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

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 A1c (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 A1C (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.
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              | 71              | 39.2            |
| Female           | 112             | 110             | 60.8            |
| Total            | 179             | 181             | 100.0           |
| Age              |                  |                  |
| ≤65 years old    | 145             | 155             | 85.6            |
| >65 years old    | 34              | 26              | 14.4            |
| Total            | 179             | 181             | 100.0           |
| Age, mean (SD) (years) | 58.1 (7.8) | 57.1 (7.7) |                  |
| Race             |                  |                  |
| Hispanic         | 179             | 181             | 100.0           |
| Total            | 179             | 181             | 100.0           |
| Marital status   |                  |                  |
| Single/never married | 27          | 35              | 19.3            |
| Living with significant other | 6       | 11              | 6.1             |
| Married          | 60              | 56              | 30.9            |
| Separated        | 26              | 26              | 14.4            |
| Divorced         | 34              | 38              | 21.0            |
| Widowed          | 25              | 12              | 6.6             |
| Data missing     | 1               | 3               | 1.7             |
| Total            | 179             | 181             | 100.0           |
| Highest degree obtained | |                  |
| None             | 159             | 151             | 83.4            |
| Technical degree | 2               | 0               | 0.0             |
| High school diploma | 3          | 8               | 4.4             |
| AA (Associate’s degree) | 4           | 8               | 4.4             |
| BA/BS/other Bachelor’s | 6           | 6               | 3.3             |
| MA/MS/other Master’s | 1           | 0               | 0.0             |
| Doctorate (PhD/MD/JD/other) | 0     | 1               | 0.6             |
| Data missing     | 4               | 7               | 3.9             |
| Total            | 179             | 181             | 100.0           |
| Education, mean (SD) (years) | 8.4 (3.9) | 8.5 (3.9) |                  |
| Employment status|                  |                  |
| Employed         | 34              | 31              | 17.1            |
| Retired          | 26              | 27              | 14.9            |
| Homemaker        | 5               | 2               | 1.1             |
| On disability    | 85              | 79              | 43.6            |
| Unemployed/not working | 28       | 39              | 21.5            |
| Data missing     | 1               | 3               | 1.7             |
| Total            | 179             | 181             | 100.0           |
| Yearly income    |                  |                  |
| <$3,000          | 13              | 26              | 14.4            |
| $3,001–5,000     | 7               | 6               | 3.3             |
| $5,001–10,000    | 73              | 72              | 39.8            |
| $10,001–20,000   | 69              | 49              | 27.1            |
| $20,001–30,000   | 8               | 20              | 11.0            |
| $30,001–40,000   | 3               | 1               | 0.6             |
| $40,001–50,000   | 2               | 2               | 1.1             |
| $60,001–75,000   | 0               | 1               | 0.6             |
| $75,001–100,000  | 0               | 0               | 0.6             |
| Data missing     | 4               | 3               | 1.7             |
| Total            | 179             | 181             | 100.0           |
| A1C, mean (SD)   |                  |                  |
| %                | 8.6             | 8.8             | 1.7             |
| mmol/mol         | 70              | 73              | 18.6            |
| LDL cholesterol, mean (SD) | 95.8 (36.5) | 97.6 (32.2) |                  |
| mg/dL            | 2.47            | 2.52            | (0.83)           |
| mmol/L           |                  |                  |
| 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
Moreover, there was a modest improvement in cholesterol levels either (Table 3). Outcomes of blood pressure and LDL-cholesterol levels were captured, but no improvement in the secondary outcomes was observed. The intention-to-treat results (data missing did not differ substantially between the two groups). Sensitivity analyses that modeled for intervention arm. Estimates from the adjusted mixed model showed no improvement in A1C levels in the intervention group, as compared with usual care, and the result was not shown, available upon request. A post hoc sensitivity analysis testing the hypothesis that intervention fidelity, measured as the number of contacts (visits, phone calls, 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 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 ($\beta$ 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 2—Analysis of primary outcome: A1C

|          | Control | Intervention | Control | Intervention |
|----------|---------|--------------|---------|--------------|
|          | $n$ Mean SD | $n$ Mean SD | $n$ Mean SE | $n$ Mean SE |
| Baseline | 177 8.58 1.59 | 178 8.77 1.68 | 8.58 0.12 | 8.77 0.12 |
| 1 year   | 155 8.53 1.54 | 149 8.40 1.57 | 8.53 0.13 | 8.42 0.13 |

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

|          | Control | Intervention | Control | Intervention |
|----------|---------|--------------|---------|--------------|
|          | $n$ Mean SD | $n$ Mean SD | $n$ Mean SE | $n$ 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 92.66 34.11 | 148 101.89 37.30 | 95.76 2.6 | 97.70 2.61 |
| 1 year    | 155 92.66 34.11 | 148 101.89 37.30 | 92.84 2.78 | 102.38 2.83 |

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. *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.
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 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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### Duality of Interest
No potential conflicts of interest relevant to this article were reported.

### Author Contributions
W.P. designed the study, oversaw its conduct as principal investigator, and wrote the manuscript. S.E.F. designed the CHW intervention, consulted in the intervention implementation, and edited the manuscript. M.M. and M.B. designed the CHW intervention, supervised the CHWs, and edited the manuscript. J.T. designed the study, oversaw the data collection and analysis, and edited the manuscript. J.K. performed central randomization, analyzed the data, and edited the manuscript. S.S. coordinated the study conduct, data collection, and analysis. E.M.F.

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

|                      | A1C\(^{*}\) ( n = 360) | SBP\(^{*}\) ( n = 359) | DBP\(^{*}\) ( n = 359) | LDL cholesterol\(^{*}\) ( n = 360) |
|----------------------|-------------------------|-------------------------|-------------------------|----------------------------------|
|                      | Estimate                | SE                      | P value                 | Estimate                        | SE                      | P value |
| Intercep             | 8.628                   | 0.077                   | <0.0001                 | 135.930                         | 0.939                   | <0.0001 |
|                      | 70.8                    | 0.8                     |                         | 80.803                          | 0.543                   | <0.0001 |
| Contacts variable    | -0.009                  | 0.005                   | 0.054                   | 0.124                           | 0.062                   | 0.047   |
|                      |                         |                         |                         | 0.004                           | 0.031                   | 0.879   |
|                      |                         |                         |                         | 96.330                          | 1.682                   | <0.0001 |

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). *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.
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