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Impact of Reinforcement of Diabetes Self-Care on Poorly Controlled Diabetes: A Randomized Controlled Trial

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Abstract

Purpose—The purpose of the study was to assess the value of reinforcing diabetes self-management for improving glycemia and self-care among adults with type 2 diabetes who had at least three hours of prior diabetes education.

Methods—In this randomized controlled trial, 134 participants (75% White, 51% female, 59±9 years old, 13±8 years with diabetes, A1C=8.4±1.2%) were randomized to either a group map-based program (Intervention) or group education on cholesterol and blood pressure (Control). Participants were assessed for A1C levels, diabetes self-care behaviors (3-day pedometer readings, 6-minute walk test, blood glucose checks, frequency of self-care), and psychosocial factors (distress, frustration, quality of life) at baseline, 3, 6 and 12 months post-intervention and health literacy at baseline.

Results—Groups did not differ on baseline characteristics including A1C levels, health literacy, or self-care; however, the Intervention group had more years of education than Controls. Intervention arm participants modestly improved A1C levels at 3 months post-intervention but did not maintain that improvement at 6 and 12 months while Control patients did not improve A1C levels at any time during follow-up. Importantly, frequency of self-reported self-care, diabetes quality of life, diabetes-related distress and frustration with diabetes self-care improved in both groups over time.

Conclusions—Reinforcing self-care with diabetes education for patients who have not met glycemic targets helps improve A1C and could be considered a necessary component of ongoing diabetes care. The best method to accomplish reinforcement needs to be established.

Keywords

Type 2 diabetes; diabetes education intervention; diabetes self-care

Type 2 diabetes is a chronic condition that requires patients to follow specific recommendations and prescriptions for the rest of their lives. Self-care recommendations include regular physical activity[1,2], frequent blood glucose monitoring accompanied by

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appropriate actions based on results[3], following meal plans [4], taking preventative measures and clinic attendance[5–7]. While these behaviors are critically linked to improved glycemic control and the prevention of complications, integrating them into one's daily life can be challenging[8–10].

Formal diabetes self-management education helps patients integrate and improve self-care behaviors and glycemia[11–14]. The Diabetes Control and Complications Trial (DCCT) established the importance of diabetes educators in supporting patients' efforts to improve self-care and glycemic control[15–18]. Despite these improvements, many patients from the Epidemiology of Diabetes Interventions and Complications Study (EDIC) follow-up study were not able to maintain glycemic targets[19]. Other diabetes interventions also have shown patients' difficulty maintaining intervention responses over an extended period of time[12,13,20]. Considering the key role diabetes education and support play in self-management, a logical approach to sustaining intervention improvements may be reinforcement of diabetes education.

Reinforcement of diabetes self-care education may be a necessary component in diabetes treatment. That is, once patients have completed a basic diabetes education program, they may lack the skill sets to maintain their own self-care behaviors at different points throughout the course of their diabetes. Ongoing and repeated education (reinforcement) may be necessary to address the progressive nature of diabetes along with the multiple challenges of diabetes self-management and to maintain the self-management learning experienced during the initial education. However, few well-designed long-term randomized controlled trials have examined the value of reinforcing diabetes self-care and the best approach to accomplish reinforcement.

This study examined whether a map-based intervention was useful in reinforcing prior diabetes self-management education for patients with type 2 diabetes who had not reached glycemic targets. Factors that may be associated with an improvement/decline in glycemic control, including diabetes-related emotional distress, frustration with diabetes self-care, and diabetes quality of life were also examined. Whether diabetes self-care should be reinforced with diabetes education to help patients maintain glycemic improvements has not been clearly established. Thus, the purpose of the study was to assess the value of reinforcing diabetes self-management for improving glycemia and self-care among adults with type 2 diabetes who had prior diabetes education. The study's hypotheses are as follows.

Hypotheses

Hypothesis 1: The map-based intervention in comparison to the control condition will lead to improved glycemic control (lowered A1C) post intervention (3 months) and at 6 and 12 months follow-up.

Hypothesis 2: The map-based intervention in comparison to the control condition will lead to improved frequency of recommended self-care behaviors post intervention (3 months) and at 6 and 12 months follow-up.

RESEARCH DESIGN AND METHODOLOGY

Design Overview

This two-arm, parallel designed trial randomized participants to either a group map-based program (Experimental Intervention) or group education on dyslipidemia and hypertension (Attention Control Intervention). Different teams of experienced diabetes nurses and dietitians, all certified diabetes educators, provided education for each arm. Written

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curriculum, pre-approved education materials, separate educator trainings, investigator observation of all group classes, and separate teams of trained, experienced diabetes educators to prevent carryover of education strategies ensured integrity of the two interventions. The Joslin Diabetes Center Committee on Human Subjects approved the protocol and all recruitment procedures and materials. All participants provided written informed consent prior to participation.

Setting and Participants

Participants were recruited via referrals from the clinical practice of the Joslin Clinic, advertisements in the Joslin Newsletter and website, and extensive mailings from Joslin's mailing lists.

Adults aged 25 to 75 years diagnosed with type 2 diabetes for at least two years who were taking insulin and/or oral medication for at least one year, able to walk briskly, free of severe complications, had at least 3 hours of previous documented diabetes education, and whose Hemoglobin A_{1c} (A1C) level >7.0% were eligible for enrollment. Exclusion criteria included inability to read and speak English, current or planned pregnancy, severe renal disease (microalbumin >300 ug/mg), severe peripheral diabetic neuropathy and/or severe peripheral vascular disease, symptomatic severe autonomic neuropathy, proliferative diabetic retinopathy based on dilated eye examination within one year of study entry, A1C levels <7.0% and A1C levels >13.0%, a history of severe unstable myocardial infarction, congestive heart failure or other severe cardiac disease, and severe hypertension (systolic ≥160 mmHg or diastolic ≥ 90 mmHg). Participants diagnosed with bipolar disorder, schizophrenia, mental retardation, organic mental disorder, and alcohol or drug abuse were excluded, as well as patients currently undergoing psychiatric treatment. These exclusions were made to avoid confounds due to concurrent changes in mental status and the effects of ongoing psychiatric treatment. Eligible participants were scheduled for a baseline and a randomization visit.

Randomization

A block randomization sequence based on a random number table was generated with randomization.com to ensure balance between the two groups at study end. Educators and study physicians had no role in randomization.

Interventions

Experimental Intervention: Conversation Maps—The US Diabetes Conversation Maps program is a set of diabetes education tools (Healthy Interactions, Inc., Chicago, IL) designed to help educators facilitate patient group discussions about diabetes self-care and goal-setting. Participants randomized to the Conversation Maps Intervention attended four one-hour sessions, each with a different map. All sessions were held in the Behavioral Research Laboratory. The four maps used for this study covered the following topics: 1) Diabetes Overview, 2) Diabetes and Healthy Eating, 3) Blood Glucose and Monitoring, and 4) The Natural Course of Diabetes (a fifth map covering gestational diabetes was not used); each map had a program manual for the group facilitator. Experienced diabetes nurses and dietitians facilitated the Map sessions. Educators helped participants focus on the diabetes information most relevant to them and their experiences. At the end of each session, educators assisted participants in setting realistic health goals and developing a plan to achieve meaningful behavior change in their lives. All Intervention educators were trained by Conversation Maps certified trainers.

Attention Control Intervention: Heart Healthy Living—The Control arm consists of two 2-hour classes focusing on 1) dyslipidemia and 2) hypertension, but not specifically

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diabetes self-care. Both conditions are common in those with type 2 diabetes. These classes have been validated and are offered in The Joslin Clinic. The curriculum consists of prepared slides, a detailed curriculum manual, and specific learning activities including goal-setting. The Heart Healthy Living Program was the ideal attention control because it does not address the outcome variables of diabetes specific self-care behavior nor glycemic control yet the information provided is valuable for people with type 2 diabetes as dyslipidemia and hypertension are common comorbidities. A registered nurse (hypertension class) and a registered dietitian (lipid class) taught the classes. All Control arm educators were trained and certified by the Clinic prior to teaching.

Measures and Follow-Up

Data were collected at baseline and 3, 6, and 12 months post group interventions. The primary outcome was A1C, measured via the Turbidimetric Inhibition Immunoassay using the Roche Integra 800 Analyzer (Roche Diagnostics Operations Inc., Indianapolis, Indiana; reference range is 4.0 to 6.0%).

In addition to sociodemographic factors (age, sex, race/ethnicity, education level, marital status, occupation) and health factors (duration of diabetes, body mass index (BMI), waist circumference, blood pressure), mean 3-day pedometer readings (Omron Healthcare, Inc., Lake Forest, Illinois), a fitness assessment (6-minute walk test), and daily blood glucose meter checks were also collected.

Finally, participants completed the following:

Self-care Inventory-R (SCI-R)[21] is a 15-item survey that measures the self-reported frequency of self-care behaviors on a 5-point Likert scale and has been validated for use with type 2 diabetes populations[21]. Four additional items inquiring about checking feet, eating heart healthy foods, looking at blood glucose patterns, and knowing about blood pressure, A1C and lipids were included.

Brief Symptom Inventory (BSI)[22] is an 18-item checklist that assesses 3 primary dimensions (somatization, depression, and anxiety) and yields a total score summarizing the overall level of psychological symptoms (Cronbach's alpha=0.89). This measure renders age and gender adjusted t-scores and is widely used with repeated assessments of its reliability and validity[22]. A t-score of 63 or greater suggests clinical depression.

Coping Styles[23]_ENREF_23_ENREF_23 is a 15-item measure assessing emotional coping and self-controlled coping. Self-controlled coping strategies include stoicism and pragmatism, indicated by statements of controlling one's emotions and problem-solving to alleviate frustration. Emotion-based coping strategies include anger, impatience, and anxiety, indicated by angry statements, impulsive actions, anxious behaviors (nervous, worried, upset, difficulty relaxing) and avoidant behaviors (not doing something or giving up). Patients are asked to rate each item on a 4-point scale, ranging from "not at all like me" to "very much like me." This measure is validated in diabetes populations[23].

Problem Areas in Diabetes (PAID)[24] is a widely used 20-item measure of diabetes-related emotional distress that assesses a broad range of feelings related to living with diabetes and its treatment, including guilt, anger, frustration, depressed mood, worry and fear[24–27]. The PAID has high internal reliability (alpha=.95)[24,27]. The PAID is sensitive to changes in glycemic control and high PAID scores are associated with lower self-reported adherence to treatment recommendations[21].

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Problems with Diabetes Self-Management (PDSM)[26] *Scale* is a 5-item scale that measures frustration with diabetes self-care: glucose control, meal plan, exercise, glucose monitoring, and medications. This measure is sensitive to barriers to performance of self-care behaviors and diabetes-related emotional distress[26].

Diabetes Quality of Life Scale (DQOL)[28] has 46 core items rated on a five point Likert scale and yields a total score with five subscales (satisfaction, general health, impact of treatment, future effects of diabetes, and social effects). Scores are converted to a 100 point scale with 100 representing highest quality of life and zero representing lowest quality of life.[28] The psychometric properties of the DQOL are well-established [28–30] and it has been tested in both type 1 and type 2 diabetes patients.[29]

Confidence in Diabetes Self-Care Scale (Type 2) (CIDS-2)[31] is a validated 21-item measure assessing self-efficacy in diabetes, that is, the confidence individuals have in their ability to perform self-care tasks.[31] Patients rate each item on a 5 point scale ranging from "No, I am sure I cannot" to "Yes, I am sure I can." The CIDS has high internal reliability (alpha=0.90).[32]

Test of Functional Health Literacy in Adults (TOFHLA)[33] is a complex measure of functional health literacy.[33] The TOFHLA is available in English and Spanish versions and requires 20 minutes for administration. The TOFHLA assesses numeracy and reading comprehension using health-related materials. The numeracy portion consists of 17 multiple-choice questions that assess a patient's ability to interpret documents and numbers. Patients interpret with different prescription bottle labels and respond to questions regarding the dose, timing and expiration of prescriptions. The short form reading comprehension consists of two passages of text and 36 multiple-choice questions. The passages of text focus on x-ray preparation and medical insurance coverage. In each passage, selected words have been deleted and replaced with blank spaces. Patients need to choose from a response set which words make the most sense in the text.

Statistical Analysis

All analyses were conducted using SAS 9.2 (SAS Institute, Carey, NC, USA). Descriptive statistics were examined to ensure that data met statistical test assumptions. Baseline characteristics were compared using Chi-square, Wilcoxon Two-Sample or Kruskal-Wallis Test to examine between-group differences and assess the randomization procedure effectiveness.

As the pattern of our missing data was arbitrary, multiple imputations with the Markov Chain Monte Carlo method (SAS Proc MI) were used to input missing data[34]. The results presented are based on combined inferences of the 15 complete data sets. The imputation model was built using demographic, psychosocial and A1C values.

For the primary analysis of the two education interventions on A1C at baseline and the three follow-up points, a linear spline model was used to estimate the observed A1C trend over time (SAS Proc Mixed). The final model consisted of two piecewise, linear trends having different slopes within each segment but joined together at a fixed time point (3 months)[35]. Included in the model were time effects, group effect, and the interactions between time and group. The intercept and time effects were specified as random effects, positing that individuals vary in their baseline A1C levels and in A1C changes over time. The spline model allows the rates of change before and after 3 months to differ both within and between groups. This approach allows the testing of variables predicting the 3-month rate of change in A1C, and provides insight into whether the two education groups differ in A1C response profiles and also how they differ.

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Similarly, for continuous secondary outcomes (self-care behaviors, diabetes quality of life), a linear mixed model was used for longitudinal data (SAS Proc Mixed). Included in the model were time effects, group effect, and the interactions between time and group.

RESULTS

Four hundred and seventy-three adults with type 2 diabetes, of whom 162 were eligible for a screening visit, were telephone-screened; 135 were randomized (Figure 1). The most common reasons for exclusion at screening were presence of complications and/or comorbid conditions (37%), not meeting criteria for hemoglobin A1C (16%), not enough prior diabetes education (12%), inability to walk briskly (9%) or starting new insulin and/or oral medication regimen (6%). Further, twelve eligible people did not return for randomization.

One randomized participant (Intervention group) did not meet eligibility requirements for planning pregnancy and became pregnant before her first follow-up visit. She was dropped from the study. Three other randomized participants did not return for follow-up visits. All four (including dropped participant) were randomized to the Intervention group; these participants did not differ on baseline characteristics from those who completed the study. An additional six participants (4 Intervention, 2 Control) did not complete any surveys at follow-up, but provided physiological and laboratory data. Thus, 131 of these participants have some follow-up data.

One hundred and thirty-four participants (75% Non-Hispanic White, 51% female, 59±9 years old, 15±3 years of education, 13±8 years with type 2 diabetes, A1C=8.4±1.2%; Table 1) attended the group map-based program (Intervention, n=67) or group education on dyslipidemia and hypertension (Control, n=67). Groups did not differ on baseline characteristics including A1C levels, health literacy, or self-care behaviors; however, the Intervention group had more years of academic education than Controls (15.9 vs 14.9 years, p=0.05). Both groups reported being satisfied with their diabetes education classes and educators immediately after completion of the intervention. However, two male participants stated that they were not satisfied with the Maps program.

Hemoglobin A_{1c} (A1C) levels

Hypothesis 1 compared glycemic improvement in the map-based intervention versus the control condition at 3, 6, and 12 months post intervention. Findings revealed participants in the Intervention arm modestly improved A1C levels at 3 months post-intervention, but not at 6 and 12 months (mean change: −0.4 points, p=0.004; −0.3 points, p=0.07; 0.04 points, p=0.8 respectively, Figure 2) while Control arm patients did not improve A1C levels at any time during follow-up (mean change: −0.02 points at 3-months, p=0.8; −0.07 points at 6-months, p=0.5; −0.2 points at 1 year, p=0.2 respectively). The linear spline model with a "knot" at 3-months, found the rate of change (beta coefficient) from baseline to 3 months for the Intervention group to be −0.114. This beta coefficient indicates a modest improvement in A1C (Table 2). However, between 3 and 12 months the parameter estimate for rate of change in A1C was 0.128 indicating the intervention's A1C levels deteriorated. The control condition that focused on dyslipidemia and blood pressure control rather than diabetes self-management resulted in maintenance of A1C at baseline levels. Thus, the linear spline model is consistent with mean group A1C levels (Figure 2).

Hypothesis 2 compared frequency of recommended self-care behaviors in the map-based intervention versus the control condition at 3, 6, and 12 months post intervention. Both the Intervention and Control arms improved self-reported frequency of self-care following the intervention; however, these improvements did not differ by type of intervention (Table 3). Objective measures of self-care (6-minute walk test, mean 3-day pedometer readings,

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number of glucose check per day) did not change over time (Table 3). Importantly, diabetes quality of life, diabetes-related distress, and frustration with diabetes self-care improved in both groups. None of the improvements in secondary outcomes differed by type of intervention.

CONCLUSIONS AND IMPLICATIONS

This single center randomized controlled trial studying 134 adults with type 2 diabetes in poor glycemic control represented a comparison of a map-based group intervention with an attention control group focused on dyslipidemia and blood pressure. The map-based intervention helped poorly controlled diabetes patients who had received prior diabetes self-management education realize a modest improvement in glycemic control at three months post-education; however, these participants were not able to maintain that improvement over time (that is, at 6- and 12-months follow-up). The Control arm did not show improvement or deterioration in A1C levels at any time during the follow-up period. Interestingly, self-care and diabetes quality of life did not differ by type of intervention at follow-up. However, neither the Intervention nor Control arms negatively impacted participants' self-reported frequency of self-care, diabetes quality of life, diabetes-related distress, or frustration with diabetes self-care over time.

To our knowledge, this study is the first of its kind to formally examine reinforcement of diabetes education. Contrary to the findings of Sperl-Hillen and colleagues[36], this study found modest improvements in A1C levels at 3-months post-intervention in the map-based group. These data suggest reinforcing diabetes education for patients who have not met glycemic targets is helpful and important; however, a map-based group education program may not be the most effective program for reinforcing and importantly maintaining improvements over time. One possibility is that patients who are struggling with self-management issues and glycemic control need more highly structured programs to help them develop and maintain new lifestyle behaviors that will last over a longer term. Structured education that incorporates scaffolding, modeling, and problem-solving skills helps patients who are struggling to integrate self-care into their daily lives[14]. Further, structured education has been shown to support maintenance of diabetes self-care and glycemic control over time[14]. More work is required to determine if highly structured diabetes self-care education embedded with behavioral strategies is more suitable than standard group education alone for reinforcement of diabetes education.

One dose of education, whether it is a full course over several weeks or one session, appears not to be enough to support diabetes self-care throughout a patients' lifetime. Patients with diabetes face important stressors/events at different points throughout the course of their illness that can impact how they manage and cope with diabetes[37–39]. Four periods necessitate special attention: 1) onset of diabetes, 2) health maintenance and prevention of complications, 3) early onset of complications, and 4) the stage of illness where complications dominate[38,39]. Each period has educational and psychological implications for the patient, family, and clinician regarding the prevention and treatment of diabetes and its complications. For example, diagnosis of a complication may evoke heightened anxiety, feelings of helplessness, and changes in self-care routines. Patients facing stressors/events typically employ coping strategies they have used in the past that have varying levels of effectiveness[37]; however, these strategies (e.g., denial, anger) may interfere with their diabetes self-management[23]. Thus, ongoing and repeated education and support that focuses on potential stressors, diagnosis/treatment of complications, and varying self-care regimens is needed to help patients maintain glycemic control and employ effective coping strategies and prevention strategies as their diabetes progresses. More research is needed to determine the amount or "dose" of education required for long-term maintenance.

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Study limitations include homogeneity of the study sample with regards to race/ethnicity (72% Non-Hispanic white), age and education, participant self-selection, and self-reported data. This trial examined the impact of only one program of group education on reinforcing diabetes education. Other group education has been shown to improve glycemic control in both the short-term and long-term[40]; however, an individual approach may be more effective for some type 2 diabetes patients[36]. Also, the Intervention and Control arms did not have follow-up support built into the programs, which may partially explain the modest glycemic improvements or lack of maintenance observed in the intervention group. Finally, the design of this randomized controlled trial did not allow for examination of the dose of the intervention or learning thresholds in patients with prior diabetes education who had not reached A1C targets. Future research aimed at reinforcing education should focus on rigorous, randomized controlled trials that compare the effectiveness of education methods and address the important issue of sustainability in behavioral change.

Diabetes self-care education is an important part of diabetes care for all people with diabetes, and our findings support the notion that people who are struggling with their diabetes self-care need ongoing and repeated education to help them improve and maintain their diabetes control. Thus, reinforcing diabetes self-management education for patients who have not met glycemic targets is a necessary component of ongoing diabetes care. The results of our study show the map-based program helped patients improve their A1C at 3 months but not over the long-term. The most effective self-care education program for maintaining improvements over the long-term needs to be determined.

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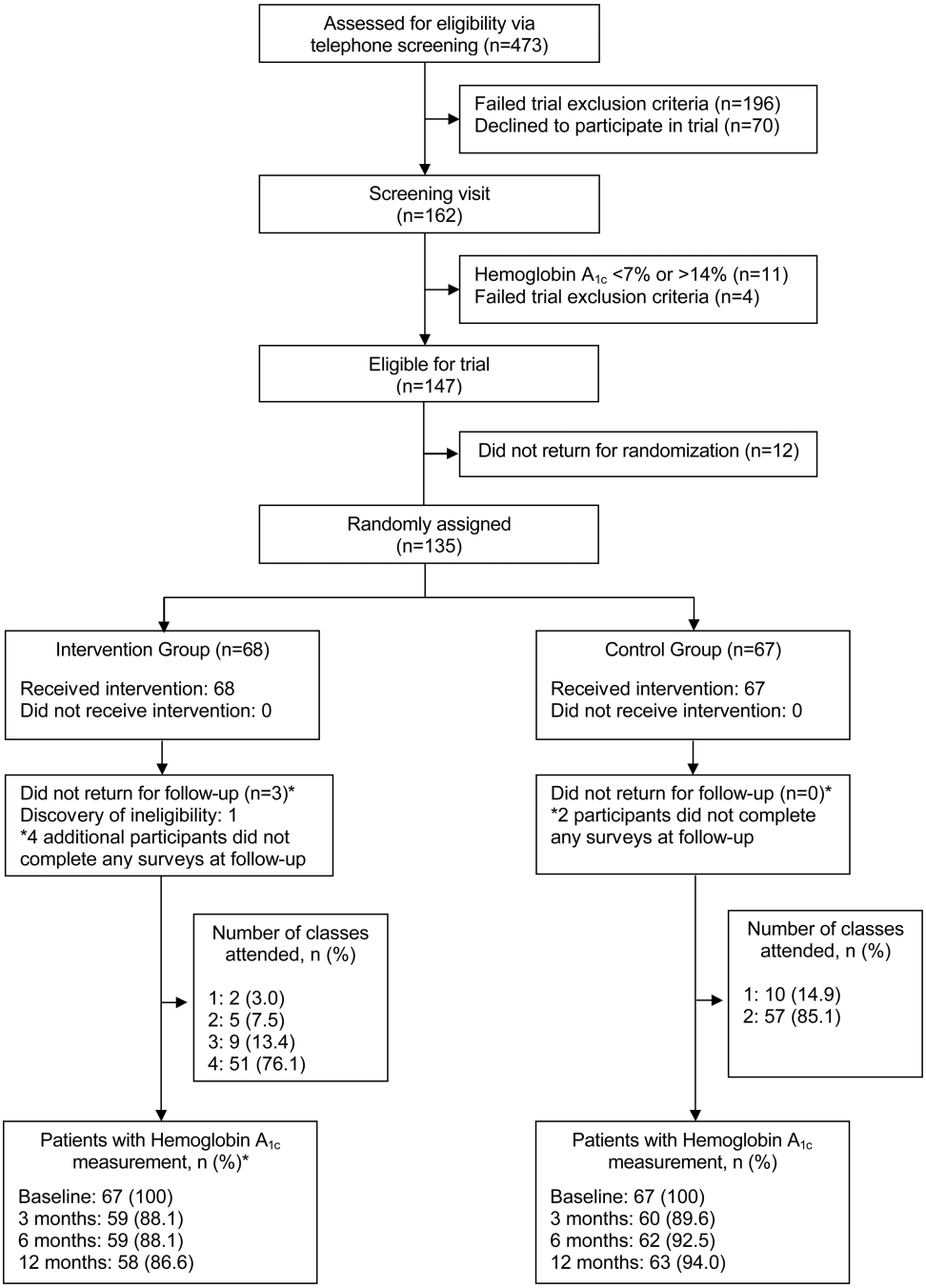

Figure 1.

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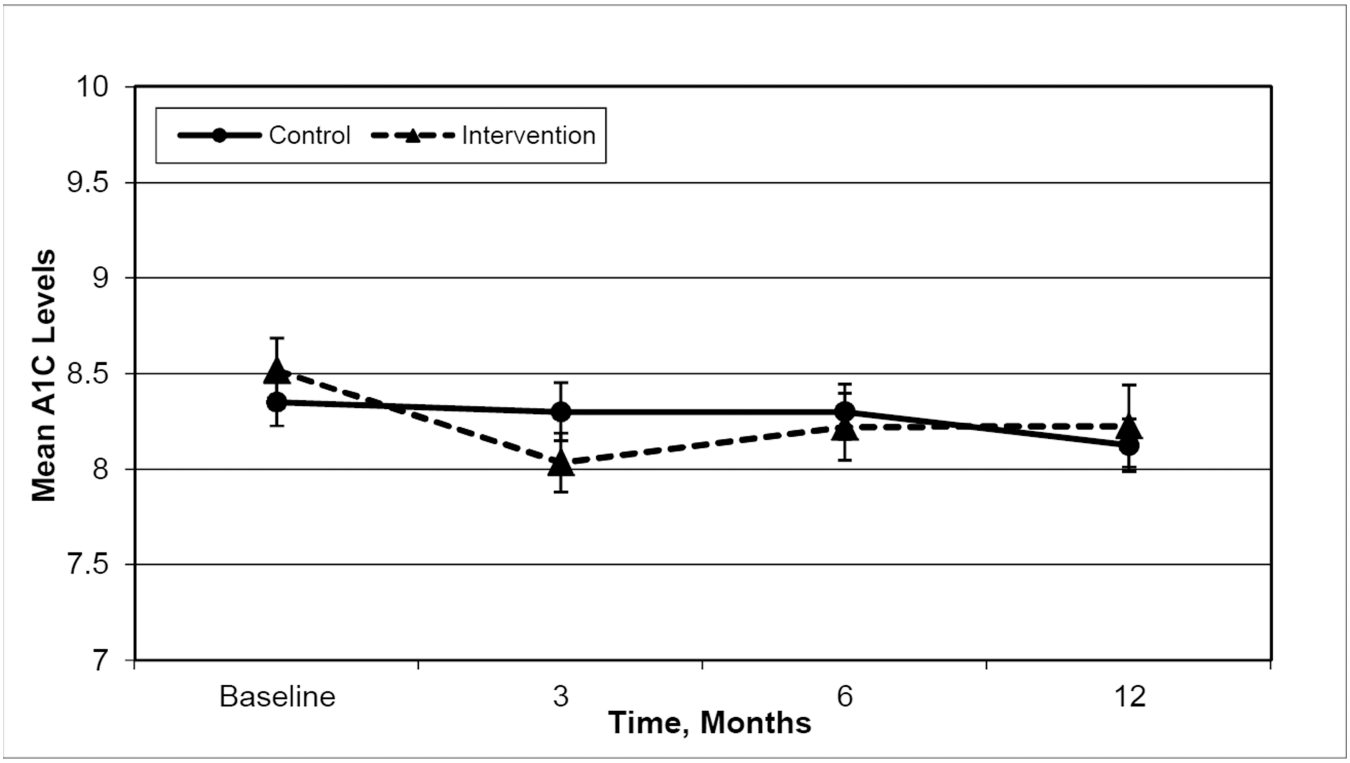

Figure 2.

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Table 1

Baseline Characteristics of Type 2 Diabetes Participants Randomly Assigned to Intervention or Control Groups[≠]

	All Patients (N=134) Mean ± SD	Intervention (N=67) Mean ± SD	Control (N=67) Mean ± SD
Demographic Variables			
Hemoglobin A_{1c} (%)	8.4±1.2	8.5±1.4	8.3±1.0
Age (years)	59.1±8.7	59.9±8.5	58.4±9.0
Females (%)	51.5	47.8	55.2
Non-Hispanic white (%)	71.6	73.1	70.2
Body mass index (kg/m^2)	34.2±7.1	34.6±7.0	33.7±7.1
Diabetes duration (years)	13.3±8.0	13.0±6.1	13.6±9.5
Education (years)	15.4±2.8	15.9±2.5	14.9±2.9 *
Self-Care and Psychosocial Variables			
Frequency of self-care (SCI-R)	59.5±13.7	59.1±12.2	60.0±15.1
Daily blood glucose checks	1.4±1.1	1.2±1.0	1.5±1.2
6-minute walk test	484.3±96.4	492.6±90.1	475.9±102.4
Pedometer steps per day	16,451±10,035	16,7943±11,895	16,097±7744
Diabetes distress (PAID)	34.1±21.7	33.3±20.3	34.8±23.1
Frustration with diabetes self-care (PDSM)	46.3±23.1	48.7±22.5	43.6±23.7
Depressive symptoms (BSI)	49.7±10.4	48.9±9.8	50.6±11.0
Anxiety symptoms (BSI)	49.0±10.0	48.1±9.1	49.8±10.9
Diabetes quality of life (DQOL)	67.4±11.4	67.9±10.6	66.9±12.1
Self-Control Coping (Coping Styles)	56.6±14.9	57.5±14.5	55.7±15.3
Emotional Coping (Coping Styles)	32.2±17.8	34.3±18.4	30.2±17.0
Diabetes self-efficacy (CIDS-2)	81.3±11.8	81.9±11.6	80.7±12.1
Health literacy (TOFHLA)	33.1±4.3	33.4±3.6	32.7±5.0
Numeracy (TOFHLA)	45.4±4.3	45.4±4.1	45.3±4.6

[≠] The randomized participant who did not meet eligibility requirements is excluded.

* indicated $p<0.05$ based on Chi-square or Wilcoxon Two-Sample Tests

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Table 2

Spline Model Estimating Rate of Change in A1C Over Time[‡]

	Estimate	Standard Error	t-value	p-value
Intercept	8.431	0.106	79.93	<.0001
Month (Baseline to 3 month)	−0.114	0.037	−3.06	0.003
Month (3 month to 12 month)	0.128	0.048	2.68	0.008
Month (Baseline to 3 month) * Education Class	0.106	0.050	2.11	0.038
Month (3 month to 12 month) * Education Class	−0.144	0.065	−2.21	0.029

[‡]The map-based education served as the reference group.

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Table 3

Linear Mixed Model with Interactions Predicting Psychosocial Outcomes over Time

	Intervention Group (N=67)	Control Group (N=67)	Mixed Model Analysis with Interactions	
	Mean ± SD	Mean ± SD	Effect	P-value
Self-Care Inventory-R				
Baseline	59.1±12.2	60.0±15.1	Time	<0.001
3 Month	61.9±12.6	65.6±14.4	Group	0.51
6 Month	64.5±10.4	65.1±15.3	Group*Time	0.52
12 Month	64.7±13.3	68.2±14.1		
Glucose checks per day				
Baseline	1.2±1.0	1.5±1.2	Time	0.50
3 Month	1.3±1.0	1.5±1.3	Group	0.12
6 Month	1.2±0.9	1.7±1.3	Group*Time	0.26
12 Month	1.2±1.0	1.8±1.6		
6-minute walk test				
Baseline	492.6±90.1	475.9±102.4	Time	0.55
3 Month	488.0±84.8	472.6±104.3	Group	0.21
6 Month	475.8±86.4	472.4±107.5	Group*Time	0.66
12 Month	485.3±79.5	476.1±94.1		
Pedometer readings				
Baseline	16,794±11,895	16,097±7744	Time	0.89
3 Month	17,567±15,711	14,633±8157	Group	0.25
6 Month	16,548±10,042	14.679±8707	Group*Time	0.83
12 Month	16,619±10,452	15,350±8745		
Body Mass Index				
Baseline	34.6±7.0	33.7±7.1	Time	0.63
3 Month	34.1±6.2	33.7±7.1	Group	0.34
6 Month	34.4±7.2	33.0±7.2	Group*Time	0.86
12 Month	34.4±7.5	33.4±6.4		
Diabetes Quality of Life				
Baseline	67.9±10.6	66.9±12.1	Time	0.03
3 Month	69.7±10.8	69.9±12.4	Group	0.63
6 Month	71.1±10.0	70.9±12.1	Group*Time	0.86
12 Month	71.0±10.6	71.1±12.3		
Problem Areas in Diabetes				
Baseline	33.3±20.3	34.8±23.1	Time	0.003
3 Month	27.7±16.9	28.9±21.1	Group	0.45
6 Month	26.1±15.3	28.3±22.5	Group*Time	0.98
12 Month	25.0±16.0	25.7±22.7		
Frustration with Self-Care				
Baseline	48.7±22.5	43.6±23.7	Time	<0.001
3 Month	39.7±23.3	36.2±23.5	Group	0.36

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	Intervention Group (N=67)	Control Group (N=67)	Mixed Model Analysis with Interactions	
	Mean ± SD	Mean ± SD	Effect	P-value
6 Month	36.3±21.0	35.2±27.0	Group*Time	0.72
12 Month	34.8±23.4	32.2±25.1		

Linear Mixed Model showed no between group differences for any variable over time.