Peer-Led Diabetes Education Programs in High-Risk Mexican Americans Improve Glycemic Control Compared With Standard Approaches

A Project Dulce promotora randomized trial

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OBJECTIVE—To evaluate the effect of a culturally sensitive diabetes self-management education program that uses a low-cost, peer-educator format (Project Dulce) on glucose control and metabolic parameters in low-income Mexican Americans with type 2 diabetes.

RESEARCH DESIGN AND METHODS—A total of 207 Mexican-American patients recruited from federally funded community health centers in San Diego County with HbA_{1c} >8% were randomly assigned to the Project Dulce peer intervention or continuation of standard diabetes care. The primary outcome of interest was HbA_{1c}.

RESULTS—The majority of subjects were born in Mexico, were female, were middle-aged, had less than an eighth-grade education, and had high baseline HbA_{1c} levels. Significant time-by-group interaction effects for HbA_{1c} ($P = 0.02$) and diastolic blood pressure ($P = 0.04$) indicated that the Project Dulce group exhibited greater improvement (i.e., decreases) across time. Within-group analyses showed that the intervention group exhibited significant improvements from baseline to month 4 in absolute levels of HbA_{1c} (−1.7%, $P = 0.001$) and HDL cholesterol (+1.4 mg/dL, $P = 0.01$) and from baseline to month 10 in absolute levels of HbA_{1c} (−1.5%, $P = 0.01$), total cholesterol (−7.2 mg/dL, $P = 0.04$), HDL cholesterol (+1.6 mg/dL, $P = 0.01$), and LDL cholesterol (−8.1 mg/dL, $P = 0.02$). No significant changes were noted in the control group.

CONCLUSIONS—This randomized trial, using the Project Dulce model of culturally sensitive, peer-led education, demonstrates improvement in glucose and metabolic control and suggests that this low-cost approach to self-management education for high-risk diabetic populations is effective.

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Health care reform is a driving force with the imperative to identify low-cost and clinically effective methods to respond to the increasing health care needs of our society. In addition, targeting effective interventions toward those with significantly elevated clinical risk factors may help to foster cost containment. By 2034, the number of patients with diagnosed and undiagnosed diabetes is predicted to increase from 23.7 to 44.1 million, and annual diabetes-related spending is expected to increase from $113 to $336 billion (1). Patients of Latino origin are a vulnerable population whose health care needs, particularly in diabetes care, are rising exponentially. Predictions are that between 45 and 55% of Hispanics born in the year 2000 will develop diabetes during their lifetime (2). Along with this disease burden, additional cultural barriers exist, preventing optimal care and clinical benefit in these groups, putting them at even greater risk for high-cost complications. Culturally appropriate, clinically sound, and cost-effective models are needed to respond to the growing and diverse populations affected by diabetes worldwide.

Improved glucose control can positively impact the health status of patients with diabetes and reduce comorbidities associated with their treatment (3–5). Latinos with type 2 diabetes in particular exhibit worse glycemic control, have greater disease severity, develop a higher rate of complications, and overall have worse health outcomes than non-Latino whites with the same condition (6–8). The peer-educator model, particularly in relation to diabetes, may be useful as a method that improves glucose control (9–13). The Project Dulce model was developed in 1997 to improve the health of underserved, ethnically diverse people with diabetes (14,15). As originally designed, this model consisted of three components: nurse case management, dietitian visits, and a series of peer-led, self-management education classes. Reports published to date on the outcomes of the Project Dulce model included all three of these components (14–16). The present trial, however, was designed to directly evaluate the effect of the peer-led education classes alone as one factor in the chronic-care model that can lead to improved clinical outcomes. Although the peer-education program has been tested in qualitative and quantitative studies over the last 10 years, it has never been rigorously tested in a randomized trial. The Project Dulce peer-education component, developed by the Scripps Whittier Diabetes Institute, uses lay community health workers, or promotoras, who act as cultural mediators among patients, community resources, and the greater health care system (16). The purpose

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of this study was to assess whether this culturally sensitive diabetes self-management education program can improve glucose control and metabolic parameters in Mexican Americans.

RESEARCH DESIGN AND METHODS

—The sample included Mexican-American men and women, aged 21–75 years, who were underinsured patients at federally qualified community health centers in San Diego County with type 2 diabetes and HbA_{1c} >8%. Individuals with a physical or mental-health condition that would preclude fulfilling the requirements of the study were ineligible to participate. Participants were recruited through provider referrals, medical-chart reviews, and waiting-room demonstrations. A total of 961 individuals were eligible after chart review (CONSORT figure available in the Supplementary Materials). Of these, 651 were excluded because they could not be reached (n = 264), reported a barrier to participation (e.g., time conflict, lack of transportation or child care, n = 236), or indicated that they were not interested in participating (n = 151). The remaining 310 individuals were screened by a bilingual/bicultural clinical-trials assistant. Those who met eligibility criteria and expressed an interest in participating provided written informed consent. A total of 207 individuals were enrolled and randomly assigned between the dates of July 2007 and March 2009. All procedures were approved by the San Diego State University and Western Institutional Review Boards.

Study design and intervention

The intervention was tested using a parallel-groups randomized clinical trial. Blocked random assignment with equal allocation was used to assign participants to the control or Project Dulce groups using a randomly generated numbers sequence. Participants were informed of their group allocation after the baseline assessment.

Study participants underwent a physical assessment with fasting venous blood draw and completed study questionnaires at baseline, month 4 (postintervention for the Project Dulce participants), and month 10 after baseline. Assessments were performed by a clinical-trials assistant at study sites. All participants were given a LifeScan One Touch blood glucose monitor, testing strips, and small gift cards at each assessment. Participants randomly assigned to the control group (n = 103) continued their usual medical care at the clinics. In addition to usual care, participants randomly assigned to the Project Dulce group (n = 104) attended eight weekly, 2-h diabetes self-management classes and subsequent monthly support groups, led by a trained peer educator. To ensure the fidelity of intervention delivery, all classes were audio recorded and reviewed using checklists to monitor the delivery or omission of curriculum components.

The Project Dulce peer-education curriculum, "Diabetes Among Friends," builds upon the effectiveness of the peer educator or promotora model in reducing Latinos' cultural barriers to care and health education (12,13). Individuals with diabetes who exemplified the traits of a natural leader were identified from the patient population and trained as promotoras over a 3-month period. In the first phase, peer educators spent 40 h learning the education curriculum, behavior modification techniques, group instruction and mediation methods, and employee standards. After meeting specific competencies, trainees cotaught two series of classes with their trainer and then finally taught two series on their own, under observation by the trainer.

The Project Dulce curriculum was delivered in the participants' and promotoras' native language (i.e., Spanish) and covered the basics of diabetes and its complications, diet, exercise, medication, blood glucose monitoring, and cultural beliefs that interfere with optimum self-management (e.g., fear of using insulin, reliance on urine or nopales, such as Mexican prickly pear cactus, as cures). Classes were interactive, providing opportunities for patients to discuss personal experiences and convey support and advice to other group members. The curriculum targets the standards of care established by the American Diabetes Association to achieve improvements in HbA_{1c}, blood pressure, lipids, and self-management behaviors (17).

The value of the promotora-delivered education program stems from their direct experience with the community and participants' living situations, support and empathy that often is difficult for professionally trained individuals to provide, and firsthand understanding of the myths, beliefs, and cultural remedies that may interfere with the adoption of health recommendations. Promotoras had access to clinical laboratory results throughout the intervention; blood pressure and weight were assessed, and participants' blood glucose–monitoring logs were reviewed at the beginning of each class. When promotoras noted that participants were not meeting the American Diabetes Association treatment goals, they encouraged the patients to follow-up with their primary care providers but were not permitted to make any medication-management recommendations. After the conclusion of the class series, support groups were provided on a monthly basis by the same peer educator that taught the classes. The peer educators conducted individual telephone calls to participants before each support-group session to encourage attendance. These support-group sessions were 2 h long and included a review of class topics and an interactive discussion facilitated by the peer educator. On occasion, guest speakers were invited to discuss an area of interest, such as eye disease, foot care, or dietary/weight-loss approaches.

Demographic and outcome measures

Participants self-reported sex, date of birth, country of origin, marital status, educational attainment, monthly income, and health insurance status. All participants chose to complete the assessment in Spanish.

The primary outcome in the current study was HbA_{1c}; lipids (total, LDL, and HDL cholesterol and triglycerides), blood pressure, and BMI were examined as secondary outcomes. All biochemical assays were conducted by Quest Diagnostics laboratories (West Hills, CA), which adhere to guidelines set forth by the College of American Pathologists, and by laboratory personnel who were blinded to group assignment. Systolic and diastolic blood pressure were measured in the seated position, after participants had rested for at least 5 min, using standard sphygmomanometers and stethoscopes. Two blood pressure readings (5 min apart) were obtained and averaged. Body weight and height were measured, using a traditional balance scale and stadiometer, to the nearest 0.1 kg and 0.5 cm, respectively. Self-management behaviors and depression also were captured via self-report and will be presented in a separate publication.

Sample-size determination and statistical analysis

A target sample size of 210 was determined to be adequate based on a power analysis incorporating the effect size for change in HbA_{1c} observed in an uncontrolled pilot

trial of the Project Dulce intervention (14,15) and targeting a power of at least 0.90 with up to 30% attrition and a type 1 error rate of 5%.

Data analysis was performed using the Statistical Package for Social Science software (version 17.0; SPSS, Chicago, IL) and Hierarchical Linear and Nonlinear Modeling software (version 6.06; Scientific Software International, Lincolnwood, IL). Descriptive statistics were obtained and distributions were examined for normality. All outcomes except HbA_{1c} included values at least 3 SDs above the mean, resulting in substantial positive skew. Transformations were applied to normalize the distributions of these variables; however, because no appreciable differences between results of analyses using transformed versus untransformed variables were observed, results are presented for untransformed data only for brevity and ease of interpretation.

Multilevel models were used to examine whether the two groups evidenced differential rates of change over time for HbA_{1c} and secondary outcomes (i.e., time-by-group interactions). Subsequent analyses investigated within-group changes over time from baseline to months 4 and 10. Finally, to evaluate a possible dosage effect on the primary outcome in the treatment group, attendance (i.e., number of classes attended) was examined as a predictor of month 4 and month 10 HbA_{1c}, controlling for HbA_{1c} values at baseline. All analyses controlled for age and sex.

Table 1—*Baseline demographic and clinical characteristics for the Project Dulce peer-education and control groups*

Demographics	Project Dulce peer-education group	Control group	*P*
n	104	103	
Age (years) [means (SD)]	52.2 (9.6)	49.2 (11.8)	0.05
Sex			
Female	69 (66.3)	77 (74.8)	
Male	35 (33.7)	26 (25.2)	0.18
Marital status			
Married	50 (48.1)	53 (51.4)	
Unmarried	54 (51.9)	50 (48.6)	0.89
Country of origin			
Mexico	89 (85.6)	92 (89.3)	
U.S.	9 (8.6)	9 (8.7)	
Other	6 (5.8)	2 (1.9)	0.36
Education			
Less than eighth-grade education	57 (54.8)	51 (49.5)	
Eighth-grade education or higher	47 (45.2)	52 (51.5)	0.18
Insurance coverage			
Insured	34 (32.7)	36 (35.0)	
Uninsured	70 (67.3)	67 (65.0)	0.76
Household monthly income			
<$1,000 per month	48 (46.2)	55 (53.4)	
$1,001 to $1,999 per month	42 (40.4)	36 (35.0)	
≥$2,000 per month	14 (13.4)	12 (11.6)	0.23
Clinical values [means (SD)]			
HbA_{1c} (%)	10.5 (1.7)	10.3 (1.7)	0.31
Total cholesterol (mg/dL)	197.0 (54.3)	194.1 (43.7)	0.68
HDL (mg/dL)	45.7 (11.6)	45.1 (11.1)	0.72
LDL (mg/dL)	109.6 (42.6)	109.4 (38.4)	0.97
Triglycerides (mg/dL)	210.4 (134.3)	205.2 (95.6)	0.75
Systolic blood pressure (mmHg)	123.9 (15.5)	121.2 (17.5)	0.24
Diastolic blood pressure (mmHg)	74.8 (7.7)	75.1 (7.9)	0.78
BMI (kg/m^2)	30.9 (6.3)	32.14 (5.9)	0.13

Data are *n* (%), unless otherwise indicated. Data are based on all individuals who completed a baseline assessment ($N = 207$). Education and income categories were collapsed for ease of presentation.

RESULTS

Participant characteristics

Patient characteristics and baseline laboratory values of the two groups are presented in Table 1. The majority of patients were low-income, were obese, were middle-aged women, were born in Mexico, were uninsured, and had less than an eighth-grade education level. They exhibited poor glycemic control with HbA_{1c} >10% but, in general, had mild elevations in LDL and triglycerides and normal blood pressure.

Fifty-one (25%) participants were lost to follow-up (Project Dulce group, $n = 35$ [33.5%]; control group, $n = 16$ [15.5%]); however, at baseline, these participants did not differ significantly from those who completed at least one follow-up assessment on any demographic or outcome variable ($P > 0.05$). Reasons for dropping out included relocation, time conflicts with classes, telephones disconnected, and changes in insurance status; the latter allowed participants to enroll in the county medically indigent adults services, which provides them access to the nurse case-management component of the original Project Dulce model.

Differential change-over-time analyses

A total of 156 participants completed at least one follow-up assessment and were included in multilevel modeling analyses examining differences in rates of change over time between the groups (Project Dulce group, $n = 69$; control group, $n = 87$). Of these, 126 subjects completed both follow-ups (Project Dulce group, $n = 55$; control group, $n = 71$), 23 subjects completed month 4 only (Project Dulce group, $n = 11$; control group, $n = 12$), and 7 subjects completed the month 10 follow-up assessment only (Project Dulce group, $n = 3$; control group, $n = 4$). Group means for all indicators at months 4 and 10 are shown in Table 2. Significant time-by-group interaction effects were observed for HbA_{1c} ($P = 0.02$) and diastolic blood pressure ($P = 0.04$), indicating that the Project Dulce group exhibited greater improvement across time. No significant time-by-group interaction effects were observed for any other clinical indicators.

Within-group analyses

The Project Dulce group exhibited a statistically significant decrease in the primary outcome, HbA_{1c}, from baseline to month 4 (−1.7%, $P = 0.001$) and from

Table 2—*Results of ANCOVAs examining within-group changes in clinical indicators from baseline to months 4 and 10*

	Month 4 assessment[a]			Month 10 assessment[b]		
	n	Means (SD) at month 4	Δ From baseline	*n*	Means (SD) at month 10	Δ From baseline
HbA_{1c} (%)						
Project Dulce	64	9.0 (1.9)	−1.7*	56	9.1 (2.0)	−1.5*
Control subjects	81	9.1 (1.9)	−1.1	74	9.7 (2.3)	−0.8
Total cholesterol (mg/dL)						
Project Dulce	64	183.3 (46.1)	−11.0	57	186.8 (44.4)	−7.2†
Control subjects	81	187.0 (40.9)	−8.5	74	192.1 (51.9)	−2.4
HDL (mg/dL)						
Project Dulce	64	47.3 (12.2)	+1.4†	57	48.1 (11.7)	+1.6†
Control subjects	82	46.8 (13.5)	+0.5	74	47.9 (14.6)	+1.7
LDL (mg/dL)						
Project Dulce	60	99.1 (40.2)	−8.1	56	99.4 (36.3)	−8.1†
Control subjects	80	104.3 (34.2)	−5.8	72	103.6 (37.7)	−7.2
Triglycerides (mg/dL)						
Project Dulce	64	180.2 (103.7)	−28.7	56	182.3 (113.6)	−20.0
Control subjects	82	192.0 (89.1)	−8.4	73	198.6 (128.3)	+7.5
Systolic blood pressure (mmHg)						
Project Dulce	65	119.6 (13.6)	−3.2	57	118.9 (14.8)	−2.5
Control subjects	82	121.7 (17.9)	+0.5	74	119.3 (16.6)	−1.6
Diastolic blood pressure (mmHg)						
Project Dulce	65	73.1 (8.1)	−1.7	57	71.8 (8.0)	−2.2
Control subjects	82	74.7 (9.7)	−0.7	74	74.8 (8.1)	+0.5
BMI						
Project Dulce	64	30.6 (6.0)	−0.1	57	30.9 (6.0)	−0.3
Control subjects	83	32.3 (6.3)	−0.1	74	31.7 (6.4)	−0.4

[a]Values reported for participants with baseline and month 4 values (total *N*: Project Dulce = 66; control subjects = 83; sample sizes for individual analyses are reduced as noted because of missing values). [b]Values reported for participants with baseline and month 10 values (total *N*: Project Dulce = 58; control subjects = 75; sample sizes for individual analyses are reduced as noted because of missing values). Change values are calculated using the baseline mean of the subset of participants who completed the follow-up under consideration. All analyses control for age and sex; however, unadjusted means are reported. *$P < 0.01$. †$P < 0.05$. Two-tailed *P* values pertain to tests of within-group changes from baseline.

baseline to month 10 (−1.5%, $P = 0.01$) (see Fig. 1). Project Dulce participants also demonstrated significant improvements from baseline to month 4 in HDL (+1.4 mg/dL, $P = 0.01$) and improvements from baseline to month 10 in total cholesterol (−7.2 mg/dL, $P = 0.04$), HDL cholesterol (+1.6 mg/dL, $P = 0.01$), and LDL cholesterol (−8.1 mg/dL, $P = 0.02$) but did not evidence changes in BMI or blood pressure. No significant changes were noted in the control group over time (Table 2).

Dosage-effect analyses

Attendance was a significant predictor of HbA_{1c} in the Project Dulce group at month 4 ($\beta = -0.29$, $P < 0.01$) and month 10 ($\beta = -0.42$, $P < 0.01$), suggesting a dose-response effect. To be specific, for each additional class attended, participants averaged an additional 0.3 decrease in HbA_{1c} at month 4 and an additional 0.4 decrease in HbA_{1c} at month 10.

CONCLUSIONS—This randomized trial of the Project Dulce peer-education model of diabetes self-management, implemented by promotoras in a culturally sensitive manner, demonstrates significant improvement in glycemic control and several metabolic parameters compared with usual care. This study suggests that if implemented on a large scale in a health care reform milieu, significant public health benefits may be realized in the epidemic of diabetes, which is rapidly increasing in the Latino population.

In this trial, all patients had initial HbA_{1c} levels of >10%, which places them at very high risk for developing complications. The peer-education group achieved a reduction in HbA_{1c} of 1.5% at month 10, an improvement that is clinically significant and has been noted with some glucose-lowering medications. This level of HbA_{1c} reduction can translate into decreased complications of retinopathy, nephropathy, and neuropathy (4,5). Of interest, a dosage effect was noted, in that participants who attended more classes evidenced larger HbA_{1c} reductions. This supports the hypothesis that the "high-touch" effect of the classes (and possibly the follow-up support groups, although not formally evaluated in the current study) can contribute to ongoing improvements in clinical outcomes. In contrast, in a recently published trial using a peer-educator approach in Ireland, no dose effect was found for glucose control (18). However, this difference in findings may be attributable, in part, to differences in methodology in Smith et al. (18) (e.g., shorter time period for training the peer educators; intervention focused on social motivation, with less emphasis on diabetes education and self-management). Finally, an additional significant finding was noted for the between-group diastolic blood pressure. Similar small, but significant, drops in blood pressure have translated into significant improvements in clinical outcomes in both epidemiologic and medication intervention trials.

In the control group, HbA_{1c} also decreased between baseline and month 4; however, values regressed back toward baseline levels by month 10. These changes did not reflect a statistically significant reduction from baseline at either time point. Although we cannot rule out other explanations, this initial improvement may reflect the motivated nature of the individuals who enrolled in the clinical trial and their desire to improve diabetes management. In contrast, within-group analyses showed that the peer-led group achieved a statistically significant decrease in HbA_{1c} by month 4 and maintained this improvement to month 10. The peer-led group also showed significant improvements from baseline to month 10 in total, HDL, and LDL cholesterol. An in-depth analysis of the support-group component of the program was not conducted as part of this study. However, monthly telephone calls and encouragement to attend the support groups by peer educators between months 4 and 10 may have influenced the intervention group's maintenance of health habits and engagement with medical providers, which in turn led to sustained improvements in HbA_{1c} at month 10. It should be emphasized that

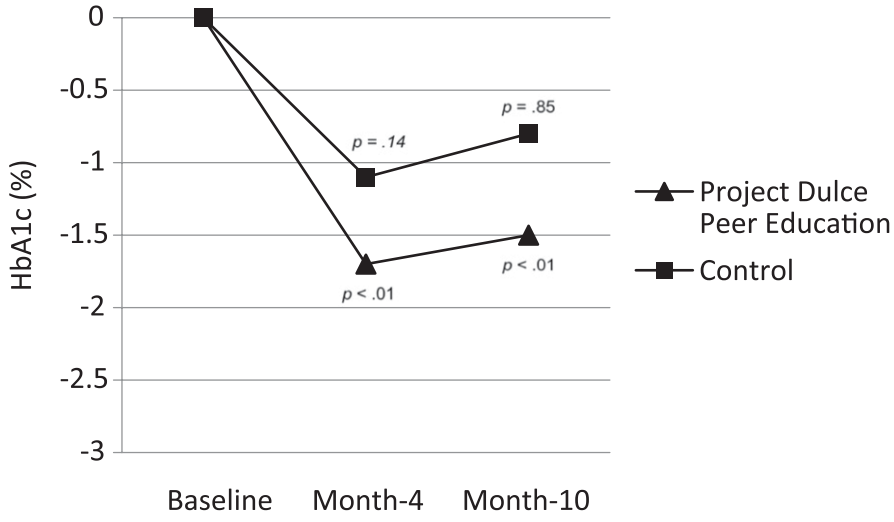

Figure 1—*Changes in absolute levels of HbA_{1c} from baseline to months 4 and 10 in the Project Dulce and control groups. Two-tailed* P *values are reported for tests of within-group changes from baseline to each time point.*

any medical intervention in this trial was purely based on the role of peer educators in advising and properly referring patients for physician follow-up. Empowering participants in the intervention group may have increased the chances that they would alert their physicians of clinical indicators that were not in the recommended target range. The treating physicians used their discretion for proper diabetes management outside the trial design. No attempt was made to directly influence physician treatment of these patients. Analysis of any changes in the medications was outside the scope of the current study.

Levels of diastolic blood pressure, lipids, and HbA_{1c} improved in the intervention group. Several aspects of the Project Dulce peer-education program may have contributed to the positive clinical effects. First, this model uses a standardized training process to prepare promotoras to deliver the curriculum. It has a multipronged approach that focuses on glucose control and management skills; ancillary education on hypertension, dyslipidemia, and dietary recommendations (e.g., reducing simple sugar, carbohydrate, and salt intake; substituting monounsaturated and polyunsaturated fats for saturated fats); and the benefits of regular exercise (e.g., walking) are discussed. Patients are taught the meaning of their clinical values, informed of targets for optimal health outcomes, and encouraged to communicate with their physicians if their values are not at target levels. Interactive discussions among group members are moderated by the peer educators, and participants encourage each other by communicating personal stories of success and sharing ideas for achieving optimal self-management within the contexts of shared living and culture environments. We speculate that by emphasizing not only glucose control but also the need to manage and prevent comorbid conditions of diabetes, the curriculum may improve corollary risk factors as well. Diabetes control in our ethnic populations is, unfortunately, worse when compared with non-Hispanic white populations (6,7,19–22). Therefore, considerable opportunity exists for using low-cost models of effectively delivered, culturally appropriate self-management education that results in HbA_{1c} and blood pressure reduction and may be especially beneficial when used in conjunction with a disease management–focused medical intervention.

Few randomized controlled trials have demonstrated improvement in glycemic control using a peer-education model for self-management education, and even fewer have shown improvement in additional clinical parameters (23–25). A trial that included 20 Mexican Americans noted a significant intervention effect on diabetes knowledge, weight, and BMI; changes in self-efficacy scores, blood glucose, and HbA_{1c} did not reach statistical significance (23). A systematic review in U.S. Latino communities concluded that community health-worker programs can achieve significant behavioral changes; however, only three of the reviewed studies reported HbA_{1c} findings (24). Of these, one did not reach statistical significance, one achieved within-group changes at month 6, and one reported small changes in HbA_{1c} in the intervention group. Lorig et al. (25) conducted a larger-scale randomized trial in 2009 with 345 participants with low baseline levels of HbA_{1c}. Although significant improvements were noted in depression, hypoglycemia symptoms, diet, and ability to read food labels in the intervention group, there were no changes in HbA_{1c} at month 6.

The current study provides an important contribution to the limited body of research that has formally evaluated the effectiveness of a peer educator–based diabetes self-management intervention relative to standard care. However, the results should be interpreted in the context of several limitations. First, the attrition rate was moderately high at 25%, which may have affected the results of the analyses. Moreover, attrition occurred at a disproportionate rate in the intervention group, and it is possible that participants who remained in the study were more engaged in the intervention, therefore leading to overestimation of intervention effects. On the other hand, the attrition-related attenuation in statistical power may have impeded our ability to detect smaller within-groups differences. To reduce participant burden, future trials may consider methods that use technology (e.g., delivering education and medication-management reminders via mobile text messaging) or other means to decrease the number of trips to the clinic for classes and assessments (e.g., conducting the month 4 assessment at the final class meeting). Second, all participants were given a blood glucose meter and testing strips at enrollment. This may have served as a minimal intervention in the control group and thus contributed to initial improvements in glycemic control. However, as noted, this improvement was neither statistically significant nor maintained in control participants, whereas intervention participants evidenced enduring improvements in glycemic control at the 10-month follow-up point. The lessons learned in working with this population, although there are limitations in the present study, represent valuable information that will guide future efforts in this underserved group.

A longer-term study will be needed to ultimately determine whether these interventions will result in sustained lifestyle changes and improved clinical outcomes. The potential significance of this

approach and these outcomes extend far beyond the borders of San Diego County. Ultimately, enduring changes in lifestyle and medication adherence are needed to reduce the complications and costs of diabetes. The use of peer educators as part of the chronic-care model can deliver an integral component of self-management education that can enhance diabetes care interventions. Economical, effective interventions with peer educators may be a critical link in our health care delivery system to achieve these outcomes.

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