

Community Outreach and Cardiovascular Health (COACH) Trial

A Randomized, Controlled Trial of Nurse Practitioner/Community Health Worker Cardiovascular Disease Risk Reduction in Urban Community Health Centers

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Background—Despite well-publicized guidelines on the appropriate management of cardiovascular disease and type 2 diabetes, the implementation of risk-reducing practices remains poor. This report describes the results of a randomized, controlled clinical trial evaluating the effectiveness of a comprehensive program of cardiovascular disease risk reduction delivered by nurse practitioner /community health worker (NP/CHW) teams versus enhanced usual care (EUC) to improve lipids, blood pressure, glycated hemoglobin (HbA1c), and patient perceptions of the quality of their chronic illness care in patients in urban community health centers.

Methods and Results—A total of 525 patients with documented cardiovascular disease, type 2 diabetes, hypercholesterolemia, or hypertension and levels of LDL cholesterol, blood pressure, or HbA1c that exceeded goals established by national guidelines were randomly assigned to NP/CHW (n=261) or EUC (n=264) groups. The NP/CHW intervention included aggressive pharmacological management and tailored educational and behavioral counseling for lifestyle modification and problem solving to address barriers to adherence and control. Compared with EUC, patients in the NP/CHW group had significantly greater 12-month improvement in total cholesterol (difference, 19.7 mg/dL), LDL cholesterol (difference, 15.9 mg/dL), triglycerides (difference, 16.3 mg/dL), systolic blood pressure (difference, 6.2 mm Hg), diastolic blood pressure (difference, 3.1 mm Hg), HbA1c (difference, 0.5%), and perceptions of the quality of their chronic illness care (difference, 1.2 points).

Conclusions—An intervention delivered by an NP/CHW team using individualized treatment regimens based on treat-to-target algorithms can be an effective approach to improve risk factor status and perceptions of chronic illness care in high-risk patients.

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Key Words: risk factors ■ secondary prevention ■ primary prevention ■ cardiovascular nursing ■ Type 2 diabetes ■ behavioral/psychosocial-treatment ■ compliance/adherence

Approximately 831 000 Americans die annually of cardiovascular disease (CVD), with lower income, prior coronary heart disease (CHD), and diabetes populations differentially represented in these deaths.¹ Despite well-publicized guidelines on the appropriate management of cardiovascular disease (CVD) and type 2 diabetes,

implementation of risk-reducing practices remains poor. Several different models of chronic disease case management have emerged to respond to growing concerns about the quality and increasing costs of health care; however, evaluation of their impact on patient outcomes or cost is limited.

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Case management by a specially trained nurse-led team, including community health workers, has been shown to be among the most efficacious strategies to improve management of CVD risk factors in many studies.^{2–6} Several studies have shown that nurse management clinics are at least as beneficial in achieving goals as are other clinics managed by physicians, and in many cases actually result in marked improvement in the outcomes including patient satisfaction and utilization of health care services, compared with usual care. For example, trained nurses providing care have demonstrated successful strategies for improving lipid levels in patients with elevated low-density lipoprotein cholesterol (LDL-C) and blood pressure (BP).^{4–9} In the nurse management models, factors such as patient education and counseling and even regular telephone follow-up by a nurse showed marked sustained improvement in medication adherence and goal achievement. Nurse case managers have been shown to improve adherence to guidelines in part by serving as a bridge to physician care and by adhering more strictly to management algorithms, including many counseling features that are not within the time frame of a busy physician in practice. Several studies suggest that a nurse-led team management program is the most effective strategy to date for reducing LDL-C.^{6,10}

Nurses managing patients with diabetes also have a more favorable impact on chronic disease parameters, including adherence to recommendations for diet and for renal testing.¹¹ Nurse case management improves control of diabetes in clinical settings, with significant reductions in fasting blood glucose, body weight, glycated hemoglobin, and LDL-C.¹² Telephone management of diabetic patients by a nurse has been shown to markedly improve CHD risk factors, including lipids. Diabetic patients were more likely to be appropriately treated with a lipid lowering therapy when managed by the nurse over the phone than patients managed solely with usual care.¹³

In low-income and minority populations, community health workers (CHWs) or lay health advisors have often participated in team-based care for the management of CVD risk factors, particularly hypertension and diabetes.^{14,15} Although there are too few randomized, clinical trials of the role of these individuals, there is sufficient collective experience to suggest that this role can be an important one in improving adherence in high-risk subsets of the population.^{9,16–18} Trained CHWs, front-line health and human service care providers, most often share the same ethnicity, geographic community, and socioeconomic background of the patients they serve. The theoretical rationale for using CHWs is a shared perspective and experience that enhances trust between CHW and the patient and enables the CHW to effectively link underserved populations to health care resources in which traditional health education and outreach efforts have failed.^{19,20} CHWs also bridge the communication barriers between patients and health care providers, which can catalyze provider and health system changes.^{21,22} CHWs have been shown to improve quality of care, satisfaction with care, increase access to care, reduce health care costs, strengthen

local economies and families, and foster community capacity building.^{15,20,23–25} CHWs also have been shown to be effective in research as interviewers and interventionists.^{9,17,21,26}

The aim of this study was to evaluate the effectiveness of a comprehensive program of CVD risk reduction delivered by nurse practitioner (NP)/CHW teams versus enhanced usual care (EUC) to improve lipids, BP, and glycated hemoglobin (HbA1c) levels in patients in urban community health centers. This effectiveness research is one of the first studies testing a model of NP/CHW team care in urban federally-qualified community health centers. We used community-based participatory research establishing a true academic health center–community practice partnership to enhance the applicability and sustainability of the intervention.

WHAT IS KNOWN

- Despite well-publicized guidelines on the appropriate management of cardiovascular disease and type 2 diabetes, the implementation of risk-reducing practices remains poor, especially in high-risk vulnerable populations.
- Case management by a specially trained nurse-led team is one of the most efficacious strategies to improve cardiovascular disease risk factor management.

WHAT THE STUDY ADDS

- An intervention delivered by a nurse practitioner/community health worker team using individualized treatment regimens based on treat-to-target algorithms improved cardiovascular disease risk factor status and perceptions of chronic illness care.
- The results of this trial support nurse-led patient-centered medical homes to improve the quality of cardiovascular disease care in high risk underserved populations.

Methods**Study Design**

The complete methods of the Community Outreach and Cardiovascular Health (COACH) study have been detailed elsewhere.²⁷ Briefly, we used community-based participatory research (CBPR) as a theoretical framework for this study. CBPR is a methodology that promotes active community involvement in the processes that shape research and intervention strategies, as well as the conduct of research studies.²⁸ This research used a Community-Provider Advisory Committee to guide all aspects of the study.

COACH was a randomized, controlled trial in which 525 patients were randomly assigned to 1 of 2 groups: comprehensive intensive management of CVD risk factors by a NP/CHW team or an EUC control group. Individuals in the control group received usual care from their primary provider, which was enhanced by feedback regarding CVD risk factors provided to the patient and their provider. Those in the intensive intervention group received EUC plus management by the NP/CHW team. The program included aggressive pharmacological management, tailored educational and behavioral counseling for lifestyle modification, identification of barriers to adherence and control, phone follow-ups between visits and preappointment reminders.

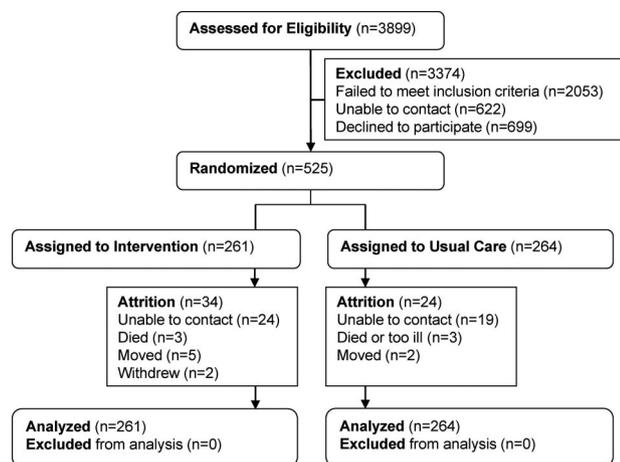


Figure. Consolidated Standards of Reporting Trials (CONSORT) diagram of the Community Outreach and Cardiovascular Health (COACH) Trial.

Participants

Patients were recruited between July 2006 and July 2009 from 2 community health centers that are part of the federally qualified community health center entitled Baltimore Medical Systems Incorporated. The focus of these clinics is on primary care in communities designated as medically underserved areas.

Patients identified from clinic-based computerized ICD 9 codes were eligible if they were African American or Caucasian and had diagnosed CVD defined as a prior MI, revascularization procedure for coronary disease, ischemic heart disease, stroke, peripheral vascular disease, or hypercholesterolemia, hypertension, or had diagnosed type 2 diabetes receiving any therapy. They had to be ≥ 21 years of age and able to speak and understand English. Patients were enrolled in the trial if they had at least 1 of the following criteria within the past 6 months at the time of the medical record reviews: (1) a LDL-C ≥ 100 mg/dL or LDL-C ≥ 130 mg/dL if no diagnosed CVD or diabetes, (2) BP $> 140/90$ mm Hg or $> 130/80$ mm Hg if diabetic or renal insufficiency, or (3) if diabetic, a HbA1c $\geq 7\%$ or glucose ≥ 125 mg. Patients were excluded if they had a serious life-threatening noncardiac comorbidity with a life expectancy of less than 5 years (AIDS or cancer, for example), had a serious physician-recorded psychiatric morbidity that would preclude participating in their own care, or were sufficiently neurologically impaired to preclude participation in their own care.

Of the 3899 screened for eligibility, 525 were enrolled in the trial (Figure). The participants were randomly assigned, stratified by race and sex, to receive the NP/CHW intervention or EUC. All participants provided written informed consent. The protocol was approved by the Johns Hopkins University Institutional Review Board.

Intervention

The NP/CHW intervention focused on behavioral interventions to effect therapeutic lifestyle changes (TLC) and adherence to medications and appointments as well as the prescription and titration of medications. Patients were followed for 1 year. The NP and CHW worked as a team. The NP functioned as the case coordinator for each study participant. She oversaw the initial assessment and tailored the intervention plan, conducted the intervention, including lifestyle modification, counseling, and medication titration and prescription, and consulted with the physician and supervised the CHW. Specific algorithms for drug treatment of hyperlipidemia, hypertension, hyperglycemia, as well as angiotensin-converting enzyme and β -blocker therapy, were developed for this study based on current guidelines and standards of care. (Algorithms can be found in the online-only Data Supplement Appendix.)

In addition to meeting with the NP, patients and their support person met with the CHW, who spent additional time problem-solving anticipated barriers to treatment adherence, including issues

important to the patient's life which might not be directly related to cardiovascular health. The CHW also reinforced instructions by the NP related to integration of lifestyle modifications and medication therapies and assisted patients in designing a set of reminders, prompts, logs, pill organizers, alarm clocks, or whatever the individual believed would work for them to assist in following complex regimens. The intensity of the NP/CHW intervention was greater among those who had not yet achieved goals. Follow-up algorithms guided the frequency and type of follow-up. Those patients not making progress toward their goal levels received more frequent telephone follow-up from the CHW.

A low-literacy Wellness Guide was developed specifically for the study as a behavioral tool for the NP, CHW, and patient team to promote TLC. The patient received the guide at the first encounter, took it home as a tool for making changes, and was asked to bring it to each visit. The Wellness Guide had sections focusing on the patient's laboratory results and therapeutic goals for weight, BP, lipids, and HbA1c (for patients with diabetes); medication reconciliation and customized tips for taking medicine; healthy eating, including strategies for portion control; increasing physical activity and a customized walking program; smoking cessation; and a place to record questions for future visits. Each section had a place for recording the patient's goals, potential barriers, strategies to deal with difficult situations, ways to reward oneself, and identification of support people to help facilitate meeting goals. This section was completed during the counseling sessions with the NP and CHW.

The lifestyle behaviors of a healthy low-fat, low-sodium diet, regular moderate-intensity physical activity, and smoking cessation were the focus of TLC counseling interventions. The nurse initiated recommendations for healthy low-fat, low-sodium eating recommended in the TLC diet, adapted for diabetics according to standards of the American Diabetes Association.²⁹ The importance of dietary adherence was emphasized as an adjunct to pharmacotherapy. Recognition of food preferences were important along with how to choose low-fat, low-sodium foods, modify recipes, self-monitor fat and sodium intake, and develop individualized low-fat, low-sodium eating plans. Some areas of focus included reducing portion size, reducing fast food intake, and avoiding processed foods high in sodium and carbohydrates. Progress review of dietary patterns, strategies for dietary change, and guides for managing difficult situations were addressed with patients by the CHW.

Patients were instructed to participate in a moderate-intensity home-based exercise program. The patient selected the mode of moderate-intensity physical activity and set realistic goals. Telephone contact was initiated by the CHW 2 weeks after inception of the program and once a month until the sixth month to monitor progress, answer questions, and provide individualized feedback and positive reinforcement.

The intervention teams included NPs who were certified adult nurse practitioners with experience in the delivery of primary care and CHWs with experience working with underserved minority populations. The NPs completed additional continuing education in the management of hypertension, hypercholesterolemia, and diabetes, and the CHWs were trained in the disease pathophysiology of CHD and diabetes and therapeutic lifestyle management approaches of nutrition and physical activity. Both NPs and CHWs were trained in motivational interviewing behavior change techniques.

Documenting the team's adherence to protocols was important to ensure intervention fidelity. Encounter forms for the NP and the CHW tracked the number, length, and content of the encounters (such as counseling on diet, exercise, medications, smoking cessation, and adherence) to determine the delivered dose of the intervention. In addition, there was a COACH Program Intervention Quality Assurance (QA) Plan to ensure adherence to study intervention protocols and treatment algorithms to promote intervention integrity throughout the study. QA assessments were conducted on a quarterly basis. The QA assessment included analysis of audiotape-recorded intervention sessions and intervention documentation in medical records. QA assessments were independently conducted by 2 COACH study investigators. The 2 independent reviewers discussed assessments and provided feedback to interventionists to provide

positive reinforcement and/or a plan for additional training in a timely basis.

Patients and their providers in the EUC group received the results of baseline lipids, BP, and HbA1c along with the recommended goal levels and a pamphlet on controlling risk factors published by the American Heart Association. In addition, providers received copies of the American Heart Association/American College of Cardiology Guidelines for Secondary Prevention.³⁰

Outcome Measures

The primary outcomes were changes from baseline to one year in lipids, BP, HbA1c, and patients' perceptions of the quality of their chronic illness care. The primary outcomes also were operationalized as meeting the goals for secondary prevention or experiencing a clinically significant change as follows: HbA1c <7% or clinically significant decrease of $\geq 0.5\%$; systolic BP <140 mm Hg or <130 mm Hg if patient had diabetes or kidney disease or clinically significant decrease of ≥ 10 mm Hg; and LDL-C <100 mg/dL or <130 if no CVD or diabetes or a clinically significant decrease of $\geq 20\%$. The chemistry laboratory at Johns Hopkins performed all biochemical measures. Total cholesterol, triglycerides, and high-density lipoprotein cholesterol (HDL-C) were measured directly after a 12-hour fast. LDL-C was estimated using the Friedewald equation.³¹ In the event of triglyceride levels >400 mg/dL, direct measurement of LDL-C through ultracentrifugation methods was performed. In participants with diabetes, HbA1c was measured using high-pressure liquid chromatography. BP was measured using the Omron Digital Blood Pressure Monitor HEM-907XL automatic BP device according to JNC VII guidelines, after 5 minutes of quiet rest, in the right arm with the person seated in a chair with arm supported at heart level. The average of 3 BPs was recorded.

The patient's ratings of care received from their health care team was measured by the Patient Assessment of Chronic Illness Care (PACIC) Survey, a 20-item patient report instrument that assesses patient's perceptions of the receipt of clinical services and actions consistent with quality care defined by the Chronic Care Model.³² The 5 subscales are Patient Activation; Delivery System/Decision Support; Goal Setting; Problem-solving/Contextual Counseling; and Follow-up/Coordination.

Secondary outcomes included the lifestyle behaviors of dietary intake measured by the Habits and History Food Frequency Questionnaire, Block 2005.1,^{33,34} and physical activity was evaluated with the Stanford 7-Day Physical Activity Recall.^{35,36} Quality of life was measured by the 5-item EuroQol questionnaire,³⁷ and resource utilization and patients' health care utilization data were collected to conduct a cost effectiveness analysis, which will be reported separately.

Statistical Analysis

The sample size for this study was determined considering the effect sizes observed in the investigators' preliminary work. Based on the calculations, a minimum of 450 participants (225 per group) were needed to detect clinically significant differences in changes in the primary outcomes of BP, LDL-C, and HbA1c at 1 year to ensure 80% power at a 0.05 significance level. This sample size accounted for an expected 25% attrition at the 1-year follow-up, yielding 180 participants per intervention.

The data analysis for this report was generated using SAS version 9.2 for Windows. Statistical tests were used to study differences in baseline demographic, clinical, and risk factor characteristics, with a *t* test used for continuous variables and a χ^2 test for categorical variables. Similar statistical tests were used to compare baseline characteristics for subjects completing the study to those lost to follow-up for any reason.

The primary outcomes are changes from baseline to 1 year in lipids, BP, HgA1c, and the patient's perception of chronic illness care. Analysis followed the intention-to-treat model including all randomly assigned participants in the analyses according to their original assignment. Participants who withdrew or did not complete the 1-year assessment were included in the analysis. Missing data were imputed with multiple imputation. Multiple imputation is an

Table 1. Baseline Sample Characteristics

Characteristic	Intervention (n=261)	Usual Care (n=264)	P
Age, y, mean (SD)	54.3 (12.0)	54.7 (11.5)	0.692
Female, n (%)	187 (71.7)	187 (70.8)	0.837
Marital status, n (%)			0.591
Single	61 (23.4)	69 (26.1)	
Married	86 (33.0)	80 (30.3)	
Separated	19 (7.3)	28 (10.6)	
Widowed	39 (14.9)	37 (14.0)	
Divorced	56 (21.5)	50 (18.9)	
Race, n (%)			0.946
Non-black	54 (20.7)	54 (20.5)	
Black	207 (79.3)	210 (79.6)	
Education, n (%)			0.051
<High school	76 (29.1)	94 (35.6)	
High school/GED	118 (45.2)	92 (34.9)	
Some college	67 (25.7)	78 (29.6)	
Employment status, n (%)			0.318
Employed	110 (42.2)	100 (37.9)	
Not employed	151 (57.9)	164 (62.1)	
Type of insurance, n (%)			0.403
Private	112 (42.9)	105 (39.8)	
Medicare and/or Medicaid	106 (40.6)	101 (38.3)	
Uninsured	43 (16.5)	55 (20.8)	
Unknown	0 (0)	3 (1.1)	
Annual income, n (%)			0.223
<\$20 000	137 (52.5)	149 (56.4)	
\geq \$20 000	120 (46.0)	105 (39.8)	
Unknown	4 (1.5)	10 (3.8)	
Comorbidity score, mean (SD)	1.6 (1.3)	1.8 (1.4)	0.193
Diastolic blood pressure, mean (SD)	83.1 (12.6)	82.3 (13.0)	0.442
Systolic blood pressure, mean (SD)	139.7 (23.8)	138.7 (19.9)	0.587
Total cholesterol, mean (SD)	199.7 (46.0)	191.3 (45.0)	0.036
LDL-C, mean (SD)	121.6 (40.0)	116.3 (40.5)	0.132
HDL-C, mean (SD)	50.8 (14.7)	50.9 (13.6)	0.92
Triglycerides, median (IQR)	113 (85)	105 (76)	0.220
Hemoglobin A1c, mean (SD)	8.9 (2.2)	8.3 (1.9)	0.006
PACIC, mean (SD)	1.5 (0.9)	1.6 (0.9)	0.883

LDL-C indicates low-density lipoprotein cholesterol; HDL-C, high-density lipoprotein cholesterol; IQR, interquartile range; and PACIC, Patient Assessment of Chronic Illness Care.

advanced statistical method for handling missing data.³⁸ This computationally intensive approach uses multiple linear regression to predict missing values with observed data. The procedure is repeated with 5 iterations. Repeatedly imputing missing values allows for quantifying the uncertainty resulting from sampling error.

Generalized linear mixed models, using a random patient-level intercept model, were used to build multilevel models comparing the effectiveness of the NP/CHW intervention with EUC on each outcome, controlling for the covariates of age, sex, race, body mass index, and insurance status, which were determined by univariate analyses to be predictive of outcomes. Mixed models are the optimal statistical method to use with preintervention and postintervention repeated-measures data, as this modeling approach accounts for the correlated data structure.

Table 2. Changes in Primary Outcomes by Group

Outcome	Intervention Group (n=261)		Usual Care Group (n=264)		P Value*	Estimated Between-Group Difference (95% CI)
	Baseline	Change	Baseline	Change		
Systolic BP, mm Hg						
Baseline	139.7±23.8	8.9±25.1	138.7±19.9	2.7±22.0	0.003	-6.2 (-10.2, -2.1)
1 y	130.8±20.7		135.9±20.5			
Diastolic BP, mm Hg						
Baseline	83.0±12.7	5.6±13.6	82.3±13.0	2.6±12.1	0.013	-3.1 (-5.3, -0.9)
1 y	77.4±12.5		79.7±12.6			
Total cholesterol,† mg/dL						
Baseline	199.7±46.0	27.0±50.7	191.3±45.0	7.3±44.5	<0.001	-19.7 (-27.9, -11.5)
1 y	172.7±44.5		184.1±41.9			
LDL,† mg/dL						
Baseline	121.6±40.0	21.6±44.0	116.3±40.5	5.7±38.9	<0.001	-15.9 (-23.0, -8.8)
1 y	100.1±39.2		110.6±36.8			
Triglycerides,†† mg/dL						
Baseline	138.1±93.4	20.1±88.3	126.8±71.5	3.8±65.6	0.013	-16.3 (-29.6, -3.0)
1 y	121.3±81.6		123.1±72.2			
HDL,† mg/dL						
Baseline	50.8±14.7	1.4±10.5	50.9±13.6	1.0±10.9	0.497	-0.4 (-2.2, 1.4)
1 y	49.4±13.5		49.9±12.9			
Hemoglobin A1c, %						
Baseline	8.9±2.2	0.6±2.3	8.3±1.9	0.1±1.8	0.034	-0.5 (-0.9, -0.2)
1 y	8.3±2.2		8.2±2.1			
PACIC						
Baseline	1.6±0.9	-1.4±1.0	1.6±1.0	-0.2±0.9	<0.001	1.2 (1.0, 1.3)
1 y	2.9±0.9		1.8±1.0			

CI indicates confidence interval; BP, blood pressure; LDL, low-density lipoprotein; HDL, high-density lipoprotein; and PACIC, Patient Assessment of Chronic Illness Care.

*Intention-to-treat analysis using general linear mixed model with group, time, group×time effects, and covariates age, sex, race, education, body mass index, insurance, and an indicator of in-control for clinical outcome at baseline.

†To convert total cholesterol, LDL cholesterol, and HDL cholesterol to mmol/L, multiply by 0.0259; to convert triglycerides to mmol/L, multiply by 0.0113.

‡Computed using a trimmed mean of triglyceride values <1000. P value based on log-triglycerides due to nonnormality.

Results

The sample was predominantly female (71%) and black (79%). A majority had at least a high school education; however, a majority had annual incomes <\$20 000 and fewer than half had private health insurance. There were no significant differences in sociodemographic and baseline measures between the 2 groups except for higher total cholesterol and HbA1c levels in the NP/CHW intervention group compared with the EUC group (Table 1). We did not find statistically significant differential attrition between the two groups. Ninety-four percent (n=467) completed the 1-year assessment, with no differences between completers and noncompleters in baseline lipids, HbA1c, BP, age, education, race, or sex.

A total of 84% of patients randomly assigned to the intervention group completed an initial visit, and 70% had at least 4 in-person visits with the nurse. Patients in the

intervention group had a mean of 7±3 in-person visits and 6±5 telephone visits with the NP/CHW team. A comprehensive cost-effectiveness analysis will be published separately.

At 12 months, patients in the intervention group had significantly greater overall improvement in total cholesterol, LDL-C, triglycerides, systolic and diastolic BP, HbA1c, and perceptions of the quality of their chronic illness care compared with patients receiving EUC (Table 2). The analyses using general linear mixed models controlled for age, sex, education, race, body mass index, insurance status, and an indicator of control status at baseline. The estimated between-group differences were clinically significant. At the 12-month follow-up, a significantly higher percentage of patients in the intervention group compared with the EUC group had values that reached guideline goals or showed clinically significant improvements in LDL-C (EUC=58%; I=75%, $P<0.001$), systolic BP (EUC=74%; I=82%, $P=0.018$), and HbA1c (EUC=47%; I=60%, $P=0.016$).

Table 3. Changes in Patient Assessment of Chronic Illness Care Scores by Group

Outcome	Intervention Group (n=261)		Usual Care Group (n=264)		P Value*
		Change		Change	
Total PACIC					
Baseline	1.6±0.9	-1.4±1.0	1.6±1.0	-0.2±0.9	<0.001
1 y	2.9±0.9		1.8±1.0		
Patient activation subscale					
Baseline	1.5±1.2	-1.3±1.5	1.4±1.2	-0.2±1.3	<0.001
1 y	2.7±1.2		1.6±1.2		
Delivery system subscale					
Baseline	2.2±1.1	-1.3±1.3	2.2±1.1	-0.1±1.2	<0.001
1 y	3.5±0.8		2.4±1.1		
Goal setting subscale					
Baseline	1.4±1.1	-1.5±1.3	1.5±1.1	-0.2±1.1	<0.001
1 y	3.0±0.9		1.7±1.2		
Problem solving subscale					
Baseline	1.9±1.2	-1.3±1.3	1.8±1.3	-0.2±1.3	<0.001
1 y	3.2±1.0		2.0±1.3		
Follow-up subscale					
Baseline	1.1±1.0	-1.2±1.3	1.1±1.1	-0.2±1.0	<0.001
1 y	2.4±1.0		1.4±1.1		

PACIC indicates Patient Assessment of Chronic Illness Care.

*Intention-to-treat analysis using general linear mixed model with group, time, and group×time effects.

Patients' assessments of their chronic illness care improved significantly from baseline to 1 year in the intervention group (Table 3). This increase was significantly greater than the modest increase in the EUC group. These significantly different changes were present for the total score on the PACIC instrument as well as the 5 subscales of Patient Activation, Delivery System Design/Decision Support, Goal Setting, Problem Solving/Contextual Counseling, and Follow-up Coordination.

Although there were greater changes in the recommended direction in the intervention group compared with EUC, there were no statistically significant differences in changes between groups in the level of physical activity, body mass index, total energy intake, saturated fat, or sodium intake from baseline to 1 year of follow-up.

Discussion

This study demonstrated that vulnerable patients with uncontrolled CVD risk factors managed by a NP/CHW intervention team achieved significant improvement in their CVD risk profiles. The improvements in the primary outcomes in this study compare favorably with changes in other studies targeting improvement in clinical outcomes and quality of care in patients with CVD and/or diabetes. In a meta-analysis of 66 trials to improve the outcomes of diabetes care, the HbA1c level decreased by a mean of 0.42% (95% confidence interval [CI], 0.29–0.54)³⁹ versus a mean of 0.50% (95% CI, 0.2–0.9) in this trial. In a recent review of 11 studies of nurse-led interventions used to improve control of high BP in people with diabetes, meta-analysis showed greater reductions in BP in favor of nurse-led interventions (systolic

weighted mean difference -5.8 mm Hg; 95% CI, -9.6 to -2.0; diastolic weighted mean difference -4.2 mm Hg; 95% CI, -7.6 to -0.7).⁴⁰ In a systematic review of 44 trials, systolic BP decreased by a mean of 4.5 mm Hg (95% CI, 1.8–6.6)⁴¹ versus a mean of 6.2 (95% CI, 2.1–10.2) in this trial. The changes in HbA1c, BP, total and LDL cholesterol, and triglycerides in this study are clinically meaningful. On a population level, they should lead to a meaningful decreases in macrovascular and microvascular disease in people with diabetes^{42,43} and decreases in events in people with CVD.¹

Patients in the intervention group rated the quality of care that they received for the management of their chronic conditions as increasing significantly more than patients who received EUC. Whether this translates into greater satisfaction with care is unclear; however, we know that satisfaction with care predicts better self-care and more favorable outcomes.⁴⁴ The NP/CHW team enhanced patient self-care by encouraging self-monitoring, mutual goal-setting and decision-making, addressing barriers to improve adherence to medications and appointment keeping, and making proactive contact with patients to assess progress. These types of interventions are consistent with the strategies described by the Chronic Care Model to improve the performance of health care systems.⁴⁵

The results of this trial support the potential for nurse-led patient-centered medical homes (PCMH) to improve the quality of care in high-risk underserved populations. The concept of a PCMH is receiving increased attention as a means to improve care and potentially reduce costs. The PCMH has its origins in care for children with chronic

conditions.⁴⁶ In March 2007, the American Academy of Pediatrics, American Academy of Family Practice, American College of Physicians, and American Osteopathic Association published a joint statement of principles calling for accessible, continuous, team-based care that focuses on the whole person, with the PCMH taking responsibility for care coordination.⁴⁷ In 2009, the American College of Physicians endorsed the inclusion of NP-led practices to test different PCMH models within the Medical Home Demonstration Project.⁴⁸ As the costs of health care for chronic diseases continues to increase, NPs are in pivotal positions to address the need for safe, effective, patient-centered, efficient, and equitable health care.⁴⁹

This study also provides evidence that a nurse-led team that includes CHWs is an effective model of care. However, adoption and sustainability of this model of care will require financing mechanisms for CHWs. Funding, reimbursement, and payment policies for CHWs must be established to ensure that CHW models are adopted in mainstream health care.^{14,50}

The limitations of the COACH Trial include the fact that it was conducted in one federally qualified community health system and used highly trained NPs and CHWs, which may limit generalizability. Second, the recruitment and screening process resulted in the inclusion of a sample of predominately black women. However, this represents the majority of patients seen in these and other similar community health clinics, which increases confidence in the generalizability of findings to similar settings. Third, physicians had patients in both the intervention and EUC groups. This may have resulted in a change in the level of care provided to their patients in the EUC group as they received laboratory reports at baseline and tended to become more vigilant with the assessment, treatment, and follow-up for cardiovascular risk factor management. This may explain the improvements in clinical measures in the EUC group. Nevertheless, improvements in clinical outcomes and perceptions of the quality of care were significantly greater among patients in the intervention group compared with the EUC group. Finally, there was a higher attrition rate in the intervention group (13%) as compared with the EUC group (9%). However, the study was powered to account for a dropout rate of 25%. The slightly differential dropout rate in the intervention group may be due to the increased commitment to participate in the intervention group, including more visits to the clinic resulting in more costs to the participant.

Conclusions

In summary, an intervention delivered by a NP/CHW team, using individualized treatment regimens based on treat-to-target algorithms, can be an effective approach to improve risk factor status and perceptions of chronic illness care in high-risk patients. The translation of new knowledge and efficacious interventions into the care of populations, particularly those at highest risk of multiple chronic diseases, disability, and mortality, remains a national problem. This study developed a partnership with Baltimore Medical Systems, specifically to implement a program to reach this high-risk population. Moreover, the design and intervention were developed in collaboration with the Community Health

Centers within this System, so that the program, if found efficacious, would be sustained for long-term effectiveness. Further analyses will evaluate the cost-effectiveness of NP/CHW model. Further study is needed to determine if this translates into improved morbidity and mortality from CVD.

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None.

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