

**Telehealth-delivered peer support to improve quality of life among Veterans with multimorbidity**

NCT05560451

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VA Puget Sound Health Care System  
RESEARCH INFORMATION STATEMENT

**VetASSIST:**  
**Telehealth-delivered peer support to improve  
quality of life among Veterans with multimorbidity**

**Principal Investigators:**

[Redacted]

**Research Staff:**

[Redacted]

**Co-Investigators:**

[Redacted]

**Researchers' Statement:**

We are inviting you to participate in a research study. The purpose of this Information Statement is to give you information you will need to help you decide whether to be in the study. Please read this form carefully. We may contact you by phone to determine your interest in and eligibility for the study. At that time, you may ask questions about the purpose of the research, what we are asking you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study. If you verbally consent (agree) to be in the study, we will ask your permission to audio-record some of the study activities, such as the health coaching sessions. You may consent to participate in the study even if you decline to be audio-recorded. The study activities you give your permission for will be securely stored as part of our study records. You may also contact our study team if you have any questions at [redacted].

**PURPOSE OF THE STUDY**

The purpose of this study ("VetASSIST") is to test whether virtual health coaching sessions with a trained Veteran peer improve health-related quality of life for Veterans with three or more long-term health conditions.

We are asking you to participate because you are a patient at VA Puget Sound Health Care System ("VA Puget Sound") and your medical records suggest you may have three or more long-term (chronic) health conditions. You may be eligible for the study if you:

- are age 18 years or older;
- have three or more long-term physical or mental health conditions;
- are willing to use your own phone or a VA-provided internet-connected device (such as a laptop or desktop computer, tablet, smart phone) with a web camera;
- receive care at VA Puget Sound Health Care System.

You will not need to come to a VA facility for any part of this study; all activities can be done from home.

This study is being conducted by VA Health Services Research and Development through a grant from VA Research and Development. The study is expected to take approximately 4 years during which time we plan to enroll approximately 294 Veterans from VA Puget Sound. If you enroll, your actual participation time will be about 1 year. You will be randomized (like flipping a coin) by computer to either the intervention or control (non-intervention)

group. You will have an equal chance of being assigned to either group. Your involvement in this study will depend on the group you are randomly assigned to. The study activities for each group are outlined below. Participants in both groups will continue to receive their usual health care from the VA.

### STUDY PROCEDURES

**Surveys (both groups):** Participants in both the intervention and control groups will complete two health surveys—one at enrollment and another a little more than one year after enrollment. You must complete the enrollment survey before you are assigned to a group. You will complete both surveys online with any device you use to access the internet (such as a laptop or desktop computer, tablet, smart phone). We will send you a link to complete the online surveys. If you are unable to complete the online survey, you will have the option to complete it over the phone or via videoconferencing with a study staff. Survey questions will collect information on your demographics (such as race/ethnicity, marital status, education, income, employment), military history (branch of service), physical and mental health status, health habits (diet, physical activity, sleep, medications), social support, and interactions with your health care team.

#### **Control (non-intervention) Group**

If you are assigned to the control (non-intervention) group, you will complete the enrollment survey and follow-up survey a little more than one year later (as described above). You will not be assigned a health coach or complete health coaching video sessions. During this time, you will continue to receive the same, usual health care from your VA care team.

#### **Intervention Group**

If you are assigned to the intervention group, you will complete the enrollment survey and follow-up survey one year later (as described above). You will be assigned a Veteran peer health coach who is trained in privacy and confidentiality and has completed in-depth instruction in health coaching and education. You will meet with your health coach 20 times over the course of one year. The first six sessions will each be up to 60 minutes and the remaining fourteen session will each be up to 30 minutes. During this time, you will continue to receive the same, usual health care from your VA care team in addition to the health coaching sessions.

Health coaching sessions will be conducted using video-conferencing technology through a VA-developed and approved application known as VA Video Connect (VVC). You will need to provide your email address or cell phone number to receive links to join the health coaching VVC sessions. If you consent, some of the health coaching sessions may be audio-recorded (video will not be recorded) for oversight of the coaches to ensure they are delivering the program as intended. Your health coach will:

- Provide health education, counseling, and links to community and VA resources to help you manage your chronic conditions;
- Help you set health goals and create plans to improve your physical and mental health, which may include managing symptoms of your chronic condition(s), managing stress or difficult emotions, eating a healthy diet, increasing physical activity, managing medications, and involving a loved one to get support for your health goals (if you choose);
- Enter notes into your VA health record about the information covered during your coaching sessions; and
- Serve as a contact between you, the VA clinic, the community, and study staff.

You may optionally involve a support partner of your choosing, such as a spouse/significant other, family member, or friend who can attend your health coaching sessions (any or all sessions). Your support partner does not need to live with you to participate. Your support partner can help you develop your health goals and plans, as well as work with you and your health coach to help you achieve your health goals.

**Voluntary satisfaction survey:** Participants in the intervention group may be asked to participate in a voluntary survey upon completion of the follow-up survey (approximately one year after enrolling in the study). The survey questions will ask about experiences with the health coaching intervention and ways it could be improved.

The timing and duration of study activities for both groups are summarized in the table below:

Study activity	When/How Often	Duration	Delivery
<b>Surveys (both groups)</b>	Enrollment Follow up (13-15 months after enrollment survey)	Up to 30 minutes each Total: Up to 1 hour	Online, phone, VA Video Connect
<b>Health coaching sessions (intervention group only)</b>	Weeks 1-6: Weekly Weeks 7-16: Every other week Weeks 17-52: Every 4 weeks	<ul style="list-style-type: none"> <li>Weeks 1-6: 60 minutes each</li> <li>Weeks 7-20: 30 minutes each</li> </ul> Total: 13 hours	VA Video Connect, phone
<b>Satisfaction survey (intervention group only)</b>	(13-15 months after enrollment survey)	Up to 20 minutes	Online, phone, VA Video Connect

### POTENTIAL RISKS AND DISCOMFORTS

Below are study-related risks that are known at this time. The potential risks to you will vary depending on which group (intervention or control group) you are assigned to:

**Loss of confidentiality:** There is a possible risk of loss of confidentiality. However, every effort will be made to prevent this from happening. Your personal information will be kept secure and only accessed by authorized staff as needed to conduct this study. See the Confidentiality section below for additional details. If you are assigned to the intervention group, there is an additional risk to confidentiality if you choose to involve a support partner. If you participate with a partner, we will stress the importance of confidentiality, but we cannot guarantee that your partner will keep all information private. Therefore, we encourage you to be as honest and open as you can but to remain aware of our limits in protecting your privacy.

**Surveys:** You may feel uncomfortable answering questions about your physical or mental health or relationships. Some of the questions may be sensitive such as, "If you needed it, how often is someone available to love and make you feel wanted?" You are free to refuse to answer any of the questions; doing so will not affect your study participation or VA benefits. If you choose to complete the enrollment or follow-up survey over the phone with study staff, there is a risk that your responses may be overheard if you are in a public place. You can minimize this risk by completing the surveys online.

**Internet:** Any activity on the internet involves risk. When using your own computer, you should take the normal precautions to ensure your system is running the most current version of your browsing software, you have up-to-

date virus protection, and you implement a software or hardware firewall to protect your computer and yourself. If you choose to use a public computer to access the internet (such as a library computer), know that your information is only as safe as that computer's safety features. Any website can be hacked. By ensuring your computer has up-to-date security measures, you can reduce the risk to yourself, but risk cannot be eliminated.

**Audio-recordings (intervention group only):** For participants assigned to the intervention group who consent to be audio-recorded, we will audio-record some of the health coaching sessions using a digital recorder or recording software (video will not be recorded). If you choose to include a support person, we will ask the support person to sign a form to give their consent to be audio-recorded. You or your support person may decline to be audio-recorded at any time by simply telling your health coach or study staff. Members of the study team may transcribe (write down word for word) the session/interview audio-recordings and review the transcriptions to ensure consistency and quality of study procedures. We will use transcriptions to provide continued training for the health coaches and improve the overall intervention. No one outside the study team will have access to any of your audio-recordings. See the Confidentiality section for additional details.

### POSSIBLE BENEFITS

It's possible that your participation in this study will not provide you with any direct, personal benefit. If you are randomized to the intervention group, you could benefit from health coaching; however, there is no guarantee. Health coaching sessions could benefit you by providing skills and resources to better manage your health conditions, increasing communication with your VA provider team, and improving social support for managing your chronic conditions. We hope the results of this study will help Veterans with multiple long-term conditions improve their health and quality of life. Study staff will send you a summary of study findings when results are available.

You could obtain these benefits by participating in another health management program (such as the VA's Whole Health program or a non-VA community health program). Please talk to your primary care physician for more information about these options.

### OTHER INFORMATION

You do not have to take part in this study. If you are in this study, you can withdraw at any time. If you decide not to participate or to withdraw, no action will be taken against you; for instance, you will not lose your VA benefits or any other benefits to which you are entitled.

### COMPENSATION

To compensate you for your participation, you will receive a \$50 payment for completing each of the two surveys for a possible total payment of \$100. Participants in the intervention group who complete the satisfaction survey will receive an additional \$15 payment. You may choose how to receive a payment (as an electronic transfer into your bank account from VA or a gift card that is mailed or emailed to you by the study team). If you choose to receive an electronic funds transfer (i.e., direct deposit) into your bank account from VA, the VA may take up to 6 months to process those payments and you may have to complete a form about your bank account information and submit it to the VA. If you already receive electronic funds transfers from VA, you may not need to complete this form.

**CONFIDENTIALITY**

Your research information will be kept confidential. However, some data may be shared, communicated, or stored during or after this research study. The following list of people or groups may know that you are in this study. They may have access to your research records, which may include your medical records:

- Research team members
- Seattle Institute for Biomedical and Clinical Research (the nonprofit institute that works with VA Puget Sound to conduct research)
- Other federal agencies including, but not limited to, the Food and Drug Administration (FDA), the Office for Human Research Protection (OHRP), the VA Office of Research Oversight (ORO), the VA Office of the Inspector General (OIG), and the Government Accountability Office (GAO)
- The VA committees that oversee research
- The VA Puget Sound Fiscal Department, Internal Revenue Service, and U.S. Department of the Treasury will be provided with your full name, address, phone number, and social security number in order to authorize payment for your participation in this study.

**Maintaining your safety and the safety of others:** The study investigators have the power to terminate your participation at any time if they feel the safety of you or a member of the study team may be compromised. If we learn you intend to harm yourself or others, we must report this information to appropriate authorities. Everything you say is confidential except if:

- You tell us you are planning to hurt yourself or someone else;
- You tell us about the ongoing abuse of a child, elderly adult, or vulnerable adult; or
- In the case of a court order or subpoena.

**Medical record:** We will look at your VA medical record to find additional information about you, including how many other VA visits you attend, certain medications you take, and diagnoses you may have. We will place a note in your medical record specifying the dates you are enrolled in this study. In addition, we will put basic information about you, such as clinical information related to your involvement in this study, into your medical record. We will also place a separate note to your provider in your medical record if you identify a health concern or issue (such as during your health coaching sessions) and the study investigators will determine if follow-up by your VA care team is needed. All approved users of the national VA medical records system can have access to your medical record, including your VA provider. This record will be retained in accordance with the VA records retention policy.

**Study code:** If you agree to participate in our study, we will assign you a unique study code. Your study code will be used to track your survey responses. We will not include personal identifiers (such as your name or social security number) on any of the information we collect from you; only your study code will be used. We will keep a master list that links study participants' names to study codes separate from the study data in a secure VA database with restricted access.

**Safekeeping/storage:** All study data will be kept confidential. Data will be kept in research offices at VA Puget Sound in locked filing cabinets or on secure, password-protected VA computer networks with access restricted to designated study staff.

**Study surveys:** VA providers or peer health coaches will not have access to any of your survey responses.

**Transcriptions and audio-recordings:** Audio-recordings and transcriptions of the recordings will be stored along with all other study data on the secure VA network. The transcriptions will be labeled with your study code and will not contain your name, social security number, or other identifying information. In addition, we will not transcribe any personal identifiers if any are mentioned during the interview. Recording devices will be stored in a locked cabinet when not in use and accessible only to authorized study staff.

**After study completion:** Once this study is completed, we will not use the study code linking you to your data, including any recordings and transcriptions, for any additional research. We will store the code linking you to your data in a secure database or in a locked filing cabinet in accordance with the VA records retention policy (which will be a minimum of 6 years after the study has been completed). We will keep your coded data indefinitely. In the future, researchers may write about the information collected from this research study. Any future publications or articles will not include any identifying information about you without your approval in writing. Neither you nor your family will gain financially from discoveries made in the future using the information you provide.

### QUESTIONS OR CONCERNS RELATED TO THE STUDY

If you have any questions about the study, you may contact the VA Institutional Review Board (IRB) Office. An IRB is an independent body made up of medical, scientific, and non-scientific members, who ensures the protection of the rights, safety, and well-being of subjects involved in research. You may call the IRB at [redacted] if you:

- Would like to speak with a neutral party who is not involved with this study.
- Have questions, concerns, or complaints about the research.
- Would like to verify the validity of the study.
- Have questions about your rights as a research subject.

### RESEARCH SUBJECT'S RIGHTS

If you have any questions about the study purpose, procedures, risks, discomforts, possible benefit, choices available to you, or your rights as a research subject after reading this Information Statement, you may contact our study team at [redacted] prior to agreeing to participate in this research study.

*We very much appreciate your consideration  
in participating in this study.  
Thank you!*