CrossMark

A problem-solving intervention for cardiovascular disease risk reduction in veterans: Protocol for a randomized controlled trial

Jason A. Nieuwsma[a,b,*], Laura O. Wray[c,d], Corrine I. Voils[e,f], Jennifer M. Gierisch[e,f], Margaret Dundon[g], Cynthia J. Coffman[e,h], George L. Jackson[e,f], Rhonda Merwin[b,e], Christina Vair[c], Karen Juntilla[e], Courtney White-Clark[e], Amy S. Jeffreys[e], Amy Harris[e], Michael Owings[d], Johnpatrick Marr[d], David Edelman[e,f]

[a] Mid-Atlantic MIRECC, Department of Veterans Affairs, Durham, NC, United States
[b] Department of Psychiatry and Behavioral Sciences, Duke University Medical Center, Durham, NC, United States
[c] VA Center for Integrated Healthcare, VA Western New York Healthcare System, Buffalo, NY, United States
[d] Department of Medicine, Jacobs School of Medicine and Biomedical Sciences, University at Buffalo, Buffalo, NY, United States
[e] Center for Health Services Research in Primary Care, Department of Veterans Affairs, Durham, NC, United States
[f] Department of Medicine, Duke University Medical Center, Durham, NC, United States
[g] National Center for Health Promotion and Disease Prevention, Department of Veterans Affairs, Durham, NC, United States
[h] Department of Biostatistics and Bioinformatics, Duke University Medical Center, Durham, NC, United States

ARTICLE INFO

ABSTRACT

Background: Health behaviors related to diet, tobacco usage, physical activity, medication adherence, and alcohol use are highly determinative of risk for developing cardiovascular disease. This paper describes a study protocol to evaluate a problem-solving intervention that aims to help patients at risk for developing cardiovascular disease address barriers to adopting positive health behaviors in order to reduce cardiovascular risk.

Methods: Eligible patients are adults enrolled in Veterans Affairs (VA) health care who have not experienced a cardiovascular event but are at elevated risk based on their Framingham Risk Score (FRS). Participants in this two-site study are randomized to either the intervention or care as usual, with a target of 400 participants. The study intervention, Healthy Living Problem-Solving (HELPS), consists of six group sessions conducted approximately monthly interspersed with individualized coaching calls to help participants apply problem-solving principles. The primary outcome is FRS, analyzed at the beginning and end of the study intervention (6 months). Participants also complete measures of physical activity, caloric intake, self-efficacy, group cohesion, problem-solving capacities, and demographic characteristics.

Conclusion: Results of this trial will inform behavioral interventions to change health behaviors in those at risk for cardiovascular disease and other health conditions.

Trial registration: ClinicalTrials.gov identifier NCT01838226

1. Introduction

Cardiovascular disease (CVD) is the leading cause of death worldwide [1]. As the principal cause of mortality in the United States (U.S.), CVD accounted for 611,105 deaths in 2013, or 23.5% of deaths from all causes [2]. An estimated 26.6 million adults in the U.S. are currently living with a diagnosis of heart disease [3]. In addition, many more are at high risk for developing CVD. Clinical risk factors include high blood pressure, high LDL cholesterol, diabetes, and obesity, which are often related to the key health behavioral risk factors of smoking, poor diet, sedentariness, and alcohol abuse [4–8]. Taken together, these risk factors place a majority of the U.S. population at risk for developing CVD or suffering a cardiovascular event.

Although multiple factors can contribute to the development of

CVD, longitudinal epidemiological data suggest that the prevalence of CVD corresponds to societal changes in health behaviors. In the U.S., while recent decades have witnessed a decline in rates of smoking [9], there has simultaneously been an increase in the prevalence of obesity [10–12], a rise in the consumption of sugar-sweetened beverages [13], and a decrease in daily physical activity [14]. These trends appear to have an influence on the morbidity and mortality rates of CVD [15].

Adopting and adhering to healthy lifestyle behaviors is a challenge. Over two thirds of adult cigarette smokers report that they want to quit [16], yet < 10% of serious quit attempts are sustained six months later [17]. For those seeking to lose weight, findings from the National Health and Nutrition Examination Survey suggest that less than one in five individuals who reported weight loss of at least 10% had maintained that loss a year later [18]. Figures for adhering to an exercise program are somewhat more challenging to accurately describe, but estimates suggest that at least half of those who begin an exercise program will dropout within six months [19,20]. In attempting to sustain health practices that can reduce CVD risk, many people clearly encounter impediments.

We propose that an intervention aimed at addressing the barriers and problems people encounter when attempting to adopt and maintain healthy habits can improve sustainability of healthy habits and ultimately decrease risk for CVD. The aim of the present randomized controlled trial is to evaluate the effectiveness of a novel problem-solving therapy (PST)-based intervention for reducing CVD risk compared to usual care in a sample of veterans at elevated risk for developing CVD. In this article, we report on study design, procedures, and development of the problem-solving intervention protocol.

2. Methods

2.1. Study design and population

The present study aims to determine the effectiveness of a PST-based intervention for CVD prevention via a multi-site, two-arm, randomized controlled trial. Participants are veterans recruited from the Durham Veterans Affairs Medical Center (VAMC) in North Carolina, the VA Western New York Healthcare System (VAWNYHS) in Buffalo New York, and affiliated satellite clinics. Target enrollment across the two sites is 400 participants. Ethical approval was obtained from the Institutional Review Board and Research and Development Committee at both the Durham VAMC and VAWNYHS.

2.2. Study overview

To be eligible, patients must have no prior history of cardiovascular event but must be at elevated risk for such an event. At baseline, participants provide written informed consent, provide information to calculate a Framingham Risk Score (FRS), and complete measures focusing on a number of secondary outcomes (Fig. 1). Eligible participants are then randomized to receive care as usual or the PST intervention. The intervention involves six 90-minute group sessions, conducted approximately monthly, with individual coaching calls (10–25 min each) occurring between each group session. Each group is composed of approximately 10 veterans. The FRS (primary study outcome) and other outcomes are measured at baseline and two follow-up time points, approximately 6 and 12-months following enrollment.

2.3. Study recruitment

Participant eligibility is determined using a multi-phase process to identify patients via first reviewing aggregated data from electronic
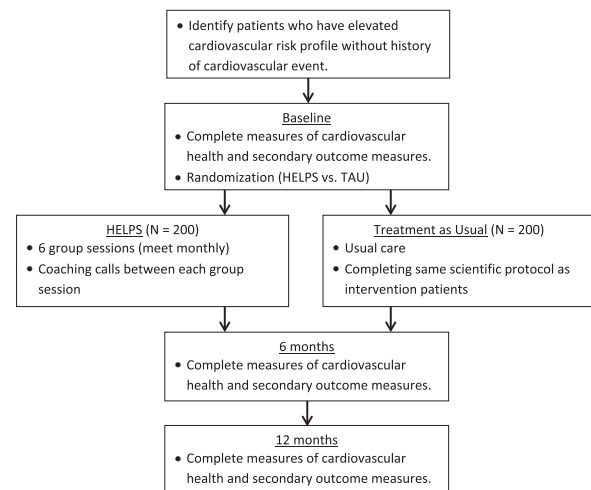

Fig. 1. Study overview.

health records (EHR), then conducting individual chart reviews, and then in-person visits to conduct interviews and collect laboratory data. Table 1 provides detail on eligibility and the enrollment process. Patients are excluded for: known cardiovascular or other atherosclerotic disease or severe intercurrent illness, either from medical record review or patient self-report; concurrent enrollment in a prevention program at time of enrollment, either from medical record review or patient self-report; or significant cognitive impairment, based on missing > 3 questions on the SPMSQ. Patients with diabetes were originally excluded but were added to the list of eligible patients after nine months of active enrollment in an effort to improve enrollment rates.

For the first phase in which aggregated data are pulled from patients' EHR, patients are being identified who are at risk for a cardiovascular event but have not yet suffered one. Eligible patients are sent a letter and allowed two weeks to call and opt out of the study. Patient eligibility is also determined based on individual chart review conducted by the study research assistant (RA). Patients who do not opt out and who remain eligible after a chart review are contacted by phone and invited into the study by the RA. During this call, interested patients have their inclusion and exclusion criteria verbally reviewed and are also administered the Short Portable Mental Health Status Questionnaire (SPMSQ) [21] to determine if the patient has potential cognitive impairment.

Eligible and interested patients at this phase are scheduled for an in-person visit that involves a blood draw and blood pressure reading in order to determine whether they have a 10-year risk of having a CVD event of at least 5%, with at least 2% of that risk reversible. Risk is assessed by calculating FRS using the Cox model described by D'Agostino et al. [22]. Sex-adjusted risk factors in this model include age, HDL cholesterol, total cholesterol, untreated systolic blood pressure or treated systolic blood pressure, smoking status, and diabetes status. One's sex-adjusted cumulative FRS then corresponds to a percent risk for experiencing a CVD event within 10 years. A 5% baseline risk was chosen to ensure that patients are sufficiently at risk to benefit from the intervention. A 2% reversible risk – which refers to the percentage of risk that can be reversed (e.g., smoking status can be reversed; age cannot) – was determined to be feasible based on our having obtained a comparable effect size in a similar study [23]. As an example, a 65-year-old male patient with no elevated risk factors would have an FRS of 12 – corresponding to a 10-year risk of 13.2% – but would not be eligible for the study since the patient would have 0% reversible risk (age being the