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Veteran peer Coaches Optimizing and Advancing Cardiac Health (Vet-COACH); design and rationale for a randomized controlled trial of peer support among Veterans with poorly controlled hypertension and other CVD risks

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ABSTRACT

Background: Peer support can improve health for patients with chronic conditions; however, evidence for disease prevention is less clear and peer recruitment strategies are not well described. This paper describes a study protocol to evaluate a peer support intervention to improve hypertension control and reduce cardiovascular disease (CVD) risk.

Methods & research design: Target enrollment for this two-site study is $n = 400$. Eligibility criteria include Veterans enrolled in Veterans Health Administration (VHA) primary care with poorly controlled hypertension and one other cardiovascular disease risk (smoking, overweight/obesity, or hyperlipidemia) who live in census tracts with high rates of hypertension. Enrolled participants are randomized to a home-based peer delivered self-management intervention (5 home visits and 5 phone calls with a peer health coach) versus usual care. The primary outcome is a change in systolic blood pressure (SBP) and secondary outcomes include change in CVD risk and health care use.

Results: Trial results are pending and participant enrollment is ongoing. We recruited peer coaches from Veterans who lived in census tracks with the highest rates of hypertension. To recruit Veteran peer coaches, we asked primary care providers ($n = 41$) and team nurses ($n = 35$) to nominate patients who they thought would be a good fit for the peer coach position (based on successful self-management and health care navigation) ($n = 73$ nominated from 964 patients). We interviewed 12 Veterans and trained 5 peer coaches.

Conclusions: Results of this trial will inform peer support programs targeted to provide community-based delivery of prevention services to patients in high-risk areas.

Trial registration: Clinicaltrial.gov identifier NCT02697422

Trial status: Enrollment for the randomized trial phase began in September 2017 and will be complete September 2019.

1. Introduction

Cardiovascular disease (CVD) is the leading cause of death in the US and among Veterans. Risk for CVD is a composite measure of several modifiable factors including hypertension, dyslipidemia, and tobacco use; which are exacerbated by sedentary lifestyle, unhealthy diet, and

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obesity [1]. CVD risk factors remain sub-optimally controlled in the US population [2], as well as among Veterans who use the Veterans Health Administration (VHA) for care [3]. Almost half of Veterans have a diagnosis of hypertension, and one quarter have poor blood pressure control [3]. Veterans who obtain care from VHA are more likely to be obese and physically inactive than the general population [4] and 25% use tobacco [5], making Veterans a group in whom CVD risk reduction is especially warranted.

Successful management of hypertension and other cardiovascular risks is a complex process that requires significant lifestyle changes but adopting and adhering to these changes is challenging. A promising approach to overcoming these challenges is utilizing peer support, defined as the provision of support and information from a member of a social group who possesses experiential knowledge and similar characteristics to the target population. Peer support falls into the social support model, which includes social relationships that improve health behaviors, health-related quality of life and well-being. Trained peers may be a novel and innovative addition to existing health care services, as peers can be effective in supporting health behavior change and make healthcare more patient-centered [6,7].

The peer support approach has not received widespread testing among Veterans cared for in VA primary care. Previous research in non-VA populations suggests that peer coaches, or community health workers, in conjunction with nurses, are effective at controlling cardiovascular risk factors [8,9]. Among Veterans, the peer support model may be more effective due to the shared military experience and camaraderie of Veterans and may be an untapped opportunity to improve health among primary care patients. This model needs further testing and refinement, including determining how best to integrate peer support into primary care. The goals of the "Veteran peer Coaches Optimizing and Advancing Cardiac Health" (Vet-COACH) study are:

(1) to test the effectiveness of a home-visit, peer health coach intervention to improve blood pressure control by promoting health behavior change for Veterans at risk for CVD; and (2) determine Veteran and provider satisfaction with the intervention and barriers and facilitators to adoption. Veteran peer coaches will provide health education and social support to link Veterans to VHA clinic and community-based resources. We are targeting health behaviors closely linked to CVD risk including hypertension control, medication adherence, and unhealthy lifestyles (e.g., cigarette smoking, lack of exercise and poor diet).

2. Methods

2.1. Study design

The Vet-COACH study aims to determine the effectiveness of a peer health coach intervention for improving health outcomes for Veterans with multiple CVD risks in a two-site randomized controlled trial. Vet-COACH is an ongoing 2-arm randomized controlled trial in which $n = 400$ participants with poorly controlled hypertension and one other CVD risk factor receive a home-based intervention over 12 months, compared to usual care. In addition, we will use a mixed methods approach to determine barriers and facilitators to adoption of, and Veteran and provider satisfaction with a peer health coach intervention. Participants are patients recruited from the Seattle and American Lake VHA primary care and women's clinics in Washington state. Approval was obtained from the VA Puget Sound Institutional Review Board (IRB) and the Research and Development Committee at the VA Puget Sound Health Care system. All participants completed an informed consent process and HIPAA authorization at the beginning of their baseline research visit.

2.2. Study overview

To be eligible, patients must have poorly controlled hypertension, one other CVD risk, and be free of cardiovascular disease hospitalization in the past 3 months (Table 1). At baseline, participants provide written informed consent, and complete measures focusing on primary and secondary outcomes. The primary outcome is a change in systolic blood pressure (SBP) from baseline to 12-month follow-up. Secondary outcomes include change in cardiovascular risk, as measured by the Framingham Risk Score [10], other cardiovascular risks (tobacco use, dyslipidemia) and health related quality of life. Additional secondary outcomes are healthcare utilization, including hospitalizations, emergency room visits and outpatient visits, determined by using administrative data at 1 year following randomization. We will assess the cost of the intervention to inform feasibility for future studies and will determine primary care provider (physician and nurse practitioners), staff and Veteran satisfaction with the intervention and barriers and facilitators to adoption using qualitative semi-structured interviews.

Table 1
Eligibility Criteria and Enrollment Process.

Step 1. Identification of potentially eligible participants from administrative data	Inclusion criteria • ≥ 1 visit to VA Puget Sound (Seattle or ALVA) primary care or women's clinic in the past year • Age ≤ 75 years • Poorly controlled hypertension (> 150/90 mm Hg) and at least one other CVD risk (overweight or obesity, body mass index (BMI) ≥ 25 kg/m^2, tobacco use, or a diagnosis of hyperlipidemia) Exclusion criteria • Hospitalized in the past 3 months for CV related conditions (IHD, CVA, PVD) • Severe illness that precludes lifestyle program or ESRD on dialysis • Nursing home resident, homeless • Severe cognitive impairment • Receiving home-based primary care
↓	
Step 2: Chart review	• Zip code identification • Exclude patients with flags for suicidality or disruptive behavior
↓	
➢ Send patient an introductory letter with opt out postcard ➢ For patients who did not opt out, call to assess interest ➢ Complete phone screen and set up enrollment interview for interested patients	
Step 3: Enrollment visit	• Completion of informed consent • Surveys, weight and blood pressure obtained • Randomize to intervention or control

2.3. Study population and recruitment

Participant eligibility is determined using a multi-step process as outlined in Table 1. Potentially eligible patients are first identified from VA administrative data. Study staff then perform a chart review to determine participant geographic location and evaluate additional exclusion criteria, including suicidality and disruptive behavior. We target our intervention in the geographic area around the Seattle and the American Lake VA (ALVA) where there is a high prevalence of hypertension among VA primary care patients. To identify these geographic areas, we collaborated with the VA Office of Analytics and Business Intelligence to utilize Geographic Information Systems (GIS) to map census tract and zip codes with the highest prevalence of hypertension. We target Veterans with elevations in systolic hypertension above the stage 1 level [11]. We chose 75 years of age as the upper age limit because the prevalence of significant co-morbidities increases with age, thus complicating disease self-management. We do not exclude Veterans with other prevalent conditions (e.g. diabetes, arthritis, or lung disease). Exclusion criteria include a CVD hospitalization in the past 3 months, severe illness, including cancer, end stage renal disease (ESRD) on dialysis, dementia, inability to give informed consent, and receiving home-based primary care. We also exclude those who are