

Using Data
Analytics and
Targeted Whole
Health Coaching
to Reduce
Frequent
Utilization of
Acute Care
among
Homeless
Veterans

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Information Sheet (Waiver of Documentation of Informed Consent)



INFORMATION SHEET FOR “Using Data Analytics and Targeted Whole Health Coaching to Reduce Frequent Utilization of Acute Care among Homeless Veterans”

You are being invited to take part in a research study that is being funded by the Department of Veteran’s Affairs Health Services Research & Development. This study involves meeting with Peer Specialists who are trained in an approach called “Whole Health Coaching.” By doing this study, we hope to learn whether this approach improves Veterans’ health, keeps them out of the hospital, and helps them rely less on using the Emergency Department for their care. Your participation in this research study is voluntary. You may choose not to participate or leave the study at any time without penalty or loss of benefits to which you were otherwise entitled.

WHY IS THIS STUDY BEING DONE?

This research study is looking at a new approach (Peer Specialists trained in Whole Health Coaching, or “Peer Whole Health”). The purpose of this study is to evaluate Peer Whole Health as a way to reduce hospital stays or unnecessary Emergency Department visits of Veterans and improve their overall health outcomes. In Peer Whole Health, Veterans meet with a Peer (a fellow Veteran with lived experience in homelessness, substance use, and mental health) who is trained to provide Whole Health Coaching. The meetings with the Peer will focus on identifying your personal health goals and how to reach them, as well as linkage to needed VA and non-VA services. The Peer would also work with your primary care team to help you meet your personal health goals and other care needs. With this research we hope to find out if this approach is effective by comparing a group of Veterans who receive Peer Whole Health with a group of Veterans who receive usual care from their primary care team. The way we will learn about differences between the two groups is by doing interviews and surveys with participants. If the research is successful, our study team will work towards distributing Peer Whole Health to other VA sites and treatment programs.

WHAT WILL HAPPEN IF I PARTICIPATE IN THIS STUDY?

If you choose to participate, the research study staff will ask you to meet with a member of the research team over the phone or by video conference (e.g., VA Video Connect). You will be asked to answer a series of questions and fill out some surveys about your background. These interviews and surveys will cover your health and treatment history, including medical, mental health, and substance use. To protect your privacy, a Certificate of Confidentiality has been obtained for this study. You may withdraw from the study at any time, and you may refuse to answer any specific questions. Your name will also not be on any questionnaire or survey to ensure confidentiality. We will ask for your social security number to access your VA medical records only to obtain information on your medical history including the type and amount of health care services you receive from the VA. None of the information collected by the research

study team will be shared outside the VA. This will only be accessed by approved members of the study's research team. This session will take about 90 minutes.

After you complete this session, you will be assigned by a computer to one of the 2 groups; you will have approximately a 50% chance of being in the group that receives Peer Whole Health, and approximately a 50% chance of being in the group that receives usual primary care. Neither you nor the study staff can decide which group you will be assigned to – this is called randomization (like flipping a coin). Regardless to which group you are assigned you will continue receiving care as usual from your primary care team or other VA providers.

We plan to recruit a total of 220 unique Veterans for the study from three VA facilities (Palo Alto, Bedford, and Little Rock).

Peer Whole Health

If you are randomized to Peer Whole Health, you will be assigned to a Peer Specialist from the project team who will work with you for 24 weeks. You will meet with the Peer at least once per week for approximately one hour for the first 12 weeks and then every other week for an additional 12 weeks. The meetings can be either in person, by phone, or by video (e.g., VA Video Connect). In-person meetings will be encouraged during the first 12 weeks. To make it easier for you to participate in these sessions, the Peer Specialist will make every attempt to meet you where you are in the community. During your sessions with the Peer, he will work with you to create a Personal Health Plan based on your goals, values, and priorities. The Peer will share this Personal Health Plan with your primary care team so that they can include it in their treatment plans for you. The sessions will also involve the Peer learning about how you prefer to receive care from the VA and reasons for being hospitalized in the past year or visiting the Emergency Department. To help link you to the VA and non-VA care that is right for you, the Peer will review your medical records and communicate with your primary care team and other VA providers.

Usual Care

If you are randomized to this condition, you will continue to receive care from your primary care team and other providers in the VA as you and your providers see fit. You will not meet with a Peer trained in Whole Health, although you may pursue care from a Peer in VA as recommended or requested by your primary care team.

Follow-Up Interviews

Regardless of which group you are assigned to (Peer Whole Health or Usual Care) you will be contacted for 3-, 6- and 9-month follow-up interviews by phone and email, which may take place at the VA, over the phone, or by video, whichever is more convenient for you. These interviews will take about 1 hour each, and a member of the research team will ask you a series of questions and to fill out some surveys about your health. Again, you may withdraw from the study at any time and you may refuse to answer any specific questions. Because you may have moved or could be hard to contact when it comes time for these interviews, we ask that participants in the study provide us with some additional ways to find you. We ask that you give us the names, addresses and phone numbers of 3 people who would know your whereabouts, and can be

reached to give us this information. We also ask that if you have a probation officer or case manager, that you give us their name and contact information. Regardless of where you are, if we cannot speak to you directly, we will not tell anyone else what the study is about. Research team members will only ask for you, and if necessary, say that the call is about a “health survey”, but nothing more about the subject matter of the study.

Peer Whole Health Phone Interview

Only if you are randomized to the Peer Whole Health group, you may also be asked to complete an extra phone interview to share your thoughts and experiences meeting with a Peer trained in Whole Health Coaching and ways to improve the program. Up to 24 Veterans will be included in this portion of the study. Additionally, if you do not complete the entirety of the Peer Whole Health sessions you may still be contacted for a phone interview to share your thoughts on your participation. We will ask that this final interview be audio-recorded in order to transcribe and code the interview. Your identity will not be made known. The information from this interview will be transcribed into a written version that can be studied by the researchers. The transcription will be performed by a professional VA medical transcription agency specifically chosen for this study. You may refuse to participate in this interview portion of the study and still take part in the rest of the study.

Your safety will be monitored by the project staff throughout your time in this study. If at any time the research study members believe that you pose a danger to yourself or others, the researchers will need to break confidentiality, which includes making a report to the proper authorities and/or providing additional help to you as dictated by VA regulations and state law.

If you agree to participate, you may withdraw from the study at any time, and you may refuse to answer any specific questions. All information will be confidential and used only for the purposes of the research study. You may contact the site PI or a research assistant with any questions at any time. We will tell you if we learn of new information that could change your mind about taking part or continuing in this research study.

ARE THERE ANY RISKS OR DISCOMFORTS?

Any procedure has possible risks. The procedures in this study may cause all, some, or none of the risks listed. Rare, unknown, or unexpected risks also may occur. Nonetheless, precautions will be taken to further reduce any risks to you in this study. Specifically, you are encouraged to have any questions answered and concerns addressed to your satisfaction prior to being asked to provide consent.

It is possible that a few of the questions asked of you (e.g., those inquiring about stressful life circumstances; alcohol and drug use; mental health symptoms; history of homelessness) may cause you some discomfort. However, such questions should not cause you any more discomfort than the questions that are typically asked of other Veterans who receive primary or specialty care in the VA. These questions are not anticipated to cause you any harm.

ARE THERE ANY BENEFITS?

You will not benefit directly from being in this study. Your participation may benefit others in the future by contributing to the researchers understanding of homelessness among Veterans.

WHO WILL SEE MY INFORMATION AND HOW WILL IT BE PROTECTED?

Taking part in this study will involve collecting private information about you. There is the potential risk of loss of privacy and confidentiality of this information. To minimize this risk, this information will be protected in the following ways:

- Records will be kept locked in filing cabinets, on computers protected with passwords, only study staff will have access to this information.
- Information about study participants may be discussed at meetings with the other sites, but you will not be identified by name.

Information about you will be combined with information from other people taking part in the study. We will write about the combined data we have gathered. Any talks or papers about this study will not identify you by name or any other information.

We will use your social security number to access your VA computer records to obtain information on your medical history including the type and amount of health care you receive from the VA. The information collected for this study will be kept confidential. 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, or our local Research and Development Committee may look at or copy portions of records that identify you.

In attempting to contact you, the research assistant will explain to any other person whom they reach that s/he is trying to locate you regarding a health survey. We will not include your name on any interview forms. Instead, these documents will be given ID numbers that are not linked to you. The list that contains names, contact information, and ID numbers will be kept on computer files that can only be seen by project staff, and all data with personal information will be stored in locked file drawers.

This informed consent will not be used to prevent disclosures to local authorities of child abuse or neglect, or harm to self or others as dictated by VA regulations and state law. This form does not prevent you or a member of your family from releasing data about yourself or your involvement in this study, if you so choose.

WILL I RECEIVE ANY PAYMENT IF I PARTICIPATE IN THIS STUDY?

Regardless of your assignment to Peer Whole Health or Usual Care, you will be asked to complete an initial interview with research staff shortly after you agree to participate in the study (in-person, by phone, or by video conference) and three follow-up interviews (in-person, by phone, by video conference, or by mail) 3, 6, and 9 months later. You will be reimbursed \$50 after completing the initial interview and the 3- and 6- month follow-up interview and \$75 for completing the 9-month follow-up interview. If you are selected to take part in the phone interview to share your thoughts and experiences meeting with a Peer trained in Whole Health Coaching, after finishing the sessions, you will be reimbursed \$25 after completion of that interview. You will be paid by gift card, debit card, or direct deposit within 4-6 weeks. Only the

PI, Project Coordinator, and Research Assistants at [SITE] will have access to the information for your direct deposit payment.

WHO CAN I TALK TO ABOUT THE STUDY?

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 participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

Every reasonable safety measure will be used to protect your well-being. 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 was due to your not following the study procedures.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY: [SITE LEVEL INFORMATION TO BE ADDED]

AFTER HOURS: VA Crisis Communications Line at 1-800-273-8255

If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Local Site Principal Investigator [TO BE ADDED]. You may contact him at [TO BE ADDED]. You should also contact him at any time if you feel you have been hurt by being a part of this study. You may also contact your local VA patient advocate [TO BE ADDED].

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB) toll free at 1-877-254-3130.