

Randomized Controlled Effectiveness Trial of VA S.A.V.E.
Suicide Prevention Gatekeeper Training for Veterans'
Close Supports

NCT06470867

May 16, 2025

Information sheet for the Veterans' Family and Friends Save Lives project

WHAT AM I BEING ASKED TO DO?

We are asking you to take part in a research study that is being funded by the Veterans Affairs Health Systems Research (HSR) service. We conduct research studies to try and answer questions about how to prevent, diagnose, and treat diseases, and how to improve health outcomes for veterans.

We are asking you to take part in this research study because you are a family member or friend of a veteran. 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?

The main purpose of this study is to learn about the effectiveness of video-based training to prevent veteran suicide. The training is tailored to people who are friends and family of veterans. We want to understand if the training helps you provide support and assistance to veterans who may be at risk for suicide.

WHAT WILL HAPPEN IF I PARTICIPATE IN THIS STUDY?

If you decide to participate, you will complete an online survey, receive a brief phone call from our study team, and watch a brief online training video. The initial survey will take approximately 10-20 minutes to complete. The training will take less than 20 minutes to complete. After your initial participation, you will be asked to complete four brief follow-up surveys after 1, 3, 6, and 12 months. Each survey should take approximately 10-20 minutes to complete. Survey questions will cover a range of topics including your personal background and your relationships with veterans. The survey will ask about any experiences you have had talking to veterans who may be at risk for suicide.

There are two additional parts of the study: an interview and a skills check. These are both optional and done online (Microsoft Teams) or on the phone. The interview will ask you about your experience with the training. It will last approximately 30-60 minutes. For the skills check, you will meet with a trained actor who will pretend to be a veteran at risk for suicide, and you will interact with the "veteran" just like you would with a real veteran. It will last approximately 20 minutes.

The estimated total number of participants for this study is 710. Of these 710 participants, approximately 48 will also complete the interview, and approximately 50 will also complete the skills check.

WHAT ARE THE RISKS and POSSIBLE DISCOMFORTS of PARTICIPATION?

This study involves collecting identifiable information from you, including your name, email, mailing address, and phone number. We need this information so we can contact you for follow-up surveys. The research team will make every effort to protect your information. A breach in confidentiality and a loss of privacy is always possible, but the research team will take every step to protect your private information.

For the survey, answering questions takes time and you may find this inconvenient. Some of the questions may seem very personal or embarrassing, or they may upset you.

WHAT ARE THE BENEFITS OF TAKING PART IN THIS STUDY?

One reason you may want to join this study is to receive a training that may be relevant to understanding and supporting the veterans in your life.

Your participation may benefit other veterans by helping us learn how to improve and share trainings for veterans and those who are close to them.

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

Your information used for this study will be kept confidential as required by law. The results of your participation in this study may be used for publication or for scientific purposes, but the results will not include any information that could identify you. Your identity will not be disclosed unless you give specific, separate consent or if required by law. All VA research records will be held in accordance with the VA records control schedule.

Information you provide on the study surveys, including contact information needed to send you follow up surveys and payments, will be stored in a database called VA REDCap. The VA REDCap database is password protected and maintained by the VA. By agreeing to participate, you give permission for this data to be stored in VA REDCap, which will maintain the security and confidentiality of the data.

We will also download and store your responses to survey questions in data files stored on a secure, password-protected computer server at the VA.

To protect you:

- A study ID number will be created for you, which will help to separate your survey responses from identifying information.
- Data files containing your survey responses will NOT contain any identifying information about you, except for your zip code which will be used to assess rurality.
- Any other identifying information, such as contact information needed for follow up surveys or payments will be stored in separate data files from your survey responses to protect your privacy. These data files will only be available to the study team.
- Any paper documents related to the study will be stored in a locked file cabinet in a locked office at a secure VA facility.

If you are invited and decide to participate in an interview or skills check, an audio recording will be made. You will be asked for your consent for participation in the recording at the start of the interview or skills check. By agreeing to participate, you authorize the use of the audio recording for research purposes. All research-related audio recordings will be held in accordance with the VA records control schedule.

There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections (OHRP), the Government Accountability Office (GAO), the Office of the Inspector General (OIG), the VA Office of Research Oversight (ORO), the VAPORHCS Institutional Review Board (IRB) and Research and Development Committee (RDC), and other study monitors may look at or copy portions of records that identify you.

Mandatory reporting of suspected child, elder, or vulnerable adult abuse. Under Oregon Law, suspected child, elder or vulnerable adult abuse must be reported to appropriate authorities.

Possibility of Disclosure and Notice of Privacy Practices.

The VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it may no longer be protected. Our Notice of Privacy Practices provides more information on how we protect your information. The Notice of Privacy Practices available online at https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=10127

In the future, identifiers may be removed, and de-identified information may be used for future research studies (not part of this study) without additional informed consent obtained from you. This means the people working on future research studies will not be able to identify who you are.

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

After verifying your information on the phone, you will be eligible to receive gift cards for completing each survey. You will receive a \$10 gift card for completing each survey. If you complete all five surveys, you will receive an additional \$10 bonus gift card, for a total of \$60 in gift cards.

In addition to the payments for surveys, you will receive a \$20 gift card if you complete an interview and a \$20 gift card if you complete a skills check. Not all participants will be selected for these study activities, therefore not all participants will be eligible to receive these additional gift cards.

All gift cards will be electronic CVS gift cards.

WHO CAN I TALK TO ABOUT THIS STUDY?

To speak to someone about the research study, call the study team at [local study phone number].

If you decide to withdraw, you will only receive compensation for the study activities that you have completed within the allotted timeframe for each activity.

It is possible that your continued participation may be terminated without your consent. In this case, you would still receive compensation for the study activities completed prior to the termination.

If you become sick or injured or if you feel your privacy or confidentiality may have been violated (e.g., someone without authorization has received personal information about you), call the Principal Investigator, [Local site PI] at [Local site PI phone number].

To speak with someone not connected with this research study about your rights, discuss problems, concerns and questions, obtain information and/or offer input, please call the [Local VA Research Administration Office name and phone number], or the [Local VA Privacy Officer name and phone number].

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 your non-compliance with study procedures. Additional compensation, beyond paying for treatment, has not been set aside.