Randomized Trial of a Literacy-Sensitive, Culturally Tailored Diabetes Self-Management Intervention for Low-Income Latinos

Latinos en Control

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OBJECTIVE—To test whether a theory-based, literacy, and culturally tailored self-management intervention, Latinos en Control, improves glycemic control among low-income Latinos with type 2 diabetes.

RESEARCH DESIGN AND METHODS—A total of 252 patients recruited from community health centers were randomized to the Latinos en Control intervention or to usual care. The primarily group-based intervention consisted of 12 weekly and 8 monthly sessions and targeted knowledge, attitudes, and self-management behaviors. The primary outcome was HbA_{1c}. Secondary outcomes included diet, physical activity, blood glucose self-monitoring, diabetes knowledge and self-efficacy, and other physiological factors (e.g., lipids, blood pressure, and weight). Measures were collected at baseline and at 4- and 12-month follow-up. Change in outcomes over time between the groups and the association between HbA_{1c} and possible mediators were estimated using mixed-effects models and an intention-to-treat approach.

RESULTS—A significant difference in HbA_{1c} change between the groups was observed at 4 months (intervention −0.88 [−1.15 to −0.60] versus control −0.35 [−0.62 to 0.07], $P < 0.01$), although this difference decreased and lost statistical significance at 12 months (intervention −0.46 [−0.77 to −0.13] versus control −0.20 [−0.53 to 0.13], $P = 0.293$). The intervention resulted in significant change differences in diabetes knowledge at 12 months ($P = 0.001$), self-efficacy ($P = 0.001$), blood glucose self-monitoring ($P = 0.02$), and diet, including dietary quality ($P = 0.01$), kilocalories consumed ($P < 0.001$), percentage of fat ($P = 0.003$), and percentage of saturated fat ($P = 0.04$). These changes were in turn significantly associated with HbA_{1c} change at 12 months.

CONCLUSIONS—Literacy-sensitive, culturally tailored interventions can improve diabetes control among low-income Latinos; however, strategies to sustain improvements are needed.

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In the U.S., 10.4% of adult Latinos compared with 6.6% of non-Latino whites have type 2 diabetes (1). Latinos also have higher rates of diabetes-related complications and are 1.6 times more likely to die from diabetes compared with non-Latino whites (2). Behavioral self-management by patients is complex but critical for glycemic control (3); however, socioeconomic, psychological, social, and cultural factors influence patients' adherence to behavioral self-management prescriptions. Interventions tailored to address these influences may enhance treatment adherence.

Behavioral interventions have shown efficacy for improving glucose control among individuals with diabetes (4). However, only two large randomized clinical trials (RCTs) in the past decade have examined the effectiveness of these interventions among low-income Latinos. These RCTs were conducted in Texas (5) and California (6), both of which are states where Latinos are predominantly Mexican American. Puerto Ricans, the largest Latino group in the northeast U.S., have among the highest prevalence of diabetes among all Latinos at 12.6% (1) but have been under-studied.

The increasing trend of diabetes among Latinos coupled with a continued growth of the Latino population in the U.S. (7) and rapidly increasing economic costs of diabetes to individuals and society (8) make efforts to improve glycemic control and secondary prevention of utmost priority. This study tested the impact of a theory-based culturally tailored literacy-sensitive diabetes self-management intervention on glycemic control (HbA_{1c}) among low-income Latinos with diabetes. Secondary outcomes included diet, physical activity, blood glucose self-monitoring, diabetes knowledge and self-efficacy, and other physiological factors (e.g., lipids, blood pressure, and weight).

RESEARCH DESIGN AND METHODS

—This RCT compared the efficacy of the Latinos en Control intervention to that of an enhanced usual-care condition (detailed methods described previously [9]). The study was approved by the institutional review boards of the University of Massachusetts and Baystate

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Medical Center. All participants provided signed informed consent. We recruited participants from five community health centers. Eligibility criteria were as follows: Latino ethnicity, age ≥18 years, documented diagnosis of type 2 diabetes; last HbA_{1c} (previous 7 months) ≥7.5%; ability to walk; no type 1 diabetes or history of ketoacidosis; no medical contraindications to participation; no use of glucocorticoid therapy within the prior 3 months; not currently participating in a cardiac rehabilitation or formal weight loss program; no plans to move out of the area within the 12-month study period; access to a telephone; ability and willingness to provide informed consent (English or Spanish); and physician approval to participate.

A multistep screening and recruitment process as described previously (10) was implemented under a Health Insurance Portability and Accountability Act waiver with consent from the primary care providers (PCPs) at the study sites. Research coordinators screened participants and obtained PCP approval for participation of screened patients. The coordinators sent letters signed by PCPs informing patients about the study and then contacted the patients to assess final eligibility, explain the study in greater detail, and invite eligible individuals to participate. Eligible and interested individuals were scheduled for a recruitment visit where consent procedures were implemented. After baseline assessments, participants were randomized into the intervention or control condition.

Randomization was at the individual level and stratified by site, sex, HbA_{1c} level, and insurance status. Within each strata, subjects were randomized in randomly allocated blocks. Given the nature of the study, we could not blind participants' PCPs; however, providers were not informed of their patients' study assignments.

Study conditions

The Latinos en Control intervention was a year-long program consisting of an intensive phase of 12 weekly sessions and a follow-up phase of 8 monthly sessions. Using social-cognitive theory (SCT) (11) as a framework, it targeted previously identified needs in this population related to key SCT constructs: diabetes knowledge, attitudes (i.e., self-efficacy or confidence in making changes), and self-management behaviors (12–14). We addressed literacy needs by simplifying complex concepts (e.g., a picture-based food guide), minimizing didactic instruction, engaging subjects in activities that reinforced key concepts over time (e.g., "foods bingo"), and modeling and experiential teaching methods (e.g., cooking lessons with participant involvement and eating healthy meals at the sessions). Cultural tailoring included the use of an educational soap opera (soap operas are popular in this population) to introduce self-management information and model attitudinal change and desired behaviors in the context of culturally relevant situations, use of bingo games (also popular in this population) to reinforce information taught, emphasis on making traditional foods healthier via healthy preparation methods, and addressing family preferences among others. All participants received a step counter and were encouraged to increase their walking steps progressively. A color-coded graph demonstrated ideal, borderline, and dangerous glucose levels. Participants received a glucose meter and simple logs to track their glucose values, diet, and physical activity. Patients received both brief personalized counseling, with feedback regarding their logs and meter data, and assistance with goal setting and problem solving of challenges. We encouraged attendance by family members or friends living in the same household.

The first session was conducted as an individual 1-h meeting in the participant's home. We conducted the remaining sessions in groups at centrally located community settings (e.g., a Latino center, a senior center, a YMCA site). Group sessions lasted for approximately 2.5 h (1st h: personalized counseling and cooking; remaining time: group protocol and meal). The intervention was guided by a detailed protocol and delivered by a trained team of two leaders and an assistant (either a nutritionist or health educator and trained lay individuals or three lay individuals supervised by two investigators). Participants received reminder calls on the evening before each session. An earlier version of this intervention was pilot-tested (15) for feasibility and potential impact.

The study diabetologist oversaw patient safety. Providers of patients who exceeded a safety threshold (defined by the study team as two or more glucose levels <70 mg/dL, two or more glucose levels ≥350 mg/dL, or one glucose level ≥500 mg/dL since the previously attended session) received an e-mail notification that contained a graph of the patient's glucose values downloaded from their meter.

Participants in the usual care condition received no intervention. All providers (both conditions) received laboratory results, including HbA_{1c}, fasting blood glucose, and lipid profiles at baseline and at 4 and 12 months, and were free to provide care as deemed appropriate or as routinely delivered.

Measures and data collection

Trained bilingual and bicultural research staff blinded to the study condition conducted assessments at baseline, postintensive intervention (4 months), and at 12 months. Patients were given a choice of language (English or Spanish), and survey measures were administered orally.

Clinical measures. Fasting blood samples were collected for determination of HbA_{1c} and lipid panel. A measure of glucose variability, the Average Daily Risk Range (16), was obtained for participants in the intervention condition using data downloaded from glucose meters at each intervention session. Blood pressure was determined using the mean of two measures taken with a Dynamap XL automated BP monitor. Height and weight and waist circumference were determined using the mean of two measures obtained using standard methods. Diabetes medications and dose were recorded directly from the participants' medication labels. A medication intensity variable was constructed by assigning a low score for regimens based on monotherapy with oral agents and increasing the score as the number of oral agents increased or insulin was included. The highest score corresponded to regimens that included a combination of fast-acting and basal insulin. Regimens with a total daily dose of insulin of >1 unit/kg of the patient's weight received higher scores.

Behavioral measures. A trained registered dietitian made unannounced telephone calls to obtain 24-h recalls of dietary intake (17), physical activity (18,19), and blood glucose self-monitoring. Three recalls were administered at baseline and 12 months (2 weekdays and 1 weekend day) and to a random subsample (56%) at 4 months (with the remaining completing a single recall at 4 months). The 24-h recall of blood glucose self-monitoring included three questions: Do you monitor your blood glucose level? Did you monitor your blood glucose yesterday? How many times did you monitor your blood glucose yesterday from the

time you woke up until bedtime? Three survey questions regarding exercise habits also were used: *1*) "In the last 7 days, on how many days did you walk for at least 10 min, without stopping, to exercise?" If patients reported walking to exercise, they were asked, "About how many minutes did you walk each time?" and *2*) "In the last 7 days, on how many days did you do some other type of exercise for at least 20 min?"

Other diabetes-related measures. Diabetes knowledge was measured using a subset of items from the Audit of Diabetes Knowledge (20), which addressed the focus of the intervention. This measure was previously pretested and adapted for the target population (21). The research team developed a 17-item tool to assess self-efficacy for dietary and physical activity change, which showed adequate psychometric properties (Chronbach's $\alpha = 0.85$).

Data analysis

Baseline characteristics between randomized groups were tested using *t* tests for continuous variables and Fisher exact tests for categorical variables. Attendance trends were tested using a mixed-effect logistic regression model with the individual as a random effect. Outcomes over time were compared using mixed-effects regression models with the individual as the random effect. Linear regression was used for means of continuous outcomes and logistic regression for proportions of binary outcomes. We used a random intercept and slope (slope versus time) model in all cases. The test of group multiplied by time interaction provided the test of the difference between intervention and control in change in outcomes over time. All estimated changes in outcomes were derived from the estimated mixed models. The association of HbA_{1c} and possible mediators was estimated using a linear regression mixed-effect model. The random effect was the individual, and the model estimated the association of change in HbA_{1c} and change in mediators (longitudinal association), controlling for cross-sectional effects.

RESULTS

Participants

A total of 252 patients were enrolled and participated in the study, with 128 randomized to the control condition and 124 randomized to the intervention condition. (A flowchart of patient screening and recruitment was published previously [10]). The sample was largely middle-aged, female, had a low literacy rate, were of Puerto Rican descent, spoke monolingual Spanish, were not employed (including 61.7% who were self-reported as disabled), and were poor (Table 1). Mean baseline HbA_{1c} was 9.0% (SD 1.87). Most had an unfavorable cardiometabolic profile, including uncontrolled blood glucose (86.9%) and obesity (74.9%) and abnormal lipid profiles (53.2% LDL cholesterol, 44.3% triglycerides, and 81.7% HDL cholesterol), or hypertension (67.7%). Most participants reported using oral hypoglycemics or insulin, with 48.8% using insulin. At baseline, the groups were balanced on the measured variables, with the exception of a significant difference in diastolic blood pressure (76.34 ± 9.9 versus 73.37 ± 8.4 mmHg, control versus intervention, respectively; $P < 0.011$). The medication intensity score was slightly but nonsignificantly higher in the control group compared with the intervention group at baseline (3.1 versus 2.7, respectively; $P = 0.07$).

Attendance at the study intervention was greater during the intensive phase (68% of patients attended ≥6 of 12 weekly sessions; 10% attended none) compared with the follow-up phase (18% attended ≥4 of 8 monthly sessions; 27% attended none). This decreasing trend in attendance was significant ($P < 0.001$).

Figure 1 shows mean changes for HbA_{1c} at the 4- and 12-month follow-ups for both groups. Linear mixed-model results showed a mean change in HbA_{1c} in the intervention group of −0.88 (range −1.15 to −0.60) postintensive intervention (at 4-month follow-up) and −0.46 (−0.77 to −0.13) at the 12-month follow-up. However, we also observed mean changes in HbA_{1c} in the control group: −0.35 (−0.62 to 0.07) at 4 months and −0.20 (−0.53 to 0.13) at 12 months, diminishing the intervention effect, which was significant at 4 months (−0.53 [−0.92 to −0.14], $P > 0.008$) but not at 12 months (−0.25 [−0.72 to 0.22], $P > 0.293$). A significant association emerged between intervention attendance and HbA_{1c}, with greater session attendance resulting in lower HbA_{1c} outcome at 12 months ($P = 0.005$). Change in HbA_{1c} was inversely associated with baseline HbA_{1c} in both groups (regression coefficient 0.42 and 0.45 for the control and the intervention condition, respectively; $P < 0.001$). The percentage of participants with HbA_{1c} <7% at 4 months was 29.1% versus 12.4% in the intervention versus control group, respectively ($P = 0.013$) and at 12 months 23% versus 16.2% ($P = 0.233$). Glucose variability (average daily risk range values) among intervention participants showed a significant decrease over the course of the intervention ($P = 0.0004$).

A significant intervention effect was evident for improvement in dietary quality, for reduction of total calories and percentage of fat of total calories ($P < 0.01$) at 4 and 12 months, and for reduction of percentage of saturated fat of total calories at 12 months ($P = 0.04$) (Table 2). The proportion of patients reporting blood glucose self-monitoring two or more times per day increased significantly in the intervention (from 59% at baseline to 84.2% and 81.5% at 4 and 12 months, respectively) compared with the control group (from 55.7% at baseline to 62.1–63.6% at 4 and 12 months, respectively) ($P = 0.02$ and $P = 0.023$ for change comparisons at 4 and 12 months). There was a greater although nonsignificant increase in the proportion of patients who self-reported walking for exercise (yes/no) in the intervention (61.3–88.4% and 70.9% at baseline and at 4 and 12 months) compared with the control condition (52.3–70.9% and 66.4% at baseline and 4 and 12 months) ($P = 0.057$ and $P = 0.435$ for change comparison at 4 and 12 months). No significant changes were observed for metabolic equivalent or total time of physical activity, time walking, or time sitting. Likewise, we saw no significant intervention effects on lipids, blood pressure, weight, or waist circumference (data not shown). Both groups showed significant increases in medication intensity at 12 months (0.32 in controls and 0.31 in intervention, $P = 0.02$ and $P = 0.03$, respectively), with no change differences between groups.

Decreases in HbA_{1c} at 12 months in the intervention group were associated with improvements in diet (specifically, an increase in dietary quality [$P = 0.036$] and decreased percentage of saturated fat [$P = 0.003$]), increased blood glucose self-monitoring ($P = 07$), increased diabetes knowledge (0.001), and increased self-efficacy ($P = 0.026$).

CONCLUSIONS—This study showed that intensive interventions tailored to the needs of low-income Latinos can result in

Table 1—*Sample demographic and clinical characteristics in the Latinos en Control study* (n = 252)

	Control	Intervention	Total	*P*
n	128	124	252	
Age (years)				0.492
18–44	22 (17.2)	19 (15.3)	41 (16.3)	
45–54	35 (27.3)	40 (32.3)	75 (29.8)	
55–64	47 (36.7)	36 (29.0)	83 (32.9)	
≥65	24 (18.8)	29 (23.4)	53 (21.0)	
Sex				0.556
Male	32 (25.0)	27 (21.8)	59 (23.4)	
Female	96 (75)	97 (78.2)	193 (76.6)	
Education (*n* = 250)				0.414
≤4th grade	39 (31)	31 (25.0)	70 (28.0)	
5th–8th grade	33 (26.2)	37 (29.8)	70 (28.0)	
9th–12th grade (not high school graduate)	27 (21.4)	21 (16.9)	48 (19.2)	
≥High school	27 (21.4)	35 (28.2)	62 (24.8)	
Birthplace: Puerto Rico	110 (85.9)	111 (89.5)	221 (87.7)	0.445
Medical insurance				0.354
Public insurance	113 (88.3)	112 (90.3)	225 (89.3)	
Commercial Insurance	10 (7.8)	5 (4.0)	15 (6.0)	
Free care	4 (3.1)	3 (2.4)	7 (2.8)	
No insurance	1 (0.8)	4 (3.2)	5 (2.0)	
Employment status (*n* = 230)				0.336
Working full or part time	15 (12.9)	11 (9.6)	26 (11.3)	
Unemployed/looking for a job	6 (5.2)	2 (1.8)	8 (3.5)	
Disabled	68 (58.6)	74 (64.9)	142 (61.7)	
Retired	10 (8.6)	15 (13.2)	25 (10.9)	
Housewife	17 (14.7)	12 (10.5)	29 (12.6)	
Self-reported household income <10,000/year (*n* = 217)	63 (56.3)	57 (54.3)	120 (55.3)	0.786
Years since diabetes diagnosis (*n* = 243)				0.170
0–5	36 (29.3)	40 (33.3)	76 (31.3)	
6–10	37 (30.1)	22 (18.3)	59 (24.3)	
11–15	23 (18.7)	23 (19.2)	46 (18.9)	
≥16	27 (22.0)	35 (29.2)	62 (25.5)	
BMI (*n* = 251)*				0.857
Normal	6 (4.7)	9 (7.3)	15 (6.0)	
Overweight	25 (19.5)	23 (18.7)	48 (19.1)	
Obese I	45 (35.2)	39 (31.7)	84 (33.5)	
Obese II	25 (19.5)	22 (17.9)	47 (18.7)	
Obese III	27 (21.1)	30 (24.4)	57 (22.7)	
HbA_{1c} (%)				0.541
≤7.0	16 (12.5)	17 (13.7)	33 (13.1)	
7.1–8.0	32 (25.0)	30 (24.2)	62 (24.6)	
8.1–9.0	21 (16.4)	28 (22.6)	49 (19.4)	
9.1–10.0	24 (18.8)	25 (20.2)	49 (19.4)	
>10.0	35 (27.3)	24 (19.4)	59 (23.4)	
HbA_{1C} above goal (>7.0%)	112 (87.5)	107 (86.3)	219 (86.9)	0.853
HDL cholesterol below goal (men <45 mg/dL, women <55 mg/dL)	108 (84.4)	98 (79.0)	206 (81.7)	0.328
LDL cholesterol above goal of >100 mg/dL†	62 (50.4)	68 (56.2)	130 (53.3)	0.373
Triglycerides above goal (men >150 mg/dL, women >35 mg/dL)	58 (45.3)	55 (44.4)	113 (44.8)	0.900
Blood pressure above goal (systolic >130 mmHg or diastolic >80 mmHg)‡	91 (71.1)	79 (64.2)	170 (67.7)	0.281
High waist circumference (men >40", women >35")‡	121 (94.5)	106 (86.2)	227 (90.4)	0.031
Diabetes medication regimen				0.221
Insulin alone	12 (9.4)	11 (8.9)	23 (9.1)	
Insulin plus oral medication	58 (45.3)	42 (33.9)	100 (39.7)	

Table 1—*Continued*

	Control	Intervention	Total	*P*
Oral medications alone	49 (38.3)	63 (50.8)	112 (44.4)	
No medications	9 (7.0)	8 (6.5)	17 (6.7)	
Test blood glucose at least twice/day (*n* = 243)	68 (55.3)	72 (60.0)	140 (57.6)	0.517
Continuous variables				
HbA_{1c} (%)	9.11 ± 2.0	8.85 ± 1.8	8.98 ± 1.9	0.261
BMI (kg/m^2)‡	34.52 ± 6.5	35.02 ± 7.4	34.76 ± 6.9	0.568
HDL cholesterol (mg/dL)	43.66 ± 9.1	44.98 ± 9.6	44.31 ± 9.3	0.263
LDL cholesterol (mg/dL)†	104.89 ± 37.5	108.45 ± 38.7	106.65 ± 38.0	0.466
Triglycerides (mg/dL)	159.32 ± 101.9	152.66 ± 119.5	156.04 ± 110.8	0.375§
Systolic blood pressure (mmHg)‡	139.49 ± 18.1	136.39 ± 15.4	137.97 ± 16.9	0.146
Diastolic blood pressure (mmHg)‡	76.34 ± 9.9	73.37 ± 8.4	74.89 ± 9.3	0.011
Waist circumference (cm)‡	111.77 ± 13.4	111.58 ± 14.5	111.68 ± 13.9	0.914
Alternative healthy eating index (*n* = 238)	30.95 ± 7.8	29.43 ± 7.6	30.21 ± 7.7	0.131
Total kcal (*n* = 238)	1,666.92 ± 521.5	1,737.04 ± 617.4	1,701.10 ± 570.1	0.344
% Fat (*n* = 238)	29.73 ± 5.4	30.5 ± 6.5	30.11 ± 5.9	0.322
% SFA (*n* = 238)	9.56 ± 2.3	9.69 ± 2.7	9.63 ± 2.5	0.681
% Carbohydrates (*n* = 238)	53.08 ± 7.1	52.75 ± 7.2	52.92 ± 7.1	0.720
Knowledge score	0.61 ± 0.1	0.59 ± 0.2	0.60 ± 0.1	0.403
Self-efficacy score	2.86 ± 0.6	2.79 ± 0.5	2.82 ± 0.6	0.309
Diabetes medication intensity score	3.11 ± 1.7	2.71 ± 1.7	2.91 ± 1.7	0.053§
Total physical activity (MET-h/day)¶	13.08 ± 6.9	12.12 ± 6.2	12.61 ± 6.6	0.263
Total physical activity duration (h/day)¶	5.00 ± 2.3	4.90 ± 2.3	4.95 ± 2.3	0.748
Walking (h/day)¶	0.12 ± 0.3	0.15 ± 0.4	0.13 ± 0.4	0.147§
Sitting (h/day)¶	9.20 ± 2.5	9.55 ± 2.3	9.37 ± 2.4	0.256

Data are *n* (%) or means ± SD unless otherwise indicated. SFA, saturated fatty acids. *BMI: normal (BMI 18.5–24.9 kg/m^2), overweight (25–29.9 kg/m^2), obese class I (BMI 30– 34.9 kg/m^2), obese class II (BMI 35– 39.9 kg/m^2), and obese class III (BMI ≥40 kg/m^2). †*n* = 244. ‡*n* = 251. §Rank-sum test. ¶*n* = 237.

clinically important short-term improvements in glucose control and glucose variability. However, strategies to sustain these improvements are needed. The clinical significance of the impact of this intervention is considerable in light of the UK Prospective Diabetes Study (UKPDS) data showing that, for every percentage point decrease in HbA_{1c}, there was a 35% reduction in risk of diabetes complications (22). Furthermore, there appears to be no sharp threshold for the clinical importance of reducing HbA_{1c} level, which even at levels associated with insulin resistance but not clinical diabetes is still a marker for increased risk of cardiovascular disease (23).

This theory-based intervention targeting patients' diabetes knowledge, self-efficacy, and self-management behaviors was successful in producing significant improvements in all three targets areas. Furthermore, these improvements were significantly associated with HbA_{1c} at 12 months, showing that the theoretical constructs mediated the effect between the intervention and HbA_{1c}. Improvements in knowledge and self-efficacy suggest that literacy-sensitive materials and strategies can bring about important and needed changes. Likewise, the focus on skills building through hands-on activities may have facilitated the development of self-efficacy and behavioral skills needed to implement the newly acquired knowledge. Of particular interest were the dietary change findings and their mediating role in the observed improvement in glycemic control. The maintenance of dietary changes at the 12-month follow-up are encouraging given the common negative attitudes toward dietary change in this population (13,14). Previous studies have not assessed the impact of intervening to promote dietary change among Latinos with diabetes (5,6). Our findings that self-monitoring twice per day or more was associated with improvements in glucose control is also relevant because the importance of blood glucose self-monitoring among patients with type 2 diabetes has been questioned (24). Our emphasis on teaching participants to use glucose data to modify their diet intake or their activity may have contributed to our findings. The lack of an important intervention impact on physical activity may reflect the relatively weaker emphasis on exercise in the protocol and probably contributed to the nonsignificant intervention effect at 12 months. However, a previous study of Latinos with diabetes also failed to produce significant improvement in physical activity (6).

Intervention attendance decreased during the follow-up phase of the intervention and correlated with the decreased impact of the intervention over time. While less than ideal, attendance rates reflect the reality of many health centers serving low-income populations (i.e., typically high cancellation and no-show rates). In contrast to efficacy studies, which recruit only highly motivated individuals (i.e., those able to demonstrate that they can adhere to study protocols before being considered for study enrollment), or clinical trials with advertisement-based recruitment methods (likely to recruit self-selected populations), we recruited from a general pool of patients with diabetes from health centers serving low-income communities, often regarded as "hard to reach." A third factor contributing to the reduced change differences between intervention and control conditions was the slight improvement in HbA_{1c} observed in the control group. This finding is consistent with those of previous trials (25), suggesting that

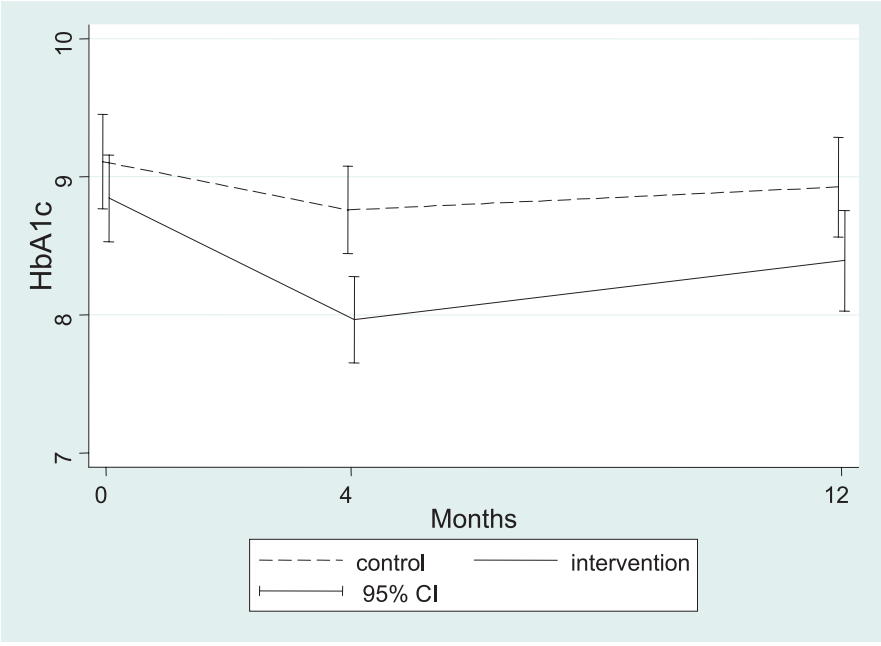

Figure 1—*Mean differences in HbA_{1c} level at 4- and 12-month follow-ups for the intervention and control conditions of the Latinos en Control study* (n = 252). *(A high-quality color representation of this figure is available in the online issue.)*

participation in a trial per se, independent of any intervention, produces glucose control improvements. As in this study, such improvements are greater among individuals with higher baseline HbA_{1c}. With regression to the mean ruled out as a possible explanation for this phenomenon (3), other mechanisms possibly accounting for HbA_{1c} improvements include contact and attention from research staff, information discussed during the screening, consenting and assessment sessions, and patient motivation. Laboratory results mailed to patients' providers also could have influenced outcomes.

A limitation of this study was the self-reported nature of the behavioral data (diet and blood glucose self-monitoring). In addition, we were unable to objectively measure physician prescription patterns and patient medication adherence or estimate the mediating effect of medications on physiological outcomes. However, our measure of diabetes medications intensity showed no differences at baseline or over time between the intervention and the control groups. Another limitation was the lack of blood glucose variability for the usual-care group.

To our knowledge, this is the first large RCT to test a culturally tailored, literacy-sensitive diabetes self-management intervention for low-income Spanish-speaking Latinos of Caribbean origin. Unlike the two previous studies of diabetes interventions targeting Latinos (5,6), this study recruited patients from real-world clinical settings; included comprehensive assessments of clinical, behavioral and theory-based constructs; and included assessment of factors mediating HbA_{1c} improvements. With currently climbing rates of obesity, the prevalence of diabetes

Table 2—*Changes in outcomes at 4-month and 12-month follow-ups in the Latinos en Control study* (n = 252)

Change from baseline	Control	Intervention	Intervention effect	Test of difference for intervention vs. control
AHEI score				
4 months	0.76 (−0.96 to 2.48)	5.05 (3.30–6.79)	4.29 (1.84–6.74)	0.001
1 year	1.04 (−0.52 to 2.60)	3.87 (2.25–5.49)	2.83 (0.58–5.08)	0.014
Kcal				
4 months	94.6 (−4.2 to 193.4)	−231.3 (−331.4 to −131.1)	−325.9 (−466.5 to −185.2)	<0.001
1 year	97.9 (−4.4 to 200.2)	−213.7 (−319.6 to −107.8)	−311.6 (−458.8 to −164.4)	<0.001
% Fat				
4 months	−0.57 (−2.10 to 0.97)	−3.88 (−5.44 to −2.33)	−3.32 (−5.50 to −1.13)	0.003
1 year	−0.54 (−1.77 to 0.70)	−3.22 (−4.51 to −1.94)	−2.68 (−4.47 to −0.90)	0.003
% SFA				
4 months	−0.31 (−0.89 to 0.27)	−1.07 (−1.65 to −0.48)	−0.75 (−1.58 to 0.07)	0.073
1 year	−0.40 (−0.93 to 0.12)	−1.19 (−1.74 to −0.65)	−0.79 (−1.55 to −0.03)	0.041
% CHO				
4 months	0.27 (−1.47 to 2.00)	1.75 (−0.01 to 3.51)	1.49 (−0.98 to 3.95)	0.237
1 year	0.01 (−1.46 to 1.49)	1.38 (−0.15 to 2.92)	1.37 (−0.76 to 3.50)	0.207
Diabetes knowledge				
4 months	0.039 (0.015–0.063)	0.083 (0.059–0.107)	0.044 (0.011–0.078)	0.010
1 year	0.033 (0.009–0.057)	0.089 (−0.065–0.113)	0.056 (0.022–0.090)	0.001
Self-efficacy				
4 months	0.132 (0.040–0.219)	0.448 (0.362–0.534)	0.316 (0.194–0.439)	<0.001
1 year	0.213 (0.113–0.313)	0.448 (0.0348–0.548)	0.235 (0.093–0.376)	0.001

Data are mean differences (range) unless otherwise indicated. AHEI, Alternative Healthy Eating Index (measure of dietary quality); SFA, saturated fatty acids; CHO, carbohydrate.

and its associated complications will continue to increase among Latinos. Future studies will need to examine innovative ways to enhance diabetes self-management, especially long-term glycemic control, and the cost-effectiveness of these interventions.

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M.C.R. was the principal investigator, designed the intervention, researched data, and wrote the manuscript. I.S.O. was the study cardiologist and reviewed and edited the manuscript. A.R. was the study diabetologist and reviewed the manuscript. M.J.W. and A.B. were the project coordinators and reviewed the manuscript. B.O. reviewed the manuscript. J.S., L.C., and G.W. were site liaisons and reviewed and edited the manuscript. G.R. was the biostatistician, researched data, and reviewed the manuscript.

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