weight, BS control, diet, PA; then q3 months visits C: Usual care q2–3 months Both groups got 3 visits/3 months basic education before randomization	Fat intake <30% of total energy, I > C at 15 months, P < 0.05 NSD energy intake NSD physical activity, Vo _{2max} at 15 months	I more visits than C No mention blinding assessor No information on nonparticipants
70	n = 75; F/U 12 months from BL; 61 years	I: Educational videos, personal and family support q2 weeks for 6 months + 3 h counseling by dietitian C: Review session × 3	Decreased self-reported fat intake, P = 0.0002 NSD self-reported total food or fiber intake	I more contact than C
71	n = 60; F/U 12 weeks from BL; 55 years	I: Individualized advice on low glycemic index foods C: Standard, individualized diet advice	Consumption of lower glycemic index foods I > C, P < 0.01	No mention blinding assessor Unclear how much intervention time
72	n = 78; F/U 2 months; 42–75 years	I-1: 5 × 2-h weekly education: calories, fat, fiber I-2: I-1 + goal setting, problem-solving, feedback C: Wait listed for I	Decreased calories and % fat F/U for I-2 at immediate and 2 months, P < 0.01 Decreased calories for I-1 at 2 months, P < 0.05	No BL information I more visits than C More attrition in C, no comparison dropouts to completers Unclear if assessor blinded Unclear how study population recruited
73	n = 70 F/U immediate 6 months; 42 years	I: Monthly (or more) meetings: diet and PA prescription, feedback, behavior modification C: Usual care, wait listed for I	Decreased total fat intake at immediate F/U, I vs. C, P = 0.047 Deterioration of diet improvements at 6 months	Incomplete BL statistics I more visits than C No mention blinding assessor Volunteer study population; cross-over design Type of DM uncertain (“IDDM”)
74	n = 102; F/U 3, 6 months from BL; 67 years	I: Ten weekly sessions: problem-solving, increased self-efficacy; diet and PA focus C: Wait listed for I	Increased problem-solving for I at 3 and 6 months; between group, P < 0.05	Randomization blocked by medication I more visits than C Volunteer study population
75	n = 66; F/U 4 months; 30–86 years	I: Five × 90-min weekly sessions by nurse: diet and PA, barriers, social and group support C: No information on care received	Improved health practices (diet, PA) I vs. C, P = 0.015	No BL statistics Volunteer study population Number of visits uncertain
76	n = 64; F/U 3, 6 months from BL; 62 years	I: 12 × 1.5-h weekly (didactic) sessions, then 6 × 1.5-h biweekly participatory sessions; based on social action theory C: One didactic class and two mailings	Increased PA 3 months; NSD 6 months	I more visits than C More C dropouts, no comparison dropouts to completers Volunteer study population
77	n = 53; F/U 16 months from BL; 55 years	I-1: 16 weekly sessions of behavioral modification: calorie logs, group PA, monetary incentives I-2: 16 weekly didactic sessions: nutrition and PA C: Four monthly didactic sessions	Improved eating and PA all groups at 4 months, NSD between groups; regression toward BL at 16 m but remained significant	I more visits than C Volunteer study population
78, 97	n = 79; F/U immediate; 68 years	I-1: 10 × 60-min diet education sessions over 4 months; adapted for elderly I-2: I-1 + peer support: group sessions; modeling, reinforcement C: Usual care	Peer support levels correlated with weight loss, glycemic control, P < 0.05	Randomized by site No BL comparisons or attrition information I more visits than C Community recruitment; volunteer study population
83	n = 596; F/U immediate, 6 months; 51 years	I: More nutrition content, follow food pyramid C: Usual education, given meal plan Both I and C: 5 × 2-h weekly group sessions	NSD physical function between choice/no choice groups or between I and C	Randomized into choice/no choice of program, then I and C Attrition 28%, dropouts younger, more male No mention blinding assessor Physician-referred patients or volunteers
93	n = 70; F/U 6 months from BL; 58 years	I: 22 h over 11 weeks, interactive teaching based on cognitive motivational theory C: Didactic teaching, 14 h over 3 days Focus for both I and C: diet and foot care	Increased dietary CHO but NSD between groups Decreased % fat for both groups at 1 month, I > C, P = 0.004	I more contact than C

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Table 3—Continued

Reference	n, F/U interval, and mean age	Interventions	Outcomes	Comments
95	n = 20; 12 months from BL; 61 years	I: Group education (diet, PA, BS control) q3 months × 4 C: Usual care	NSD quality of life	I more contact than C Unclear if study population represents target population
106	n = 53; F/U 16 weeks from BL; 55 years	I-1: Nutrition education: 16 weekly sessions; exchange system diet, goal-setting I-2: Nutrition education: four monthly sessions; exchange system diet, goal-setting C: Behavior modification: 16 weekly visits; calorie-counting diet, goal-setting	Decreased caloric intake and % calories from fat in I and C, P < 0.001; NSD between groups	I-2 more visits than C Volunteer study population I-1 and I-2 combined in analysis, as NSD between groups
107	n = 152; F/U 10, 14 weeks from BL; >50 years	I: 10 × 2-h sessions over 14 weeks, culturally sensitive video; nutrition focus C: No intervention	Decreased intake kcal/d C males, P = 0.04 Decreased cholesterol intake C females, P = 0.013	No BL comparisons I more visits than C Attrition 30.2% No information on dropouts No information on blinding assessor Volunteer study population
4. Skills teaching interventions				
90	n = 50; F/U 1 year from BL; 54 years	I: Focused on relationship weight loss and BS control; monetary incentives C: Weight loss program Both groups: 12 weekly meetings, then monthly × 6, F/U in 3 months; behavioral weight control program	Reduction in medications both groups, NSD between groups Decreased caloric intake C, P < 0.004 Decreased depression both groups, NSD between groups	Volunteer study population
5. Coping skills interventions				
86	n = 32; F/U 2 years; 68 years	I-1: Six weekly sessions + 18 monthly support group sessions: coping, discussion, education I-2: Six weekly sessions only; wait list for support group C: Visual care	Increased quality of life Decreased stress I-1 vs. C at 6 months P < 0.05	C is nonrandomized comparison group More visits for I-1 > I-2 > C No information on attrition Unclear if study population represents target population Type of DM unclear

BL, baseline; BS, blood sugar; BP, blood pressure; C, C-1, C-2, control groups; CAI, computer-assisted instruction; CHO, carbohydrate; D/SBP, diastolic/systolic blood pressure; diabetes mellitus; DM2, type 2 diabetes; FBS, fasting blood sugar; F/U, follow-up; HCW, health-care worker; I, I-1, I-2, I-3, intervention groups; IP, inpatient; NSD, no significant difference; OP, outpatient; PA, physical activity; q, every; RN, registered nurse; SD, significant difference; TC, telephone call.

effect on outcomes, and studies with a follow-up period of ≤6 months tended to demonstrate greater effectiveness (31–33,48,50,71,76,84). Few studies had follow-up periods longer than 1 year after the last intervention contact, and these showed mixed effects on glycemic control. The positive studies were either very intensive interventions (79) or had a high attrition rate, leaving a very select group at follow-up (28). Studies with prolonged interventions (follow-up periods >1 year and regular contacts with the intervention subjects during that time) also had mixed results. Two studies (47,65) demonstrated improved glycemic control, although generalizability of these studies is difficult due to a low participation rate (65) and a lack of information on study participation (47). Ten others produced no significant effects, despite regular patient contact (29,34,35,67,69,82,86,88–90).

For knowledge and information in-

terventions, the method of delivery seemed to have a relationship to glycemic control. Compared with didactic interventions, collaborative interventions produced somewhat more favorable results, particularly if interventions were repetitive and ongoing (26,28,48,50,76,84,86).

Most studies focusing on changes in lifestyle generally failed to show improvements in glycemic control compared with control groups (36,39,43,49,66,67,70,72–74,77,78,81–83,88,90–95), but a few studies (31,71,79,84) showed improved glycemic control in researcher-selected or volunteer populations with follow-up <6 months. Improved glycemic control was associated with weight loss in some studies (28,47,48,76,79) and not others (31,65,71,84). Increased physical activity levels were associated with improved glycemic control in one study (65), although another study noted no

changes in physical activity despite improvements in glycemic control (76).

Improved glycemic control and increased knowledge were not consistently correlated. Although a number of studies demonstrated an increase in knowledge with an improvement in glycemic control (26–28,31–33,50), others demonstrated improved metabolic control with no change in knowledge (47,76), and eight studies demonstrated increased knowledge but no significant improvement in glycemic control (29,34–36,40,49,80,88). Two of three studies focusing on coping-skills training produced improvements in glycemic control (85,86); these involved frequent group support meetings.

Computers have been used recently as an educational tool in a number of studies, and effects on glycemic control have been mixed: positive results in three studies (32,39,50) and negative results in another study (67,68). Additionally, vid-

Table 4—Effect of self-management training on glycemic control

Reference	n, F/U interval, and mean age	Interventions	Outcomes	Comments
1. Didactic, knowledge, and information interventions				
33	n = 60; F/U immediate, 4 weeks, ?age	I: Four weekly group sessions; individual sessions as needed C: Started same education 4 weeks later	Decreased HbA _{1c} at 4 weeks I vs. C, P < 0.05	I more visits than C No BL statistics Attrition 29%, dropouts not equal to completers at BL Low participation rate, but NSD participants and nonparticipants
34	n = 345; F/U immediate; 58 years	I: Nine multimedia education classes over 1.5 years C: Usual care	NSD HbA _{1c} or FBS	No mention blinding assessor Low participation rate; nonparticipants older, more male
35	n = 77; F/U 6–18 months from BL; 33 years	I: Five days IP teaching; didactic, individual F/U q3 months, phone access; instruction in self-adjustment insulin C: Five days IP “traditional” education + written information; 3 × 1.5-h sessions; q3 months F/U	Decreased FBS for C and I at 1 month, NSD between groups NSD from BL at 6 months	No BL comparison statistics; no attrition information; No blinding for diet history Low recruitment rate and no information on nonparticipants
47	n = 51; F/U 12 months from BL; 53 years	I: Three weekly didactic, small group sessions q4 months + q2 months visit with doctor C: Visit with doctor q2 months	Decreased HbA _{1c} and FBS in I vs. C, P < 0.05 Exact values not given	I more visits than C No information on participation rates
57	n = 31; F/U 1 week, HbA _{1c} F/U 2 months; 65 years	I: Four weekly TC after hospital discharge: identify deficits and teach C: No TC or other contact	NSD HbA _{1c} between groups	I more contacts than C Unclear if assessor blinded No information on nonparticipants
65, 109	n = 1,139; F/U 5 years; 46 years	I-1: Didactic individual and group sessions q3 months; focus on diet, PA, smoking, BP and BS control I-2: I-1 + clofibrilic acid C: Usual care at DM clinics; q3–4 months	Decreased FBS in I vs. C, P < 0.01	No mention blinding assessor Low participation rate, no information on nonparticipants Clofibrilic acid arm double-blinded
2. Collaborative, knowledge, and information interventions				
26	n = 80; F/U 6 months from BL; 53 years	I: Group sessions: didactic and discussions; no details duration or frequency; F/U q3 months C: Care at general medical clinic q3 months	Decreased FBS in I vs. C at 6 months (9.7 vs. 6.4 mmol/l), P < 0.01	Attrition 25%, no comparison dropouts to completers
27, 28	n = 532; F/U 12–14 months; 57 years	I: Average 2.4 sessions × 1.5-h over 2 months + home visit, TC F/U, contracting, skill exercises, goal-setting; over 26 months C: Usual care	Decreased HbA _{1c} in I (0.43%), P < 0.05, increased in C (0.35%) Decreased FBS I vs. C, P < 0.05	I more visits than C Attrition 51%, differences dropouts and completers No blinding assessor Low participation rate
29	n = 238; F/U 3, 6, 12 months post BL; 56 years	I-1: 13 individual sessions in 12 months I-2: Three-day group interactive course + F/U 3 and 9 months + 2 individual sessions I-3: Six or more individual sessions based on cognitive behavioral theory, TC F/U over 12 months C: 2 × 1-h group education	Decreased HbA _{1c} for all groups at all F/U intervals NSD between groups	BL differences: I-2 better educated; I-1 had longer duration DM I more visits than C Dropouts longer duration DM than completers Unclear if study population represents target population
30	n = 46; F/U immediate, 6 months; 66 years	I: 8 × 2-h small group sessions over 3 months; problem- and participant-focused C: One-day didactic teaching	NSD HbA _{1c} at 6 months	More C excluded due to poor control I more visits than C No mention blinding assessor Nonparticipants older and heavier
32	n = 174; F/U 4–6 months; 57 years	I-1: Computer knowledge assessment program (KAP) + interactive computer teaching (60 min) I-2: KAP (20–40 min) + feedback I-3: KAP only C: No intervention	Decreased HbA _{1c} I-2 (−1.3%, P < 0.05) and I-3 (−0.08%, P < 0.05)	Randomization by year and month birth (no details given) I more contact than C NIDDM results reported here (49% of total study population “IDDM”)
40, 60	n = 558; F/U 6 months; 45 years	I-1: Collaborative education by HCW, 3 h/week × 4 weeks I-2: Same education led by fellow patient C: No intervention I based on Fishbein and Ajzen Health Belief Model	NSD HbA _{1c} at 6 months	Hospitals randomized I more visits than C Uncertain blinding assessor
48	n = 82; F/U 6 months post BL; 56 years	I-1: 11 × 2-h weekly didactic course + 1 individual session I-2: 11-week course + three individual sessions: barriers and support C: Usual care	FBS and HbA _{1c} decreased for I-1 and I-2 at 3 and 6 months, P < 0.05	No BL statistics comparing groups I more visits than C Attrition 40%, no comparison dropouts to completers Volunteer study population

Continued on following page

Table 4—Continued

Reference	n, F/U interval, and mean age	Interventions	Outcomes	Comments
50	n = 40; F/U 3 months; 57 years	I: CAI, 4 × 1-h session: didactic, some feedback and testing C: Didactic group teaching; 4 × 3-h	Decreased GHb I (relative change 11%), P < 0.05, increased C (14%), P < 0.05, between group difference, P = 0.001	No BL group comparison statistics Low participation rate, no information on nonparticipants or dropouts
54	n = 1.07; F/U 1, 4 months; 60 years	I: 2 × 2-h group didactic + practice + feedback + usual care C: Usual care: individual education based on perceived patient need Both in IP setting	NSD BS at 4 months	Randomized by hospital number No blinding assessor No information on participation rates
55	n = 41; F/U 2 months; 60 years	I-1: Three-day program + group session with pharmacist I-2: Three-day program + individual session with pharmacist; TC F/U C: Standard center 3-day education program	NSD % change in BS between I and C	No BL comparisons I more contact than C 23% had unusable data for SMBG
59	n = 60; F/U 3 months from BL; 55 years	I: Three-day group education, with F/U of 4 TC and 1 home visit; reinforce knowledge and skills C: Three-day group education	NSD HbA _{1c} between groups	I more contact than C Unclear if study population represents target population
87	n = 247; F/U 12 months from BL; 54 years	I: 12 weekly sessions over 3 months; Spanish videos, followed by 14 group support sessions in 9 months, by lay HCW C: Wait listed for the intervention	Decreased GHb 1.7% in I, increased 0.3% in C Decreased FBS 18.9 mg/dl in I, increased 3.9 in C	No BL comparison I more contact than C No information on attrition No mention blinding assessor No statistics
96	n = 156; F/U ? immediate; 58 years	I-1: Patient selects behavior for improvement I-2: Behavioral strategies to increase compliance I-3: Behavioral strategies + instruction on behavioral analysis C: Routine care with consistent F/U by RN: I-1,2,3 based on social cognitive theory I over 13 months	NSD GHb I and C	No information on attrition Volunteer study population Number of patient contacts unclear F/U interval unclear
98	n = 22; F/U 32 weeks from baseline; 61 years	I: Weekly to biweekly home visits: nutrition, exercise, foot care, SMBG; by nursing students C: Usual care	NSD GHb or BS at 32 weeks	Attrition 24%, no comparison dropouts to completers No mention blinding assessor Unclear if study population represents target population
99	n = 56; F/U 6 months; 64 years	I: Monthly ×6 group sessions: behavior modification (contracts, feedback), general knowledge C: Usual care	Decreased GHb immediate F/U I and C (P < 0.05), NSD between groups; NSD at 6 months Decreased FBS I at immediate F/U, NSD between groups	I more contact than C Attrition 32%, no comparison dropouts to completers Participation rate 37%, no comparison participants to nonparticipants
3. Lifestyle interventions				
31	n = 40; F/U 6 months from BL; 35 years	I-1: Lunch demonstrations I-2: Videotape education C: Dietitian instruction and written information Three visits total for all groups over 6 months	Decreased HbA _{1c} I-1 (-2.4%, P < 0.025) and I-2 (-3.3%, P < 0.001) Decreased HbA _{1c} correlated with decreased CHO variation, P < 0.02	No mention blinding assessor Study population selected by researchers; low participation rate Type of diabetes unclear (“insulin dependent”)
36	n = 87; F/U 12 months from BL; 56 years	I: Five group sessions over 6 months, focus on weight loss C: Individual education on weight loss by dietitian; 3 or more visits in 12 months	Decreased HbA _{1c} I at 6 months, P < 0.001; NSD I vs. C at 1 year	
39	n = 105; F/U immediate, 12 months; 45 years	I: Interactive computer program on diet; 90 min/month over 6 months C: Wait listed for I Both groups received 5 days of teaching	NSD HbA _{1c} or fructosamine at immediate F/U Decreased HbA _{1c} at 18 months (10.8 to 9.6, P < 0.001)	I more contact than C Attrition appears to be 76% at 12 months F/U; no comparison dropouts to completers No mention blinding assessor Crossover design No information on patient recruitment
43	n = 201; F/U 6 months; 53 years	I: Culturally appropriate flashcards: diet, SMBG; delivered by lay HCW C: Usual care	Decreased HbA _{1c} in I (-0.34%, P > 0.05)	I more contact than C Intensity of intervention unclear

Continued on following page

Table 4—Continued

Reference	n, F/U interval, and mean age	Interventions	Outcomes	Comments
49	n = 41, F/U 6 months; 61 years	I: Psychologist-led group sessions on PA and diet C: Didactic lectures on diet and DM Both groups 10 × 1-h sessions over 6 months	Decreased HbA _{1c} for I and C, NSD between groups Decreased mean BS at 6 months for I, between group difference, P < 0.05	Dropouts (22%) had higher mean BS; equal number dropouts I and C Low participation rate, no information on nonparticipants
66	n = 148; F/U 6 months from BL; 55 years	I: Advice to decrease fat to <30% total calorie intake C: Advice to decrease CHO to <40% total calorie intake Both I and C received individual counseling by dietitian; three home visits	NSD HbA _{1c} between groups NSD fasting plasma glucose between groups	
67, 68, 104	n = 206; F/U 12 months from BL; 62 years	I: Single visit: focus on diet; goal-setting, interactive video on barriers, F/U q3 months C: Usual care q3 months	NSD HbA _{1c} at 12 months	Unclear if food record reviewers were blinded Low participation rate; participants differ from nonparticipants
69, 82, 89, 103	n = 86; F/U 15, 27 months from BL; 53 years	I: Six individual visits at 2-month intervals; intensive therapy for weight, BS control, diet, PA; then q3 months visits C: Usual care q2–3 months Both groups 3 visits/3 months basic education before randomization	Decreased FBS for I > C at 15 months, P = 0.02; NSD 27 months NSD HbA _{1c} 15 and 27 months	I more visits than C No mention blinding assessor No information on nonparticipants I more contact than C
70	n = 75; F/U 12 months from BL; 61 years	I: Educational videos, personal and family support q2 weeks for 6 months + 3 h counseling by dietitian C: Review session × 3	NSD GHb	
71	n = 60; F/U 12 weeks from BL; 55 years	I: Individualized advice on low glycemic index foods C: Standard, individualized diet advice	Decreased FBS I and C, significant only for I, P < 0.05 Decreased fructosamine I vs. C, P < 0.05	No mention blinding assessor Unclear how much intervention time
72	n = 78; F/U 2 months; 42–75 years	I-1: 5 × 2-h weekly education: calories, fat, fiber I-2: I-1 + goal setting, problem-solving, feedback C: Wait listed for I	NSD GHb	No BL information I more visits than C More attrition in C, no comparison dropouts to completers Unclear if assessor blinded Unclear how study population recruited
73	n = 70; F/U immediate, 6 months; 42 years	I: Monthly (or more) meetings: diet and PA prescription, feedback, behavior modification C: Usual care; wait listed for I	NSD HbA _{1c} immediate or 6 months	Incomplete BL statistics I more visits than C No mention blinding assessor Volunteer study population Crossover design Type of DM uncertain (“IDDM”)
74	n = 102; F/U 3, 6 months from BL; 67 years	I: 10 weekly sessions: problem-solving, increased self efficacy, diet and PA focus C: Wait listed for I	Decreased HbA _{1c} in I and C at 3 months (0.5%), NSD between groups, return to BL at 6 months	Randomization blocked by medication I more visits than C Volunteer study population
76	n = 64; F/U 3, 6 months from BL; 62 years	I: 12 × 1.5-h weekly (didactic), sessions then 6 × 1.5-h biweekly participatory diet and exercise sessions, based on social action theory C: One didactic class and two mailings	Decreased HbA _{1c} at 3 months (−1.5%) and 6 months (−1.1%), P < 0.01	I more visits than C More C dropouts, no comparison dropouts to completers Volunteer study population
77	n = 53; F/U 16 weeks, 16 months from BL; 55 years	I-1: 16 weekly sessions: behavioral modification, calorie logs, group PA, monetary incentives I-2: 16 weekly didactic sessions nutrition and PA C: Four monthly didactic sessions	Decreased FBS and HbA _{1c} all groups at 16 weeks, P < 0.01, NSD between groups NSD FBS and HbA _{1c} at 16 months	I more visits than C Volunteer study population
78, 97	n = 79; F/U immediate; 68 years	I-1: 10 × 60-min diet education sessions over 4 months; adapted for elderly I-2: I-1 + peer support: group sessions, modeling, reinforcement C: Usual care	Decreased HbA _{1c} at 8 weeks, for I-2, P < 0.05, not maintained at 16 weeks	Randomized by site No BL comparisons or attrition information I more visits than C Community recruitment; volunteer study population

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Table 4—Continued

Reference	n, F/U interval, and mean age	Interventions	Outcomes	Comments
79, 100, 101	n = 76; F/U 3, 6, 18 months from BL; 54 years	I-1: Diet focus; goal-setting, modify environment I-2: PA focus with participation I-3: Diet + PA C: Didactic teaching All groups: 10 × 2-h weekly sessions: I based on behavior and cognitive modification strategies	Decreased BS I-1 vs. C at 6 months, P < 0.037; NSD HbA _{1c} Decreased HbA _{1c} 1-3 vs. C at 18 months (difference 1.8%, P < 0.05)	Randomized by group meeting attended Volunteer study population
80	n = 40; F/U 2, 5 months from BL; 59 years	I: 3 × 1.5-h individual learning activity packages with diet information, goals, activities C: 3 × 1.5-h didactic lectures	Decreased HbA _{1c} in C (4.5%) at 5 months, P < 0.05; NSD I group	Attrition 23%, no comparison dropouts to completers Volunteer study population from DM education program
81, 102	n = 247; F/U 6 months from BL; 57 years	I: Three or more individual visits with dietitian, over 6 weeks, following practice guidelines C-1: One visit producing nutrition care plan C-2: Nonrandomized comparison group; no intervention	Decreased FBS and HbA _{1c} I at 6 months, P < 0.001; decreased C-1, P < 0.01; NSD between I and C-1	Nonrandomized C-2 C less time with dietitian Attrition 28% for lab studies, unclear if dropouts equal completers at BL Volunteer study population or physician-referred
83	n = 596; F/U immediate, 6 months; 51 years	I: More nutrition content, follow food pyramid C: Usual education, given meal plan Both I and C: 5 × 2-h weekly group sessions	Decreased HbA _{1c} in C (0.9%, P = 0.035) Patient choice had no effect	Randomized into choice/no choice of program, then I and C Attrition 28%, dropouts younger, more male No mention blinding assessor Physician-referred patients or volunteers
84	n = 163; F/U immediate, 6 months; 64 years	I: Six monthly sessions on diet C: Usual care; wait listed	Decreased postprandial BS at 6 months in I vs. C, P = 0.009	No BL statistics I more visits than C Attrition 47%, but dropouts equal completers at BL No information on patient recruitment Type of DM unclear
88	n = 80; F/U 12 months from BL; 56 years	I: Six individual sessions on diet, by nurse C: Physician gave handout at initial visit on weight loss Both groups 6 visits/12 months	Decreased FBS all groups, P < 0.01, NSD between groups Decreased HbA _{1c} C females and I males, P < 0.001, NSD between groups	No BL statistics
90	n = 50; F/U 1 year from BL; 54 years	I: Focused on relationship weight loss and BS control; monetary incentives C: Weight loss program Both groups: 12 weekly meetings, then monthly ×6, F/U in 3 months; behavioral weight control program	NSD HbA _{1c} at 1 year for I or C	Volunteer study population
91	n = 120; F/U 7, 11 months from BL; 54 years	I-1: Six monthly small-group meetings, diet and PA information; audio-visual materials culturally sensitive I-2: 1-h didactic + five monthly discussions on BS control C: 1-h didactic only	NSD HbA _{1c} between or within groups at 7 or 11 months	I more visits than C Attrition 32% at 11 months, NSD dropouts to completers
92	n = 40; F/U immediate, 6 weeks; 54 years	I: Behavioral group: 6 × 1.5-h weekly meetings; cues for eating, daily record C: Individual diet counseling, total 1.25 h	Decreased BS immediate F/U for I, P < 0.05, NSD 6 weeks NSD between groups for BS	I more visits than C Unclear how patients selected
93	n = 70; F/U 6 months from BL; 58 years	I: 22 h over 11 weeks, interactive teaching based on cognitive motivational theory C: Didactic teaching, 14 h over 3 days Focus for both I and C: diet and foot care	NSD FBS either group Decreased fructosamine both groups at 1 month, P < 0.0001, return to BL at 6 months	I more contact than C

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Table 4—Continued

Reference	n, F/U interval, and mean age	Interventions	Outcomes	Comments
94	n = 23; F/U 6 months from BL; 33–70 years	I: Self-management skills (stimulus control, monitoring, reinforcement); 5 diet classes/day for 5 days C: Conventional teaching 1 h/day × 5; Both groups: 5-days IP admission; F/U q2 weeks for 2 months, then 3 and 6 months	FBS decreased both groups, NSD between groups at 6 months	Randomized by week of admission No BL statistics No mention blinding assessor Patients selected by physicians
95	n = 120; 12 months from BL; 61 years	I: Group education (diet, PA, BS control) q3 months × 4 C: Usual care	NSD HbA _{1c} , FBS	I more contact than C Unclear if study population represents target population
4. Skills teaching interventions				
61	n = 20; F/U 1 year from end 16-week I; 53 years	I: Information on how to use BS measures by adjusting diet and PA C: Self-monitoring of BS; no feedback Both groups: 13 sessions over 16 weeks, then 9 in 6 months; didactic and participatory; focus on weight control	Decreased HbA _{1c} both I and C at immediate F/U, $P < 0.0001$, NSD between groups, NSD from BL at 1 year	No mention blinding assessor Volunteer study population
63	n = 50; F/U 6 months; adult	I: Additional participatory teaching on foot care during OP education C: Usual education, with routine, didactic foot education Both groups: 5 days OP DM education	Decreased HbA _{1c} I, $P = 0.002$ and C, $P = 0.051$ No values or between group statistics	Randomized by week entering program; no BL comparisons Attrition 35% I, 44% C, no comparison dropouts to completers No mention blinding assessor No demographic data; type of DM unclear
5. Coping skills interventions				
85	n = 64; F/U 6 weeks; 50 years	I: 6 × 2-h weekly group sessions: patient empowerment, goal-setting, problem-solving, stress management C: Wait listed	Decreased HbA _{1c} I > C $P = 0.05$, I decreased 0.73%	No BL comparisons; 18 patients not randomly assigned I more contact than C Volunteer study population 64% DM2 HbA _{1c} measured immediately after program for C, 6 weeks after for I
86	n = 32; F/U 2 years from BL; 68 years	I-1: Six weekly sessions + 18 monthly support group sessions: coping, discussion, education I-2: Six-weekly sessions only; wait list for support group C: Usual care	Decreased HbA _{1c} I-1 and I-2 vs. C at 2 years, $P < 0.05$; NSD between I-1 and I-2	C is nonrandomized comparison group More visits for I-1 > I-2 > C No information on attrition Unclear if study population represents target population Type of DM unclear
105	n = 55; F/U 3, 6, 12, 18 months from BL; 53 years	I-1: Behavior modification: focus on self-control procedures; records of diet and exercise I-2: Cognitive modification: focus on cognitions; self-statements; goal-setting I-3: Cognitive-behavior modification: combined I-1 and I-2 C: Relaxation training to cope with stress All groups got nine weekly sessions of 1.5 h	NSD HbA _{1c}	

BL, baseline; BS, blood sugar; BP, blood pressure; C, C-1, C-2, control groups; CAI, computer-assisted instruction; CHO, carbohydrate; D/SBP, diastolic/systolic blood pressure; DM, diabetes mellitus; DM2, type 2 diabetes; FBS, fasting blood sugar; F/U, follow-up; HCW, health-care worker; I, I-1, I-2, I-3, intervention groups; IP, inpatient; NSD, no significant difference; OP, outpatient; PA, physical activity; q, every; RN, registered nurse; SD, significant difference; TC, telephone call.

eatapes have been used as adjuncts for teaching, with positive (31) and negative (91) results.

Cardiovascular disease risk factors

A large number of studies examined the effects of diabetes self-management training on risk factors for cardiovascular disease, including body weight, serum lipid

levels, and blood pressure (Table 5). Thirteen studies demonstrated positive effects on weight loss; the average weight loss for these studies was ~2 kg (range 1.3–3.1) (28,36,38,47,66,72,74,76,80,82,84,89). Most studies with positive results involved regular contacts or reinforcement sessions (38,47,66,76,82,84) or very short follow-up periods (72,74), al-

though four studies had follow-up periods of ≥ 5 months (36,38,80,82). All other studies with follow-up of ≥ 6 months after the end of the intervention failed to show significant differences in weight loss between control and intervention groups (30,31,61,65,71,73,77,79,84,87,88,90,91). A number of other studies with shorter follow-up periods also had

Table 5—Effect of self-management training on cardiovascular disease risk factors and cardiovascular disease

Reference	n, F/U interval, and mean age	Interventions	Outcomes	Comments
1. Didactic, knowledge, and information interventions				
34	n = 345; F/U immediate; 58 years	I: Nine multimedia education classes over 1.5 years C: Usual care	NSD BP, weight, lipids	No mention blinding assessor Low participation rate; nonparticipants older, more male
47	n = 51; F/U 12 months from BL; 53 years	I: Three weekly didactic, small group sessions q4 months + q2 months visit with doctor C: Visit with doctor q2 months	Decreased weight 2 kg in I vs. C, P < 0.05 NSD cholesterol, triglycerides between groups	I more visits than C No information on participation rates
65, 109	n = 1,139; F/U 5 years; 46 years	I-1: Didactic individual and group sessions q3 months; focus on diet, PA, smoking, BP and BS control I-2: I-1 + clofibrac acid C: Usual care at DM clinics; q3–4 months	NSD myocardial infarctions, ischemic heart disease, mortality; NSD BMI Increased cholesterol in all groups, NSD between groups	No mention blinding assessor Low participation rate, no information on nonparticipants Clofibrac acid arm double-blinded
2. Collaborative, knowledge, and information interventions				
27, 28	n = 532; F/U 12–14; 57 years	I: Average 2.4 sessions × 1.5 h over 2 months + home visit, TC F/U, contracting, skill exercises, goal-setting; over 26 months C: Usual care	Decreased SBP, DBP, between group difference, P < 0.05 Decreased weight 1, between group difference 2.8 lb, P < 0.05	I more contact than C Attrition 51%, differences dropouts and completers No blinding assessor Low participation rate
29	n = 238; F/U 3, 6, 12 months from BL; 56 years	I-1: 13 individual sessions in 12 months I-2: Three-day group interactive course + F/U 3 and 9 months + two individual sessions I-3: Six or more individual sessions based on cognitive behavior theory, TC F/U over 12 months C: 2 × 1-h group education	NSD SBP, total cholesterol and BMI Decreased DBP I-3 vs. C at 12 months, P < 0.01	BL differences: I-2 better educated; I-1 longer duration DM I more visits than C Dropouts longer duration DM than completers Unclear if study population represents target population
30	n = 46; F/U immediate, 6 months; 66 years	I: 8 × 2-h small group sessions over 3 months; problem- and participant-focused C: One-day didactic teaching	NSD serum lipids or weight at 6 months	I more visits than C More C excluded due to poor control No mention blinding assessor Nonparticipants older and heavier
48	n = 82; F/U 6 months from BL; 56 years	I-1: 11 × 2-h weekly didactic course + one individual session I-2: 11-week course + three individual sessions: barriers and support C: Usual care	Decreased cholesterol all three groups at 3 months, maintained at 6 months Decreased weight at 3 months all three groups, P < 0.01, maintained at 6 months NSD between groups; average loss 10 lb at 6 months	No BL statistics comparing groups I more visits than C Attrition 40%, no comparison dropouts to completers Volunteer study population
59	n = 60; F/U 3 months from BL; 55 years	I: Three-day group education, with F/U of four TC and one home visit; reinforce knowledge and skills C: Three-day group education	NSD weight between groups	I more contact than C Unclear if study population represents target population
87	n = 247; F/U 12 months from BL; 54 years	I: 12 weekly sessions over 3 months: Spanish videos, followed by 14 group support sessions in 9 m; by lay HCW C: Wait listed for the intervention	Decreased weight at 6 months (4 lb in I); back to BL at 12 months	No BL comparison I more contact than C No information on attrition No mention blinding assessor; no statistics
96	n = 156; F/U ? immediate; 58 years	I-1: Patient selects behavior for improvement; I-2: Behavioral strategies to increase compliance I-3: Behavioral strategies + instruction on behavioral analysis C: Routine care with consistent F/U by RN I-1,2,3 based on social cognitive theory; I over 13 months	NSD weight between I and C	No information on attrition Volunteer study population; F/U interval unclear Number of patient contacts unclear
98	n = 22; F/U 32 weeks from BL; 61 years	I: Weekly to biweekly home visits; nutrition, exercise, foot care, SMBG; by nursing students C: Usual care	NSD weight between groups	Attrition 24%, no comparison dropouts to completers No mention blinding assessor Unclear if study population represents target population

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Table 5—Continued

Reference	n, F/U interval, and mean age	Interventions	Outcomes	Comments
99	n = 56; F/U 6 months; 64 years	I: Monthly ×6 group sessions: behavior modification (contracts, feedback), general knowledge C: Usual care	Decreased LDL, total cholesterol at immediate F/U, $P < 0.05$; NSD 6 months Decreased weight at 6-month I (−8 lb), $P = 0.02$; NSD between groups	I more contact than C Attrition 32%, no comparison dropouts to completers Participation rate 37%, no comparison participants to nonparticipants
3. Lifestyle interventions				
31	n = 40; F/U 6 months from BL; 35 years	I-1: Lunch demonstrations I-2: Videotape education C: Dietitian instruction and written information Three visits total for all groups over 6 months	NSD BMI	No mention blinding assessor Study population selected by researchers; low participation rate Type of diabetes unclear (“insulin dependent”)
36	n = 87; F/U 12 months from BL; 56 years	I: Five group sessions over 6 months, focus on weight loss C: Individual education on weight loss by dietitian; 3 or more visits in 12 months	Decreased weight I (5.5 kg) and C (3 kg) at 1 year, between group difference, $P < 0.05$	
38	n = 32; F/U immediate, 1 year; 53 years	I: Two sessions: dietitian and CAI C: 2 × 30-min sessions: dietitian only Teaching for both over approximately 1 month	Decreased weight I (4.6 lb, $P < 0.005$), maintained at 1 year, NSD C	No BL statistics Unclear if blinding assessor Type of DM uncertain
39	n = 105; F/U immediate, 12 months; 45 years	I: Interactive computer program on diet, 90 min/month over 6 months C: Wait listed for 1 Both groups received 5 days teaching	NSD weight	I more contact than C Attrition appears to be 76% at 12 months F/U, no comparison dropouts to completers No mention blinding assessor No information on patient recruitment Crossover design
49	n = 41; F/U 6 months; 61 years	I: Psychologist-led group sessions on PA and diet C: Didactic lectures on diet and DM Both groups 10 × 1-h sessions over 6 months	NSD % overweight	Dropouts (22%) higher mean BS; equal number dropouts I and C Low participation rate, no information on nonparticipants
66	n = 148; F/U 6 months from BL; 55 years	I: Advice to decrease fat <30% total calorie intake C: Advice to decrease CHO to <40% total calorie intake Both I and C received individual counseling by dietitian, three home visits	Obese patients decreased weight I > C, $P < 0.05$ Decreased cholesterol in both groups I > C, $P < 0.001$ NSD HDL or triglycerides	
67, 68, 104	n = 206; F/U 12 months from BL; 62 years	I: Single visit: focus on diet, goal-setting, interactive video on barriers; F/U q3 months C: Usual care q3 months	Decreased cholesterol for I vs. C at 12 months, $P = 0.002$ NSD BMI	Unclear if food record reviewers were blinded Low participation rate; participants differ from nonparticipants
69, 82, 89, 103	n = 86; F/U 15, 27 months from BL; 53 years	I: Six individual visits at 2-month intervals: intensive therapy for weight, BS control, diet, PA; then q3 months visits C: Usual care q2–3 months Both groups 3 visits/3 months basic education before randomization	Increased HDL I at 15 months, $P < 0.001$, NSD 27 months Weight loss I (3.1 kg) > C at 15 months, $P = 0.022$; NSD from BL at 27 months NSD BP 15 months	I more visits than C No mention blinding assessor No information on nonparticipants
70	n = 75; F/U 12 months from BL; 61 years	I: Educational videos, personal and family support q2 weeks for 6 months + 3 h counseling by dietitian C: Review session × 3	NSD weight, BP, cholesterol	I more contact than C
71	n = 60; F/U 12 weeks from BL; 55 years	I: Individualized advice on low glycemic index foods C: Standard, individualized diet advice	NSD weight either group Decreased cholesterol I vs. C, $P < 0.05$	No mention blinding assessor Unclear how much intervention time
72	n = 78; F/U 2 months; 42–75 years	I-1: 5 × 2-h weekly education: calories, fat, fiber I-2: I-1+ goal setting, problem-solving, feedback C: Wait listed for 1	Decreased weight for I-2 at 2 months, $P < 0.05$	No BL information I more visits than C More attrition in C, no comparison dropouts to completers Unclear if assessor blinded Unclear how study population recruited

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Table 5—Continued

Reference	n, F/U interval, and mean age	Interventions	Outcomes	Comments
73	n = 70; F/U, immediate, 6 months; 42 years	I: Monthly (or more) meetings: diet and PA prescription, feedback, behavior modification C: Usual care; wait listed for I	NSD weight F/U immediate or 6 months NSD BP Increased Vo _{2max} at 6 months	Incomplete BL statistics I more visits than C No mention blinding assessor Volunteer study population Cross-over design Type of DM uncertain (“IDDM”)
74	n = 102; F/U 3, 6 months from BL; 67 years	I: 10 weekly sessions: problem-solving, increased self efficacy, diet, and PA focus C: Wait listed for I	Decreased weight for I at 3 months (6 lb), maintained at 6 months (4.5 lb, P < 0.002)	Randomization blocked by medication I more visits than C Volunteer study population
75	n = 66; F/U 4 months; 30–86 years	I: 5 × 90-min weekly sessions by nurse: diet, PA, barriers, social and group support C: No information on care received	NSD BMI	No BL statistics Volunteer study population Number of visits uncertain
76	n = 64; F/U 3, 6 months from BL; 62 years	I: 12 × 1.5-h weekly didactic sessions, then 6 × 1-h biweekly participatory sessions; based on social action theory C: One didactic class and two mailings	Decreased weight I at 3 and 6 months (−1.3 kg), P < 0.01 NSD SBP; decreased DBP 6 months, P < 0.05 NSD lipids	I more visits than C More C dropouts, no comparison dropouts to completers Volunteer study population
77	n = 53; F/U 16 weeks, 16 months from BL; 55 years	I-1: 16 weekly sessions: behavioral modification, calorie logs, group PA, monetary incentives I-2: 16 weekly didactic sessions: nutrition and PA C: Four monthly didactic sessions	Decreased weight I-1 at 16 weeks (−6.3 kg), between group, P < 0.01 Decreased weight all groups at 16 months, average change −2.8 kg, NSD between groups	I more visits than C Volunteer study population
78, 97	n = 79; F/U immediate; 68 years	I-1: 10 × 60-min diet education sessions over 4 months; adapted for elderly I-2: I-1 + peer support: group sessions, modeling, reinforcement C: Usual care	Decreased weight I-2 at 8 weeks (5.5 lb, P < 0.05), NS gain to 16 weeks, NSD between groups	Randomized by site; no BL comparisons or attrition information I more visits than C Community recruitment; volunteer study population
79, 100, 101	n = 76; F/U 3, 6, 18 months from BL; 54 years	I-1: Diet focus: goal-setting, modify environment I-2: PA focus with participation I-3: Diet + PA C: Didactic teaching All groups: 10 × 2-h weekly sessions; I based on behavior and cognitive modification strategies	Decreased weight I-1 at 3 months (between group difference 3.9 kg, P < 0.03), and 6 months (4.5 kg, P < 0.02); NSD from BL at 18 months Decreased LDL I-1, P < 0.05 and I-3, P < 0.01 vs. C at 6 months Increased HDL I-1 vs. other groups, P < 0.05 at 3 months; NSD 6 months	Randomized by group meeting attended Volunteer study population
80	n = 40; F/U 2, 5 months from BL; 59 years	I: 3 × 1.5-h individual learning activity packages with diet information, goals, activities C: 3 × 1.5-h didactic lectures	Decreased % ideal body weight for I at 5 months, P < 0.05	Attrition 23%; no comparison dropouts to completers Volunteer study population from DM education program
81, 102	n = 247; F/U 6 months from BL; 57 years	I: Three or more individual visits with dietitian, over 6 weeks, following practice guidelines C-1: One visit producing nutrition care plan C-2: Nonrandomized comparison group; no intervention	Decreased total cholesterol I at 6 months, P < 0.05; NSD C NSD HDL or LDL I or C Decreased weight I and C, P < 0.01	Nonrandomized C-2 C less time with dietitian Attrition 28% for lab studies, unclear if dropouts equal completers at BL Volunteer study population or physician-referred
83	n = 596; F/U immediate, 6 months; 51 years	I: More nutrition content, follow food pyramid C: Usual education, given meal plan Both I and C: 5 × 2-h weekly group sessions	NSD BMI between group with choice and no choice Decreased cholesterol in I, between group difference, P = 0.04	Randomized into choice/no choice of program, then I and C Attrition 28%, dropouts younger, more male No mention blinding assessor Physician-referred patients or volunteers
84	n = 163; F/U immediate, 6 months; 64 years	I: Six monthly sessions on diet C: Usual care; wait listed	Decreased weight females at immediate F/U, P = 0.0061 (amount of loss uncertain)	No BL statistics I more visits than C Attrition 47%, but dropouts equivalent to completers at BL No information on patient recruitment Type of DM unclear

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Table 5—Continued

Reference	n, F/U interval, and mean age	Interventions	Outcomes	Comments
88	n = 80; F/U 12 months from BL; 56 years	I: Six individual sessions on diet, by nurse C: Physician gave handout at initial visit on weight loss Both I and C 6 visits/12 months	Decreased weight both groups, NSD between groups NSD lipids or BP	No BL statistics
91	n = 120; F/U 7, 11 months from BL; 54 years	I-1: Six monthly small-group meetings, diet and PA; audiovisual materials culturally sensitive I-2: 1-h didactic + five monthly discussions on BS control C: 1-h didactic only	Decreased weight I-1 at 7 months, (1 kg) $P < 0.05$, not sustained at 11 months NSD triglycerides or cholesterol	I more visits than C Attrition 32% at 11 months, NSD dropouts to completers
92	n = 40; F/U immediate, 6 weeks; 54 years	I: Behavioral group: 6 × 1.5-h weekly meetings; cues for eating, daily record C: Individual diet counseling, total 1.25 h	Decreased weight C > I at 6 weeks, $P < 0.01$ Decreased triglycerides C at 12 weeks, $P < 0.05$ NSD LDL and HDL	I more visits than C Unclear how patients selected
93	n = 70; F/U 6 months from BL; 58 years	I: 22 h over 11 weeks, interactive teaching based on cognitive motivational theory C: Didactic teaching, 14 h over 3 days Focus for both I and C: diet and foot care	Decreased BMI both groups; NSD between groups Decreased cholesterol I at 6 months, between group, $P = 0.003$	I more contact than C
94	n = 23; F/U 6 months from BL; 33–70 years	I: Self-management skills (stimulus control, monitoring, reinforcement); five classes/day for 5 days; diet focus C: Conventional teaching 1 h/day × 5 Both groups: 5-days IP admission F/U q2 weeks for 2 months, then 3 and 6 months	Decreased % overweight I vs. C at 6 months, $P < 0.01$	Randomized by week of admission No BL statistics No mention blinding assessor Patients selected by physicians
95	n = 120; 12 months from BL; 61 years	I: Group education (diet, PA, BS control) q3 months × 4 C: Usual care	Decreased weight, BMI I and C; NSD between groups	I more contact than C Unclear if study population represents target population
107	n = 152; F/U 10, 14 weeks from BL; 61 years	I: 10 × 2-h sessions over 14 weeks, culturally sensitive video; nutrition focus C: No intervention	Decreased weight I and C males at 14 weeks (2 kg)	No BL comparisons I more visits than C Attrition 30.2%, no information on dropouts No information on blinding assessor Volunteer study population
4. Skills teaching interventions				
61	n = 20; F/U 1 year from end 16-week I; 53 years	I: Information on how to use BS measures by adjusting diet and PA C: Self-monitoring of BS; no feedback Both groups: 13 sessions over 16 weeks, then 9 in 6 months; didactic and participatory; focus on weight control	Decreased weight both I and C (6.0 kg end course, 3.7 kg at 1 y); NSD between groups	No mention blinding assessor Volunteer study population
64	n = 203; F/U 13 months I, 9 months C; ?age	I: 1-h didactic group education on foot care C: No education	NSD mortality	Randomized on SSN No information on dropouts No mention blinding assessor No information on nonparticipants Type of DM unclear Volunteer study population
90	n = 50; F/U 1 year from BL; 54 years	I: Focused on relationship weight loss and BS control; monetary incentives C: Weight loss program Both groups: 12 weekly meetings, then monthly ×6, F/U in 3 months; behavioral weight control program	Decreased weight I and C at 1 year (6.1 kg), NSD between groups Decreased SBP both I and C at 1 year; NSD between groups NSD cholesterol and HDL; decreased triglycerides both I and C	Volunteer study population

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Table 5—Continued

Reference	n, F/U interval, and mean age	Interventions	Outcomes	Comments
5. Coping skills and interventions				
105	n = 55; F/U 3, 6, 12, 18 months from BL; 53 years	I-1: Behavior modification: focus on self-control procedures; records of diet and exercise I-2: Cognitive modification: focus on cognitions: self-statements; goal setting I-3: Cognitive-behavior modification: combined I-1 and I-2 C: Relaxation training to cope with stress All groups got nine weekly sessions of 1.5 h	Decreased weight (8 lb in men, 0.1 in women) at 18 months, I-1 > I-2,3 and C	

BL, baseline; BS, blood sugar; BP, blood pressure; C, C-1, C-2, control groups; CAI, computer-assisted instruction; CHO, carbohydrate; D/SBP, diastolic/systolic blood pressure; DM, diabetes mellitus; DM2, type 2 diabetes; FBS, fasting blood sugar; F/U, follow-up; HCW, health-care worker; I, I-1, I-2, I-3, intervention groups; IP, inpatient; NSD, no significant difference; OP, outpatient; PA, physical activity; q, every; RN, registered nurse; SD, significant difference; TC, telephone call.

negative results (29,34,39,59,75,78,82, 92,96–99). Only three studies involved didactic interventions (34,47,65), and only one of these studies showed a decrease in weight (47).

A large number of studies examined the effects of self-management training on lipid levels, and some produced improvement in total cholesterol (range -0.9 to -0.07 mmol/dl) (66,68,81,83,93), LDL (-0.4 mmol/dl) (100), and HDL (+0.1 mmol/dl) (100). Others found initial positive results but no significant difference from baseline at final follow-up (69,82,101). Positive studies involved interactive, generally individualized, repetitive interventions. Some studies have shown no beneficial effects on lipids (29,34,47,65,76,88,91,92). Of the three didactic studies (34,47,65), none resulted in improved lipid profiles.

Studies examining blood pressure control also revealed mixed results. Some studies demonstrated a decrease in systolic blood pressure (-4 mmHg) (28) and diastolic blood pressure (-3 to -8 mmHg) (27–29,76), whereas others showed no significant changes (34,73,82, 89).

Only two studies examined cardiovascular disease events or mortality, one of which found no significant difference in cardiovascular disease or mortality events after 5 years of visits every 3 months (65); the other study found no significant difference in mortality 13 months after a 1-h group didactic educational session (64).

Economic and health-care utilization outcomes

Most studies examining economic outcomes and health-care utilization (Table 6) failed to demonstrate improvements in measured parameters (34,46,60), except the study by Wood (54), which demonstrated a decrease in emergency room visits 4 months after a short-duration intervention. Glasgow et al. (68) calculated that the cost of a social cognitive theory-based lifestyle intervention, effective in decreasing cholesterol and in improving food habits, was \$137 per patient. Franz et al. (102) found the per-patient cost-per-unit change in glycohemoglobin to be lower for control subjects than for intervention patients. They also demonstrated (102) a cost-effectiveness ratio (direct costs only) of \$56.26 per percent change in HgA_{1c} for results achieved at 6-month follow-up. No cost-benefit analyses of diabetes education were identified.

CONCLUSIONS — A large number of randomized controlled trials of the effectiveness of self-management training in individuals with type 2 diabetes have been performed. Despite limitations in methodology and heterogeneous population characteristics, settings, interventions, outcomes, and lengths of follow-up, a number of generalizations can be made from these studies (Table 7).

Effectiveness of interventions

In reviewing the literature, it is clear that diabetes self-management training has

evolved from the primarily didactic interventions of the 1970s and 1980s into the collaborative, more theoretically based “empowerment” models of the 1990s (12). Didactic interventions focusing on the acquisition of knowledge and information demonstrate positive effects on knowledge but mixed results on glycemic control and blood pressure and no effect on weight. Collaborative interventions focusing on knowledge tend to demonstrate positive effects on glycemic control in the short term and mixed results with follow-up >1 year. Effects of collaborative interventions on lipids, weight, and blood pressure were mixed.

It is apparent that factors other than knowledge are needed to achieve long-term behavioral change and that this may account for the lack of a consistent positive relationship between knowledge and glycemic control. It has been suggested that 1) although intensive treatment can improve metabolic control, the role of patient education in that process is uncertain (34); 2) changes in attitude and motivation are needed to achieve metabolic control (35); 3) integrating education with other therapies, such as intensified insulin treatments, is important in improving glycemic control (60); 4) a minimum threshold of diabetes knowledge is required; and 5) improved personal attitudes and motivations are more effective than knowledge in improving metabolic control (110). Many have also noted the lack of a relationship between SMBG and glycemic control for

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Table 6—Effect of self-management training on economic and health care utilization outcomes

Reference	n, F/U interval, and mean age	Interventions	Outcomes	Reordered comments
1. Didactic, knowledge, and information interventions				
34	n = 345; F/U immediate; 58 years	I: Nine multimedia education classes over 1.5 years C: Usual care	NSD sick days, admissions, emergency room or OP visits	No mention blinding assessor Low participation rate; nonparticipants older, more male
65, 109	n = 1,139; F/U 5 years; 46 years	I-1: Didactic individual and group sessions q3 months: focus on diet, PA, smoking, BP and BS control I-2: I-1 + clofibrilic acid C: Usual care at DM clinics, q3–4 months	More sick leave events/year for C vs. I, $P < 0.05$ NSD duration sick leave events	No mention blinding assessor Low participation rates, no information on nonparticipants Clofibrilic acid arm double-blinded
2. Collaborative, knowledge, and information interventions				
40, 60	n = 558; F/U 6 months; 45 years	I-1: Collaborative education by HCW, 3 h/week × 4 weeks I-2: Same education by fellow patients C: No intervention I based on Fishbein and Ajzen Health Belief Model	NSD quality of life NSD sick days, use of health services, daily insulin dosage, number injections Cost per intervention patient (including indirect costs): \$100	Hospitals randomized I more visits than C Uncertain blinding assessor
46	n = 471; F/U 6, 12 months from BL; 52 years	I: Home visits, teaching based on needs assessment, maximum 12 visits C: Usual care	NSD emergency room and physician visits, hospitalizations, length of stay, DM-related sick days at 1 year	Attrition 20%; no comparison dropouts to completers 70% of eligible participated
54	n = 107; F/U 1, 4 months; 60 years	I: 2 × 2-h group didactic + practice + feedback + usual care C: Usual care: individual education based on perceived patient need Both in IP setting	Decreased emergency room visits for I vs. C, $P = 0.005$	Randomized by hospital number No blinding assessor No information on participation rates
3. Lifestyle interventions				
67, 68, 104	n = 206; F/U 12 months from BL; 62 years	I: Single visit: focus on diet, goal-setting, interactive video on barriers; F/U q3 months C: Usual care q3 months	Direct costs of intervention \$137 per patient NSD quality of life	Unclear if food record reviewers were blinded Low participation rate; participants differ from nonparticipants
79, 100, 101	n = 76; F/U 3, 6, 18 months from BL; 54 years	I-1: Diet focus: goal-setting, modify environment I-2: PA focus with participation I-3: Diet + PA C: Didactic teaching All groups: 10 × 2-h weekly sessions: I based on behavior and cognitive modification strategies	Increased quality of life for I-3 at 18 months, $P < 0.05$	Randomized by group meeting attended Volunteer study population
81, 102	n = 203; F/U 6 months from BL; 57 years	I: Three or more individual visits with dietitian, over 6 weeks, following practice guidelines C-1: One visit producing nutrition care plan C-2: Nonrandomized comparison group: no intervention	Cost per % change GHb lower for C; no statistics Cost effectiveness ratio \$56.26 per % change in HbA _{1c}	Nonrandomized C-2 C less time with dietitian Attrition 28% for lab studies, unclear if lab dropouts equal completers at BL Volunteer study population or physician-referred

BL, baseline; BS, blood sugar; BP, blood pressure; C, C-1, C-2, control groups; CAI, computer-assisted instruction; CHO, carbohydrate; D/SBP, diastolic/systolic blood pressure; DM, diabetes mellitus; DM2, type 2 diabetes; FBS, fasting blood sugar; F/U, follow-up; HCW, health-care worker; I, I-1, I-2, I-3, intervention groups; IP, inpatient; NSD, no significant difference; OP, outpatient; PA, physical activity; q, every; RN, registered nurse; SD, significant difference; TC, telephone call.

subjects with type 2 diabetes (111–116), although several randomized controlled trials have shown a relationship in type 1 diabetes (117,118).

The literature is divided regarding the relative merits of group versus individual therapy, and in our review, both types of delivery demonstrated mixed results for interventions that focused on knowledge, lifestyle, or skills. Lifestyle interventions were generally more effective in group settings, with positive outcomes noted for

weight loss (8,36,47,48,72,74,76,77,94) and glycemic control (31,36,71,76,79), although two studies of lifestyle interventions in individual settings had positive effects on weight (38,80). Both individual (38,39,66–68) and group (72,75,93) lifestyle interventions had positive effects on diet and self-care behaviors. It is notable that skills teaching was effective in both group (41,62) and individual settings (45,58).

Others have drawn conclusions simi-

lar to ours about effective interventions in diabetes self-management training. Brown's meta-analyses (9,10) support the effectiveness of diabetes education, with positive effect sizes (from largest to smallest) for the outcomes of knowledge, dietary compliance, skill performance, metabolic control, psychological outcomes, and weight loss. Padgett et al. (11) reviewed the effectiveness of diabetes education in 1988 and found diet instruction and approaches based on social

Effect of Self-Management Training on Glycemic Control

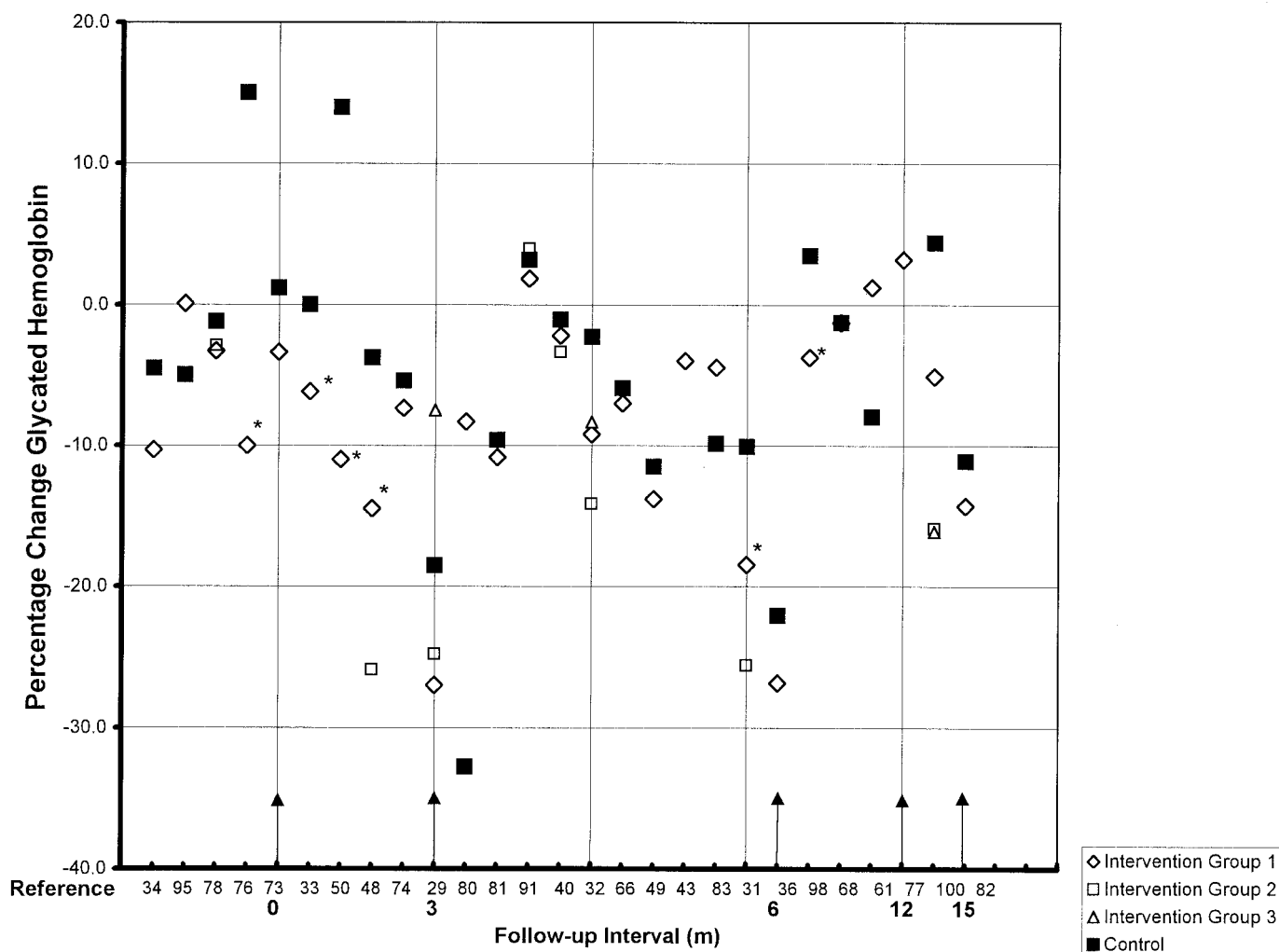


Figure 1—Percentage change in glycated hemoglobin for control and intervention groups for studies referenced on the x-axis. For studies with more than one intervention group, results are shown for each group. Follow-up intervals from end of the intervention are noted on the x-axis, with studies to the left of each arrow having the follow-up interval indicated. *Significant difference between intervention and control groups. m, month.

learning theory to be the most effective interventions; physical outcomes and knowledge were most improved. A qualitative review of diabetes self-management education concluded that behavior change strategies were much more effective than didactic methods and that patient education was most effective when combined with health-care provider medication adjustment and reinforcement of educational messages (5). Anderson (119) noted that effective diabetes-management programs must be noncomplex, individualized to a person's lifestyle, and reinforced over time, and they must respect an individual's habits and routines and incorporate social support. Similar generalizations are found in

reviews of chronic disease care. Von Korff et al. (120) concluded that effective programs in chronic disease care include collaborative problem definition; targeting, goal setting, and planning; a continuum of self-management training and support services; and active and sustained follow-up. Wagner et al. (121) stated that chronic illness programs require psycho-educational programming, and they emphasized the importance of responding to patients' individual needs, readiness to change, and self-efficacy. Mullen et al. (122) noted that the most beneficial components of educational interventions in chronic diseases were individualization, relevance, feedback, reinforcement, and facilitation.

Methodological issues

There are important limitations in execution of many of these studies. Internal validity was frequently threatened by 1) lack of blinding of the assessor, 2) infeasibility of blinding study subjects, 3) high attrition, 4) contamination of the control group, 5) unintended cointerventions, 6) lack of detail on allocation concealment (20), 7) response-set bias whereby intervention group participants report dietary and other habits that match the goals of the intervention rather than actual behavior (123), and 8) deficits in the reliability and validity of the instruments used to measure knowledge, self-care, and dietary habits. Brown (124) has previously noted that the measurement of knowl-

Table 7—Conclusions of a review of randomized, controlled trials of the effectiveness of self-management training in type 2 diabetes

A. Effectiveness of interventions

1. In the short term (<6 months), knowledge levels, SMBG skills, and self-reported dietary habits improve.
2. In the short term, improvements in glycemic control, knowledge, and diet are more readily demonstrated than improvements in weight and physical activity levels.
3. Improved glycemic control does not correspond to measured changes in knowledge or SMBG skills.
4. Weight loss can be demonstrated with repetitive interventions or with short-term follow-up (<6 months).
5. Physical activity levels are variably affected by interventions.
6. Effects on lipids and blood pressure are variable and more likely to be positive with interactive or individualized, repetitive interventions.
7. Studies with short-term follow-up are more likely to demonstrate positive effects on glycemic control and behavioral outcomes than studies with longer follow-up intervals.
8. Interventions with regular reinforcement are more effective than one-time or short-term education.
9. Interventions that involve patient participation and collaboration seem to produce somewhat more favorable effects on glycemic control, weight loss, and lipid profiles than didactic ones.
10. Group education is more effective for lifestyle interventions and seems to be equally effective for interventions focusing on knowledge and SMBG.
11. The focus of the current literature has been on knowledge and glycemic control outcomes; there is little literature measuring quality of life and long-term clinical outcomes.

B. Methodological issues

1. Descriptive information is frequently lacking, including type of diabetes and the representativeness of study populations to target populations.
2. Threats to internal validity (selection, performance, attrition, and detection bias) are common.
3. Generalizability of study results is often limited by enrollee or researcher selection into study populations or by lack of information on the representativeness of the study population.

C. Potential future research topics

1. Systematic review of the effectiveness of self-management training interventions in patients with type 2 diabetes using study designs other than randomized, controlled trials.
2. Effectiveness studies to define optimal long-term and maintenance interventions with respect to content, frequency, and method of delivery.
3. Studies to further delineate the impact of self-management training on intermediate outcomes, such as self-efficacy, problem-solving, and coping skills, and to better define the relationship between these outcomes and behavior change, glycemic control, and long-term outcomes.
4. Studies examining the feasibility, effectiveness, and cost-effectiveness of population-based self-management training, as compared with individual patient-centered training.
5. Quantitative review of self-management training effectiveness to further examine the heterogeneity of the literature, and the relationships between population characteristics, study design and quality, intervention characteristics, and outcomes.
6. Effectiveness studies focusing on long-term cardiovascular, quality of life, and economic outcomes.

edge is seriously flawed. More recent studies have demonstrated little improvement. In addition, most studies compare a more intensive intervention to basic care and education, as it is generally considered unethical to randomize a group to receive no education, thus minimizing measured effects of the intervention.

There was frequently an inadequate description of study interventions and participants, including the representativeness of study populations. Generalizability was also frequently limited by the volunteer nature of the study populations. Glasgow and Osteen (125) noted similar deficiencies in information on the representativeness of study populations in diabetes self-management training studies, as well as in the reporting of patient characteristics.

The behavioral theories on which interventions were based are documented in a few studies (29,40,60,67,68,79,93,96), as were the behavioral tools (27,30,46,48–50,72,73,75,76–78,91,92,94). However, data are insufficient to determine which behavioral tools and theories are most advantageous.

Although only randomized, controlled trials were reviewed, there is an important body of literature with other study designs. It is more difficult to draw conclusions about causality from nonexperimental designs than from an experimental design (16). Nonetheless, nonexperimental designs, if methodologically sound, reveal important information about the effectiveness of interventions (126). Randomized, controlled trials in this area of research are not always feasi-

ble, or even desirable, particularly when examining community educational interventions. Glasgow et al. (127) note the increasing importance of recognizing the complexity of disease determinants and multilevel system interventions. Classic randomized, controlled trials emphasize efficacy, to the exclusion of factors influencing effectiveness, such as adoption, reach, and institutionalization (127).

This review supports concerns expressed by others that researchers may not be measuring the most important outcomes (125,127). Glasgow and Osteen (125) reviewed Brown's 1990 meta-analysis (10) and concluded that "Program evaluations to date have focused too narrowly on assessing knowledge and GHb outcomes to the exclusion of other important variables." They stated that

process and mediating variables (such as self-efficacy, problem-solving, and coping skills) and quality-of-life outcomes must receive much more attention in intervention research. Unfortunately, our review suggests that little has changed in the past 10 years, as researchers have continued to focus on knowledge and glycemic control to the exclusion of outcomes reflecting a more holistic view of patient function, longevity, and quality of life.

Future research

There are clearly many gaps in the literature on effectiveness of diabetes self-management training in type 2 diabetes (Table 7). More work must be done to identify the predictors and correlates of glycemic control, because knowledge levels and SMBG do not correlate well with blood glucose. Behavioral theory must have a more explicit role in future studies to improve the understanding of behavior change in the self-management of chronic illness. The role of electronic media in diabetes self-management training, the role of nontraditional health-care providers, and the optimal training of health educators has yet to be determined. The role of individual needs assessment within the context of group teaching has not been clarified. Quality-of-life outcomes must be brought to the forefront of future research.

The objectives for ideal self-management interventions in diabetes are clear: behavioral interventions must be practical and feasible in a variety of settings; a large percentage of the relevant population must be willing to participate; the intervention must be effective for long-term important physiological outcomes, behavioral end points, and quality of life; patients must be satisfied; and the intervention must be relatively low-cost and cost-effective (68). How best to achieve these objectives is not entirely clear. There are some well-designed and -executed studies that support the effectiveness of self-management training for patients with type 2 diabetes, particularly in the short term. The challenge is to expand upon this current knowledge to achieve all of the objectives of ideal self-management. Further research of high methodological quality in diverse study populations and settings and using generalizable interventions is needed to assess the effectiveness of self-management interventions on sustained glycemic con-

trol, cardiovascular disease risk factors, and ultimately, microvascular and cardiovascular disease and quality of life.

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