

# Structured Telehealth Community Health Worker–Clinician Feedback and Diabetes Outcomes

## A Randomized Clinical Trial

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**IMPORTANCE** Community health workers (CHWs) improve chronic disease management in underserved populations, but scalable integration strategies are limited.

**OBJECTIVE** To evaluate whether a multidimensional intervention incorporating telementored CHWs and a structured participant-CHW-clinician feedback loop can improve diabetes outcomes.

**DESIGN, SETTING, AND PARTICIPANTS** This 12-month randomized clinical trial was conducted at 3 institutionally and geographically diverse community clinics in Texas between September 1, 2023, and April 30, 2025, and included low-income, uninsured White Hispanic adults with type 2 diabetes identified through clinic databases. Data were analyzed between May 1 and July 31, 2025.

**INTERVENTION** Individuals were randomized 1:1 to the intervention or control. For the intervention, CHWs delivered (1) group diabetes education, (2) individualized telehealth-based coaching, and (3) a novel participant-CHW-clinician feedback loop to facilitate communication, address participant concerns, and improve care coordination. The control was usual care (quarterly clinician visits and access to multidisciplinary and social services).

**MAIN OUTCOMES AND MEASURES** The primary outcome was baseline to 12-month change in hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) level. Secondary outcomes included changes in cholesterol levels, American Diabetes Association (ADA) guideline adherence, participant recruitment, intervention fidelity, and feedback loop issue resolution.

**RESULTS** Of 257 participants included in the intention-to-treat analysis (mean [SD] age 54 [11] years; 166 [64.6%] female), 129 were in the intervention group and 128 were in the control group. The intervention reduced HbA<sub>1c</sub> (net difference, −1.0 [95% CI, −1.5 to −0.4] percentage points [pp];  $P = .001$ ), total cholesterol (net difference, −35.4 mg/dL; 95% CI, −54.6 to −17.2 mg/dL;  $P = .02$ ), and low-density lipoprotein cholesterol (net difference, −29.7 mg/dL; 95% CI, −44.5 to −14.9 mg/dL;  $P < .001$ ) levels compared with control. ADA guideline adherence improved for foot examinations (absolute risk [AR], 19.2 [95% CI, 7.4–30.9] pp; relative risk [RR], 1.65 [95% CI, 1.19–2.27];  $P = .03$ ) and urine microalbumin screening (AR, 15.8 [95% CI, 5.3–26.3] pp; RR, 1.24 [95% CI, 1.07–1.43];  $P = .048$ ). CHWs addressed 490 participant concerns (87.2%) via the feedback loop, including medication refills, glucose management, and access to care.

**CONCLUSIONS AND RELEVANCE** In this randomized clinical trial, the CHW intervention significantly improved diabetes outcomes in low-income settings, potentially by reducing fragmentation through structured feedback. Findings also highlight limitations in usual care, underscoring the need for scalable strategies to strengthen chronic disease management in low-income populations.

**TRIAL REGISTRATION** ClinicalTrials.gov Identifier: [NCT04835493](#)

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Diabetes disproportionately affects low-income Hispanic populations. Systemic barriers, including limited access to care and cultural discordance, are associated with higher prevalence of diabetes and complications, such as blindness, amputations, and kidney failure.<sup>1-6</sup> In manual labor-intensive communities, diabetes-related functional impairment jeopardizes employment and household financial stability.<sup>7</sup> Combined, these disparities contribute to the significant economic burden associated with diabetes, consuming roughly 1 in 4 health care dollars,<sup>8</sup> underscoring the need for evidence-based interventions to reduce both clinical complications and socioeconomic impacts in high-risk groups.

We previously tested a multidimensional community health worker (CHW)-led intervention for type 2 diabetes in low-income, uninsured Hispanic adults through clinical trials.<sup>9-14</sup> The intervention empowered CHWs<sup>15-18</sup>—trusted liaisons between communities and health systems—and included strategies to improve health care access, such as CHW-participant support via mobile health (mHealth), a type of telehealth using mobile devices to support medical care (eg, text, phone calls). Compared with the control group, intervention participants achieved better glycemic control (57% vs 25% achieved the target hemoglobin A<sub>1c</sub> [HbA<sub>1c</sub>] level; HbA<sub>1c</sub> level, -1.43% vs -0.45%;  $P = .002$ ) (to convert to proportion of total hemoglobin, multiply by 0.01), greater American Diabetes Association (ADA) guideline adherence, and sustained improvements for 24 months, providing evidence for feasibility and internal validity. We developed robust training protocols for CHWs that included approximately 200 hours of certification and training; however, mentoring was informal, typically in person, and limited, constraining caseloads to approximately 4 to 6 participants per CHW. Sample sizes were small (mean, <100), and interventions were largely given at a single site, highlighting the need for larger-scale, randomized trials with structured mentoring and expanded telehealth integration to determine effectiveness across diverse clinical settings.<sup>9-14</sup>

Scaling CHW-led interventions is limited by insufficient real-time support and supervision in a rapidly evolving scientific landscape.<sup>19,20</sup> Unlike other health care workers, who receive structured supervision through clerkships and residencies, CHWs have no comparable system.<sup>20-22</sup> Modest formal education, variable skill levels, absence of national certification, and minimal mentorship can produce inconsistent intervention delivery and variable effectiveness.<sup>21-24</sup> Although CHWs often have extensive patient contact and deep insight into patient circumstances, they are frequently disconnected from clinic staff, leaving important concerns unshared.<sup>19,24,25</sup> Strengthening CHW support and integration with care teams could substantially enhance CHWs' effectiveness.

Telehealth delivers health information virtually, unlike telemedicine, in which clinicians provide medical care.<sup>26</sup> Telehealth has expanded since the COVID-19 pandemic, including for CHW training and patient care.<sup>27,28</sup> However, structured CHW support via telehealth is rarely reported.<sup>19,29</sup> Pairing telehealth with live, structured mentoring (ie, telementoring) offers 1-on-1 real-time guidance from a trained mentor rather than

## Key Points

**Question** Can a multidimensional, telehealth-based intervention with a structured participant-community health worker (CHW)-clinician feedback loop improve diabetes outcomes across diverse clinical sites compared with usual clinical care?

**Findings** In this randomized clinical trial of 257 low-income White Hispanic adults with type 2 diabetes, the CHW-delivered intervention improved hemoglobin A<sub>1c</sub> levels compared with usual care. CHWs addressed 87.2% of participant concerns through the feedback loop.

**Meaning** In this trial, the intervention significantly improved diabetes outcomes, possibly by reducing fragmentation through the feedback loop, providing a scalable approach for low-income settings.

standard group-based or asynchronous telehealth education. Incorporating telementoring into interventions can help CHWs function more effectively within care teams, thereby expanding program reach and enhancing impact.

Building on this approach, the present study evaluated whether a multidimensional intervention incorporating telementored CHWs and a structured participant, CHW, and clinician communication system (ie, feedback loop) could improve clinical outcomes across 3 sites.<sup>30</sup> Low-income Hispanic adults with type 2 diabetes were randomized to the intervention or usual care (control). We hypothesized that this model would reduce care fragmentation through structured communication, resulting in improved diabetes outcomes and providing a foundation for geographic expansion.

## Methods

### Study Design and Setting

This 12-month randomized clinical trial (NCT04835493) (September 1, 2023, to April 30, 2025) was conducted across 3 diverse health systems in Texas serving predominantly (>70%) low-income (<200% federal poverty level), uninsured Hispanic populations. Two clinics were 501(c)(3) nonprofit organizations, and 1 was a federally qualified health center; together they provide more than 75 000 patient visits annually. The trial protocol is given in Supplement 1. The study received institutional review board approval from the University of Texas Medical Branch and followed the Consolidated Standards of Reporting Trials (CONSORT) reporting guideline. Participants provided oral informed consent.

### Community-Based Participatory Research

Community-based participatory research enhances relevance and sustainability through shared ownership to meet community needs while maintaining scientific rigor (eg, safety, oversight).<sup>31</sup> We engaged stakeholders (ie, clinic staff, clinicians, administrators, board members, and community members) in intervention co-design, ongoing communication, and refinement, including CHW selection and role definition to ensure culturally relevant education and support.

## Research and Clinic Teams

The research team included the investigators and 6 CHW instructors from a nonprofit training center<sup>32</sup>; analysts were blinded to study arm. The clinic team was composed of 1 to 2 clinician coordinators and 5 to 6 CHWs per cohort. Community health workers were trusted Spanish-speaking community members and were provided with secure tablets and institutional communication platforms. One CHW per cohort, designated by our team as a CHW champion based on leadership and organizational skills, met weekly by videoconference with the clinician coordinator to address participant concerns (feedback loop). Community health workers worked about 5 hours per week with 10 to 15 intervention participants each.

## Participants

Eligible participants were uninsured, Spanish-speaking, self-identified White Hispanic adults (age  $\geq 18$  years) with type 2 diabetes ( $\text{HbA}_{1c}$  level  $\geq 6.5\%$ , fasting glucose level  $>125$  mg/dL [to convert to millimoles per liter, multiply by 0.0555], or clinician documentation).<sup>33</sup> Exclusion criteria included conditions affecting  $\text{HbA}_{1c}$  measurement accuracy (eg, corticosteroid use), pregnancy, severe cognitive impairment, or type 1 diabetes (*International Statistical Classification of Diseases and Related Health Problems, Tenth Revision* code E10.x). Participants were identified through clinic databases and recent ( $\pm 1$  month from baseline) electronic health record  $\text{HbA}_{1c}$  values, with testing arranged if needed. Spanish-speaking staff obtained informed consent by phone. Participants were stratified by sex and  $\text{HbA}_{1c}$  level and randomized 1:1 (block size, 4-6) to the intervention or usual care (control).

## Usual Care

Usual care included quarterly clinician visits and access to multidisciplinary and social services. Community health workers had no contact with controls; clinician coordinators had no protocol-mandated contact with participants in either arm.

## Intervention

**Table 1** details the 12-month intervention and its 3 CHW-delivered components: (1) monthly in-person diabetes education, (2) weekly mHealth coaching via telehealth, and (3) the participant-CHW-clinician feedback loop, conducted weekly via videoconference. Supportive components included CHW training and telementoring as well as procedures to ensure safety, fidelity, and appropriate adaptations (eTable 1 in [Supplement 2](#)). The eFigure in [Supplement 2](#) illustrates the feedback loop, a structured communication system designed to reduce fragmented care, developed in response to the recognition that CHWs often work parallel to rather than integrated with clinicians.<sup>34,35</sup> The intervention was based on prior studies, the chronic care model, and community-based participatory research principles.<sup>14,31,36</sup> As the intervention was designed to complement and not replace standard care, participants continued routine clinic visits.

## Clinical Outcomes and Participant Questionnaire

Outcomes included comparisons of changes from baseline to 12 months between the intervention and control arms in  $\text{HbA}_{1c}$  level (primary outcome), cholesterol levels (total, low-density lipoprotein [LDL], high-density lipoprotein [HDL], and triglycerides), blood pressure, weight, body mass index (BMI; calculated as weight in kilograms divided by height in meters

**Table 1. Components of the 12-Month CHW-Led Intervention in Patients With Type 2 Diabetes<sup>a</sup>**

| Component                                                           | Description                                                                                            | Content                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|---------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Diabetes education                                                  |                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Group seminars                                                      | Monthly CHW-delivered diabetes education, in person for 1 h                                            | Build knowledge, self-efficacy, and self-management skills; 20-min large group and two 20-min breakout sessions addressing behavior and social barriers on 1 of 12 monthly topics: diabetes overview, medication adherence, nutrition, preventive care (twice), complications, sexual health, alcohol and tobacco use, exercise rationale (twice), activity plans, and sustainable goals.                                                          |
| Videos                                                              | Monthly CHW instructor- and investigator-created 10- to 20-min videos <sup>32</sup> delivered via text | Abbreviated group seminar topics to reinforce topics.                                                                                                                                                                                                                                                                                                                                                                                              |
| Glucometer use                                                      | Monthly education and supplies, in person via mHealth                                                  | CHWs demonstrated accurate self-monitoring in month 1 and provided supplies and ongoing education through month 12. CHWs escalated abnormal values identified during group seminars or mHealth interactions via the feedback loop.                                                                                                                                                                                                                 |
| mHealth coaching                                                    |                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| mHealth CHW support                                                 | Weekly CHW-delivered self-management coaching via mHealth (text, phone call)                           | CHWs (1) identified concerns, (2) addressed concerns (eg, recipe question, scheduling) or notification of clinician-addressed concern (eg, hyperglycemia, medication need), and (3) reinforced group seminar topics; CHW-participant interactions were supportive, relationship-based; incorporated motivational interviewing and problem-solving, with transactional components (eg, scheduling) to facilitate care; about 5 min/wk. <sup>b</sup> |
| Team spreadsheet                                                    | Weekly CHW-participant interactions via secure online spreadsheet                                      | CHWs documented, identified, and addressed concerns; monitored weekly by CHW instructors to ensure fidelity.                                                                                                                                                                                                                                                                                                                                       |
| Participant-CHW-clinician feedback loop: communication <sup>c</sup> | Weekly via 30-min videoconferencing using team spreadsheet data                                        | A designated CHW reported CHW-identified concerns to clinician (eg, abnormal glucose level, medications, supplies, access, and other), solutions were determined, and relayed back to CHWs, who informed participants.                                                                                                                                                                                                                             |

Abbreviations: CHW, community health worker; mHealth, mobile health.

<sup>a</sup> Supportive components are listed in eTable 1 in [Supplement 2](#).

<sup>b</sup> Mean time spent during 12-month intervention, in which some weekly interactions were shorter than 5 minutes and others were longer pending

discussion of participant concerns. Not all items were discussed each week pending participant needs and time constraints.

<sup>c</sup> The feedback loop is shown in the eFigure in [Supplement 2](#).

squared), and ADA guideline adherence (retinal, vitamin B<sub>12</sub>, and urinary microalbumin screening; influenza vaccination; foot examination; and statin therapy).<sup>33</sup> Values were extracted from electronic health records or obtained via scheduled testing ( $\pm 1$  month or  $\pm 6$  months for 12-month lipid levels due to slower change with less frequent routine assessments). Adherence to ADA guidelines was coded yes or no based on completion within 12 months. Reductions of 0.5% or greater in HbA<sub>1c</sub> level are considered clinically meaningful and are associated with fewer vascular complications.<sup>37</sup> Baseline and month 12 questionnaires assessed participants' health behaviors and perceptions (eg, blood glucose monitoring).<sup>11,38-40</sup>

### Intervention-Only Measures

Postintervention surveys evaluated participant, CHW, and stakeholder (clinic staff, clinicians, administrators, board members, and community members) program satisfaction, CHW support, education, and overall experience.<sup>11,38-40</sup> Satisfaction scores for participants were measured on a 4-point Likert scale of 3 items and a 10-point Likert scale for 5 items; for CHWs, on a 6-point Likert scale for 11 items; and for stakeholders, on a 10-point Likert scale for 5 items.

Monthly in-person education attendance was documented but optional (target, 10%-20% of appointments), as prior data indicated transportation and work barriers limited participation.<sup>10</sup> Weekly CHW-participant mHealth contact was categorized as call, text, mixed, or unsuccessful (1 entry/week). Feedback loop metrics included the number of CHW-identified concerns and the proportion successfully addressed, defined as action for a participant (eg, scheduling an appointment for hyperglycemia).

### Sample Size and Power Calculations

We conducted a simulation-based power analysis assuming a 2-sided  $\alpha = .05$  and parameter values informed by prior data.<sup>11,12</sup> A sample of 258 provided 80% power to detect an effect size as small as Cohen  $d = 0.4$  between arms, assuming 20% dropout.

### Statistical Analysis

Descriptive statistics included means (SD) and frequencies (percentages). Missing data at 12 months ranged from 7.8% (HbA<sub>1c</sub> level) to 40% (lipid levels), with higher missingness in the control arm. The primary outcome was analyzed using a linear mixed model with fixed effects for time (baseline, month 12), group, and the interaction of time and group and a random intercept to account for individual baseline differences and correlation among repeated measures. The interaction tested whether the mean change in HbA<sub>1c</sub> level from baseline to 12 months differed between the 2 groups. Clinic effects were examined exploratively by adding clinic main effects and clinic interactions with group and time but were not significant and were excluded. For secondary clinical outcomes, we tested the missing data mechanism using the Little missing completely at random test, which indicated that the missing data were not completely at random; therefore, multiple imputation was applied under the missing-at-random assumption.<sup>41</sup> The im-

putation model included group, clinic, demographics, and baseline and 12-month outcomes using fully conditional specification.<sup>42</sup> Five imputed datasets were generated; changes in secondary outcomes were compared between groups using a 2-sample  $t$  test, with results statistically combined. The primary analysis used an intention-to-treat approach.

Exploratory subgroup analyses included participants with uncontrolled baseline diabetes, clinic-level comparisons, and per-protocol participants ( $\geq 1$  CHW interactions). Planned secondary analyses compared the proportion of patients achieving the target HbA<sub>1c</sub> level and ADA guideline adherence using  $\chi^2$  tests, with reporting of absolute risks (ARs) and relative risks (RRs) with 95% CIs. Two-sample  $t$  tests assessed survey outcomes. To address multiplicity and control the family-wise type I error rate,  $P$  values were adjusted using the step-down Holm-Bonferroni method.

Effectiveness was defined as change in HbA<sub>1c</sub> level from baseline to 12 months. In another exploratory analysis, cost savings were calculated as mean change in HbA<sub>1c</sub> level  $\times$  number of participants  $\times$  \$736 per 1% HbA<sub>1c</sub> level reduction.<sup>43</sup> Intervention costs included CHW salaries, supplies, and clinician time ( $< 1$  hour/week), which together were estimated at \$300 per participant. Net savings were defined as estimated savings minus intervention costs.

Data were analyzed between May 1 and July 31, 2025. All analyses were 2-sided and conducted in SAS, version 9.4 (SAS Institute Inc).  $P \leq .05$  was considered statistically significant.

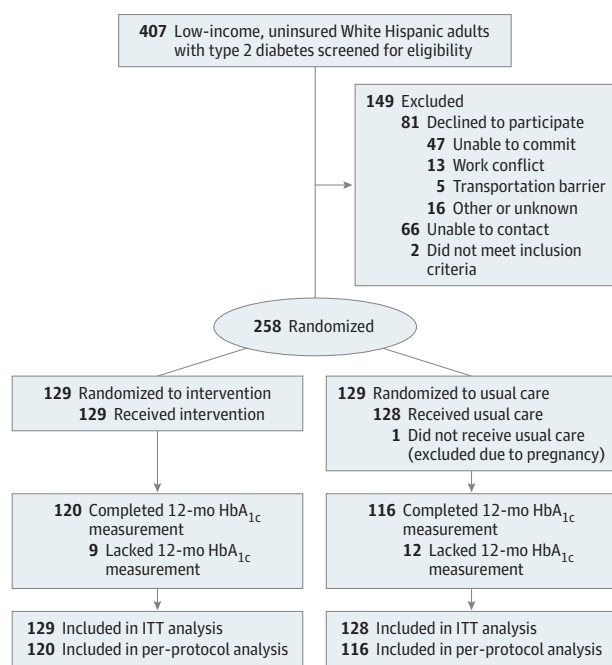
## Results

Figure 1 shows the CONSORT flow diagram. Of 407 individuals screened (246 [60.4%] female; 161 [39.6%] male), 66 were unreachable, 2 were ineligible, and 81 declined, primarily due to an inability to commit to the study or personal preference (47 [58%]), work conflicts (13 [16%]), or transportation barriers (5 [6.2%]). The remaining 258 were randomized: 129 to the intervention and 129 to usual care. One control participant was excluded because of pregnancy and did not receive usual care. This left 129 individuals in the intervention group and 128 in the control group in the intention-to-treat analysis ( $N = 257$ ). Overall attrition was 7.8%.

### Participant Characteristics

Baseline characteristics were similar between arms (Table 2). Participants were predominantly female (166 [64.6%]; 91 [35.4%] were male), mean (SD) age was 53.8 (10.7) years, and all identified as White Hispanic; most worked in domestic labor, manual labor, or food service (196 [76.3%]). Most (200 [77.8%]) had uncontrolled diabetes (HbA<sub>1c</sub> level  $\geq 7.0\%$  for age  $< 65$  years and  $\geq 7.5\%$  for age  $\geq 65$  years<sup>33</sup>), and only 22 (8.6%) had a normal BMI. Most were taking oral glucose-lowering medications alone (133 [51.8%]) or combined with injectables (111 [43.2%]). A total of 10 participants (3.9%) had coronary artery disease; 14 (5.4%), kidney disease; and 3 (1.2%), cerebrovascular disease. More intervention participants than controls received oral agents and injectables (60 [46.5%] vs 51 [39.8%]), while more controls used injectables only (5 [3.9%])

Figure 1. CONSORT Flowchart of Study Participants



HbA<sub>1c</sub> indicates hemoglobin A<sub>1c</sub>; ITT, intention-to-treat.

vs 0). Baseline mean (SD) diabetes duration was 9.8 (8.3) years in the intervention group and 9.1 (8.2) years in the control group, 64 participants in the intervention group (49.6%) and 72 in the control group (56.3%) had a BMI indicating obesity, and mean (SD) LDL cholesterol levels were 97.1 (36.4) mg/dL in the control group and 104.5 (38.3) mg/dL in the intervention group (to convert to millimoles per liter, multiply by 0.0259).

## Overall Outcomes

### Clinical Outcomes

Intervention participants had greater HbA<sub>1c</sub> level reductions than controls. Mean (SD) HbA<sub>1c</sub> levels were 9.2% (2.6%) at baseline and 8.2% (1.6%) at 12 months (mean [SD] difference, −1.0 [2.3] percentage points [pp]) in the intervention group compared with 8.9% (2.0%) and 8.8% (2.1%), respectively (mean [SD] difference, 0.0 [2.2] pp), in the control group, with a between-group net difference of −1.0 pp (95% CI, −1.5 to −0.4 pp;  $P = .001$ ; Cohen  $d = 0.42$ ) (Table 3). Among those with uncontrolled diabetes, HbA<sub>1c</sub> level reductions were larger in the intervention arm (mean [SD] difference, −1.4 [2.5] pp) than in the control group (mean [SD] difference, −0.3 [2.1] pp) (between-group net difference, −1.0 pp; 95% CI, −1.7 to −0.4 pp;  $P = .03$ ; Cohen  $d = 0.45$ ) (Figure 2).

Total cholesterol level (mean [SD] difference, −22.9 [45.4] mg/dL vs 12.4 [50.0] mg/dL; between-group difference, −35.4 mg/dL; 95% CI, −54.6 to −17.2 mg/dL [to convert to millimoles per liter, multiply by 0.0259]) and LDL cholesterol level (mean [SD] difference, −18.1 [35.9] mg/dL vs 11.6 [36.7] mg/dL; between-group difference, −29.7 mg/dL; 95% CI, −44.5 to

−14.9 mg/dL;  $P = .02$ ) improved more in the intervention arm than in the control arm; HDL and triglyceride levels did not differ between the groups. Adherence to ADA guidelines improved for foot examinations (AR, 19.2 [95% CI, 7.4–30.9] pp; RR, 1.65 [95% CI, 1.19–2.27];  $P = .03$ ) and urine microalbumin screening (AR, 15.8 [95% CI, 5.3–26.3] pp; RR, 1.24 [95% CI, 1.07–1.43];  $P = .048$ ), with no difference in other measures. Per-protocol analysis results were consistent with intention-to-treat analysis results and across health systems.

### Participant Questionnaire

Intervention participants reported improvements across most measures compared with controls in the participant questionnaire. There was a significant difference found only in blood glucose monitoring frequency between the 2 groups (eTable 2 in Supplement 2).

### Costs

The intervention cost about \$38 700 for 129 individuals. With HbA<sub>1c</sub> level changes of 0% (control) and −1.0% (intervention) and \$736 saved per every 1% HbA<sub>1c</sub> level reduction,<sup>43</sup> total savings were \$0 (control) and \$94 944 (intervention), yielding net savings of \$56 244 per year (\$436 per participant).

## Intervention-Only Outcomes

### Participant Satisfaction

Participants reported high program satisfaction across all domains, including CHW support (mean [SD] score, 9.4 [1.7]), education (mean [SD] score, 9.5 [1.6]), likelihood of recommending the program (mean [SD] score, 9.6 [1.3]), and perceived quality-of-life improvement (mean [SD] score, 9.3 [1.7]) (eTable 3 in Supplement 2). Qualitative feedback highlighted appreciation for diabetes education, nutritional information, self-care activation, group connection, and CHWs' empathy and support.

### CHW Satisfaction

Community health workers rated all domains of training and mentoring very high: overall (mean [SD] score, 5.9 [0.2]), instructors (mean [SD] score, 5.9 [0.2]), education (mean [SD] score, 5.9 [0.2]), telementoring (mean [SD] score, 5.9 [0.2]), topics (mean [SD] score, 5.9 [0.2]), knowledge (mean [SD] score, 5.9 [0.2]), and interest (mean [SD] score, 5.9 [0.2]). Community health workers described the program as valuable, motivating, and well-taught and expressed gratitude, highlighting the need for continued education and support for vulnerable populations.

### Stakeholder Satisfaction

Stakeholders reported high satisfaction across all domains: CHWs improved care (mean [SD] score, 10.0 [0]), CHW-led education (mean [SD] score, 9.8 [0.5]), clinical operations (mean [SD] score, 9.0 [2.0]), staff performance (mean [SD] score, 9.0 [2.0]), and likelihood of recommending the program (mean [SD] score, 9.8 [0.5]). Individuals emphasized improved patient-clinic communication, timely follow-up, patient engagement, feasibility, low clinician time burden, and strong support for expansion.

Table 2. Participant Baseline Demographic and Clinical Information

| Characteristic                              | Participants (N = 257) <sup>a</sup> |                       |
|---------------------------------------------|-------------------------------------|-----------------------|
|                                             | Intervention arm (n = 129)          | Control arm (n = 128) |
| Sex                                         |                                     |                       |
| Female                                      | 82 (63.6)                           | 84 (65.6)             |
| Male                                        | 47 (36.4)                           | 44 (34.4)             |
| White Hispanic race and ethnicity           | 129 (100)                           | 128 (100)             |
| Employment                                  |                                     |                       |
| Domestic labor                              | 53 (41.2)                           | 48 (37.5)             |
| Manual labor                                | 24 (18.6)                           | 26 (20.3)             |
| Food service                                | 20 (15.5)                           | 25 (19.5)             |
| Transportation                              | 8 (6.2)                             | 4 (3.1)               |
| Unemployed                                  | 17 (13.2)                           | 15 (11.7)             |
| Other or unknown                            | 6 (4.7)                             | 10 (7.8)              |
| Diabetes status                             |                                     |                       |
| Controlled <sup>b</sup>                     | 30 (23.3)                           | 27 (21.1)             |
| Uncontrolled                                | 99 (76.7)                           | 101 (78.9)            |
| Weight status <sup>c</sup>                  |                                     |                       |
| Underweight                                 | 1 (0.8)                             | 1 (0.8)               |
| Normal                                      | 8 (6.2)                             | 14 (10.9)             |
| Overweight                                  | 53 (41.1)                           | 38 (29.7)             |
| Obesity                                     | 64 (49.6)                           | 72 (56.3)             |
| Diabetes therapy                            |                                     |                       |
| Lifestyle only                              | 1 (0.8)                             | 5 (3.9)               |
| Oral medications only                       | 68 (52.7)                           | 65 (50.8)             |
| Injectables only                            | 0                                   | 5 (3.9)               |
| Oral agents and injectables                 | 60 (46.5)                           | 51 (39.8)             |
| Medical history                             |                                     |                       |
| Coronary artery disease                     | 4 (3.1)                             | 6 (4.7)               |
| Chronic kidney disease                      | 8 (6.2)                             | 6 (4.7)               |
| Cerebrovascular disease                     | 1 (0.8)                             | 2 (1.6)               |
| Age, mean (SD), y                           | 53.7 (11.3)                         | 53.8 (10.0)           |
| HbA <sub>1c</sub> level, mean (SD), %       |                                     |                       |
| All participants                            | 9.2 (2.64)                          | 8.9 (2.04)            |
| Uncontrolled only <sup>d</sup>              | 10.0 (2.5)                          | 9.5 (1.8)             |
| Diabetes duration, mean (SD), y             | 9.8 (8.3)                           | 9.1 (8.2)             |
| Systolic blood pressure, mean (SD), mm Hg   |                                     |                       |
| All participants                            | 127.8 (20.5)                        | 127.4 (20.5)          |
| Uncontrolled only (≥140 mm Hg) <sup>e</sup> | 155.3 (17.7)                        | 156.3 (15.9)          |
| Diastolic blood pressure, mean (SD), mm Hg  |                                     |                       |
| All participants                            | 75.6 (10.1)                         | 74.7 (11.0)           |
| Uncontrolled only (≥90 mm Hg) <sup>e</sup>  | 84.2 (12.2)                         | 83.5 (12.7)           |
| Weight, mean (SD), kg                       | 80.9 (18.2)                         | 79.8 (18.0)           |
| BMI, mean (SD)                              | 31.3 (5.9)                          | 31.4 (6.4)            |
| Cholesterol, mean (SD), mg/dL               |                                     |                       |
| Total                                       | 188.6 (44.4)                        | 180.4 (48.9)          |
| Low-density lipoprotein                     | 104.5 (38.3)                        | 97.1 (36.4)           |
| High-density lipoprotein                    | 47.5 (12.1)                         | 48.4 (12.8)           |
| Triglycerides                               | 202.3 (112.0)                       | 196.3 (178.0)         |

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); HbA<sub>1c</sub>, hemoglobin A<sub>1c</sub>.

SI conversion factors: To convert HbA<sub>1c</sub> to proportion of total hemoglobin, multiply by 0.01; total, low-density lipoprotein, and high-density lipoprotein cholesterol levels to millimoles per liter, multiply by 0.0259; and triglyceride levels to millimoles per liter, multiply by 0.0113.

<sup>a</sup> Data are presented as number (percentage) of participants unless otherwise indicated.

<sup>b</sup> HbA<sub>1c</sub> level less than 7% if younger than 65 years or less than 7.5% if 65 years or older.<sup>33</sup>

<sup>c</sup> Underweight, BMI less than 20.0; normal, BMI of 20.0 to 24.9; overweight, BMI of 25.0 to 29.9; obesity, BMI of 30.0 or greater.

<sup>d</sup> Intervention: n = 99; control: n = 102.

<sup>e</sup> Intervention: n = 59; control: n = 59.

Table 3. Clinical Outcomes of the Community Health Worker Intervention in 257 Patients With Type 2 Diabetes

| Outcome                                        | Intervention arm (n = 129) <sup>a</sup> |                    |                         | Control arm (n = 128) <sup>a</sup> |                    |                         | Month 12             |                     |                                    | Cohen d | P value <sup>b</sup> |
|------------------------------------------------|-----------------------------------------|--------------------|-------------------------|------------------------------------|--------------------|-------------------------|----------------------|---------------------|------------------------------------|---------|----------------------|
|                                                | Baseline (n = 129)                      | Month 12 (n = 121) | Change (n = 121)        | Baseline (n = 128)                 | Month 12 (n = 116) | Change (n = 116)        | AR (95% CI), pp      | RR (95% CI)         | Mean difference in change (95% CI) |         |                      |
| HbA <sub>1c</sub> level, %                     |                                         |                    |                         |                                    |                    |                         |                      |                     |                                    |         |                      |
| All individuals                                | 9.2 (2.6)                               | 8.2 (1.6)          | -1.0 (2.3) <sup>c</sup> | 8.9 (2.0)                          | 8.8 (2.1)          | 0.0 (2.2) <sup>c</sup>  | NA                   | NA                  | -1.0 (-1.5 to -0.4) <sup>c</sup>   | 0.42    | .001                 |
| Uncontrolled HbA <sub>1c</sub> <sup>d</sup>    | 10.0 (2.5)                              | 8.6 (1.6)          | -1.4 (2.5) <sup>c</sup> | 9.5 (1.8)                          | 9.1 (2.0)          | -0.3 (2.1) <sup>c</sup> | NA                   | NA                  | -1.0 (-1.7 to -0.4) <sup>c</sup>   | 0.45    | .03                  |
| Achieved target HbA <sub>1c</sub> <sup>e</sup> | 29 (22.5)                               | 36 (29.8)          | 7 (7.3)                 | 27 (21.1)                          | 23 (19.8)          | -4 (1.3)                | 9.9 (-1.0 to 20.8)   | 1.50 (0.95 to 2.40) | NA                                 | NA      | .88                  |
| Blood pressure, mm Hg                          |                                         |                    |                         |                                    |                    |                         |                      |                     |                                    |         |                      |
| Systolic                                       | 127.7 (20.5)                            | 130.1 (18.0)       | 2.5 (16.1)              | 127.6 (20.6)                       | 130.4 (18.8)       | 2.9 (17.9)              | NA                   | NA                  | -0.4 (-5.1 to 4.2)                 | 0.02    | >.99                 |
| Diastolic                                      | 75.5 (10.1)                             | 76.5 (10.5)        | 1.0 (8.8)               | 74.8 (11.0)                        | 75.4 (9.7)         | 0.6 (11.9)              | NA                   | NA                  | 0.3 (-2.4 to 3.0)                  | 0.03    | >.99                 |
| Weight, kg                                     | 80.9 (18.2)                             | 80.8 (18.3)        | 0.0 (3.9)               | 79.8 (17.9)                        | 79.3 (17.9)        | -0.5 (5.0)              | NA                   | NA                  | 0.5 (-0.9 to 1.8)                  | 0.10    | >.99                 |
| BMI                                            | 31.3 (5.9)                              | 31.3 (5.9)         | 0.0 (1.5)               | 31.4 (6.3)                         | 31.2 (6.4)         | -0.2 (2.0)              | NA                   | NA                  | 0.2 (-0.4 to 0.7)                  | 0.09    | >.99                 |
| Cholesterol level, mg/dL                       |                                         |                    |                         |                                    |                    |                         |                      |                     |                                    |         |                      |
| Total                                          | 189.1 (44.6)                            | 166.2 (42.7)       | -22.9 (45.4)            | 180.3 (48.9)                       | 192.7 (42.5)       | 12.4 (50.0)             | NA                   | NA                  | -35.4 (-54.6 to -17.2)             | 0.74    | .02                  |
| LDL                                            | 105.0 (38.1)                            | 86.9 (36.8)        | -18.1 (35.9)            | 97.1 (36.5)                        | 108.7 (32.5)       | 11.6 (36.7)             | NA                   | NA                  | -29.7 (-44.5 to -14.9)             | 0.82    | .02                  |
| HDL                                            | 47.5 (12.0)                             | 46.3 (11.5)        | -1.2 (9.1)              | 48.2 (12.7)                        | 47.2 (11.4)        | -1.0 (9.5)              | NA                   | NA                  | -0.3 (-2.9 to 2.3)                 | 0.03    | >.99                 |
| Triglycerides                                  | 202.6 (111.6)                           | 186.8 (123.2)      | -15.8 (118.8)           | 197.2 (178.5)                      | 208.6 (147.8)      | 11.4 (140.4)            | NA                   | NA                  | -27.2 (-78.0 to 23.5)              | 0.21    | >.99                 |
| ADA guideline adherence <sup>f</sup>           |                                         |                    |                         |                                    |                    |                         |                      |                     |                                    |         |                      |
| Comprehensive foot examination                 | NA                                      | 63 (48.8)          | NA                      | NA                                 | 38 (29.7)          | NA                      | 19.2 (7.4 to 30.9)   | 1.65 (1.19 to 2.27) | NA                                 | NA      | .03                  |
| Urine microalbumin screening                   | NA                                      | 106 (82.2)         | NA                      | NA                                 | 85 (66.4)          | NA                      | 15.8 (5.3 to 26.3)   | 1.24 (1.07 to 1.43) | NA                                 | NA      | .048                 |
| Statin therapy                                 | NA                                      | 112 (87.5)         | NA                      | NA                                 | 102 (79.7)         | NA                      | 7.8 (-1.2 to 16.8)   | 1.10 (0.98 to 1.22) | NA                                 | NA      | .90                  |
| Vitamin B <sub>12</sub> (serum) monitoring     | NA                                      | 40 (31)            | NA                      | NA                                 | 34 (26.6)          | NA                      | 4.5 (-6.6 to 15.5)   | 1.17 (0.79 to 1.72) | NA                                 | NA      | >.99                 |
| Retinal screening                              | NA                                      | 63 (48.8)          | NA                      | NA                                 | 51 (39.8)          | NA                      | 9.0 (-3.1 to 21.1)   | 1.23 (0.93 to 1.62) | NA                                 | NA      | >.99                 |
| Received influenza vaccine                     | NA                                      | 54 (52.4)          | NA                      | NA                                 | 56 (54.9)          | NA                      | -2.5 (-16.1 to 11.2) | 0.95 (0.74 to 1.23) | NA                                 | NA      | >.99                 |

Abbreviations: ADA, American Diabetes Association; AR, absolute risk; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); HbA<sub>1c</sub>, hemoglobin A<sub>1c</sub>; HDL, high-density lipoprotein; LDL, low-density lipoprotein; NA, not applicable; pp, percentage points; RR, relative risk.

SI conversion factors: To convert HbA<sub>1c</sub> to proportion of total hemoglobin, multiply by 0.01; total, LDL, and HDL cholesterol levels to millimoles per liter, multiply by 0.0259; and triglyceride levels to millimoles per liter, multiply by 0.013.

<sup>a</sup> Data are presented as mean (SD) for continuous variables and number (percentage) for categorical values.

<sup>b</sup> P value for difference between intervention and usual care in change from baseline to 12 months. All listed P values are unadjusted (raw) P values.

<sup>c</sup> Values shown are pp.

<sup>d</sup> HbA<sub>1c</sub> level of 7% or higher if younger than 65 years or 75% or higher if 65 years or older. In the intervention group, n = 99 at baseline and n = 94 at month 12; in the control group, n = 102 at baseline and n = 92 at month 12.

<sup>e</sup> HbA<sub>1c</sub> level less than 7% if younger than 65 years or less than 7.5% if 65 years or older, based on complete data.

<sup>f</sup> All variables were analyzed using complete data.

### Attendance and mHealth

In-person education attendance goals met the 10% to 20% target, with a median of 20.0% ( $n = 21$ ) attending and range from 9.3% ( $n = 12$  at months 6, 8, and 10) to 36.4% ( $n = 47$  at month 12). Community health workers completed 6269 participant-scheduled contacts (mean [SD], 45.4 [5.4] per participant; median, 46.0 [range, 37.0-51.0]; 64 [47.2%] were mixed calls and texts, 32 [28.0%] were calls only, 21 [18.6%] were texts only, and 1 [6.2%] were unsuccessful).

### Feedback Loop

Community health workers identified 562 participant concerns (mean [SD], 4.4 [3.23] per participant), including concerns about abnormal glucose levels (147 [26.7%] of total concerns), including hyperglycemia (126 [22.4%]) and hypoglycemia (21 [3.7%]); medications (106 [18.9%]); general health (106 [18.9%]); diabetes-related supplies and/or use (122 [21.7%]); access to care (11 [7.1%]); appointments (40 [7.1%]); blood pressure (16 [2.9%]); clinic eligibility (11 [2.0%]); financial constraints (8 [1.4%]); and transportation (6 [1.4%]). Nearly all participants (120 [93%]) reported at least 1 concern during the 12-month intervention (median, 4 [range, 0-13] per participant).

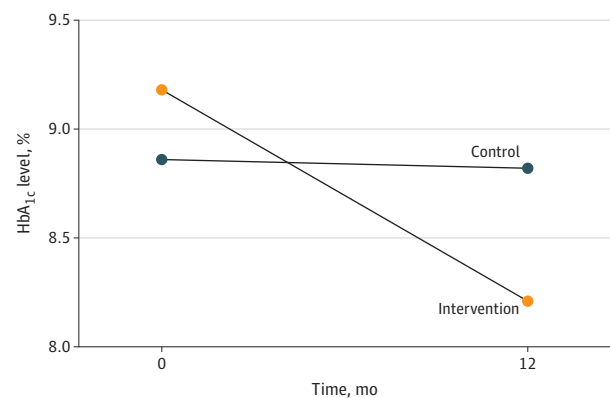
Most concerns (490 [87.2%]) were addressed through a variety of mechanisms, with many requiring more than 1 for action. For example, to address hyperglycemia, CHWs may have connected participants to a case manager for clinic eligibility, to patient scheduling for appointments, and to a clinician for medication questions. All categories resulted in actions in 90% to 100% of cases except transportation (3 cases [50.0%]) and hyperglycemia (63 cases [51.8%]).

## Discussion

This randomized clinical trial demonstrated that a multidimensional intervention incorporating telementored CHWs and structured clinician feedback improved outcomes for low-income adults with type 2 diabetes compared with usual care. The CHW-led intervention significantly improved HbA<sub>1c</sub> level, cholesterol levels, and ADA guideline adherence, reducing mean HbA<sub>1c</sub> level by 1.0 pp, which is twice the clinically significant threshold and the between-group difference in similar studies.<sup>44,45</sup> Given rising diabetes disparities in low-income populations, this intervention could offer connections for individuals to reduce fragmentation and provide a scalable model for geographic expansion.

The lack of HbA<sub>1c</sub> improvement in controls highlights substantial gaps in diabetes care in low-income settings. Even control participants, typically positioned for improvement (eg, more trust in health care, resources), showed no gains,<sup>46,47</sup> suggesting that outcomes in broader populations could be worse.<sup>48</sup> At our sites, 20% of patients with diabetes account for 50% of appointments, demonstrating the heavy clinic burden. Nationally, about \$413 billion annually in direct medical costs and indirect costs is attributable to diabetes.<sup>8</sup> The modest costs of the intervention yielded economic benefits (net savings of \$56 244 per year), demonstrating a scalable,

**Figure 2. Line Graph Showing Baseline to 12-Month Changes in Hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) Levels Among 257 Low-Income, Uninsured Hispanic Adults With Type 2 Diabetes in the Intervention ( $n = 129$ ) and Control ( $n = 128$ ) Arms**



economically practical strategy for improving outcomes in resource-constrained settings.

Successful patient reach may need to be reconceptualized as broad connection, ranging from in-person visits to asynchronous support. A likely contributor of improved outcomes in the intervention—and potentially why usual care showed minimal change—was strengthened connections through multiple modalities (eg, calls, texts, videos, and in person), unlike in traditional care, which is more limited.<sup>49</sup> These strategies increased recruitment from 15% to 38% in earlier studies (in which 66% declined participating due to attendance requirements) to more than 60%.<sup>10</sup> The feedback loop reduced care fragmentation by addressing participant concerns; CHWs reached participants in 5882 of 6269 attempts (93.8%), identifying 562 concerns and addressing 87.2%, mostly medication- or appointment-related, enabling timely adjustments. Telehealth provided 1-on-1 CHW mentoring and participant coaching, a critical element often missing in scaled programs. Telehealth may have also indirectly improved engagement, reflected by increases in foot examinations and urine microalbumin testing, even though clinic visit attendance was not directly measured. Together, these approaches may enable meaningful care and support transition from clinical trials to community practice, where cohorts may number in the thousands or millions.

With 800 million individuals living with diabetes worldwide,<sup>50</sup> most of whom are facing resource constraints,<sup>2</sup> there is an urgent need for pragmatic, scalable programs. Few studies have reported data on CHW program expansion. One study with 35 CHWs across 5 sites and another with 97 CHWs across 17 sites highlighted the need for standardized components and structured processes to reduce acute care use and sustain interventions.<sup>51,52</sup> A systematic review of 20 studies identified CHW integration barriers, including lack of support (6 studies), insufficient resources (4 studies), and heavy reliance on technology (4 studies).<sup>53</sup>

Participating clinics expressed strong interest in sustaining the intervention. Future work should examine implementation and cost-effectiveness. The model could expand to other

aspects of diabetes care, such as equipping CHWs to support continuous-glucose-monitor use—often limited in low-income settings due to educational barriers<sup>54</sup>—and transitions to newer medications, such as glucagon-like peptide-1 receptor agonists, once they are more affordable. Equipping CHWs in these roles could promote equitable access and inform personalized diabetes care policies.

### Strengths and Limitations

The key strength of our intervention was the integration of CHWs into a structured participant-CHW-clinician feedback loop within clinics as opposed to service teledelivery only. This model connected participants to care and resources, facilitated CHW-clinician communication, and enabled timely, individualized support. Implementation barriers were addressed through 1-on-1 telementoring, ongoing support via a non-profit CHW training center,<sup>32</sup> standardizing CHW training with technology access, and stakeholder engagement.

Limitations include the predominance of Hispanic adults, limiting generalizability; 12-month follow-up, which may not capture long-term outcomes; and unmeasured system-level factors affecting broader implementation. The study captured CHW-identified rather than clinician-identified concerns because clinician documentation would likely have been

burdensome and prior research showed that CHWs identified approximately 85% of issues<sup>11</sup>; however, this may have underestimated the full impact of the intervention. Concerns were often multifactorial and multidisciplinary, further limiting the captured impact of the intervention; for example, hyperglycemia could stem from inadequate clinic access, medication questions, and financial barriers involving case managers, CHWs, and clinicians. Future research should include a pragmatic multiphase optimization strategy trial to identify the most effective or cost-conscious intervention components.

### Conclusions

In this randomized clinical trial, a multidimensional intervention with telementored CHWs and a structured participant-CHW-clinician feedback loop significantly improved diabetes outcomes, including lowering HbA<sub>1c</sub> levels, in low-income populations compared with usual care. By addressing care fragmentation through personalized connections and leveraging scalable, cost-sensitive strategies, this model may offer a pragmatic approach to reducing disparities and guiding the broader implementation of community-based diabetes care programs.

#### ARTICLE INFORMATION

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