Impact of a Community Health Workers–Led Structured Program on Blood Glucose Control Among Latinos With Type 2 Diabetes: The DIALBEST Trial

Rafael Pérez-Escamilla,[1,2] Grace Damio,[3] Jyoti Chhabra,[4] Maria L. Fernandez,[2] Sofia Segura-Pérez,[3] Sonia Vega-López,[5] Grace Kollannor-Samuel,[1] Mariana Calle,[6] Fatma M. Shebl,[1] and Darrin D'Agostino[7]

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OBJECTIVE

Latinos with type 2 diabetes (T2D) face major healthcare access and disease management disparities. We examined the impact of the Diabetes Among Latinos Best Practices Trial (DIALBEST), a community health worker (CHW)–led structured intervention for improving glycemic control among Latinos with T2D.

RESEARCH DESIGN AND METHODS

A total of 211 adult Latinos with poorly controlled T2D were randomly assigned to a standard of healthcare (*n* = 106) or CHW (*n* = 105) group. The CHW intervention comprised 17 individual sessions delivered at home by CHWs over a 12-month period. Sessions addressed T2D complications, healthy lifestyles, nutrition, healthy food choices and diet for diabetes, blood glucose self-monitoring, and medication adherence. Demographic, socioeconomic, lifestyle, anthropometric, and biomarker (HbA_{1c}, fasting blood glucose, and lipid profile) data were collected at baseline and 3, 6, 12, and 18 months (6 months postintervention). Groups were equivalent at baseline.

RESULTS

Participants had high HbA_{1c} at baseline (mean 9.58% [81.2 mmol/mol]). Relative to participants in the control group, CHWs had a positive impact on net HbA_{1c} improvements at 3 months (−0.42% [−4.62 mmol/mol]), 6 months (−0.47% [−5.10 mmol/mol]), 12 months (−0.57% [−6.18 mmol/mol]), and 18 months (−0.55% [−6.01 mmol/mol]). The overall repeated-measures group effect was statistically significant (mean difference −0.51% [−5.57 mmol/mol], 95% CI −0.83, −0.19% [−9.11, −2.03 mmol/mol], *P* = 0.002). CHWs had an overall significant effect on fasting glucose concentration that was more pronounced at the 12- and 18-month visits. There was no significant effect on blood lipid levels, hypertension, and weight.

CONCLUSIONS

DIALBEST is an effective intervention for improving blood glucose control among Latinos with T2D.

[1]*Yale School of Public Health, New Haven, CT*
[2]*University of Connecticut, Storrs, CT*
[3]*Hispanic Health Council, Hartford, CT*
[4]*Hartford Hospital, Hartford, CT*
[5]*Arizona State University, Phoenix, AZ*
[6]*Worcester State University, Worcester, MA*
[7]*University of North Texas, Denton, TX*

Corresponding author: Rafael Pérez-Escamilla, rafael.perez-escamilla@yale.edu.

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Latinos, the fastest growing minority group in the U.S. (1), suffer from a disproportionate burden of type 2 diabetes (T2D) (2) and related complications (3,4). Tangible disparities exist among Latinos in socioeconomic status, health insurance coverage, and use and quality of healthcare services (5,6). Prevalence of obesity (37.9% vs. 33.9%) (7) and physical inactivity (8)—risk factors associated with poor diabetes control—are also more prevalent among Latinos.

Effective metabolic glycemic control has been consistently shown to reduce the incidence of diabetes-related complications in large clinical trials (9,10). Current T2D care guidelines emphasize healthy lifestyles and behavioral change, such as eating a healthy diet, getting regular physical activity, attending primary and specialty clinic visits, and monitoring glycemic control (11). Traditional treatment strategies that focus on medication alone are not enough to achieve diabetes goals among Latinos (12). Limited English proficiency often leads to communication barriers between healthcare providers and Latino patients (13). Lack of provider cross-cultural communication skills to address cultural values among Latinos might result in patient dissatisfaction, treatment noncompliance, and delay in seeking medical help (14). Medical education and support delivered in a community setting by well-trained and supervised local, bilingual community health workers (CHWs) who understand the community's social determinants of health are likely to improve T2D care among Latinos (15,16).

Only a handful of randomized controlled trials (RCTs) have tested the effectiveness of diabetes education programs delivered by CHWs (17–26). Collectively, these studies demonstrated significant improvements in healthy lifestyle behaviors, diabetes knowledge, and HbA_{1c} levels. Most intervention strategies have been group based (17,19–25), clinic based (18), or telephone based (20,25) rather than home based (26). In the only home-based intervention study (26), CHWs were not integrated as part of the healthcare management team, and the sustainability of impact on glycemic control postintervention was not assessed. Thus, the objective of the present community-based RCT was to evaluate whether home-based, culturally appropriate counseling delivered by CHWs integrated as part of the healthcare management team can improve glycemic control among Latino adults with T2D and whether the impact is sustained after the intervention ends.

RESEARCH DESIGN AND METHODS

Study Design

The Diabetes Among Latinos Best Practices Trial (DIALBEST) was a parallel, community-based RCT. DIALBEST targeted Latino adults with T2D who attended a community-based ambulatory primary care clinic. Baseline screening was conducted using an electronic medical record database to identify eligible candidates who were contacted in person by recruiters on their clinical appointment day at the primary care clinic. Patients were eligible to participate if they *1*) were aged ≥21 years; *2*) had a documented diagnosis of T2D for >12 months; *3*) lived in Hartford County, CT; *4*) had HbA_{1c} levels ≥7% (53 mmol/mol); and *5*) self-identified as Hispanic/Latino. Exclusion criteria were *1*) pregnancy or breastfeeding; *2*) renal failure; *3*) active cancer; *4*) active hepatitis or advanced cirrhosis; *5*) end-stage liver disease; *6*) cognitive impairment, dementia, or Alzheimer disease; *7*) active and severe mental health problems; *8*) a cardiovascular disease event in the previous 12 months (assessed by a physician at the clinic); *9*) medical conditions that completely limit ability to perform physical activity independently (e.g., limb amputation, permanent physical disability, blindness); and *10*) inability to consume meals orally. Written informed consent and contact information were collected at the clinic.

A total of 211 participants were enrolled from December 2006 to February 2009 and were randomly assigned into either the standard of care (n = 106) or standard of care plus a 12-month-long, CHW-led, culturally tailored diabetes education and counseling treatment group (n = 105). Block randomization involving randomly selected block sizes of four was implemented through computer-generated binary random group assignment. The CHWs visited the treatment group participants at home weekly during the first month, biweekly during months 2 and 3, and monthly thereafter until month 12. Data collection took place at baseline and 3, 6, and 12 months postenrollment to assess the intervention phase and then 6 months thereafter to assess the intervention maintenance phase. Overall, the 18-month attrition rate was 29.9% (34.9% in the control group vs. 24.8% in the intervention group, P = 0.107) (Fig. 1).

Standard of Care

At the time of the study, clinic providers were trained based on American Diabetes Association guidelines and the practice guidelines developed for the clinics. Goals for care, metrics for success, and quality outcomes were monitored to ensure compliance with these guidelines. Every physician (resident or attending) was trained to check HbA_{1c} levels every 3 months and to conduct yearly foot, urine, and eye examinations. The standard practice in the clinic was to measure height, weight, and blood pressure at each visit. Five attending physicians served as mentors to ~42–48 residents per year equally split across 3 years of residency. The resident physicians were considered as the primary providers and, thus, were responsible for scheduled appointments and routine medical follow-ups. Patients needing urgent evaluation or intervention were able to access the same clinic system but often had to be seen by a different physician for acute care. All patients with T2D were given a glucometer and prescription for glucose test strips and were educated on their proper use. Patients were referred to a clinic dietitian if during a medical visit the healthcare provider discovered major nutrition-related issues. Patients were allowed to purchase their prescriptions at a hospital-based pharmacy at greatly discounted costs. In the last year of this program, the dispensing of discounted medications was discontinued, but study participants received their medications free of cost from the hospital for the duration of their enrollment so as not to adversely affect the study design. This study was approved by the institutional review boards of the University of Connecticut, Hartford Hospital, and the Hispanic Health Council.

CHW DIALBEST Intervention Curriculum

The DIALBEST curriculum was built upon extensive community-based participatory research work in the target community (27,28) and was designed to provide

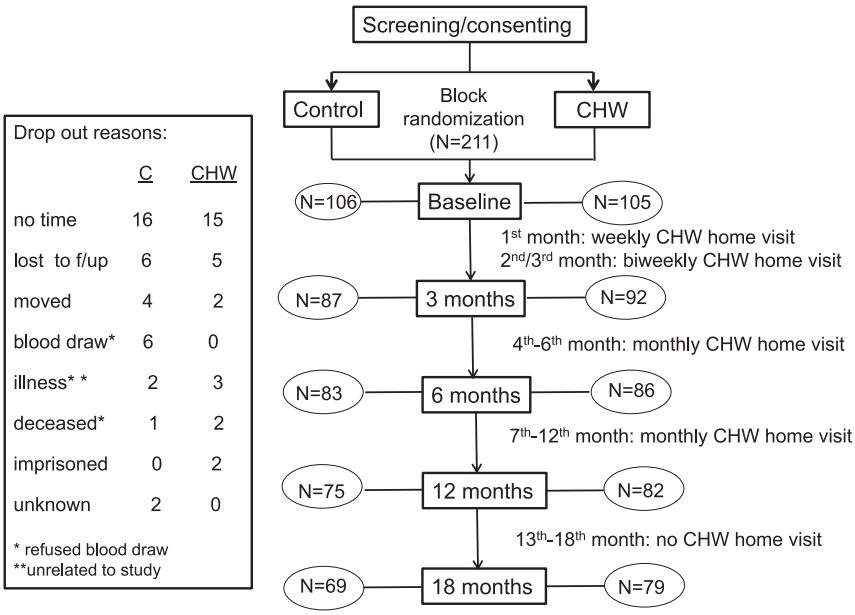

Figure 1—Study design flowchart. f/up, follow-up.

culturally and health literacy appropriate counseling, including informational and instrumental education, skills, and support in the areas of nutrition and food access, physical activity, blood glucose monitoring, medication adherence, and compliance with medical appointments. The DIALBEST curriculum was organized into 17 home-visit sessions delivered by two well-trained and supervised bilingual/bicultural CHWs. Each participant in the intervention group was randomly assigned to and only seen by one of the CHWs. The CHW delivered a comprehensive set of well-structured curriculum modules that exceeded the American Diabetes Association medical nutrition therapy standards (29). The modules focused on T2D and its complications, nutrition, physical activity, blood glucose self-monitoring, adherence to medications and medical appointments, and mental health (Supplementary Table 1). Each module included educational materials with graphics to illustrate key concepts and hands-on activities to improve instrumental knowledge for T2D self-management (e.g., onsite supermarket education on comparative shopping guided by food label reading).

DIALBEST was patient centered and grounded in principles of behavioral change theory, including stages of change, problem-solving theory, and motivational interviewing. As recommended (29,30), the intervention was individually tailored, taking heavily into account the language preference and specific socioeconomic circumstances of each participant. At each visit, the CHW and patient jointly developed a T2D self-management plan based on the individual patient's clinical history and previous challenges experienced with T2D self-management. Further individual tailoring was determined based on the patient's stage of change, level of motivation, health literacy, and social support. Home visits were scheduled only during weekdays. If endorsed by the patient, family members present at home during home sessions were allowed to participate.

CHW Training

The two DIALBEST bilingual/bicultural CHWs, a nurse trained in Puerto Rico and a medical assistant originally from El Salvador, underwent 65 h of core training that included T2D pathophysiology and risk factors, lifestyle strategies for glycemic control (nutrition, physical activity, prevention of diabetes complications, and diabetes care), glucose self-monitoring, and T2D medications. More than 25 h of supplemental training were provided, including program delivery topics on motivational interviewing and communication skills (Supplementary Table 2) and topics related to social determinants of health and cultural competence. The trainings were delivered by an interdisciplinary team of academics and practitioners with expertise in clinical medicine, health inequities, Latino health, diabetes self-management, diabetes medications, nutrition, exercise, cross-cultural counseling, and mental health.

CHW Integration Into Healthcare Management Team

The CHWs were employed at a community-based nonprofit organization. They attended weekly meetings with the field supervisor as well as with the health management coordination team at the clinic, which included the primary care clinic medical team and the clinic's dietitian. At these meetings, the CHWs informed the healthcare professionals of any serious barriers and challenges and T2D management issues faced by participants in the intervention group. Medical providers explained various treatment and management options that might work better with those patients unable to self-manage their T2D. This helped to coordinate the feedback of the CHWs with the care given. Feedback was delivered to the individual providers by the clinic director, who was also the study's medical director, along with education indicating why management change was suggested. Recommended management changes included adjustments in medication type or dose, timing for eating, timing for taking medication, and adding a snack in the diet before bed (to manage nocturnal hypoglycemia) as well as the type of bedtime snack (high in protein to prevent hyperglycemia at night). Thus, one of the key goals of DIALBEST was to improve the continuum of care of highly impoverished patients with T2D following the Chronic Care Model framework (31).

Data Collection

Data were collected at each participant's home at baseline and 3, 6, 12, and 18 months by one of five community bilingual interviewers not involved with the healthcare team and blinded to the care delivery group. At baseline, a battery of questions captured socioeconomic; demographic; acculturation; social support; T2D self-management knowledge, attitudes, and behaviors (diet, physical activity, blood glucose self-monitoring, and medication use); and mental health information (32–34). Findings of the impact of the intervention on T2D self-management will be reported elsewhere.

A blood collection home visit was conducted for each participant after a 12-h overnight fast by a DIALBEST phlebotomist blinded to study group allocation. HbA_{1c} levels were measured in the home using the A1cNow InView point-of-care device (Metrika Inc., Sunnyvale, CA) from fasting capillary blood. Venous blood (20 mL) was collected into evacuated tubes coated with EDTA and EDTA/sodium fluoride for the measurement of plasma glucose and lipid concentrations (triglycerides and total, HDL, and LDL cholesterol). Blood samples were transported to the laboratory, centrifuged at 2,200*g* for 30 min at 4°C to separate plasma, and stored at −70°C until analyzed by trained laboratory assistants blinded to group assignment. All biomarkers were measured in duplicate. Body weight (kg), height, waist and hip circumferences (cm), and blood pressure (assessed using a portable sphygmomanometer) were measured by trained interviewers in triplicate following recommended procedures.

A process evaluation ancillary study was conducted in the sample of participants who completed the intervention (n = 76). A research staff member not involved with the delivery of the intervention or prior data collection reviewed the CHWs' home visit intake forms and progress notes and phone call logs. He also reviewed changes in T2D self-management knowledge assessed by the CHWs during the home visits following a pre/posttest and interviewed the intervention completers to assess their satisfaction with DIALBEST (Supplementary Data) (35–38).

Data Analyses

We used SAS for Windows version 9.3 (SAS Institute Inc., Cary, NC) to impute missing values in all the analyses. We used multiple imputation methods to create five data sets with nonmissing values using the PROC MI procedure and then ran all the analyses on each data set followed by combining the estimates from multiple data sets to obtain a single estimate using the PROC MIANALYZE procedure. Fully conditional specification methods were used, with linear or logistic regression to impute continuous and binary variables, respectively (39), which achieved >90% relative efficiency. To assess baseline group balance, we conducted between-group baseline comparisons for demographic, socioeconomic, blood glycemic and lipid levels, and anthropometric characteristics using the χ^2 test for categorical variables and independent samples ANOVA for continuous variables. Confounders of the primary and secondary outcomes were selected on the basis of the following criteria: *1*) did not interact with intervention and *2*) was significantly related to the outcome and intervention in the bivariate analysis. To assess the impact of the intervention on the primary outcome HbA_{1c} and to be able to compare and contrast the results to previously published studies, we modeled the HbA_{1c} outcome in three different ways: the measured raw HbA_{1c} values, HbA_{1c} reduction values, and HbA_{1c} percent change values. HbA_{1c} reduction at 3, 6, 12, and 18 months were defined as the HbA_{1c} values at 3, 6, 12, and 18 months minus the HbA_{1c} baseline value, respectively. HbA_{1c} percent change was calculated at 3, 6, 12, and 18 months as the HbA_{1c} reduction value divided by the HbA_{1c} baseline value. Subsequently, we followed two approaches. First, we conduct a linear mixed-effects (LME) repeated-measures analysis of HbA_{1c} raw values, HbA_{1c} reduction values, and HbA_{1c} percent change, adjusting for baseline HbA_{1c}, and included an interaction term that allowed us to estimate the net between-group HbA_{1c} difference across time points adjusted for confounders. The second approach was to conduct an LME repeated-measures analysis of postbaseline (i.e., excluding the baseline point from the model) HbA_{1c} raw values, HbA_{1c} reduction values, and HbA_{1c} percent change adjusted for time and confounders. We used the PROC MIXED procedure to conduct all LME modeling. LME models were also used to assess the secondary outcomes, including lipid profile, blood pressure, and weight. In all LME analyses of primary and secondary outcomes, we selected the best variance–covariance structure and final fixed- and random-effects models using Akaike information criteria. The best model was the one with the smallest Akaike information criteria value. All analyses were conducted based on intention-to-treat principles, and values were imputed to replace missing data as indicated previously.

Attrition Bias Analysis

To assess attrition bias, we compared the baseline characteristics described previously between completers (n = 148) and noncompleters (n = 63) at 18 months using χ^2 test for categorical variables and independent samples t test for continuous variables.

RESULTS

Sample Descriptive Characteristics

Study participants were, on average, 56 years old; 29% were married or living in common law; 26% had at least a high school education; 32% had a home computer, 22% Internet service at home, and 48% a car; 60% had a monthly income of ≤$1,000, 84% were covered by Medicaid, 68.9% received supplemental security income, and 73% were enrolled in the Supplemental Nutrition Assistance Program. There were no significant between-group differences in any of the demographic and socioeconomic variables compared at baseline (Table 1).

At baseline, blood glycemic and lipid profiles were not different between groups, but mean systolic blood pressure was significantly higher in the intervention group yet within normal limits. Mean HbA_{1c} was 9.6% (81 mmol/mol), glucose 10.6 mmol/L, triglycerides 1.75 mmol/L, total cholesterol 4.65 mmol/L, LDL cholesterol 2.55 mmol/L, HDL cholesterol 1.33 mmol/L, and systolic blood pressure 118 mmHg. Likewise, there were no between-group differences in baseline anthropometry, including waist circumference (107.2 cm), weight (85.1 kg), height (1.58 m), and BMI (33.7 kg/m^2) (Table 2).

DIALBEST Impact on HbA_{1c}

Results of the LME models that included time-by-intervention interaction and adjusted for baseline HbA_{1c} levels and age revealed that the DIALBEST intervention led to a net reduction HbA_{1c} difference from baseline of −0.42% (−4.62 mmol/mol) at 3 months (P = 0.043) followed by a net reduction difference of −0.47% (−5.10 mmol/mol) at 6 months (P = 0.050), −0.57% (−6.18 mmol/mol) at 12 months (P = 0.021), and −0.55% (−6.01 mmol/mol) at 18 months (P = 0.009) in favor of the CHW group (Table 3, Fig. 2). Consistent with these findings, the LME repeated-measures analyses that adjusted for baseline HbA_{1c} levels and age and were restricted to

Table 1—Demographic and socioeconomic characteristics among Connecticut Latinos with T2D participating in the DIALBEST trial

Variable	All (*N* = 211)	Control (*n* = 106)	CHW (*n* = 105)	*P* value
Age (years)	56.3 ± 11.8	57.3 ± 12.1	55.4 ± 11.5	0.245
Female sex	73.5	74.5	72.4	0.724
Language				0.439
English and Spanish	34.6	32.1	37.1	
Spanish	65.4	67.9	47.8	
Marital status				0.861
Single	28.0	29.2	26.7	
Married	22.3	22.6	21.9	
Common law	7.1	4.7	9.5	
Separated	10.9	11.3	10.5	
Divorced	17.1	17.0	17.1	
Widowed	14.7	15.1	14.3	
Highest school grade				0.628
No schooling	4.3	3.8	4.8	
≤8th grade	47.9	49.1	46.7	
Some high school	21.8	24.5	19.0	
High school/GED	17.1	15.1	19.0	
Technical	2.8	3.8	1.9	
Some college	5.2	2.8	7.6	
College	0.9	0.9	1.0	
Working	15.6	14.2	17.1	0.550
Possessions				
Telephone	77.3	82.1	72.4	0.093
Cell phone	64.5	67.0	61.9	0.441
Radio/CD player	77.7	77.4	78.1	0.898
Cable television	86.7	86.8	86.7	0.595
Video player	63.0	62.3	63.8	0.973
DVD player	69.0	71.7	66.3	0.402
Computer	32.2	31.1	33.3	0.732
Internet	22.3	20.8	23.8	0.713
Car	48.3	49.1	47.6	0.835
Microwave oven	93.8	94.3	93.3	0.748
Total monthly income				0.548
$0–500	53.6	53.8	53.4	
$501–1,000	25.4	24.5	26.2	
$1,001–1,500	4.8	2.8	6.8	
$1,501–2,000	2.4	3.8	1.0	
$2,001–3,000	7.2	8.5	5.8	
Unknown	6.7	6.6	6.8	

Data are mean ± SD or %. CD, compact disc; DVD, digital video disc; GED, General Educational Development.

postbaseline time points identified a significant overall group effect such that the intervention group had lower HbA_{1c} levels compared with the control group (mean difference −0.51% [−5.57 mmol/mol], 95% CI −0.83, −0.19% [−9.11, −2.03 mmol/mol], *P* = 0.002). Similarly, the HbA_{1c} percent change was significantly higher in the CHW group compared with the control group (mean difference −5.52% [−7.33 mmol/mol], 95% CI −8.93, −2.11% [−11.9, −2.81 mmol/mol], *P* = 0.002) (Table 3).

DIALBEST Impact on Secondary Outcomes

We also observed a significant effect of the intervention on fasting glucose. The CHW group had lower glucose concentrations compared with the control group (mean difference −1.08 mmol/L [95% CI −1.79, −0.39 mmol/L], *P* = 0.002) (Table 3). The intervention did not have a significant effect on HDL, LDL, and total cholesterol; triglycerides; systolic blood pressure; or weight (Table 3).

Attrition Bias Analysis

The overall dropout rate was 29.9% at 18 months, which was slightly lower among intervention than control participants (24.8% vs. 34.9%, respectively, *P* = 0.107). The majority of the noncompleters reported lack of time as a reason for dropping out (Fig. 1). Completers and noncompleters were similar in baseline characteristics except that of 31 baseline comparisons, completers were more likely to have a cell phone (68.9% vs. 54%, *P* = 0.038) and were less likely to be married (18.2% vs. 31.7%, *P* = 0.013).

Process Evaluation

The positive impact of DIALBEST is well supported by the process evaluation conducted with study completers by a research assistant not involved with the trial. Specifically, the process evaluation based on CHW logs documented strong fidelity in the delivery of the intervention by CHWs, which in turn translated into improved T2D self-management knowledge. Client satisfaction with DIALBEST was very high (35–38) (Supplementary Data).

CONCLUSIONS

DIALBEST Impact

To our knowledge, this RCT is the first to document the strong impact a home-based model can have on improving glycemic control among highly impoverished Latinos when a CHW is fully integrated within the healthcare management team. The study has several design and community-based methodological strengths. The 12-month-long intervention was followed by a 6-month postintervention maintenance period, allowing us to document the sustainability of the impact. All intervention procedures and data collection occurred in the participants' homes. Although the nature of the intervention did not lend itself to total concealment, the data were collected by highly trained community interviewers (one of which also served as the study's community phlebotomist) not involved in the delivery of the CHW intervention, and the individuals conducting laboratory analyses were blinded to group assignment. The findings have strong internal validity because the RCT achieved remarkable between-group baseline balance. The strong community- and clinic-based supervisory system assured strong intervention fidelity that relied on having only two highly trained CHWs who provided consistent information to participants (Supplementary Data).

The present findings of an HbA_{1c} reduction among the CHW group, ranging from −0.93% [−10.3 mmol/mol] at 3

Table 2—Health insurance, food assistance, social protection, and baseline biomedical factors among Connecticut Latinos with T2D participating in the DIALBEST trial

Variable	All (N = 211)	Control (n = 106)	CHW (n = 105)	P value
Health insurance, food assistance, and social protection				
Medicare	33.7	34.0	33.3	0.924
Medicaid	84.1	80.0	88.3	0.099
Supplemental security income	68.9	69.8	68.0	0.773
SNAP	73.3	69.8	76.9	0.244
Systolic blood pressure (mmHg)	118 ± 0.48	116 ± 0.65	119 ± 0.70	0.001
Fasting HbA_{1c}, plasma glucose, and lipid concentrations				
HbA_{1c} (%)	9.58 ± 0.12	9.58 ± 0.17	9.57 ± 0.18	0.981
HbA_{1c} (mmol/mol)	81.2 ± 1.36	81.2 ± 1.91	81.1 ± 1.94	0.981
Glucose (mmol/L)	10.57 ± 0.32	10.48 ± 0.48	10.67 ± 0.44	0.765
Triglycerides (mmol/L)	1.75 ± 0.08	1.69 ± 0.10	1.81 ± 0.12	0.487
Total cholesterol (mmol/L)	4.65 ± 0.08	4.60 ± 0.11	4.69 ± 0.11	0.578
HDL (mmol/L)	1.33 ± 0.02	1.37 ± 0.02	1.29 ± 0.04	0.145
LDL (mmol/L)	2.55 ± 0.07	2.49 ± 0.09	2.61 ± 0.10	0.382
Anthropometry				
Waist circumference (cm)	107.16 ± 1.11	105.85 ± 1.44	108.49 ± 1.70	0.237
Weight (kg)	85.07 ± 1.59	83.34 ± 1.87	86.82 ± 2.57	0.275
Height (cm)	158.48 ± 0.61	158.22 ± 0.85	158.75 ± 0.88	0.669
BMI (kg/m^2)	33.74 ± 0.53	33.38 ± 0.74	34.10 ± 0.77	0.498

Data are % or mean ± SE. SNAP, Supplemental Nutrition Assistance Program.

months to −0.85% [−9.3 mmol/mol] at 12 months followed by sustaining the effect size during the 6-month maintenance period, strongly suggest a clinical (9) and public health (40) impact of DIALBEST. The size of the HbA_{1c} reduction observed in our intervention group at 6 months post enrollment of −0.9% [−9.8 mmol/mol] is fully consistent with the one documented by Spencer et al. (24) of −0.8% [−8.7 mol/mol] at the same time point in their RCT targeting African Americans and Latinos (predominantly Mexican Americans) with T2D living in Detroit predominantly through group sessions (vs. individual home visits as in the present study). In that study, the CHW intervention comprised 11 2-h-long comprehensive diabetes education group sessions offered every other week at community agencies, 2 60-min-long home visits, and 1 clinic visit with a healthcare provider. The study by Rothschild et al. (26) documented among Mexican Americans that 36 CHW home sessions delivered over 2 years led to a net HbA_{1c} reduction of −0.69% [−7.5 mmol/mol] compared with a net reduction of −0.55% [−6.01 mmol/mol] at 18 months post-enrollment in our study. Thus, DIALBEST was found to have a similarly strong glycemic control benefit compared with a stand-alone group-based and a more intensive home-based model. However, their study design differed from DIALBEST because it did not integrate CHWs as part of the healthcare management team, the control arm was a newsletter (vs. usual healthcare in DIALBEST), and the study did not assess the sustainability of impact once the intervention ended, included twice as many CHW home visits, and the intervention lasted twice as long. In addition, participants in the Rothschild et al. study had better blood glucose control compared with DIALBEST participants, with ∼30% of their participants having a baseline HbA_{1c} <7% (53 mmol/mol) (vs. 5.2% of DIALBEST participants), and they targeted Mexican Americans (vs. Puerto Ricans/Dominicans in DIALBEST). Thus, DIALBEST adds significant new knowledge from both the perspective of community-based healthcare delivery of T2D self-management and the impact of CHWs on blood glucose control among a highly impoverished population with very poor blood glycemic control. DIALBEST represents the testing of a community-based real-world healthcare model that can be replicated elsewhere and that is closely aligned with the priorities of the Affordable Care Act.

The more-advanced formal education of the present study's CHWs contrasts with the lower levels of formal education of CHWs used in the study by Rothschild et al. (26). Thus, it is likely that CHWs with lower levels of education than those in DIALBEST can also improve T2D self-management.

Study Limitations

The main study design limitation is that because provider-level data were not collected, it is not possible to disentangle the CHW- and provider-driven pathways that may have led to the significant impact of DIALBEST on improved glycemic control. On the one hand, it is possible that the T2D self-management education provided by the CHWs led to this outcome. On the other hand, because CHWs were integrated as part of the healthcare management team, it is possible that healthcare providers adjusted the treatment of patients accordingly. We speculate that it is likely that both pathways played a role in the observed results, although this hypothesis would need to be tested through further research. Control group participants did not receive the CHW intervention but were also visited at home for data collection, including HbA_{1c} assessment. This may explain why HbA_{1c} also declined in this group, biasing findings toward the null hypothesis.

Conclusion

DIALBEST is a successfully implemented culturally and health literacy–appropriate

Table 3—LME models of intervention on primary and secondary outcomes among Connecticut Latinos with T2D participating in the DIALBEST trial

Outcome	Control	CHW	Group! difference	*P* value
Primary outcome				
HbA_{1c} (%)@	9.36 (8.96, 9.75)	8.85 (8.41, 9.28)	−0.51 (−0.83, −0.19)	0.002
HbA_{1c} (mmol/mol)	78.8 (74.4, 83.1)	73.2 (68.4, 78.0)	−5.57 (−9.11, −2.03)	0.002
HbA_{1c} (%)@@				0.002~
Baseline	9.76 (9.35, 10.2)	9.70 (9.30, 10.1)	−0.06 (−0.44, 0.33)	0.780
3 months	9.19 (8.71, 9.67)	8.77 (8.34, 9.17)	−0.42 (−0.83, −0.01)	0.043
6 months	9.28 (8.90, 9.66)	8.81 (8.37, 9.26)	−0.47 (−0.93, 0.0001	0.050
12 months	9.42 (9.07, 9.77)	8.85 (8.47, 9.23)	−0.57 (−1.04, −0.09)	0.021
18 months	9.32 (8.91, 9.74)	8.77 (8.35, 9.20)	−0.55 (−0.96, −0.14)	0.009
HbA_{1c} (mmol/mol)@@				0.002~
Baseline	83.2 (78.7, 87.6)	82.6 (78.1, 87.0)	−0.61 (−4.85, 3.64)	0.780
3 months	76.9 (71.7, 82.2)	72.3 (67.7, 77.0)	−4.62 (−9.09, −0.14)	0.043
6 months	77.9 (73.7, 82.1)	72.8 (67.9, 77.7)	−5.10 (−10.2, −0.002)	0.050
12 months	79.4 (75.6, 83.3)	73.3 (69.1, 77.4)	−6.18 (−11.4, −0.96)	0.021
18 months	78.4 (73.9, 83.0)	72.4 (67.7, 77.0)	−6.01 (−10.5, −1.50)	0.009
HbA_{1c} percent change (%)*	−0.96 (−4.96, 3.04)	−6.48 (−11.0, −1.99)	−5.52 (−8.93, −2.11)	0.002
HbA_{1c} percent change (mmol/mol)*	−0.68 (−5.89, 4.53)	−8.01 (−13.9, −2.13)	−7.33 (−11.9, −2.81)	0.002
HbA_{1c} percent change (%)**				0.002~
3 months	−2.26 (−7.69, 3.17)	−6.90 (−11.9, −1.93)	−4.64 (−9.17, −0.11)	0.045
6 months	−1.48 (−6.00, 3.03)	−6.40 (−11.6, −1.24)	−4.92 (−10.0, 0.19)	0.059
12 months	0.16 (−3.75, 4.08)	−6.02 (−10.4, −1.63)	−6.19 (−11.1, −1.24)	0.015
18 months	−0.39 (−5.17, 4.38)	−6.76 (−11.8, −1.72)	−6.37 (−11.1, −1.64)	0.009
HbA_{1c} percent change (mmol/mol)**				0.002~
3 months	−2.45 (−9.51, 4.61)	−8.55(−15.1, −2.04)	−6.10 (−12.1, −0.12)	0.046
6 months	−1.44 (−7.35, 4.48)	−7.90 (−14.7, −1.09)	−6.47 (−13.2, 0.26)	0.059
12 months	0.81 (−4.32, 5.94)	−7.45 (−13.2, −1.70)	−8.26 (−14.7, −1.82)	0.012
18 months	0.19 (−6.04, 6.41)	−8.35 (−15.0, −1.74)	−8.54 (−14.8, −2.26)	0.008
Secondary outcomes				
Glucose (mmol/L)#	11.3 (10.4, 12.3)	10.3 (9.26, 11.3)	−1.08 (−1.78, −0.39)	0.002
Glucose (mmol/L)##				0.002~
Baseline	11.3 (10.4, 12.3)	11.3 (10.3, 12.2)	−0.06 (−1.05, 0.94)	0.913
3 months	10.9 (9.64, 12.1)	10.1 (9.12, 11.2)	−0.75 (−1.84, 0.34)	0.179
6 months	10.7 (9.74, 11.7)	10.3 (9.37, 11.3)	−0.43 (−1.50, 0.65)	0.434
12 months	11.6 (10.7, 12.5)	10.2 (9.07, 11.4)	−1.38 (−2.52, −0.25)	0.018
18 months	11.7 (10.8, 12.6)	9.92 (8.75, 11.1)	−1.79 (−2.94, −0.64)	0.003
Triglycerides (mmol/L)$	1.65 (1.53, 1.79)	1.59 (1.47, 1.73)	−0.05 (−0.23, 0.13)	0.549
Triglycerides (mmol/L)$$				0.523~
Baseline	1.68 (1.53, 1.85)	1.73 (1.57, 1.90)	0.05 (−0.18, 0.27)	
3 months	1.59 (1.41, 1.77)	1.63 (1.46, 1.81)	0.04 (−0.23, 0.31)	
6 months	1.68 (1.51, 1.86)	1.53 (1.36, 1.69)	−0.16 (−0.40, 0.08)	
12 months	1.66 (1.46, 1.86)	1.56 (1.37, 1.75)	−0.11 (−0.40, 0.19)	
18 months	1.74 (1.55, 1.93)	1.67 (1.49, 1.86)	−0.06 (−0.36, 0.24)	
Total cholesterol (mmol/L)%	4.51 (4.38, 4.64)	4.56 (4.40, 4.71)	−0.05 (−0.17, 0.28)	0.628
Total cholesterol (mmol/L)%%				0.865~
Baseline	4.60 (4.40, 4.79)	4.61 (4.43, 4.82)	0.01 (−0.26, 0.28)	
3 months	4.48 (4.30, 4.69)	4.53 (4.35, 4.74)	0.04 (−0.24, 0.32)	
6 months	4.62 (4.40, 4.82)	4.62 (4.43, 4.82)	−0.00 (−0.28, 0.29)	
12 months	4.53 (4.33, 4.71)	4.62 (4.43, 4.82)	0.09 (−0.20, 0.38)	
18 months	4.55 (4.33, 4.77)	4.49 (4.20, 4.79)	−0.06 (−0.48, 0.36)	
HDL cholesterol (mmol/L)^	1.39 (1.34, 1.44)	1.40 (1.36, 1.45)	0.01 (−0.05, 0.08)	0.720
HDL cholesterol (mmol/L)^^				0.564~
Baseline	1.35 (1.30, 1.41)	1.33 (1.27, 1.39)	−0.02 (−0.10, 0.06)	
3 months	1.33 (1.28, 1.39)	1.39 (1.31, 1.45)	0.05 (−0.05, 0.14)	
6 months	1.39 (1.31, 1.47)	1.36 (1.30, 1.43)	0.03 (−0.12, 0.07)	
12 months	1.39 (1.32, 1.46)	1.47 (1.40, 1.53)	0.08 (−0.02, 0.18)	
18 months	1.40 (1.34, 1.47)	1.40 (1.33, 1.47)	−0.003 (−0.08, 0.08)	
LDL cholesterol (mmol/L)&	2.39 (2.26, 2.52)	2.45 (2.30, 2.62)	0.06 (−0.15, 0.27)	0.564
LDL cholesterol (mmol/L)&&				0.598~
Baseline	2.39 (2.34, 2.69)	2.58 (2.40, 2.75)	0.06 (−0.19, 0.32)	
3 months	2.41 (2.23, 2.59)	2.46 (2.26, 2.46)	0.05 (−0.22, 0.31)	
6 months	2.46 (2.26, 2.67)	2.55 (2.35, 2.75)	0.09 (−0.20, 0.37)	
12 months	2.38 (2.19, 2.56)	2.42 (2.22, 2.62)	0.04 (−0.22, 0.31)	

Continued on p. 204

Table 3—Continued

Outcome	Control	CHW	Group! difference	*P* value
18 months	2.38 (2.17, 2.59)	2.36 (2.10, 2.62)	−0.02 (−0.43, 0.40)	
Weight (kg)+	86.1 (83.7, 88.4)	86.0 (83.3, 88.7)	−0.07 (−3.34, 3.19)	0.964
Weight (kg)++				0.964~
Baseline	84.8 (82.2, 87.5)	85.3 (82.7, 87.9)	0.49 (−3.24, 4.21)	
3 months	86.9 (83.4, 90.3)	85.3 (82.1, 88.4)	−1.62 (−6.69, 3.44)	
6 months	85.9 (82.9, 88.9)	85.3 (82.1, 88.5)	−0.60 (−5.03, 3.83)	
12 months	86.4 (82.3, 90.5)	87.3 (84.0, 90.6)	0.90 (−3.31, 5.11)	
18 months	85.4 (82.5, 88.2)	85.9 (81.6, 90.3)	0.54 (−5.70, 6.78)	
Systolic blood pressure (mmHg)=	116 (115, 118)	118 (116, 120)	1.71 (−1.45, 4.86)	0.279
Systolic blood pressure (mmHg)==				0.313~
Baseline	119 (116, 121)	120 (117, 123)	1.50 (−2.40, 5.39)	
3 months	115 (112, 117)	117 (114, 119)	2.09 (−1.74, 5.92)	
6 months	118 (114, 121)	117 (113, 120)	−1.02 (−7.11, 5.08)	
12 months	118 (114, 121)	119 (117, 122)	1.20 (−2.70, 5.11)	
18 months	116 (113, 119)	119 (116, 122)	2.87 (−1.74, 7.47)	

Data are mean (95% CI). !Reference is the control group. @Models of HbA_{1c} % and HbA_{1c} change gave identical results. Models included group, time, baseline HbA_{1c} level, age, and antidiabetic medications. @@Models of HbA_{1c} % and HbA_{1c} change gave identical group mean difference results. Models included group, time, group-by-time interaction, baseline HbA_{1c} level, age, and antidiabetic medications. ~Overall effect *P* value; *P* values for time point comparisons not reported if $P > 0.05$. *Model included group, time, baseline HbA_{1c} level, age, and antidiabetic medications. **Model included group, time, group-by-time interaction, baseline HbA_{1c} level, age, and antidiabetic medications. #Model included group, time, baseline glucose level, age, and antidiabetic medications. ##Model included group, time, group-by-time interaction, baseline glucose level, age, and antidiabetic medications. $Model included group, time, baseline triglyceride level, glucose level, and total cholesterol level. $$Model included group, time, group-by-time interaction, baseline triglyceride level, glucose level, and total cholesterol level. %Model included group, time, baseline total cholesterol level, triglyceride level, and anticholesterol medications. %%Model included group, time, group-by-time interaction, baseline total cholesterol level, triglyceride level, and anticholesterol medications. ^Model included baseline HDL level and triglyceride level. ^^Model included group, time, group-by-time interaction, baseline HDL level, and triglyceride level. &Model included group, time, baseline LDL level, triglyceride level, and anticholesterol medications. &&Model included group, time, group-by-time interaction, baseline LDL level, triglyceride level, and anticholesterol medications. +Model included group, time, and baseline weight. ++Model included group, time, group-by-time interaction, and baseline weight. =Model included group, time, baseline systolic blood pressure, total cholesterol level, and antihypertension medications. ==Model included group, time, group-by-time interaction, baseline systolic hypertension, total cholesterol level, and antihypertension medications.

intervention that took into account language preferences and socioeconomic circumstances while tailoring the intervention to individual participants. CHWs proved to be essential not only for delivering education on topics directly relevant to T2D self-management but also for providing care coordination and social support services to patients. Thus, CHWs filled huge vacuums of needs that are currently not being addressed by healthcare, public care, and social assistance systems surrounding the target community. The Affordable Care Act may represent an opportunity to formalize the role of CHWs as part of T2D healthcare management teams. CHW models should take into account needed service intensity of highly impoverished populations.

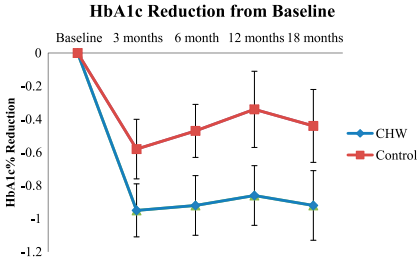

Figure 2—Participant HbA_{1c} percent decline compared with baseline. Net reduction difference in HbA_{1c} between CHW and control groups at 3, 6, 12, and 18 months were −0.42% ($P = 0.043$), −0.47% ($P = 0.050$), −0.57% ($P = 0.021$), and −0.55% ($P = 0.009$), respectively. Mean differences and *P* values are from adjusted LMEs.

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