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The Effect of a Structured Behavioral Intervention on Poorly Controlled Diabetes

A Randomized Controlled Trial

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Background: Although maintaining nearly normal glycemia delays onset and slows progression of diabetes complications, many patients with diabetes and their physicians struggle to achieve glycemic targets. The best methods to support patients as they follow diabetes prescriptions and recommendations are unclear.

Methods: To test the efficacy of a behavioral diabetes intervention in improving glycemia in long-duration, poorly controlled diabetes, we randomized 222 adults with diabetes (49% type 1) (mean [SD] age, 53 [12] years; mean [SD] disease duration 18 [12] years; mean [SD] hemoglobin A_{1c} [HbA_{1c}] concentration, 9.0% [1.1%]) to attend (1) a 5-session manual-based, educator-led structured group intervention with cognitive behavioral strategies (*structured behavioral arm*); (2) an educator-led attention control group education program (*group attention control*); or (3) unlimited individual nurse and dietitian education sessions for 6 months (*individual control*). Outcomes were baseline and 3-, 6-, and 12-month post-intervention HbA_{1c} levels (primary) and frequency of diabetes self-care, 3-day pedometer readings, 24-hour diet recalls, average number of glucose checks, physical fitness, depression, coping style, self-efficacy, and quality of life (secondary).

Results: Linear mixed modeling found that all groups showed improved HbA_{1c} levels ($P < .001$). However, the structured behavioral arm showed greater improvements than the group and individual control arms (3-month HbA_{1c} concentration changes: –0.8% vs –0.4% and –0.4%, respectively ($P = .04$ for group × time interaction). Furthermore, participants with type 2 disease showed greater improvement than those with type 1 ($P = .04$ for type of diabetes × time interaction). Quality of life, glucose monitoring, and frequency of diabetes self-care did not differ by intervention over time.

Conclusions: A structured, cognitive behavioral program is more effective than 2 control interventions in improving glycemia in adults with long-duration diabetes. Educators can successfully use modified psychological and behavioral strategies.

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DESPITE THE AVAILABILITY of new medications and treatment devices and the emphasis placed on diabetes treatment adherence over the last decade, National Health and Nutrition Examination Survey (NHANES) data show that 45% of patients with diabetes have not achieved glycemic targets of lower than 7%.[1,2] While some patients may not receive optimal treatment (eg, need higher targets, have severe comorbidities, undergo inappropriate treatment), an important reason for poor glycemic control is patients' difficulty in following treatment prescriptions and self-management and lifestyle recommendations.[3] Although nonspecific behavioral and/or psychological approaches may be effective in addressing these problems,[4] whether clinicians are able to incorporate these techniques into their clinical practice is not clear.[5-7]

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Many psychosocial factors impact how well diabetes patients are able to follow their treatment prescriptions and self-care recommendations. Depression, which is more common in patients with diabetes than in the general population,[8,9] is associated with poor glycemic control,[10] reduced self-care

behaviors,[11,12] and increased morbidity[13] and mortality.[14] Interestingly, treatment of depression alone is not enough to improve hemoglobin A_{1c} (HbA_{1c}) levels.[15,16] High stress and chaotic lifestyles also can lead to other poor self-care and resultant inability to improve glycemia. While several diabetes adherence and lifestyle interventions have been developed by behavioral scientists and psychologists,[17-22] few are well used in clinical practice, possibly because psychologists, physicians, and other medical professionals treating diabetes all have different skill sets and practice patterns and may have difficulty using behavioral techniques. Furthermore, few well-designed longer-term randomized controlled trials have examined this issue.

Thus, the goal of this randomized controlled trial was to test the efficacy of a highly structured behavioral diabetes education program in helping patients with long-duration, poorly controlled diabetes improve glycemic control through comparisons with curriculum-based standard group education and 1-on-1 education with nurse and dietitian educators. The secondary objective was to assess which factors (eg, coping processes, affective issues, type of diabetes, adherence to recommendations) were associated with an improvement in glycemic control.

METHODS

DESIGN OVERVIEW

After baseline assessment, this 3-arm trial parallel assigned randomized participants to the structured behavioral experimental arm or to 1 of 2 control arms: (1) a 5-session (over 6 weeks) manual-based, highly structured group diabetes education program that included behavioral support for implementing self-care behaviors and cognitive behavioral strategies (*structured behavioral intervention*); (2) a 5-session (over 6 weeks) manual-based attention control group diabetes education, ie, a control condition that was matched to the structured behavioral arm in terms of exposure to health professionals and diabetes education content (*group attention control*); or (3) unlimited individual diabetes education sessions (*individual control*) for 6 months. Different teams of experienced diabetes nurses and dietitians who were certified diabetes educators provided education for each arm. A steering committee composed of study investigators and coordinators and a data safety monitoring board oversaw the conduct of the study. The Joslin Diabetes Center Committee on Human Subjects approved the protocol and all recruitment procedures and materials. All participants provided informed, written consent prior to participation.

SETTING AND PARTICIPANTS

Participants were recruited from the clinical practice of the Joslin Clinic, advertisements in its newsletter, extensive mailings from Joslin's database, and advertisements in local papers and radio stations. Adults aged 18 to 70 years diagnosed as having type 1 or type 2 diabetes for at least 2 years who were taking insulin and/or oral medication for at least 1 year, were able to walk briskly, were free of severe complications, and whose HbA_{1c} level was higher than 7.5% were eligible for enrollment.

Exclusion criteria included inability to read and speak English, current or planned pregnancy, severe psychopathologic condition, unstable depression, albumin to creatinine ratio higher than 300 μg/mg, untreated proliferative retinopathy, unstable heart disease, severe hypertension (≥160/90 mm Hg), recent alcohol or drug dependence, initiation of insulin treatment within 1 year, participation in diabetes education within the previous 6 months, severe neuropathy, or any physical issue such as arthritis that prevented brisk walking. Inclusion and exclusion criteria were assessed via telephone screening, medical chart review, and a screening visit. Eligible participants were scheduled for a baseline and randomization visit.

RANDOMIZATION AND INTERVENTIONS

Randomization consisted of a 2-step process to ensure approximately equal groups and minimize waiting time prior to interventions. The first step assigned participants by type of diabetes to either the individual or group program using a computer-generated block assignment scheme (performed by the principal investigator, K.W.) that research assistants unveiled during the randomization visit. Individual arm participants began education immediately. When 7 to 10 participants were assigned to a group, the second step randomized them to either the control or structured behavioral arms. Educators and study physicians had no role in randomization.

All group sessions were separated by type of diabetes. Structured behavioral and control group participants received similar core education on nutrition, medication management, exercise, and glucose monitoring; both programs were manual-based and balanced for time and homework. The group control arm sessions and nurse educator sessions for the individual arm were held in the Joslin Clinic. Dietitians from the Clinical Research Center who work on large multisite lifestyle studies but not in the Clinic provided nutrition education for the individual arm. Experienced nurses and dietitians currently working as certified diabetes educators outside the Joslin Clinic taught the structured behavioral arm within the behavioral research laboratory.

The structured behavioral intervention consisted of five 2-hour sessions, delivered over 6 weeks, of highly structured behavior-based activities and information including (1) group review of glucose logs to identify patterns and dietary, exercise, and medication factors that influence those patterns; (2) educator-facilitated self-care goal setting to help participants achieve and evaluate progress toward self-care goals; and (3) instruction, modeling, and practice of problem-solving skills to help participants identify and overcome barriers to implementing self-care behaviors. Each session opened with a review of the prior week's homework including glucose logs, food choices, and physical activity. The educators leading the structured behavioral arm received 6 hours of group training in behavioral strategies (cognitive behavioral approaches, use of goal-setting techniques that helped participants identify specific steps necessary to reach their goals, and the structured cognitive-behavioral–based curriculum). These strategies were brief, focused, and adapted to the educators' skills and practice patterns and stressed their role as educators, not therapists.

The attention control arm's program was designed with the same length of time and amount of contact with health professionals and of homework. The curriculum consisted of prepared slides, a detailed curriculum manual, and specific learning activities including homework and the importance of goal setting but not training in cognitive behavior strategies or structured goal-setting activities. These educators received 3 hours of training in the curriculum.

Participants assigned to the individual control arm had access to unlimited 1-on-1 appointments with diabetes nurse and dietitian educators for 6 months after randomization; however, they were not required to attend any education appointments. The content was determined by the educator based on her assessment and not by study protocol. Participants were sent 2 reminders about the availability of these education services, and research assistants were available to help them schedule appointments. Educators in the 2 control arms had access to all Clinic teaching materials and assessment guides.

Integrity of the interventions was ensured via written curriculum, preapproved education materials, separate educator trainings, investigator observation of group education, and separate teams of trained, experienced diabetes educators to prevent carryover of education strategies.

OUTCOMES AND FOLLOW-UP

We collected data at baseline, at 3, 6, and 12 months after group intervention (5, 8, and 14 months after the baseline visit), and at 5, 8, and 14 months after starting individual education in the 1-on-1 control arm. The primary outcome was HbA_{1c} level using the high-performance liquid chromatography ion capture method (Tosoh Medics Inc, San Francisco, California) (reference range, 4.0%-6.0%).

In addition to sociodemographic factors (age, sex, race/ethnicity, education level, marital status, and occupation) and health factors (duration of diabetes, body mass index [BMI], waist circumference, and blood pressure), we also measured frequency of diabetes self-care behaviors on a 5-point Likert scale (Self-Care Inventory-R[23]), mean 3-day pedometer readings (Accusplit Eagle, Livermore, California), 24-hour diet recalls, and the mean daily blood glucose meter checks. To assess physical fitness, participants not taking β-blockers underwent a YMCA bicycle test.[24,25] Finally, we measured diabetes-related distress (Problem Areas in Diabetes,[26,27] a validated scale that rates distress on a 5-point Likert scale), depression and anxiety symptoms (Brief Symptom Inventory-18,[28] which renders a t-score for each subscale), emotion-based and controlled coping styles (Coping Styles[29,30]), diabetes-specific self-efficacy (Confidence in Diabetes Self-Care Scale,[31] rated on a 5-point Likert scale), self-esteem (Rosenberg Self-esteem scale[32,33]), frustration with self-care (Self-care Questionnaire,[3,34]), and diabetes quality of life (Diabetes Quality of Life Questionnaire,[35,36] scored on a 100-point scale where a high score indicates a high quality of life).

STATISTICAL ANALYSIS

For the primary end point of HbA_{1c} level, we estimated that we needed 64 participants per arm to detect a clinically significant 0.5-point difference with 80% power ($\alpha = 0.05$, two-tailed test). Based on prior experience with patients with poorly controlled diabetes,[3,37] we assumed a 15% attrition rate and targeted recruitment at approximately 74 participants per arm.

We used SAS statistical software, version 9.2 (SAS Institute Inc, Cary, North Carolina) for data analysis. We examined descriptive statistics to ensure that data met statistical test assumptions. We compared baseline characteristics using χ^2, Wilcoxon 2-sample or Kruskal-Wallis tests to examine between-group differences and assess the randomization procedure effectiveness.

For primary analyses, we used a linear mixed model for repeated measures over time by type of diabetes (SAS Proc Mixed) to analyze the impact of the 3 education interventions on HbA_{1c} at baseline and follow-up with fixed effects of time, group, type of diabetes, the interactions between time and group, and between time and type of diabetes. This procedure prevented listwise deletion due to missing data. We also tested whether baseline characteristics including sociodemographic and psychological variables were associated with changes in HbA_{1c} levels over time. To assess group differences in the proportion achieving a 0.5-point improvement in HbA_{1c} level, we used logistic regression with SAS Proc NLMixed.

To assess the impact of missing data, we conducted a sensitivity analysis using SAS Proc MI and MIAnalyze. First, Proc MI generated 15 imputed data sets, and then we used multivariate regression models that included baseline characteristics, group assignment, and numbers of hours of education to analyze the imputations. Next, we used Proc MIAnalyze to combine the analysis results to derive valid inference for missing HbA_{1c} data. We present the most conservative *P* value estimates. For continuous secondary outcomes (quality of life, diabetes-related distress, and self-care behaviors), we used the same approach as the primary analysis, controlling for demographic and psychosocial variables.

RESULTS

Between 2003 and 2008, we telephone screened 2027 people, of whom 464 were eligible for a screening visit, and randomized 222 (110 with type 1 diabetes and 112 with type 2 diabetes) (**Figure 1**). The most common reasons for exclusion at screening were not meeting criteria for HbA_{1c} level (49%), presence of complications (8%), age (6%), or inability to walk briskly (3%). Twenty-six eligible people did not return for randomization. Baseline groups did not differ on demographic or psychosocial characteristics. However, those in the structured behavioral arm were more active (steps per day) and a subset of those were more fit on the YMCA bicycle test than those in the other arms (**Table 1**). The intervention groups also did not differ by type of treatment. For those with type 1 diabetes at baseline, 66.4% were undergoing treatment with multiple daily injections, 7.3% with insulin pump insulin, and 28.2% with NPH (neutral protamine Hagedorn) insulin plus sliding scale. For those with type 2 diabetes, 21.4% were taking insulin only; 33.9% were taking insulin plus oral diabetes agents; 18.8% were taking only 1 oral agent (no insulin); 25.9% were taking 2 or more oral agents (no insulin). As expected, some baseline characteristics differed by type of diabetes (Table1).

PROTOCOL VIOLATIONS

Unknown to us during screening, 1 randomized participant did not meet eligibility requirements for being free of severe psychopathologic conditions and, after one class, could not continue in the study. Six other participants completed education but did not return for follow-up visits. They did not differ on baseline characteristics from those who completed the study. Finally, for 1 group of 7 participants in the structured behavioral arm, 6 weeks elapsed between the first and second classes owing to severe winter storms. Follow-up visits were scheduled based on the last class.

HbA_{1c} LEVELS

The linear mixed model found that participants all showed glycemic improvement ($P < .001$); also both the group-time interaction and the type of diabetes–time interaction were statistically significant ($P = .04$ for each) (**Table 2** and **Figure 2**). Thus, although all 3 groups showed improved HbA_{1c} levels at 3 months, participants in the structured behavioral condition showed more improvement than those in the control conditions (mean HbA_{1c} change at 3 months: –0.8% vs –0.4% [attention group control] and –0.4% [individual control]). Those with type 2 diabetes showed greater improvement than those with type 1 diabetes (HbA_{1c} change at 3 months:

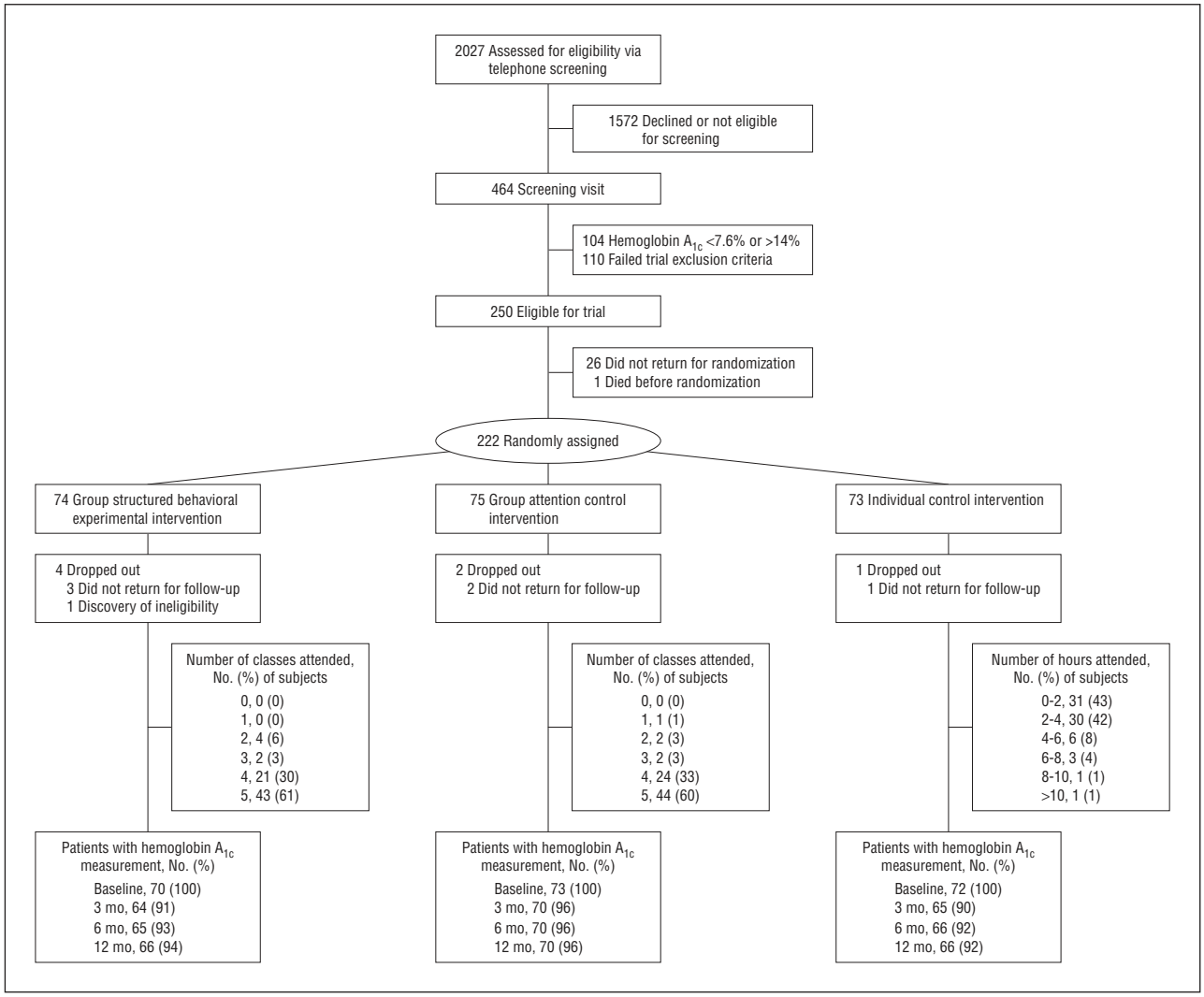

Figure 1. Study flow diagram.

–0.7% vs –0.3%). Figure 2 shows the mean HbA_{1c} over time for the 3 groups for total participants (Figure 2A) and then by type of diabetes (Figure 2B and C). Glycemic condition deteriorated slightly at 6 months but was basically maintained at 12 months for the 2 group interventions (Table 2 and Figure 2). When we controlled for age, duration of diabetes, and baseline pedometer steps, the association with the interventions remained statistically significant at the same levels; however, the association with type of diabetes was lost ($P = .09$). When we controlled for baseline fitness level, both the intervention effect and the effect of type of diabetes remained intact; however, 27% type 2 and 11% type 1 participants were taking β-blocker medications and therefore did not participate in the YMCA bicycle protocol.

Finally, we used logistic regression to identify characteristics that were associated with a clinically significant improvement in HbA_{1c} level (**Table 3**). Of baseline characteristics, only a higher HbA_{1c} level predicted a 0.5-percentage-point 3-month improvement; and of 3-month characteristics, higher diabetes quality of life, less frustration with diabetes self-care, and more emotion-based coping were associated with an HbA_{1c} level improvement.

SECONDARY OUTCOMES

Diabetes quality of life (total score and subscales), number of daily meter checks, and frequency of self-care behaviors did not differ by type of intervention over time. However, those with type 2 diabetes had higher quality of life scores than those with type 1 diabetes (Table 2).

Participants with type 2 diabetes were heavier at baseline and throughout the study (baseline BMI, 33.2 vs 26.7, calculated as weight in kilograms divided by height in meters squared) ($P < .001$) than those with type 1 diabetes. At 6 months, those with type 1 diabetes gained 0.45 BMI units while those with type 2 diabetes initially lost about 0.08 units, although they regained this weight by 12 months (main effect of time, $P < .04$; type of diabetes–time interaction, $P < .04$). Intervention assignment did not impact BMI (Table 2).

ADVERSE EVENTS

Participants reported no episodes of hypoglycemia that required assistance of others. One participant endorsed "sometimes" on thoughts of suicidal ideation on the Brief

Table 1. Baseline Characteristics of Patients Assigned to the 3 Study Groups

Characteristic	Type of Diabetes		Intervention Group		
	Type 1 (n=110)	Type 2 (n=112)	Structured Behavioral Group (n=74)	Attention Control Group (n=75)	Individual Control Group (n=73)
Age, median (range), y	46.6 (21.6-74.2)	58.4 (36.6-75.1)[a]	51.8 (23.7-74.2)	54.7 (25.0-75.1)	56.2 (21.6-74.8)
Women, No. (%)	62 (56.4)	50 (44.6)	34 (46)	36 (48)	42 (58)
Non-Hispanic white, No. (%)	105 (95.5)	89 (79.5)[a]	65 (88)	67 (89)	62 (85)
Type 1 diabetes, No. (%)	NA	NA	37 (50)	37 (49)	36 (49)
Type 2 diabetes, No. (%)	NA	NA	37 (50)	38 (50)	37 (49)
Patients of Joslin Diabetes Center, No. (%)	85 (77.3)	67 (59.8)	44 (60)	54 (74)	54 (72)
Type 1 diabetes, No. (%)	NA	NA	28 (76)	29 (78)	28 (78)
Type 2 diabetes, No. (%)	NA	NA	16 (43)	25 (66)	26 (70)
Education level, median (range), y	16.0 (6.0-20.0)	14.5 (10.0-20.0)[a]	16.0 (9.0-20.0)	16.0 (10.0-20.0)	14.0 (6.0-20.0)
Duration of diabetes, median (range), y	23.7 (2.2-66.1)	10.7 (1.3-41.1)[a]	14.9 (1.3-66.1)	15.0 (2.6-48.5)	16.8 (2.2-45.7)
HbA_{1c}, median (range), %	8.7 (7.6-12.6)	9.0 (7.6-13.6)	9.0 (7.6-12.6)	8.8 (7.6-13.6)	8.6 (7.6-13.1)
LDL-cholesterol, median (range), mg/dL[b]	95.8 (55-189)	104.0 (39.6-208.0)[a]	98.5 (56.0-186.0)	95.0 (39.6-197.0)	100.5 (55.0-208.0)
HDL-cholesterol, median (range), mg/dL[b]	57 (31-128)	42 (22-98)	50 (22-101)	43 (27-90)	50 (24-128)
Triglycerides, median (range), mg/dL[b]	66 (21-273)	138 (22-536)[a]	100 (29-299)	118 (21-437)	82.5 (32.0-536.0)
BMI, median (range)	26.1 (17.8-48.9)	32.4 (19.0-57.8)[a]	29.4 (18.6-51.5)	29.4 (20.3-57.8)	29.0 (17.8-50.4)
Pedometer results, median (range), steps/d[b]	7175 (595-21 567)	4681 (156-18 938)[a]	7273 (156-20 121)	5641 (595-15 339)	5524 (275-21 567)[a]
Daily energy expenditure, median (range), PAR	2613 (1504-5134)	3100 (1893-6170)[a]	2882 (1547-5133)	2924 (1743-6170)	2880 (1504-4241)
Dietary recall, median (range), carbohydrates, g[b]	213.2 (62.2-738.3)	183.35 (62.5-536.0)	188.4 (62.2-401.9)	202.2 (75.0-452.6)	224.1 (72.8-738.9)
Estimated level of fitness, median (range), estimated $\dot{V}O_2$ max, mL/kg/min[b]	27.3 (15.6-46.9)	22.0 (7.9-46.1)[a]	26.8 (9.2-46.9)	24.2 (7.9-43.6)	23.5 (15.6-46.1)[a]
Problem Areas in Diabetes score,[26,27] median (range)	30.6 (0.0-91.3)	32.5 (1.3-73.8)	34.4 (2.5-91.3)	30.0 (3.8-85)	32.5 (0.0-80.0)
BSI score,[28] depression, median (range)[b]	48 (40-73)	45 (40-79)	48 (40-79)	45 (40-79)	48 (40-79)
BSI score,[28] anxiety, median (range)[b]	48 (38-71)	47 (38-81)	47 (38-69)	48 (38-81)	47 (38-71)
Self-Care Inventory-R[23] score, mean (SD)	56.3 (14.5)	57.9 (15.7)	56.3 (14.6)	57.1 (13.2)	57.9 (17.5)
DQOL total score, mean (SD)	64.7 (10.8)	69.6 (10.0)[a]	67.1 (10.4)	66.6 (10.4)	67.8 (11.3)
DQOL score, diabetes worry subscale, median (range)	67.5 (28.8-90.0)	75.0 (45.0-97.5)[a]	72.5 (28.8-97.5)	72.5 (46.3-90.0)	72.2 (45.0-90.0)
DQOL score, global health subscale, median (range)	66.7 (0.0-100.0)	66.7 (0.0-100.0)	66.7 (0.0-100.0)	66.7 (0.0-100.0)	66.7 (0.0-100.0)
DQOL score, satisfaction subscale, mean (SD)	57.9 (15.1)	60.8 (16.3)	57.9 (15.1)	59.1 (15.8)	61 (16.2)
DQOL, social worry subscale, median (range)	75.0 (18.8-100.0)	81.3 (43.8-100.0)[a]	81.3 (31.3-93.8)	75 (25-100)	81.3 (18.8-100.0)
Rosenberg Self-esteem Scale,[32] median (range)	50.0 (36.7-70.0)	50 (30-80)	53.3 (30.0-80.0)	53.3 (36.7-80.0)	50.0 (36.7-70.0)
Social provisions total 96-point scale,[34] median (range)	79 (46-96)	80 (32-96)	79 (32-96)	79 (48-96)	80 (53-96)

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); BSI, Brief Symptom Inventory[28]; DQOL, Diabetes Quality of Life Questionnaire[35,36]; HbA_{1c}, hemoglobin A_{1c}; HDL, high-density lipoprotein; LDL, low-density lipoprotein; NA, not applicable; PAR, physical activity ratio; $\dot{V}O_2$ max, maximum volume of oxygen.

SI unit conversions: To convert LDL or HDL cholesterol to millimoles per liter, multiply by 0.0259; triglycerides to millimoles per liter, multiply by 0.0113.

[a] $P < .05$ based on χ^2, Wilcoxon 2-sample, or Kruskal-Wallis test.

[b] Values were missing for LDL (n=15); HDL (n=15); triglycerides (n=15); pedometer steps per day (n=17); dietary recall (n=7), estimated level of fitness (n=46); BSI, depression (n=1); BSI, anxiety (n=1); and all DQOL subscales (n=1).

Symptom Inventory[28]; this participant was assessed by the study psychologist and found not to be suicidal but was referred for treatment of depression. Three participants reported non–study-related adverse events at follow-up: chest pain prior to follow-up visit, breast cancer, and traumatic foot injury resulting in amputation.

COMMENT

This single-center randomized controlled trial, studying 222 adults with poorly controlled type 1 or type 2 diabetes, represented a head-to-head comparison of an intervention with embedded behavioral strategies with 2 forms of diabetes education: 1-on-1 nurse and dietitian counseling and standard group education. Although glycemic control improved in all 3 arms, the group assigned to the highly structured behavioral arm, in which the nurse and dietitian educators were trained to use scaffolding techniques and brief cognitive behavioral strategies, showed more improvement. Furthermore, the structured behavioral group intervention was more effective in improving glycemic control for those with type 2 diabetes, while those with type 1 diabetes responded equally well to 1-on-1 control sessions as to the structured behavioral condition.

The impact of glycemic control on preventing complications in type 2 diabetes has been well documented in the long-term Diabetes Control and Complications Trial (DCCT)[38] and United Kingdom Prospective Diabetes Study (UKPDS)[39] clinical trials. Although our participants did not achieve glycemic targets of less than 7%, extrapolating from the UKPDS results, we believe that a 0.67% reduction in HbA1c level observed at 12 months, if sustained over the long term, should by itself result in about a 20% reduction in microvascular end points and about a 10% reduction in cardiovascular end points.[39] We also demonstrated that clinical staff can successfully in-

Table 2. Hemoglobin A_{1c} Levels and Secondary Outcomes by Type of Diabetes and Intervention Group at Each Measurement[a]

Measurement	Type of Diabetes		Intervention Group			Mixed Model Analysis With Interactions	
	Type 1	Type 2	Structured Behavioral Group	Attention Control Group	Individual Control Group	Effect	*P* Value[b]
			HbA_{1c}, %				
Baseline	8.93 (1.0) (n = 106)	9.15 (1.2) (n = 109)	9.12 (1.1) (n = 70)	9.09 (1.2) (n = 73)	8.9 (1.1) (n = 72)	Time	<.001
3 mo	8.57 (0.9) (n = 98)	8.45 (1.3) (n = 101)	8.3 (1.1) (n = 64)	8.67 (0.9) (n = 70)	8.53 (1.2) (n = 65)	Type	.88
6 mo	8.6 (0.9) (n = 101)	8.53 (1.2) (n = 100)	8.4 (1.1) (n = 65)	8.68 (1.1) (n = 70)	8.61 (1) (n = 66)	Group	.54
12 mo	8.61 (1) (n = 99)	8.55 (1.5) (n = 103)	8.45 (1.3) (n = 66)	8.6 (1.3) (n = 70)	8.69 (1.3) (n = 66)	Group × time	.04
						Type × time	.04
			LDL Cholesterol, mg/dL				
Baseline	101.1 (27.4) (n = 94)	110.1 (34.2) (n = 108)	105.8 (33.5) (n = 65)	108.5 (35) (n = 69)	103.4 (25.2) (n = 68)	Time	.15
6 mo	104.2 (23.7) (n = 77)	106.6 (33) (n = 93)	108.3 (32) (n = 53)	100.4 (26.5) (n = 62)	108.6 (28.8) (n = 55)	Type	.08
12 mo	98.7 (25.1) (n = 91)	104.4 (36.8) (n = 99)	103.1 (29) (n = 64)	98.7 (31.9) (n = 65)	103.4 (34.7) (n = 61)	Group	.72
						Group × time	.09
						Type × time	.50
			HDL Cholesterol, mg/dL				
Baseline	59.7 (17.8) (n = 94)	43.3 (11.3) (n = 108)	50.9 (15.2) (n = 65)	48.9 (16.2) (n = 69)	53 (18.7) (n = 68)	Time	.01
6 mo	61.6 (19) (n = 78)	43.1 (13.2) (n = 93)	52.8 (19.3) (n = 53)	49.7 (18.2) (n = 62)	52.4 (18.1) (n = 56)	Type	<.001
12 mo	59.3 (20.6) (n = 91)	42.1 (13) (n = 99)	52.1 (21.4) (n = 64)	47.6 (17.1) (n = 65)	51.5 (18.6) (n = 61)	Group	.20
						Group × time	.81
						Type × time	.37
			BMI				
Baseline	26.7 (4.9) (n = 106)	33.2 (6.9) (n = 109)	29.1 (6.6) (n = 70)	31 (7.3) (n = 73)	29.9 (6.6) (n = 72)	Time	.04
3 mo	26.7 (5) (n = 99)	32.7 (7.1) (n = 102)	28.6 (6.3) (n = 64)	31.1 (7.5) (n = 72)	29.5 (6.4) (n = 65)	Type	<.001
6 mo	27 (5) (n = 101)	32.7 (6.7) (n = 98)	28.4 (5.5) (n = 64)	31.5 (7.3) (n = 71)	29.5 (6.3) (n = 64)	Group	.16
12 mo	27 (4.7) (n = 98)	33.1 (7.3) (n = 101)	28.9 (6.7) (n = 66)	31.3 (7.4) (n = 68)	30.1 (6.5) (n = 65)	Group × time	.27
						Type × time	.04
			Glycemia Checks, No./d				
Baseline	3 (1.7) (n = 97)	1.4 (1.1) (n = 88)	2.1 (1.4) (n = 53)	2.2 (1.5) (n = 67)	2.4 (2) (n = 65)	Time	<.001
3 mo	3.9 (1.9) (n = 98)	2 (2.1) (n = 90)	3 (2.0) (n = 60)	3.2 (2.7) (n = 66)	2.8 (1.9) (n = 62)	Type	<.001
6 mo	3.6 (1.8) (n = 99)	1.9 (1.4) (n = 91)	2.7 (1.9) (n = 62)	3.0 (1.9) (n = 69)	2.7 (1.7) (n = 59)	Group	.63
12 mo	3.6 (1.9) (n = 95)	2.1 (1.9) (n = 96)	3 (2.6) (n = 66)	2.9 (2) (n = 67)	2.6 (1.5) (n = 58)	Group × time	.61
						Type × time	.63

(continued)

corporate modified psychological and behavioral strategies designed to support diabetes self-care rather than address psychopathologic conditions.

Meta-analyses of small studies of diabetes education interventions found that these interventions were successful in improving glycemia, particularly when a behavioral intervention was incorporated.[17-19,40] However, little is known about the specific behavioral components and/or education that are necessary to support lifestyle changes and self-care behaviors. The Diabetes Prevention Program[41] demonstrated that educator-led lifestyle interventions prevented diabetes for people at risk more than metformin alone. Interestingly, a well-designed cognitive behavioral intervention that was not embedded in an education intervention had a relatively minimal impact on glycemia for people with diabetes.[22] Few, if any, studies do head-to-head comparisons of interventions to determine if clinical staff can successfully incorporate behavioral techniques into their clinical practices. Thus, our study represents one of the first randomized controlled

Table 2. Hemoglobin A_{1c} Levels and Secondary Outcomes by Type of Diabetes and Intervention Group at Each Measurement[a] (continued)

Measurement	Type of Diabetes		Intervention Group			Mixed Model Analysis With Interactions	
	Type 1	Type 2	Structured Behavioral Group	Attention Control Group	Individual Control Group	Effect	*P* Value[b]
Pedometer Readings, Steps/d							
Baseline	7822 (3737) (n = 101)	5388 (3622) (n = 98)	7601 (4186) (n = 65)	6198 (3425) (n = 68)	6099 (3851) (n = 66)	Time	.11
3 mo	8245 (3931) (n = 87)	5961 (4496) (n = 76)	8408 (4974) (n = 49)	6859 (3855) (n = 60)	6421 (4077) (n = 54)	Type	<.001
6 mo	8006 (3996) (n = 90)	5530 (4274) (n = 79)	8287 (4922) (n = 54)	6005 (4199) (n = 62)	6371 (3329) (n = 53)	Group	.04
12 mo	7526 (3573) (n = 84)	5850 (4617) (n = 69)	7422 (4240) (n = 47)	6510 (4312) (n = 58)	6446 (3859) (n = 48)	Group × time	.55
						Type × time	.42
Diabetes-Related Distress[26,27]							
Baseline	35.3 (22.1) (n = 106)	33.1 (18.7) (n = 109)	34.8 (19.3) (n = 70)	33.6 (20.8) (n = 73)	34.0 (21.5) (n = 72)	Time	<.001
3 mo	28.4 (17.5) (n = 98)	27 (20.1) (n = 91)	30.5 (17.4) (n = 62)	25.5 (18.3) (n = 65)	27.4 (20.4) (n = 62)	Type	.25
6 mo	28.9 (18.7) (n = 100)	27 (19.6) (n = 94)	30.4 (18.1) (n = 63)	26.9 (18.8) (n = 71)	26.8 (20.6) (n = 60)	Group	.45
12 mo	26.7 (17.8) (n = 95)	22.7 (15.1) (n = 95)	28.5 (17.2) (n = 65)	22.6 (15.9) (n = 67)	22.7 (16.2) (n = 58)	Group × time	.53
						Type × time	.67
Self-Care Inventory-R[23] Score							
Baseline	56.8 (14.2) (n = 106)	57.9 (15.9) (n = 109)	56.9 (14.6) (n = 70)	56.9 (13.4) (n = 73)	58.3 (17.1) (n = 72)	Time	<.001
3 mo	63.4 (13.9) (n = 99)	62.7 (14.1) (n = 91)	62.6 (14.4) (n = 62)	64.1 (13.7) (n = 66)	62.6 (14) (n = 62)	Type	.53
6 mo	63.1 (15) (n = 100)	60.5 (13.6) (n = 94)	60.9 (14.8) (n = 63)	63.3 (13.6) (n = 71)	61.2 (14.9) (n = 60)	Group	.53
12 mo	63.4 (15.3) (n = 95)	62.4 (14.1) (n = 97)	60.5 (14.7) (n = 66)	65.9 (13.8) (n = 67)	62.2 (15.3) (n = 59)	Group × time	.09
						Type × time	.07
Diabetes Quality of Life Scale Score[35,36]							
Baseline	64.7 (10.8) (n = 106)	69.4 (10) (n = 109)	67.0 (10.2) (n = 70)	66.4 (10.4) (n = 73)	67.8 (11.4) (n = 72)	Time	<.001
3 mo	67.6 (10.8) (n = 99)	73.1 (10.3) (n = 91)	69.8 (10.7) (n = 62)	70.5 (11.3) (n = 66)	70.5 (10.7) (n = 62)	Type	.001
6 mo	68 (12) (n = 100)	72 (10.6) (n = 94)	68.8 (10.8) (n = 63)	69.4 (12.1) (n = 71)	71.6 (11.6) (n = 60)	Group	.76
12 mo	68.6 (11.5) (n = 95)	73.4 (10) (n = 97)	69.4 (11.3) (n = 66)	72.2 (10.5) (n = 67)	71.6 (11.2) (n = 59)	Group × time	.21
						Type × time	.56

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); BSI, Brief Symptom Inventory[28]; HbA_{1c}, hemoglobin A_{1c}; HDL, high-density lipoprotein; LDL, low-density lipoprotein; PAR, physical activity ratio.

SI unit conversion factors: To convert LDL or HDL cholesterol to millimoles per liter, multiply by 0.0259.

[a] Unless otherwise noted, data are reported as mean (SD) values.

[b] *P* values associated with type 3 tests of fixed effects.

trials to conduct head-to-head comparisons of self-care interventions.

Successful diabetes treatment requires participant active involvement in multiple self-care behaviors and treatment prescriptions necessary for achieving glycemic targets.[42,43] Our findings demonstrate that a diabetes self-management support intervention is an important component of treatment for participants who have not achieved therapeutic targets, evidenced by all 3 arms achieving an improvement in glycemia by 3 months after intervention. We also found that nurses and dietitians were able to implement successfully specific behavioral strategies and techniques, including high structure, modified cognitive restructuring, and modeling of behavior, and that when applied, participants with poorly controlled diabetes were able to improve glycemic status. These strategies were not used for therapeutic counseling of psychopathologic illness but rather as support for participants who were attempting to change lifestyle approaches.

Patients often struggle to follow recommended health behaviors. Our study found that participants improved their glycemic status, although many did not achieve glycemic targets of less than 7%. One explanation for some patients' struggles may be their inability to impose their own structure on their life behavior. Our highly structured behavioral intervention provided a scaffold that allowed participants to integrate specific dietary and physical activity behaviors into their busy schedules. Another explana-

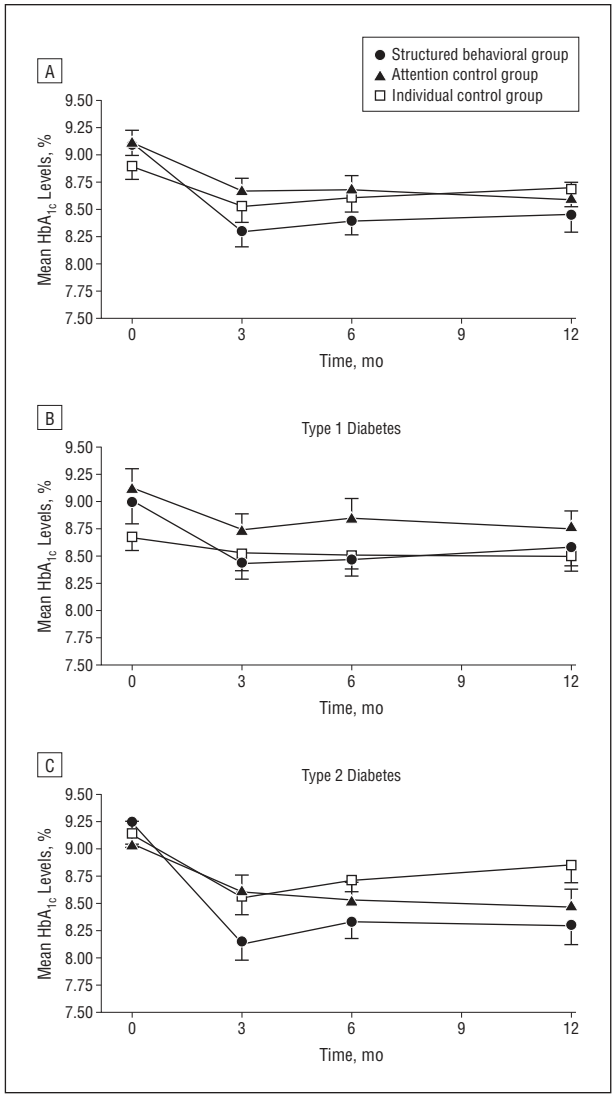

Figure 2. Mean hemoglobin A_{1c} (HbA_{1c}) levels over time for the 3 intervention groups for all participants (A) and those with type 1 (B) and type 2 (C) diabetes.

tion may be that struggling patients lack contact with others who have diabetes and therefore have little opportunity to discuss or reinforce self-management strategies. The structured behavioral group intervention may have provided social support that led to more engagement in their self-care. However, one of the control conditions was a group education intervention that provided a similar amount of professional and non–health professional support for participants, making the differential improvement solely due to increased social support unlikely.

Furthermore, type 1 diabetes showed equal improvement in the highly structured behavioral group arm and in the individual arm, while type 2 diabetes improved more in the structured behavioral arm than in the control group and individual arms. Participants with type 2 diabetes were particularly responsive to the education, and many maintained that response over time. These findings may result from those with type 1 diabetes receiving more basic educational and behavioral support at diagnosis and throughout the course of their diabetes than those with type 2 diabetes. One study examining the long-term value of diabetes education provided at diagnosis found beneficial effects in terms of weight loss and smoking.[44] Another explanation may be that patients with type 1 diabetes who struggle with achieving glycemic targets need more help with emotional and psychological issues than support with diabetes self-management skills.

Table 3. Logistic Regression Model of Characteristics Associated With at Least a 0.5-Percentage Point Improvement in Hemoglobin A_{1c} Levels at 3 Months

Parameter	ORE (95% Wald CI)	*P* Value[a]
Intercept	NA	<.001
Hemoglobin A_{1c} at baseline	2.55 (1.78-3.65)	<.001
Diabetes Quality of Life Scale,[35,36] measured at 3 mo, unit = 10	1.52 (1.01-2.28)	.04
Frustration with self-care, 3 mo, unit = 10[3,34]	0.83 (0.70-0.99)	.03
Emotion-based coping measured at 3 mo, unit = 10[29,30]	1.58 (1.18-2.11)	.002
Structured behavioral group, dummy variable	2.54 (1.14-5.62)	.02
Attention control group, dummy variable	0.75 (0.35-1.62)	.47

Abbreviations: CI, confidence interval; NA, not applicable; ORE, odds ratio estimate.
[a] χ^2 *P* value.

Our study has several limitations. The interventions did not have follow-up support built into the program. To protect the integrity of each arm of the study, classes and sessions were held in different sections of the center. By design, only the attention control group was embedded in the clinic because this was the most conservative approach. Furthermore, the structured behavioral arm had more patients receiving their care outside of the clinic, and they may not have received the same intensity of medical and/or educational follow-up. Thus, the important issue of sustainability will need to be studied in a future trial. Furthermore, the mechanisms underlying the differential response, whether associated with subclinical depression, organizational and executive functioning abilities, or some other factor, cannot be addressed.

In summary, our primary objective of this randomized controlled trial was to determine whether a structured, cognitive behavioral group education program was more effective in improving glycemic control than an attention control diabetes education program or individual education. We also aimed to determine if diabetes clinicians, in this case educators, could incorporate these psychological and/or behavioral techniques into their clinical approaches. We found that participants with poor glycemic control in all 3 education arms improved their glycemic status, and the highly structured behavioral group arm, which used cognitive behavioral strategies, was most effective in helping these participants improve their glycemic status and maintain that improvement over 1 year.

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INVITED COMMENTARY

ONLINE FIRST

Improving Glycemic Control When "Usual" Diabetes Care Is Not Enough

Reducing the burden and impact of diabetes in the United States has become a major priority across all levels of the US health system—resulting in substantial investment in basic science research, new drug development, health services research, and public health. Despite this investment, many patients living in the United States have not achieved optimal control of their diabetes. This has served to refocus attention to research aimed specifically at implementing health care interventions to improve glycemic control through increased adoption of existing diabetes treatments and improving self-management–related behaviors.

See also pages 2001 and 2011

This issue of the *Archives* includes 3 implementation research studies that evaluate the impact of different patient education and counseling strategies on diabetes self-management and glycemic control (hemoglobin A_{1c} [HbA_{1c}] levels).[1-3] Two studies were based in primary care, and all study populations consisted primarily of patients with suboptimally controlled diabetes (mean HbA_{1c} range, 8.1%-9.8%). All studies included educational content that promoted diabetes self-management, behavioral goal setting, and action planning relating to medication adherence, diet, physical activity, and glucose monitoring. One study in a safety net community clinic population found no difference between telephone health coaching and a printed educational brochure—both reduced HbA_{1c} levels by 0.25% at 6 months.[1] A study with patients belonging to a large integrated medical group (HealthPartners in Minnesota and New Mexico) found individual education and counseling sessions by certified diabetes educators to be more effective (–0.54%) than group education visits (–0.27% at 6 months) and usual care (–0.25% at 6 months).[2] The third study at the Joslin Diabetes Center in Boston, Massachusetts, found a structured behavioral group visit program was more effective (–0.70% at 6 months) than standard group education (–0.37%) and individual education (–0.24%) programs.[3]

WHAT CAN EXPLAIN THE DIFFERENCES REPORTED?

These studies' findings could be due to a true difference between the interventions, or the results could be due confounding, bias or chance. These are randomized controlled studies of generally high quality. Treatment group assignment was randomized; outcome assessment was masked; loss-to-follow-up was limited; and intention-to-treat analyses were performed. However, there were significant differences in the demographics of the study populations: 1 study included type 1 diabetes and only 1 study included non-English speakers. None of the studies reported on the health literacy of their study populations. The intervention descriptions do not allow direct comparison of the content, intensity, and degree of tailoring of the counseling to individuals' diabetes needs. Recent studies have shown that both tailoring and follow-up of patient-generated action plans in diabetes interventions are critical to improving diabetes-related outcomes.[4,5] Although they describe using mixed-effect models, they do not explicitly identify the cluster variable(s) or provide information about the number of unique educators participating in the trial. Without such information, it is not possible to determine if adequate adjustment for clustering occurred, which can increase variance estimates and reduce the statistical significance of comparisons between groups.

HOW DO THESE INTERVENTION STRATEGIES DIFFER?

One way to conceptualize these trials is that they are comparing different implementation strategies for the same type of intervention—interactive patient education and counseling. A key feature of interactive education is that it allows the educator to tailor information, assess comprehension, clarify difficult concepts and use motivational interviewing techniques and action plans. The advantage of group visits over individual visits is the