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COACH trial: A randomized controlled trial of nurse practitioner/community health worker cardiovascular disease risk reduction in urban community health centers: Rationale and design

Jerilyn K Allen[a,b,c], **Cheryl R Dennison Himmelfarb**[a,b], **Sarah L Szanton**[a], **Lee Bone**[c], **Martha N Hill**[a,b,c], and **David M Levine**[a,b,c]

[a]Johns Hopkins University School of Nursing, 525 North Wolfe Street, Baltimore, Maryland 21205, United States

[b]Johns Hopkins University School of Medicine, 600 North Wolfe Street, Baltimore, Maryland 21205, United States

[c]Johns Hopkins University School of Public Health, 615 North Wolfe Street, Baltimore, Maryland 2120, United States

Abstract

Background—Despite well-publicized guidelines on the appropriate management of cardiovascular disease (CVD) and type 2 diabetes, implementation of risk-reducing practices remains poor. This paper describes the rationale and design of a randomized controlled clinical trial evaluating the effectiveness of a comprehensive program of CVD risk reduction delivered by nurse practitioner (NP)/community health worker (CHW) teams versus enhanced usual care in improving the proportion of patients in urban community health centers who achieve goal levels recommended by national guidelines for lipids, blood pressure, HbA1c and prescription of appropriate medications.

Methods—The COACH (Community Outreach and Cardiovascular Health) trial is a randomized controlled trial in which patients at federally-qualified community health centers were randomly assigned to one of two groups: comprehensive intensive management of CVD risk factors for one year by a NP/CHW team or an enhanced usual care control group.

Results—A total of 3899 patients were assessed for eligibility and 525 were randomized. Groups were comparable at baseline on sociodemographic and clinical characteristics with the exception of statistically significant differences in total cholesterol and hemoglobin A1c.

Conclusions—This study is a novel amalgam of multilevel interdisciplinary strategies to translate highly efficacious therapies to low-income federally-funded health centers that care for patients who carry a disproportionate burden of CVD, type 2 diabetes and uncontrolled CVD risk factors. The impact of such a community clinic-based intervention is potentially enormous.

Corresponding Author: Jerilyn K Allen, Johns Hopkins University, 525 N. Wolfe Street, Room 534, Baltimore, Maryland 21205, United States, Telephone: 410-614-4882, Fax: 410-614-1446, jallen@son.jhmi.edu.

Keywords

Randomized trial; Cardiovascular disease; Diabetes; Prevention; Case management; Translational research

1. Introduction

Approximately 1.5 million Americans die annually from cardiovascular disease (CVD), with lower income, prior coronary heart disease (CHD), and diabetes populations disproportionately represented in these deaths. Despite well-publicized guidelines on the appropriate management of cardiovascular disease (CVD) and type 2 diabetes, implementation of risk-reducing practices remains poor. In spite of the known benefit of lowering low-density lipoprotein cholesterol (LDL-C) levels below 100 mg/dl in persons with existing heart disease [1–5], as many as 50–70% of eligible CVD patients are not placed on lipid-lowering therapy by their providers and from 20–80% of patients do not achieve the goals of therapy [6–9]. The benefits of controlling high blood pressure (HBP) are well established yet national rates of HBP control have not improved significantly from a national average of 29–31% despite decades of provider and patient education [10–12]. In addition, research demonstrates that control of hyperglycemia, hyperlipidemia, and HBP reduce the risk of vascular complications in people with diabetes, 75% of whom die from some form of heart or blood vessel disease [13,14].

Several different models of chronic disease case management have emerged to respond to growing concerns about increasing costs of health care; however, evaluation of their impact on patient outcomes or cost is limited [15]. Moreover, there is a paucity of research using a true experimental design to examine the outcomes of comprehensive CVD case-management models using a culturally relevant, multidisciplinary team approach. Nursing is ideally prepared to coordinate and maximize the use of limited resources within health care facilities and the community, particularly in underserved areas. Nurse case management and community health workers (CHWs) have become increasingly popular strategies for coordinating health care services to high-risk populations. This study is a novel amalgam of multilevel interdisciplinary strategies to translate highly efficacious therapies to low-income federally-funded health centers that care for patients who carry a disproportionate burden of CVD and other patients at very high-risk, primarily type 2 diabetics. The impact of such a community clinic-based intervention is potentially enormous.

In this paper, we describe the rationale and design of a randomized controlled clinical trial evaluating the effectiveness of a comprehensive program of CVD risk reduction delivered by nurse practitioner (NP)/CHW teams versus enhanced usual care in improving the proportion of patients in urban community health centers who achieve goal levels recommended by national guidelines for lipids, blood pressure, HbA1c and prescription of appropriate medications. The secondary objectives are to determine the cost-effectiveness of the comprehensive intensive intervention relative to enhanced usual care and to determine the effectiveness of the comprehensive intensive intervention on the secondary outcomes of patients' perceptions of their chronic illness care and health care utilization. It is hypothesized that the comprehensive intervention will yield an increase in achievement of treatment goals for lipid management, BP control, diabetes control, lifestyle behaviors and utilization of antiplatelet agent, beta blocker, and ACE inhibitor therapies in patients with existing CVD, type 2 diabetes, or CVD risk factors.

2. Methods

2.1. Phase One

Phase one of the study utilized the model of community-based participatory research to refine the study plan. Community-based participatory research 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 [16,17]. Participatory methodologies have significant potential to reduce health disparities as they incorporate the knowledge of community members in the design of culturally appropriate and sensitive interventions enhancing the likelihood of effectiveness and long-term sustainability. Community participation is a broad concept including individual/patient capacity building, governance and advisory boards and training and employment of community/neighborhood residents. Partnership structure can vary but often includes an advisory committee or other organizational means to seek broad participation [18].

This research utilizes a Community-Provider Advisory Committee as the locus for building community-based participatory research. This Committee guides all aspects of the study, participates in decision making regarding study planning, design of implementation plans, interventions and evaluation as well as dissemination of results and planning for sustainability if the intervention model is shown to be effective. This Community/Provider Advisory Committee met quarterly during Phase 1 of the study. Membership includes six consumer members (clinic patients with CVD or diabetes) and four Baltimore Medical Systems (BMS) provider members (two physicians, one nurse clinical services coordinator, and one community outreach worker). The Committee assisted in the naming of the program, creating the logo, increasing awareness within the BMS intervention sites, reviewing and helping to refine the intervention protocols for cultural acceptability and relevance, advising on recruitment and retention of study participants, reviewing job descriptions and recruiting and selecting CHWs and NPs, reviewing questionnaires for acceptability and cultural relevance, and naming the study. The study was titled the COACH Program (Community Outreach and Cardiovascular Health Program).

2.2. Phase Two

Phase two of the study is a randomized controlled trial in which 525 patients were randomly assigned to one of two groups: comprehensive intensive management of CVD by a NP/CHW team or an enhanced usual care control group. Individuals in the control group receive 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 enhanced usual care plus management by the NP/CHW team. The program included aggressive pharmacologic management, tailored educational and behavioral counseling for lifestyle modification, identification of barriers to adherence and attainment of goals, telephone follow-ups between visits and pre-appointment reminders.

2.3. Sample

Patients were recruited from two community health clinics which are part of the federally - qualified community health center entitled Baltimore Medical Systems Incorporated (BMS). The focus of these clinics is on primary care in areas 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 have diagnosed type 2 diabetes

receiving any therapy. They had to be ≥ 21 years of age, speak and be able to understand English. Patients were enrolled in the trial if they had at least one of the following criteria at the time of the medical record reviews: (1) an LDL-C ≥100 mg/dl or LDL-C ≥ 130 mg/dl if no diagnosed CVD or diabetes, (2) a blood pressure > BP 140/90 mm Hg or > 130/80 mm Hg if diabetic or renal insufficiency, or (3) if diabetic, a HbA1c 7% or greater or glucose ≥ 125 mg. Patients were excluded if they had a serious life-threatening non-cardiac co-morbidity with a life expectancy of less than 5 years (AIDS or cancer for example), had a serious physician-recorded psychiatric morbidity or neurologic impairment that would preclude participation in their own care.

2.4 Recruitment, screening and enrollment

Participants were recruited from the patient population at BMS. In an effort to manage the logistics of the project and enrollment of participants over time, every six months the patient ID numbers of eligible participants based on ICD-9 codes were identified from the administrative data base of computerized records of patients who had been seen in the clinics. Trained study staff reviewed the electronic medical records of identified patients to screen for eligibility based on the inclusion and exclusion criteria. Patients who met the eligibility criteria based on record review were sent a letter co-signed by the BMS center medical director and the principal investigator indicating that they may be eligible for a cardiovascular risk reduction study at their clinic. The letter explained the purpose of the study and notified them of a follow-up telephone contact within the next two weeks to further explain the study. A postage paid return postcard was included for patients to decline further contact by study staff or indicate an opportune time for telephone contact. A follow-up telephone call to patients included further explanation of the study and scheduling of an appointment with study staff at the clinic for a lipid profile, blood pressure, and hemoglobin A1c (HbA1c) evaluation to confirm their eligibility.

All participants completed the informed consent process and HIPAA authorization at the beginning of their baseline research visit. The study was approved through the Johns Hopkins School of Medicine Institutional Review Board, and recruitment procedures were in accordance with the Health Information Portability and Accountability Act regulations. See Figure 1 for the study flow chart describing the number of participants at each stage.

Participants were asked to fast for 12 hours prior to their baseline assessment which included measurement of blood pressure, lipids, and in patients with diabetes, HbA1c to confirm the lack of control of at least one risk factor. Eligible patients were stratified by race (Black and nonblack) and sex (men and women) and randomized into one of two groups, comprehensive intervention (CI) or enhanced usual care (UC), using a computerized randomization schema generated by the Johns Hopkins Research Pharmacy where this is done routinely for clinical trials.

2.5 Measurements

Table 1 describes the data collection schedule. Participants were compensated for their time at the baseline, six month and 12 month assessments for a total of $85.

2.5.1 Biological and physical measures—Venipuncture was performed by a trained phlebotomist with the participant sitting upright after a 12 hour overnight fast. The chemistry laboratory at Johns Hopkins performed all biochemical measures with technicians blinded to participants' intervention assignment. Total cholesterol, triglycerides, and high-density lipoprotein cholesterol (HDL-C) were measured directly. Low-density lipoprotein cholesterol (LDL-C) was estimated using the Friedewald equation [19]. In the event of triglyceride levels greater than 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. Blood pressure was measured using the Omron Digital Blood Pressure Monitor HEM-907XL automatic blood pressure device according to JNC VII guidelines,[12] following five minutes of quiet rest in the right arm with the person seated in a chair with arm supported at heart level. The average of three blood pressures was recorded. Weight and height were measured with research participants in light clothing using a stadiometer and balance scale. Body mass index was calculated as weight in kilograms/height in meters squared. Waist circumference was measured with a measuring tape according to the obesity guidelines [20]. With the participant standing, the upper hip bone was palpated to locate the right iliac crest. A measuring tape was positioned horizontally to the floor just above the uppermost lateral border of the right iliac crest and a measurement was made around the abdomen at normal minimal respiration.

2.5.2 Lifestyle behaviors—Physical activity was evaluated with the Stanford 7-Day Physical Activity Recall. This interviewer administrated survey takes about 20 minutes to complete and estimates total daily energy expenditure by asking participants to estimate the number of hours spent in sleep and activities classified into moderate, hard, and very hard activities over the previous seven days [21,22]. Light activity is calculated as the remaining time. The amount of time spent in each category is multiplied by the average metabolic equivalent (METs, or kcal/kg/hr) of each category and summed to calculate energy expenditure in terms of kcal/kg/day. Average daily time spent in the activity categories also can be determined.

Smoking status was assessed by self-report with standard questions from prior studies. Participants who were smokers at baseline received the smoking cessation intervention and had their smoking status evaluated at follow-up and confirmed by measuring the level of carbon monoxide (CO) in exhaled air. Exhaled CO was measured with a portable carbon monoxide monitor manufactured by Vitalograph, Inc. The machine was calibrated to zero by the operator prior to each use and was sent to the manufacturer once a year for calibration. Participants were asked to take a deep breath, hold it as long as possible and breathe steadily through the mouthpiece over a period of 20 seconds. The highest number that appeared on the monitor within 40 seconds after the subject has completed the test was recorded. More than 8 ppm on an average on 2 readings was considered a smoker.

Dietary intake was measured by the Habits and History Food Frequency Questionnaire, Block 2005.1. Development and validation of the dietary questionnaire has been described in publications by Block and her colleagues [23,24] and now contains a list of foods commonly consumed in African American and other minority populations. Data represent habitual intake and include average energy, total fat, saturated fat, monounsaturated fats, polyunsaturated fats, protein, carbohydrates, and micronutrients consumed per day.

2.5.3 Quality of life—Quality of life was measured by the 5 item EuroQol questionnaire (EQ-5D)[25]. This brief questionnaire asks individuals to indicate whether they have no problem, a small problem, or a large problem in each of five domains: usual activities, self-care, pain, anxiety/depression, and mobility. The instrument will be used to estimate the cost-utility of the intervention. Analysis will compare individual measures of EQ-5D levels as well as averages experienced by each group.

2.5.4 Assessment of chronic illness care—The Patient Assessment of Chronic Illness Care (PACIC) Survey is a 20-item patient report instrument that assesses patient's receipt of clinical services and actions consistent with the Chronic Care Model[26]. Respondents rate how often they experienced the content described in the item on a 5-point scale ranging from 1 (no or never) to 5 (yes or always). Patients rated the care received from

their health care team. The five subscales were Patient Activation; Delivery System/ Decision Support; Goal Setting; Problem-solving/Contextual Counseling; and Follow-up/ Coordination.

2.5.5 Healthcare utilization—Patients self-reported the number of visits to a physician's office, clinic, hospital emergency room, and hospital admissions. For hospital admissions the number of days were recorded.

2.5.6 Sociodemographic and health variables—Age in years, education in years, income, insurance status, and marital status were assessed from a standardized questionnaire used in our prior studies. Comorbidity was assessed by abstracting data from the medical history at the time of enrollment. The comorbidity index developed by Charlson, a widely accepted, validated weighted index designed to evaluate the longitudinal risk of mortality attributable to comorbid disease was used to quantify comorbidity [27].

2.5.7 Resource utilization/Cost—Data were collected on the resources consumed that resulted in direct medical costs being incurred by the COACH intervention These resources included those associated with delivery of the intervention such as labor, supplies and capital equipment. The NPs and CHWs who delivered the intervention completed data collection forms developed specifically for the study that captured the encounter and non-encounter time spent delivering the intervention. We will perform a cost-effectiveness analysis by comparing the relative cost and outcomes of the comprehensive intervention to that of usual care. We will report the incremental cost of the intervention over the usual care group from the perspective of the health care system.

2.5.8 Process measures—Documenting the team's adherence to protocols and the strength of the intervention delivered was an important process variable. 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 dose of the intervention. In addition there was a COACH Program Intervention Quality Assurance (QA) Plan to assure adherence to study intervention protocols and treatment algorithms to promote intervention integrity throughout the study. The QA assessments, which were conducted on a quarterly basis, included analysis of audio-tape recorded intervention sessions and intervention documentation in medical records. The QA assessments were independently conducted by two COACH study investigators who discussed the assessments and provided feedback to interventionists to provide positive reinforcement and / or a plan for additional training in a timely basis.

2.6 Interventions

2.6.1 Comprehensive intensive intervention—The CI focused on behavioral interventions to affect therapeutic lifestyle changes and adherence to medications and appointments as well as the prescription and titration of medications for one year. The NP and CHW work as a team. The NP functioned as the case manager for each CI study participant. She oversaw the initial assessment and, in collaboration with the CHW, tailored the intervention plan, conducted the intervention including lifestyle modification counseling, medication titration and prescription, consulted with the physician, and supervised the CHW. The NP/patient encounters were optimized to improve adherence including 1) review of laboratory results, 2) communication of the treatment plan in specific detail accompanied by educational materials written for low-literacy populations, 3) discussion of barriers or enhancers and assessment of the regimen, 4) assessment of self-reported adherence, 5) provision of reminder tools and referral for discussion with the CHW, 6) review of all lifestyle and drug regimens, adherence to all, discussion of the complexity and any side

effects, 7) discussion of any medical concerns or issues directly with the primary provider, 8) reinforcement for positive changes, and 9) scheduling of the next visits. Participants were asked to identify a support person who was invited to attend sessions.

In addition to meeting with the NP, CI participants 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 may not have been directly related to the control of cardiovascular health. The CHW also reinforced instructions by the NP related to integration of lifestyle modifications and medication therapies and assisted participants in designing a set of reminders, prompts, logs, pill organizers, alarm clocks, or whatever the individual believed would help them remember 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 participants not making progress towards their goal levels received a home visit from the CHW. This visit provided additional information to enhance understanding of barriers and offer the opportunity to activate the patient's social support system. The CHW made reminder calls the day before scheduled appointments and called after missed appointments.

2.6.1.1 Therapeutic Lifestyle Changes (TLC): 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 participant received the Guide at the first encounter, took it home as a tool for making changes and regularly brought it to each visit. The Wellness Guide had sections focusing on the patient's test results and therapeutic goals for weight, blood pressure, lipids, and HbA1c (for patients with diabetes); medication reconciliation and customized tips for taking your 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 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 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 [28]. The importance of dietary adherence was emphasized as an adjunct to pharmacotherapy. Recognition of food preferences were incorporated 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. Areas of focus included reducing portion size, reducing fast food intake, 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 participants by the CHW.

Participants in the CI group were instructed to participate in a moderate-intensity home-based exercise program. They selected the mode of moderate-intensity physical activity and set achievable goals. Telephone contact was initiated by the CHW two 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.

Smoking cessation counseling for current smokers was tailored to their readiness to change. At the initial intervention, the NP conducted a smoking history to evaluate the participant's level of addiction to smoking and their stage of readiness to change [29]. Those who identified an intention to stop smoking rated their self-efficacy or confidence to resist

smoking in various high-risk situations. The NP and participant identified specific strategies to resist the triggers for smoking relapse. The CHW initiated monthly telephone follow-up for up to six months to monitor self-reported progress and provide the appropriate reinforcement or offer further counseling.

2.6.1.2 Pharmacotherapy: Specific algorithms for drug treatment of hyperlipidemia, HBP, hyperglycemia, ACE, and β-blocker therapy were developed for this study based on current guidelines and standards of care [30]. An important role of the NP and CHW was to identify barriers to adherence. They addressed logistical and financial barriers to filling prescriptions and to medication adherence with referral to and assistance in completing the necessary paperwork for social services and pharmacy assistance programs.

2.6.1.3 Motivational interviewing: Behavioral counseling implemented by the NP and CHW used the techniques of motivational interviewing. Sessions began with a review of laboratory results and assessment of the patient's progress towards goals. This was followed by assessment of the patient's motivation and confidence for adherence or health behavior change; identification of barriers, concerns, and positive self-motivational feedback; problem solving that identified possible solutions to barriers and the identification of the pros and cons of the proposed behavior change; development of new goals which were written into the Wellness Guide.

2.6.2 Enhanced usual care—Patients and their providers in the UC group receive the results of baseline lipids, BP, and HbA1c along with the recommended goal levels and a pamphlet on controlling their risk factors published by the American Heart Association. In addition, providers received copies of the AHA/ACC Guidelines for Secondary Prevention [30].

2.7 Analysis plan

The primary outcomes are changes from baseline to one year in lipids, BP, and HgA1c. Analysis will follow the intention- to- treat model including all randomized participants in the analyses according to their original assignment. Participants who withdraw or do not complete the one year assessment will be included in the analysis by using regression estimation of their values using covariates of their baseline values and values of similar participants. Generalized linear mixed models (GLMM) will be used to build multilevel models comparing the effectiveness of the CI with UC on each outcome, controlling for covariates that may potentially have an effect on the outcomes such as age, sex, level of education, level of medical co-morbidity, dietary intake, level of physical activity, social support, depression if they are determined by univariate analyses to be predictive of outcomes. This approach also controls for within-patient variation in outcomes.

Secondary analyses will evaluate the intervention on several secondary outcomes including assessment of chronic illness care, healthcare utilization, and an incremental cost-effectiveness analysis from the perspective of the health care system.

2.8 Sample size justification

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 the conservative differences in changes in the primary outcomes at one year to ensure 80% power at a 0.05 significance level. This sample size accounts for an expected 25% attrition at the one-year follow-up yielding 180 participants per intervention.

3. Results

A total of 525 participants were randomized to the COACH Program. Table 2 shows the baseline characteristics of those randomized to CI and UC. There were no significant differences in sociodemographic and baseline measures between the two groups except for higher total cholesterol and HbA1c levels in the CI group compared to the UC group. The sample was predominantly Black women. A majority had at least a high school education; however, a majority had annual incomes less than $20,000 and less than half had private health insurance.

4. Discussion

Case management by a specially trained nurse-led team, including CHWs, has been shown to be among the most efficacious strategies to improve management of CVD risk factors in many studies [31–42]. 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 healthcare services, compared with usual care. For example, trained nurses providing care have demonstrated the most successful of strategies for improving lipid levels in patients with elevated LDL-C and BP [32,35,43–51]. In the nurse management models, factors such as patient education and counseling and 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 [52,53]. Several studies suggest that a nurse-led team management program is the most effective strategy to date for reducing LDL-C [54].

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 [55]. Nurse case management improves control of diabetes in clinical settings, with significant reductions in fasting blood glucose, body weight, glycosylated hemoglobin, and LDL-C [56]. 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 [57].

In low income and minority populations, CHWs or lay health advisors have participated in team-based care for the management of CVD risk factors, particularly hypertension and diabetes [58–60]. While 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 [46,61–63]. Trained CHWs, front line health and human service care providers, are most often indigenous workers who 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. This unique connection not only enhances trust between CHW and the patient, but enables the CHW to effectively link underserved populations to healthcare resources where traditional health education and outreach efforts have failed [64,65]. CHWs also serve as a bridge between the patient population and health care providers with communication of barriers to care and treatment which catalyze provider and health system changes [66,67]. CHWs have been shown to improve quality of care, satisfaction with care, increase access to care, reduce healthcare costs, strengthen local economies and families, and foster community capacity building [58,65,68–70]. CHWs also

have been shown to be effective in research as interviewers and interventionists [46,63,69,71].

This clinical trial addresses some limitations of previous studies by the incorporation of a rigorous cost-effectiveness evaluation, integration of the care model into federally-qualified community health centers, and adoption of a translational approach by not providing free clinical care or free medications. There are limitations of the COACH Trial. First, 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 community health clinics which increases confidence in the generalizability of findings to similar settings and populations. Second, physicians had patients in both the CI and UC groups. This may have resulted in a change in the level of care provided to their patients in the UC group as they tended to become more vigilant with the assessment, treatment and follow-up for cardiovascular risk factor management. This may result in a type-2 error if no differences are found in the final analysis.

This effectiveness study will provide critical, real-world data regarding the implementation and testing of a NP/CHW case management intervention for the reduction of total cardiovascular risk in a high-risk vulnerable population. The community-based participatory research partnership has provided the opportunity to address a serious problem with the capacity to study it well, and intervene using the best practices incorporated into settings where the need is greatest with the potential to demonstrate an impact on health disparities. The proposed increase in the percentage of high-risk women and men who receive recommended therapies and achieve goal levels could potentially result in a marked decrement in the annual CVD-related mortality and costs if applied within primary care settings to populations with the characteristics of the target groups in this study.

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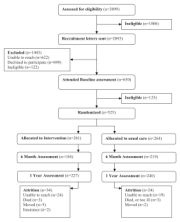

Figure 1.
COACH Trial Flowchart.

Table 1

Schedule of Study Measures.

Measures	Baseline	6 Months	12 Months
Socio-demographics: Sex, race, education, income, employment status, marital status, smoking, insurance	x		x
Clinical measures: height, weight, blood pressure, waist circumference, exhaled carbon monoxide, blood pressure, total cholesterol, triglycerides, LDL-C[a], HDL-C[b], HbA1c[c]	x		x
Charlson Co-morbidity Index	x		
Prescribed medication	x	x	x
Patient Assessment of Chronic Illness Care	x		x
Health Habits and History FFQ[d], Block 2005.1	x		x
Stanford 7 day physical activity recall	x		x
EuroQol	x		x
Social Support	x		x
Center for Epidemiological Studies Depression Index (CES-D)	x		x
Healthcare utilization		x	x

[a] LDL-C = low density lipoprotein cholesterol;

[b] HDL-C = high density lipoprotein cholesterol;

[c] HbA1c = Hemoglobin A1c

[d] FFQ = Food frequency questionnaire

Table 2

Baseline sample characteristics

Characteristic	Intervention (n = 261)	Usual Care (n = 264)	*P*
Age, y, mean (SD)[a]	54.3 (12.0)	54.7 (11.5)	0.692
Female, n (%)	187 (71.7)	187 (70.8)	0.837
Marital status, n (%)			0.595
Single	61 (23.4)	69 (26.1)	
Married	87 (33.3)	80 (30.3)	
Separated	19 (7.3)	28 (10.6)	
Widowed	39 (14.9)	37 (14.0)	
Divorced	55 (21.1)	50 (18.9)	
Race, n (%)			0.947
White	54 (20.7)	54 (20.5)	
Black	207 (79.3)	210 (79.6)	
Education, n (%)			0.053
<High School	77 (29.5)	94 (35.6)	
High school/GED	118 (45.2)	92 (34.9)	
Some college	66 (25.3)	78 (29.6)	
Employment status, n (%)			0.318
Employed	110 (42.2)	100 (37.9)	
Not employed	151 (57.8)	164 (62.1)	
Type of insurance, n (%)			0.202
Private	113 (43.3)	105 (39.8)	
Medicare and/or Medicaid	105 (40.2)	101 (38.3)	
Uninsured	43 (16.5)	55 (20.8)	
Unknown	0 (0)	3 (1.1)	
Annual income, n (%)			0.123
<$20,000	136 (52.1)	149 (56.4)	
≥$20,000	121 (46.4)	105 (39.8)	
Unknown	4 (1.5)	10 (3.8)	
Comorbidity score, n (%)			0.177
0	82 (31.4)	87 (33)	
1–2	151 (57.9)	136 (51.5)	
3–4	16 (6.1)	31 (11.7)	
≥5	12 (4.6)	10 (3.8)	
Diastolic Blood Pressure, mean (SD)	83 (12.7)	82.3 (13.0)	0.521
Systolic Blood Pressure, mean (SD)	139.7 (23.8)	138.7 (19.9)	0.571
Total Cholesterol, mean (SD)	199.7 (46.0)	191.3 (45.0)	0.036
LDL-C[b], mean (SD)	121.6 (40.0)	116.3 (40.5)	0.130

Characteristic	Intervention (n = 261)	Usual Care (n = 264)	*P*
HDL-C[c], mean (SD)	50.8 (14.7)	50.9 (13.6)	0.92
Triglycerides, median (IQR)[d]	113 (85)	105 (76)	0.220
Hemoglobin A1c, mean (SD)	8.9 (2.2)	8.3 (1.9)	0.006
PACIC[e], mean (SD)	1.5 (0.9)	1.6 (0.9)	0.879

[a] SD = standard deviation;

[b] LDL-C = low density lipoprotein cholesterol;

[c] HDL-C = high density lipoprotein cholesterol;

[d] IRQ = interquartile range;

[e] PACIC = Patient Assessment of Chronic Illness Care;