

# Diabetes Self-Management Among Low-Income Spanish-Speaking Patients: A Pilot Study

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## ABSTRACT

**Background:** The prevalence of type 2 diabetes and diabetes-related morbidity and mortality is higher among low-income Hispanics when compared to that of Whites. However, little is known about how to effectively promote self-management in this population. **Purpose:** The objectives were first to determine the feasibility of conducting a randomized clinical trial of an innovative self-management intervention to improve metabolic control in low-income Spanish-speaking individuals with type 2 diabetes and second to obtain preliminary data of possible intervention effects. **Methods:** Participants for this pilot study were recruited from a community health center, an elder program, and a community-wide database developed by the community health center, in collaboration with other agen-

cies serving the community, by surveying households in the entire community. Participants were randomly assigned to an intervention ( $n = 15$ ) or a control ( $n = 10$ ) condition. Assessments were conducted at baseline and at 3 months and 6 months postrandomization. The intervention consisted of 10 group sessions that targeted diabetes knowledge, attitudes, and self-management skills through culturally specific and literacy-sensitive strategies. The intervention used a cognitive-behavioral theoretical framework. **Results:** Recruitment rates at the community health center, elder program, and community registry were 48%, 69%, and 8%, respectively. Completion rates for baseline, 3-month, and 6-month assessments were 100%, 92%, and 92%, respectively. Each intervention participant attended an average of 7.8 out of 10 sessions, and as a group the participants showed high adherence to intervention activities (93% turned in daily logs, and 80% self-monitored glucose levels at least daily). There was an overall Group  $\times$  Time interaction ( $p = .02$ ) indicating group differences in glycosylated hemoglobin over time. The estimated glycosylated hemoglobin decrease at 3 months for the intervention group was  $-0.8\%$  (95% confidence intervals =  $-1.1\%$ ,  $-0.5\%$ ) compared with the change in the control group ( $p = .02$ ). At 6 months, the decrease in the intervention group remained significant,  $-0.85\%$  (95% confidence intervals =  $-1.2$ ,  $-0.5$ ), and the decrease was still significantly different from that of the controls ( $p = .005$ ). There was a trend toward increased physical activity in the intervention group as compared to that of the control group ( $p = .11$ ) and some evidence (nonsignificant) of an increase in blood glucose self-monitoring in the intervention participants but not the control participants. Adjusting for baseline depressive scores, we observed a significant difference in depressive symptoms between intervention participants and control participants at the 3-month assessment ( $p = .02$ ). **Conclusions:** Low-income Spanish-speaking Hispanics are receptive to participate in diabetes-related research. This study shows that the pilot-tested diabetes self-management program is promising and warrants the conduct of a randomized clinical trial.

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## INTRODUCTION

Diabetes is a rapidly growing problem in the United States. Diabetes prevalence is higher among older, low-income, and minority individuals (1–3); however, most diabetes self-management research has focused on White middle-class populations (4–9). Hispanics/Latinos are 1.9 times as likely as similarly aged non-Hispanic Whites to have type 2 diabetes (3,10). The prevalence of type 2 diabetes, already rising at a rapid rate (10), will soar in the coming years among Hispanics, because they are now the largest U.S. minority group (11) and have the fastest growing population of elderly individuals in the United States (11). Diabetes-related morbidity and mortality also are higher among Hispanics as compared to that of Whites (12,13).

Despite these statistics and the possibility of preventing human suffering and costs related to poorly controlled diabetes, few studies have tested the effectiveness of self-management interventions with Hispanic groups (14,15) or examined provider behaviors and system-level factors that likely contribute to poor glycemic control in this population. Diabetes is a complex disease with a number of factors that affect its control. From the patient's standpoint, it requires an understanding of basic physiology and the concept that one's behavior—dietary intake, physical activity (PA), self-monitoring of blood glucose (SMBG), and medication administration patterns—has an impact on blood glucose levels. The high prevalence of low literacy and illiteracy among Hispanic groups (16) poses a challenge to the appropriate understanding of diabetes, its management, and the behavioral changes necessary for improved diabetes control that are likely to play an important role in the significantly poorer glycemic control of Hispanics as compared to that of non-Hispanic Whites of the same age (17). There has been little research conducted with low-literate and illiterate individuals. Often, non-English-speaking individuals and those with little or no education are specifically excluded from research studies (18) despite the fact that it is precisely these individuals who are reported to have worse health status on a number of indicators when compared to that of educated English-speaking populations. In the past 5 years, however, several national initiatives have made it a priority to eliminate racial and ethnic disparities in health, and several sources of funding have been made available for supporting research on diabetes self-management in low-income and minority individuals (19,20). Before embarking on large-scale trials, appropriate methodologies need to be adapted or developed and tested for feasibility in the target populations. This study examined the feasibility of a future clinical trial and the potential efficacy of an innovative diabetes self-management intervention in low-income Spanish-speaking individuals of Puerto Rican heritage who had type 2 diabetes.

## METHODS

### Participants

The study protocol was approved by the Institutional Review Boards of the University of Massachusetts and Baystate Medical Center, and written informed consent was obtained from each participant. Participants were recruited from a community health center (CHC), an elder health service affiliated to

the CHC (both located in a large metropolitan area in western Massachusetts), and a community-wide database. The community includes 10,000 people, with approximately 80% having Puerto Rican heritage, and has the lowest educational attainment and one of the lowest per capita incomes in Springfield, Massachusetts. Illiteracy (either Spanish or English) is prevalent, and less than 10% of elders have a high school education. The unemployment rate is 70%, and only 30% of households report having a working member. In sum, 65% of individuals have public insurance, and 12% are uninsured (21,22). The community-wide database was developed by the CHC in collaboration with other agencies serving the community (North End Outreach Network). Its development has involved a community-based network of health workers (each assigned to 1 of 10 zones) that do door-to-door canvassing of the neighborhood (as well as use other methods), conduct intakes of each family (including collection data on self-reported medical conditions), assess health and social needs, and make referrals to other service providers in the area (including health services). Statistics gathered from the work with these families are part of the North End Outreach Network community-wide database.

A list of individuals with type 2 diabetes was randomly generated by each recruitment site (all individuals with a diagnosis of type 2 diabetes at each site had an equal chance of being selected to be in the list), with the director of each site choosing one of every five individuals from a list ordered by record number. Eligibility criteria included (a) having a health care provider, (b) having a doctor-confirmed diagnosis of type 2 diabetes, (c) being 18 years of age or older, (d) having a home phone, (e) having a doctor's approval to participate in the PA component of the intervention, and (f) being able to provide informed consent in English or Spanish. Exclusion criteria included (a) having a history of diabetic ketoacidosis, (b) having current gestational diabetes, (c) planning to move out of the area within the study period, (d) using steroids for short periods during the previous year, and (e) having had a cardiovascular event within the previous 6 months.

### Study Conditions

Upon recruitment and attainment of baseline information, individuals were randomized into either an intervention or a control condition. Given that individuals such as those in the target population (low literate or illiterate, Spanish speaking) are rarely included in research trials, the control group was included to assess whether patients would enroll and stay in a research endeavor that involved randomization, completion of multiple assessments, and no active intervention. The control condition was included to provide data of feasibility. Participants were grouped as closely as possible by age, gender, and insulin status (whether or not they used insulin) and randomized to intervention or control in a 3:2 ratio. Eligibility criteria required that all participants have a health care provider and continue to receive their usual medical care. All participants were given a commonly used, simple booklet describing the importance of lifestyle factors in diabetes management and providing recommendations for diet, PA, and SMBG. Primary care providers of both

intervention and control participants received copies of laboratory results following each assessment time point. Intervention participants participated in the program as described in the following section.

### Intervention Development and Components

The development of the intervention was informed by preliminary studies of knowledge, attitudes and barriers to adherence (18), and views and preferences for diabetes education among individuals in the target population (23). The intervention involved an initial 1-hr individual session, followed by 10 weekly 2½- to 3-hr group sessions and two 15-min individual sessions that occurred during the 10-week period immediately prior to the group session. It was delivered by a diabetes nurse, a nutritionist, and an assistant in a community room well known to community residents and located approximately three blocks from the CHC and two blocks from the elder program. The intervention targeted diabetes-related knowledge, attitudes, and selected self-management skills (i.e., diet, PA, SMBG, medication adherence) using principles from social cognitive theory (24). Knowledge objectives included enhancing understanding of basic facts about the disease, the effect of behaviors on glucose control, and the role of medications. Objectives related to diabetes-related attitudes included increasing awareness of barriers to and resources and strengths for self-management, as well as enhancing self-efficacy and adopting a problem-solving approach to cope with barriers. Behavioral objectives included improving dietary intake in accordance to guidelines (25,26), increasing physical activity with an emphasis on walking, improving both adherence to daily blood glucose self-monitoring and understanding of values, and improving adherence to all medications. The method for intervention delivery was guided by Ockene and colleagues' patient-centered counseling model (27). The intervention curriculum and strategies are depicted in Table 1.

The intervention was tailored to low-literacy needs and imparted through culturally familiar experiences. A drama (soap opera) was developed to convey important messages to be discussed at each session. In the context of a love story, the characters of the drama communicate key diabetes-related messages, present common self-management challenges, and model successful coping strategies to overcome such challenges. The idea for the drama emerged from work that indicated that watching soap operas for several hours every day is a common activity among men and women in this population. This drama was read to participants during the session, with pauses to highlight and discuss important messages.

The intervention also utilized the concept of a traffic light for simplifying educational messages. Accordingly, large visuals were prepared using this concept to convey information about dietary guidelines and normal, borderline, and abnormal glucose values. With input from the participants, visuals were developed to categorize the foods that they consumed most frequently. Foods that can be eaten in larger amounts were represented in green, foods that should be eaten cautiously were represented in yellow, and foods to avoid were represented in red.

Self-monitoring logs, also using the traffic light concept and pictures, were designed for daily recording of diet, PA, and SMBG. Recording of dietary intake was based on number of portions for meals consumed from each section of the traffic light, with rows of boxes in the three colors to be checked off as appropriate. Pictures represented when to test and log fasting morning and evening postprandial blood glucose values. Printed feet at the bottom of the log indicated where to record the number of steps walked during the day (based on a step counter), the main physical activity emphasized in the intervention.

The intervention curriculum provided multiple opportunities to increase self-efficacy for self-management through direct means (e.g., meal preparation and group luncheons at each session to learn a healthier way of preparing traditional ethnic recipes and taste new foods, use of step counters), vicarious means (e.g., experiences of other participants and the drama characters), and verbal means (e.g., guided group discussions).

### Training of Interventionists

A nutritionist, nurse, and intervention assistant (all bilingual) were trained in the intervention's theoretical and delivery models, intervention goals, counseling skills, and use of materials. A detailed intervention manual was developed and modified over the course of the intervention to meet the needs identified by participants and/or interventionists.

### Measures

Feasibility of study implementation was assessed by recruitment rate, assessment completion rates, and session attendance rates in the intervention group. Demographics and medical history data were collected at baseline. Physiological, behavioral, and psychosocial assessments were conducted at baseline, 3 months, and 6 months. Participants were offered incentives equivalent to \$90 for completing the study assessments (regardless of attendance to intervention sessions) distributed over the three assessment time points.

Physiological assessments included measures of glycosylated hemoglobin (HbA1c) and a lipid profile. Blood samples were drawn at the CHC and transferred to the UMass Memorial laboratory for analysis. Three measures of blood pressure, height and weight, and waist and hip circumference were also taken at each assessment time point by two research assistants according to standard procedures (28) and averaged for analysis.

Behavioral assessments included two unannounced administrations of a 24-hr dietary recall (29) (one on a weekday and the other one on a weekend day), a modified version of the Community Healthy Activities Model Program for Seniors (30) PA questionnaire, and a 24-hr recall of SMBG. The 24-hr dietary recall utilized the Nutritional Data System software program, version 4.04\_32, released in 2001 and supported by the University of Minnesota. Any missing foods were resolved with the University of Minnesota Nutrition Coordinating Center according to Nutritional Data System protocol. The 24-hr recall of SMBG was conducted by asking individuals whether they had checked their blood sugar level in the previous 24 hr and, if so, what time

TABLE 1  
Cognitive-Behavioral Intervention Outline

Theoretical framework: Social Cognitive Theory

Format:

- Intensive curriculum (10 weekly 2½- to 3-hr sessions). Key messages were repeated on multiple occasions at each session, and homework reviews, food preparations and meals with guided discussions occurred at all sessions. Concepts emphasized at each session include:
  1. Assessment of motivational, perceptual, and historical factors related to behavior change and medication intake; and family support (individual session)
  2. Understanding diabetes; SMBG
  3. Dietary guidelines
  4. Physical activity (walking)
  5. Self-regulation: role of diet, PA, medications
  6. Menu planning
  7. Complications
  8. Stress management
  9. Supermarket tour
  10. Review of key messages

<i>Intervention Strategies</i>	<i>Behaviors</i>					
	<i>Knowledge</i>	<i>Attitudes</i>	<i>Diet</i>	<i>PA</i>	<i>SMBG</i>	<i>Medication Adherence</i>
Soap opera with guided group discussion	X	X	X	X	X	X
Group cooking and cooking demonstrations	X	X				
Group meals with guided group discussions	X	X	X			
Multiple presentations of key intervention messages	X		X	X	X	X
Emphasis on one message at a time	X					
Self-monitoring demonstrations	X	X			X	
Cognitive reframing		X				
Quick quizzes	X					
Modeling		X	X	X	X	
Family support	X	X	X	X	X	X
Behavioral “experiments” (or trials)		X	X	X	X	
Stress management		X	X	X	X	
Label reading	X		X			
Use of measuring aids	X		X	X	X	
Feedback opportunities (logs review, discussion of downloaded blood glucose values, reinforcement of positive attitudes and behaviors)	X	X	X	X	X	X
Visual aids (large visuals, pictorial log sheets, pictorial food books)	X		X		X	
Supermarket tour	X		X			
Step counters		X		X		
Goal setting (group and individual)			X	X	X	X
Problem solving (group and individual)	X	X	X	X	X	X
Group “games”	X	X	X	X	X	X

Cultural components:

- Attendance by family members to elicit home-based support/approval
- Teaching of diabetes-related knowledge through culturally popular activities (e.g., a soap opera)
- Teaching/counseling about dietary change by modifying ethnic foods and recipes
- Inclusion of opportunities for socializing (e.g., “coffee time” for informal conversation prior to beginning of each session)
- Delivery of intervention in the preferred language (English/Spanish)

Low-literacy considerations:

- Tailoring of all educational materials and strategies to be understood by illiterate patients
- Facilitation of frequent feedback in a prompt manner
- Intensive intervention (multiple sessions over an extended time period)
- Use of visual materials
- Action oriented (how to implement in one’s life the information learned through the program)
- Simplification of complex concepts (e.g., a large colorful chart with traffic light colors was used to illustrate ideal glucose values [green], borderline values to watch for [yellow], and dangerous values [red]. The same concept was applied to understanding diet-related information. Foods in the green section represented those that individuals could eat in larger amounts, foods in the yellow section represented those that should be eaten cautiously, and foods in the red section were those that should be avoided or eaten infrequently in small amounts)
- Repetition of key concepts and skills to be learned throughout the duration of the program
- Facilitation of small successive approximations of desired behaviors (e.g., try brown rice in the sessions and discuss taste/additional ways to enhance flavor; give participants a small bag of brown rice to prepare at home; discuss with the group their experiences preparing and eating it at home)

Note. SMBG = self-monitoring blood glucose; PA = physical activity.

it was checked and what value was obtained. The modified Community Healthy Activities Model Program for Seniors consisted of an eight-item version that focused on the activities most common in the population targeted by this study. These assessments were telephone administered in Spanish by a trained, native-Spanish-speaking dietitian. Interview assessments present many advantages when working with low-literate individuals from ethnic groups (31).

Psychosocial assessments included adapted versions of the following scales: the Audit of Diabetes Knowledge (ADKnowl) (32), the Audit of Diabetes Dependent Quality of Life (ADDQoL) (33), the Insulin Management Self-Efficacy Scale (34), and the Center for Epidemiological Studies–Depression Scale (CES–D) (35). Briefly, scale adaptation involved the following: First, all four instruments, originally designed for self-administration, were modified for telephone administration by an interviewer, given the low literacy level of the target population; second, the scales underwent a qualitative analysis (utilizing cognitive interviewing) to assess clarity and understanding of instructions and wording of the items by older low-literate Caribbean Hispanics. Preliminary psychometric data of the adapted scales provided evidence of adequate internal consistency and test–retest reliability (ADKnowl,  $K-R 20 = .78$ ,  $n = 41$ , and intraclass  $r = .79$ ,  $n = 19$ ; ADDQoL,  $\alpha = .90$ ,  $n = 21$ , and intraclass  $r = .90$ ,  $n = 19$ ; Self-efficacy,  $\alpha = .84$ ,  $n = 48$ , and intraclass  $r = .72$ ,  $n = 19$ ; CES–D,  $\alpha = .87$ ,  $n = 45$ , and intraclass  $r = .64$ ,  $n = 16$ ). All scales were telephone administered in Spanish by a trained, native-Spanish-speaking interviewer. Verbal administration of assessments is a preferred method over paper-and-pencil self-reports when working with low-literate individuals (36).

### Statistical Analysis

Continuous data were summarized using means and standard deviations, and discrete data were summarized using counts and percentages. Completion rates were estimated along with 95% confidence intervals (CIs). Changes from baseline were estimated at 3 months and 6 months. Tests of differences between the intervention and control in change over time were carried out using a likelihood ratio test of the Group  $\times$  Time interaction term within a random effects linear model (37) for each outcome. For the indicator of monitoring twice per day, a mixed effects logit model was used. This provided an overall test of significance of differences in changes over time between groups. In cases where the  $p$  value was less than .1, we indicated the  $p$  value associated with individual time point (3 months and 6 months) coefficients of the interaction. The primary test was of change in HbA1c. The  $p$  values reported for the large number of intermediary and process variables are for exploratory purposes only and do not account for testing of multiple factors within the same population.

## RESULTS

Each site generated an initial list of potentially eligible patients (12–15 patients). Significant difficulties contacting patients (i.e., incorrect and disconnected telephone numbers, no

answer) from the community database were faced. Thus, given the apparent limited viability (limited feasibility) of this source of patients for a later randomized clinical trial, an additional list of potentially eligible patients was requested from the CHC in an effort to recruit a more even number of participants from the CHC and the elder center. Participants were recruited from a pool of 54 Hispanic individuals with a diagnosis of type 2 diabetes, for an overall recruitment rate of 43% (23/54; 95% CI = 29%, 57%). The recruitment rate at the CHC was 48% (14 of 29 patients were recruited), and it was 69% at the elder program (9 of 13 patients were recruited). Recruitment through the community database was less successful, at 8% (1 of 12 individuals was recruited). Two additional CHC individuals who were not included in the CHC-generated patient list but who had learned about the study by word of mouth and wanted to participate were included in the sample. Reasons for not participating included having health problems that precluded participation, being unable to attend group meetings, and having a spouse already in the study. In addition, despite medical record evidence of a diagnosis of type 2 diabetes, 1 individual from the health center refused to participate and said that she did not believe that she had diabetes.

Twenty-five individuals were enrolled (15 in the intervention group and 10 in the control group). Table 2 shows the demographic and medical care characteristics of the sample at baseline: 72% of participants were younger than 65, 80% were female, 60% had less than a sixth-grade education, none of the participants worked, 84% reported household incomes under \$10,000 per year, all but 1 spoke only Spanish, and 96% had at least Medicaid insurance. Average duration of diagnosed diabetes was 8 years, most reported frequent visits to primary care providers, and all participants reported one or more diabetes-related complications (e.g., retinopathy, neuropathy, cardiovascular disease). One third of participants received transportation assistance (provided by the study) to complete assessments requiring an appointment (blood draws and anthropometric measures) and to attend intervention sessions. Assessment completion rates were 100% at baseline (95% CI = 86%, 100%) and 92% (95% CI = 74%, 99%) at the 3- and the 6-month assessments.

Data on the feasibility of implementing the intervention showed that each session had a 78% average attendance (range = 53%–100%) and that each participant attended an average of 7.8 of 10 sessions (range = 4–10). Reasons for nonattendance included illness (including depression), conflicting medical appointments, and unexpected transportation problems. Attendance by family members was encouraged and included spouses, in-laws, adult children, and grandchildren. Most participants (11/15, or 73%) brought a family member to at least one session, and several participants brought more than one family member. Adherence to assignments by intervention participants was consistently high, with only 1 of 15 intervention participants failing to return completed weekly diaries (all remaining participants turned in all their diaries—fully or partially completed). At the completion of the intervention, several participants requested additional sessions. One follow-up ses-

TABLE 2  
Sample Characteristics at Baseline

	<i>All Participants</i>	<i>Intervention</i>	<i>Control</i>
Age (years)			
<i>M (SD)</i>	62.6 (8.6)	62.7 (8.1)	62.4 (9.7)
Range	45–82	48–80	45–82
Gender			
Male	20% (5)	20% (3)	20% (2)
Female	80% (20)	80% (12)	80% (8)
Education			
≤ 5th grade	50% (12)	47% (7)	50% (5)
6th–8th grade	24% (6)	20% (3)	30% (3)
9th–12th grade	24% (6)	27% (4)	20% (2)
Work status			
Housewife	24% (6)	20% (3)	30% (3)
Disabled	20% (5)	20% (3)	20% (2)
Unemployed	4% (1)	6.7% (1)	0%
Never worked	4% (1)	6.7% (1)	0%
Pension	48% (12)	47% (7)	50% (5)
Income per year			
≤ 10,000	84% (21)	80% (12)	90% (9)
\$10,001–\$20,000	16% (4)	20% (3)	10% (1)
Insurance status			
Medicaid only	40% (10)	40% (6)	40% (4)
Medicaid and supplemental	60% (15)	60% (9)	60% (6)
Perceived health			
Excellent	4% (1)	0%	10% (1)
Very good	4% (1)	0%	10% (1)
Good	8% (2)	13% (2)	0%
Fair	72% (18)	73% (11)	70% (7)
Poor	12% (3)	13% (2)	10% (1)
Diabetes history			
Years with diagnosed diabetes ( <i>M, SD</i> )	8.2 (5.8)	7.2 (4.2)	9.8 (7.8)
Diabetes-related complications	16.0% (4)	13.3% (2)	20.0% (2)
1 complication	84.0% (21)	86.7% (13)	80.0% (8)
2 or more complications			
≥ 1 family member with diabetes	84% (21)	80% (12)	90% (9)
Medical care			
Frequency of visits to primary care			
> 4 per year	88% (22)	93% (14)	80% (8)
2–4 per year	12% (3)	7% (1)	20% (2)
Owns a glucometer at baseline	92% (23)	93% (14)	90% (9)
Has ever seen a diabetes educator	24% (6)	20% (3)	30% (3)
Has ever seen a nutritionist	80% (20)	80% (12)	80% (8)
Has ever had a foot exam	88% (22)	87% (13)	90% (9)
Has ever had an eye exam	96% (24)	93% (14)	100% (10)
Total past emergency room visits ( <i>M, SD</i> )	2.0 (2.7)	2.3 (3.1)	1.7 (1.9)
0 visits	40% (10)	40% (6)	40% (4)
Type of diabetes treatment			
Diet treated only	4% (1)	7% (1)	0%
Oral hypoglycemics only	44% (11)	53% (8)	30% (3)
Using insulin only	32% (8)	13% (2)	60% (6)
Combination (oral and insulin)	20% (5)	27% (4)	10% (1)
Use of alternative medicines	21% (5)	7% (1)	40% (4)

Note. Values are percentages (count) unless otherwise noted.

sion was conducted 1 month following the last intervention session, with an 80% attendance rate.

In addition to the primary aim of providing data on the feasibility of conducting a future randomized clinical trial with the target population, a secondary aim of this study was to provide preliminary (pilot) data of possible intervention effects. Table 3 shows the physiological, behavioral, and psychosocial outcomes at baseline and changes in these outcomes at 3 months and 6 months for the intervention and the control groups. Given the number of comparisons,  $p$  values should not be viewed in the traditional sense of "significant" or "not significant" (reject or not reject the null hypothesis) but as indicators of which process variables in this pilot trial suggest differences between the groups for hypothesis-generating purposes. There was an overall Group  $\times$  Time interaction ( $p = .02$ ) indicating that changes from baseline in HbA1c were different between intervention and control groups. At 3 months, the intervention group had an estimated decrease of  $-0.8\%$  (95% CI =  $-1.1\%$ ,  $-0.5\%$ ) in HbA1c compared with the change in the control group ( $p = .02$ ). At 6 months the decrease in the intervention group remained significant,  $-0.85\%$  (95% CI =  $-1.2$ ,  $-0.5$ ), and the decrease was still significantly different from that of the controls ( $p = .005$ ). In models adjusting for baseline HbA1c levels, the difference between intervention and control groups remained at both 3 months ( $p = .009$ ) and 6 months ( $p = .01$ ).

There was a trend toward increased physical activity in the intervention group as compared to that of the control group (overall  $p = .11$ ) with differences estimated to be 640 kcal/week at 3 months ( $p = .08$ ) and 789 kcal/week at 6 months ( $p = .06$ ). There was also some evidence of an increase in SMBG in both groups, with the intervention group reaching 80% (number of patients self-monitoring at least twice per day) at 3 months and 74% at 6 months, but the increase was not statistically different from the control (50% at 3 months and 38% at 6 months). An analysis of "actual" SMBG-utilizing data downloaded from glucose monitoring machines of intervention participants showed a significant increase in self-monitoring over time ( $p < .001$ ). In addition, statistically significant group differences ( $p = .03$ ) were observed in changes in depression symptoms at 3 months ( $p = .006$ ), and a similarly sized difference in change was seen at 6 months ( $p = .047$ ). Adjusted for baseline depression levels, the difference between groups remained significant ( $p = .02$ ) at 3 months. At 6 months the size of the effect was reduced and was not significant ( $p = .26$ ).

## DISCUSSION

The main objectives of this study were to determine the feasibility of conducting a randomized clinical trial with a low-income group of Caribbean Hispanic individuals with type 2 diabetes and to make preliminary estimates of possible intervention effects. The sample participating in this study was representative of the target community in terms of age, education, and income (according to the 2000 U.S. Census data for the community, 70% of the residents were younger than 65 years old; 59% had less than a high school education; \$7,400 was the average

per capita income, with 90% of incomes 200% below the poverty level) (21,22). A greater number of individuals in our sample had insurance compared to that of individuals in the community (12% uninsured in the community) (21,22); this can be explained by the fact that most study participants were recruited through health care service sites.

The main finding of this study was the evidence that it provided supporting the feasibility of conducting a research study of an intensive diabetes self-management intervention with this population of Spanish-speaking low-income (low-literate/illiterate) Hispanic patients with type 2 diabetes when recruited through health services (recruitment from other sources, such as the community database used in this study, may be less feasible). Feasibility evidence is provided by the recruitment and retention rates, attendance to intervention sessions, and participants' requests for additional sessions. These data are encouraging given the need for effective self-management interventions to help underserved Hispanic/Latino patients (individuals who have traditionally been understudied) (38,39) with type 2 diabetes improve their glycemic control. It is interesting that moderate to high attrition rates have been reported in studies of diabetes interventions for primarily White middle-class individuals (8), suggesting the need for increased tailoring of interventions for the majority population as well.

Although this study was not designed to assess the effectiveness of the intervention, its findings are suggestive of a beneficial effect of the intervention on diabetes control with a significant improvement in HbA1c. HbA1c is the most stable of the outcome measures with a high within-subject correlation. Each percentage change contributes importantly to diabetes control status. We also observed a trend toward increased physical activity. The lack of statistically significant behavioral findings may be partly related to the greater difficulty of measuring these outcomes (e.g., due to limited resources, we used only two 24-hr recalls of dietary intake rather than the standard set of three recalls recommended, due to the significant variability in individuals' dietary intake). Findings of differences in depressive symptoms in favor of the intervention group may be explained by the social nature of the intervention and the emphasis on physical activity (40,41), because both factors have been associated with fewer depression symptoms. These same factors explain why the difference in depression symptoms was not maintained 3 months following the completion of the intervention.

Challenges to intervention implementation included the availability of bilingual providers who were experienced in working with culturally similar low-literate populations and who had strong behavioral counseling skills. The dearth of educational materials appropriate for low literacy also presented a number of challenges. In addition, our own observations of participants throughout the intervention suggested that this population may not have sufficient skills or experience for learning from information on paper, as shown by reluctance to look at print intervention materials, with comments such as "I cannot read" or "I cannot read well" (even though the materials primarily displayed pictures). These observations receive support from studies that suggest that illiterate individuals have difficulty in

TABLE 3  
Changes in Outcomes of Interest at the 3-Month and 6-Month Follow-Up Assessments

	Baseline M (SD)		Change (3 Month to Baseline) M (SD)		Change (6 Month to Baseline) M (SD)		p <sup>a</sup>
	I group	C group	I group	C group	I group	C group	
<b>Physiological variables</b>							
HbA1c	7.7 (1.2)	9.3 (1.8)	-80 (0.47)	-24 (0.81)*	-0.85 (0.56)	-0.12 (0.91)**	.02
Percentage change in HbA1c <sup>b</sup>	—	—	-9.9% (5.1)	-2.8% (9.1)*	-10.8% (6.5)	-1.7 (10.3)*	.004
Total cholesterol (mg/dl)	197.0 (19.9)	193.4 (33.4)	-80 (27.3)	2.4 (15.5)	-2.0 (24.7)	11.2 (0.17)	.52
HDL (mg/dl)	43.9 (10.7)	49.3 (17.9)	-3.6 (7.7)	-5.1 (6.1)	-3.8 (7.9)	-1.8 (4.6)	.51
LDL (mg/dl)	120.9 (24.7)	122.8 (29.1)	4.0 (21.2)	2.6 (16.8)	3.2 (17.9)	12.5 (13.5)	.51
Triglycerides (mg/dl)	161.0 (86.3)	157.4 (138)	-5.6 (37.0)	26.1 (57.4)	-6.9 (52.1)	3.8 (24.0)	.21
Log (triglycerides)	4.9 (0.51)	4.5 (0.33)	0.025 (0.24)	0.17 (0.36)	-0.01 (0.34)	0.02 (0.20)	.23
BMI (kg/m <sup>2</sup> )	32.4 (4.5)	32.7 (7.4)	-2.5 (1.7)	-1.7 (3.0)	-0.10 (1.9)	0.11 (1.8)	.75
Waist circumference (in.)	105.3 (11.6)	99.1 (10.4)	-2.1 (7.2)	1.2 (3.3)	-4.2 (4.3)	-0.13 (0.09)	.17
Systolic BP (mmHg)	141.6 (15.7)	128.3 (14.3)	5.4 (18.2)	1.4 (9.0)	1.8 (16.7)	2.0 (16.0)	.63
Diastolic BP (mmHg)	78.7 (9.6)	73.5 (8.9)	-9.7 (9.4)	1.9 (8.5)	-0.71 (24.7)	0.76 (8.2)	.95
<b>Behavioral variables</b>							
<b>Dietary intake</b>							
Total kcal	1,724 (574)	1,530 (503)	-106 (503)	-163 (532)	-179 (460)	-97.5 (549)	.78
Total fat (%)	29.6 (5.6)	30.1 (7.6)	0.26 (9.2)	-2.96 (4.7)	-4.3 (6.2)	-8.6 (7.6)	.33
Saturated fat (%)	8.4 (2.0)	8.1 (1.6)	.79 (4.0)	-4.7 (2.3)	-0.30 (3.7)	-1.0 (2.2)	.68
Total carbohydrates (g)	243.3 (79.0)	203.5 (67.4)	-19.54 (68.9)	-7.25 (79.7)	-18.1 (75.4)	23.2 (65.8)	.39
Total carbohydrates (%)	56.6 (5.5)	54.4 (7.9)	-1.21 (7.7)	3.52 (6.2)	0.99 (7.7)	8.4 (9.5)	.20
Fiber	14.6 (6.7)	15.3 (5.9)	1.0 (5.2)	-2.0 (9.3)	1.2 (7.1)	-28 (9.4)	.61
Physical activity (kcal/week)	660 (705)	976 (1154)	439 (935)	-180 (1262)	272 (929)	-512 (967)	.11
<b>Blood glucose self-monitoring</b>							
(no./day capped at 2)	1.17 (0.80)	1.25 (0.53)	0.63 (0.26)	0.19 (0.35)	0.63 (0.24)	0.06 (0.27)	.94
% 2/day both calls	5/15 (34%)	1/8 (13%)	12/15 (80%)	4/8 (50%)	11/15 (74%)	3/8 (38%)	.81
<b>Psychosocial variables</b>							
Diabetes knowledge (ADKnowl)	0.54 (0.15)	0.64 (0.12)	0.05 (0.15)	-0.02 (0.11)	0.05 (0.13)	-0.03 (0.08)	.27
<b>Self-efficacy for</b>							
Diet	2.8 (0.6)	(0.3)	0.03 (0.4)	0.44 (0.3)*	0.10 (0.6)	0.13 (0.4)	.06
Exercise	2.7 (1.1)	2.5 (1.0)	0.11 (0.9)	0.24 (0.6)	0.04 (0.6)	-0.14 (1.0)	.62
Self-monitoring	3.0 (0.8)	3.3 (0.5)	0.3 (1.0)	-0.3 (0.7)	0.30 (1.0)	-0.07 (0.7)	.20
Oral glycemic agents	3.9 (0.2)	4.0 (0.0)	-0.1 (0.3)	0 (0)	0.04 (0.1)	-0.25 (0.5)	.14
Insulin	3.2 (0.9)	3.1 (0.6)	-0.14 (1.3)	-0.2 (0.5)	0.01 (0.6)	-0.27 (0.4)	.42
Depression (CES-D)	18.4 (9.3)	8.8 (8.6)	-3.7 (7.6)	7.6 (8.9)**	1.4 (9.8)	9.57 (11.0)*	.03
Quality of life (ADDQoL)	-2.8 (2.1)	-2.5 (2.2)	-0.35 (1.4)	-0.8 (1.0)	-2.4 (2.0)	-1.3 (2.3)	.72
Global	0.13 (1.1)	1.0 (0.7)	0.3 (1.0)	-0.14 (0.7)	0.6 (1.2)	0.01 (1.3)	.44
Specific	-1.5 (0.6)	-1.1 (0.7)	-0.07 (0.9)	-0.14 (0.7)	-0.3 (0.6)	-0.3 (1.0)	.97

Note. I group = intervention group; C group = control group; HDL = high-density lipoprotein; LDL = low-density lipoprotein; BMI = body mass index; BP = blood pressure; ADKnowl = Audit of Diabetes Knowledge Scale; CES-D = Center for Epidemiological Studies-Depression Scale; ADDQoL = Audit of Diabetes Dependent Quality of Life Scale.

<sup>a</sup>From a test of Group × Time interaction in a random effects (participant as random effect) model (except for the case of percentage change from baseline for HbA1c, p represents group differences in percentage change from baseline). <sup>b</sup>Change in HbA1c as a percentage of baseline.

\*p < .05 for difference between intervention and control in change from baseline. \*\*p < .01 for difference between intervention and control in change from baseline.



interpreting, naming, and producing two-dimensional representations of information (42). Furthermore, studies of literate and illiterate groups using brain imaging have concluded that learning to read and write during childhood influences the functional architecture of the adult human brain (43). These studies and our own experience indicate that customized and innovative learning materials are needed to assist low-literate and illiterate individuals with control of diabetes.

Identifying and reframing individual negative attitudes (e.g., a common belief with respect to new foods was "I have never tried it before, [therefore] I won't like it," and there were fears of the effect of medications) in a group setting can be difficult, and the inclusion of relatively brief individual counseling sessions was helpful. Participants experienced visual problems/blindness, dental problems, arthritis, and other medical conditions, which presented challenges in the delivery of the intervention or adherence to the intervention goals. Several of our participants were smokers, others were depressed, and one had a fear of needles that we were unable to address in a group setting. Issues such as these will require referrals to the appropriate health professionals. Although a curriculum for the delivery of the intervention had been designed in advance, it was imperative to continually adapt the curriculum based on participant feedback and researchers' observations of identified knowledge deficits and needs for additional reinforcement of previously taught information.

Multiple feedback opportunities were built into the curriculum, which allowed the interventionists to provide patients with timely instruction on lifestyle changes and to assist them to accurately evaluate the impact of circumstances. The intervention had a strong emphasis on skills acquisition, given the evidence that teaching diabetes information does not necessarily lead to the appropriate application of knowledge (8).

This study demonstrates the feasibility of conveying diabetes lifestyle management in ways that are familiar and acceptable to low-income, low-literate Caribbean Hispanics, and its results warrant continued efforts to conduct a randomized clinical trial of the effectiveness of this intervention. Last, given the shared environmental influences on health with family members (44–46), studies are needed to examine the effects of the intervention on family members participating in the group sessions to support study participants.

This was the first study that targeted a low-income Puerto Rican population. Although in the past decade there has been increased acknowledgment of the need to develop diabetes self-management interventions that are effective for underserved and minority populations, only two published randomized clinical trials have been conducted to evaluate the effectiveness of self-management interventions on HbA1c levels in Hispanic individuals (15,47), and they show a need to develop more effective interventions for these populations. These studies limited their samples to Mexican Americans, and their interventions were highly tailored to the Mexican American culture, with findings not generalizable to other Hispanic groups due to significant variability in language and culture (among other issues) in the various subgroups.

Limitations of this study include the following. The greater number of women compared to men in the study sample could have introduced bias and may limit the generalizability of the study findings. Likewise, findings may only be generalizable to individuals seen at community health centers and satellite services. The intervention was highly tailored to cultural traditions and preferences of Puerto Rican individuals, and thus the study findings may not be generalizable to other Hispanic subgroups. The study intervention addressed only patient factors related to glucose control and did not address provider or organizational (e.g., health care system structure) factors that also contribute to it. This study also is limited in its ability to determine the degree to which the intervention effect observed on HbA1c was the result of improved self-management behaviors. To make such determination, future studies will have to assess other factors that may influence glycemic control (e.g., stress, individual metabolic factors, appropriateness of regimen prescriptions, medication adherence) (48). An additional limitation includes the small sample size, which made it difficult to interpret findings on depression scores and other variables assessed.

Several strengths of this pilot study should also be noted. Due to the inclusion of a control group, this feasibility study was able to show that low-income (and low-literate and illiterate) individuals with type 2 diabetes, often excluded from research studies (18), were willing to participate in randomized studies and complete multiple assessments over time, even when they did not have the direct "benefit" of an active intervention. This is particularly significant in the context of the often-reported low participation rate and somewhat high attrition rate found in at least one third of diabetes self-management studies with higher income populations (4) and in current efforts to decrease racial/ethnic disparities in health (49). However, our experiences suggest that recruitment may be most effective when conducted at community health services or centers, compared to other sources in the community. Another strength of the study is that the process involved in developing the intervention, which used a defined theoretical framework, involved preliminary formative research (interviews and focus groups with individuals from the target community) (23,50) as well as input from the study participants in tailoring the intervention to the cultural traditions and learning styles of the target population. In addition, psychosocial measures were previously adapted for use with this population, and assessments were conducted by interviewers who were blind to treatment condition. Finally, although the use of a usual care condition as the control group (with no control for attention) may be perceived as a weakness of the study, this design is justified given the pilot nature of the study and the lack of a standard or traditional self-management intervention shown to be effective for the target population. To our knowledge, only one randomized clinical trial has been conducted with Hispanic individuals, and its intervention was highly tailored for Mexican American participants. The next step will be to evaluate the effectiveness of this intervention in a randomized controlled trial with an adequate sample size and appropriate controls. Furthermore, additional research is needed to design and investigate the impact of interventions that target provider and system factors in addition to patient factors in underserved communities.

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