Health Coaching by Medical Assistants to Improve Control of Diabetes, Hypertension, and Hyperlipidemia in Low-Income Patients: A Randomized Controlled Trial

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ABSTRACT

PURPOSE Health coaching by medical assistants could be a financially viable model for providing self-management support in primary care if its effectiveness were demonstrated. We investigated whether in-clinic health coaching by medical assistants improves control of cardiovascular and metabolic risk factors when compared with usual care.

METHODS We conducted a 12-month randomized controlled trial of 441 patients at 2 safety net primary care clinics in San Francisco, California. The primary outcome was a composite measure of being at or below goal at 12 months for at least 1 of 3 uncontrolled conditions at baseline as defined by hemoglobin A_{1c}, systolic blood pressure, and low-density lipoprotein (LDL) cholesterol. Secondary outcomes were meeting all 3 goals and meeting individual goals. Data were analyzed using χ^2 tests and linear regression models.

RESULTS Participants in the coaching arm were more likely to achieve both the primary composite measure of 1 of the clinical goals (46.4% vs 34.3%, $P = .02$) and the secondary composite measure of reaching all clinical goals (34.0% vs 24.7%, $P = .05$). Almost twice as many coached patients achieved the hemoglobin A_{1c} goal (48.6% vs 27.6%, $P = .01$). At the larger study site, coached patients were more likely to achieve the LDL cholesterol goal (41.8% vs 25.4%, $P = .04$). The proportion of patients meeting the systolic blood pressure goal did not differ significantly.

CONCLUSIONS Medical assistants serving as in-clinic health coaches improved control of hemoglobin A_{1c} and LDL levels, but not blood pressure, compared with usual care. Our results highlight the need to understand the relationship between patients' clinical conditions, interventions, and the contextual features of implementation.

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INTRODUCTION

Cardiovascular disease is the leading cause of death in the United States,[1] and it accounts for more than $500 billion of health care spending annually.[2] Despite the demonstrated effectiveness of pharmaceutical therapies and lifestyle modifications for improving cardiovascular disease outcomes, 50% of people with hypertension, 43% with diabetes, and 80% with hyperlipidemia have not reached their goals for blood pressure, glycemic control, or lipids, respectively.[3-5] One-half of patients do not take their chronic disease medications as prescribed, and only 1 in 10 patients follow recommended guidelines for lifestyle changes, such as smoking cessation or weight loss.[6] Minority and low-income communities bear a disproportionate burden of chronic disease and its complications,[7] and they are less likely to engage in effective self-management of their conditions.[8,9]

Contributors to this gap in self-management include a lack of patient understanding of, and agreement with, the care plan, and low confidence and motivation to make healthy choices. Health coaching addresses this

gap by equipping people with the knowledge, skills, and confidence to manage their chronic conditions.[10]

With primary care clinicians in increasingly short supply[11] and overwhelmed by the expanding preventive and chronic care needs of their growing patient populations,[12,13] new evidence-based models of care are needed to provide self-management support through other members of the care team. To be effective, this support must be culturally appropriate and financially sustainable in resource-poor settings. Medical assistants represent an untapped resource for health coaching. One of the fastest-growing allied health professions,[14] the medical assistant workforce is more culturally and linguistically concordant with patient populations than are other medical professions.[15]

Previous studies of medical assistant health-coaching programs found positive trends in clinical indicators such as hemoglobin A_{1c} (HbA_{1c}) but lacked power to find statistically significant differences,[16] or were not designed as randomized trials.[17-19] They focused on a single condition such as diabetes or hypertension.[16-19] Medical assistant health coaching could be a viable model for providing self-management support in primary care if its effectiveness were demonstrated across the most prevalent cardiovascular conditions. We conducted a randomized controlled trial to test the effectiveness of clinic-based medical assistant health coaching vs usual care to improve clinical indicators among low-income patients with uncontrolled type 2 diabetes, hypertension, and hyperlipidemia.

METHODS

A description of the study sites, recruitment protocol, and participant demographics of this trial, conducted between 2011 and 2013, has been previously published.[20] The protocol was approved by the University of California, San Francisco Committee on Human Research (approval number 10-02813), and the study was registered with clinicaltrials.gov (NCT01220336).

Setting and Participants
Participants were enrolled from 2 sites within the safety net of primary care clinics that serve San Francisco's low-income population. Clinic A was a not-for-profit federally qualified health care center serving a predominantly Latino population (89%), with many uninsured patients (79% of adults). Clinic B was a public primary care clinic whose patient population was predominantly African American (64%) and publicly insured (73%). Neither clinic had used a medical assistant health-coaching model before.

Potential participants were identified through chronic disease registries and billing data. They met at least 1 of 3 clinical criteria: (1) uncontrolled diabetes if they had an HbA_{1c} of at least 8.0% in the last 3 months; (2) uncontrolled hypertension if they had a systolic blood pressure (SBP) of at least 140 mm Hg at baseline and at the previous visit 2 weeks to 1 year before baseline; or (3) uncontrolled hyperlipidemia if they had a low-density lipoprotein (LDL) cholesterol level of at least 160 mg/dL (if not diabetic) or at least 100 mg/dL (if diabetic) within the past 6 months. If triglycerides were 40 mg/dL or lower, or were at least 400 mg/dL, then non–high-density lipoprotein (HDL) cholesterol (total cholesterol minus high-density lipoprotein cholesterol) was used to determine eligibility, with thresholds of at least 190 mg/dL and at least 130 mg/dL for nondiabetic and diabetic patients, respectively.[21] Additional eligibility criteria included being between the ages of 18 to 75 years, having had at least 1 visit within the past 12 months, and planning to attend the clinic for the next 12 months (Figure 1). Primary care clinicians were asked to identify patients who should be excluded because of serious health conditions or behavioral health issues such as uncontrolled schizophrenia that would preclude working with a health coach (3.7% of patients screened).
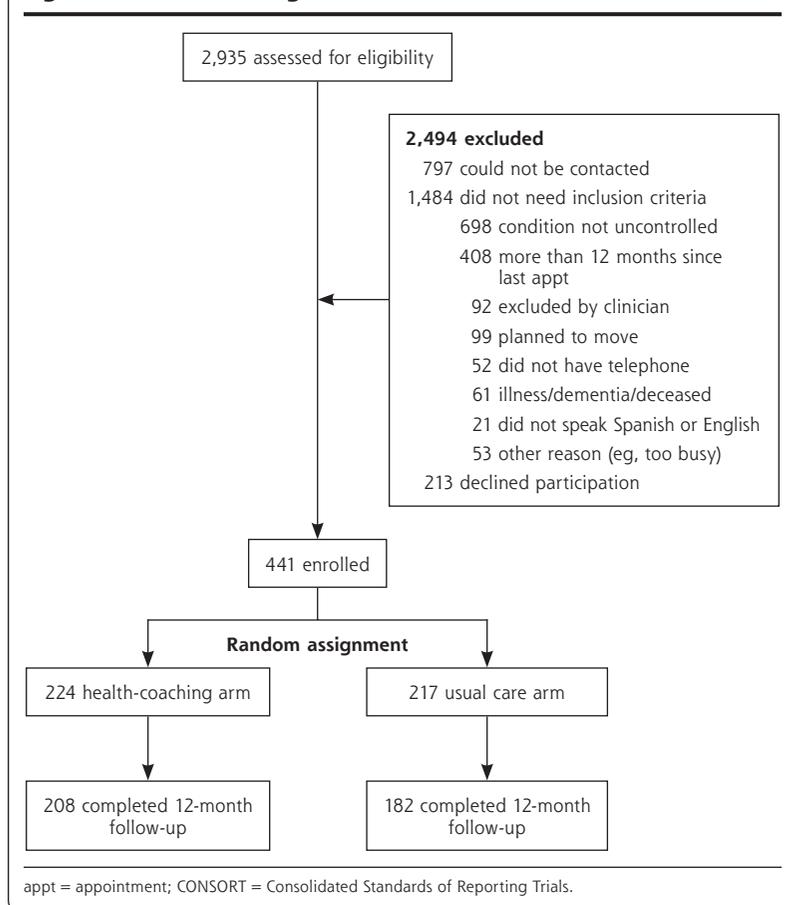
Health Coach Training
The 3 health coaches had diplomas from 3- to 12-month medical assistant programs, were women aged younger than 40 years, self-identified as Latina, and were bilingual in English and Spanish. None had graduated from a 4-year college. All received 40 hours of health coach training (Table 1), details of which have been previously published.[10,20,22,23] The health coaches were embedded as part of the care team at their clinic: 2 were placed at site A and 1 at site B.

Enrollment and Randomization
Patients were approached by letter, telephone, and in person to be further screened and invited to take part in the study. All participants provided informed consent. A random binary sequence, stratified by diabetes diagnosis but not by site, was used to order study arm assignment into sequentially numbered envelopes. Research assistants conducted a 45-minute verbal interview and updated clinical measures. Patients then opened the next envelope in the sequence, assigning them to health coaching or usual care. Participants received $10 for each interview.

Intervention
Patients assigned to the coaching (intervention) arm received 12 months of coaching from the medical assistants trained as health coaches, who worked full time at the clinic sites. Following an established

Figure 1. CONSORT diagram.

appt = appointment; CONSORT = Consolidated Standards of Reporting Trials.

lected at baseline and at 12 months using the same techniques.[20] For diabetic patients, HbA_{1c} was measured using the NGSP-certified DCA Vantage point-of-care testing system (Siemens).[24,25] Lipid panels (including calculated LDL) were measured by the clinical laboratory at site A using a Pentra 400 system (HORIBA Medical) and at site B using the Cholesterol Reference Method Laboratory Network (CRMLN)-certified CardioChek point-of-care testing system (PTS Diagnostics).[26] Blood pressures were measured at enrollment and at 12 months by trained research assistants using a calibrated Omron Home Blood Pressure Monitor Model 711-AC (OMRON Healthcare). In accordance with American Heart Association guidelines,[27] blood pressure was recorded as the average of 2 blood pressure readings, unless the 2 systolic readings differed by more than 5 points, in which case a third blood pressure reading was taken and the average of all 3 readings used.

Outcomes

A priori study goals were defined for HbA_{1c} (<8.0%), SBP (<140 mm Hg if nondiabetic or <130 mm Hg if diabetic), and cholesterol (LDL cholesterol <130 mg/dL or non-HDL cholesterol <160 mg/dL if nondiabetic and LDL cholesterol <100 mg/dL or non-HDL cholesterol <130 mg/dL if diabetic) among patients enrolled with uncontrolled diabetes, hypertension, and hyperlipidemia, respectively.

model,[22] health coaches met in the clinic with the patient before the visit, remained in the examination room during the visit, reviewed the care plan with the patient immediately after the visit, and followed up with patients between visits in person and by telephone. Health coaches were assigned up to 100 patients and instructed to contact them at least once a month and to have an in-person visit at least once every 3 months.

Usual Care

Patients randomized to usual care had access to any resources available at the clinic, including visits with their clinician, diabetes educators, nutritionists, chronic care nurses, educational classes, and registry data to plan care.

Measures

Interviews at baseline and 12 months captured demographics and other patient-reported measures. HbA_{1c}, blood pressure, lipid levels, weight, and height were col-

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Table 1. Training of Health Coaches: Topics and Skills

Collaborative communication	**Medication adherence**
Eliciting patient knowledge and motivation	Assessing patient knowledge and motivation
Closing the loop (teach back)	Addressing barriers to adherence
Setting the agenda	**Working with primary care clinicians**
Reviewing laboratory numbers	Taking notes during a visit
Action plans	Checking understanding
Assessing patient motivations	Offering help
Exploring ambivalence	Advocating for a patient's agenda
Disease-specific knowledge	**Community and clinic resources**
Basics of study conditions	Behavior health
Monitoring control	Physical activity and healthy eating
Medication management	Smoking cessation
	Social determinants of health

The primary outcome was a composite[28] of the proportion of patients in each arm reaching at least 1 of the above goals for which they were uncontrolled at baseline. Secondary outcomes were the proportion in each arm meeting goal for all conditions uncontrolled at baseline; the proportion meeting each of the individual goals; and the mean change in HbA_{1c}, SBP, and LDL cholesterol levels for patients enrolled with uncontrolled diabetes, hypertension, and hyperlipidemia, respectively.

Sample Size Calculation

Sample size and power calculations were performed for the primary composite measure. Enrolling 440 patients provided for more than 80% power to detect the estimated effect size of 15%, after allowing for attrition of up to 20%, using the standard threshold for a significant difference of .05 (2-sided).

Statistical Analysis

We compared differences between groups using independent sample t tests and χ^2 tests for continuous and categorical data, respectively. All analyses used the intent-to-treat principle in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines for reporting results from clinical trials.[29] The change in continuous secondary outcomes was compared between study arms using linear regression models, with the composite and individual clinical outcomes as the outcome variables, and study arm as the predictor variable. Analyses were conducted on the total sample and by site. The role of site was further explored in multivariate linear and logistic regression models by controlling for site and examining the interaction between study arm and site on the primary and secondary outcomes. We initially analyzed the data as collected, without imputation for missing values (ie, used the missing-at-random approach). To assess the robustness of the results, we repeated the same analyses using multiple imputation to supply values for missing data. Because there were no meaningful differences between the results of the analyses with or without data imputation, we chose to present the results of the initial analysis using the missing-at-random (non-imputed) data. All statistical analyses were performed using SPSS 19.0 (SPSS Inc) except for imputation of missing data, conducted using NORM version 2 software (Pennsylvania State University),[30] which imputes data through the expectation-maximization algorithm.

RESULTS

Of 654 patients identified as eligible, 441 (67.4%) were enrolled, with 224 randomized to the health-coaching group and 217 to the usual care group (Fig-

ure 1). Three-quarters (75.3%) of the participants were recruited from clinic site A, and the remainder were recruited from clinic site B. Patients at clinic site A and Spanish speakers were more likely to participate in the study than patients from site B and English speakers.

Overall, the sample had a mean age of 53 years, and slightly more than one-half were women (Table 2). Many participants were first-generation immigrants and spoke Spanish as their primary language. About one-third reported their annual household income to be less than $5,000. There were no significant baseline differences between the 2 intervention groups for any key variables, including the number of uncontrolled conditions or the proportion of patients in each arm with each condition. There were several differences between sites, however, (Table 3), with participants from site A more likely to report a primary language of Spanish and have lower education. Participants in the health-coaching arm received an average of 12.4 contacts with their health coach over the intervention period, with participants from site A receiving a greater number of contacts and reporting higher quality of health coach contacts.

Overall attrition was 11.6% from baseline to 12 months and was lower in the health-coaching arm than the usual care arm (7.1% vs 16.1%, $P = .003$). Attrition status was not related to any demographic or outcome variable, and there were no significant between-group differences in attrition with the exception of baseline HbA_{1c}, whereby participants who were lost to follow-up had higher baseline mean HbA_{1c} levels in the control arm than in the coaching arm (10.5% [1.3%] vs 9.2% [0.4%], $P = .03$). Study clinical outcome measures (HbA_{1c}, LDL cholesterol, or SBP) were available for 94% (132) of 144 patients enrolled with uncontrolled diabetes, 95% (156) of 165 patients enrolled with uncontrolled hypertension, and 83% (169) of 203 patients enrolled with uncontrolled hyperlipidemia.

Participants in the health-coaching arm were more likely than those in the usual care arm to achieve both the primary composite measure of reaching at least 1 of their clinical goals and the secondary composite measure of reaching all of their clinical goals (Table 4). Additionally, almost twice the proportion of participants in the health-coaching arm achieved the HbA_{1c} study goal of 8.0% or lower. Differences in the primary and secondary composite goals and in 2 of 3 secondary goals (improvement in HbA_{1c} and LDL cholesterol) were significant at clinic site A but not at clinic site B. There were no significant differences in the proportion of participants meeting the SBP goal by study arm overall or when examined by clinic site. Essentially the same results were seen using imputed data, although the difference in the secondary composite measure for

Table 2. Characteristics of Participants, Overall and by Study Arm

Characteristic	All Participants (N = 441)	Study Arm	
		Usual Care (n = 217)	Health Coaching (n = 224)
Demographic characteristics			
Clinic site, % (No.)			
Clinic site A	75.3 (332)	76.0 (165)	74.6 (167)
Clinic site B	24.7 (109)	24.0 (52)	25.4 (57)
Age, mean (SD), y	52.7 (11.1)	52.9 (11.5)	52.6 (10.7)
Sex (female), % (No.)	55.3 (244)	52.2 (127)	58.5 (117)
Married/long-term relationship, % (No.)	53.1 (234)	57.1 (124)	49.1 (110)
Born in the United States, % (No.)	25.6 (113)	24.9 (54)	26.3 (59)
Years in United States, mean (SD)[a]	18.2 (11.2)	17.9 (11.9)	18.5 (10.4)
Primary language, % (No.)			
English	27.7 (122)	26.7 (58)	28.6 (64)
Spanish	68.7 (303)	69.5 (151)	67.9 (152)
Other	3.6 (16)	3.7 (8)	3.6 (8)
Race/ethnicity, % (No.)			
Asian	4.1 (18)	5.1 (11)	3.1 (7)
African American	19.0 (84)	18.4 (40)	19.6 (44)
Latino or Hispanic	70.1 (309)	71.0 (154)	69.2 (155)
White	2.5 (11)	2.3 (5)	2.7 (6)
Other	4.3 (19)	3.2 (7)	5.4 (12)
Working status, % (No.)			
Full time	18.6 (82)	16.1 (35)	21.0 (47)
Part time	25.6 (113)	26.3 (57)	25.0 (56)
Homemaker	13.8 (61)	17.1 (37)	10.7 (24)
Unemployed	16.1 (71)	16.1 (35)	16.1 (36)
Retired/disabled/SSI/other	25.9 (114)	24.3 (53)	27.2 (61)
Education, % (No.)			
≤5th grade	22.7 (100)	23.1 (50)	22.3 (50)
6th to 8th grade	21.1 (93)	20.7 (45)	21.4 (48)
Some high school	13.4 (59)	12.4 (27)	14.3 (32)
High school graduate or GED	17.7 (78)	16.6 (36)	18.8 (42)
Some college	15.6 (69)	19.4 (42)	12.1 (27)
College graduate	9.5 (42)	7.8 (17)	11.2 (25)
Income, % (No.)			
≤$5,000	34.0 (150)	31.3 (68)	36.6 (82)
$5,000-$10,000	24.3 (107)	25.3 (55)	23.2 (52)
$10,000-$20,000	29.5 (130)	29.0 (63)	29.9 (67)
≥$20,000	12.2 (54)	14.2 (31)	10.2 (23)
Number of PCP visits in year before study, mean (SD)	5.4 (3.9)	5.5 (4.3)	5.4 (4.1)
Clinical characteristics			
BMI, mean (SD), kg/m^2	31.4 (6.7)	31.4 (6.3)	31.5 (7.0)
HbA$_{1c}$, mean (SD), %[b]	9.9 (1.5)	10.0 (1.4)	9.8 (1.5)
LDL cholesterol, mean (SD), mg/dL[b]	147.0 (35.6)	147.8 (34.1)	146.3 (36.9)
SBP, mean (SD), mm Hg[b]	159.4 (15.4)	160.9 (16.8)	157.7 (13.5)
Uncontrolled at baseline, % (No.)			
For 1 condition	72.6 (320)	73.3 (159)	71.9 (161)
For 2 conditions	23.6 (104)	23.5 (51)	23.7 (53)
For 3 conditions	3.9 (17)	3.2 (7)	4.5 (10)
For HbA$_{1c}$	35.8 (158)	33.6 (73)	37.9 (85)
For SBP	43.5 (192)	46.5 (101)	40.6 (91)
For cholesterol	51.9 (229)	49.8 (108)	54.0 (121)

BMI = body mass index; GED = general equivalency diploma; HbA$_{1c}$ = hemoglobin A$_{1c}$; LDL = low-density lipoprotein; PCP = primary care provider; SBP = systolic blood pressure; SSI = supplemental security income.

[a] For the 328 participants born outside the United States.
[b] Includes only patients qualifying for the study on this measure (158 for HbA$_{1c}$, 218 for LDL, and 192 for SBP).

the overall sample dropped from 9.3% to 7.2% and was no longer significant ($P = .10$). Because of the introduction of new guidelines for SBP control for patients with diabetes,[31] we conducted a post hoc analysis of the proportion of patients in each arm meeting the more recent standard of a value less than 140 mm Hg that also found no statistically significant differences between arms.

A similar pattern was found when examining the mean change in HbA$_{1c}$ and LDL cholesterol levels (Table 5), although the difference in change in LDL cholesterol levels was statistically significant only at clinic site A. There were no significant interactions between clinic and study arm.

DISCUSSION

This is the first randomized controlled trial we are aware of that is sufficiently powered to detect significant improvements in clinical indicators for patients receiving medical assistant health coaching compared with usual care. Patients who received health coaching were more likely to reach their goal for 1 or more of the conditions uncontrolled at baseline. They were also more likely to achieve control of all conditions. Almost twice the proportion of people in the health-coaching group achieved goals for glycemic control compared with the usual care group, and at the larger site, people receiving coaching were more likely to achieve the LDL cholesterol goal. These findings are consistent with those of previous randomized controlled trials showing positive benefits for other models of self-management support using peers, registered nurses, or community health workers.[32-35]

Health coaching did not improve control of hypertension

in this study. Previous studies of health coaching to improve blood pressure control have yielded mixed results, with a number of multicondition studies failing to show improvement in blood pressure,[36-38] while others have shown benefit.[32,39]

We found site-related differences in outcomes. Significant clinical improvements were seen with coaching at the larger site A, but not at site B. There were indications that the quality of coaching differed at the latter site, including fewer interactions per patient and lower patient-reported trust in their health coach. The health coach at that site was absent for more than 8 weeks of the study and reported struggling to implement coaching principles. Unlike the coaches at the other site, this coach was not culturally concordant with the majority of patients. In addition, the sites differed in demographics of study participants and in the usual care delivery model. Interpreting these site differences provides an opportunity to glean lessons learned for implementation. More study is needed to replicate these findings and to identify the essential elements of coaching, the required dose, the people best suited to serve in this emerging role, the optimal context, and the patients who most benefit.

Our study has several limitations. Participating clinics were part of the safety net caring for uninsured or low-income populations, and only 3 coaches delivered the intervention, so generalizability to other settings, participants, and coaches may be limited. Although research assistants were not blinded to patient assignment at the 12-month follow-up, the potential for bias seems relatively small, particularly for the laboratory test outcomes (HbA_{1c}

Table 3. Characteristics of Participants, Overall and by Clinic Site

Characteristic	All Participants (N = 441)	Clinic Site		
		Clinic Site A (n = 332)	Clinic Site B (n = 109)	P Value
Demographic characteristics				
Age, mean (SD), y	52.7 (11.1)	52.3 (11.3)	54.0 (10.5)	.18
Sex (female), % (No.)	55.3 (244)	53.3 (177)	61.5 (67)	.14
Born in the United States, % (No.)	25.6 (113)	6.0 (20)	85.3 (93)	<.001
Primary language, % (No.)				<.001
English	27.7 (122)	7.8 (26)	88.1 (96)	
Spanish	68.7 (303)	89.5 (297)	5.5 (6)	
Other	3.6 (16)	2.7 (9)	6.4 (7)	
Race/ethnicity, % (No.)				<.001
Asian	4.1 (18)	3.3 (11)	6.4 (7)	
African American	19.0 (84)	1.8 (6)	71.6 (78)	
Latino or Hispanic	70.1 (309)	90.7 (30)	7.3 (8)	
White	2.5 (11)	1.5 (5)	5.5 (6)	
Other	4.3 (19)	2.7 (9)	9.2 (10)	
Working status, % (No.)				<.001
Full time	18.6 (82)	22.0 (73)	8.3 (9)	
Part time	25.6 (113)	28.0 (93)	18.3 (20)	
Homemaker	13.8 (61)	16.9 (56)	4.6 (5)	
Unemployed	16.1 (71)	13.6 (45)	23.9 (26)	
Retired/disabled/SSI/other	25.9 (114)	19.5 (65)	44.9 (49)	
Education, % (No.)				<.001
≤5th grade	22.7 (100)	29.6 (98)	1.8 (2)	
6th to 8th grade	21.1 (93)	27.1 (90)	2.8 (3)	
Some high school	13.4 (59)	11.1 (37)	20.2 (22)	
High school graduate or GED	17.7 (78)	14.2 (47)	28.4 (31)	
Some college	15.6 (69)	9.9 (33)	33.0 (36)	
College graduate	9.5 (42)	8.1 (27)	13.8 (15)	
Income, % (No.)				.52
≤$5,000	34.0 (150)	33.7 (112)	34.9 (38)	
$5,000-$10,000	24.3 (107)	23.8 (79)	25.7 (28)	
$10,000-$20,000	29.5 (130)	31.0 (103)	24.8 (27)	
≥$20,000	12.2 (54)	11.4 (38)	14.7 (16)	
Clinical characteristics				
BMI, mean (SD), kg/m²	31.4 (6.7)	30.6 (4.7)	34.0 (10.2)	<.001
HbA_{1c}, mean (SD), %[a]	9.9 (1.5)	9.8 (1.4)	10.3 (1.9)	.17
LDL cholesterol, mean (SD), mg/dL[a]	147.0 (35.6)	147.3 (36.7)	145.2 (28.9)	.75
SBP, mean (SD), mm Hg[a]	159.4 (15.4)	158.3 (13.5)	160.9 (17.5)	.25
Number of PCP visits in year before study, mean (SD)	5.4 (4.1)	5.2 (3.5)	6.1 (5.5)	<.05
Number of coach interactions, mean (SD)	12.4 (7.4)	14.1 (6.7)	7.6 (7.2)	<.001
Total time interaction, mean (SD), min	540.8 (307.6)	621.1 (281.1)	305.5 (258.7)	<.001

continues

BMI = body mass index; GED = general equivalency diploma; HbA_{1c} = hemoglobin A_{1c}; LDL = low-density lipoprotein; PCP = primary care physician; SBP = systolic blood pressure; SSI = supplemental security income.

[a] Includes only patients qualifying for the study on this measure (158 for HbA_{1c}, 218 for LDL cholesterol, and 192 for SBP).

[b] On a scale of 1 to 5, where 5 = best.

[c] On a scale of 1 to 5, where 5 = high.

and LDL cholesterol levels). Because randomization was by the patient rather than the clinician or practice, health coaching may have affected nonintervention

Table 3. Characteristics of Participants, Overall and by Clinic Site (continued)

Characteristic	All Participants (N = 441)	Clinic Site		
		Clinic Site A (n = 332)	Clinic Site B (n = 109)	P Value
Clinical characteristics (continued)				
Number of interactions by topic/ activity addressed, mean (SD)				
Medications	9.3 (6.0)	11.0 (5.4)	4.1 (4.6)	<.001
Reviewing clinical values and goals	7.4 (4.6)	8.4 (3.9)	4.5 (5.2)	<.001
Discussing lifestyle changes	7.4 (5.0)	9.1 (4.3)	2.1 (2.2)	<.001
Agenda setting	5.7 (4.3)	7.1 (4.1)	1.7 (1.9)	<.001
Navigational support	5.1 (5.1)	6.4 (5.3)	1.5 (1.8)	<.001
Action plans for behavior change	4.2 (3.2)	5.1 (2.9)	1.6 (2.3)	<.001
Facilitating communication with PCP	3.3 (3.8)	4.0 (4.1)	1.1 (1.5)	<.001
Closing the loop (teach back)	5.3 (3.6)	6.1 (3.3)	2.8 (3.4)	<.001
Patient-reported quality of health-coaching interactions, mean (SD)[b]	3.3 (0.7)	3.4 (0.5)	2.8 (0.9)	<.001
Patient-reported trust in health coach, mean (SD)[c]	4.1 (0.5)	4.1 (0.5)	3.9 (0.7)	<.005

BMI = body mass index; GED = general equivalency diploma; HbA_{1c} = hemoglobin A_{1c}; LDL = low-density lipoprotein; PCP = primary care physician; SBP = systolic blood pressure; SSI = supplemental security income.

[a] Includes only patients qualifying for the study on this measure (158 for HbA_{1c}, 218 for LDL cholesterol, and 192 for SBP).

[b] On a scale of 1 to 5, where 5 = best.

[c] On a scale of 1 to 5, where 5 = high.

Table 4. Primary Composite and Condition-Specific Outcomes by Study Arm, for Total Sample and by Clinic Site

Outcome	Health Coaching, % (No./n)	Usual Care, % (No./n)	Difference, % (95% CI)	P Value
Total sample				
Composite (primary)[a]	46.4 (90/194)	34.3 (57/166)	12.1 (2 to 23)	.02
Composite (secondary)[b]	34.0 (66/194)	24.7 (41/166)	9.3 (1 to 19)	.05
HbA_{1c} goal achieved[c]	48.6 (36/74)	27.6 (16/58)	21.0 (5 to 39)	.01
Cholesterol goal achieved[d]	42.7 (41/96)	32.0 (24/75)	10.7 (−4 to 25)	.15
SBP goal achieved[e]	23.8 (19/80)	28.9 (22/76)	−5.1 (−9 to 19)	.46
Clinic site A				
Composite (primary)[a]	49.7 (73/147)	32.8 (42/128)	16.9 (5 to 29)	.01
Composite (secondary)[b]	36.1 (53/147)	24.2 (31/128)	11.9 (1 to 23)	.03
HbA_{1c} goal achieved[c]	52.3 (34/65)	29.4 (15/51)	22.9 (5 to 41)	.01
Cholesterol goal achieved[d]	41.8 (33/79)	25.4 (16/63)	16.4 (1 to 32)	.04
SBP goal achieved[e]	25.5 (12/47)	31.9 (15/47)	−6.4 (−11 to 25)	.49
Clinic site B				
Composite (primary)[a]	36.2 (17/47)	39.5 (15/38)	−3.3 (−17 to 24)	.76
Composite (secondary)[b]	27.7 (13/47)	26.3 (10/38)	1.4 (−18 to 20)	.89
HbA_{1c} goal achieved[c]	22.2 (2/9)	14.3 (1/7)	7.9 (−31 to 46)	.69
Cholesterol goal achieved[d]	47.1 (8/17)	66.7 (8/12)	−19.6 (−18 to 56)	.29
SBP goal achieved[e]	21.2 (7/33)	24.1 (7/29)	−2.9 (−18 to 24)	.78

HbA_{1c} = hemoglobin A_{1c}; HDL = high-density lipoprotein; LDL = low-density lipoprotein; SBP = systolic blood pressure.

Note: Analyses used missing-at-random (nonimputed) data. See statistical analysis in Methods section for details.

[a] Achieved target for control of 1 or more of specific conditions for which patient was uncontrolled at baseline.

[b] Achieved target for control of all conditions for which patient was uncontrolled at baseline.

[c] Goal was <8.0%.

[d] Goal for diabetic patients was LDL cholesterol <100 mg/dL or non–HDL cholesterol <130 mg/dL if triglycerides >400 mg/dL, and for nondiabetic patients was LDL cholesterol l<130 mg/dL or non–HDL cholesterol <160 mg/dL if triglycerides >400 mg/dL.

[e] Goal was <130 mm Hg for diabetic patients and <40 mm Hg for nondiabetic patients.

patients. Attrition of patients, especially those with poor glycemic control, was greater in the usual care group; however, these differences would result in a conservative estimate of the intervention effect.

Medical assistant health coaching has the potential to alleviate nationwide deficiencies in glucose, blood pressure, and cholesterol control even in an environment of deepening primary care clinician shortage. This model may satisfy several conditions needed for diffusion of innovation[40] including relative advantage, compatibility, and scalability. As ubiquitous[41] and relatively affordable[42] members of the care team, medical assistants could provide critical self-management support even in resource-scarce settings. New payment models, such as capitated payments and shared savings, may allow health coaching to emerge as a means to produce positive clinical outcomes at lower costs.[43] The medical assistant health-coaching model is acceptable to patients and clinicians.[44,45] Because health coaches were dedicated staff who augmented clinic resources, the model had minimal impact on clinic flow, and the coaches off-loaded responsibilities from busy clinic staff. An ongoing cost analysis will be reported. Moreover, health coaching can help practices to satisfy requirements of patient-centered medical home accrediting agencies to provide patient self-management support.[46] Scalability depends on the relative simplicity of implementing an intervention, which may be facilitated by cross-organizational exchange of training materials, workflows, and tools.

Table 5. Secondary Condition-Specific Outcomes by Study Arm, for Total Sample and by Clinic Site

Outcome	n	Health Coaching Baseline, Mean (SD)	12 Months, Mean (SD)	DIM	n	Usual Care Baseline, Mean (SD)	12 Months, Mean (SD)	DIM	Difference Between Arms (95% CI)	P Value
Total sample										
HbA$_{1c}$, %	74	9.8 (1.5)	8.6 (2.0)	−1.2	58	9.9 (1.4)	9.4 (2.0)	−0.5	−0.7 (−1.4 to 0.0)	.06
LDL, mg/dL	95	147.2 (36.3)	119.3 (52.8)	−27.9	73	143.4 (33.2)	125.4 (39.1)	−18.1	−9.8 (−21.6 to 2.0)	.10
SBP, mm Hg	80	157.3 (13.8)	148.7 (16.5)	−8.6	76	160.5 (16.4)	150.3 (18.2)	−10.2	1.6 (−7.6 to 4.4)	.59
Clinic site A										
HbA$_{1c}$, %	65	9.8 (1.5)	8.5 (2.0)	−1.3	51	9.8 (1.4)	9.3 (2.0)	−0.6	−0.7 (−1.4 to −0.0)	.04
LDL, mg/dL	79	148.2 (38.3)	122.6 (55.1)	−25.6	62	145.0 (35.0)	130.5 (37.6)	−14.5	−11.1 (−23.9 to 1.7)	.09
SBP, mm Hg	47	154.9 (10.5)	144.8 (12.5)	−10.0	47	160.5 (15.1)	148.5 (18.9)	−12.0	2.0 (−5.1 to 9.0)	.59
Clinic site B										
HbA$_{1c}$, %	9	10.2 (1.4)	9.5 (2.1)	−0.7	7	10.5 (1.5)	10.1 (1.7)	−0.5	−0.2 (−2.9 to 2.5)	.89
LDL, mg/dL	16	142.8 (29.4)	103.6 (37.8)	−39.2	11	136.9 (29.2)	98.6 (36.9)	−38.4	−0.8 (−31.3 to 29.6)	.96
SBP, mm Hg	33	160.7 (15.8)	154.1 (19.9)	−6.6	29	160.6 (19.2)	153.2 (17.0)	−7.4	0.8 (−10.0 to 11.6)	.88

DIM = difference in means; HbA$_{1c}$ = hemoglobin A$_{1c}$; LDL = low-density lipoprotein; SBP = systolic blood pressure.

Note: Analyses used missing-at-random (nonimputed) data. See statistical analysis in Methods section for details.

Primary care practices struggle to provide self-management support to their growing numbers of patients with chronic conditions. This medical assistant health-coaching model may provide an important answer to the barriers of time, resources, and cultural concordance faced by many primary care practices seeking to implement self-management support. Our study demonstrates that medical assistants can successfully serve as in-clinic health coaches to improve glycemic and cardiovascular health indicators over usual care.

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