


Community Health Workers Supporting Clinical Pharmacists in Diabetes Management: A Randomized Controlled Trial

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OBJECTIVES To evaluate the effectiveness of clinical pharmacists and community health workers (CHWs) in improving glycemic control within a low-income ethnic minority population.

METHODS In a two-arm 2-year crossover trial, 179 African-American and 65 Hispanic adult patients with uncontrolled diabetes mellitus (hemoglobin A_{1c} [HbA_{1c}] of 8% or higher) were randomized to CHW support either during the first or second year of the study. All participants received clinical pharmacist support for both years of the study. The primary outcome was change in HbA_{1c} over 1 and 2 years.

RESULTS Similar HbA_{1c} declines were noted after receiving the 1 year of CHW support: -0.45% (95% confidence interval [CI] -0.96 to 0.05) with CHW versus -0.42% (95% CI -0.93 to 0.08) without CHW support. In addition, no differences were noted in change on secondary outcome measures including body mass index, systolic blood pressure, high-density lipoprotein and low-density lipoprotein cholesterol, quality of life, and perceived social support. A difference in diastolic blood pressure change was noted: 0.80 mm Hg (95% CI -1.92 to 3.53) with CHW versus -1.85 mm Hg (95% CI -4.74 to 1.03) without CHW support ($p=0.0078$). Patients receiving CHW support had more lipid-lowering medication intensifications (0.39 [95% CI $0.27-0.52$]) compared with those without CHW support (0.26 [95% CI $0.14-0.38$], $p<0.0001$). However, no significant differences in intensification of antihyperglycemic and antihypertensive medications were observed between patients receiving CHW support and those without CHW support. Patients with low health literacy completed significantly more encounters with the pharmacist and CHW than those with high health literacy, although outcomes were comparable.

CONCLUSIONS No significant differences were noted between a clinical pharmacist-CHW team and clinical pharmacist alone in improving glycemic control within a low-income ethnic minority population.

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Approximately 9% of American adults are diagnosed with type 2 diabetes mellitus, although individuals living in poverty and ethnic minorities are disproportionately affected.¹ Current health care delivery approaches for these vulnerable groups, particularly African American and Hispanic/Latino, are inadequate.² A range of interventions with primary care providers, nurses, dietitians, pharmacists, and community health workers (CHWs) designed to improve glucose and cardiovascular control in diverse patient populations have resulted in mixed results.^{3, 4} However, the most effective interventions studied to date consist of multidisciplinary teams providing a range of components.³ Within the routine clinical environment, these interventions are most consistent with the patient-centered medical home framework.⁵ This model of care typically involves coordinated team-based disease management that considers patient context including family and community. Clinical pharmacists and CHWs are often involved in medical home teams working with patients on chronic disease management.⁶

Clinical pharmacists provide expertise in medication-related issues (e.g., drug interactions and cost), encourage adherence, provide patient education, and adjust therapy in collaboration with providers, resulting in improvements in a range of clinical outcomes.^{7–9} A recent meta-analysis of diabetes outcomes with clinical pharmacy support identified 35 studies and found a moderate effect representing a mean reduction in hemoglobin A_{1c} (HbA1C) of 1.1% (95% confidence interval [CI] 0.88–1.27) with pharmacist care in the ambulatory setting.⁴ Pharmacist involvement varied from providing patient education to medication adjustment via prescriptive authority.

Community health workers are uniquely prepared to work with vulnerable populations. Patients trust CHWs who understand their sociocultural barriers, provide social support, speak the same language, and can increase the relevancy of disease self-management for individuals who are often struggling to manage competing priorities. Importantly, mounting evidence suggests that CHW involvement can contribute to improvement in diabetes

self-management as well as significant decreases in HbA1C that have ranged from 0.5–0.9%.^{10–14}

A pilot study partnering clinical pharmacists with CHWs to serve minority patients with poorly controlled type 2 diabetes mellitus demonstrated the feasibility of this collaborative approach.¹⁵ In the pilot, nine Latino patients with HbA1C values of 8% or higher were recruited from within a general medicine clinic. During a 6-month period, a bilingual Latina CHW provided self-management guidance, medical follow-up assistance, and support for increased medication adherence during home and clinic visits, along with telephone contact. Additionally, pharmacists met in person with the patient and the CHW to conduct medication therapy management. Although this pilot study was small and without a comparison group, mean HbA1C values among participants declined from 9.6–9.0%. Building on this work, the present randomized controlled trial explored the effectiveness of a clinical pharmacist/CHW team compared with clinical pharmacy services alone in improving HbA1C (primary outcome), lipids, and blood pressure within a high-risk group of Hispanic/Latino and African-American patients with type 2 diabetes mellitus. The crossover design investigated the benefit derived from adding CHW support following receipt of clinical pharmacist services for 1 year and the maintenance of any HbA1C improvement after phasing out CHW support.

Materials and Methods

The University of Illinois (UI) at Chicago institutional review board approved the study protocol. Details of the design of this randomized two-arm, two-period crossover study were published previously (including sample size determination).¹⁶

Inclusion criteria were self-identified as Hispanic/Latino or African American; verbal fluency in English or Spanish; 21 years of age or older; existing diagnosis of type 2 diabetes mellitus; HbA1C of 8% or higher in the past year; received primary care through UI Health during the past year; and prescribed at least one oral medication for diabetes or hypertension.

Exclusion criteria were inability to verbalize comprehension of study or evidence of impaired decision making (e.g., dementia); resided outside of the Chicago area 3 or more months of the year or planned to move from the Chicago area; had a household member already participating in the same study; or currently pregnant or trying to become pregnant.

Recruitment and Randomization

A convenience sample was recruited from four primary care ambulatory sites within an academic medical setting that provides care for a diverse low-income population in Chicago. Research assistants (RAs) fluent in the participants' preferred language (English or Spanish) worked with clinic staff to identify patients with type 2 diabetes presenting for a regularly scheduled visit. The RAs screened interested patients for initial eligibility and provided study details when appropriate. Patients provided telephone numbers to be contacted for study enrollment pending confirmation of HbA1C of 8% or higher in the past year by a physician investigator who reviewed each patient's electronic medical record (EMR). Upon arrival, RAs obtained written informed consent and Health Insurance Portability and Accountability Act authorization followed by a computer-assisted personal interview. A nurse conducted venipuncture for HbA1C and lipid profile and measured height, weight, and sitting blood pressure. Laboratory values were entered into the EMR by a study physician and forwarded to the primary care physician (PCP) and pharmacist. Follow-up data were similarly collected at 12 and 24 months with \$40 compensation for each data collection.

After baseline data collection, RAs scheduled an initial pharmacist encounter and determined sequence assignment. Randomization was blocked by sex, ethnicity, and site using a computer-generated random order of sequence assignments. One sequence received only clinical pharmacist visits during the first year, with the CHW added during the second year. The second sequence received a clinical pharmacist plus CHW during the first year but only the pharmacist in year 2. The project coordinator independently applied randomization, maintained concealment, and logged the information separately. Those randomized to a CHW met the worker face to face and scheduled an initial home visit. In rare instances when a CHW

introduction was not possible, patients received a written welcome letter from the CHW (with photograph) and the CHW contacted the patient within 24 hours to schedule a visit.

Pharmacist Intervention

Pharmacists provided medication and disease management services to patients following an established Pharmacist Management Protocol¹⁶ that included a comprehensive needs assessment, health promotion, patient-centric goal setting and education, interventions to encourage behavioral change, and collaboration with the PCP. The CHWs were present during pharmacist encounters when schedules allowed and often translated for Spanish-speaking patients. The initial pharmacist encounter included medication reconciliation, identification of therapeutic goals (particularly HbA1C and blood pressure), formulation of a PCP-approved plan of care, and documentation of the plan in the EMR. The CHWs worked with patients to maintain a record of home glucose and blood pressure monitoring data that was encouraged and reviewed by pharmacists when available. The PCPs and pharmacists used medication intensification algorithms based on national guidelines.^{17, 18} Per guidelines, less stringent goals were implemented for patients with a history of severe hypoglycemia, limited life expectancy, advanced micro- or macrovascular disease, or extensive comorbid conditions. In collaboration with CHWs, pharmacists assessed common barriers to medication adherence, including poor memory, lack of diabetes knowledge, health beliefs, cost, medication burden, physical disabilities, and social barriers. Pharmacists also addressed medications (name and purpose of medications; time, strength, and method of administration); drug interactions and side effects; goals of therapy; basic lifestyle modifications; and use of pillboxes, low-literacy medication lists, or other adherence aids. Communication between the pharmacist and CHW included secure e-mails, telephone contact, and face-to-face discussion before or after patient encounters.

Community Health Worker Intervention

Although college educated, the CHWs otherwise shared many sociodemographic characteristics with the patient population served, including ethnic background and language

(ethnic concordance was ensured between patients and CHWs). Standardized CHW training included two educational curricula: the Diabetes Empowerment Education Program¹⁹ and the adapted Training Curriculum for Health Coaches.²⁰ Additional training was provided by a licensed clinical dietician with certification in diabetes health education (3 hours), an endocrinologist (1 hour), motivational interviewing certified trainer (4 hours), pharmacist (2 hours), clinical health psychologist (3 hours), and PCP (2 hours). CHWs shadowed pharmacists to observe pharmacist-patient interactions in the UI Health Medication Therapy Management Clinic for 2 days to gain insight into routine clinical pharmacist activities. CHW competencies in counseling and diabetes-related clinical skills were assessed with feedback in structured patient simulations.

CHWs visited patients in their homes and communicated with them by telephone. They attempted to meet with patients monthly for the first 3–4 months to establish a relationship; however, the number of home visits per year varied based on patient availability and willingness. With patients' permission, CHWs accompanied them to PCP and pharmacist encounters. These interactions included preparing questions for providers and identifying goals for each visit beforehand. After visits, information was reinforced (e.g., provider instructions, scheduling tests and appointments, medication changes, etc.). Specific CHW activities were individualized based on patient preferences, needs, and values. Examples included social support, diabetes self-management education, problem-solving skill building, health care navigation, translation, and referrals to resources (e.g., food pantries and housing shelters). As mentioned, CHWs and pharmacists communicated with each other in person, by telephone, and through secure e-mail to coordinate patient management. CHWs participated in weekly face-to-face supervision facilitated by a study PCP and health psychologist throughout the study period. During these weekly team meetings, they discussed patients seen during the past week, those unable to be reached, and individuals with challenging and complex psychological and social problems. The meetings ensured CHWs followed the protocol, minimizing drift in intervention delivery. Team meetings also offered CHWs psychological support as they managed patients with severe poverty and stressful life events.

Outcomes and Measurements

The primary outcome was change in HbA1C. The secondary outcomes were changes in systolic and diastolic blood pressure, high-density lipoprotein (HDL) cholesterol, low-density lipoprotein (LDL) cholesterol, body mass index (BMI), quality of life, and perceived social support. Alverno Laboratory (Hammond, IN; National Glycohemoglobin Standardization Program certified) processed all blood testing. Blood pressure was measured after participants sat quietly for 5 minutes (Welch Allyn Spot Vital Signs LXi device, Skaneateles Fall, NY). Height was obtained via stadiometer, and weight was measured with light clothing and without shoes. The surveys included validated measures of diabetes-specific quality of life (four-item Diabetes Distress Scale);²¹ social support from friends, family, and health care team (selected four items);²² health literacy (three-item health literacy screen);²³ diabetes knowledge (Spoken Knowledge in Low Literacy in Diabetes scale);²⁴ depression (Patient Health Questionnaire-2 screen);²⁵ a single-item global health status²⁶ (self-reported); and demographics. These survey measures were considered as potential covariates in mixed-effect modeling.

Medical Record Abstraction

At the end of the study, EMRs were abstracted to capture number of pharmacist encounters and number of intensifications of diabetes, hypertension, and/or hyperlipidemia medications. Medication changes were considered intensification events when a progress note indicated an increase in the number of agents (a new therapeutic class), an increase in the medication dosage, or a change to a different agent.

The number of intensification events, as well as percentage of patients with any intensification events, were reported. In addition, CHW contact records with participants were tabulated. Face-to-face contact was defined as a home visit or encounter within the health care setting before or after a scheduled provider visit.

Statistical Analyses

All analyses were intention to treat. Descriptive statistics for continuous variables were expressed as mean \pm SD, whereas categorical variables were expressed as frequencies and proportions. The *p* values <0.05 were considered statistically

significant. To detect differences in baseline characteristics, intensification events, and outcome measures between the two sequence arms, two-sample *t* tests or nonparametric Wilcoxon rank sum tests were used for continuous variables, and χ^2 tests or Fisher exact tests for categorical variables. Sex, ethnicity, and site were included as control variables in the models initially but are not shown because the results were unchanged. Given the crossover design of this study, mixed-effect modeling was performed on primary and secondary outcomes. The mixed-effect model with random intercept controls for repeated measurement and produces correct standard errors of estimates. Each outcome was analyzed as a measure at each time point and as a change within each time period. For the crossover design, treatment was defined as receipt of CHW support (true or false), period as year in time (1 or 2), and sequence as year receiving CHW support (1 or 2). The final model included fixed effects for design variables (treatment, period, and sequence), demographic characteristics (age, sex, race, insurance, and health literacy), and baseline HbA1C with random effects for subject. These variables were selected because they were clinically relevant and/or statistically associated with the outcome ($p < 0.1$). All statistical analyses were conducted by SAS v.9.4 (SAS Institute Inc., Cary, NC).

Treatment of Missing Data

Missing HbA1C data were obtained from the EMR when available. HbA1C values near the targeted data collection date were identified in 28 instances. For the remaining missing data, multiple imputation followed by fitting of the mixed-effect model on the imputed data was conducted. The reported estimated means and mean changes were combined from 20 imputed data sets. As a secondary analysis, extreme changes of HbA1C values were truncated, and the same analyses were repeated. The main results did not differ with the additional EMR data, imputation, or truncation of extreme values. Missing data for the additional outcomes were addressed with the same multiple imputation procedures. To explore the unexpected finding of diastolic blood pressure change between treatments, multiple imputation was conducted with a worst case scenario where missing values were replaced with the worst observed value during the study period. The same mixed-effects model was then applied with no difference in result.

Results

Figure 1 describes the screening, randomization, and participant flow during the 24-month study period. Of the 538 patients screened, 334 were deemed eligible for the study (62%), and 247 completed baseline data collection. However, three of those patients were subsequently deemed ineligible, resulting in a final sample of 244 patients. For year 1, 124 patients were randomized initially to receive only pharmacist support and 120 to receive both pharmacist and CHW support. Baseline characteristics were balanced between the two randomly assigned sequence groups (Table 1).

Utilization of Interventions

Clinical pharmacist and CHW contact varied among participants. During the study period, 83.6% of the 244 participants had at least one pharmacist encounter, with a mean of 7.1 (SD = 8.2) per participant over 2 years. Pharmacist utilization was greater during year 1 than year 2 (1162 vs 564 encounters, $p < 0.001$), but no differences were found in the number of encounters between treatment groups (6.7 for pharmacist only vs 7.4 with CHW, $p = 0.504$). The number of pharmacist encounters did not differ by ethnic group. However, those with low health literacy completed on average 9.7 (SD = 10.4) pharmacist visits compared with 7.2 (SD = 7.7, $p < 0.05$) among those with high literacy.

Overall, 77.5% of participants completed at least one CHW encounter. However, 91.7% of those with CHW support during year 1 completed at least one encounter versus 63.7% receiving CHW support in year 2 ($p < 0.0001$). In addition, a significant difference was noted in the number of CHW encounters between groups. On average, those who received CHW in year 1 completed 6.5 (SD = 5.3) encounters compared with 3.4 (SD = 4.1, $p < 0.001$) with CHW support in year 2. Patients with low health literacy had a mean 8.4 (SD = 7.0) CHW visits compared with 6.5 (SD = 5.2, $p = 0.012$) CHW visits in those with high health literacy.

Glycemic Control and Secondary Outcomes

Of the 244 patients enrolled, 197 (81%) completed 12-month and 192 (79%) completed 24-month data collection. Both treatments showed a similar decline in HbA1C (Table 2). Patients

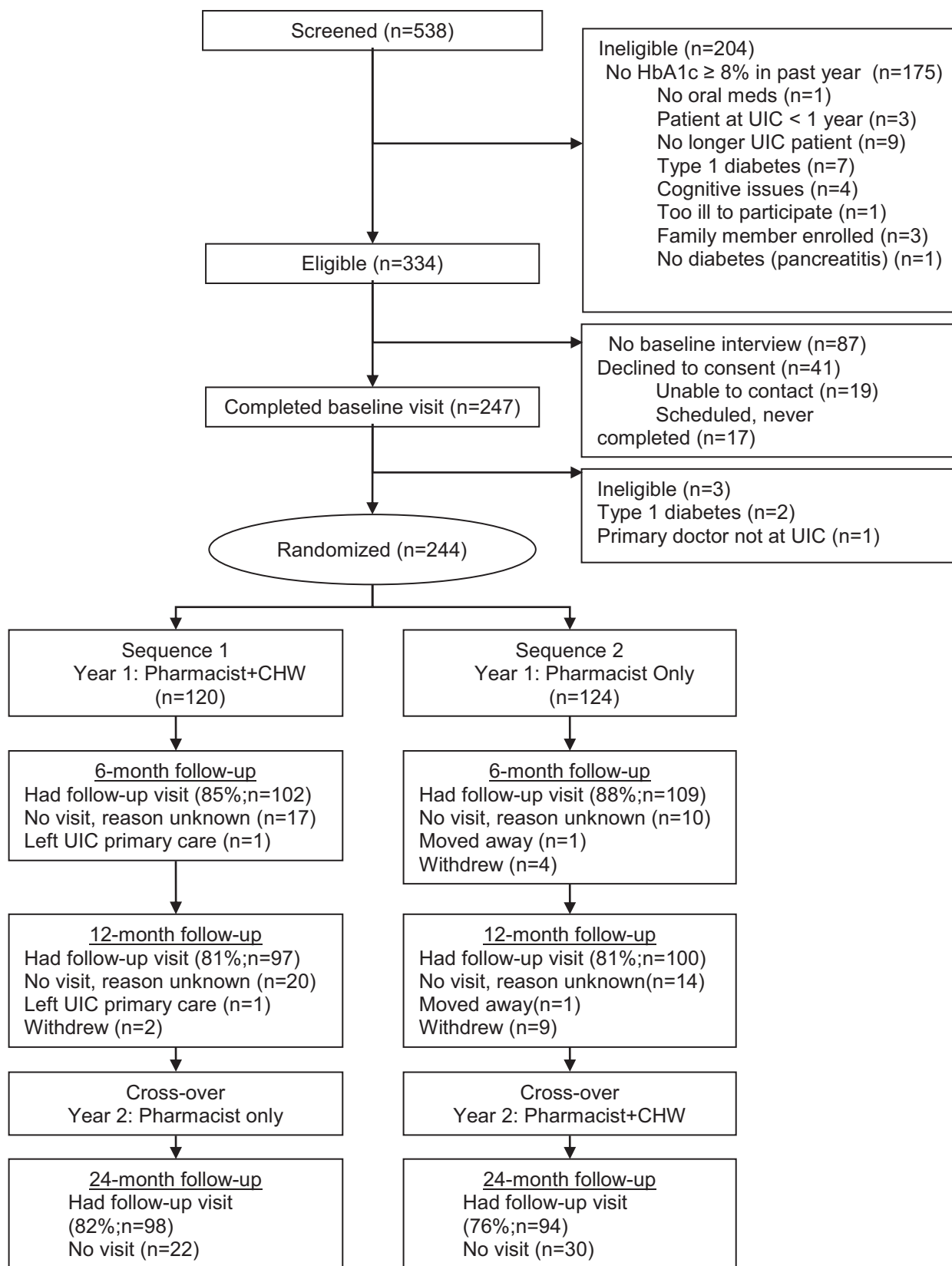


Figure 1. Study design and randomization. CHW = community health worker; HbA_{1c} = hemoglobin A_{1c}; UIC = University of Illinois at Chicago.

Table 1. Demographic Characteristics at Baseline

Characteristic	Sequence 1 Pharmacist + CHW ^a (N=120)	Sequence 2 Pharmacist only ^a (N=124)	Both groups combined (N=244)	Between-group difference p value
Age, yrs, mean (SD)	53.83 (10.5)	54.57 (11.7)	54.21 (11.15)	0.61
Sex, N (%)				
Female	83 (69.2)	81 (65.3)	164 (67.2)	0.52
Male	37 (30.8)	43 (34.7)	80 (32.8)	
Race/Ethnicity, N (%)				
African American/Black	88 (73.3)	91 (73.4)	179 (73.4)	0.99
Hispanic/Latino	32 (26.7)	33 (26.6)	65 (26.6)	
Income level, ^b N (%)				
< \$10,000	46 (46.5)	40 (36.7)	86 (41.4)	0.35
\$10,000–\$20,000	25 (25.3)	31 (28.4)	56 (26.9)	
>\$20,000	28 (28.3)	38 (34.86)	66 (27.1)	
Highest education level, N (%)				
Less than high school	33 (27.5)	39 (31.5)	72 (29.5)	0.74
High school diploma/GED	58 (48.3)	59 (47.6)	117 (48.0)	
Some college/Graduated college	29 (24.2)	26 (21)	55 (22.5)	
Employment status, N (%)				
Disabled and unable to work	61 (50.8)	56 (45.5)	117 (48.2)	0.46
Retired	14 (11.7)	21 (17.1)	35 (14.4)	
Out of work/Unemployed	18 (15.0)	13 (10.6)	31 (12.8)	
Work (full or part time)	25 (21.2)	28 (23.7)	53 (21.7)	
Marital status, N (%)				
Single, never married	50 (41.7)	54 (43.6)	104 (42.6)	0.90
Married or living with partner	34 (28.3)	36 (29.0)	70 (28.7)	
Widowed/Separated/Divorced	36 (30.0)	34 (27.4)	70 (28.7)	
Health insurance, N (%)				
None	4 (3.3)	9 (7.4)	13 (5.4)	0.30
Public aid/Medicaid/Medicare	96 (80)	89 (73.6)	185 (75.8)	
HMO/PPO	20 (16.7)	23 (19.0)	43 (17.8)	
Health status, N (%)				
Excellent/Very good/Good	47 (39.2)	49 (39.5)	96 (39.3)	0.96
Fair/Poor	73 (60.8)	75 (60.5)	148 (60.7)	
Diabetes duration, mean, yrs (SD)	13.24 (8.7)	13.66 (8.9)	13.45 (8.8)	0.71
Health literacy, mean (SD)	6.43 (3.4)	6.59 (3.5)	6.51 (3.42)	0.73
Diabetes knowledge, mean (SD)	5.29 (1.8)	5.45 (1.9)	5.37 (1.8)	0.50
Diabetes social support, mean (SD)	15.73 (4.2)	15.94 (3.9)	15.83 (4.1)	0.69
Quality of life, mean (SD)	13.77 (6.3)	13.38 (5.7)	13.57 (6.0)	0.61
Depression, PHQ-2, mean (SD)	1.90 (2.0)	1.80 (1.9)	1.85 (2.0)	0.69
Physiologic				
HbA1C, %, mean (SD)	9.43 (2.0)	9.57 (1.8)	9.50 (1.9)	0.57
SBP, mm Hg, mean (SD)	134.18 (20.5)	134.17 (17.9)	134.17 (19.2)	0.99
DBP, mm Hg, mean (SD)	79.08 (13.7)	80.25 (12.1)	79.67 (12.9)	0.48
BMI, kg/m ² , mean (SD)	35.74 (8.9)	36.81 (9.6)	36.29 (9.3)	0.37
LDL, mg/dl, mean (SD)	98.19 (41.3)	91.90 (33.4)	94.97 (37.5)	0.20
HDL, mg/dl, mean (SD)	48.72 (14.3)	47.90 (12.7)	48.30 (13.5)	0.64

BMI = body mass index; CHW = community health worker; DBP = diastolic blood pressure; GED = general education diploma; HbA1C = hemoglobin A_{1c}; HDL = high-density lipoprotein; HMO = health maintenance organization; LDL = low-density lipoprotein; PHQ-2 = Patient Health Questionnaire-2; PPO = preferred provider organization; SBP = systolic blood pressure; SD = standard deviation.

^aInitial treatment assignment in year 1.

^bIncome in sequence 1 missing (N=21) and sequence 2 missing (N=15).

receiving pharmacist plus CHW support had an average decrease of HbA1C of -0.45% (95% CI $[-0.96$ to $0.05]$) compared with -0.42% (95% CI $[-0.93$ to $0.08]$) in those receiving only pharmacist support. No differences were found between treatments in change in secondary outcomes including BMI, systolic blood pressure, HDL and LDL cholesterol, self-reported medication adherence, quality of life, and perceived

social support. Change in diastolic blood pressure was 0.80 mm Hg (95% CI $[-1.92$ to $3.53]$) for pharmacist plus CHW compared with -1.85 mm Hg (95% CI $[-4.74$ to $1.03]$) for pharmacist only ($p=0.0078$).

The final crossover design mixed-effects model showed no significant treatment or sequence effects. However, a greater reduction was found in HbA1C during year 1 compared

Table 2. Results of Crossover (Mixed-Effects Model) Analysis

Outcome	Pharmacist + CHW Estimate (95% CI)	Pharmacist only Estimate (95% CI)	Difference			
			Estimate	SD	95% CI	p value
HbA1C, %						
Change	−0.45 (−0.96 to 0.05)	−0.42 (−0.93 to 0.08)	−0.03	0.15	−0.32 to −0.26	0.84
Raw	8.84 (8.36–9.32)	8.89 (8.40–9.38)	−0.05	0.13	−0.31 to 0.22	0.72
SBP, mm Hg						
Change	1.26 (−3.15 to 5.67)	−1.00 (−5.64 to 3.62)	2.27	1.61	−0.90–5.43	0.16
Raw	133.0 (128.76–137.24)	132.78 (128.53–137.02)	0.22	1.31	−2.34 to 2.79	0.86
DBP, mm Hg						
Change	0.80 (−1.92 to 3.53)	−1.85 (−4.74 to 1.03)	2.65	0.99	0.70–4.61	0.0078
Raw	78.38 (75.93–80.83)	77.77 (75.32–80.22)	0.61	0.82	−1.00 to 2.21	0.46
BMI, kg/m ²						
Change	−0.20 (−1.15 to 0.74)	−0.22 (−1.17 to 0.73)	0.02	0.20	−0.38 to 0.41	0.93
Raw	35.91 (35.00–36.83)	36.16 (35.23–37.08)	−0.24	0.19	−0.62 to 0.14	0.21
LDL, mg/dl						
Change	−2.93 (−10.60 to 4.74)	−2.66 (−9.79 to 4.467)	−0.27	2.76	−5.70–5.16	0.92
Raw	91.34 (82.99–99.70)	91.08 (82.87–99.28)	0.266	2.05	−3.74 to 4.28	0.90
HDL, mg/dl						
Change	−0.82 (−3.14 to 1.49)	−1.61 (−3.87 to 0.65)	0.79	0.79	−0.77 to 2.34	0.32
Raw	46.63 (44.83–48.43)	46.96 (45.17–48.76)	−0.34	0.58	−1.47 to 0.80	0.56
Social support						
Change	0.53 (−0.30 to 1.36)	0.64 (−0.22 to 1.50)	−0.11	0.26	−0.63 to 0.41	0.65
Raw	16.58 (15.59–17.57)	16.53 (15.53–17.52)	0.06	0.21	−0.35 to 0.46	0.79
Quality of life						
Change	−1.51 (−2.89 to −0.13)	−1.59 (−2.95 to −0.22)	0.08	0.43	−0.78 to 0.93	0.86
Raw	11.46 (10.26–12.67)	11.60 (10.37–12.83)	−0.14	0.36	−0.85 to 0.58	0.71

Overall (pooled) estimates of main outcomes for pharmacist and pharmacist + CHW interventions from multiple imputed data. Pharmacist + CHW and Pharmacist columns represent the estimated effect of the intervention adjusted for sequence, period, and covariates. The difference column represents the estimated difference between the two treatments (with and without CHW).

BMI = body mass index; CHW = community health worker; CI = confidence interval; DBP = diastolic blood pressure; HbA1C = hemoglobin A_{1c}; HDL = high-density lipoprotein; LDL = low-density lipoprotein; SBP = systolic blood pressure; SD = standard deviation.

with year 2 ($p < 0.0001$) with baseline HbA1C ($p < 0.0001$) negatively associated with the mean change in HbA1C. No other covariates were significant. Additional exploratory analyses showed no difference between having a pharmacist-CHW team compared with a pharmacist alone in terms of the number of patients reaching goal in HbA1C (either 7% or lower or 8% or lower), at either 12 or 24 months.

Medication Intensification

The number of intensification events was similar across treatments for antihyperglycemic and antihypertensive medications (Table 3). However, more intensifications in lipid-lowering medications occurred when working with pharmacist plus CHW (0.39 [95% CI 0.27–0.52])

compared with the pharmacist alone (0.26 [95% CI 0.14–0.38]), $p < 0.0001$). Similarly, a comparable percentage of patients working with a CHW and pharmacist versus only a pharmacist had any antihyperglycemic or antihypertensive medication intensifications, whereas significantly more patients working with a CHW and pharmacist had intensifications in antilipid medication compared with those working with only a pharmacist (Table 4).

Discussion

Patients receiving pharmacist management, with or without CHW support, demonstrated improvement in HbA1C. The magnitude of change may be clinically significant with an estimated mean decrease of 0.42–0.45% over

Table 3. Number of Medication Intensifications

Intensification	Pharmacist + CHW estimate (95% CI)	Pharmacist estimate (95% CI)	Difference			
			Estimate	SE	95% CI	p value
Antihyperglycemic	1.51 (0.83–2.18)	1.60 (0.93–2.28)	−0.09	0.11	−0.31 to 0.12	0.38
Antihypertensive	0.49 (0.20–0.78)	0.40 (0.11–0.69)	0.09	0.06	−0.02 to 0.21	0.11
Antilipid	0.39 (0.27–0.52)	0.26 (0.14–0.38)	0.13	0.03	0.08–0.19	<0.0001

CI = confidence interval; CHW = community health worker; SE = standard error.

Table 4. Percentage of Patients with Medication Intensification by Year

Intensification	Year 1			Year 2		
	Pharmacist + CHW, %	Pharmacist, %	p value	Pharmacist + CHW, %	Pharmacist, %	p value
Antihyperglycemic	70.83	70.97	0.98	56.45	54.17	0.72
Antihypertensive	35.00	31.45	0.56	31.45	24.17	0.20
Antilipid	29.17	15.32	0.01	20.16	10.00	0.03

CHW = community health worker.

2 years.^{27–29} Secondary outcomes were unchanged with the exception of diastolic blood pressure (participants with pharmacist-only intervention experienced slightly lower diastolic pressure, possibly a spurious relationship). Finally, significantly more intensifications of lipid-lowering medication were noted when participants were working with the CHW compared with the pharmacist alone. A recent study of diabetic Latinos receiving CHW support also demonstrated an increase in lipid-lowering intensification.¹³ The reason for this effect is unclear. It is conceivable that CHW-pharmacist communication, including medication reconciliation, created more opportunities to restart or intensify statin prescriptions. Although a CHW intervention with patients experiencing acute coronary syndrome did result in lower LDL and total cholesterol, similar outcomes were not extended to CHW interventions and patients with diabetes.^{13, 14, 30}

From a process standpoint, it was noteworthy that patients randomized to receive CHW support during their first year had more face-to-face visits with CHWs than those who received CHW support after 1 year of pharmacist-only support. Several factors might account for this pattern of engagement. Introducing CHWs to patients immediately following data collection was challenging, particularly mid-study because patients were accustomed to leaving immediately after data collection. Many patients reported reasons why they could not stay to meet with CHWs (e.g., need to get to work, a ride cannot wait, etc.). Relatedly, limited change in HbA1C was noted during the second year overall, possibly due to lower patient motivation, less patient-pharmacist contact, and some patients reaching their therapeutic goals.

As is common with behavioral interventions, some patients were engaged more than others. Specifically, patients with low health literacy had more visits with both CHWs and pharmacists than those with high health literacy, and Hispanics/Latinos had more CHW visits than African Americans. Low health literacy is a known barrier to diabetes self-management.³¹

Furthermore, mistrust of health care providers is more common among patients with diabetes and low health literacy than those with adequate health literacy.³² The higher incidence of visits with pharmacists among the patients with low health literacy may relate to the fact that the CHWs accompanied patients to pharmacy visits and translated for Spanish-speaking patients. The CHW model is uniquely suited to patients with low health literacy, mistrust, and poor communication with providers. Unfortunately, more visits did not translate into improved outcomes when compared with those with high health literacy. Notably, many Hispanic/Latino patients appreciated having a Spanish-speaking advocate within the clinical setting where language barriers were prevalent. Indeed, language discordance between patient and provider contributes to poor glycemic control.³³ However, the small number of Hispanic/Latino patients with limited English proficiency reduced the ability to make meaningful comparisons by ethnic groups.

Overall, the 2-year improvement in HbA1C was comparable with other CHW-driven intervention studies, yet slightly less than other pharmacist-collaborator models, which average a 1.1% decrease in HbA1C over 6–12 months.^{4, 25, 34–36} In comparison, the improvement in HbA1C over the first 12 months was 0.87% in this study. As is commonly found in pharmacist-led chronic disease programs,⁹ our study provided frequent follow-up encounters to conduct medication monitoring and patient education. Although it may be anticipated that prescriptive authority could result in greater improvement in HbA1C, other factors must be considered. For example, a lack of reliable transportation represents an important barrier to care access among our population and reportedly limited the number of pharmacist visits.³⁷

This study has several limitations. First, all participants received pharmacist support, making it impossible to know what change might have occurred with routine medical care alone. Specifically, regression toward the mean³⁸

cannot be excluded. Second, individuals were randomized within clinics (not cluster randomized). It is possible, although unlikely, that patients receiving CHW support may have influenced those in the other condition, consequently reducing between-treatment differences in outcomes. Also, carryover remains a potential issue in crossover design. The CHWs' contributions were mostly immediate and within the period of CHW exposure, such as problem solving and direct support. However, it is possible that CHWs also conveyed knowledge or modeled how to resolve problems, some of which sequence-1 participants may have partially retained, so there could have been a degree of carryover effect as well into year 2. Third, these results might not generalize to other practices and settings. The pharmacist/CHW teams were implemented in several sites within a single academic medical center, and the effectiveness of the pharmacist/CHW team likely varied. Pharmacist and CHW communication about patient care was challenging outside of pharmacist encounters, despite the fact that the pharmacists reported positive experiences working with CHWs and felt that patients likely benefited from their involvement.³⁹ Work-related scheduling conflicts prevented consistent and ongoing collaboration. The "intervention dose" provided by the CHW and pharmacist varied across patients, as is common in similar studies.¹³ For example, whereas some patients completed monthly face-to-face encounters with the CHW and pharmacist, others may have had only a few pharmacist encounters or preferred telephone contact with the CHWs. The relatively low engagement by some patients, particularly in year 2, may further reduce the probability of detecting changes in outcomes between treatments and may affect differences detected between time periods, following our intention-to-treat analysis. Also, a relationship between the number of CHW encounters and HbA1C improvement was not detected in analyses. Although some may conclude that CHWs truly offer no additional benefit to clinical pharmacy support in terms of HbA1C control, this conclusion may be premature. The population under study had numerous comorbid health conditions along with complicated psychosocial challenges and other serious barriers (e.g., death of loved ones, housing instability, and exacerbation of other chronic illnesses).⁴⁰ The CHWs reported that these contextual issues challenged patients' ability to focus on diabetes self-management.

Documentation from CHWs' visits suggested that they often spent time providing psychological support and resources to patients. A number of patients lacked basic access to adequate food, a safe environment, or sufficient finances. The CHWs were trained to assess the patient's life context and then work with them to increase their diabetes self-management skills within the reality of that context. Some patients possibly engaged with the CHW component more for the resources and advocacy for their daily needs than for the diabetes-related self-management support.

The CHWs reported that several patients refused to engage in ongoing pharmacist support because of the need for transportation to attend an additional visit and waiting room time. A randomized study is currently being conducted to evaluate whether the use of remote clinical pharmacist video conferencing and text messaging can address these barriers. Video conferencing, where CHWs provide Internet-enabled tablets to patient homes, will allow patient interactions with clinical pharmacists routinely without need for transportation. Text messaging will further promote patient-CHW communication, including patient reminders for self-care activities and other forms of support. These intervention enhancements, in addition to the study comparing patients who do not receive pharmacist or CHW support, may further the understanding of this unique model of diabetes care.

In conclusion, no significant differences were found between a clinical pharmacist/CHW team and clinical pharmacist alone in improving glycemic control in this sample of low-income African-American and Hispanic/Latino patients with uncontrolled diabetes. The magnitude of HbA1C change may be considered clinically meaningful at the end of the study period. Collaboration between pharmacists and CHWs did result in greater intensification of lipid-lowering medication (but without effect on LDL). The differential patient engagement with the pharmacists and CHWs suggests that future research should explore which patients most benefit from such services.

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