Pilot of Peers Enhancing Engagement for Pain Services

NCT05681520

February 23, 2023

PI name: [redacted]
Study Title: Pilot of Peers Enhancing Engagement for Pain Services

Information Sheet

SUMMARY

This is a research study seeking to understand how peer specialists may be able to help Veterans during treatment for chronic pain. We are interested in learning more about Veteran's experience working with peer specialists, in addition to their usual treatment with their pain team. Participation in the study will last approximately three months and take approximately five hours of your time.

PROCEDURES

If you choose to participate, first you will talk to a research staff member to learn about the study and make sure you are eligible. If you are eligible and agree to participate, we will schedule a time for you to participate in a telephone interview with a member of our research team. The interviewer will complete a series of questionnaires with you getting information about yourself, about your pain and how it may interfere with your life, how you currently manage your pain, your quality of life, and how you engage with healthcare. This telephone interview will take approximately 30 minutes.

Following this telephone interview, you will be introduced to a peer specialist and given a pedometer. The peer specialist is a Veteran who has chronic pain and uses VHA healthcare. You and the peer specialist will meet six times, every other week, for 30 minutes. The goal of meeting with the peer is to have additional support while you work with the pain team. The peer will provide support to help you cope with your pain and work towards improvements in your function and your quality of life. The peer may ask permission to audio record your sessions so that the researchers can understand what the peer specialist talks about during the sessions. The peer may also ask you to track your activity using the pedometer.

Following your work with the peer specialist (approximately 12 weeks after your first session), a member of our research team will reach out once more to ask you to participate in another telephone interview, similar to the first telephone interview, lasting about 30 minutes. Then, the interviewer will ask if you are willing to talk for an additional 30 minutes to share more about your experiences working with the peer specialist. The interviewer will ask permission to audio record your answers so that we can accurately capture your ideas.

RISKS

There are a few risks associated with being in a research study. One risk is that participation in research can cause a loss of privacy. We will do everything we can to protect your privacy and minimize this risk. In this study we may obtain information about which clinics or types of treatments you've received. We will keep this information about you as confidential as possible by keeping any information we collect from you coded by an ID number rather than your name or other personally identifiable information.

We will ask to make an audio recording of your sessions with the peer and of your patient experience interview if you participate in the study. These recordings are optional, but they help us accurately capture what happens in the study and what you think about the intervention. The recording will not be shared outside of the research and transcription team. The electronic audio recordings will be encrypted and stored securely behind VA's Firewall.

Only research staff will have access to the information collected in this study. This includes research study staff at the VA Connecticut Healthcare System. All research information will be secured behind VA firewalls on restricted research drives. Organizations that may look at and/or copy your research records for research, quality assurance, and data analysis include VA Regulatory Personnel (e.g., Department of VA Research & Development Committee) and VA Connecticut Institutional Review Board.

A second risk may be the experience of emotional distress while answering questions about your experience with VA healthcare for pain symptoms. Based on previous qualitative studies such as this one, the discomfort, if present at all, will be mild, transient and manageable. In most cases, we do not foresee individuals having difficulty. However, if you feel uncomfortable about any question, you can decline to answer and we will skip to the next question. You can let study staff know that you would like to stop your participation at any time. If, for any reason, you experience significant distress, we will discuss it with you and help you connect with your current mental health provider or assist with a referral to one. You also have the option of calling the study Principal Investigator, [redacted].

BENEFITS

By participating in this study, you may benefit from receiving additional support related to pain management. This might help you improve your function and quality of life. However, even if you do not benefit directly from this study, your participation may lead to improved healthcare for other Veterans.

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ALTERNATIVE TREATMENT
If you decide not to participate in this study, there will be no penalty to you. You will not lose any of your regular VA benefits, and you can still get your care from the VA the way you usually do. Your alternative to being in this study is not to participate.

CONFIDENTIALITY
We will do everything we can to ensure your information is kept private, however, there are certain situations in which your information may be given out if required by law. For instance, if it were learned through the research study that you were a danger to yourself or others, we are required to notify the authorities. If you express suicidal thoughts, we will contact your VA provider so that he/she is aware and can contact you for assistance.

Only research staff at the VA Connecticut Healthcare System will have access to the information collected in this study. We may also share your information with people who are in charge of reviewing and approving our research**,** for instance VA Connecticut IRBs and VA Regulatory Personnel. If information from this study is published or presented at scientific meetings, your name and personal information will never be used.

The Department of Veterans Affairs (VA) requires some information to be recorded in the VA electronic medical record for veteran and non-veteran research subjects. Therefore, if you participate in this study, a medical record will be created if you do not already have one. Notes from your visits, procedures, and laboratory tests will be included in this record. In addition to the research team, and the VA staff who provide clinical services, other researchers may be granted approval to access this information in the future. Federal laws and regulation that protect privacy of medical records will apply to your VA record.

PAYMENT
As compensation for your time, you will be mailed a $50 check following each set of questionnaires (approximately 30 minutes each time) and an additional $50 following the one-on-one interview about your experiences (approximately 30 minutes), for a total possible compensation of $150. Payment after completing each visit may take up to 6-8 weeks to be processed and is subject to withholding for outstanding Federal debts; for example, defaulted student loans, child support or back taxes. If you have any Federal debt, there is a possibility that you may not receive any money after your participation.

QUESTIONS
If you have any general questions about the study, complaints, or concerns, or you experience any distress related to the study, you can call the principal investigator, [redacted]

If you have questions about your rights as a study subject, or you want to make sure this is a valid VA study, you may contact the Research Office at [redacted].

PARTICIPATION IS VOLUNTARY
You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

FUTURE USE OF DATA
Your information or biospecimens collected as part of the research, even if identifiers are removed, will not be used, or distributed for future research studies.

INJURY
If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study subject with study procedures. Emergency and ongoing medical treatment will be provided as needed.