Effectiveness of a Community Health Worker Intervention Among African American and Latino Adults With Type 2 Diabetes: A Randomized Controlled Trial

Michael S. Spencer, PhD, MSSW, Ann-Marie Rosland, MD, MS, Edith C. Kieffer, PhD, MPH, Brandy R. Sinco, MS, Melissa Valerio, PhD, MPH, Gloria Palmisano, MA, Michael Anderson, BA, J. Ricardo Guzman, MSW, MPH, and Michele Heisler, MD, MPA

African American and Latino adults experience a 50% to 100% higher burden of illness and mortality as a result of type 2 diabetes than do White Americans.[1-5] Both African American and Latino adults with diabetes have worse glycemic control and report experiencing more barriers to diabetes self-management than do non-Latino White adults.[6-9] Community health worker (CHW) interventions have demonstrated promise in improving health behaviors and outcomes, particularly for racial and ethnic minority communities and those who have traditionally lacked access to adequate health care.[10-17] CHW interventions enlist and train community members who work as bridges between their ethnic, cultural, or geographic communities and health care providers to promote health.[18-20] In chronic disease care, CHWs often educate patients, identify resources, provide case management, coordinate care in partnership with the health care system, and become part of the individual's support network.[16]

Although initial results from CHW programs are encouraging,[11,12,16] many have had methodological limitations, including lack of grounding in behavioral theory and inadequately rigorous evaluation.[11,16,20] In particular, as noted in a recent Cochrane review of evaluations of CHW programs,[21] most have not used a randomized controlled trial design and thus have not adequately addressed potential threats to their external validity, such as selection bias and unmeasured differences between intervention and control groups. Moreover, in most prior evaluations of diabetes self-management interventions targeting underserved populations, the participating communities were not actively involved in identifying needs or in developing, implementing, and evaluating the interventions, which may have limited their effectiveness and potential sustainability.

Objectives. We tested the effectiveness of a culturally tailored, behavioral theory–based community health worker intervention for improving glycemic control.

Methods. We used a randomized, 6-month delayed control group design among 164 African American and Latino adult participants recruited from 2 health systems in Detroit, Michigan. Our study was guided by the principles of community-based participatory research. Hemoglobin A1c (HbA1c) level was the primary outcome measure. Using an empowerment-based approach, community health workers provided participants with diabetes self-management education and regular home visits, and accompanied them to a clinic visit during the 6-month intervention period.

Results. Participants in the intervention group had a mean HbA1c value of 8.6% at baseline, which improved to a value of 7.8% at 6 months, for an adjusted change of -0.8 percentage points (*P*<.01). There was no change in mean HbA1c among the control group (8.5%). Intervention participants also had significantly greater improvements in self-reported diabetes understanding compared with the control group.

Conclusions. This study contributes to the growing evidence for the effectiveness of community health workers and their role in multidisciplinary teams engaged in culturally appropriate health care delivery. (*Am J Public Health.* 2011; 101:2253–2260. doi:10.2105/AJPH.2010.300106)

The intervention that we describe sought to address these deficiencies. The current intervention is among several diabetes interventions conducted since 2000 by the REACH Detroit Partnership, as part of the Centers for Disease Control and Prevention (CDC)-funded Racial and Ethnic Approaches to Community Health (REACH) Initiative. Using community-based participatory research (CBPR) principles,[22-26] community, health system, and academic partners completed a 1-year planning process to develop interventions to improve diabetes prevention and treatment in the participating communities.[27] Using a socioecological model, family, health system, and community-level interventions were developed to address sources of diabetes disparities at each level.[12,27,28] CHWs were central to each intervention. Interventions were grounded in empowerment theory, which emphasizes

a collaborative approach to facilitating the self-directed behavior change of patients.[29-36] The empowerment philosophy includes self-determination and autonomy motivation theory, which postulates that an individual will be more successful in a disease-management plan if that individual's goals, objectives, and resources guide the development of that plan.[37-39] Empowerment-based approaches have been found to be effective in improving chronic disease self-management among racial and ethnic minority patients.[29-36]

To date, we have completed 2 cohorts of the study intervention. Our first cohort included 180 African American and Latino participants who received CHW services and were compared with a historical control. Participants in that study had improved hemoglobin A1c (HbA1c) values compared with the control group at 6 months follow-up.[12] These encouraging

findings led to the approval by our community partners of the 6-month randomized controlled trial design used in the current study. We report the results of a randomized controlled trial that tested whether a culturally tailored CHW intervention for diabetes self-management improved HbA1c levels, blood pressure, lipid levels, diabetes knowledge, diabetes self-management behavior, and diabetes-related distress more than usual care among low-income, inner-city African Americans and Latinos with diabetes.

METHODS

We randomized African American and Latino participants with diabetes into a CHW intervention group or a control group in which the CHW intervention was delayed for 6 months. All participants in the study, whether in the intervention or control group, received information on, and had access to, REACH Detroit community activities that provided free, publicly available healthy eating demonstrations, physical fitness activity (e.g., dance and exercise classes, walking clubs), and a weekly community farmers' produce market. All participants also received health care at facilities in which health care providers were trained by REACH Detroit in culturally competent diabetes care through our health systems intervention.

Setting

All participants lived in either southwest Detroit, where residents were predominantly Latino of Mexican origin (70%) and had an annual median household income of $11 500, or eastside Detroit, which is largely African American (80%) with a median household income of $25 020.[40] Participants from southwest Detroit received medical care at a federally qualified community health center, whereas participants from eastside Detroit received medical care at a major local health system.
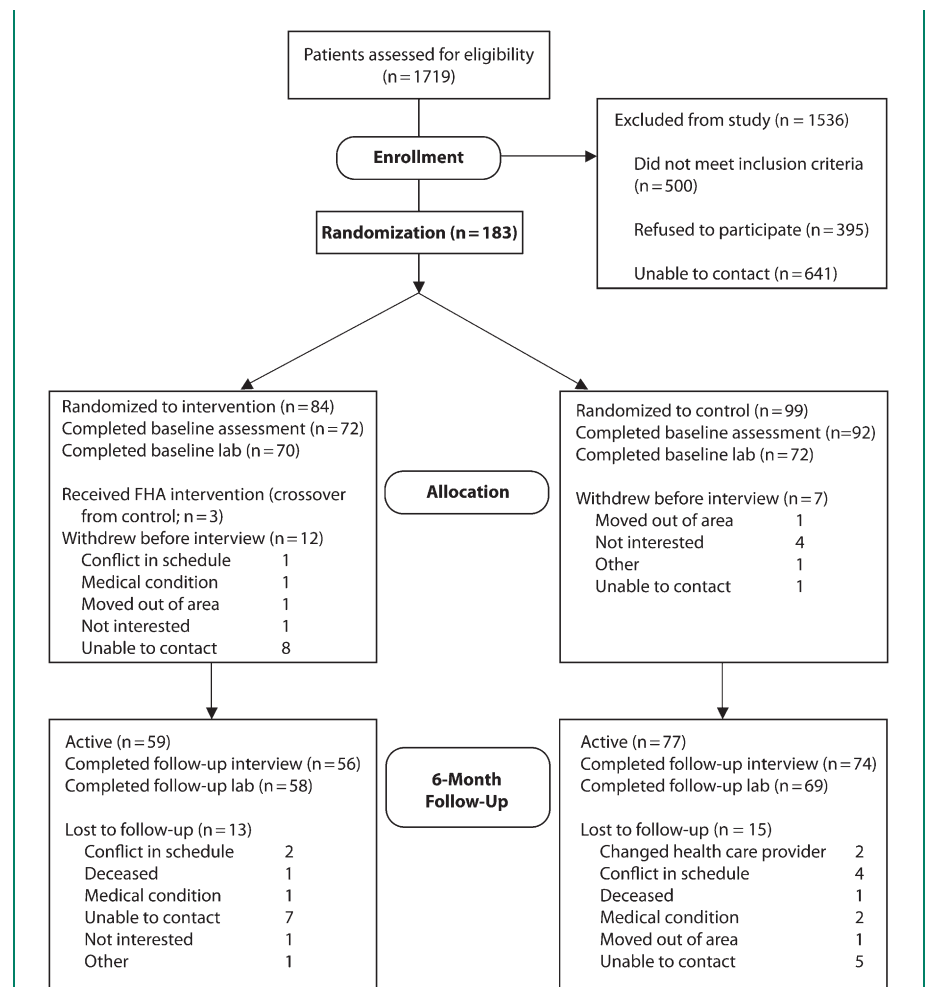
Participants

Through medical records we identified eligible participants who were at least 18 years of age, had physician-diagnosed type 2 diabetes, self-identified as African American or Latino/Hispanic, and lived in targeted zip codes. We excluded individuals who already had serious

diabetes-related complications, such as blindness, amputated limbs, or kidney failure. We recruited participants from September 2004 to July 2006. Participants were stratified by race/ethnicity and health care site during randomization to ensure that these variables were equally distributed across the 2 arms of the intervention. To account for possible attrition due to our delayed design, we assigned 45% of participants to treatment and 55% to control. Participants assigned to the control group were aware of the randomized structure of the study and were informed that they would receive the intervention after the 6-month control period. Because of the nature of the study design, CHWs and interviewers were not

blinded to the group assignment of the participants; however, data analysts were blinded.

Of 1719 potentially eligible patients, 29% did not meet eligibility criteria, 23% refused to participate, and 37% could not be contacted (Figure 1). Of 183 randomized participants, 164 completed the baseline interview. At the 6-month follow-up, 136 participants completed the study protocols and were analyzed for the primary outcome (attrition rate=17.7%). Because of severe medical conditions, 3 participants assigned to the control group received the CHW intervention; however, following intention-to-treat principles, these participants remain assigned to the control group in our analyses. Withdrawal from the study was not

FIGURE 1—Study participant flow diagram of enrollment and loss to follow-up: REACH Detroit, 2004–2006.

independently associated with treatment arm, age, gender, education, diabetes duration, baseline HbA1c, low-density lipoprotein (LDL) cholesterol, or blood pressure. However, African American participants were more likely to withdraw from the study and to be missing HbA1c data than were Latino participants. In addition, race/ethnicity was nested within treatment site; we therefore included an indicator of race/ethnicity and site as a covariate in the outcomes models.

Intervention

Trained CHWs, known in this study as family health advocates, promoted healthy lifestyle and diabetes self-management activities. We recruited the family health advocates from the 2 participating communities, where they were ethnically matched with their assigned participants, underwent more than 80 hours of training, and conducted 3 primary activities: (1) diabetes education classes, (2) 2 home visits of about 60 minutes each in length per month to address participants' specific self-management goals, and (3) 1 clinic visit with the participant and his or her primary care provider. The diabetes education classes were culturally tailored group classes in both English and Spanish. Eleven 2-hour group sessions of 8 to 10 participants were held every 2 weeks at community locations. The development, implementation, and evaluation of these curricula are described in depth elsewhere.[12,28] In home visits, family health advocates assisted participants in setting patient-specific goals and supporting their progress. In addition, family health advocates helped participants improve their patient–provider communication skills and facilitated necessary referrals to other service systems. Family health advocates also contacted intervention participants by phone once every 2 weeks. Participants in the control group were contacted once per month to update contact information.

Family health advocates were trained in empowerment-based approaches to inform their approach to each component on the intervention.[31,32] For example, they received training in approaches based on motivational interviewing, which is used to elicit participants' goals and help participants formulate their own action plans. They also used empowerment theory in the diabetes education classes by

eliciting participants' experiences and requests for information to be provided during the sessions.

Outcome Measures

We abstracted physiological measures of HbA1c, LDL cholesterol, and blood pressure from medical records. When these measures were not available at baseline or 6 months, we selected the closest values in time. On average, laboratory tests were performed 0.3 months after the baseline interview (range=5.7 months before to 2.5 months after interview) and, for the 6-month follow-up, 7 months after the baseline interview (range=3.7–9.5 months after interview). The time between the 2 sets of laboratory tests was always greater than 3 months. We obtained all other measures from a survey conducted in person, in either English or Spanish.

We measured self-management knowledge by participants' response to the validated question "How well do you understand how to manage your diabetes?"[41] and the following 2 items: "I agree that what one eats effects blood sugar control" and "Exercise helps to control blood sugar."[42] We measured diabetes self-management by 5 questions from the Summary of Diabetes Self-Care Activities scale[43] on adherence to a healthy eating plan, glucose testing, medication taking, foot checks, and shoe inspections. We measured diabetes-specific psychological distress by the validated Problem Areas in Diabetes scale.[44–46] We measured diabetes self-efficacy, one estimate of participant empowerment, with the Perceived Competence for Diabetes scale.[47]

We assessed physical activity and dietary practices through questions from the CDC's Behavioral Risk Factor Surveillance System.[48] We report the percentage of participants who engaged in moderate levels of physical activity 30 minutes per day at least 5 days per week, meeting American Diabetes Association recommendations for physical activity. Specific dietary measures included servings per day of fruits and vegetables, consumption of 2 or more servings per week of fried or fatty foods, and consumption of 2 or more servings per week of soda pop or fruit-flavored drinks.

We assessed the demographic variables gender, age, education, and race/ethnicity. Because 97% of the Latinos spoke Spanish as their primary language, respondents' primary

language was not included in the analyses for Latinos. Health status variables assessed at baseline were self-reported medication regimen and number of years since diabetes diagnosis.

Analysis

We compared baseline characteristics between the intervention and control groups with the Student t test for continuous variables and the Pearson χ^2 test for categorical variables. Skewed linear variables were log transformed. To adjust for repeated measures, we evaluated intervention effects on outcomes using linear mixed models for continuous variables and generalized estimating equations for dichotomous variables. We analyzed participant data as part of their original random group assignment, following intention-to-treat principles. For each analysis, we included all available participant data for the particular outcome at baseline and at 6 months. Both linear mixed models and generalized estimating equations use all available data at particular time points for estimates.[49–52] We used SAS version 9.2 (SAS Institute, Cary, NC) for all analyses. Because we were missing data for some participants' HbA1c values, we conducted a second analysis that imputed missing data.[53,54] Our results in these analyses were unchanged, so we report the unimputed analyses.

RESULTS

Table 1 presents the baseline characteristics for each group. Because age significantly differed by treatment group, it is included as a covariate in outcomes analyses. Because gender was associated with HbA1c at outcome (data not shown), it is also included as a covariate. Among those completing the baseline assessment, 86.1% attended at least 1 intervention class and 54.2% attended all 11 classes. The mean number of classes attended was 8.1 (SD=4.2).

Figure 2 shows the unadjusted mean change in HbA1c values from baseline to 6-month follow-up, which shows a -0.99 intervention effect ($P<.01$). Table 2 reports the results of linear mixed models of changes in physiological measures in each group, adjusted for age, race/ethnicity and site, and gender. Results of unadjusted and adjusted analyses did not significantly differ between groups or over time.

TABLE 1—Baseline Participant Characteristics: REACH Detroit, 2004–2006

	Intervention Group (n = 72)	Control Group (n = 92)	P
Latino adults, no. (%)	34 (47)	36 (39)	.3[a]
African American adults, no. (%)	38 (53)	56 (61)	
Spanish primary language,[b] no./total no. (%)	32/34 (94)	35/36 (97)	.6[c]
Women, no. (%)	54 (75)	62 (67)	.29[a]
Age, y mean (95% CI)	50 (47, 52)	55 (53, 57)	.02[d]
High school graduate, no. (%)	43 (60)	54 (59)	.89[a]
BMI,[e] kg/m², mean (95% CI)	34 (32, 36)	35 (33, 37)	.64[e]
Diabetes duration,[c] y, mean (95% CI)	8 (6, 9)	9 (7, 11)	.7[e]
Hemoglobin A1c level,[c] % (95% CI)	8.6 (8.0, 9.1)	8.5 (8.0, 8.9)	.88[e]
Self-efficacy score,[f] mean (95% CI)	72.7 (69.2, 76.2)	64.6 (61.1, 68.1)	.03[d]
Taking diabetes medications, no. (%)			.73[a]
No medications	8 (11)	7 (8)	
Oral medications only	43 (61)	57 (63)	
Insulin	19 (27)	26 (29)	

Note. BMI = body mass index; CI = confidence interval. Intervention group received treatment after baseline interview; control received treatment 6 months after baseline interview.
[a]Pearson χ^2 test.
[b]Only applicable to Latinos (n = 70).
[c]Fisher's exact test.
[d]Student *t* test.
[e]Student *t* test on log transform; untransformed mean and confidence interval displayed.
[f]Perceived Competence for Diabetes scale.[47] The scale is based on 4 questions on a 1-5 Likert scale to assess the client's confidence in carrying out the management of type 2 diabetes. The 0-100 score is computed by subtracting 1 from each response and by multiplying the average response to the 4 questions by 25.

Adjusted mean HbA1c level was 8.6% at baseline in the intervention group; this level improved to 7.8% at 6 months, for a change of -0.8 percentage points (*P*<.01). Change in HbA1c level for the control group was not significant (mean = 8.5% at baseline and 6-month follow-up). The difference in the change in HbA1c level between the 2 groups was -0.8%. Intervention group participants' LDL cholesterol level also improved significantly from baseline to 6-month follow-up (mean = 105 mg/dL at baseline and 95 mg/dL at 6-month follow-up; *P*<.05 within group). The difference in change in LDL level between the 2 groups was not significant. Changes in blood pressure were not significant.

Table 3 presents the results of linear mixed models of age, race/ethnicity and site, and gender-adjusted changes in self-management knowledge and behavioral variables from baseline to 6-month follow-up. Responses to all 3 self-reported self-management knowledge questions showed statistically significant differences within the intervention group (*P*<.01

for each), as well as significant differences between the intervention and the control groups (*P*<.05 between groups for each).

Both the intervention and the control groups demonstrated a statistically significant increase in meeting guidelines for physical activity: from 37% to 53% for the intervention group (*P*<.05) and from 32% to 53% for the control group (*P*<.01). However, there was no significant difference in change in physical activity between the groups. Although the daily servings of fruits and vegetables increased by close to half a serving for both groups, the increase was statistically significant for the control group (*P*<.05) but not for the intervention group. Changes in the consumption of fried or fatty foods and soda pop or fruit-flavored drinks were not statistically significant. Participants within the intervention group significantly improved adherence to inspecting the inside of their shoes every day at the 6-month follow-up (49%-77%; *P*<.01), and also improved significantly compared with the control group (*P*<.01).

The intervention group significantly improved in adherence to testing blood sugar as recommended (from 74% to 87%; *P*<.05), but there was no significant difference between groups. The control group significantly improved adherence to daily diabetes medications between baseline (88%) and 6-month follow-up (96%; *P*<.01). Mean diabetes-specific psychological distress improved for the intervention group (3.2 mean decrease from baseline to 6-month follow-up); however, this change was not statistically significant. Finally, there were no significant changes or between-group differences in mean diabetes self-efficacy. No adverse effects were noted among participants as a result of the intervention.

DISCUSSION

In this randomized controlled trial of 164 African American and Latino adults with type 2 diabetes, the average decrease in HbA1c levels from baseline to 6-month follow-up was 0.8% greater for the CHW intervention group than for the delayed-intervention control group. This significant difference provides both statistical and clinical[55] evidence for the effectiveness of the intervention in improving glycemic control in a low-income, underserved population. We have contributed to the growing
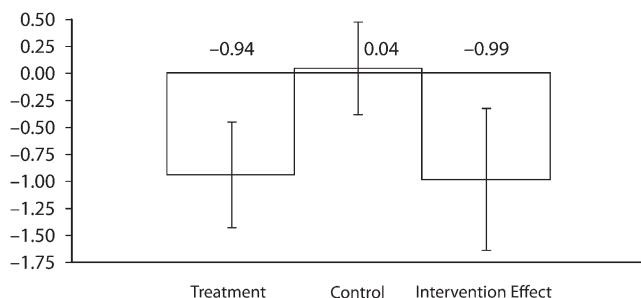

FIGURE 2—Unadjusted decreases in hemoglobin A1c levels from baseline to 6-month follow-up, by intervention arm with 95% confidence intervals: REACH Detroit, 2004–2006.

TABLE 2—Changes in Physical Measurements of Study Participants From Baseline to 6-Month Follow-Up: REACH Detroit, 2004–2006

	Intervention Group				Control Group				
	Baseline	6 Months	Change	No.[a]	Baseline	6 Months	Change	No.[a]	Intervention Effect
Mean HbA1c, % (95% CI)	8.6 (8.1, 9.2)	7.8 (7.3, 8.3)	−0.8** (−1.2, −0.4)	56	8.5 (8.0, 9.1)	8.5 (8.0, 9.1)	0.0 (−0.4, 0.4)	57	−9.7** (−15.9, −3.0)
Mean LDL, mg/dL (95% CI)	105 (95, 115)	95 (86, 104)	−10* (−17, −2)	51	112 (103, 122)	108 (99, 118)	−4 (−12, 4)	55	−5.8 (−15.6, 5.1)
Mean SBP, mm Hg (95% CI)	131 (127, 134)	129 (125, 133)	−2 (−6, 2)	54	130 (127, 133)	127 (124, 130)	−3 (−6, (1)	65	1.0 (−3.1, 5.1)
Mean DBP, mm Hg (95% CI)	77 (74, 80)	77 (74, 79)	0 (−3, 3)	54	77 (74, 79)	75 (72, 77)	−2 (−5, 1)	65	2.2 (−3.1, 7.9)
Mean BMI, kg/m^2 (95% CI)	32.7 (30.8, 34.6)	33.0 (31.1, 35.0)	0.3 (−0.4, 1.1)	52	34.1 (32.4, 35.9)	33.7 (32.0, 35.6)	−0.4 (−1.1, 0.3)	65	2.1 (−1.0, 5.3)

Note. BMI = body mass index; DBP = diastolic blood pressure; HbA1c = hemoglobin A1c; LDL = low-density lipoprotein cholesterol; SBP = systolic blood pressure. Reported data are mean values adjusted for age, gender, race/ethnicity, and site. Estimates and *P* values are from repeated measures models with log transforms. The estimates of change within the intervention and control arms were computed by inverting the log transformed results. The intervention effect estimates are for percent change between intervention and control groups.
[a]Number with complete data at baseline and 6-month follow-up.
*P < .05; **P < .01.

body of literature that suggests that CHWs can have a positive impact on improving racial and ethnic minority participants' health status (particularly HbA1c levels),[56,57] self-reported diabetes knowledge and education,[58,59] and some self-care behaviors.[59,60] A unique strength of our study is the use of CHWs who were trained in empowerment approaches to promote the self-management of diabetes in their own communities. Additionally, our study joins the small group of rigorous CHW studies that have compared the health outcomes of those receiving CHW services and those receiving usual health care,[11,21,60] and it has important implications for further integrating CHWs as an important part of multidisciplinary teams in health care systems.

Our findings support our main hypothesis that the intervention would significantly improve HbA1c levels in the intervention group compared with the control group. When we examined study outcomes in self-management knowledge and behaviors, several possible mechanisms for the intervention effect on HbA1c emerged. Most notable were significant improvements in self-reported knowledge about diabetes self-management and physical activity in the intervention group. The intervention group also showed improvements in healthy eating; however, these changes were not statistically significant. These findings could be a result of sample size limitations in the study. The sample size in the control group (n=92) was 28% larger than that of the intervention group (n=72), so some within-group change might be significant in the control group but not in the intervention group. For example, the magnitude of the average increase in fruit and vegetable servings was similar between the 2 groups (0.6

in the control group vs 0.5 in the intervention group), even though this increase was statistically significant only for the larger control group. Also, the overall limited sample size could have led to false negatives in between-group comparisons. In addition, from baseline to 6-month follow-up, the intervention group reduced consumption of fried or fatty foods (from 37.7% to 21.7% mean decrease) and of soda pop or fruit-flavored drinks (from 23.3% to 12.4%), and mean consumption of these unhealthy foods was only slightly changed in the control group.

These qualitatively significant differences in intervention group eating habits may have contributed to reductions in HbA1c levels, even though the between-group differences were not statistically significant. Another statistical concern is the high rate of reported medication adherence in the intervention group at baseline (89%), which may have led to limited ability to detect a statistically significant improvement. Comprehensive exploration of possible mechanisms for the intervention's effect will be an important area for future investigation. In addition, it will be important to assess potential moderators of intervention effects such as baseline literacy levels, as well as the possible dose–response effect of the intervention classes and family health advocate contacts. Because these exposures were not randomly assigned, however, their relationship with outcomes is likely to be confounded by patients' need for assistance as well as intrinsic motivation for improving their diabetes self-care.

The control group also made significant improvements in fruit and vegetable consumption, physical activity, and medication adherence during the study. These improvements may

have been due to the communitywide healthy eating and physical activity programs available to and promoted among both groups as part of REACH Detroit's community-level programs. In addition, all participants' health care providers were invited to participate in diabetes continuing medical education courses sponsored by REACH Detroit. REACH Detroit's goal is to reduce barriers to healthy lifestyles and self-management in under-resourced communities, beyond individual- and family-level behavior change. Withholding community resources and continuing education for providers of the control group may have improved our ability to detect differences between groups. However, community input through our CBPR process supported our decision to keep community resources and provider education available to all, holding firm to our commitment to a comprehensive approach to reducing diabetes health disparities.

Our findings also confirm the feasibility of conducting rigorous research in disempowered communities using CBPR principles and methods. A CBPR approach affects health disparities in underserved communities in at least 3 ways: through building capacity, through focusing attention on social justice, and through sharing of power and resources.[22–26] Our process of developing, implementing, and evaluating the intervention adhered to the principle of partnership on which CBPR is based—that better understanding of the nature and consequences of the disparities, and of how they might be solved, depends on insight from those affected by them. The rigor of the methods we pursued further reinforces the view that it is possible to follow

TABLE 3—Study Participants' Changes in Knowledge of Diabetes and in Behavioral Variables From Baseline to 6-Month Follow-Up: REACH Detroit, 2004–2006

	Intervention (n = 72)				Control (n = 92)				Intervention Effect
	Baseline	6 Months	Change	No.[a]	Baseline	6 Months	Change	No.[a]	
Knowledge									
Self-management score,[b] mean (95% CI)	3.3 (3.1, 3.6)	4.0 (3.7, 4.3)	0.7** (0.4, 1.0)	56	3.3 (3.0, 3.5)	3.3 (3.1, 3.6)	0.1 (−0.2, 0.3)	74	0.6** (0.2, 1.0)
What you eat affects blood sugar,[c] % (95% CI) or (OR; 95% CI)	80.5 (67.7, 89.1)	98.3 (87.4, 99.8)	(13.8**; 2.0, 94.7)	55	80.0 (69.3, 87.6)	82.8 (72.2, 90.0)	(1.2; 0.6, 2.6)	74	(11.4*; 1.4, 90.4)
Exercise helps control blood sugar,[d] % (95% CI) or (OR; 95% CI)	54.9 (42.3, 67.0)	83.0 (70.1, 91.0)	(4.0**; 1.9, 8.6)	52	44.6 (33.5, 56.2)	42.8 (30.9, 55.7)	(0.9; 0.5, 1.6)	71	(4.3**; 1.7, 10.9)
Diet and exercise									
Meeting physical activity guidelines,[e] % (95% CI) or (OR; 95% CI)	36.6 (25.2, 49.7)	52.9 (38.2, 67.1)	(1.9*; 1.02, 3.7)	55	31.7 (22.4, 42.8)	52.8 (40.8, 64.4)	(2.4**; 1.3, 4.3)	72	(0.8; 0.3, 1.9)
Daily fruit and vegetable servings, mean (95% CI)	4.3 (3.8, 4.9)	4.9 (4.3, 5.4)	0.5 (0.0, 1.1)	56	3.6 (3.2, 4.1)	4.2 (3.7, 4.7)	0.6* (0.1, 1.1)	73	0.0 (−0.8, 0.7)
Fried, fatty foods ≥2/wk, % (95% CI) or (OR; 95% CI)	37.7 (25.8, 51.2)	21.7 (12.3, 35.4)	(0.5; 0.19, 1.1)	56	52.4 (40.1, 64.5)	47.8 (34.9, 61.0)	(0.8; 0.5, 1.5)	73	(0.6; 0.2, 1.6)
Soda pop or fruit-flavored drinks ≥2/wk, % (95% CI) or (OR; 95% CI)	23.3 (14.1, 36.1)	12.4 (5.7, 25.1)	(0.5; 0.17, 1.3)	56	37.8 (27.9, 48.8)	37.8 (27.1, 50.0)	(1.0; 0.6, 1.6)	74	(0.5; 0.2, 1.4)
Diabetes self-management[f]									
Take recommended insulin dose or pills every day, % (95% CI) or (OR; 95% CI)	88.8 (77.1, 94.9)	89.6 (78.6, 95.3)	(1.1; 0.53, 2.2)	52	88.0 (78.6, 93.6)	96.2 (90.5, 98.6)	(3.5**; 1.4, 8.8)	70	(0.3; 0.1, 1.0)
Follow healthful eating plan every day, % (95% CI) or (OR; 95% CI)	41.3 (29.1, 54.7)	43.1 (29.4, 58.0)	(1.1; 0.57, 2.0)	54	37.3 (26.9, 48.9)	27.7 (18.3, 39.7)	(0.6; 0.4, 1.1)	72	(1.7; 0.7, 3.9)
Test blood sugar as recommended once/wk, % (95% CI) or (OR; 95% CI)	73.6 (61.0, 83.2)	86.7 (74.3, 93.6)	(2.3*; 1.1, 5.0)	56	70.5 (59.6, 79.5)	78.0 (66.8, 86.2)	(1.5; 0.8, 2.6)	74	(1.6; 0.6, 4.0)
Check feet every day, % (95% CI) or (OR; 95% CI)	80.2 (68.3, 88.4)	86.9 (75.1, 93.6)	(1.6; 0.7, 3.9)	56	75.3 (65.1, 83.3)	67.1 (55.2, 77.1)	(0.7; 0.4, 1.1)	73	(2.5; 0.9, 6.7)
Inspect inside of shoes every day, % (95% CI) or (OR; 95% CI)	49.1 (36.1, 62.2)	76.7 (62.9, 86.5)	(3.4**; 1.7, 6.8)	56	43.8 (33.2, 55.0)	44.5 (33.0, 56.7)	(1.0; 0.6, 1.7)	72	(3.3**; 1.4, 7.9)
Psychological									
Problem Areas in Diabetes (PAID) scale score,[g,h] mean (95% CI)	11.9 (8.5, 16.6)	8.7 (6.0, 12.4)	−3.2 (−5.6, 0.1)	56	13.8 (10.2, 18.5)	12.9 (9.4, 17.6)	−0.9 (−4.0, 3.2)	74	−21.9% (−49.0, 19.4)
Perceived Competence for Diabetes scale (range = 0–100),[i] Self-efficacy score, mean (95% CI)	74.9 (69.8, 80.1)	78.3 (72.6, 83.9)	3.3 (−2.7, 9.3)	56	65.5 (60.9, 70.0)	70.7 (65.7, 75.7)	5.2 (0.0, 10.4)	74	−1.9 (−9.9, 6.1)

Note. CI = confidence interval; OR = odds ratio. Data are adjusted for age, gender, race/ethnicity, and site. Estimates and *P* values are from repeated measures models.

[a] Number with complete data at baseline and 6-month follow-up.

[b] Determined by answer to the question, "How well do you understand how to manage your diabetes?" (1–5; 1 = not at all; 5 = very well).[41]

[c] Percentage who "Strongly agree that what you eat will make a big difference in your ability to control blood sugar levels."

[d] From Outcome Expectations for Exercise Scale.[42] The % and ORs denote clients who strongly agree that exercise helps to control blood sugar.

[e] Moderate activity at least 30 minutes a day and 5 days a week or vigorous activity at least 20 minutes a day and 3 days a week.[48]

[f] Summary of Diabetes Self-Care Activities Measure.[43] Clients who reported practicing the various self-management behaviors every day are represented in the various percentages and odds ratios. For example, if a client reported checking his/her feet every day, s/he would be included in the % or OR for that outcome; anything less than every day would be coded as "No."

[g] Estimates from log transform. The estimates of change within the intervention and control arms were computed by inverting the log transformed results. The intervention effect estimates are for percentage change, intervention compared with control.

[h] Problem Areas in Diabetes scale (20 items; 0 = not a problem to 4 = serious problem; Cronbach α = 0.94).[44,45]

[i] Perceived Competence for Diabetes scale (range = 0–100).[47]

*P < .05; **P < .01.

CBPR principles while meeting the highest standards of scientific, randomized controlled trials.[61]

Limitations

Several limitations should be noted in interpreting our findings. First, our modest sample size may have limited our power to detect significant differences other than in HbA1c levels. Second, we used medical chart reviews to obtain our clinical measures, and the lab tests did not always correspond precisely with our baseline and 6-month interview dates. However, we used only clinical measures that were taken within 3 months of baseline and 2 months of the 6-month assessment dates, which would have had less of an effect on HbA1c data but could have affected other outcomes, such as LDL or blood pressure. Finally, self-reported data also were used for all behavioral measures, possibly resulting in socially desirable responses.

Besides the significant improvement in HbA1c levels in the intervention group compared with the control group, our study demonstrates several accomplishments. First, we have developed an effective CHW diabetes management model that future research can build on, using CBPR principles and methods. Second, we further developed diabetes self-management educational curricula and materials that are culturally and linguistically tailored and replicable and that are rooted in an empowerment-based approach. Finally, we demonstrated the feasibility of conducting a randomized controlled intervention with 2 underrepresented racial/ethnic communities that is attentive to the historical distrust of research by racial/ethnic groups, but rigorous in its consideration of design and methods.

Practice and Policy Implications

A major aim of our study was to provide evidence for the effectiveness of CHWs and their role as members of multidisciplinary teams engaged in culturally appropriate health and social services delivery. Through this evidence, we hope to promote the development and expansion of CHW programs in the United States. However, major challenges need to be addressed before these programs will be more widely accepted throughout the various health sectors, including inadequate and unstable funding and the low value often placed on CHW work, which impedes their recognition as legitimate providers.[62-66] The task of addressing these challenges can be accomplished through further research on CHW effectiveness and continued advocacy by health care providers. Our study represents a major step toward demonstrating such effectiveness and can be used in state and national advocacy efforts aimed at increasing public and private funds for supporting programs using CHWs and other lay health workers. As the widening gap in health and social disparities continues to challenge our nation and its strained systems of care, our study lends evidence that CHW interventions provide one possible solution to meeting the needs of disenfranchised communities and are ready and natural allies for health care providers who share the common goals of social equality and culturally appropriate care. ∎

About the Authors

Michael S. Spencer, Edith C. Kieffer, and Brandy R. Sinco are with the School of Social Work; Ann-Marie Rosland is with the Department of Internal Medicine; and Melissa Valerio is with the School of Public Health, University of Michigan, Ann Arbor. Gloria Palmisano, Michael Anderson, and J. Ricardo Guzman are with Community Health and Social Services (CHASS) and the REACH Detroit Partnership, Detroit, MI. Michele Heisler is with the VA Center for Clinical Management Research, Ann Arbor.

Correspondence should be sent to Michael S. Spencer, University of Michigan, School of Social Work, 1080 S University Ave, Ann Arbor, MI 48109-1106 (e-mail: spencerm@umich.edu). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints/Eprints" link.

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Contributors

M.S. Spencer conceptualized the study and supervised all aspects of its implementation. A. Rosland contributed to the conceptualization of the study and the writing of all sections of the article. E.C. Kieffer assisted with the conceptualization of the project and contributed to the writing. B.R. Sinco conducted the analyses and contributed to the writing of the Methods and Results sections. M. Valerio contributed to the conceptualization of the project and the interpretation of the findings. G. Palmisano, M. Anderson, and J.R. Guzman are community partners who contributed to the conceptualization of the project, its implementation, and the interpretation of the findings. M. Heisler contributed to the conceptualization of the project and to the writing of all sections of the article. All authors contributed to reviewing drafts of the article.

Human Participant Protection

The research was approved by the University of Michigan Health Sciences institutional review board.

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