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# 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], and **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

## 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

**Corresponding Author**: Jason A. Nieuwsma, Ph.D., VA Mid-Atlantic MIRECC, 3022 Croasdaile Dr., Suite 301, Durham, NC 27705, (919)384-8582, ext. 4048 (phone), (919)384-8598 (fax), jason.nieuwsma@duke.edu.

**Trial registration:** ClinicalTrials.gov identifier NCT01838226

**Trial status**
Enrollment for the randomized controlled trial phase of this study began in January 2015 and will be completed in May 2017.

(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.

### Keywords

problem-solving therapy; cardiovascular disease; prevention; health behavior; behavioral intervention; veterans

## 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 less than 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 (Figure 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 minutes 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 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 more than 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 the presence of 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. (2008) [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 only factor elevating this risk score). If patients remain eligible, they may enroll in the study and are subsequently randomized to receive the intervention or usual care.

## 2.4 Randomization

A randomization table was generated using a computerized random-number generator by the study statistician prior to study enrollment. Randomization was stratified by gender, site, and smoking status in blocks of fewer than 8. Only study statisticians were aware of randomization sequence. Group cohorts begin at each site once 8–10 patients are enrolled in the intervention arm.

## 2.5 Intervention

**2.5.1 Problem-solving background—**PST equips individuals to effectively manage, cope with, and solve life problems by training them in specific problem-solving skills and steps as well as in how to be psychologically prepared to engage in effective problem-solving. PST is predicated on the notion that barriers interfere with the accomplishment of goals [24]. For example, someone who has the goal of exercising more may encounter barriers including difficulty finding time, lack of access to equipment, and emotional or motivational barriers. An individual who is better able to problem-solve such barriers might reasonably be more successful at adhering to an exercise regimen over time.

Being an effective problem-solver has been found to confer a number of benefits. Persons who are more effective at problem-solving have been found to be better able to cope with stress [25], and as a result experience fewer depressive symptoms in the presence of stress

[26]. Further, it appears that problem-solving skills can be taught. A series of foundational experimental studies by Thomas D'Zurilla and Art Nezu found that it was feasible and beneficial to train individuals in better defining social problems [27,28], generating alternatives for solving problems [29], and making effective decisions [30].

The PST approach has demonstrated the most efficacy in the treatment of depression [31,32] and other psychological disorders [33–37]. Empirical trials of PST have also found it to be effective in improving the coping capacities of patients with physical illnesses, such as cancer [38], arthritis [39], diabetes [40], and chronic pain [41]. Furthermore, a few studies have found PST to be efficacious in addressing problems related to CVD — such as comorbid CVD and depression [42], hypertension [43], and obesity [44] — though studies of PST to date have not examined it specifically for use in the prevention of CVD.

**2.5.2 Intervention development—**The HEalthy Living Problem-Solving (HELPS) intervention used in the present study is derived from a problem-solving intervention entitled Moving Forward, a protocol that was developed to help veterans cope with emotional distress and common daily life challenges [45,46]. Moving Forward was selected as the foundation from which to build the HELPS intervention for a number of reasons: it was designed for veterans; it has evidence of acceptability and efficacy in this population; it uses a group-based approach; and it is designed to use problem-solving principles to address problems beyond psychopathology.

The HELPS intervention utilizes a number of the same core problem-solving principles [24] as employed in Moving Forward while shifting the primary focus of the intervention to health behavior change. As described in the participant manual, the "program HELPS you identify barriers to making healthy lifestyle changes, and then it HELPS you use practical solutions for dealing with these barriers." The intervention consists of six group sessions, with individualized coaching calls between each session.

**2.5.3 Group sessions—**There are six HELPS group sessions, which occur approximately once per month (with initial sessions slightly closer in time). Group sessions are led by PhD-level clinical psychologists. However, the intervention is manualized and could be led by other mental health care professionals (e.g., clinical social workers) with training in the problem-solving approach and principles of the HELPS intervention. Group sessions are the key place where participants are introduced to intervention content, and the group format is a key part of the intervention design. Group format was chosen for several reasons. First, content in the early group sessions includes a significant amount of instruction and can thus be effectively delivered in a group. Second, patients can learn from one another's experiences using the problem-solving methods and can encourage one another to achieve health-related objectives. Third, more patients can be efficiently seen without sacrificing individualization of content, as there is significant time in group sessions (particularly in later sessions) to share experiences, and one-on-one coaching calls in between group sessions allow time for personalization.

The six group sessions are designed such that the first three sessions cover a substantial amount of instructional content and the final three sessions focus on skill application, though

interventionists are encouraged to spread out the instructional content over the first four sessions as needed in order to promote sufficient group engagement and interaction early on. Session 1 covers habit formation, health-related values and goals, strategies for creating good goals, barriers to reaching health goals, and particular health-related "HELPS objectives" that participants are asked to choose from to focus on throughout the intervention. The HELPS objectives listed in the participant manual are: improving diet and eating habits; reducing calorie intake; exercising regularly/being physically active; quit using tobacco; reducing use of harmful substances (e.g., alcohol); and taking cholesterol/blood-pressure medications as prescribed. Participants are encouraged to develop goals related to these objectives that are SMART (specific, measurable, action-oriented, realistic, and time-based) [47] and are assisted in using problem-solving principles in service to achieving their goals.

Session 2 introduces patients to core problem-solving principles. It begins with the acronym SSTA, which stands for Stop (noticing thoughts, feelings, and sensations that signal a problem exists), Slow down (using techniques like deep breathing, yawning, and relaxation), Think (employing problem-solving skills to develop a plan), and Act (carrying out and evaluating the plan). Substantial attention is devoted in this second session to describing the planful problem-solving method, which includes the steps of defining the problem, generating alternative solutions, making a decision, developing an action plan, and carrying out the plan. In session 3, these steps are considered in fuller detail along with ways to improve as a problem-solver in each domain, and participants are also taught how to use externalization, visualization, and simplification as methods for coping in the face of problems.

Sessions 4–6 focus heavily on practice, with session 4 also providing time for the interventionist to finish covering material from the prior group session if needed. Worksheets that were assigned as homework at the end of sessions 1–3 continue to be used in these later group sessions to guide patients through the problem-solving process. In particular, participants continue working with SMART goals worksheets (first assigned as homework after session 1; see Appendix A) and focus especially on applying problem-solving practices from the HELPS worksheets (assigned as homework after sessions 2 and 3; see Appendix B). In addition to focusing on SMART goal principles and problem-solving methods, both worksheets also invite participants to consider their values (e.g., "why your HELPS objective is important to you") and use a confidence rating technique from motivational interviewing [48] to help motivate patients to implement their action plans.

**2.5.4 Coaching calls—**Between each group session, participants receive an individualized telephone call from a trained health coach. Health coaches have master's level training in counseling or a related discipline. The coaching calls focus on helping individuals apply content from the preceding group session, including going through related worksheets assigned as "homework" (especially the SMART goals worksheet and the HELPS worksheet), to develop personalized strategies and goals guided by the participant's personal values, beliefs, and capabilities. As such, coaches employ techniques informed by motivational interviewing in helping patients develop individualized goals and plans for implementation [48]. Calls are structured as follows: check in on group session and

homework; provide opportunities to deepen understanding of content covered in group; and practice key PST skills. The first three calls reinforce the content from the group sessions and offer participants opportunities to practice setting SMART goals and defining barriers to achieving goals. Sessions four through six focus on planful problem solving to find solutions to barriers to achieving their SMART health-related goals in service of their overall HELPS objective.

**2.5.5 Fidelity—**Group leaders and coaches for the calls both received intensive, multi-day training in problem-solving therapy and in motivational interviewing, and both participate in regular group supervision meetings. All group sessions are recorded, and fidelity checklists specific to each session are used by two clinical psychologist supervisors to rate fidelity. A pilot group was conducted at the Durham site prior to beginning the trial, and all six sessions were rated for fidelity, with feedback provided to the interventionist. For the trial, both psychologist supervisors listen to and rate the first four sessions at each site and provide feedback to interventionists. Thereafter, one of every six sessions is randomly selected for review and rating by a supervisor, with sessions 1–3 being reviewed twice as frequently as sessions 4–6. This decision was made due to sessions 4–6 all being practice sessions.

All coaching calls are recorded. A sample of 10% is listened to and evaluated by study investigators familiar with the principles behind the techniques used for the calls. Calls are evaluated for adherence to behavioral principals included in the intervention (e.g., ensuring that SMART goals and action plans are made, problem-solving is used to identify and address barriers to goal achievement). Feedback is used to reinforce the relevant aspects of the intervention to the coaches, and also to refine the coaching intervention itself.

### 2.6 Outcome Assessment

All outcomes are measured at each of three scientific time points: baseline (pre-randomization); approximately 6-months post-enrollment; and approximately 12-months post-enrollment. The 6-month time point is primary as it is closest to the completion of the intervention; the 12-month time point allows us to examine the maintenance effect of the intervention following the intervention.

The primary outcome is FRS, calculated the same way as it is to determine eligibility. The inputs into the FRS are: age; gender; diabetes status; total and HDL cholesterol (measured directly by standard VA laboratory methods); smoking status (measured by self-report); use of blood pressure medications (measured by VA medical record and self-report); and systolic blood pressure. All of these components except age are measured at the three scientific time points, with blood pressure being the average of two electronic blood pressure readings taken seated with a rest period of 5 minutes in between.

Secondary measures evaluate outcomes in the domains of behavior change, mechanisms of action of the intervention, and covariates or population descriptors. The secondary outcomes used in this study are: physical activity, as measured by the complete International Physical Activity Questionnaire (IPAQ) [49] and using total leisure-time physical activity as the outcome; caloric intake, as measured by the Block Brief 2000 Food Frequency Questionnaire (FFQ) [50,51]; labor cost, as calculated based on time spent by intervention

and supervisory personnel; self-efficacy, as measured by the Patient Activation Measure (PAM) [52]; and problem-solving capacities, as measured by the Social Problem-Solving Inventory-Revised (SPSI-R) [53].

Key covariates for potential secondary analyses include: demographics, including race, age, marital status, education level, gender, adequacy of annual income, and number of people living in the household; and group cohesion, as measured by the Group Cohesion Scale (GCS) [54]. Age and sex of enrolled participants will be examined to ensure representativeness as compared to the eligible VA population. Group cohesion is measured only among patients in the intervention arm.

### 2.7 Sample size and power

For the primary hypothesis, a sample size of 400 (200 per arm) is needed to detect a change in FRS of 2% between arms at 6 months with 80% power and a two-sided type-I error rate (alpha) of 0.05. Sample size procedures for group-randomized designs came from Donner and Klar [55], and we employed the following assumptions: standard deviation of the change of 6.3; correlation between 6 month intervals of 0.9 [23]; an intraclass correlation coefficient (ICC) of 0.03; an average size of 10 for HELPS groups; and a 10% attrition rate at 6 month follow-up [56].

### 2.8 Data analyses

The main conclusions drawn from this trial will be based on the pre-specified primary hypothesis tested with two-sided p-values at the standard 0.05 level with associated effect size differences and confidence intervals. All secondary analyses conclusions will be based on interpretations of effect size and confidence intervals, not strictly p-value significance. Primary analyses will be conducted on an intent-to-treat basis; participants will be analyzed in the group to which they were assigned, regardless of intervention adherence, using all follow-up data or up to last available measurement prior to exclusion or dropout [57]. Statistical analyses will be performed using SAS for Windows (Version 9.4: SAS Institute, Cary, NC) and R (http://www.R-project.org).

For the first aim, our primary hypothesis will be tested using a general linear mixed model; baseline and follow-up values in the response vector will be used to estimate changes in FRS scores over time. We will use an unstructured covariance to account for the correlation between repeated measurements, and include a group-level random effect for intervention arm patients to account for the intraclass correlation between patients in the same prevention group. The predictors in the model include a dummy coded time effect and an indicator variable for the intervention interacting with the time effect fitting a constrained longitudinal model (cLDA) [58]. The cLDA model is comparable to an ANCOVA model; the two models are equivalent when there is no missing data. However, unlike an ANCOVA, subjects who are missing all follow-up measurements are included in the model because baseline is part of the response vector. We will estimate model parameters using the SAS procedure MIXED (Cary, NC). This estimation procedure yields unbiased parameter estimates when missing outcomes are assumed to be ignorable; that is they are related to either observed covariates or response variables [59]. Depending on the type and scope of missing data, we will also

explore the use of multiple imputation in sensitivity analyses to include auxiliary variables that may be related to dropout [60,61]. Furthermore, if the probability of dropout is related to unobservable quantities, additional methods such as selection and pattern mixture models may be used in sensitivity analyses [62]. As recommended by the Committee for Proprietary Medicinal Products (CPMP) [63], the model will also be adjusted for stratification variables of site, gender, and smoking status for improvement in precision.

Similar to the FRS, the secondary outcomes are all continuous and measured at baseline, month 6, and month 12 to determine effectiveness of HELPS. Analyses of these outcomes will thus proceed as described above for FRS.

## 3. Discussion

Many of the leading causes of death in the U.S. can be linked to health behaviors [64]. This is certainly the case for the most common cause of death: cardiovascular disease. Health behaviors that put individuals at greater risk for cardiovascular disease — such as tobacco use, excessive weight, poor diet, medication nonadherence, lack of exercise, and excessive alcohol use — are relatively well understood. However, numerous personal, social, environmental, and other barriers can interfere with adopting healthy cardiovascular behaviors, even when people understand the health habits that they should be adopting. Problem-solving therapy has been efficaciously used across an array of mental and physical health conditions to help people approach and effectively resolve barriers to better health. The results of this trial will contribute to the body of work on problem-solving approaches and inform the question of whether problem-solving principles can be employed to reduce risk for cardiovascular disease.

### 3.1 Limitations

The present intervention concurrently targets an array of different health behaviors within each cohort of group participants. Patients can decide to focus on diet, tobacco usage, exercise, alcohol use, and/or medication adherence. While this diversity allows for a range of participants to participate in the intervention and allows participants to exercise choice in where to focus change efforts, there are also potential challenges from the study perspective. The first is that although analytic methods may be used to some extent to disentangle participants who focused on making changes in different health domains, it will still be difficult to discern precisely which areas of focus yielded the most benefit. The second is that some of the health behaviors that participants can choose to focus on may prove more challenging to alter than others. Should a disproportionate number of participants attempt to make improvements in the more challenging domains it could mute the effect of the intervention on behaviors that are easier to initiate. The third is that it is possible that problem-solving methods may be more effective when used in groups that focus on a common health behavior and can share experiences and lessons learned with one another (e.g., tobacco use cessation) as opposed to in groups that do not have as much shared experience. An additional limitation is that smoking status, physical activity, and dietary intake are self-reported.

### 3.2 Strengths

The current study advances cardiovascular disease care by intervening prior to the development of the disease. In taking this disease prevention stance, the present study aims to recognize substantial benefits in terms of improved quantity and quality of life for patients as well as potential cost savings for health care systems. The HELPS intervention also holds promise as a behavioral intervention that complements growing interest in implementing behavioral health care within primary care settings [65]. While allowing study participants to select from a diverse set of health goals entails the limitations described above, this focus on diverse health behaviors is also a study strength. Filling groups is made more feasible by allowing for a broad focus on a range of different health risk behaviors. Also, health behaviors can be complexly and dynamically interrelated with one another (e.g., regularly exercising may increase motivation to eat healthier and to quit smoking), and problem-solving techniques can be flexibly and individually applied to a range of diverse patient presentations. Finally, having patients focus on making changes in related yet diverse health behavior domains encourages group participants to learn from one another about an array of ways that problem-solving principles might be fruitfully applied.

## 4.0 Conclusions

Effective behavioral interventions to address cardiovascular disease and other illnesses that have behavioral components are much needed. Public health campaigns and technological advances in health care did much to dramatically diminish deaths due to infectious disease and thereby increase life expectancy during the 20$^{th}$ century [11]. In the 21$^{st}$ century, the major causes of death in the developed world are tied to health behaviors. Research into interventions that address health behaviors is still in the early stages. The present study aims to evaluate a novel application of problem-solving strategies to reduce cardiovascular disease risk. Results should help to inform both efforts to address cardiovascular disease as well as broader efforts in the arena of using behavioral interventions to address a range of health conditions. Studies on additional applications of problem-solving and other behavioral interventions should be encouraged.

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## Appendix A: SMART goals worksheet

### SMART Goals Worksheet (pg 1)

**HEALTH VALUES**

Think about the values you have in your life that guide your choices. These values can guide our health choices as well. What are the values you have that made you want to improve your cardiovascular health?

**HELPS Objectives**

**My HELPS Objective is:**

- ☐ Improving diet & eating habits
- ☐ Reducing calorie intake
- ☐ Exercising regularly / being physically active
- ☐ Quit using tobacco
- ☐ Reducing use of harmful substances (e.g., alcohol)
- ☐ Taking my cholesterol / blood-pressure medications as prescribed

**Why is this objective important to you? Which of your values are helped by this objective?**

## SMART Goals Worksheet (pg 2)

### How to Set SMART Goals

A health goal is a specific thing you are going to do to achieve your broad HELPS objective. You should chose your goal carefully. People are more likely to reach their health goals if they set reasonable and specific goals that they can work towards over a short period of time. You can create goals by remembering the acronym SMART, which stands for goals that are:

- **S**pecific – Goal is concrete and clear.
- **M**easurable – Goal can be assessed.
- **A**ction-oriented – Goal involves action you commit to.
- **R**ealistic – Goal is achievable given available time and resources.
- **T**ime-based – Goal can be completed within a specific time frame.

### SMART Goal Examples

Examples of weak and strong goals:

| | | |
|---|---|---|
| **1.** | *Instead of…* | I'm going to work on eating a low-fat diet. (**WEAK**) |
| | *Try…* | Over the next 2 weeks, I will cut back on the fat in my diet by choosing grilled chicken over fried chicken at lunch and write down how much fat I eat each day in my food journal. (**STRONG**) |
| **2.** | *Instead of…* | I want to eat out less frequently. (**WEAK**) |
| | *Try…* | Over the next 2 weeks, I will eat out 2 times per week instead of 5 times per week and will track how often I eat out by putting an "X" mark on my calendar. (**STRONG**) |
| **3.** | *Instead of…* | I want to eat fewer desserts. (**WEAK**) |
| | *Try…* | Over the next 2 weeks, I will cut back on sweets by eating 1 cup of low-fat ice cream once per week instead of 3 times week and will track my progress by writing down each time I eat ice cream in my food journal. (**STRONG**) |

## SMART Goals Worksheet (pg 3)

### Setting of a SMART Goal

I chose to work on this particular goal now because…

_____

_____

To reach this goal, I will do the following (list specific actions, being specific to include when, where, and how):

_____

_____

_____

_____

_____

### Confidence Rating

**I believe that I can achieve my SMART Goal:** (Circle the number that matches how confident you feel, then ask yourself why you circled the number you did instead of a lower number.)

**0 1 2 3 4 5 6 7 8 9 10**

**Not at All Confident** **Somewhat Confident** **Very Confident**

### Homework

**CARRY OUT YOUR PLAN and observe the consequences. Be prepared to talk about:**

- **Are you satisfied that your plan worked?**
- **What went well?**
- **What could be better?**
- **What you could do differently next time?**
- **Were there any "barriers" (problems) you faced, and how were you able to solve them?**

## Appendix B: HELPS worksheet

### Healthy Living Problem-Solving (HELPS) Worksheet (pg 1)

**My HELPS Objective is:**

- ☐ Improving diet & eating habits
- ☐ Reducing calorie intake
- ☐ Exercising regularly / being physically active
- ☐ Quit using tobacco
- ☐ Reducing use of harmful substances (e.g., alcohol)
- ☐ Taking my cholesterol / blood-pressure medications as prescribed

**Briefly remind yourself why your HELPS Objective is important to you:**

**Describe any barriers to achieving your HELPS Objective that you have experienced or expect. Place a checkmark next to the one(s) you decide to problem-solve.**

## Healthy Living Problem-Solving (HELPS) Worksheet (pg 2)

**Once you've selected the barrier(s) to problem-solve and written below, follow these three steps to using the below problem-solving table:**

1) **Generate a list of different solutions (at least 3) to overcome the barriers that you listed to achieving your SMART goal. Be creative! DO NOT begin evaluating your solutions until after you've generated a list of possibilities.**
2) **Once you've generated this list, then go through and weigh the major "pros" (positive consequences) and "cons" (negative consequences) for each potential solution.**
3) **After weighing the pros and cons, place a checkmark(s) next to the solution(s) that you choose.**

**Barrier(s):** _____

_____

_____

| Solution | Pros | Cons |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

## Healthy Living Problem-Solving (HELPS) Worksheet (pg 3)

**Based on the solution(s) you choose, develop a SMART goal and write down an action plan below. Your action plan should be specific to include when, where, and how.**

### Confidence Rating

**I believe that I can achieve my SMART Goal:** (Circle the number that matches how confident you feel, then ask yourself why you circled the number you did instead of a lower number.)

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|
| **Not at All Confident** | | | | **Somewhat Confident** | | | | | **Very Confident** | |

### Homework

**CARRY OUT YOUR PLAN and observe the consequences. Be prepared to talk about:**

- **Are you satisfied that your plan worked?**
- **What went well?**
- **What could be better?**
- **What you could do differently next time?**
- **Were there any "barriers" (problems) you faced, and how were you able to solve them?**

***EXAMPLE WORKSHEET: Reducing Calorie Intake***

## Healthy Living Problem-Solving (HELPS) Worksheet (pg 1)

**My HELPS Objective is:**

- ☐ Improving diet & eating habits
- ☑ Reducing calorie intake
- ☐ Exercising regularly / being physically active
- ☐ Quit using tobacco
- ☐ Reducing use of harmful substances (e.g., alcohol)
- ☐ Taking my cholesterol / blood-pressure medications as prescribed

**Briefly remind yourself why your HELPS Objective is important to you:**

*I don't want to have a stroke like my father. I want to be able to dance like a fool at my new grand-baby's wedding in 20 years.*

**Describe any barriers to achieving your HELPS Objective that you have experienced or expect. Place a checkmark next to the one(s) you decide to problem-solve.**

- *It's hard to maintain motivation to stick to a good diet.*

✓ - *I find myself in situations where it's hard to stick to "the plan" – which is a 2,000 calorie/day diet at least 5 out of 7 days a week. For instance, I plan to go out with the guys to watch the game on Thursday (which means pizza, beer, wings, etc.).*

- *I eat when I'm stressed or depressed.*

- *It feels impossible.*

***EXAMPLE WORKSHEET: Reducing Calorie Intake***

## Healthy Living Problem-Solving (HELPS) Worksheet (pg 2)

**Once you've selected the barrier(s) to problem-solve and written below, follow these three steps to using the below problem-solving table:**

1) **Generate a list of different solutions (at least 3) to overcome the barriers that you listed to achieving your SMART goal. Be creative! DO NOT begin evaluating your solutions until after you've generated a list of possibilities.**
2) **Once you've generated this list, then go through and weigh the major "pros" (positive consequences) and "cons" (negative consequences) for each potential solution.**
3) **After weighing the pros and cons, place a checkmark(s) next to the solution(s) that you choose.**

**Barrier(s):** *Going out with guys to watch the game = tempted to cheat on my diet (situations where it's hard to stick to the plan).*

| | Solution | Pros | Cons |
|---|---|---|---|
| | *Stay home.* | *I'd be in full control.* | *Less fun.* |
| | *Have the guys over and serve them celery!* | *Help to have the guys over.* | *They hate celery ☺. There go my friends. Plus, don't want to get house ready.* |
| | *Go out but only drink water or soda.* | *Less calories* | *Not realistic with this group.* |
| | *Save up all my calories for the day.* | *Could do this if I plan ahead* | *I'd be starving by time we go out and would eat like a horse at the bar.* |
| ✓ | *Eat light the day before and afterward to make up for extra calories.* | *Less calories* | *This may be hard to do if I have to cut out too many calories.* |
| ✓ | *Alternate beer and water.* | *Could still go out and enjoy some beer. Be more in control.* | *Not many.* |
| ✓ | *Ride the stationary bike one extra time* | *Feel energized afterwards* | *Finding the time and motivation to do it* |

***EXAMPLE WORKSHEET: Reducing Calorie Intake***

**Healthy Living Problem-Solving (HELPS) Worksheet (pg 3)**

**Based on the solution(s) you choose, develop a SMART goal and write down an action plan below. Your action plan should be specific to include when, where, and how.**

*Over the next 2 weeks, I will develop a specific plan for how to stick to my diet in situations where I know I'll be tempted to cheat. For this coming Thursday with the guys, I'm going to have smaller lunch and breakfast that day, I'm going to have a glass of water after every beer, and I'm also going to make sure I ride the stationary bike a total of four times this week. I'll write down what I eat and the biking in my food and exercise journal.*

**Confidence Rating**

**I believe that I can achieve my SMART Goal:** (Circle the number that matches how confident you feel, then ask yourself why you circled the number you did instead of a lower number.)

**0 1 2 3 4 5 6 7 8 9 10**

**Not at All Confident** **Somewhat Confident** **Very Confident**

**Homework**

**CARRY OUT YOUR PLAN and observe the consequences. Be prepared to talk about:**

- **Are you satisfied that your plan worked?**
- **What went well?**
- **What could be better?**
- **What you could do differently next time?**
- **Were there any "barriers" (problems) you faced, and how were you able to solve them?**

*It went pretty well. On Thursday, I drank water between beers and no one even seemed to notice. I had pizza but not as much as I would have in the past. I felt more in control. I had a smaller lunch that day as well, although I didn't end up doing the stationary bike. I didn't plan any time for a workout, which I need to better consider next time. I was also able to develop specific plans for a birthday party at work and a family get-together.*

## Abbreviations

| | |
|---|---|
| **ANCOVA** | analysis of covariance |
| **CVD** | cardiovascular disease |
| **CPMP** | Committee for Proprietary Medicinal Products |
| **cLDA** | constrained longitudinal model |

| | |
|---|---|
| **VA** | Department of Veterans Affairs |
| **EHR** | electronic health records |
| **FFQ** | Food Frequency Questionnaire |
| **FRS** | Framingham Risk Score |
| **GCS** | Group Cohesion Scale |
| **HELPS** | HEalthy Living Problem-Solving |
| **IPAQ** | International Physical Activity Questionnaire |
| **HDL** | high-density lipoprotein |
| **LDL** | low-density lipoprotein |
| **PAM** | Patient Activation Measure |
| **PST** | problem-solving therapy |
| **RA** | research assistant |
| **SPMSQ** | Short Portable Mental Health Status Questionnaire |
| **SPSI-R** | Social Problem-Solving Inventory-Revised |
| **SMART** | specific measurable, action-oriented, realistic, time-based |
| **SSTA** | stop slow down, think, act |
| **VAMC** | Veterans Affairs Medical Center |

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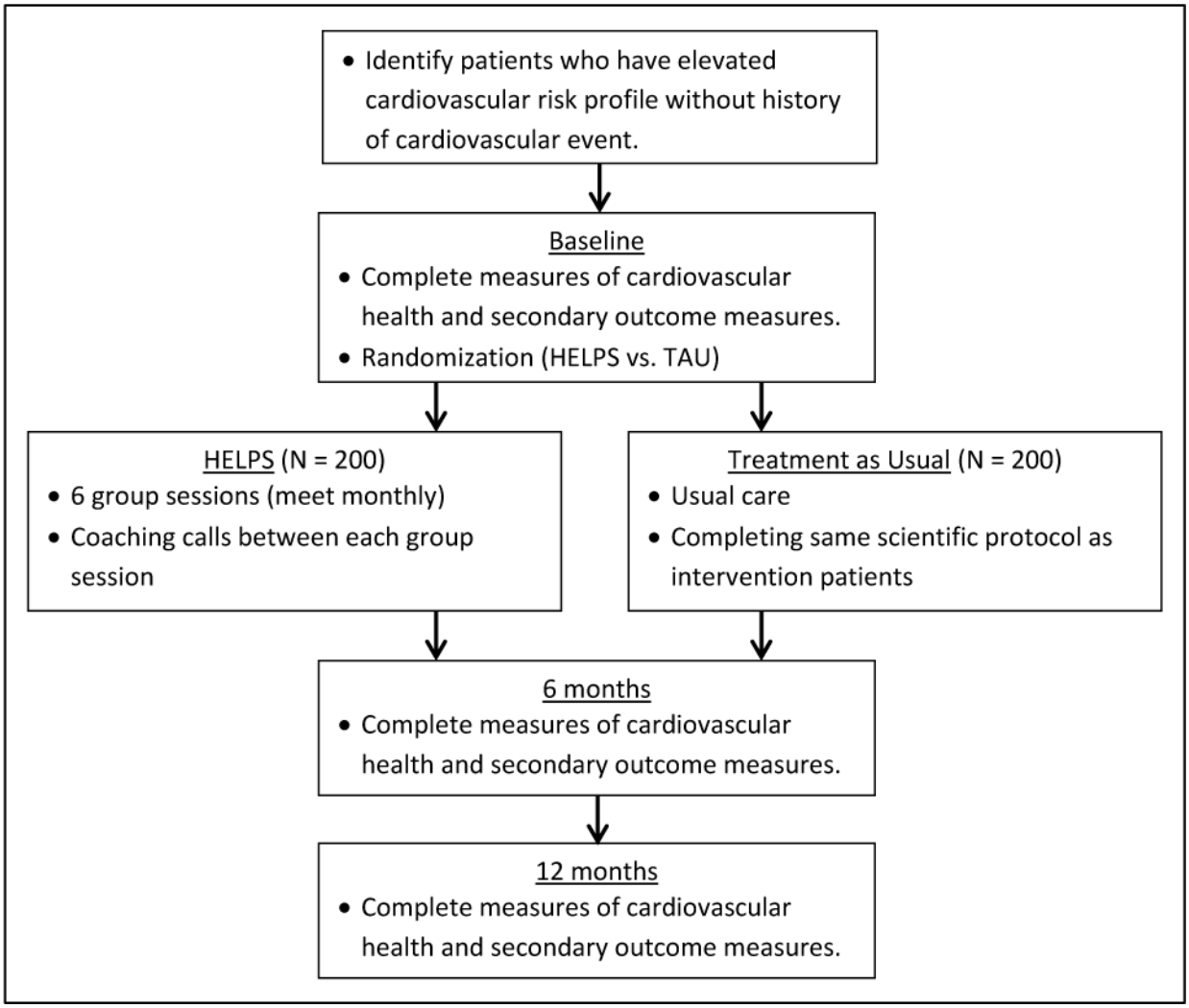


**Figure 1.**
Study overview

## Table 1

Eligibility criteria and enrollment process

| Phase | | Inclusion and Exclusion Criteria |
|---|---|---|
| Phase 1: | Accrual of eligible patients from database | Inclusion criteria<br>• Diagnosis of inadequately controlled hypertension (ICD-9 code of 401.x and most recent systolic blood pressure > 140mmHG or diastolic > 90 mmHG)<br>OR<br>• Inadequately controlled dyslipidemia (most recent total cholesterol > 200 mg/dl, or HDL cholesterol < 35 mg/dl)<br>OR<br>• Current smoking (which can be identified via a clinical reminder in the electronic medical record) |
| | | Exclusion criteria<br>• Personal history of CAD or other major cardiovascular disease (ICD-9 codes of 410–414 or 425–429)<br>• Cerebrovascular disease (433–438)<br>• Peripheral arterial disease (440.x or 443.x)<br>• Diabetes (250.x) *<br>• Use of a medication in formulary class OH501 (diabetic medications) * |
| | | Contact eligible patients with letter.<br>If do not call to opt out within 1 week,<br>proceed to phase 2. |
| Phase 2: | Chart review | Exclusion criteria<br>• Chart reveals any exclusion listed for phase 1<br>• Chart reveals no longer meet phase 1 inclusion criteria<br>• Active treatment of any malignancy (except hormone treatment for breast or prostate cancer)<br>• Renal dialysis or cirrhosis of the liver<br>• Psychiatric hospitalization within the last 3 years<br>• Requirement for oxygen at any waking hour<br>• Already engaged in formal efforts to improve cardiovascular risk behavior (e.g., smoking cessation) |
| | | Contact eligible patients by phone,<br>verbally reassess eligibility of interested patients,<br>and proceed to phase 3. |
| Phase 3: | Interview and labs | Inclusion criteria<br>• Blood pressure and lipid panel from blood draw at interview session, combined with additional demographic and interview data, result in a Framingham Risk Score with at least 5% risk for a cardiovascular event and at least 2% of that risk potentially reversible |
| | | Enroll if remain eligible<br>and interested. |
| | | **Randomize to treatment or control** |

* Patients with diabetes were originally excluded but were added to the list of eligible patients in an effort to improve enrollment rates.