Results of the Northern Manhattan Diabetes Community Outreach Project: A Randomized Trial Studying a Community Health Worker Intervention to Improve Diabetes Care in Hispanic Adults

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OBJECTIVE

The Northern Manhattan Diabetes Community Outreach Project evaluated whether a community health worker (CHW) intervention improved clinically relevant markers of diabetes care in adult Hispanics.

RESEARCH DESIGN AND METHODS

Participants were adult Hispanics, ages 35–70 years, with recent hemoglobin A_{1c} (A1C) ≥8% (≥64 mmol/mol), from a university-affiliated network of primary care practices in northern Manhattan (New York City, NY). They were randomized to a 12-month CHW intervention (*n* = 181), or enhanced usual care (educational materials mailed at 4-month intervals, preceded by phone calls, *n* = 179). The primary outcome was A1C at 12 months; the secondary outcomes were systolic blood pressure (SBP), diastolic blood pressure, and LDL-cholesterol levels.

RESULTS

There was a nonsignificant trend toward improvement in A1C levels in the intervention group (from unadjusted mean A1C of 8.77 to 8.40%), as compared with usual care (from 8.58 to 8.53%) (*P* = 0.131). There was also a nonsignificant trend toward an increase in SBP and LDL cholesterol in the intervention arm. Intervention fidelity, measured as the number of contacts in the intervention arm (visits, phone contacts, group support, and nutritional education), showed a borderline association with greater A1C reduction (*P* = 0.054). When assessed separately, phone contacts were associated with greater A1C reduction (*P* = 0.04).

CONCLUSIONS

The trend toward A1C reduction with the CHW intervention failed to achieve statistical significance. Greater intervention fidelity may achieve better glycemic control, and more accessible treatment models, such as phone-based interventions, may be more efficacious in socioeconomically disadvantaged populations.

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Hispanics (or Latinos) are now the largest minority group in the U.S.; they constitute 16.7% of the nation's population (1). The current diabetes epidemic is more severe in U.S. Hispanics, as compared with whites, both in its prevalence and the frequency of complications (2). Hispanics suffer from less access to care and poorer control of their diabetes (3,4). Therefore, there is a need for the development and validation of culturally appropriate models of care that maximize access and improve self-care in Hispanics with diabetes (5,6). Those models of care should be patient-centered and embrace the linguistic and cultural characteristics of U.S. Hispanic communities (7).

Community health workers (CHWs, known as *promotoras* or *promotores de salud* in Spanish) have been shown to be efficacious in improving health care delivery around the world, including Latin America and the U.S. (8). However, the value of CHW interventions to improve diabetes care in Hispanics remains unclear. There have been seven randomized clinical trials in U.S. minority populations assessing the efficacy of CHW interventions to improve glycemic control, as determined by a reduction in serum hemoglobin A_{1c} (A1C). Some of those trials reported a significant reduction in A1C through the CHW intervention (9–13), while others did not (14,15). However, they differed greatly in quality. Only three of them evaluated the intervention over at least 12 months (9,10,15), a major concern because shorter studies of chronic disease management may overestimate therapeutic benefit. Five studies did not report the use of allocation concealment during randomization (9–13,15), while another used a random numbers table (14). In regards to the outcome, one study did not perform a standardized A1C measurement (13), and another did not report the A1C measurement method (14). Two of the studies had high attrition rates, ~20–28% in the intervention arms and ~50% in the control arms (11,14). Importantly, one study did not compare one randomized arm to the other (11), while two additional studies did not report applying the intention-to-treat principle to the analysis (12,14).

We describe in this study the results of the Northern Manhattan Diabetes Community Outreach Project (NOCHOP), a randomized controlled trial testing the efficacy of a 12-month CHW intervention to improve the care of Hispanics with poorly controlled type 2 diabetes residing in northern Manhattan (16).

RESEARCH DESIGN AND METHODS

NOCHOP

Study design and methods were previously described in detail (16); thus, a brief description follows. NOCHOP is a community-based participatory research project. Two partner institutions from northern Manhattan, Alianza Dominicana, Inc., and Columbia University Medical Center (CUMC), designed and conducted the study in a collaborative manner, following the community-based participatory research principles of fairness and full partnership (17).

Study Participants

NOCHOP recruited 360 Hispanic participants with poorly controlled type 2 diabetes, aged 35–70 years, who were receiving care at one of several primary care practice sites affiliated with CUMC in northern Manhattan (18). Participants were classified as having poorly controlled diabetes if their last A1C measurement (performed in the preceding 12 months) was ≥8.0% (≥64 mmol/mol). Exclusion criteria were: *1*) type 1 diabetes and/or diabetes with onset before age 25 years; *2*) subjects who did not self-identify as Hispanic or Latino; *3*) any life-threatening or extreme medical comorbidity, such as an active cancer or end-stage cardiopulmonary disease; *4*) a diabetes diagnosis for <1 year; *5*) planning to move out of the neighborhood during the next year; *6*) enrollment in any other study; and *7*) arm circumference of >47 cm (due to inability to accurately measure blood pressure using an oscillometric device). All participants provided informed consent prior to enrollment; the study protocol was approved by the Institutional Review Board of CUMC. After providing informed consent, participants were remotely randomized using an SAS macro in a 1:1 ratio, within primary care provider (PCP) practice, to either intervention (CHW intervention) or enhanced usual care, both for a period of 12 months. Randomization was performed within a PCP practice to maximize the probability that participants followed by the same PCP were randomized in similar proportions to intervention or control and thus avoid confounding by PCP practice patterns. As an additional safeguard, the analytic model also included a term identifying the individual PCP, thereby adjusting for any postrandomization clustering effects—this is particularly useful when the number of participants randomized within PCP practices is rather small, as imbalances may occur. Concealed randomized allocation was performed by an operator, who was blinded to all participant characteristics except PCP practice, at the Hebrew Home for the Aged at Riverdale. The randomization algorithm accounted for both within-PCP practice randomization and rolling enrollment. The first participant was randomized on 19 November 2008.

NOCHOP Study Outcomes

The primary study outcome was glycemic control, measured by A1C. The secondary outcomes were systolic and diastolic blood pressure (SBP and DBP, respectively) and LDL-cholesterol levels. All samples were processed in batches, identified only by ad hoc numbers, to ensure blinding. Data were collected at two visits at CUMC, the baseline and the 1-year follow-up examinations. Subjects were instructed to come to examinations fasting and having held their diabetes medications, but taking their blood pressure medications. A1C was measured using a latex agglutination assay (Hitachi 912; Polymedco, Inc., Cortlandt Manor, NY). Cholesterol levels were measured using enzymatic colorimetric methods (Vitros; Johnson & Johnson, New Brunswick, NJ). LDL cholesterol was calculated using the Friedewald Equation (19). For subjects with a triglyceride level ≥300 mg/dL (≥3.39 mmol/L), LDL cholesterol was measured directly using a homogeneous assay (Polymedco, Inc.). Resting blood pressure was measured using a BpTRU automated oscillometric device

(Coquitlam, British Columbia, Canada). Three measurements were obtained following 5 min of rest. The average of the second and third measurements was recorded as the resting blood pressure. Questionnaire data were collected using a computer-assisted personal interviewing system in English and Spanish (20). Constructs measured through validated questionnaires included: medication adherence (21), dosage and intensity (22), physical activity (23), diet (24), and depression (25).

CHW Intervention

The intervention has been fully described elsewhere (16). Two full-time CHWs based at Alianza Dominicana, Inc. delivered a multicomponent intervention that included one-on-one visits, group visits, and telephone follow-up. Overall, the interaction with participants was guided by the CHWs using an adaptation of the Small Steps, Big Rewards framework, which was customized according to the needs of individual participants (26). In addition, the focus of the one-on-one visits was to assess existing barriers to health care (diabetes and nondiabetes), empowering the patient to overcome these barriers and then developing achievable goals for the upcoming year. A needs assessment was performed throughout the year, prompting referrals for social and support services, such as housing, and medical insurance assistance. The group visits focused mainly on nutrition education (including cooking classes) and exercise activities. The phone intervention served as a follow-up mechanism for adherence to the individualized plan and reinforcement; it also served as an alternative for participants who could not or preferred not to attend individual or group visits. The CHW intervention was highly flexible and tailored to each participant's needs and preferences, but the goal was to perform at least 4 one-on-one visits, 10 group sessions, and 10 follow-up phone calls per subject, over a 12-month period.

Enhanced Usual Care

Patients randomized to the control group receive usual care from their PCP. In addition, they received four sets of Spanish-language educational

Table 1—Baseline demographics of NOCHOP participants (n = 360)

	Control		Intervention	
Sex				
Male	67	37.4	71	39.2
Female	112	62.6	110	60.8
Total	179	100.0	181	100.0
Age				
≤65 years old	145	81.0	155	85.6
>65 years old	34	19.0	26	14.4
Total	179	100.0	181	100.0
Age, mean (SD) (years)	58.1	(7.8)	57.1	(7.7)
Race				
Hispanic	179	100.0	181	100.0
Total	179	100.0	181	100.0
Marital status				
Single/never married	27	15.1	35	19.3
Living with significant other	6	3.4	11	6.1
Married	60	33.5	56	30.9
Separated	26	14.5	26	14.4
Divorced	34	19.0	38	21.0
Widowed	25	14.0	12	6.6
Data missing	1	0.6	3	1.7
Total	179	100.0	181	100.0
Highest degree obtained				
None	159	88.8	151	83.4
Technical degree	2	1.1	0	0.0
High school diploma	3	1.7	8	4.4
AA (Associate's degree)	4	2.2	8	4.4
BA/BS/other Bachelor's	6	3.4	6	3.3
MA/MS/other Master's	1	0.6	0	0.0
Doctorate (PhD/MD/JD/other)	0	0.0	1	0.6
Data missing	4	2.2	7	3.9
Total	179	100.0	181	100.0
Education, mean (SD) (years)	8.4	(3.9)	8.5	(3.9)
Employment status				
Employed	34	19.0	31	17.1
Retired	26	14.5	27	14.9
Homemaker	5	2.8	2	1.1
On disability	85	47.5	79	43.6
Unemployed/not working	28	15.6	39	21.5
Data missing	1	0.6	3	1.7
Total	179	100.0	181	100.0
Yearly income				
<$3,000	13	7.3	26	14.4
$3,001–5,000	7	3.9	6	3.3
$5,001–10,000	73	40.8	72	39.8
$10,001–20,000	69	38.5	49	27.1
$20,001–30,000	8	4.5	20	11.0
$30,001–40,000	3	1.7	1	0.6
$40,001–50,000	2	1.1	2	1.1
$60,001–75,000	0	0.0	1	0.6
$75,001–100,000	0	0.0	1	0.6
Data missing	4	2.2	3	1.7
Total	179	100.0	181	100.0
A1C, mean (SD)				
%	8.6	(1.6)	8.8	(1.7)
mmol/mol	70	(17.5)	73	(18.6)
LDL cholesterol, mean (SD)				
mg/dL	95.8	(36.5)	97.6	(32.2)
mmol/L	2.47	(0.94)	2.52	(0.83)
SBP, mean (SD) (mmHg)	136.7	(17.1)	136.1	(18.6)
DBP, mean (SD) (mmHg)	80.8	(10.0)	81.1	(9.7)

Data are n %, unless otherwise indicated.

materials containing information on communication between physician and patient, diabetes management, mental health, and a diabetes cookbook. Control group participants also received quarterly phone calls, with the following goals: *1*) to ensure that participants had received the mailed brochures and that they found those brochures appropriate for their own literacy; and *2*) to maximize retention in the study.

Statistical Analysis

We estimated that 180 participants per arm would provide at least 80% power to detect an effect size (difference in mean A1C change between intervention and control participants) of 0.5 percentage points, adjusting for correlation within PCP practices, and for a participant attrition rate during follow-up as high as 30%, applying a conventional significance threshold of $P < 0.05$ (16). For all other analysis, including the three secondary outcomes (LDL cholesterol, DBP, and SBP), a prespecified significance threshold of $P < 0.01$ was applied.

Treatment effects were assessed taking into account both the correlation among repeated measures over time on the same subject and the possible correlation of treatment effects between patients seeing the same PCP (27). The outcomes were treated continuously, and assessed with a longitudinal mixed-effects model, using SAS PROC MIXED (SAS). Hypothesis testing was performed through the interaction term of (randomization group $\times$ time). That interaction term indicates whether there are significant differences in changes in the outcome between the randomization groups. To account for missing data at follow-up, the intention-to-treat analyses were repeated using multiple imputation sensitivity analyses (28). Sensitivity analyses examining dose of the intervention were conducted using a variable that was the sum of the number of visits (home and office), phone call contacts, and meetings (group and nutrition). We also assessed separately the effect the number of phone calls and in-person contact (visits plus meetings) had on A1C levels. Finally, to explore whether the therapeutic effect of the intervention differed in participants with optimal glycemic control at the time of randomization, we also stratified the analysis by baseline A1C levels (A1C <7 or $\geq 7\%$).

RESULTS

Of the 360 participants, 181 were randomized to intervention and 179 to the control arm. There were no clinically meaningful differences between the study groups at baseline (Table 1). After 12 months, 81.2% of the intervention participants and 87.7% of the control participants returned for the end-of-study examination visit (Fig. 1). An analysis of noncompleters ($n = 56$) as contrasted with completers ($n = 304$) showed no significant differences in the characteristics described for all study participants in Table 1 (data not shown, available upon request). Adherence to the intervention protocol varied greatly across participants. Overall, the median (interquartile range) number of meetings was as follows: 3 (4–2) one-on-one meetings, 0 (4–0) group sessions, and 10 (14–7.5) phone calls. However, 93 participants only received a phone-based intervention; they had 10 (14–7.5) phone calls. In regards to the control participants, we were not able

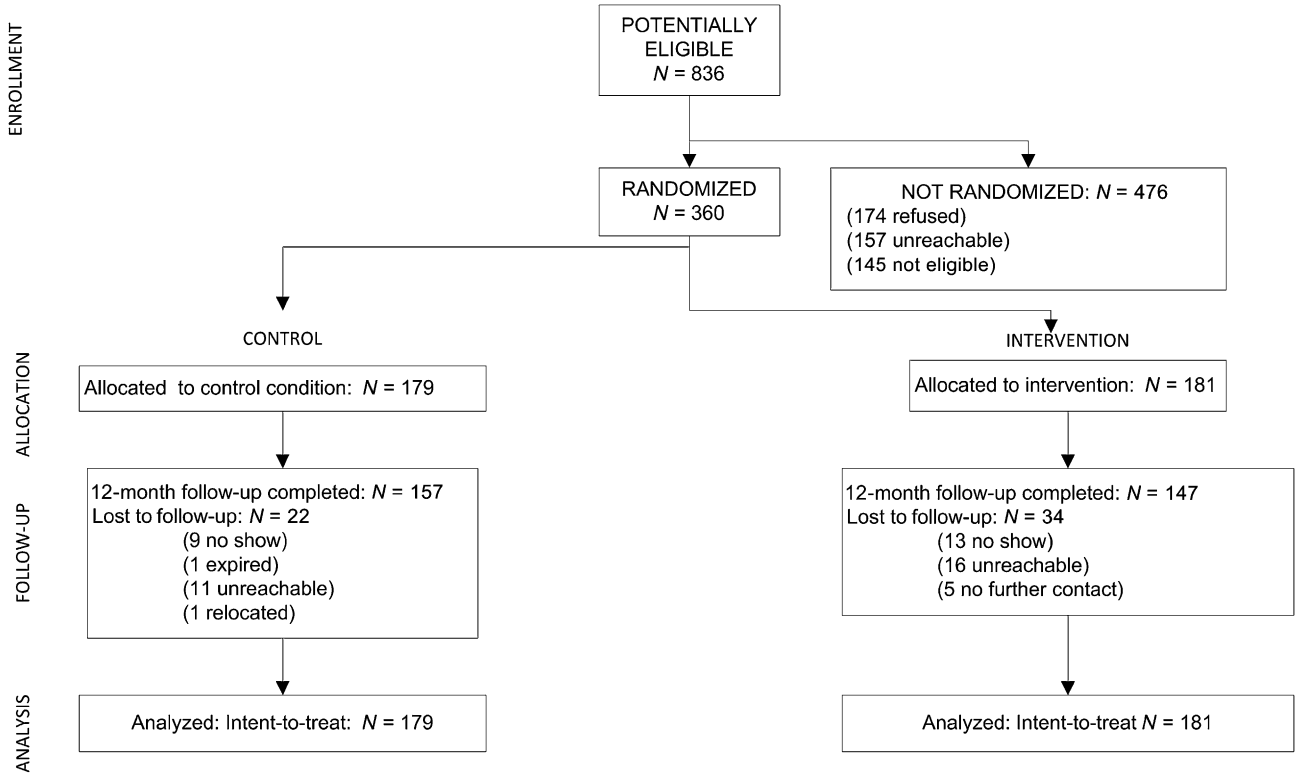

Figure 1—Recruitment and retention in the NOCHOP study.

Table 2—Analysis of primary outcome: A1C

	Unadjusted						Adjusted[a]			
	Control			Intervention			Control		Intervention	
	n	Mean	SD	*n*	Mean	SD	Mean	SE	Mean	SE
Baseline	177	8.58	1.59	178	8.77	1.68	8.58	0.12	8.77	0.12
		70	17.4		72	18.4	70	1.3	72	1.3
1 year	155	8.53	1.54	149	8.40	1.57	8.53	0.13	8.42	0.13
		70	16.8		68	17.2	70	1.4	69	1.4

A1C values are given in percent units (first row) and mmol/mol units (second row). The (treatment arm × time) interaction term was not statistically significant for any of the outcomes. [a]Repeated-measures analysis performed using SAS Proc Mixed assuming a compound symmetry covariance structure and adjusting for clustering within primary care physician. All participants with at least one case of data were included in the analysis.

to maintain contact with 13 of them. In two cases, we learned that the subjects had died, another participant moved out of town, and 10 additional subjects could not be contacted despite all efforts.

At 12 months, there was a modest improvement in A1C levels in the intervention group, as compared with usual care, but it lacked statistical significance ($P = 0.131$) (Table 2). There was no improvement in the secondary outcomes of blood pressure and LDL-cholesterol levels either (Table 3). Moreover, there was a modest nonsignificant increase in LDL-cholesterol levels and SBP in the intervention arm. Estimates from sensitivity analyses that modeled for missing data did not differ substantially from the intention-to-treat results (data not shown, available upon request). A post hoc sensitivity analysis testing the hypothesis that intervention fidelity, measured as the number of contacts (visits, phone contacts, group support, and nutritional education), was predictive of A1C reduction showed that there was a modest improvement in A1C levels in the intervention group, as compared with usual care, and the result fell was close to nominal statistical significance, with $P = 0.054$ for the cluster-adjusted comparison (Table 4). The same analysis also showed an increase in SBP as the number of contacts increased in the intervention group that was not significant for our prespecified threshold of 0.01 for secondary outcomes. When we separated phone calls from in-person contacts (visits plus meetings), only the number of phone calls was associated with a statistically significant reduction in A1C levels (β coefficient [SE]: −0.02 [0.01]; $P = 0.04$; results not shown). In regards to glycemic control at the time of randomization, stratified analysis showed similar effects of the intervention in those who had optimal glycemic control (baseline A1C <7%, $n = 46$) as compared with those who did not (baseline A1C ≥7%, $n = 314$; results not shown).

CONCLUSIONS

Intention-to-treat analysis of our primary outcome, A1C at 12 months, showed modest improvement favoring the CHW intervention, but that improvement failed to reach statistical significance at the prespecified threshold of $P < 0.05$ [$P = 0.131$ for the (randomization group × time) term in the adjusted mixed model]. In regards to the secondary outcomes, we also failed to observe improvements in blood pressure or LDL-cholesterol levels.

Our study is one of only a few to rigorously test the efficacy of CHW interventions on diabetes intermediate outcomes among minority populations. Only three of the previous randomized controlled CHW studies had a clinically meaningful follow-up period of at least 12 months (9,10,15). There are several differences between those three studies and ours. In those studies, the CHWs were part of a larger intervention team

Table 3—Analysis of secondary outcomes: SBP, DBP, and LDL cholesterol

	Unadjusted						Adjusted[a]			
	Control			Intervention			Control		Intervention	
	n	Mean	SD	*n*	Mean	SD	Mean	SE	Mean	SE
SBP (mmHg)										
Baseline	177	136.71	17.12	179	136.08	18.57	136.60	1.38	135.97	1.38
1 year	147	135.22	17.20	141	138.64	19.62	135.28	1.48	138.02	1.50
DBP (mmHg)										
Baseline	177	80.83	9.97	179	81.14	9.68	80.80	0.78	81.08	0.78
1 year	147	79.80	10.15	141	81.48	10.87	80.20	0.83	81.15	0.85
LDL cholesterol										
Baseline	178	95.78	36.47	181	97.63	32.17	95.76	2.6	97.70	2.61
		2.47	0.94		2.52	0.83	2.47	0.06	2.53	0.06
1 year	155	92.66	34.11	148	101.89	37.30	92.84	2.78	102.38	2.83
		2.39	0.88		2.63	0.96	2.40	0.07	2.65	0.07

LDL-cholesterol values are given as mg/dL (first row) and mmol/L (second row). The (treatment arm × time) interaction term was not statistically significant for any of the outcomes. [a]Repeated-measures analysis performed using SAS Proc Mixed assuming a compound symmetry covariance structure and adjusting for clustering within primary care physician. All participants with at least one case of data were included in the analysis.

Table 4—Results of sensitivity analyses with inclusion of number of contacts

	A1C[a] (*n* = 360)			SBP[a] (*n* = 359)			DBP[a] (*n* = 359)			LDL cholesterol[a] (*n* = 360)		
	Estimate	SE	*P* value	Estimate	SE	*P* value	Estimate	SE	*P* value	Estimate	SE	*P* value
Intercept	8.628 70.8	0.077 0.8	<0.0001	135.930	0.939	<0.0001	80.803	0.543	<0.0001	96.330 2.49	1.682 0.04	<0.0001
Contacts variable	−0.009	0.005	0.054	0.124	0.062	0.0470	0.004	0.031	0.879	0.167	0.114	0.146

A1C values are given as percent units (first row) and mmol/mol units (second row). LDL-cholesterol values are given as mg/dL (first row) and mmol/L (second row). [a]Repeated-measures analysis performed using SAS Proc Mixed assuming a compound symmetry covariance structure and adjusting for clustering within primary care physician. An adjustment for homogeneity in cluster and residual variances was included for SBP. All participants with at least one case of data were included in the analysis.

that included other health professionals such as nurse practitioners, nurses, and dietitians. Our study was designed to determine if an intervention delivered solely by lay CHWs could improve A1C. Further, our population consisted of urban Hispanics, mainly of Dominican origin, whereas in two of the other studies, the sample was predominantly African American (9,15). In the study among Latinos, the participants were of Mexican origin and had much poorer diabetes control at enrollment (10). Methodological differences notwithstanding, there seems to be a consistent pattern across long-term studies toward showing benefit in the CHW arm. In two studies, there was a statistically significant improvement in A1C through the CHW intervention (9,10), while in the other, like in NOCHOP, there was a trend toward improvement, albeit not statistically significant (15).

Given the lack of a statistically significant finding for the primary outcome, issues of statistical power merit consideration. However, our study was designed to have >80% power to detect a change in A1C of 0.5 even if we had a 30% attrition (double what we observed). In addition, results of sensitivity analyses that compensated for missing data through different models did not vary substantially from the intention-to-treat findings.

More likely is that our power was limited by problems with intervention fidelity. The highly variable uptake of the CHW intervention may have impaired our ability to detect improvements in A1C levels. This explanation is bolstered by our secondary analyses examining intervention intensity, suggesting that increased CHW service intensity was associated with greater of A1C reduction. Within the framework of the intention-to-treat principle, all participants including intervention participants with low adherence to the protocol were analyzed. Yet, in over half of the intervention group, the CHWs were not able to deliver any of the planned one-on-one or small group sessions and only able to contact participants by phone. In this sense, we believe it is encouraging that our sensitivity analysis detected a significant association between the number of phone calls and A1C reduction. This suggests that future studies may use a phone-based intervention in order to facilitate access to participants and thus maximize intervention fidelity.

In addition to the problems created by suboptimal intervention fidelity, other limitations are noteworthy. At the time NOCHOP was conducted, several initiatives were taking place, both at our clinic network and at the city level, aimed at improving the care of people with diabetes. This may have resulted in better care over time of participants randomized to the usual care arm. Furthermore, our findings may be in part reflective of the very specific socioeconomic and cultural characteristics of our patient population, who are predominantly of Dominican origin. This may affect the applicability of our findings to other populations. Finally, our participants did not have very high A1C levels at the time of randomization. Studies with relatively lower baseline values of the variable of interest may tend to show a less significant reduction in that variable, because it cannot drop much further, a phenomenon known as the "floor effect."

In summary, our study failed to show a statistically significant A1C reduction by the CHW intervention among Hispanics in northern Manhattan. We did observe a nonsignificant trend toward improved A1C, and a post hoc analysis suggested that a modified CHW intervention, maximizing the use of phone calls, could result in better adherence and greater efficacy in populations facing socioeconomic hardship. Nondefinitive findings like ours are best interpreted in the context of all available evidence. In that regard, two of the long-term randomized controlled CHW studies conducted thus far found a statistically significant A1C reduction, while the other two, including ours, found a nonsignificant trend toward benefit. Meta-analysis of the available data and the completion of currently undergoing trials should add substantial information about this topic.

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participated in participant recruitment and data collection and edited the manuscript. J.A.L. designed the study, participated in participant recruitment, and edited the manuscript. O.C. conceived and designed the study, including the CHW intervention, and edited the manuscript. W.P. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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