

VOICES Socials for Older Veterans with Depression

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Participant Name: _____ Date: _____

Title of Study: VOICES Socials for Older Veterans with Depression

Principal Investigator: Jay Gorman, PhD VA Facility: VA Bedford Healthcare System

Sponsor of Study: VA Office of Research and Development

We are asking you to choose whether to volunteer for a research study. This information sheet will describe the study and be reviewed with you to help you decide whether you want to participate. Taking part in this study is completely voluntary.

SUMMARY OF IMPORTANT INFORMATION

This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

1. WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

You are invited to join the first part of a two-part research study. This study will help us better understand the challenges some Veterans 65+ experience engaging with those in their community. Your participation will last for approximately 60 minutes. This study is being done to help develop programming for Veterans 65+. It is being funded by the VA Office of Research Development.

2. WHAT DOES THE STUDY INVOLVE AND HOW LONG WILL IT LAST?

This study will ask you to participate in a virtual interview with one research staff member. A total of 13 Veterans will be asked to participate in an in-person interview for this study. After we review this information sheet with you and you decide to participate and give consent, a researcher will ask for your permission to record the interview. Only researchers affiliated with this study will have access to your recording. The recording will help us remember what you said. Your recording will not be disclosed outside of the VA. If you agree to participate and to be audio and visually recorded, a researcher will ask you some open-ended questions to better understand challenges you have experienced in engaging in the community and socializing with others. You will be asked to talk about topics related to your mental health, social history, and identity. At the end of this interview, your participation in this study will be complete.

3. WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You will not receive any benefits from the study but your participation may help us to develop a social program for Veterans 65+.

4. WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

There is the possibility that answering some questions may be emotionally upsetting. You have the choice to not answer any question that makes you feel uncomfortable. If you believe this may be too difficult to do, you may not want to participate. You can withdraw from the study at any time.



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5. DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to participate in the study, it should be because you want to volunteer. You will not lose any services, benefits, or rights you would normally have if you chose not to volunteer.

6. WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is **Jay A Gorman, PhD**, of the VA Bedford Healthcare System in Bedford MA. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is: **781-879-5726**.

WHAT ARE THE POSSIBLE RISKS OR DISCOMFORTS OF TAKING PART IN THIS STUDY?

It is possible that you will experience some distress when you answer questions about your social history, mental health, and identity. You may stop the interview session at any time if you become upset. You may withdraw from the study at any time. We will continue to use data that was collected prior to your withdrawal in order to maintain the integrity or reliability of the research.

If you need to take a break or leave, you are free to do so. A researcher will notify you of mental health counseling available at the Bedford VA in the event that you'd like to discuss any of uncomfortable thoughts/feelings that arise for you as a result of completing these surveys.

Causes for Early Discharge: You will be discharged if the study researcher decides that staying in the study may cause you emotional harm. If you are discharged from the study, we will contact your regular clinician to coordinate and provide you with the most appropriate care to address these issues. If you do not have a regular clinician, a researcher will notify you of mental health counseling available at the Bedford VA and will help connect you to care.

ARE THERE ANY UNANTICIPATED RISKS?

If you have any unusual or uncomfortable feelings during the study, please let the research staff know.



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Confidentiality of Information: Participation in research may involve a loss of privacy.

Your research records will be kept as confidential as possible. Only a code number will identify your research records. The code number will not be based on any information that could be used to identify you (for example, social security number, initials, birth date, etc.). Your interview will be recorded using a VA computer recording device. Recordings will be stored on a secure server with strict security measures. Only researchers affiliated with this project will have access to these recorded files.

All research information will be kept in a locked office and a locked file cabinet at all times. Your identity will not be revealed in any reports or publications resulting from this study. Only authorized persons will have access to the information gathered in this study. Federal Agencies such as the Office for Human Research Protection (OHRP), Government Accountability Office (GAO) and Food and Drug Administration (FDA) may have access to the records.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

As with any research study involving the participation and the collection of information, there may be a loss of privacy. However, numerous safeguards will keep electronic and hard copy data secure. The web-based platform is HIPAA compliant meaning that connection between the computers have end-to-end encryption and meets required access controls so data in transit cannot be intercepted by someone else. In other words, someone outside of the research team cannot listen to what is being said or get information.

Your research records will be kept as confidential as possible. Your identity will not be revealed in any reports or publications resulting from this study. Only a code number will identify your research records. The code number will not be based on any information that could be used to identify you (for example, social security number, initials, birth date, etc.)

Only authorized persons will have access to the information gathered in this study. Federal Agencies such as the Office for Human Research Protection (OHRP) and the Government Accountability Office (GAO) may have access to the records.

Identifiers might be removed from the identifiable private information that is collected. After that removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.



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WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You, or your insurance, will not be charged for any treatments or procedures that are part of this study. If you usually pay copayments for VA care and medications, you will still pay these copayments for VA care and medications that are not part of this study.

DO I HAVE TO TAKE PART IN THE STUDY?

Participation in this research study is voluntary. You may refuse to participate and your refusal to participate will involve no penalty or loss of benefits to which you are entitled. You may also discontinue participation at any time without penalty or loss of benefits to which you are entitled.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call Dr. Jay Gorman at 781-879-5726 during the day, and after hours call 781-687-2000 and have the doctor on call paged. VA Medical Facilities shall provide, or arrange for, necessary medical treatment to a research subject injured as a result of participation in a research project. This does not apply to treatment for injuries due to non-compliance by the subject with the study procedures.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

The study team will inform you of any important information about your participation that may affect you or your willingness to be in this study.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have any questions about the research, you may contact Dr. Jay Gorman at 781-879-5726. If you have any questions, concerns, or complaints about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Institutional Review Board Coordinator, Denise Carr at 781-687-2839, and the information will be given to the Institutional Review Board. This is the Board that is responsible for overseeing the safety of human participants in this study.

IS THERE AN ALTERNATIVE TO THIS?

The alternative to participation in this study is to not participate in this study.

HOW WILL THE RESEARCH RESULTS BE USED.

If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent. Your medical records will be maintained according to VA requirements.



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WILL I BE COMPENSATED FOR MY TIME?

You will receive a \$45 gift card for your participation in this research project, which will be sent to you after the interview. You get to keep the voucher even if you choose to stop participating in this study before the interview is completed.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr. Gorman or study staff have explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.