A Scalable Model for Promoting Functioning and Well-Being among Veterans with a History of Mental Health Challenges via Meaningful Social Interactions: Project V-SPEAK!

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NCT05506839

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: A Scalable Model for Promoting Functioning and Well-Being among Veterans with a History of Mental Health Challenges via Meaningful Social Interactions: Project V-SPEAK!

Principal Investigator: John D. Piette, Ph.D., Department of Health Behavior and Health Education, University of Michigan

Co-Investigator Paul Pfieffer, MD, MS Department of Psychiatry, University of Michigan

You are invited to take part in a research study. This form contains information that will help you decide whether to join the study.

Taking part in this research project is voluntary. You do not have to participate and you can stop at any time. Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

2. PURPOSE OF THIS STUDY

The purpose of this study is to test a program called “V-SPEAK!” (Veteran Service Promoting English Acquisition and Knowledge). In this program, veterans with symptoms of depression or anxiety or who have been diagnosed with depression or anxiety help English-language learners improve their English skills by having conversations. The conversations take place by videoconference. As part of testing the V-SPEAK! program, we will be learning how to recruit participants, how to implement the program, how to retain participants, and the program’s impact on the participants.

3. WHO CAN PARTICIPATE IN THE STUDY

3.1 Who can take part in this study?

In order to participate, you must be a veteran, 18 years of age or older, a fluent speaker of English, and be able to participate in videoconference conversations. The videoconference conversations can be done on a smartphone, tablet, laptop, or desktop computer in your home or another location. To be eligible, participants have to report experiencing some symptoms that are associated with depression, anxiety, or Post Traumatic Stress Disorder (PTSD), or have been told by a health professional that they have one of these disorders. You will not be eligible if you have a history of traumatic brain injury, schizophrenia, or current alcohol or drug abuse/dependence not in remission and that would affect your ability to participate in the study. You will also not be eligible if you have life-threatening health problems, for example active treatment for cancer other than skin cancer, advanced heart disease or COPD, or advanced dementia, that would affect your ability to participate in the study.

3.2 How many people are expected to take part in this study?

A total of 100 people are expected to participate (50 veterans and 50 English-language learners).

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

If you choose to participate in this study, you will be asked to complete the baseline survey over the phone or via videoconference during your first appointment. The baseline survey will ask you questions about topics like general health, well-being, quality of life, loneliness, depressive symptoms, health service use, and demographic information such as your age and education level.

You will be given or sent the V-SPEAK! program materials. We will then contact you when we identify an English-language learner who is available when you are. We will pair you with that learner and work with you and the learner to find a day and time for the weekly videoconference conversations. You and the English-language learner will have videoconference conversations every week for 8 weeks. We will use a standard videoconferencing platform such as Zoom. The first two sessions will be facilitated by study staff who will introduce each session, assist with technical issues, and ensure that both participants have their materials and are comfortable. All sessions will be video and audio recorded. Additionally, if both participants are in agreement after the second session, they can complete the following 6 sessions without a staff member monitoring their sessions. A brief questionnaire will be sent to you via email after each session, to allow both the veteran and learner a chance to privately express any issues or concerns. Research staff will actively review responses after every session. They will take note of any concerns, and they will follow-up with participant if necessary.

After the 8 weeks of videoconference conversations, you will be asked to schedule the second appointment to complete the follow-up survey over the phone or via videoconference. We will contact you to schedule and remind you about the second appointment. The follow-up survey will last about a half hour and will ask you questions about topics like your well-being, quality of life, loneliness, depressive symptoms, health service use, and program satisfaction. After completing the follow-up survey, your participation in the study will be complete.

If you choose to participate in this study, you will be asked to provide your name, mailing address, a telephone number, and an email address. Your identifying information is needed in order for study staff to contact you and to send study reminders and study materials. You will also be assigned a unique study identification (ID) number that will be used for the duration of the study. All the data collected about you as part of this study, including the recordings, will be entered and maintained in your study record under your study ID number (not under your name or other identifying information).

4.2 How much of my time will be needed to take part in this study?

Participants will be asked to complete one baseline survey and one follow-up survey over the phone or via videoconference. Each survey is expected to take about a half hour. Participants will be asked to participate in one videoconference conversation each week for 8 weeks as part of the study. Each videoconference conversation is expected to take about one hour.

4.2.1 When will my participation in the study be over?

Your participation in the study will be over after about 8 weeks.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The potential risks for this study are: emotional discomfort, breach of confidentiality (people outside the study seeing information about you), and the rare possibility that your videoconference sessions, video recordings, or session reminders sent via phone, email, or text message may be accessed by someone who is not on the study team (hackers watching or listening in).

The researchers will try to minimize these risks. Any recorded videos containing your face or identifying information will not be shared publicly and will be deleted at the end of the study. You can discontinue an interview or videoconference conversation that you find bothersome at any time. You do not have to answer any questions you do not want to answer. You can also drop out of the study at any time. The study staff will be available if you want to discuss any problems or concerns you have about the study.

Additionally, there is a small risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 How could I benefit if I take part in this study? How could others benefit?

It is possible that you will not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study. You might benefit from being in the study by learning a new skill of using videoconferencing software and increasing a sense of social engagement and purpose which may improve your mood.

5.3 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study.

6. ENDING THE STUDY

6.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 9. "Contact Information". If you choose to tell the researchers why you are leaving the study, your reasons may be kept as part of the study record. The researchers will keep the information collected about you for the research unless you ask us to delete it from our records. If the researchers have already used your information in a research analysis it will not be possible to remove your information.

7. FINANCIAL INFORMATION

7.1 Will I be paid or given anything for taking part in this study?
There is no compensation for this study.

8. PROTECTING AND SHARING RESEARCH INFORMATION

8.1 How will the researchers protect my information?
We will protect the confidentiality of your study records, including the recordings of your conversations with your language partner, by assigning you a unique study identification number that will serve as your primary identifier for the duration of the study. We will create a secure electronic tracking file that is only accessible to the study's principal investigator and authorized staff members that links your identifying information to the study ID number. A hard copy of that file will be maintained in a locked file cabinet separately from other study-related documents. The research data collected as part of the study will only be accessible to the study's principal investigator and authorized staff members.

A description of this clinical trial will be available on http://www.clinicaltrials.gov/, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

8.2 Who will have access to my research records?
There are reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- University, government officials, study sponsors or funders, auditors, and/or the Institutional Review Board (IRB) may need the information to make sure that the study is done in a safe and proper manner.

8.3 What will happen to the information collected in this study?
As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:
- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

The results of this study could be published in an article or presentation, but will not include any information that would let others know who you are.

8.4 Will my information be used for future research or shared with others?
We may use or share your research information for future research studies. If we share your information with other researchers it will be de-identified, which means that it will not contain your name or other information that can directly identify you. This research may be similar to this study or completely different. We will not ask for your additional informed consent for these studies.

9. CONTACT INFORMATION

Who can I contact about this study?
Please contact the researchers listed below to:
- Obtain more information about the study
- Ask a question about the study procedures
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: John D. Piette
Email: SPEAK-Study@med.umich.edu

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

University of Michigan
Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS)
2800 Plymouth Road
Building 520, Room 1169 Ann Arbor, MI 48109-2800
Telephone: 734-936-0933 or toll free (866) 936-0933
Fax: 734-936-1852
E-mail: irbhsbs@umich.edu

10. YOUR CONSENT

Consent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with research staff. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 9 (above). I understand that I will receive a copy of this form at the time I consent to participate in the study and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Consent to video/audio recording solely for purposes of this research

This study involves video and/or audio recording. If you do not agree to be recorded, you cannot take part in the study.

Please tell the research staff member whether you agree to participate in the research study, whether you agree to participate in conversation sessions with the partner you will be paired with, and whether you agree to be video/audio recorded.