

The Effect of Screening and Referral for Social Determinants of Health on Veterans' Outcomes

NCT04977583

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VA C-IRB 20-07 PI/SC The Effects of Screening and Referral for Social Determinants of Health on Veterans' Outcomes – FACT SHEET

This document is provided to each participant in hard copy by mail. Verbal informed consent is affirmed during initial phone call.

STUDY FACT SHEET

Study Title: The Effects of Screening and Referral for Social Determinants of Health on Veterans' Outcomes (hereafter called the “**Veteran Resource Needs Study**”)

Name of Overall Study Lead (also called “Principal Investigator”): Deborah Gurewich, PhD

Name of Study Lead at your VA (also called “Local Site Investigator”): [REDACTED]

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 you by phone up to 5 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 calls described above, this phone interview would involve a longer list of questions and 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 7-12 months after your first call. If you agree to the interview, the researcher will then schedule a time that is convenient for you. 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
<ul style="list-style-type: none"> • Postcard listing local and national VHA help lines 	<ul style="list-style-type: none"> • Postcard listing local and national VHA help lines • Resource sheet listing agencies and programs to address specific resource needs 	<ul style="list-style-type: none"> • Postcard listing local and national VHA help lines • Resource sheet listing agencies and programs to address specific resource needs • 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 VA 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 and who will have access to it? 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 (LOCATION REDACTED). 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.

There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Central IRB, our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you.

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 if I have questions? If you have any questions, concerns, or complaints about the research study, you may contact your study coordinator at [REDACTED]. 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 \$15 for each brief questionnaire you complete, and \$25 if you participate in a telephone interview.

Thank you for your interest in our research study.

VA C-IRB 20-07 PI/SC The Effects of Screening and Referral for Social Determinants of Health on Veterans' Outcomes – PHONE SCRIPT

RECRUIT/IC/ENROLL PHONE SCRIPT

This script is used to review the Fact Sheet with the candidate and collect verbal informed consent over the phone.

Not Present: Hello, my name is _____, I'm calling from the [Name of VAMC]. I am trying to reach [Name of Veteran]. I'll call back another time, thank you. Is there a good time to try calling back?

Voicemail: Hello, my name is [name of research team member] and I work at the [Name of VAMC]. I wanted to speak with [Name of Veteran] about a letter we sent a few weeks ago regarding a research study. If you are interested in learning more about this study, please contact me at [phone number]. If you get my voicemail please leave your name, the best number to reach you at, and the most convenient times to reach you. Thank you.

Present: Hello, my name is [name of research team member] and I work at the [Name of VAMC]. I wanted to speak with [Name of Veteran] about a letter we sent you a few weeks ago about a research study.

(IF VETERAN ASKS "WHAT STUDY?" SAY, "VETERAN RESOURCE NEEDS STUDY". REFER TO THE STUDY WITH THIS NAME THROUGHOUT IF ASKED.)

1. Do you have some time now?

If Yes: We are conducting a research study about Veterans' resource needs. We sent you a letter a couple of weeks ago that included a Study Fact Sheet, describing the study. Do you remember getting it?

If Yes: (SKIP TO #2)

If No: I apologize for that. We can mail you another letter if you would like or I can also email the letter along with the Study Fact Sheet right now. What would work best for you?

Re-Send Packet: Okay, no problem. I will make sure a letter is sent to you. I just want to confirm your mailing address [confirm]. Thank you for your time. You can call me back when you get the packet, but this is not expected of you. Otherwise you'll hear from me in about 2 weeks." (END CALL)

Email Letter and Fact Sheet Now: (SECURE EMAIL ADDRESS AND EMAIL LETTER and FACT SHEET AND SKIP TO #4)

Don't Re-Send or Email Fact Sheet But Interested in Study (If Veteran does not have email access and doesn't want to wait for mail). (SKIP TO #4)

If No (they don't have time now): Ok, can I schedule another time to call you to describe the study and see if you might be interested in participating?

If Yes: (SCHEDULE A TIME)

If No: Thank you for your time. Good-bye. (END CALL)

2. Would you be interested in getting some more information about the study?

If not Interested: Thank you for your time. Good-bye. *(END CALL)*

If interested: *(GO TO #3)*

3. Ok great. The letter you received included a Study Fact Sheet. Do you have the Fact Sheet?

If YES: Great, it would be helpful to have the Study Fact Sheet in front of you, so we can go through it together. I can wait while you get it. *(WAIT AS NEEDED AND THEN GO TO #4)*

If NO: No problem at all. *(GO TO #3A)*

3a. If you have access to email, I could email the Study Fact Sheet to you. Would you like me to do that? *(IF YES OR NO, GO TO #4)*

4. I will now review important information about the study. You will have the opportunity to ask questions, and to confirm that you understand your role in the study, should you agree to participate. Does this sound OK? *(ADDRESS ANY QUESTIONS AND PROCEED)*

- The purpose of the study is to understand how VHA can help Veterans with resource needs. Resource needs are things like having trouble getting enough to eat, or a hard time paying the electric or gas bill. This research study does not involve any medical care. Importantly, we need all Veterans to participate in the study, whether or not they have resource needs to understand which Veterans do and do not have resource needs and how VHA can help Veterans connect with services that might help with those needs. Your participation in the study, whether you have resource needs or not would be of great value to the VA and Veterans.
- The study involves two parts:
 - In **Part One**, a member of the research team will conduct a brief questionnaire with you by phone about your resource needs. Depending on your answers, you may be eligible for Part Two of the study.
 - If you are not eligible for Part Two, your participation will end with Part One. The Part One questionnaire is estimated to take about 10 minutes to complete.

- If you are eligible for **Part Two***, following the Part One questionnaire, you will be randomly assigned to one of three study groups (random is like a flip of a coin).
- Participants in different study groups will receive varying levels of assistance with their resource needs. This is detailed in Table 1 in the Fact Sheet. I'll give you some time now to review that table and let me know when you're finished. **For Vets with no Fact Sheet:** Group one will receive a list of local and national VA help lines. Group 2 will additionally receive a longer list of resources for the specific needs they identify. Group 3 will receive the same lists and will also be offered assistance from a Social Worker. **(RESUME HERE)** It's important that you understand that you could be assigned to any one of these groups, and for research purposes you would not be able to switch groups. Your participation in Part Two of the study is expected to last 12 months but during this time, the study team will only contact you twice by phone to conduct two brief questionnaires, one in Month 2 and the second in Month 6. Each questionnaire will take less than 10 minutes to complete. If you are assigned to Group 3 and accept the assistance of a Social Worker, they will additionally contact you within 2 days of your enrollment in Part 2. In addition, between month 7 and 12, you may be invited to participate in one 45-60-minute phone interview. *(If the Veteran expresses the desire not to participate in an interview later, they can still participate in the study and remain in the arm to which they are assigned.)*

*** If Veteran asks, "What will make me eligible for Part Two?" you can say:**

Your eligibility for Part Two will be based on your responses to the Part One questionnaire. I am unable to tell you the type of responses that would make you eligible for Part Two – or which group you'd be randomly assigned to which is why it is important for you to understand, that by agreeing to participate today in Part One, you still may or may not be eligible for Part Two

4a. Do you have any questions so far about what the study involves and how long it would last?
(RESPOND TO ANY QUESTIONS ASKED)

- There are a few key additional points I want to highlight from the Study Fact Sheet. These include:
 - This study involves research.
 - Your participation is completely voluntary and if you choose to participate, you can withdraw at any time.
 - If you do participate, the information we collect from you will be kept confidential and your identity will not be revealed in any of the results we report or publish.
 - With any research study, there are risks and benefits – but for this study, we believe the risks are minimal. The risks include that you may get upset answering questions about resource needs, or you may find the phone calls inconvenient. We will do everything we can to minimize these risks. The **benefits** of participating are that you may have a better idea about available resources; and importantly, you may help VA to better serve Veterans with resource needs.

- There are no costs associated with participating in the study; and, as a thank you for participation, you will receive \$15 (DESCRIBE METHOD) for each brief questionnaire you complete. And, if you're selected (and agree) to participate in an interview, you will receive \$25 (DESCRIBE METHOD).

4b. Do you have any questions? (*RESPOND TO ANY QUESTIONS ASKED*)

5. Do you agree to participate in the study?

If No: Thank you very much for your time today. Goodbye. (*END CALL*)

If Yes: Thank you for agreeing to participate in this study! We really appreciate it. (*ENTHUSIASTIC RESPONSE*) If you have time now, about 10 minutes, we can get started with Part One right now.

If don't have time: When is a good time for you to answer some questions about your resource needs? (*SCHEDULE A TIME AND CONFIRM BEST CONTACT NUMBER*)

If have time now: Complete Index Unmet Need Screen (*Appendix D*).

6. Among participants who identified zero needs: Thank you for completing Part One of the study. It appears that you are not eligible for Part Two of this study, so today's call will end the study team's contact with you. We will be providing \$15 (DESCRIBE METHOD) (VERIFY MAILING ADDRESS.)

6a. Do you have any questions? (*RESPOND TO ANY QUESTIONS ASKED*)

Thank so much you for your time (*END CALL*).

7. Among Participants who identified one or more needs, randomize to one of three study arms. (*OPEN ENVELOPE ON TOP OF THE PILE*)

8. Among participants randomized to Arm 1 (Screening): Thank you for completing Part One of the study. You are eligible for Part Two of the study and have been randomized to Group 1. This means that in 8 weeks, I will contact you to ask a few more questions about your needs. I would like to remind you of the resource postcard that was included with the letter we sent to you inviting participation in the study and to contact those resources if you need them. Do you have any questions? (*RESPOND TO ANY QUESTIONS ASKED*). (*MENTION \$15 AND VERIFY MAILING ADDRESS.*) Thank you for your time.

9. Among participants randomized to Arm 2 (Awareness): Thank you for completing Part One of the study. You are eligible for Part Two of the study and have been randomized to Group 2. I would like to provide you with some written material about programs and agencies that might be able to help you with the needs you identified. I will mail you this material within the next two business days. If you like, I can also email the material to you right now and we can review it together over the phone. Would you like to do that?

If Yes to email: Great, I can email that to you right now. (*ASK FOR PARTICIPANT'S EMAIL ADDRESS AND SEND ENCRYPTED EMAIL. CONFIRM THAT PARTICIPANT RECEIVES IT.*)

If No to email: No problem. You can look for a written list of resources in the mail in the next several days.

9a. For clarity, we encourage you to review the resource sheet(s) and follow-up directly with one or more of the resources that are listed. I'd also like to remind you of the resource postcard we sent you and to reach out to those resources if you need them. In 8 weeks, I will contact you to ask a few more questions about your needs. Do you have any questions? (RESPOND TO ANY QUESTIONS ASKED). (VERIFY MAILING ADDRESS FOR \$15/RESOURCES.) Thank you for your time.

10. Among participants randomized to Arm 3 (Assistance): Thank you for completing Part One of the study. You are eligible for Part Two of the study and have been randomized to Group 3. I would like to provide you with some written material about programs and agencies that might be able to help you with the needs you identified. I will mail you this material within the next two business days. If you like, I can also email the material to you right now and we can review it together over the phone. Would you like to do that?

If Yes to email: Great, I can email that to you right now. (ASK FOR PARTICIPANT'S EMAIL ADDRESS AND SEND **ENCRYPTED** EMAIL. CONFIRM THAT PARTICIPANT RECEIVES IT.)

If No to email: No problem. You can look for a written list of resources in the mail in the next several days.

10a. I would also like to offer you the assistance of a Study Social Worker (SW), who can assist you to connect to the programs and agencies listed on the resource sheet(s) I've given you. Would you like to receive this assistance?

If No: I encourage you to accept this assistance because it can be helpful. Are you sure you don't want assistance from a SW to assist you to connect to services?

If does not want SW assistance: (GO TO #10b) (Note: Participant remains in Arm 3)

If wants SW assistance: (GO TO NEXT QUESTION)

If Yes: Terrific. The SW on the study team – his/her name is [insert name]-- will call you within two business days.

10b. For clarity, we encourage you to review the resource sheet(s) and follow-up directly with one or more of the resources that are listed. I'd also like to remind you of the resource postcard we sent you and to reach out to those resources if you need them. In 8 weeks, I will contact you to ask a few more questions about your needs. Do you have any questions? (RESPOND TO ANY QUESTIONS ASKED). (VERIFY MAILING ADDRESS FOR \$15/RESOURCES.)

Thank you for your time.