BMJ Open

# Protocol for a randomized controlled trial evaluating the effects of screening and referral for social determinants of health on Veterans' outcomes



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| Journal: | *BMJ Open* |
| Manuscript ID | bmjopen-2021-058972 |
| Article Type: | Protocol |
| Date Submitted by the Author: | 04-Nov-2021 |
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| Keywords: | Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Adult cardiology < CARDIOLOGY |
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**Title Page**

# Protocol for a randomized controlled trial evaluating the effects of screening and referral for social determinants of health on Veterans' outcomes

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Key Words: social determinants of health, randomized control trial, primary care, Veterans, cardiovascular disease

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**Abstract**

*Introduction*: Health policy leaders recommend screening and referral (S&R) for unmet social needs (e.g., food) in clinical settings, and the American Heart Association recently concluded that the most significant opportunities for reducing cardiovascular (CVD) death and disability lie with addressing the social determinants of CVD outcomes. A limited but promising evidence base supports these recommendations, but more rigorous research is needed to guide health care-based S&R efforts. Funded by the Veteran Health Administration (VA), our study will conduct a mixed method randomized controlled trial (RCT) to assess the efficacy of S&R on Veterans' connections to new resources to address social needs, reduction of unmet needs, and other outcomes (adherence, utilization, and clinical outcomes).

*Methods and analysis*: We will conduct an RCT at three VA sites and compare outcomes among Veterans with CVD and CVD-risk. Participants will be randomized within each site to one of three study arms (N=880), representing referral mechanisms of varying intensity. For each Veteran, we will examine associations of unmet social needs with baseline outcomes, and longitudinally compare the impact of each approach on connection to new resources and follow-up outcomes over a 12-month period. We will additionally conduct qualitative interviews with key stakeholders to identify potential explanatory factors related to the relative success of the interventions.

*Ethics and dissemination*: This study was approved by the VA Central Internal Review Board on July 13, 2021 (Reference #: 20-07 – Amendment No. 02). Guided by Maslow's hierarchy of needs model, our study will provide much-needed evidence to document a broad range of Veterans' unmet needs, inform how best to address unmet needs, and assess how such a process can affect Veterans' outcomes. We will develop tools and processes that, if efficacious, can be implemented within VA and other clinical systems.

*Trial registration*: NCT04977583.

**Article Summary**

Strengths and limitations of this study

- Prior studies have examined cross-sectionally how addressing unmet needs is associated with health outcomes, but we will examine these associations longitudinally, which will allow a better assessment of causality and possible mechanisms for associations.
- We will conduct this study within the largest integrated health system in the United States – the Department of Veterans Affairs - which will provide an opportunity for widespread dissemination within this health system.
- Often RCTs end data collection with their outcomes data but for this study, we enhance our findings to understand facilitators, barriers and potential explanatory factors related to the relative success of the interventions.

## INTRODUCTION

Social Determinants of Health (SDoH) are "the structural determinants and conditions in which people are born, grow, live, work and age."[1] These conditions shape the degree to which basic needs are met both at the individual-level (e.g., housing, food, social connections) and the community-level (e.g., safe neighborhoods). They also shape health trajectories as recent estimates suggest that clinical care accounts for less than 20% of modifiable health outcomes whereas other factors, including SDoH, are more significant drivers of morbidity and mortality.[2, 3] Consequently, there is consensus that improving population health will require health care delivery systems, including the Veterans Health Administration (VHA), to address unmet social and economic needs (hereafter: unmet needs), rather than addressing disease from only a biomedical perspective.

The relationship between unmet needs and health is strikingly evident for patients with or at risk for cardiovascular disease (CVD), [4, 5] the leading cause of morbidity and mortality in the US.[6] For example, lower socioeconomic status is associated with greater prevalence of CVD risk factors and higher mortality from CVD.[7-9]; the risk for myocardial infarction is highest in the first year of unemployment and increases with the number of job losses[10]; and lack of social support is associated with increased CVD mortality.[11] Thus, the American Heart Association (AHA) recently declared that, "at present, the most significant opportunities for reducing death and disability from CVD in the US lie with addressing the social determinants of cardiovascular outcomes."[4]

The AHA is not alone in this perspective. The World Health Organization[1], National Academy of Medicine[12], and American College of Physicians[13] also emphasize the need for health systems to screen for unmet needs at health care visits. These recommendations rest on limited, yet promising, evidence that implementing systematic screening and referral (S&R) for unmet needs leads to greater receipt of resources that address identified needs[14, 15] as well as reduction in unmet needs.[16] Such a process can potentially improve both proximal outcomes, such as adherence to medications and care appointments[17], as well as more distal outcomes, such as overall health.[18-21] However, much of the limited evidence on programs to address unmet needs is based in pediatric settings or specialized settings (e.g., women's health clinics). Importantly, as far as we know, there are no randomized controlled trials (RCT) demonstrating the impact of systematic S&R for unmet needs on patients' connection to resources or other utilization and health outcomes in the general adult ambulatory care setting. In short, there is no definitive guidance on how best to screen for and address unmet needs in clinical settings, creating a key barrier to implementing this practice in health care delivery systems.[22]

Given the simultaneously high prevalence of CVD and its risk factors and unmet needs among Veterans enrolled in the VA, Veterans' outcomes may be improved by comprehensively assessing and addressing unmet needs.[23, 24] Currently, the VA administers system-wide clinical screens for two unmet needs (housing and food insecurity), yet other unmet needs are not routinely identified. While VA invests in social work (SW) to address a wide range of unmet needs, referral to and staffing of SW is highly variable across and within facilities. Many Veterans who could benefit from VA SW are not systematically identified and referred. Further, there are no comprehensive data on Veterans' unmet needs, nor on their association with utilization and clinical outcomes, hampering VA's ability to understand the effects of unmet needs and to target resources to address them. Finally, it is not known whether a social worker is required to address all unmet needs; it is plausible that a less resource- or personnel-intense process

can address identified unmet needs and improve outcomes, as suggested by a recent pediatric S&R intervention. [19]

Funded by the VA's Health Services and Research Development division, the aim of this study is to assess the efficacy of comprehensive S&R among Veterans with or at-risk for CVD. The study is guided by the Outcomes from Addressing SDoH in Systems (OASIS) framework (see Figure 1).[25] This framework, developed by the study team, is based on Maslow's Hierarchy of Needs model, which specifies that basic physiological needs (e.g., food, shelter) must be met before higher order needs (e.g., adhering to antihypertensive medications for a symptomless condition to avert a possible stroke in the future) can be addressed.[26] Our study objectives are three-fold: 1) to describe the prevalence and distribution of unmet needs and identify their associations with baseline sociodemographic characteristics, adherence, utilization and clinical outcomes; 2) to compare the effectiveness of three S&R strategies of increasing intensity on connection to new resources to address unmet needs (primary outcome) and on secondary outcomes of post-intervention change in unmet needs, adherence, utilization, and clinical outcomes; and 3) to identify barriers and facilitators to Veterans' connecting with resources to address unmet needs and getting needs met, and explore potential explanatory factors related to the relative success of each study arm.

## METHODS

### Overview

We will conduct a mixed method RCT (see Figure 2) and SPIRIT checklist (see additional file). For Objective 1, we will survey Veterans at three VA sites about their unmet needs and conduct quantitative analyses of survey, administrative, and clinical data to characterize the prevalence of unmet needs and their association with baseline outcomes (adherence, utilization, and clinical). For Objective 2, we will randomize Veterans who screened positive for one or more unmet needs within each site to one of three interventions defined by referral approaches of varying intensity. Quantitative analyses will longitudinally compare the effects of the referral approaches on the primary outcome (connections to new resources) and secondary outcomes (reduction in unmet needs, adherence, utilization, and health outcomes). Often RCTs end data collection with their outcomes data. For this study, we enhance our findings to understand more about the facilitators, barriers and potential explanatory factors related to the relative success of the interventions. Therefore, for Objective 3, we will conduct qualitative interviews with a purposeful sample of key stakeholders, including Veterans. We first describe the methods for Objectives 1 and 2 (quantitative), followed by the methods for Objective 3 (qualitative).

### Objectives 1 and 2

*Study Setting and Participant Eligibility*

For Objective 1, the study population will be comprised of Veterans with, or at risk for, cardiovascular disease (CVD) seen in primary care (PC) clinics of three urban VA medical centers. Veterans must have at least one PC visit in the year prior to the RCT start date to ensure that included study subjects are at least minimally engaged in VA care. Using data from VA's Corporate Data Warehouse (CDW), we will identify CVD patients as those with International Classification of Disease 10 (ICD10) diagnoses for coronary artery disease, cerebrovascular disease, or peripheral artery disease, and patients with CVD risk as having diagnoses of hypertension, diabetes mellitus (DM), or hyperlipidemia. For Objective 2, the

study population will be comprised of the subset of Objective 1 participants who have one or more unmet needs.

*Study Procedures and Randomization*

On a weekly basis for the 12-month trial, we will identify potentially eligible Veterans with upcoming primary care appointments who will be mailed a recruitment package. The recruitment package will include a description of the study and elements of informed consent (see Appendix A), as well as an opt-out post card. Trained Research Assistants (RA) at each study site will contact Veterans (who have not opted-out) via telephone to explain the research protocol, review the elements of informed consent, secure verbal consent, and enroll the Veteran. During this phone call, if verbal informed consent is obtained, the RA will administer a brief survey to screen for nine unmet needs (housing, food insecurity, utility insecurity, transportation, legal needs, employment, safety, stress, social isolation), hereafter referred to as the "index screen." If a Veteran reports no unmet needs, their study participation will be restricted to Objective 1. If a Veteran reports one or more unmet needs, the RA will randomize them to one of the three trial arms using the sealed opaque envelope method. [27] The Data Analyst will be responsible for randomly generating the treatment allocations within the sealed envelopes. Once an envelope is open, the RA will inform the Veteran of their arm assignment.

*The Intervention*

Following the naming convention used by Centers for Medicare & Medicaid Services for the arms in the Accountable Healthy Communities trial, we have the following study arms: 1) Unmet needs screening and provision of a postcard with a list of generic VA resources (hereafter: "Screening" arm), 2) Screening and provision of a postcard with a list of generic VA resources plus provision of a tailored Resource Sheet listing available resources in VA and/or the community to address identified unmet needs (hereafter: "Awareness" arm), or 3) Screening and provision of generic resources plus provision of a tailored Resource Sheet plus Social Work (SW)-supported referral to assist with connection to resources for unmet needs (hereafter: "Assistance" arm). Administering the intervention will not be blinded to group assignment.

Screening: Veterans in the Screening arm will receive a post card listing the phone numbers for general resources available to Veterans including the Veteran's VA Medical Center, VA Veterans Crisis Line, and National Call Center for Homeless Veterans. The post card will be included in the initial recruitment packet mailed to all potential study participants. We include this feature to address ethical concerns about assessing unmet needs without responding to endorsed needs in our least-intense arm.

Awareness: Veterans in the Awareness arm will receive the post card listing generic resources as described above. Additionally, for each unmet need identified through the index screen, Veterans will receive by mail a tailored Resource Sheet that will include the names of available resources within VA and/or the local community that can help address the identified need(s). During the index screen, the RA will additionally ask participants if they would like to receive the Resource Sheet(s) as an email attachment. For Veterans who respond affirmatively, the RA will send the Resource Sheets as an email attachment during the index screen phone call and offer to review its content with them. To ensure the Resource Sheets stay current, the RA will contact listed programs monthly for current contact information and ability to accept referrals.

Assistance: Veterans in the Assistance arm will receive the post card listing generic resources and tailored Resource Sheets as described above. Additionally, during the in-clinic encounter, the RA will offer these Veterans assistance from a Social Worker specifically hired and trained (one per site) to support Veterans with connecting to resources. With Veteran assent, the SW will contact the Veteran by phone within two business days of the in-clinic encounter. During this initial call, the SW will use a standardized bio-psychosocial assessment tool and proven motivational interviewing methods to develop an action plan for the Veteran to connect to needed resources. [28, 29] The SW will conduct follow-up by phone one week after the action plan development, with projected subsequent phone outreach every two weeks for up to seven weeks. At each call, the SW will review progress and as needed, employ motivational interviewing methods to re-affirm the action plan and/or modify the action plan to address unexpected barriers.

*Data Collection and Management*

All data will be collected by RAs uninvolved in patient care. All study participants will be asked to complete a brief telephone-based survey to assess unmet needs during the index screen. We refer to this as Survey #1. All RCT participants will be asked to complete two additional brief telephone-based surveys. Survey #2 will occur eight weeks after the index screen, when the RA will assess if trial participants connected to any new resources in the intervening time, and if so, to which one(s). Survey #3 will occur six months after the index screen, when the RA will re-screen all trial participants for unmet needs. The 12-month recruitment period is planned to commence January 1, 2022 and all follow-up is planned to be complete by June 30, 2023. Data will be recorded via the REDCap system and will be cleaned and checked for accuracy by the project manager and data analyst. Survey data will be merged with administrative data from the VA Corporate Data Warehouse (CDW) within the VA Informatics and Computing Infrastructure (VINCI). CDW includes demographics, diagnoses, vital signs, lab values, prescriptions, and data on service use. Only the principal investigator and study team members conducting data analyses will have access to the data set.

*Planned Outcomes*

Table 1 provides a complete list of planned outcome measures for Objectives 1 and 2. The primary outcomes for Objective 1 will be various measures of treatment adherence, utilization, and clinical outcomes. The primary outcome for Objective 2 (the RCT) will be connection to new resources to address unmet needs. Secondary outcomes will be reduction of unmet needs, various measures of treatment adherence, utilization, and clinical outcomes. Our rationale for this ordering of outcomes for Objective 2 is the importance of understanding whether S&R leads to connection to new resources, the first step in our conceptual model (see Figure 1) that we anticipate will, in turn, lead to improved adherence, utilization, and ultimately, clinical outcomes. As further rationale for considering clinical outcomes as secondary, we posit they may be difficult to change over the study's time-limited 12-month period. Moreover, while much existing literature demonstrates associations between unmet needs and clinical health outcomes, there is a dearth of preliminary data assessing the impact of interventions (e.g., S&R) on these clinical outcomes. This precluded us from reliably estimating effect sizes for comparisons across intervention arms or needed sample size to adequately power such comparisons.

*Sample Size Calculations*

Power analyses were used to determine sample size based on an effect size estimate for our primary outcome from a prior study. [14] Our sample sizes ensure adequate power (80%) to detect small-to-medium effect sizes for each of the primary and secondary outcomes even if the attrition rate for survey #2 and survey #3 are both as high as 50%. The team's prior study with a demographically similar Veteran population found only a 35% attrition rate.[30]

*Analysis*

Objective 1: We will generate descriptive statistics (e.g., proportions, 95% confidence intervals) to characterize the prevalence and distribution of each of the eight unmet needs at baseline across all study sites. We will next conduct inferential analyses to examine associations between unmet needs and sociodemographic characteristics (including race and ethnicity) as well as baseline outcomes (i.e., adherence, utilization, and clinical outcomes drawn from CDW data in the 12-months before the index screening for each Veteran). General linear mixed models (GLMM) will be used to control for the nesting of patients within sites, and logistic models will be used as appropriate for binary variables. Variables found to have statistically significant associations with unmet needs will be entered into multivariable models to better understand the correlates of each need. Bonferroni-corrected significance levels will control for multiple comparisons.

Objective 2: We will compare connection to new resources at 8-weeks post-index screen across the study arms. GLMM will be used to control for the nesting of patients within sites. In all models, patient-level intercepts and slopes will be treated as random effects. In addition to examining how the intervention conditions influence connection to new SDoH resources, we will conduct supplemental exploratory analyses to examine whether there is differential impact between the three intervention arms on connection to new SDoH resources, unmet need reduction, and clinical outcomes among Veterans defined by differing socioeconomic characteristics including race and ethnicity.

Using a difference-in-difference approach, we will compare more distal outcomes (adherence, utilization, and clinical outcomes) across study arms. We will examine whether changes from baseline at 6-months and 12-months post-referral differ across the three arms in a series of GLMM analyses. As with the other analyses, all models will treat patient-level intercepts and predictors as random effects. Similar analyses will be used to examine differences across our three study arms in change from baseline in the proportion of unmet needs among the sub-sample of participants who complete the re-screening at 6-months post-referral. To the extent that we discover differences across intervention arms in any of our more distal outcomes, we will also conduct exploratory analyses to test appropriate causal mediational paths as proposed in our conceptual model using a series of GLMM analyses.

Finally, we will conduct additional analyses controlling for connection to SDoH resources prior to enrollment in our intervention because it is possible that individuals already connected to resources before enrolling in our intervention may be more likely to seek out additional support/resources (e.g., because they already have successful experiences using VA or non-VA resources to meet certain unmet needs) or less likely to seek out additional support/resources (e.g., because they feel they already have the support they most need).

For all analyses, we hypothesize that providing SW support (Assistance arm) will generally have a larger impact on outcomes than providing a tailored Resource Sheet alone (Awareness arm), but it will be beneficial to know if either the tailored Resource Sheet alone or provision of generic resources alone

(Screening arm) is sufficient to produce comparable changes in outcomes among Veterans with certain unmet needs or among Veterans with fewer unmet needs. If true, future implementation research could create tailored interventions that funnel the resources for more time- and cost-intensive referral strategies to only those Veterans who need it most.

**Objective 3**

*Study Setting and Participant Eligibility*

We will recruit for qualitative interviews a purposeful sample of two stakeholder groups: 1) Veterans enrolled in the RCT (N=60), and; 2) representatives of the VA and community programs to which trial participants are referred (N=15). For the Veteran interviews, we will seek three Veteran types (20 per type): Veterans who did not connect to new resources; Veterans who connected to at least one new resource but did not have their unmet need(s) met, and Veterans who connected to new resources and had one or more needs met. This sampling plan will allow us to understand the conditions that facilitate or impede a Veteran connecting to resources, and the conditions under which resources do or do not address a Veteran's needs. For the VA and community program representatives, we will seek up to five of the most frequently used programs at each study site. We will first identify all VA- and community-based programs that trial participants used because of the intervention based on data derived from Survey #2 (see Data Collection). We will then seek up to five of the most frequently used programs at each study site. By concentrating on the most highly used programs, this sampling plan will allow us to understand the experience of programs more likely to "feel" the intervention.

*Data Collection and Management*

All data will be collected by research assistants (RAs) uninvolved in patient care. Interviews will be conducted by phone using a semi-structured interview guide. We will ask Veterans about their experience participating in the trial (e.g., being screened, receiving resource sheets); experience with the unmet needs they identified; decision-making around accessing resources, and; experience connecting to and using resources to address unmet needs. We will ask representatives of VA- and community-based programs about their funding structure and services provided; experiences with increased demand for their services during the trial period; and the factors that facilitate and impede addressing Veterans' needs. Interviews will be digitally audio-recorded, with the permission of each respondent. De-identified audio-recordings will be transcribed by a premier service provider for the VA. The study team will store recordings on a secure VA server and will be password protected. All names and places mentioned will be deleted to protect confidentiality.

*Analysis*

We will transcribe interviews verbatim and employ both deductive and inductive coding methods. For the former, our work will be guided by Anderson's model of service utilization.[31] The model posits that a Veteran's use of resources is determined by three interacting factors: predisposing factors (e.g., belief that available resources can meet their need); enabling factors (e.g., accessibility of identified resources), and need (e.g., level of perceived unmet needs). Additional emergent codes will be identified, grounded in the data. Coding will be guided by the constant comparative method.[32] That is, previously coded material will be constantly compared to the new data to determine whether the same concept is being expressed and, if so, to be sure that all exemplars of that concept are assigned to the

most recently refined category. After coding is complete, code output will be analyzed to identify themes within and across sample strata.

**Patient and Public Involvement**

During the study design process, we engaged a Veteran consultant from VA's Veteran Engagement in Research Group (VERG) to provide input on the intervention, including the burden of being screened for multiple unmet needs and receiving facilitated referral services. Veteran will not be involved in the recruitment to and conduct of the study, and we do not have plan to disseminate results to study participants.

**ETHICS AND DISSEMINATION**

This study protocol was approved by the VA Central Internal Review Board (CIRB) (Reference #: 20-07 – Amendment No. 02). A Data and Safety Monitoring Board (DSMB) will oversee the study. DSMB is an independent review board chartered by HSR&D that meets at specified intervals and requires routine reporting from the PI. The PI will follow a specific Data and Safety Monitoring Plan (DAP), which has been reviewed and approved by the DSMB. We will conduct monthly assessments with each trial site to monitor serious adverse events. Should we receive any negative feedback from research subjects or have any unexpected serious or adverse events as reported by site staff, the PI will report this information to the Data Safety Monitoring Board (DSMB), CIRB, and R&D immediately.

We are conducting a benign behavioral intervention and while the risks of adverse events are thus minimal, there is the potential that some participants will get upset answering questions about unmet social needs. To protect against this risk, we will train study RAs to be sensitive to the individual needs of each participant and to create an environment that feels safe and nonjudgmental. RAs will also be trained to remind participants that they may decline to answer any survey question or discontinue with the surveys at any time. We will additionally establish procedures for the intervention research staff to connect patients with site staff who can assist and facilitate referrals to services and providers within the VA, as needed.

The study results will be disseminated regardless of effect direction and size through publications in peer-reviewed journal and presentations at conferences. Final data sets underlying all publications resulting from this research will be shared outside the VA. Quantitative data meeting VA standards for discloser to the public will be made available within 1 year of publications. Prior to distribution, a local privacy officer will certify that the data set contains to PHI, PII or VA Sensitive Information prior to release outside VA. Qualitative data will not be shared. The sensitive nature of the study data precludes asking participants to consent and grant HIPAA authorization for disclosing data outside the VA.

**DISCUSSION**

This study will provide much-needed evidence to document the prevalence of Veterans' unmet needs at three large urban VA Medical Centers, inform how best to address unmet needs, and assess how such a process can affect adherence, utilization, and clinical outcomes. If any of our intervention study arms demonstrate greater improvements in one or more study outcomes overall or for particular Veteran types (e.g., those with certain unmet needs), these findings can be tested and spread through future implementation research and processes. Importantly, the addition of our stakeholder interviews and analysis is unique to most clinical trials and will help to identify barriers and facilitators to future

implementation as well as potential needed modifications to the intervention. Doing so will facilitate future uptake of the intervention should it prove effective. Further, our focus on the sentinel condition of CVD may help bridge the substantial sociodemographic gap in life expectancy related to CVD, and our methods can be used to examine the effects of interventions to address unmet needs on other conditions.

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**Author Statement**: DG, NK, BB, AL, MD, KH, GF and BN made substantial contributions to the conception and design of the study; DG drafted the work and NK, BB, AL, MD, KH, GF and BN substantially revised it. All authors have approved the submitted version and have agreed both to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated resolved, and the resolution documented in the literature. The authors also appreciate the contributions of Jolie Wormwood, Rory Ostrow, and our Veteran consultant.

**Funding**: This study is funded by the Veterans Health Administration (VA)'s Health Service Research and Development Service. The views in this article are those of the authors and do not necessarily reflect the position or policy of the VA or the United States government. Dr. Fix is a VA HSR&D Career Development awardee at the Bedford VA (CDA 14-156).

**Conflicts of Interest**: The authors declare that they have no conflicts of interest.

**Word Count**: 3999

Table 1. Planned Outcomes

| Outcome | Data Source | Description |
|---|---|---|
| PRIMARY (OBJECTIVE 1) AND SECONDARY (OBJECTIVE 2) | | |
| Preventable hospitalizations | CDW[1] | Prevention Quality Indicators (PQI) using AHRQ criteria.[33] |
| Urgent care utilization | CDW[1] | Emergency Department and urgent care visits. (CDW[1]) |
| Medication adherence | CDW[1] | Proportion of days covered (PDC) of each CVD and CVD risk factors medication.[17, 34] |
| Clinic visit appointment attendance | CDW[1] | Proportion of PC and cardiology appointments classified as no-show, relative to the total number of appointments scheduled in both.[35] |
| Blood pressure (BP) | CDW[1] | Controlling for antihypertensive medications treatment intensification, using methods from prior work.[36] |
| Hemoglobin A1c (HbA1c) | CDW[1] | To ensure values reflect health status around time of index screen and 12-month follow-up window, we will only include Veterans with DM who have an Hba1c in the 6 months prior to each time point. |
| PRIMARY (OBJECTIVE 2) | | |
| Connection to new resources | Survey #2[2] | Veteran connecting to one or more new resources 8 weeks after index screen. |
| SECONDARY (OBJECTIVE 2) | | |
| Unmet need reduction | Surveys #1 and #3[2] | Measured two ways: 1) one or more of index needs no longer identified as unmet at 6-month rescreen, and; 2) percentage of index needs not reported as unmet at 6-month rescreen. |

[1] VA Corporate Data Warehouse (CDW).

[2] Described under Data Collection.

**Figure 1. Legend**

Green Links are supported by data; blue links need further investigation

[A] For patients with multiple unmet social needs, resolution of one need may enable them to address another. Reduced competing demands includes freeing up various resources (money, time, energy) to address other needs, which in turn can affect health outcomes.

[B] Clinical outcomes may include but are not limited to conditions where adherence to therapy directly impacts outcomes, such as hypertension, diabetes, and asthma.

[C] Identification of unmet social needs may be beneficial, even without referring to resources. For patients with transportation problems, for example, delivering prescriptions through mail order can bypass the barrier posed by the unmet transportation need without directly addressing it.

[D] Improved outcomes, such as improved well-being, may help patients connect to resources

[E] Costs may be reduced through improved control of chronic conditions, such as hypertension, which could avert costly future admissions for stroke or target organ damage. But increased costs to address unmet social needs may affect the equation for other conditions.

**Figure 2. Legend**

On a weekly basis for the 12-month trial, we will identify potentially eligible Veterans with upcoming primary care appointments. Trained Research Assistants (RA) will contact Veterans to explain the research protocol, review the elements of informed consent, and secure verbal consent. During this phone call, if verbal informed consent is obtained, the RA will screen for unmet needs (hereafter: "index screen"). If a Veteran reports no unmet needs, their study participation will be restricted to Objective 1. If a Veteran reports one or more unmet needs, the RA will randomize them to one of the three trial arms. Trial participants will be re-surveyed 8-weeks after the index screen to assess resource connection and 6-months after the index screen to assess unmet need reduction.

**Figure 1.**

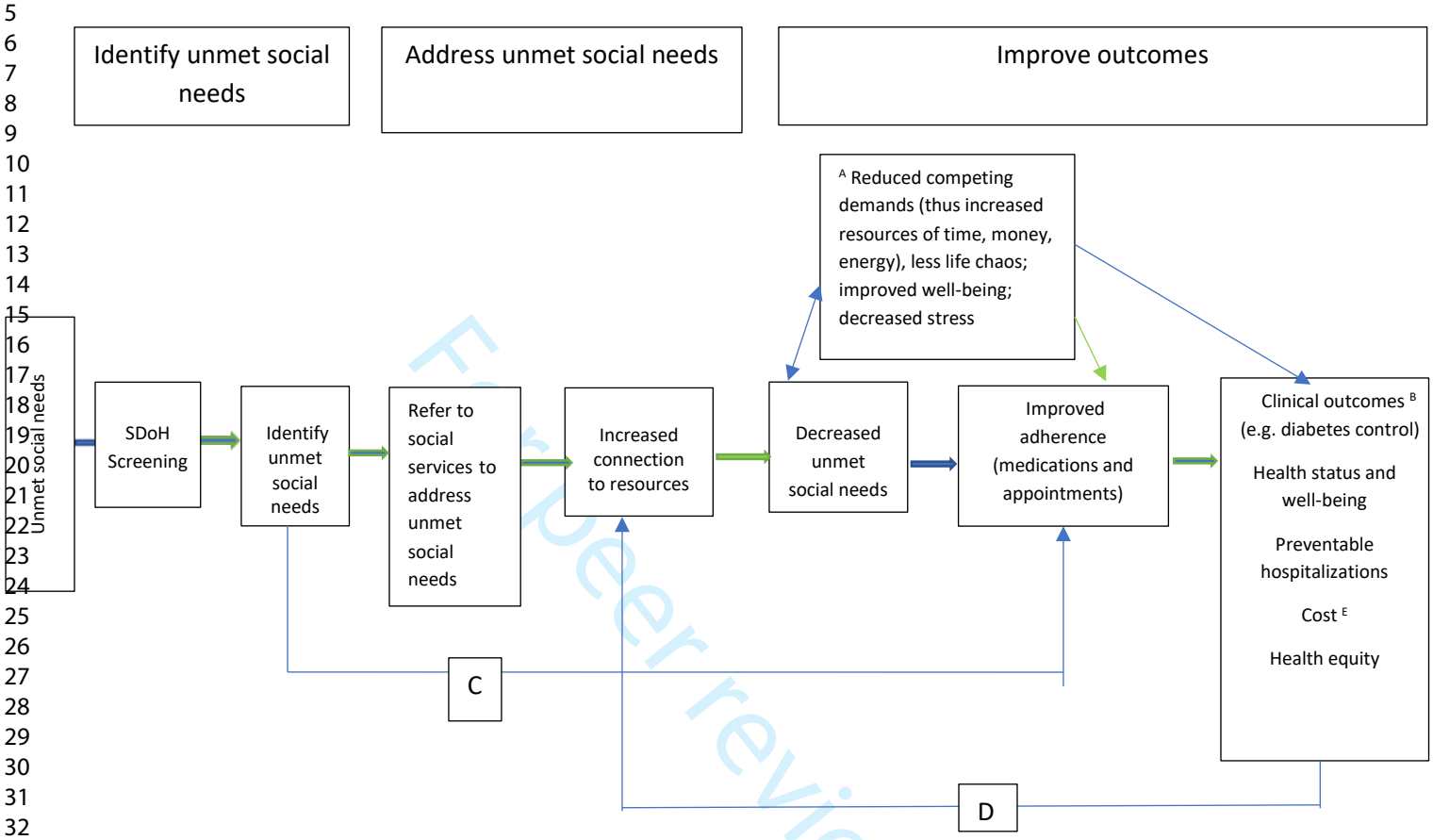
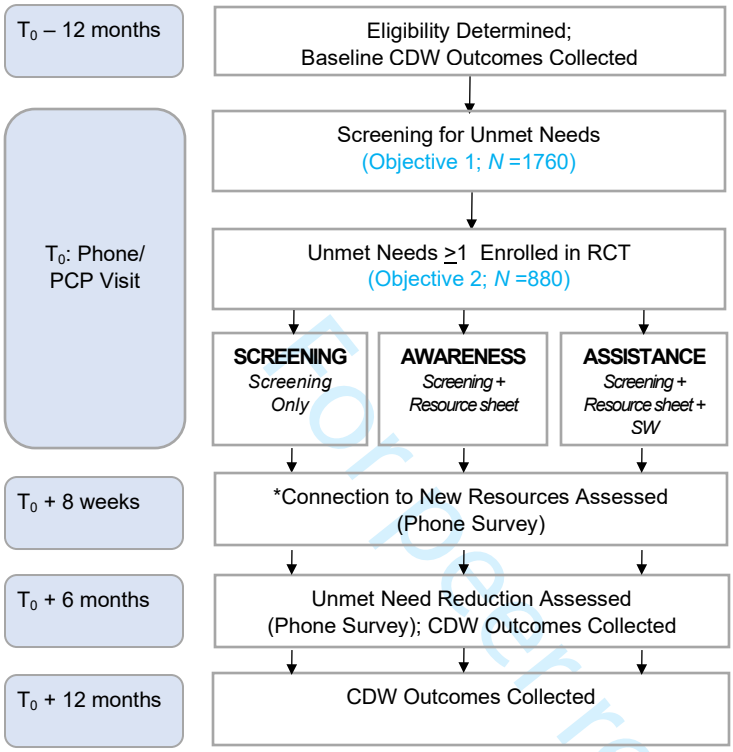


Figure 2. Study Design



**Appendix A. Participant Informed Consent**

**STUDY FACT SHEET**

**Study Title:** The Effects of Screening and Referral for Social Determinants of Health on Veterans' Outcomes

**Name of Study Lead (also called "Principal Investigator")**: Deborah Gurewich, PhD

Name of Study Lead at your VA (also call "Local Site Investigator"): (insert relevant name)

**1. What is the purpose of the study?** To understand how the Veterans Health Administration (VHA) can best help Veterans who have *resource needs*. *Resource needs* are also called social determinants of health. These are things like having trouble paying for housing or a hard time paying important bills, like electric or gas bills.

**2.Who is invited to participate?** You are eligible to participate if you

a) have heart disease or cardiovascular disease (CVD) or are at risk for heart disease (for example, because you have high blood pressure), *and*
b) get primary care at the Boston, Charleston, or Philadelphia VA Healthcare Systems.

**3. What does the study involve and how long will it last?** The study has two parts.

In **Part One**, someone from the research team will call you. They will want to talk for about 30 minutes. They will go over the study and answer any questions you might have. Next, they will conduct a brief questionnaire with you about your resource needs (for example, they will ask about your housing). Depending on your answers, you may be eligible for Part Two of the study. If you are not eligible for Part Two, that will be the end of your participation in the study.

If you are eligible for **Part Two** of the study, you will be contacted by phone two more times – eight weeks and six months after the first telephone call. During these calls, a researcher will conduct brief questionnaires with you about your resource needs. These phone calls should take only 5-10 minutes.

For Part Two of the study, you will be randomly assigned to one of three study groups: A, B, or C (see Table 1). Being randomly assigned is like a flip of a coin for which group you would be placed in.

- Group A: Participants in this group will receive a postcard listing local and national VHA help lines that may help with resource needs.
- Group B: Participants in this group will receive a postcard and also a written list of resources (i.e., agencies and programs) tailored to each participant's specific resource needs.
- Group C: Participants in this group will receive a postcard, a written list of resources, and also be offered help from a social worker who is part of the research team. The social worker may contact you by phone to learn more about your resource needs and help you connect to agencies and programs. The social worker could contact the you by phone up to 5 more times.

If you are in Groups B or C, you might also be asked to participate in a phone interview. In contrast to the brief questionnaires described above, the phone interview will involve a longer list of questions and will take more time, we estimate 45-60 minutes. If you are selected for an interview, a member of the research team will contact you by phone between months 7 and 12. If you agree, the researcher will

then schedule a time that is convenient for you to conduct the interview. Before the interview begins, we will ask your permission to audio record the interview. If you do not want the interview recorded, that is Ok and you can still participate in the interview. During the interview you will be asked about your experience participating in the study. Veterans who participate in Part Two of study will be in the study for 12 months.

**Table 1. What Participants Will Receive by Study Group**

| Group A | Group B | Group C |
|---|---|---|
| • Postcard listing local and national VHA help lines | • Postcard listing local and national VHA help lines<br>• Resource sheet listing agencies and programs to address specific resource needs | • Postcard listing local and national VHA help lines<br>• Resource sheet listing agencies and programs to address specific resource needs<br>• Assistance from a Social Worker to help connect to agencies and programs |

**4. What are the benefits of participating?** People who participate in this study may have a better understanding of the resources that can help Veterans with resource needs. Your participation may also add much needed knowledge about resource needs among Veterans and how the VHA can better meet the needs of Veterans with resource needs.

**5. What are the possible risks or discomforts of participating?** Some people may feel uncomfortable or upset discussing resource needs during the telephone calls with research staff. You may choose to skip a question or stop the telephone call at any time. You can also withdraw from the study at any time. Some people may find the telephone calls inconvenient. We will make every effort to schedule phone calls when it is convenient for you and will try to keep them short. Finally, there is a general risk of loss of confidentiality, but we believe this risk is minimal.

**6. How will my private information be protected?** Information collected for this research study will be kept confidential as required by law and will not be shared with your care team. However, you are welcome to follow-up with your care team at any time during your participation this the study. The results of this study may be published for scientific purposes, but your record or identity will not be revealed unless required by law. We will store your information in ways we think are secure. We will store paper files in locked cabinets. We will store electronic files in computer systems with password protection and encryption. However, we cannot guarantee complete confidentiality. To help protect your personal information, we will assign you a study ID so that your identifiable information is not connected to you.

We will limit access to your personal information to members of the research team who need to review this information in order to conduct the study. In addition, a description of this study will be available at http://www.ClinicalTrials.gov as required by U.S law. This website will not include information that can identify you.

Your research records will be destroyed in accordance with the VHA Record Control Schedule (www1.va.gov/VHAPUBLICATIONS/RCS10/rcs10-1/pdf). Records will be destroyed when allowed in the following manner: Paper records will be shredded; electronic records and audio recordings will be destroyed in a manner in which they cannot be retrieved.

Participating in this study will not affect your VHA healthcare including your healthcare providers' ability to see your records as part of normal care and will not affect your right to have access to your records during and after the study is completed.

**7. What are the costs of participating in the study?** You will not be charged for any activities or procedures that are part of this study.

**8. Do I have to take part in this study?** No. Participating in the study is voluntary and if you refuse to take part in the study, there will be no penalty or loss of benefits to which you are otherwise entitled to from the VHA. There are also no consequences if you decide to withdraw from the study. In this instance, for data already collected prior to your withdrawal, the research team may continue to review the data already collected for the study but will not collect further information from you.

**9. Who do I contact about this study of I have questions?** If you have any questions about the research study, concerns or complaints, you can contact the project manager at 857-364-2350. If you have questions about your rights as a study participant, or want to make sure the study is valid, you may contact the VHA Central Institutional Review Board toll free at 1-877-254-3130. This is the Board that is responsible for overseeing the safety of human participants in this study. You may call them if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

**10. Will I be compensated for being in this study?** As a thank you for your participation, you will receive a $15 gift voucher to CVS for each brief questionnaire you complete and a $25 gift voucher to CVS if you participate in a telephone interview.

SPIRIT Checklist

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BMJ Open

# Protocol for a randomized controlled trial evaluating the effects of screening and referral for social determinants of health on Veterans' outcomes



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|---|---|
| Journal: | *BMJ Open* |
| Manuscript ID | bmjopen-2021-058972.R1 |
| Article Type: | Protocol |
| Date Submitted by the Author: | 16-Jun-2022 |
| Complete List of Authors: | Gurewich, Deborah; VA Boston Health Care System Jamaica Plain Campus, Center for Healthcare Organization and Implementation Research<br>Kressin, Nancy; Boston University School of Medicine, General Internal Medicine<br>Bokhour , BG; Boston University School of Public Health,<br>Linsky, Amy; VA Boston Health Care System Jamaica Plain Campus<br>Dichter, Melissa; VA Medical Center Corporal Michael J Crescenz<br>Hunt, Kelly J.; Ralph H Johnson VAMC<br>Fix, G; VA Edith Nourse Rogers Memorial Veterans Hospital<br>Niles, Barbara; VA Boston Healthcare System, National Center for PTSD; Boston University School of Medicine, Psychiatry |
| Primary Subject Heading: | Research methods |
| Secondary Subject Heading: | Cardiovascular medicine, General practice / Family practice, Health policy, Health services research |
| Keywords: | Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Adult cardiology < CARDIOLOGY |
| | |

**Title Page**

# Protocol for a randomized controlled trial evaluating the effects of screening and referral for social determinants of health on Veterans' outcomes

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Key Words: social determinants of health, randomized control trial, primary care, Veterans, cardiovascular disease

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**Abstract**

*Introduction*: Health policy leaders recommend screening and referral (S&R) for unmet social needs (e.g., food) in clinical settings, and the American Heart Association recently concluded that the most significant opportunities for reducing cardiovascular (CVD) death and disability lie with addressing the social determinants of CVD outcomes. A limited but promising evidence base supports these recommendations, but more rigorous research is needed to guide health care-based S&R efforts. Funded by the Veteran Health Administration (VA), the study described in this paper will assess the efficacy of S&R on Veterans' connections to new resources to address social needs, reduction of unmet needs, and health-related outcomes (adherence, utilization, and clinical outcomes).

*Methods and analysis*: We will conduct a 1-year mixed-methods randomized controlled trial at three VA sites, enrolling Veterans with CVD and CVD-risk. 880 Veterans experiencing one or more social needs will be randomized within each site (N=293 per site) to one of three study arms representing referral mechanisms of varying intensity (screening only, screening and provision of resource sheet(s), screening and provision of resource sheet(s) plus social work assistance). For each Veteran, we will examine associations of unmet social needs with health-related outcomes at baseline, and longitudinally compare the impact of each approach on connection to new resources (primary outcome) and follow-up outcomes over a 12-month period. We will additionally conduct qualitative interviews with key stakeholders, including Veterans to identify potential explanatory factors related to the relative success of the interventions.

*Ethics and dissemination*: Ethics approval was obtained from the VA Central Internal Review Board on July 13, 2021 (Reference #: 20-07 – Amendment No. 02). Findings will be disseminated through reports, lay summaries, policy briefs, academic publications, and conference presentations.

*Trial registration*: NCT04977583.

**Article Summary**

Strengths and limitations of this study

- Prior studies have examined cross-sectionally how addressing unmet needs is associated with health outcomes, but we will examine these associations longitudinally, which will allow a better assessment of causality and possible mechanisms for associations.
- We will conduct this study within the largest integrated health system in the United States – the Department of Veterans Affairs - which will provide an opportunity for widespread dissemination within this health system.
- Often RCTs end data collection with their outcomes data but for this study, we enhance our findings to understand facilitators, barriers and potential explanatory factors related to the relative success of the interventions.

## INTRODUCTION

Social Determinants of Health (SDH) are "the structural determinants and conditions in which people are born, grow, live, work and age."[1] These conditions shape the degree to which basic needs are met both at the individual-level (e.g., housing, food, social connections) and the community-level (e.g., safe neighborhoods). They also shape health trajectories as recent estimates suggest that clinical care accounts for less than 20% of modifiable health outcomes whereas other factors, including SDH, are more significant drivers of morbidity and mortality.[2,3] Consequently, there is consensus that improving population health will require health care delivery systems, including the Veterans Health Administration (VA), to address unmet social and economic needs (hereafter: unmet needs), rather than addressing disease from only a biomedical perspective.

The relationship between unmet needs and health is strikingly evident for patients with or at risk for cardiovascular disease (CVD), [4,5] the leading cause of morbidity and mortality in the US.[6] For example, lower socioeconomic status is associated with greater prevalence of CVD risk factors and higher mortality from CVD.[7-9]; the risk for myocardial infarction is highest in the first year of unemployment and increases with the number of job losses[10]; and lack of social support is associated with increased CVD mortality.[11] Thus, the American Heart Association (AHA) recently declared that, "at present, the most significant opportunities for reducing death and disability from CVD in the US lie with addressing the social determinants of cardiovascular outcomes."[4]

The AHA's recommendations, as well as similar recommendations from other leading health policy groups[1 12 13] rests on limited, yet promising, evidence that implementing systematic screening and referral (S&R) for unmet needs leads to greater receipt of resources that address identified needs[14,15] as well as reduction in unmet needs.[16] Such a process can potentially improve both proximal outcomes, such as adherence to medications and care appointments[17], as well as more distal outcomes, such as overall health.[18-21] However, much of the limited evidence on programs to address unmet needs is based in pediatric or specialized settings (e.g., women's health clinics), or on interventions targeting a single need, such as food insecurity.[22] Importantly, as far as we know, there are no randomized controlled trials (RCT) demonstrating the impact of systematic S&R for unmet needs on patients' connection to resources or other utilization and health outcomes in the general adult ambulatory care setting nor among a Veteran population. In short, there is no definitive guidance on how best to screen for and address unmet needs in clinical settings, creating a key barrier to implementing this practice in health care delivery systems.[23]

The criteria ("means test") prioritizing access to VA services to those with financial need, in addition to those with service-related health conditions, results in many Veterans using VA health care services having low incomes, poor quality of life, and multiple comorbidities.[24,25] For these reasons, Veterans are at especially high risk of experiencing unmet social needs. For example, up 24% have been reported to experience food insecurity.[26] Given the simultaneously high prevalence of CVD and its risk factors and unmet needs among Veterans enrolled in the VA, Veterans' outcomes may be improved by comprehensively assessing and addressing unmet needs.

Currently, the VA administers system-wide clinical screens for two unmet needs (housing and food insecurity), yet other unmet needs are not routinely identified. While VA invests in social work (SW) to address a wide range of unmet needs, referral to and staffing of SW is highly variable across and within facilities. Many Veterans who could benefit from VA SW are not systematically identified and referred.

Further, there are no comprehensive data on Veterans' unmet needs, nor on their association with utilization and clinical outcomes (blood pressure and A1c control), hampering VA's ability to understand the effects of unmet needs and to target resources to address them. Finally, it is not known whether a social worker is required to address all unmet needs; it is plausible that a less resource- or personnel-intense process can address identified unmet needs and improve outcomes, as suggested by a recent pediatric S&R intervention. [19]

Funded by the VA's Health Services and Research Development division, the aim of this study is to assess the efficacy of comprehensive S&R among Veterans with or at-risk for CVD. Our study objectives are three-fold: 1) to describe the prevalence and distribution of unmet needs and identify their associations with baseline sociodemographic characteristics, adherence, utilization and clinical outcomes; 2) to compare the efficacy of three S&R strategies of increasing intensity on connection to new resources to address unmet needs (primary outcome) and on secondary outcomes of post-intervention change in unmet needs, adherence, utilization, and clinical outcomes; and 3) to identify barriers and facilitators to Veterans' connecting with resources to address unmet needs and getting needs met, and explore potential explanatory factors related to the relative success of each study arm.

## METHODS

### Overview

We are conducting a mixed method RCT (see Figure 1). The RCT protocol adheres to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) (see additional file). The study will take place three VA medical facilities between February 2021 and January 2024. For Objective 1, we will use baseline trial data gathered via a survey of Veterans at the study sites about their unmet needs and conduct quantitative analyses of survey, administrative, and clinical data to characterize the prevalence of unmet needs and their association with baseline outcomes (adherence, utilization, and clinical). For Objective 2, Veterans who screened positive for one or more unmet needs in the survey will be randomized within each site to one of three trial study arms defined by referral approaches of varying intensity. Quantitative analyses will longitudinally compare the effects of the referral approaches on the primary outcome (connections to new resources) and secondary outcomes (reduction in unmet needs, adherence, utilization, and health outcomes). Often RCTs end data collection with their outcomes data. For this study, we enhance our findings to qualitatively understand more about the facilitators, barriers and potential explanatory factors related to the relative success of the interventions. Therefore, for Objective 3, we will conduct qualitative interviews with a purposeful sample of key stakeholders who participated in the trial, including Veterans. We first describe the methods for the RCT (objectives 1 and 2) followed by the methods for the qualitative inquiry (objective 3).

### Evaluation Frameworks and Theory of Change

The study is guided by the Outcomes from Addressing SDH in Systems (OASIS) framework (see Figure 2).[27] This framework, developed by the study team is based on Maslow's Hierarchy of Needs model, which specifies that basic physiological needs (e.g., food, shelter) must be met before higher order needs (e.g., medication adherence) can be addressed.[28] Following OASIS, our theory of change is therefore that S&R will result in more patients connecting to resources to address those needs and that connection to resources will then have multiple downstream effects, including reduced needs and

enhanced adherence to medical treatments and care. In turn, better adherence will lead to improved outcomes.

The qualitative inquiry is additionally guided by Anderson's model of service utilization.[29] The model posits that a Veteran's connection to resources is determined by three interacting factors: predisposing factors (e.g., belief that available resources can meet their need); enabling factors (e.g., accessibility of identified resources), and need (e.g., level of perceived unmet needs). We will explore the degree to which these factors help to explain why some participants do or do not connect with resources to address unmet needs.

**Randomized Controlled Trial (Objectives 1 and 2)**

*Study Setting and Participant Eligibility*

For Objective 1, the study population will be comprised of Veterans with, or at risk for, cardiovascular disease (CVD) seen in primary care (PC) clinics of three urban VA medical centers. Veterans must have at least one PC visit in the year prior to the RCT start date to ensure that included study subjects are at least minimally engaged in VA care. Veterans who have impaired decision-making and/or are illiterate or have limited of no English proficiency are excluded from the study. Using data from VA's Corporate Data Warehouse (CDW), we will identify CVD patients as those with International Classification of Disease 10 (ICD10) diagnoses for coronary artery disease, cerebrovascular disease, or peripheral artery disease, and patients with CVD risk as having diagnoses of hypertension, diabetes mellitus (DM), or hyperlipidemia. For Objective 2, the study population will be comprised of the subset of Objective 1 participants who have one or more unmet needs.

*Study Procedures and Randomization*

On a weekly basis for the 12-month trial, we will identify potentially eligible Veterans with upcoming primary care appointments who will be mailed a recruitment package. The recruitment package will include a description of the study and elements of informed consent (see Appendix A), as well as an opt-out post card. Trained Research Assistants (RA) at each study site will contact Veterans (who have not opted-out) via telephone to explain the research protocol, review the elements of informed consent, secure verbal consent, and enroll the Veteran.

During this phone call, among enrolled Veterans, the RA will administer a brief survey to screen for nine unmet needs (housing, food insecurity, utility insecurity, transportation, legal needs, employment, safety, stress, social isolation), hereafter referred to as the "index screen." As part of the brief survey, each unmet need measure, if endorsed, is followed by a question about whether the Veteran is already receiving assistance for the need. To inform selection of the nine unmet needs, we used similar criteria to what other leading healthcare groups have used: 1) strength of the evidence linking the domain with CVD outcomes; 2) availability of a valid measure of the domain, 3) stakeholder priorities (input from VA providers, operational partners, and a Veteran Engagement Resource Group (VERG) Veteran consultant), and 4) ability to meet the need with available resources in VA and/or community.[23,30,31] This process yielded the final set of 9 unmet needs. The unmet need measures themselves were then reproduced or adapted from previously validated measures.

If a Veteran reports no unmet needs, their study participation will be restricted to Objective 1. If a Veteran reports one or more unmet needs, the RA will randomize them to one of the three trial arms

using the sealed opaque envelope method. [32] The Data Analyst will be responsible for randomly generating the treatment allocations within the sealed envelopes. Once an envelope is open, the RA will inform the Veteran of their arm assignment.

*The Intervention*

Following the naming convention used by Centers for Medicare & Medicaid Services for the arms in the Accountable Healthy Communities trial, we have the following study arms: 1) Unmet needs screening and provision of a postcard with a list of generic VA resources (hereafter: "Screening" arm), 2) Screening and provision of a postcard with a list of generic VA resources plus provision of a tailored Resource Sheet listing available resources in VA and/or the community to address identified unmet needs (hereafter: "Awareness" arm), or 3) Screening and provision of generic resources plus provision of a tailored Resource Sheet plus Social Work (SW)-supported referral to assist with connection to resources for unmet needs (hereafter: "Assistance" arm). Administering the intervention will not be blinded to group assignment.

Screening: Veterans in the Screening arm will receive a post card listing the phone numbers for generic resources available to Veterans including the Veteran's VA Medical Center, VA Veterans Crisis Line, and National Call Center for Homeless Veterans. The post card will be included in the initial recruitment packet mailed to all potential study participants. in our least-intense arm. The screening arm reflects enhanced usual care. At present, VA systematically screens for only 2 of the 9 unmet social needs (housing and food insecurity) being assessed in this study and while VA refers Veterans to the resources listed on the post card, it is on an as-needed basis, not as part of usual care. We included the generic resource post card to address ethical concerns raised by the VA CIRB about assessing unmet needs without offering any resources.

Awareness: Veterans in the Awareness arm will receive the post card listing generic resources as described above. Additionally, for each unmet need identified through the index screen, Veterans will receive by mail a tailored Resource Sheet that will include the names of available resources within VA and/or the local community that can help address the identified need(s). During the index screen, the RA will additionally ask participants if they would like to receive the Resource Sheet(s) as an email attachment. For Veterans who respond affirmatively, the RA will send the Resource Sheets as an email attachment during the index screen phone call and offer to review its content with them. To ensure the Resource Sheets stay current, the RA will contact listed programs monthly for current contact information and ability to accept referrals.

Assistance: Veterans in the Assistance arm will receive the post card listing generic resources and tailored Resource Sheets as described above. Additionally, during the in-clinic encounter, the RA will offer these Veterans assistance from a Social Worker specifically hired and trained (one per site) to support Veterans with connecting to resources. With Veteran assent, the SW will contact the Veteran by phone within two business days of the in-clinic encounter. During this initial call, the SW will use proven motivational interviewing methods to develop an action plan for the Veteran to connect to needed resources. [33,34] The SW will conduct follow-up by phone one week after the action plan development, with projected subsequent phone outreach every two weeks for up to seven weeks. At each call, the SW will review progress and as needed, employ motivational interviewing methods to re-affirm the action plan and/or modify the action plan to address unexpected barriers.

*Fidelity*

The research RAs and SWs responsible for delivering the intervention will be provided written Standard Operation Procedures (SOP) detailing their roles and training on their respective SOPs. The SWs will additionally complete a training module on Motivational Interviewing. We will assess fidelity via data captured in REDCap (detailed below) and monitor the quality of calls with participants as part of regular check-ins (weekly for the first few months of the trial but likely reducing to monthly thereafter).

*Data Collection and Management*

All data will be collected by RAs and SWs uninvolved in the medical care of patients. All study participants will be asked to complete a brief telephone-based survey to assess unmet needs during the index screen. We refer to this as Survey A. All RCT participants will be asked to complete two additional brief telephone-based surveys. Survey B will occur eight weeks after the index screen, when the RA will assess if trial participants connected to any new resources in the intervening time, and if so, to which one(s). Survey C will occur six months after the index screen, when the RA will re-screen all trial participants for unmet needs. The 12-month recruitment period is planned to commence January 1, 2022 and all follow-up is planned to be complete by June 30, 2023. For participants randomized to the Assistance arm, SWs will capture their interactions with participants, including the timing, duration, and outcomes of their interactions. Data will be recorded via the REDCap system and will be cleaned and checked for accuracy by the project manager and data analyst. Survey data will be merged with administrative data from the VA Corporate Data Warehouse (CDW) within the VA Informatics and Computing Infrastructure (VINCI). CDW includes demographics, diagnoses, vital signs, lab values, prescriptions, and data on service use. Only the principal investigator and study team members conducting data analyses will have access to the data set.

*Planned Outcomes*

Table 1 provides a complete list of planned outcome measures for Objectives 1 and 2. The primary outcomes for Objective 1 will be various measures of treatment adherence, utilization, and clinical outcomes. The primary outcome for Objective 2 (the RCT) will be connection to new resources to address unmet needs. Connection to resources will be defined as a Veteran connecting to one or more new resources since the index screen, as indicated by their responses to the question, “Since you completed the unmet need social need screen on (insert date), were you able to connect with any of the programs or resources to help with (insert need(s) identified)?” Secondary outcomes will be reduction of unmet needs, various measures of treatment adherence, utilization, and clinical outcomes. Our rationale for this ordering of outcomes for Objective 2 is the importance of understanding whether S&R leads to connection to new resources, the first step in our conceptual model (see Figure 1) that we anticipate will, in turn, lead to improved adherence, utilization, and ultimately, clinical outcomes. As further rationale for considering clinical outcomes as secondary, we posit they may be difficult to change over the study’s time-limited 12-month period. Moreover, while much existing literature demonstrates associations between unmet needs and clinical health outcomes, there is a dearth of preliminary data assessing the impact of interventions (e.g., S&R) on these clinical outcomes. This precluded us from reliably estimating effect sizes for comparisons across intervention arms or needed sample size to adequately power such comparisons.

*Sample Size Calculations*

Power analyses were used to determine sample size based on an effect size estimate for our primary outcome from a prior study. [14] Our sample size (N=880) ensure adequate power (80%) to detect small-to-medium effect sizes for each of the primary and secondary outcomes even if the attrition rate for survey B and survey C are both as high as 50%. The team's prior study with a demographically similar Veteran population found only a 35% attrition rate.[35]

*Analysis*

Objective 1: We will generate descriptive statistics (e.g., proportions, 95% confidence intervals) to characterize the prevalence and distribution of each of the eight unmet needs at baseline across all study sites. We will next conduct inferential analyses to examine associations between unmet needs and sociodemographic characteristics (including race and ethnicity) as well as baseline outcomes (i.e., adherence, utilization, and clinical outcomes drawn from CDW data in the 12-months before the index screening for each Veteran). General linear mixed models (GLMM) will be used to control for the nesting of patients within sites, and logistic models will be used as appropriate for binary variables. Variables found to have statistically significant associations with unmet needs will be entered into multivariable models to better understand the correlates of each need. Bonferroni-corrected significance levels will control for multiple comparisons.

Objective 2: We will compare connection to new resources at 8-weeks post-index screen across the study arms. GLMM will be used to control for the nesting of patients within sites. In all regression models, patient-level intercepts and slopes will be treated as random effects. In addition to examining how the intervention conditions influence connection to new SDH resources, we will conduct supplemental exploratory analyses to examine whether there is differential impact between the three intervention arms on connection to new SDH resources among Veterans defined by differing sociodemographic characteristics including race and ethnicity.

Using a difference-in-difference approach, we will compare the secondary outcomes (unmet need reduction, adherence, utilization, and clinical outcomes) across study arms. We will examine whether changes from baseline at 6-months and 12-months post-referral differ across the three arms in a series of GLMM analyses. As with the other analyses, all models will treat patient-level intercepts and predictors as random effects. Similar analyses will be used to examine differences across our three study arms in change from baseline in the proportion of unmet needs among the sub-sample of participants who complete the re-screening at 6-months post-referral. To the extent that we discover differences across intervention arms in any of our more distal outcomes, we will also conduct exploratory analyses to test appropriate causal mediational paths as proposed by the OASIS framework using a series of GLMM analyses.

Finally, we will conduct additional analyses controlling for connection to SDH resources prior to enrollment in our intervention because it is possible that individuals already connected to resources before enrolling in our intervention may be more likely to seek out additional support/resources (e.g., because they already have successful experiences using VA or non-VA resources to meet certain unmet needs) or less likely to seek out additional support/resources (e.g., because they feel they already have the support they most need).

For all analyses, we hypothesize that providing a tailored Resource Sheet plus SW support (Assistance arm) will generally have a larger impact on outcomes than providing a tailored Resource Sheet alone

(Awareness arm). We do so because navigating the social service delivery system can be challenging and may be especially challenging for Veterans experiencing unmet social needs. This means that simply being made aware of available resources may be an insufficient mechanism for connecting participants to resources. In contrast, being made aware of resources *and* provided navigation assistance may enable participants to overcome barriers and by extension increase the likelihood of connecting to resources. However, it will be beneficial to know if either the tailored Resource Sheet alone or provision of generic resources alone (Screening arm) is sufficient to produce comparable changes in outcomes among Veterans with certain unmet needs or among Veterans with fewer unmet needs. If true, future implementation research could create tailored interventions that funnel the resources for more time- and cost-intensive referral strategies to only those Veterans who need it most.

**Qualitative Inquiry (Objective 3)**

*Study Setting and Participant Eligibility*

We will recruit for qualitative interviews a purposeful sample of two stakeholder groups: 1) Veterans enrolled in the RCT (N=60), and; 2) representatives of the VA and community programs to which trial participants are referred (N=15). If thematic saturation is achieved before we reach these targeted sample sizes, we will stop recruiting. For the Veteran interviews, we will seek three Veteran types (20 per type): Veterans who did not connect to new resources; Veterans who connected to at least one new resource but did not have their unmet need(s) met, and Veterans who connected to new resources and had one or more needs met. This sampling plan will allow us to understand the conditions that facilitate or impede a Veteran connecting to resources, and the conditions under which resources do or do not address a Veteran's needs. For the VA and community program representatives, we will seek up to five of the most frequently used programs at each study site. We will first identify all VA- and community-based programs that trial participants used because of the intervention based on data derived from Survey #2 (see Data Collection). We will then seek up to five of the most frequently used programs at each study site. By concentrating on the most highly used programs, this sampling plan will allow us to understand the experience of programs more likely to "feel" the intervention.

*Data Collection and Management*

All data will be collected by research assistants (RAs) uninvolved in patient care. Interviews will be conducted by phone using a semi-structured interview guide. We will ask Veterans about their experience participating in the trial (e.g., being screened, receiving resource sheets); experience with the unmet needs they identified; decision-making around accessing resources, and; experience connecting to and using resources to address unmet needs. We will ask representatives of VA- and community-based programs about their funding structure and services provided; experiences with increased demand for their services during the trial period; and the factors that facilitate and impede addressing Veterans' needs. Interviews will be digitally audio-recorded, with the permission of each respondent. De-identified audio-recordings will be transcribed by a premier service provider for the VA. The study team will store recordings on a secure VA server and will be password protected. All names and places mentioned will be deleted to protect confidentiality.

*Analysis*

We will transcribe interviews verbatim and employ both deductive and inductive coding methods. For the former, codes will be informed by the previously described Anderson model of service utilization.[29] Additional emergent codes will be identified, grounded in the data. Coding will be guided by the constant comparative method.[36] That is, previously coded material will be constantly compared to the new data to determine whether the same concept is being expressed and, if so, to be sure that all exemplars of that concept are assigned to the most recently refined category. After coding is complete, code output will be analyzed to identify themes within and across sample strata.

**Patient and Public Involvement**

During the study design process, we engaged a Veteran consultant from VA's Veteran Engagement in Research Group (VERG) to provide input on the intervention, including the burden of being screened for multiple unmet needs and receiving facilitated referral services. Veterans will not be involved in the recruitment to and conduct of the study. We will disseminate findings via VERG, as well to individual study participants, upon request. .

**ETHICS AND DISSEMINATION**

This study protocol was approved by the VA Central Internal Review Board (CIRB) (Reference #: 20-07 – Amendment No. 02). A Data and Safety Monitoring Board (DSMB) will oversee the study. DSMB is an independent review board chartered by HSR&D that meets at specified intervals and requires routine reporting from the PI. The PI will follow a specific Data and Safety Monitoring Plan (DAP), which has been reviewed and approved by the DSMB. We will conduct monthly assessments with each trial site to monitor serious adverse events. Should we receive any negative feedback from research subjects or have any unexpected serious or adverse events as reported by site staff, the PI will report this information to the Data Safety Monitoring Board (DSMB), CIRB, and R&D immediately.

We are conducting a benign behavioral intervention and while the risks of adverse events are thus minimal, there is the potential that some participants will get upset answering questions about unmet social needs. To protect against this risk, we will train study RAs to be sensitive to the individual needs of each participant and to create an environment that feels safe and nonjudgmental. RAs will also be trained to remind participants that they may decline to answer any survey question or discontinue with the surveys at any time. We will additionally establish procedures for the intervention research staff to connect patients with site staff who can assist and facilitate referrals to services and providers within the VA, as needed.

The study results will be disseminated regardless of effect direction and size through publications in peer-reviewed journal and presentations at conferences. Final data sets underlying all publications resulting from this research will be shared outside the VA. Quantitative data meeting VA standards for discloser to the public will be made available within 1 year of publications. Prior to distribution, a local privacy officer will certify that the data set contains to PHI, PII or VA Sensitive Information prior to release outside VA. Qualitative data will not be shared. The sensitive nature of the study data precludes asking participants to consent and grant HIPAA authorization for disclosing data outside the VA.

**DISCUSSION**

This study will provide much-needed evidence to document the prevalence of Veterans' unmet needs at three large urban VA Medical Centers, inform how best to address unmet needs, and assess how such a

process can affect adherence, utilization, and clinical outcomes. If any of our intervention study arms demonstrate greater improvements in one or more study outcomes overall or for particular Veteran types (e.g., those with certain unmet needs), these findings can be tested and spread through future implementation research and processes. Importantly, the addition of our stakeholder interviews and analysis is unique to most clinical trials and will help to identify barriers and facilitators to future implementation as well as potential needed modifications to the intervention. Doing so will facilitate future uptake of the intervention should it prove effective. Further, our focus on the sentinel condition of CVD may help bridge the substantial sociodemographic gap in life expectancy related to CVD, and our methods can be used to examine the effects of interventions to address unmet needs on other conditions.

Table 1. Planned Outcomes for the RCT

| Outcome | Data Source | Description |
|---|---|---|
| PRIMARY OUTCOME | | |
| Connection to new resources | Survey B[1] | Veteran connecting to one or more new resources 8 weeks after index screen. |
| SECONDARY OUTCOMES | | |
| Unmet need reduction | Surveys A & C[1] | Measured two ways: 1) one or more of index needs no longer identified as unmet at 6-month rescreen, and; 2) percentage of index needs not reported as unmet at 6-month re-screen. |
| Preventable hospitalizations | CDW[2] | Prevention Quality Indicators (PQI) using AHRQ criteria.[37] |
| Urgent care utilization | CDW[2] | Emergency Department and urgent care visits. (CDW[1]) |
| Medication adherence | CDW[2] | Proportion of days covered (PDC) of each CVD and CVD risk factors medication.[17,38] |
| Clinic visit appointment attendance | CDW[2] | Proportion of PC and cardiology appointments classified as no-show, relative to the total number of appointments scheduled in both.[39] |
| Blood pressure (BP) | CDW[2] | Controlling for antihypertensive medications treatment intensification, using methods from prior work.[40] |
| Hemoglobin A1c (HbA1c) | CDW[2] | To ensure values reflect health status around time of index screen and 12-month follow-up window, we will only include Veterans with DM who have an Hba1c in the 6 months prior to each time point. |

[1] Described under Data Collection.

[2] VA Corporate Data Warehouse (CDW).

escribed under Data Collection.

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**Author Statement**: DG, NK, BB, AL, MD, KH, GF and BN made substantial contributions to the conception and design of the study; DG drafted the work and NK, BB, AL, MD, KH, GF and BN substantially revised it. All authors have approved the submitted version and have agreed both to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated resolved, and the resolution documented in the literature. The authors also appreciate the contributions of Jolie Wormwood, Rory Ostrow, and our Veteran consultant.

**Funding**: This study is funded by the Veterans Health Administration (VA)'s Health Service Research and Development Service. The views in this article are those of the authors and do not necessarily reflect the position or policy of the VA or the United States government. Dr. Fix is a VA HSR&D Career Development awardee at the Bedford VA (CDA 14-156).

**Conflicts of Interest**: The authors declare that they have no conflicts of interest.

**Word Count**: 4650

**Figure 1. Legend**

On a weekly basis for the 12-month trial, we will identify potentially eligible Veterans with upcoming primary care appointments. Trained Research Assistants (RA) will contact Veterans to explain the research protocol, review the elements of informed consent, and secure verbal consent. During this phone call, if verbal informed consent is obtained, the RA will screen for unmet needs (hereafter: "index screen"). If a Veteran reports no unmet needs, their study participation will be restricted to Objective 1. If a Veteran reports one or more unmet needs, the RA will randomize them to one of the three trial arms. Trial participants will be re-surveyed 8-weeks after the index screen to assess resource connection and 6-months after the index screen to assess unmet need reduction.

**Figure 2. Legend**

Green Links are supported by data; blue links need further investigation

[A] For patients with multiple unmet social needs, resolution of one need may enable them to address another. Reduced competing demands includes freeing up various resources (money, time, energy) to address other needs, which in turn can affect health outcomes.

[B] Clinical outcomes may include but are not limited to conditions where adherence to therapy directly impacts outcomes, such as hypertension, diabetes, and asthma.

[C] Identification of unmet social needs may be beneficial, even without referring to resources. For patients with transportation problems, for example, delivering prescriptions through mail order can bypass the barrier posed by the unmet transportation need without directly addressing it.

[D] Improved outcomes, such as improved well-being, may help patients connect to resources

[E] Costs may be reduced through improved control of chronic conditions, such as hypertension, which could avert costly future admissions for stroke or target organ damage. But increased costs to address unmet social needs may affect the equation for other conditions.

Figure 1. Study Design

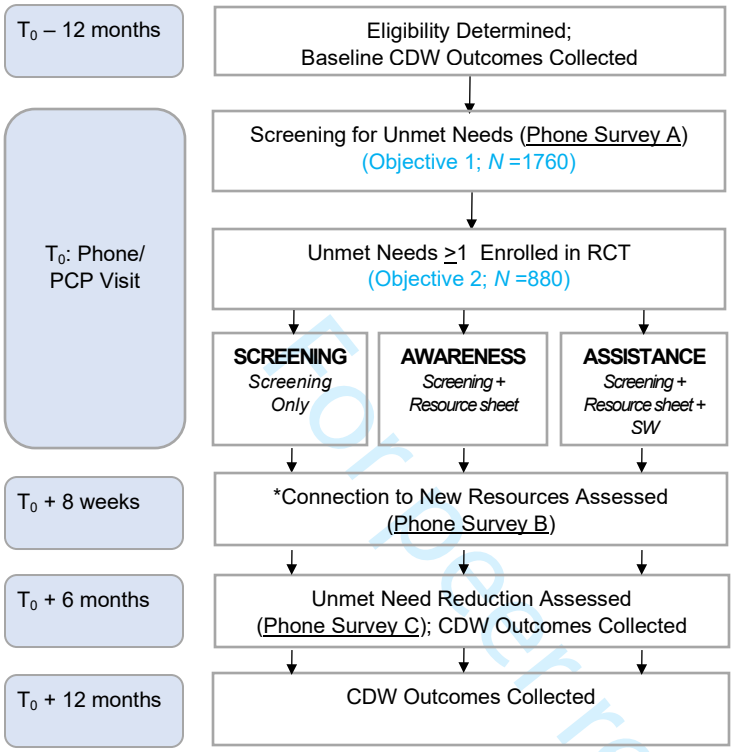
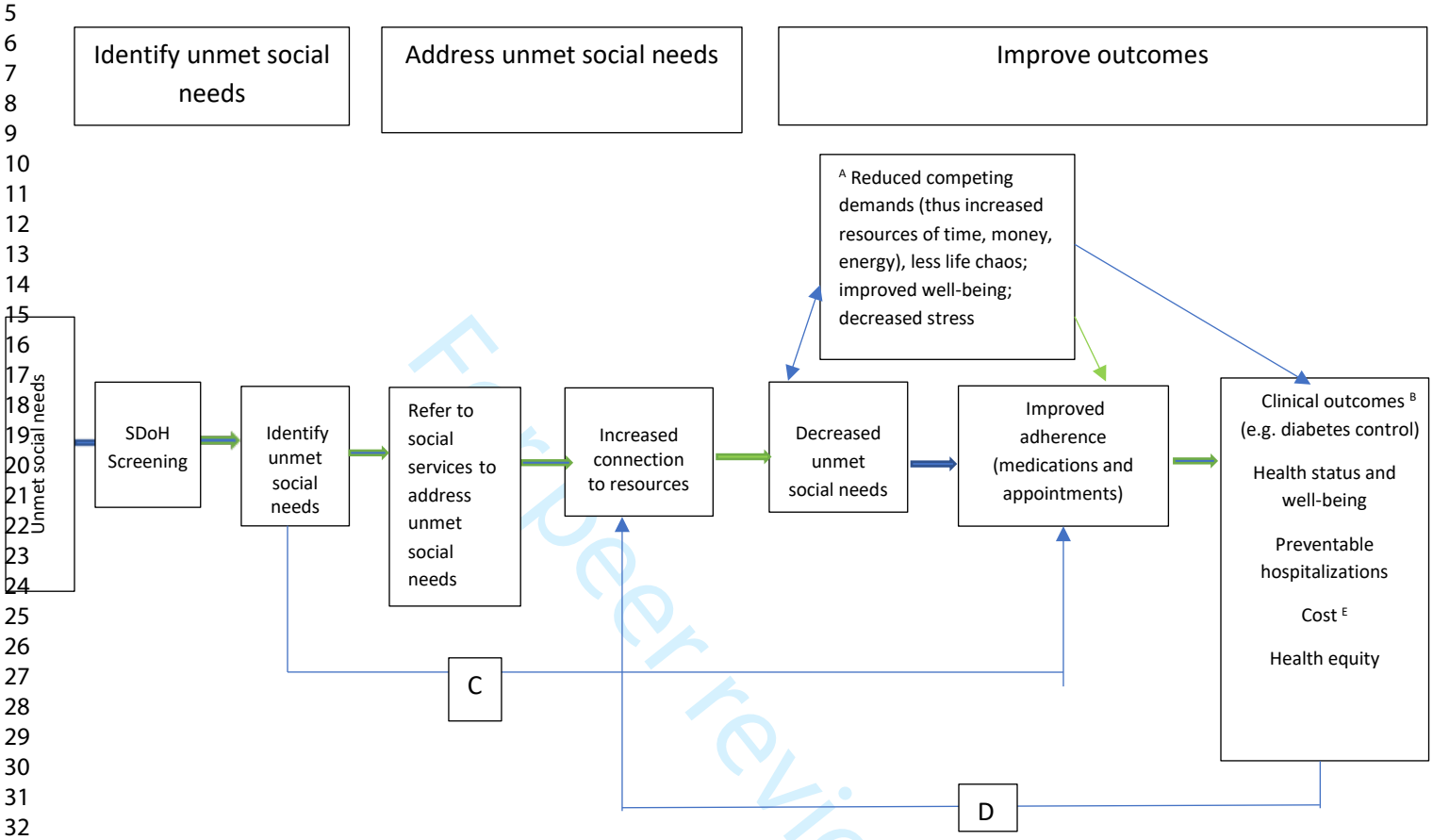


**Figure 2.**



**Appendix A. Participant Informed Consent**

**STUDY FACT SHEET**

**Study Title:** The Effects of Screening and Referral for Social Determinants of Health on Veterans' Outcomes

**Name of Study Lead (also called "Principal Investigator")**: Deborah Gurewich, PhD

Name of Study Lead at your VA (also call "Local Site Investigator"): (insert relevant name)

**1. What is the purpose of the study?** To understand how the Veterans Health Administration (VHA) can best help Veterans who have *resource needs*. *Resource needs* are also called social determinants of health. These are things like having trouble paying for housing or a hard time paying important bills, like electric or gas bills.

**2.Who is invited to participate?** You are eligible to participate if you

a) have heart disease or cardiovascular disease (CVD) or are at risk for heart disease (for example, because you have high blood pressure), *and*
b) get primary care at the Boston, Charleston, or Philadelphia VA Healthcare Systems.

**3. What does the study involve and how long will it last?** The study has two parts.

In **Part One**, someone from the research team will call you. They will want to talk for about 30 minutes. They will go over the study and answer any questions you might have. Next, they will conduct a brief questionnaire with you about your resource needs (for example, they will ask about your housing). Depending on your answers, you may be eligible for Part Two of the study. If you are not eligible for Part Two, that will be the end of your participation in the study.

If you are eligible for **Part Two** of the study, you will be contacted by phone two more times – eight weeks and six months after the first telephone call. During these calls, a researcher will conduct brief questionnaires with you about your resource needs. These phone calls should take only 5-10 minutes.

For Part Two of the study, you will be randomly assigned to one of three study groups: A, B, or C (see Table 1). Being randomly assigned is like a flip of a coin for which group you would be placed in.

- Group A: Participants in this group will receive a postcard listing local and national VHA help lines that may help with resource needs.
- Group B: Participants in this group will receive a postcard and also a written list of resources (i.e., agencies and programs) tailored to each participant's specific resource needs.
- Group C: Participants in this group will receive a postcard, a written list of resources, and also be offered help from a social worker who is part of the research team. The social worker may contact you by phone to learn more about your resource needs and help you connect to agencies and programs. The social worker could contact the you by phone up to 5 more times.

If you are in Groups B or C, you might also be asked to participate in a phone interview. In contrast to the brief questionnaires described above, the phone interview will involve a longer list of questions and will take more time, we estimate 45-60 minutes. If you are selected for an interview, a member of the research team will contact you by phone between months 7 and 12. If you agree, the researcher will

then schedule a time that is convenient for you to conduct the interview. Before the interview begins, we will ask your permission to audio record the interview. If you do not want the interview recorded, that is Ok and you can still participate in the interview. During the interview you will be asked about your experience participating in the study. Veterans who participate in Part Two of study will be in the study for 12 months.

**Table 1. What Participants Will Receive by Study Group**

| Group A | Group B | Group C |
|---|---|---|
| • Postcard listing local and national VHA help lines | • Postcard listing local and national VHA help lines<br>• Resource sheet listing agencies and programs to address specific resource needs | • Postcard listing local and national VHA help lines<br>• Resource sheet listing agencies and programs to address specific resource needs<br>• Assistance from a Social Worker to help connect to agencies and programs |

**4. What are the benefits of participating?** People who participate in this study may have a better understanding of the resources that can help Veterans with resource needs. Your participation may also add much needed knowledge about resource needs among Veterans and how the VHA can better meet the needs of Veterans with resource needs.

**5. What are the possible risks or discomforts of participating?** Some people may feel uncomfortable or upset discussing resource needs during the telephone calls with research staff. You may choose to skip a question or stop the telephone call at any time. You can also withdraw from the study at any time. Some people may find the telephone calls inconvenient. We will make every effort to schedule phone calls when it is convenient for you and will try to keep them short. Finally, there is a general risk of loss of confidentiality, but we believe this risk is minimal.

**6. How will my private information be protected?** Information collected for this research study will be kept confidential as required by law and will not be shared with your care team. However, you are welcome to follow-up with your care team at any time during your participation this the study. The results of this study may be published for scientific purposes, but your record or identity will not be revealed unless required by law. We will store your information in ways we think are secure. We will store paper files in locked cabinets. We will store electronic files in computer systems with password protection and encryption. However, we cannot guarantee complete confidentiality. To help protect your personal information, we will assign you a study ID so that your identifiable information is not connected to you.

We will limit access to your personal information to members of the research team who need to review this information in order to conduct the study. In addition, a description of this study will be available at http://www.ClinicalTrials.gov as required by U.S law. This website will not include information that can identify you.

Your research records will be destroyed in accordance with the VHA Record Control Schedule (www1.va.gov/VHAPUBLICATIONS/RCS10/rcs10-1/pdf). Records will be destroyed when allowed in the following manner: Paper records will be shredded; electronic records and audio recordings will be destroyed in a manner in which they cannot be retrieved.

Participating in this study will not affect your VHA healthcare including your healthcare providers' ability to see your records as part of normal care and will not affect your right to have access to your records during and after the study is completed.

**7. What are the costs of participating in the study?** You will not be charged for any activities or procedures that are part of this study.

**8. Do I have to take part in this study?** No. Participating in the study is voluntary and if you refuse to take part in the study, there will be no penalty or loss of benefits to which you are otherwise entitled to from the VHA. There are also no consequences if you decide to withdraw from the study. In this instance, for data already collected prior to your withdrawal, the research team may continue to review the data already collected for the study but will not collect further information from you.

**9. Who do I contact about this study of I have questions?** If you have any questions about the research study, concerns or complaints, you can contact the project manager at 857-364-2350. If you have questions about your rights as a study participant, or want to make sure the study is valid, you may contact the VHA Central Institutional Review Board toll free at 1-877-254-3130. This is the Board that is responsible for overseeing the safety of human participants in this study. You may call them if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

**10. Will I be compensated for being in this study?** As a thank you for your participation, you will receive a $15 gift voucher to CVS for each brief questionnaire you complete and a $25 gift voucher to CVS if you participate in a telephone interview.

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BMJ Open

# Protocol for a randomized controlled trial evaluating the effects of screening and referral for social determinants of health on Veterans' outcomes



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|---|---|
| Journal: | *BMJ Open* |
| Manuscript ID | bmjopen-2021-058972.R2 |
| Article Type: | Protocol |
| Date Submitted by the Author: | 12-Aug-2022 |
| Complete List of Authors: | Gurewich, Deborah; VA Boston Health Care System Jamaica Plain Campus, Center for Healthcare Organization and Implementation Research<br>Kressin, Nancy; Boston University School of Medicine, General Internal Medicine<br>Bokhour , BG; Boston University School of Public Health,<br>Linsky, Amy; VA Boston Health Care System Jamaica Plain Campus<br>Dichter, Melissa; VA Medical Center Corporal Michael J Crescenz<br>Hunt, Kelly J.; Ralph H Johnson VAMC<br>Fix, G; VA Edith Nourse Rogers Memorial Veterans Hospital<br>Niles, Barbara; VA Boston Healthcare System, National Center for PTSD; Boston University School of Medicine, Psychiatry |
| Primary Subject Heading: | Research methods |
| Secondary Subject Heading: | Cardiovascular medicine, General practice / Family practice, Health policy, Health services research |
| Keywords: | Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Adult cardiology < CARDIOLOGY |
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**Title Page**

# Protocol for a randomized controlled trial evaluating the effects of screening and referral for social determinants of health on Veterans' outcomes

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Key Words: social determinants of health, randomized control trial, primary care, Veterans, cardiovascular disease

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**Abstract**

*Introduction*: Health policy leaders recommend screening and referral (S&R) for unmet social needs (e.g., food) in clinical settings, and the American Heart Association recently concluded that the most significant opportunities for reducing cardiovascular (CVD) death and disability lie with addressing the social determinants of CVD outcomes. A limited but promising evidence base supports these recommendations, but more rigorous research is needed to guide health care-based S&R efforts. Funded by the Veteran Health Administration (VA), the study described in this paper will assess the efficacy of S&R on Veterans' connections to new resources to address social needs, reduction of unmet needs, and health-related outcomes (adherence, utilization, and clinical outcomes).

*Methods and analysis*: We will conduct a 1-year mixed-methods randomized controlled trial at three VA sites, enrolling Veterans with CVD and CVD-risk. 880 Veterans experiencing one or more social needs will be randomized within each site (N=293 per site) to one of three study arms representing referral mechanisms of varying intensity (screening only, screening and provision of resource sheet(s), screening and provision of resource sheet(s) plus social work assistance). For each Veteran, we will examine associations of unmet social needs with health-related outcomes at baseline, and longitudinally compare the impact of each approach on connection to new resources (primary outcome) and follow-up outcomes over a 12-month period. We will additionally conduct qualitative interviews with key stakeholders, including Veterans to identify potential explanatory factors related to the relative success of the interventions.

*Ethics and dissemination*: Ethics approval was obtained from the VA Central Internal Review Board on July 13, 2021 (Reference #: 20-07 – Amendment No. 02). Findings will be disseminated through reports, lay summaries, policy briefs, academic publications, and conference presentations.

*Trial registration*: NCT04977583.

**Article Summary**

Strengths and limitations of this study

- Prior studies have examined cross-sectionally how addressing unmet needs is associated with health outcomes, but we will examine these associations longitudinally, which will allow a better assessment of causality and possible mechanisms for associations.
- We will conduct this study within the largest integrated health system in the United States – the Department of Veterans Affairs - which will provide an opportunity for widespread dissemination within this health system.
- Often RCTs end data collection with their outcomes data but for this study, we enhance our findings to understand facilitators, barriers and potential explanatory factors related to the relative success of the interventions.

## INTRODUCTION

Social Determinants of Health (SDH) are "the structural determinants and conditions in which people are born, grow, live, work and age."[1] These conditions shape the degree to which basic needs are met both at the individual-level (e.g., housing, food, social connections) and the community-level (e.g., safe neighborhoods). They also shape health trajectories as recent estimates suggest that clinical care accounts for less than 20% of modifiable health outcomes whereas other factors, including SDH, are more significant drivers of morbidity and mortality.[2,3] Consequently, there is consensus that improving population health will require health care delivery systems, including the Veterans Health Administration (VA), to address unmet social and economic needs (hereafter: unmet needs), rather than addressing disease from only a biomedical perspective.

The relationship between unmet needs and health is strikingly evident for patients with or at risk for cardiovascular disease (CVD), [4,5] the leading cause of morbidity and mortality in the US.[6] For example, lower socioeconomic status is associated with greater prevalence of CVD risk factors and higher mortality from CVD[7-9]; the risk for myocardial infarction is highest in the first year of unemployment and increases with the number of job losses[10]; and lack of social support is associated with increased CVD mortality.[11] Thus, the American Heart Association recently declared that, "at present, the most significant opportunities for reducing death and disability from CVD in the US lie with addressing the social determinants of cardiovascular outcomes."[4]

The American Heart Association's recommendations, as well as similar recommendations from other leading health policy groups[1 12 13] rests on limited, yet promising, evidence that implementing systematic screening and referral (S&R) for unmet needs leads to greater receipt of resources that address identified needs[14,15] as well as reduction in unmet needs.[16] Such a process can potentially improve both proximal outcomes, such as adherence to medications and care appointments[17], as well as more distal outcomes, such as overall health.[18-21] However, much of the limited evidence on programs to address unmet needs is based in pediatric or specialized settings (e.g., women's health clinics), or on interventions targeting a single need, such as food insecurity.[22] Importantly, as far as we know, there are no randomized controlled trials (RCT) demonstrating the impact of systematic S&R for unmet needs on patients' connection to resources or other utilization and health outcomes in the general adult ambulatory care setting nor among a Veteran population. In short, there is no definitive guidance on how best to screen for and address unmet needs in clinical settings, creating a key barrier to implementing this practice in health care delivery systems.[23]

The criteria prioritizing access to VA services to those with financial need, in addition to those with service-related health conditions, results in many Veterans using VA health care services having low incomes, poor quality of life, and multiple comorbidities.[24,25] For these reasons, Veterans are at especially high risk of experiencing unmet social needs. For example, up 24% have been reported to experience food insecurity.[26] Given the simultaneously high prevalence of CVD and its risk factors and unmet needs among Veterans enrolled in the VA, Veterans' outcomes may be improved by comprehensively assessing and addressing unmet needs.

Currently, the VA administers system-wide clinical screens for two unmet needs (housing and food insecurity), yet other unmet needs are not routinely identified. While VA invests in social work (SW) to address a wide range of unmet needs, referral to and staffing of SW is highly variable across and within facilities. Many Veterans who could benefit from VA SW are not systematically identified and referred.

Further, there are no comprehensive data on Veterans' unmet needs, nor on their association with utilization and clinical outcomes (blood pressure and A1c control), hampering VA's ability to understand the effects of unmet needs and to target resources to address them. Finally, it is not known whether a social worker is required to address all unmet needs; it is plausible that a less resource- or personnel-intense process can address identified unmet needs and improve outcomes, as suggested by a recent pediatric S&R intervention. [19]

Funded by the VA's Health Services and Research Development division, the aim of this study is to assess the efficacy of comprehensive S&R among Veterans with or at-risk for CVD. Our study objectives are three-fold: 1) to describe the prevalence and distribution of unmet needs and identify their associations with baseline sociodemographic characteristics, adherence, utilization and clinical outcomes; 2) to compare the efficacy of three S&R strategies of increasing intensity on connection to new resources to address unmet needs (primary outcome) and on secondary outcomes of post-intervention change in unmet needs, adherence, utilization, and clinical outcomes; and 3) to identify barriers and facilitators to Veterans' connecting with resources to address unmet needs and getting needs met, and explore potential explanatory factors related to the relative success of each study arm.

## METHODS

### Overview

We are conducting a mixed method RCT (see Figure 1). The RCT protocol adheres to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) (see additional file). The study will take place three VA medical facilities between February 2021 and January 2024. For Objective 1, we will use baseline trial data gathered via a survey of Veterans at the study sites about their unmet needs and conduct quantitative analyses of survey, administrative, and clinical data to characterize the prevalence of unmet needs and their association with baseline outcomes (adherence, utilization, and clinical). For Objective 2, Veterans who screened positive for one or more unmet needs in the survey will be randomized within each site to one of three trial study arms defined by referral approaches of varying intensity. Quantitative analyses will longitudinally compare the effects of the referral approaches on the primary outcome (connections to new resources) and secondary outcomes (reduction in unmet needs, adherence, utilization, and health outcomes). Often RCTs end data collection with their outcomes data. For this study, we enhance our findings to qualitatively understand more about the facilitators, barriers and potential explanatory factors related to the relative success of the interventions. Therefore, for Objective 3, we will conduct qualitative interviews with a purposeful sample of key stakeholders who participated in the trial, including Veterans. We first describe the methods for the RCT (objectives 1 and 2) followed by the methods for the qualitative inquiry (objective 3).

### Evaluation Frameworks and Theory of Change

The study is guided by the Outcomes from Addressing SDH in Systems (OASIS) framework (see Figure 2).[27] This framework, developed by the study team is based on Maslow's Hierarchy of Needs model, which specifies that basic physiological needs (e.g., food, shelter) must be met before higher order needs (e.g., medication adherence) can be addressed.[28] Following OASIS, our theory of change is therefore that S&R will result in more patients connecting to resources to address those needs and that connection to resources will then have multiple downstream effects, including reduced needs and

enhanced adherence to medical treatments and care. In turn, better adherence will lead to improved outcomes.

The qualitative inquiry is additionally guided by Anderson's model of service utilization.[29] The model posits that a Veteran's connection to resources is determined by three interacting factors: predisposing factors (e.g., belief that available resources can meet their need); enabling factors (e.g., accessibility of identified resources), and need (e.g., level of perceived unmet needs). We will explore the degree to which these factors help to explain why some participants do or do not connect with resources to address unmet needs.

**Randomized Controlled Trial (Objectives 1 and 2)**

*Study Setting and Participant Eligibility*

For Objective 1, the study population will be comprised of Veterans with, or at risk for, cardiovascular disease (CVD) seen in primary care (PC) clinics of three urban VA medical centers. Veterans must have at least one PC visit in the year prior to the RCT start date to ensure that included study subjects are at least minimally engaged in VA care. Veterans who have impaired decision-making and/or are illiterate or have limited of no English proficiency are excluded from the study. Using data from VA's Corporate Data Warehouse (CDW), we will identify CVD patients as those with International Classification of Disease 10 diagnoses for coronary artery disease, cerebrovascular disease, or peripheral artery disease, and patients with CVD risk as having diagnoses of hypertension, diabetes mellitus (DM), or hyperlipidemia. For Objective 2, the study population will be comprised of the subset of Objective 1 participants who have one or more unmet needs.

*Study Procedures and Randomization*

On a weekly basis for the 12-month trial, we will identify potentially eligible Veterans with upcoming primary care appointments who will be mailed a recruitment package. The recruitment package will include a description of the study and elements of informed consent (see Appendix A), as well as an opt-out post card. Trained Research Assistants (RA) at each study site will contact Veterans (who have not opted-out) via telephone to explain the research protocol, review the elements of informed consent, secure verbal consent, and enroll the Veteran.

During this phone call, among enrolled Veterans, the RA will administer a brief survey to screen for nine unmet needs (housing, food insecurity, utility insecurity, transportation, legal needs, employment, safety, stress, social isolation), hereafter referred to as the "index screen." As part of the brief survey, each unmet need measure, if endorsed, is followed by a question about whether the Veteran is already receiving assistance for the need. To inform selection of the nine unmet needs, we used similar criteria to what other leading healthcare groups have used: 1) strength of the evidence linking the domain with CVD outcomes; 2) availability of a valid measure of the domain, 3) stakeholder priorities (input from VA providers, operational partners, and a Veteran consultant from the VA Veteran Engagement Resource Group), and 4) ability to meet the need with available resources in VA and/or community.[23,30,31] This process yielded the final set of 9 unmet needs. The unmet need measures themselves were then reproduced or adapted from previously validated measures.

If a Veteran reports no unmet needs, their study participation will be restricted to Objective 1. If a Veteran reports one or more unmet needs, the RA will randomize them to one of the three trial arms

using the sealed opaque envelope method. [32] The Data Analyst will be responsible for randomly generating the treatment allocations within the sealed envelopes. Once an envelope is open, the RA will inform the Veteran of their arm assignment.

*The Intervention*

Following the naming convention used by Centers for Medicare & Medicaid Services for the arms in the Accountable Healthy Communities trial, we have the following study arms: 1) Unmet needs screening and provision of a postcard with a list of generic VA resources (hereafter: "Screening" arm), 2) Screening and provision of a postcard with a list of generic VA resources plus provision of a tailored Resource Sheet listing available resources in VA and/or the community to address identified unmet needs (hereafter: "Awareness" arm), or 3) Screening and provision of generic resources plus provision of a tailored Resource Sheet plus Social Work (SW)-supported referral to assist with connection to resources for unmet needs (hereafter: "Assistance" arm). Administering the intervention will not be blinded to group assignment.

Screening: Veterans in the Screening arm will receive a post card listing the phone numbers for generic resources available to Veterans including the Veteran's VA Medical Center, VA Veterans Crisis Line, and National Call Center for Homeless Veterans. The post card will be included in the initial recruitment packet mailed to all potential study participants.. The screening arm reflects enhanced usual care. At present, VA systematically screens for only 2 of the 9 unmet social needs (housing and food insecurity) being assessed in this study and while VA refers Veterans to the resources listed on the post card, it is on an as-needed basis, not as part of usual care. We included the generic resource post card to address ethical concerns raised by the VA Central Internal Review Board about assessing unmet needs without offering any resources.

Awareness: Veterans in the Awareness arm will receive the post card listing generic resources as described above. Additionally, for each unmet need identified through the index screen, Veterans will receive by mail a tailored Resource Sheet that will include the names of available resources within VA and/or the local community that can help address the identified need(s). During the index screen, the RA will additionally ask participants if they would like to receive the Resource Sheet(s) as an email attachment. For Veterans who respond affirmatively, the RA will send the Resource Sheets as an email attachment during the index screen phone call and offer to review its content with them. To ensure the Resource Sheets stay current, the RA will contact listed programs monthly for current contact information and ability to accept referrals.

Assistance: Veterans in the Assistance arm will receive the post card listing generic resources and tailored Resource Sheets as described above. Additionally, during the in-clinic encounter, the RA will offer these Veterans assistance from a Social Worker specifically hired and trained (one per site) to support Veterans with connecting to resources. With Veteran assent, the SW will contact the Veteran by phone within two business days of the in-clinic encounter. During this initial call, the SW will use proven motivational interviewing methods to develop an action plan for the Veteran to connect to needed resources. [33,34] The SW will conduct follow-up by phone one week after the action plan development, with projected subsequent phone outreach every two weeks for up to seven weeks. At each call, the SW will review progress and as needed, employ motivational interviewing methods to re-affirm the action plan and/or modify the action plan to address unexpected barriers.

*Fidelity*

The research RAs and SWs responsible for delivering the intervention will be provided written Standard Operation Procedures (SOP) detailing their roles and training on their respective SOPs. The SWs will additionally complete a training module on Motivational Interviewing. We will assess fidelity via data captured in REDCap (detailed below) and monitor the quality of calls with participants as part of regular check-ins (weekly for the first few months of the trial but likely reducing to monthly thereafter).

*Data Collection and Management*

All data will be collected by RAs and SWs uninvolved in the medical care of patients. All study participants will be asked to complete a brief telephone-based survey to assess unmet needs during the index screen. We refer to this as Survey A. All RCT participants will be asked to complete two additional brief telephone-based surveys. Survey B will occur eight weeks after the index screen, when the RA will assess if trial participants connected to any new resources in the intervening time, and if so, to which one(s). Survey C will occur six months after the index screen, when the RA will re-screen all trial participants for unmet needs. Participants will receive a $15 gift voucher for each survey they complete. The 12-month recruitment period started May 2, 2022 and all follow-up is planned to be complete by April 28, 2023. For participants randomized to the Assistance arm, SWs will capture their interactions with participants, including the timing, duration, and outcomes of their interactions. Data will be recorded via the REDCap system and will be cleaned and checked for accuracy by the project manager and data analyst. Survey data will be merged with administrative data from the VA Corporate Data Warehouse (CDW) within the VA Informatics and Computing Infrastructure. CDW includes demographics, diagnoses, vital signs, lab values, prescriptions, and data on service use. Only the principal investigator and study team members conducting data analyses will have access to the data set.

*Planned Outcomes*

Table 1 provides a complete list of planned outcome measures for Objectives 1 and 2. The primary outcomes for Objective 1 will be various measures of treatment adherence, utilization, and clinical outcomes. The primary outcome for Objective 2 will be connection to new resources to address unmet needs. Connection to resources will be defined as a Veteran connecting to one or more new resources since the index screen, as indicated by their responses to the question, “Since you completed the unmet need social need screen on (insert date), were you able to connect with any of the programs or resources to help with (insert need(s) identified)?” Secondary outcomes will be reduction of unmet needs, various measures of treatment adherence, utilization, and clinical outcomes. Our rationale for this ordering of outcomes for Objective 2 is the importance of understanding whether S&R leads to connection to new resources, the first step in our conceptual model (see Figure 1) that we anticipate will, in turn, lead to improved adherence, utilization, and ultimately, clinical outcomes. As further rationale for considering clinical outcomes as secondary, we posit they may be difficult to change over the study’s time-limited 12-month period. Moreover, while much existing literature demonstrates associations between unmet needs and clinical health outcomes, there is a dearth of preliminary data assessing the impact of interventions (e.g., S&R) on these clinical outcomes. This precluded us from reliably estimating effect sizes for comparisons across intervention arms or needed sample size to adequately power such comparisons.

*Sample Size Calculations*

Power analyses were used to determine sample size based on an effect size estimate for our primary outcome from a prior study. [14] Our sample size (N=880) ensure adequate power (80%) to detect small-to-medium effect sizes for each of the primary and secondary outcomes even if the attrition rate for survey B and survey C are both as high as 50%. The team's prior study with a demographically similar Veteran population found only a 35% attrition rate.[35]

*Analysis*

Objective 1: We will generate descriptive statistics (e.g., proportions, 95% confidence intervals) to characterize the prevalence and distribution of each of the eight unmet needs at baseline across all study sites. We will next conduct inferential analyses to examine associations between unmet needs and sociodemographic characteristics (including race and ethnicity) as well as baseline outcomes (i.e., adherence, utilization, and clinical outcomes drawn from CDW data in the 12-months before the index screening for each Veteran). General linear mixed models (GLMM) will be used to control for the nesting of patients within sites, and logistic models will be used as appropriate for binary variables. Variables found to have statistically significant associations with unmet needs will be entered into multivariable models to better understand the correlates of each need. Bonferroni-corrected significance levels will control for multiple comparisons.

Objective 2: We will compare connection to new resources at 8-weeks post-index screen across the study arms. GLMM will be used to control for the nesting of patients within sites. In all regression models, patient-level intercepts and slopes will be treated as random effects. In addition to examining how the intervention conditions influence connection to new SDH resources, we will conduct supplemental exploratory analyses to examine whether there is differential impact between the three intervention arms on connection to new SDH resources among Veterans defined by differing sociodemographic characteristics including race and ethnicity.

Using a difference-in-difference approach, we will compare the secondary outcomes (unmet need reduction, adherence, utilization, and clinical outcomes) across study arms. We will examine whether changes from baseline at 6-months and 12-months post-referral differ across the three arms in a series of GLMM analyses. As with the other analyses, all models will treat patient-level intercepts and predictors as random effects. Similar analyses will be used to examine differences across our three study arms in change from baseline in the proportion of unmet needs among the sub-sample of participants who complete the re-screening at 6-months post-referral. To the extent that we discover differences across intervention arms in any of our more distal outcomes, we will also conduct exploratory analyses to test appropriate causal mediational paths as proposed by the OASIS framework using a series of GLMM analyses.

Finally, we will conduct additional analyses controlling for connection to SDH resources prior to enrollment in our intervention because it is possible that individuals already connected to resources before enrolling in our intervention may be more likely to seek out additional support/resources (e.g., because they already have successful experiences using VA or non-VA resources to meet certain unmet needs) or less likely to seek out additional support/resources (e.g., because they feel they already have the support they most need).

For all analyses, we hypothesize that providing a tailored Resource Sheet plus SW support (Assistance arm) will generally have a larger impact on outcomes than providing a tailored Resource Sheet alone (Awareness arm). We do so because navigating the social service delivery system can be challenging and may be especially challenging for Veterans experiencing unmet social needs. This means that simply being made aware of available resources may be an insufficient mechanism for connecting participants to resources. In contrast, being made aware of resources *and* provided navigation assistance may enable participants to overcome barriers and by extension increase the likelihood of connecting to resources. However, it will be beneficial to know if either the tailored Resource Sheet alone or provision of generic resources alone (Screening arm) is sufficient to produce comparable changes in outcomes among Veterans with certain unmet needs or among Veterans with fewer unmet needs. If true, future implementation research could create tailored interventions that funnel the resources for more time- and cost-intensive referral strategies to only those Veterans who need it most.

**Qualitative Inquiry (Objective 3)**

*Study Setting and Participant Eligibility*

We will recruit for qualitative interviews a purposeful sample of two stakeholder groups: 1) Veterans enrolled in the RCT (N=60), and; 2) representatives of the VA and community programs to which trial participants are referred (N=15). If thematic saturation is achieved before we reach these targeted sample sizes, we will stop recruiting. For the Veteran interviews, we will seek three Veteran types (20 per type): Veterans who did not connect to new resources; Veterans who connected to at least one new resource but did not have their unmet need(s) met, and Veterans who connected to new resources and had one or more needs met. This sampling plan will allow us to understand the conditions that facilitate or impede a Veteran connecting to resources, and the conditions under which resources do or do not address a Veteran's needs. Veterans who participate in a qualitative interview will receive a $25 gift voucher. For the VA and community program representatives, we will seek up to five of the most frequently used programs at each study site. We will first identify all VA- and community-based programs that trial participants used because of the intervention based on data derived from Survey 2 (see Data Collection). We will then seek up to five of the most frequently used programs at each study site. By concentrating on the most highly used programs, this sampling plan will allow us to understand the experience of programs more likely to "feel" the intervention.

*Data Collection and Management*

All data will be collected by study RAs who are uninvolved in patient care. Interviews will be conducted by phone using a semi-structured interview guide. We will ask Veterans about their experience participating in the trial (e.g., being screened, receiving resource sheets); experience with the unmet needs they identified; decision-making around accessing resources; and experience connecting to and using resources to address unmet needs. We will ask representatives of VA- and community-based programs about their funding structure and services provided; experiences with increased demand for their services during the trial period; and the factors that facilitate and impede addressing Veterans' needs. Interviews will be digitally audio-recorded, with the permission of each respondent. De-identified audio-recordings will be transcribed by a premier service provider for the VA. The study team will store recordings on a secure VA server and will be password protected. All names and places mentioned will be deleted to protect confidentiality.

*Analysis*

We will transcribe interviews verbatim and employ both deductive and inductive coding methods. For the former, codes will be informed by the previously described Anderson model of service utilization.[29] Additional emergent codes will be identified, grounded in the data. Coding will be guided by the constant comparative method.[36] That is, previously coded material will be constantly compared to the new data to determine whether the same concept is being expressed and, if so, to be sure that all exemplars of that concept are assigned to the most recently refined category. After coding is complete, code output will be analyzed to identify themes within and across sample strata.

**Patient and Public Involvement**

During the study design process, we engaged a Veteran consultant from VA's Veteran Engagement in Research Group to provide input on the intervention, including the burden of being screened for multiple unmet needs and receiving facilitated referral services. Veterans will not be involved in the recruitment to and conduct of the study. We will disseminate findings via the Veteran Engagement in Research Group, as well to individual study participants, upon request. .

**ETHICS AND DISSEMINATION**

This study protocol was approved by the VA Central Internal Review Board (Reference #: 20-07 – Amendment No. 02). A Data and Safety Monitoring Board (DSMB) will oversee the study. DSMB is an independent review board chartered by the VA Health Services Research and Development Service that meets at specified intervals and requires routine reporting from the PI. The PI will follow a specific Data and Safety Monitoring Plan, which has been reviewed and approved by the DSMB. We will conduct monthly assessments with each trial site to monitor serious adverse events. Should we receive any negative feedback from research subjects or have any unexpected serious or adverse events as reported by site staff, the Principal Investigator will report this information to the DSMB), Central Internal Review Board, and R&D immediately.

We are conducting a benign behavioral intervention and while the risks of adverse events are thus minimal, there is the potential that some participants will get upset answering questions about unmet social needs. To protect against this risk, we will train study RAs to be sensitive to the individual needs of each participant and to create an environment that feels safe and nonjudgmental. RAs will also be trained to remind participants that they may decline to answer any survey question or discontinue with the surveys at any time. We will additionally establish procedures for the intervention research staff to connect patients with site staff who can assist and facilitate referrals to services and providers within the VA, as needed.

The study results will be disseminated regardless of effect direction and size through publications in peer-reviewed journal and presentations at conferences. Final data sets underlying all publications resulting from this research will be shared outside the VA. Quantitative data meeting VA standards for discloser to the public will be made available within 1 year of publications. Prior to distribution, a local privacy officer will certify that the data set contains to Protected Health Information, Personal Identifiable Information or VA Sensitive Information prior to release outside VA. Qualitative data (i.e., transcripts) will not be shared. The sensitive nature of the study data precludes asking participants to

consent and grant authorization as required by the Health Insurance Portability and Accountability Act for disclosing data outside the VA.

## DISCUSSION

This study will provide much-needed evidence to document the prevalence of Veterans' unmet needs at three large urban VA Medical Centers, inform how best to address unmet needs, and assess how such a process can affect adherence, utilization, and clinical outcomes. If any of our intervention study arms demonstrate greater improvements in one or more study outcomes overall or for particular Veteran types (e.g., those with certain unmet needs), these findings can be tested and spread through future implementation research and processes. Importantly, the addition of our stakeholder interviews and analysis is unique to most clinical trials and will help to identify barriers and facilitators to future implementation as well as potential needed modifications to the intervention. Doing so will facilitate future uptake of the intervention should it prove effective. Further, our focus on the sentinel condition of CVD may help bridge the substantial sociodemographic gap in life expectancy related to CVD, and our methods can be used to examine the effects of interventions to address unmet needs on other conditions.

Table 1. Planned Outcomes for the RCT

| Outcome | Data Source | Description |
|---|---|---|
| PRIMARY OUTCOME | | |
| Connection to new resources | Survey B[1] | Veteran connecting to one or more new resources 8 weeks after index screen. |
| SECONDARY OUTCOMES | | |
| Unmet need reduction | Surveys A & C[1] | Measured two ways: 1) one or more of index needs no longer identified as unmet at 6-month rescreen, and; 2) percentage of index needs not reported as unmet at 6-month re-screen. |
| Preventable hospitalizations | CDW[2] | Prevention Quality Indicators using Agency for Healthcare Research and Quality criteria.[37] |
| Urgent care utilization | CDW[2] | Emergency Department and urgent care visits. (CDW[1]) |
| Medication adherence | CDW[2] | Proportion of days covered of each CVD and CVD risk factors medication.[17,38] |
| Clinic visit appointment attendance | CDW[2] | Proportion of PC and cardiology appointments classified as no-show, relative to the total number of appointments scheduled in both.[39] |
| Blood pressure (BP) | CDW[2] | Controlling for antihypertensive medications treatment intensification, using methods from prior work.[40] |
| Hemoglobin A1c (HbA1c) | CDW[2] | To ensure values reflect health status around time of index screen and 12-month follow-up window, we will only include Veterans with DM who have an Hba1c in the 6 months prior to each time point. |

[1] Described under Data Collection.

[2] VA Corporate Data Warehouse (CDW).

escribed under Data Collection.

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**Author Statement**: DG, NK, BB, AL, MD, KH, GF and BN made substantial contributions to the conception and design of the study; DG drafted the work and NK, BB, AL, MD, KH, GF and BN substantially revised it. All authors have approved the submitted version and have agreed both to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated resolved, and the resolution documented in the literature. The authors also appreciate the contributions of Jolie Wormwood, Rory Ostrow, and our Veteran consultant.

**Funding**: This study is funded by Health Services Research and Development (IIR 19-013). The views in this article are those of the authors and do not necessarily reflect the position or policy of the VA or the United States government. Dr. Fix is a VA HSR&D Career Development awardee at the Bedford VA (CDA 14-156).

**Conflicts of Interest**: The authors declare that they have no conflicts of interest.

**Word Count**: 4693

**Figure 1. Legend**

On a weekly basis for the 12-month trial, we will identify potentially eligible Veterans with upcoming primary care appointments. Trained Research Assistants (RA) will contact Veterans to explain the research protocol, review the elements of informed consent, and secure verbal consent. During this phone call, if verbal informed consent is obtained, the RA will screen for unmet needs (hereafter: "index screen"). If a Veteran reports no unmet needs, their study participation will be restricted to Objective 1. If a Veteran reports one or more unmet needs, the RA will randomize them to one of the three trial arms. Trial participants will be re-surveyed 8-weeks after the index screen to assess resource connection and 6-months after the index screen to assess unmet need reduction.

**Figure 2. Legend**

Green Links are supported by data; blue links need further investigation

[A] For patients with multiple unmet social needs, resolution of one need may enable them to address another. Reduced competing demands includes freeing up various resources (money, time, energy) to address other needs, which in turn can affect health outcomes.

[B] Clinical outcomes may include but are not limited to conditions where adherence to therapy directly impacts outcomes, such as hypertension, diabetes, and asthma.

[C] Identification of unmet social needs may be beneficial, even without referring to resources. For patients with transportation problems, for example, delivering prescriptions through mail order can bypass the barrier posed by the unmet transportation need without directly addressing it.

[D] Improved outcomes, such as improved well-being, may help patients connect to resources

[E] Costs may be reduced through improved control of chronic conditions, such as hypertension, which could avert costly future admissions for stroke or target organ damage. But increased costs to address unmet social needs may affect the equation for other conditions.

Figure 1. Study Design

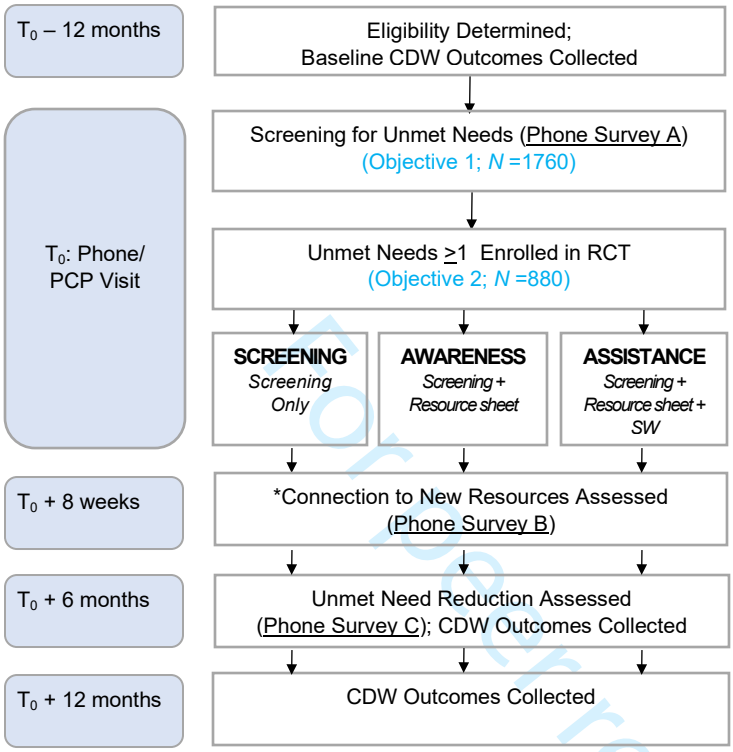
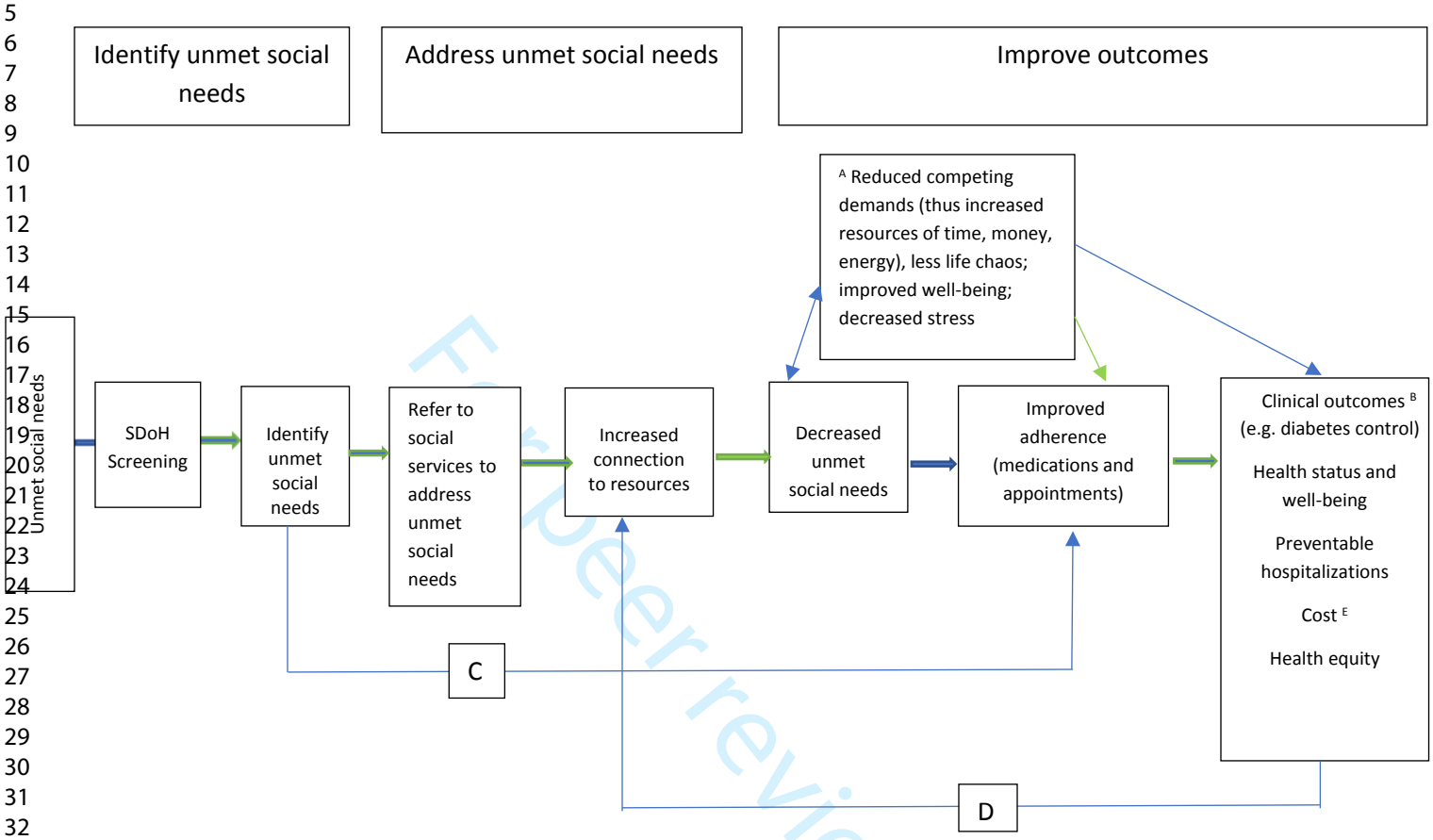


**Figure 2.**



**Appendix A. Participant Informed Consent**

**STUDY FACT SHEET**

**Study Title:** The Effects of Screening and Referral for Social Determinants of Health on Veterans' Outcomes

**Name of Study Lead (also called "Principal Investigator")**: Deborah Gurewich, PhD

Name of Study Lead at your VA (also call "Local Site Investigator"): (insert relevant name)

**1. What is the purpose of the study?** To understand how the Veterans Health Administration (VHA) can best help Veterans who have *resource needs*. *Resource needs* are also called social determinants of health. These are things like having trouble paying for housing or a hard time paying important bills, like electric or gas bills.

**2.Who is invited to participate?** You are eligible to participate if you

a) have heart disease or cardiovascular disease (CVD) or are at risk for heart disease (for example, because you have high blood pressure), *and*
b) get primary care at the Boston, Charleston, or Philadelphia VA Healthcare Systems.

**3. What does the study involve and how long will it last?** The study has two parts.

In **Part One**, someone from the research team will call you. They will want to talk for about 30 minutes. They will go over the study and answer any questions you might have. Next, they will conduct a brief questionnaire with you about your resource needs (for example, they will ask about your housing). Depending on your answers, you may be eligible for Part Two of the study. If you are not eligible for Part Two, that will be the end of your participation in the study.

If you are eligible for **Part Two** of the study, you will be contacted by phone two more times – eight weeks and six months after the first telephone call. During these calls, a researcher will conduct brief questionnaires with you about your resource needs. These phone calls should take only 5-10 minutes.

For Part Two of the study, you will be randomly assigned to one of three study groups: A, B, or C (see table on page 2). Being randomly assigned is like a flip of a coin for which group you would be placed in.

- Group A: Participants in this group will receive a postcard listing local and national VHA help lines that may help with resource needs.
- Group B: Participants in this group will receive a postcard and also a written list of resources (i.e., agencies and programs) tailored to each participant's specific resource needs.
- Group C: Participants in this group will receive a postcard, a written list of resources, and also be offered help from a social worker who is part of the research team. The social worker may contact you by phone to learn more about your resource needs and help you connect to agencies and programs. The social worker could contact the you by phone up to 5 more times.

If you are in Groups B or C, you might also be asked to participate in a phone interview. In contrast to the brief questionnaires described above, the phone interview will involve a longer list of questions and will take more time, we estimate 45-60 minutes. If you are selected for an interview, a member of the research team will contact you by phone between months 7 and 12. If you agree, the researcher will

then schedule a time that is convenient for you to conduct the interview. Before the interview begins, we will ask your permission to audio record the interview. If you do not want the interview recorded, that is Ok and you can still participate in the interview. During the interview you will be asked about your experience participating in the study. Veterans who participate in Part Two of study will be in the study for 12 months.

**What Participants Will Receive by Study Group**

| Group A | Group B | Group C |
|---|---|---|
| • Postcard listing local and national VHA help lines | • Postcard listing local and national VHA help lines<br>• Resource sheet listing agencies and programs to address specific resource needs | • Postcard listing local and national VHA help lines<br>• Resource sheet listing agencies and programs to address specific resource needs<br>• Assistance from a Social Worker to help connect to agencies and programs |

**4. What are the benefits of participating?** People who participate in this study may have a better understanding of the resources that can help Veterans with resource needs. Your participation may also add much needed knowledge about resource needs among Veterans and how the VHA can better meet the needs of Veterans with resource needs.

**5. What are the possible risks or discomforts of participating?** Some people may feel uncomfortable or upset discussing resource needs during the telephone calls with research staff. You may choose to skip a question or stop the telephone call at any time. You can also withdraw from the study at any time. Some people may find the telephone calls inconvenient. We will make every effort to schedule phone calls when it is convenient for you and will try to keep them short. Finally, there is a general risk of loss of confidentiality, but we believe this risk is minimal.

**6. How will my private information be protected?** Information collected for this research study will be kept confidential as required by law and will not be shared with your care team. However, you are welcome to follow-up with your care team at any time during your participation this the study. The results of this study may be published for scientific purposes, but your record or identity will not be revealed unless required by law. We will store your information in ways we think are secure. We will store paper files in locked cabinets. We will store electronic files in computer systems with password protection and encryption. However, we cannot guarantee complete confidentiality. To help protect your personal information, we will assign you a study ID so that your identifiable information is not connected to you.

We will limit access to your personal information to members of the research team who need to review this information in order to conduct the study. In addition, a description of this study will be available at http://www.ClinicalTrials.gov as required by U.S law. This website will not include information that can identify you.

Your research records will be destroyed in accordance with the VHA Record Control Schedule (www1.va.gov/VHAPUBLICATIONS/RCS10/rcs10-1/pdf). Records will be destroyed when allowed in the following manner: Paper records will be shredded; electronic records and audio recordings will be destroyed in a manner in which they cannot be retrieved.

Participating in this study will not affect your VHA healthcare including your healthcare providers' ability to see your records as part of normal care and will not affect your right to have access to your records during and after the study is completed.

**7. What are the costs of participating in the study?** You will not be charged for any activities or procedures that are part of this study.

**8. Do I have to take part in this study?** No. Participating in the study is voluntary and if you refuse to take part in the study, there will be no penalty or loss of benefits to which you are otherwise entitled to from the VHA. There are also no consequences if you decide to withdraw from the study. In this instance, for data already collected prior to your withdrawal, the research team may continue to review the data already collected for the study but will not collect further information from you.

**9. Who do I contact about this study of I have questions?** If you have any questions about the research study, concerns or complaints, you can contact the project manager at 857-364-2350. If you have questions about your rights as a study participant, or want to make sure the study is valid, you may contact the VHA Central Institutional Review Board toll free at 1-877-254-3130. This is the Board that is responsible for overseeing the safety of human participants in this study. You may call them if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

**10. Will I be compensated for being in this study?** As a thank you for your participation, you will receive a $15 gift voucher to CVS for each brief questionnaire you complete and a $25 gift voucher to CVS if you participate in a telephone interview.

SPIRIT Checklist

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