Effectiveness and Implementation of eScreening in Post 9/11 Transition Programs

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Study Title: Effectiveness and Implementation of eScreening in Post 9/11 Transition Programs

Principal Investigator: James O. E. Pittman, PhD, LCSW

VA Facility: VA San Diego Healthcare System

Participant Name:	Date:

STUDY SUMMARY

You are being asked to participate in a research study. This section summarizes key information about this study to assist you, or your legally authorized representative, in understanding the reasons why you may or may not want to participate in the research. Your participation is voluntary. You may refuse to participate or withdraw at any time. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer. Carefully review this section and the detailed information that follows before you agree to participate.

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

This study will evaluate an innovative VHA technology, eScreening, for the timely detection of, and intervention for, mental health symptoms, including identifying high risk Veterans who may require additional follow-up for suicidal ideation. This study will also evaluate a strategy designed to help programs implement eScreening in new sites. It is being funded by the Department of Veterans Affairs. By doing this study, we hope to identify best practices for mental health screening and suicide prevention for Post-9/11 Veterans enrolling in VHA and provide information on how best to implement technology-based screening into clinical care programs.

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

You will be asked to participate in one 30-minute virtual individual survey/interview to assess the feasibility and acceptability of the eScreening implementation strategy, three 10 to 15 minute web-based surveys to collect information about implementation, and two virtual 60-minute individual interviews to evaluate factors affecting adoption, implementation, and sustained use. Your individual participation in this research project will occur over the course of approximately 1.5 years and take approximately 3 hours in total of your time. The 1 survey/interview will take place during pre-implementation (now). The web-based survey will be delivered via Qualtrics at 3 time points: during the pre-implementation phase (now), at the end of the active implementation period (approximately 12 months from now), and at 9 months post-implementation (approximately 18 months from now). The individual interviews will take place at the end of the active implementation period (approximately 12 months from now) and at 9 months post-implementation (approximately 18 months from now).

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

There is no direct benefit to participation in this study, but the researchers hope to identify best practices for mental health screening and suicide prevention for Post-9/11 Veterans enrolling in VHA and to learn how best to implement technology-based screening into clinical care programs.

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

Potential risks associated with participation in the study are 1) loss of confidentiality and 2) feeling discomfort during participation, both of which are research risks as this project involves no medical or psychological treatment intervention. A complete description of risks is included in the Research Details Study Risks section.

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Participation is voluntary and the only alternative is to not participate.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is James Pittman, PhD, LCSW of the VA San Diego Healthcare System. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is: James.Pittman@va.gov; 858.552.8585 x7787.

RESEARCH DETAILS

WHO IS CONDUCTING THIS RESEARCH AND WHY?

James Pittman, Ph.D., LCSW and VA colleagues are asking for your consent to this research. This study is sponsored by a Merit Award from the Department of Veterans Affairs. This study involves evaluating the impact of a technology based screening system (eScreening) on speed and rate of mental health screening for Veterans in the VA. Dr. Pittman, the study Primary Investigator, and a Co-Investigator Dr. Niloofar Afari are named as inventors on a pending provisional patent application, which describes the functionality of eScreening, that was submitted through the VA Technology Transfer Program (TTP). The VA ID No. is 2018-359 entitled, "Methods And Systems For Comprehensive Patient Screening." The study results could affect the value of the patent application and potentially benefit the inventors.

The purpose of the research is to evaluate effectiveness and implementation of an electronic screening program called eScreening compared to standard of care paper and oral based screening methods in 8 different VHA Transition Care Management (TCM) program sites. You are being asked to participate because you have direct or indirect involvement with implementation of eScreening at your site.

Approximately 4-8 staff at each of the 8 VHA sites who have direct or indirect involvement with implementation of eScreening will be asked to take part in this research (45 participants in total across all sites).

Post 9/11 Veterans who enroll in VA health care frequently present with mental health symptoms. Studies show that screening for mental health symptoms, particularly those associated with suicide, can lead to early detection, referral to effective treatment, and a decrease in suicide risk. We will evaluate eScreening compared to current screening methods used by transition care managers, to improve rate and speed of screening including PTSD, depression, and alcohol; subsequent suicide screening and evaluation; and referral to mental health treatment. This study will also evaluate a strategy designed to help programs implement eScreening in new sites.

FOR HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take 4 years. However, your individual participation in this research project will occur over the course of approximately 1.5 years and take approximately 3 hours in total of your time. The surveys and interviews will take place: now, 12 months from now, and 18 months from now.

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WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?

If you decide to take part in this study, you will participate in **1 individual virtual survey/interview**, **2 individual virtual interviews**, and **3 online surveys**.

Virtual Survey/Interview.
The individual survey/interview will take place now and is expected to take approximately 30 minutes to complete. It will focus on assessing the feasibility and acceptability of the eScreening implementation strategy. It will be conducted virtually using Microsoft (MS) Teams and will be audio and video recorded, and transcribed using MS Teams.

Virtual Interviews.
The individual interviews will take place: 12 months from now and 18 months from now. Each interview will take approximately 60 minutes to complete. The interviews will focus on factors affecting adoption, implementation, and sustained use of eScreening, and may include questions like: Does the proposed multi-component implementation strategy seem easy to use? What works well in the current process of implementing eScreening in Transitional Care Management program in your facility? What kind of adaptations or modifications did you have to make to the eScreening program or its implementation over time? You can skip any interview questions that make you uncomfortable and can stop at any time. The qualitative interviews will be conducted virtually using MS Teams. Interviews will be audio and video recorded, and transcribed using MS Teams.

Online Survey**.**
A secure web-based survey will take place**:** now, 12 months from now, and 18 months from now. The online survey is expected to take 10 to 15 minutes to complete (about 30 to 45 minutes across all three time points) and will collect information about implementation. You will receive a link to the online Qualtrics survey via your VA email. You can skip any survey questions that make you uncomfortable and can stop at any time.

We will collect PII from participating site staff in this project including names, email addresses, telephone/fax numbers, VA office address, and demographic information. Social security numbers and PHI will **NOT** be collected. All data will be obtained specifically for research purposes. All interviews will be conducted by highly trained members of the research team.

WHICH PROCEDURE/S OR TREATMENT/S ARE DONE FOR RESEARCH?

Research procedures include the individual survey/interview, the two individual interviews, and the online survey.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Potential risks associated with participation in the study are 1) loss of confidentiality and 2) feeling discomfort during participation, both of which are research risks as this project involves no medical or psychological treatment intervention. Such risks are not likely and would not lead to serious consequences.

Surveys and Interviews: Some people become uncomfortable at being asked to make judgements and offer opinions. If, for any reason, you wish not to answer specific questions or you wish to terminate the session, you will be able to do so.

The study team has explained that by signing this Informed Consent Document, you voluntarily and without separate compensation authorize video and audio recording(s) and written transcripts to be made of you by the study team while you are participating in this study. The qualitative interview data will generate digital video and audio files and written transcripts, which are considered identifiers. The said recordings and transcript are intended: to obtain information regarding the feasibility and acceptability of eScreening prior to implementation; as well as to obtain detailed information on factors affecting the adoption and implementation of eScreening after the active implementation phase and during the sustainment phase. Both mindset and practical issues will be explored to illustrate implementation issues, challenges, and underpinnings of success.

The study team has also explained that you will not receive any royalty, fee or other compensation for such use. If you refuse to grant consent, there will be no effect on any VA benefits to which you may be entitled. You may at any time exercise the right to cease being recorded and may rescind your consent for up to a reasonable time before the recording is used.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There are no direct benefits to participating. However, eScreening may inform best practices for mental health screening and suicide prevention. eScreening may have several advantages over usual screening, including time savings for providers and use of fewer organizational resources.

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

The VA will provide necessary medical treatment should you be injured as a result of participating in this study. At no cost to you or your insurance, the VA will treat you for the injury, but no additional compensation is available.

If you should have a concern or get hurt or sick as a result of taking part in this study, call:
Dr. James Pittman: (858) 552-8585 ext. 7787
VASDHS Research Compliance Officer: (858) 642-3817
VA Regional Counsel: (858) 642-1540
VASDHS IRB: (858) 642-6362

DO I HAVE TO TAKE PART IN THIS STUDY?

Taking part in this research study is your decision. Your participation in this study is voluntary. You do not have to take part in this study, but if you do, you can stop at any time. You have the right to choose not to participate in any study activity or completely withdraw from continued participation at any point in this study without penalty or jeopardy to the medical care you will receive at this institution or loss of benefits to which you are entitled. Participation will be voluntary and will in no way affect employment, performance ratings, or subsequent recommendations. You may discontinue taking part at any time without any penalty or loss of benefits.

There are no adverse consequences to withdrawal from the study. Should you withdraw, the investigator may continue to review the data already collected for the study but cannot collect further information.

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

There will be no costs to you as part of this research study

WHAT COMPENSATION WILL I RECEIVE IF I TAKE PART IN THIS STUDY?

You will not receive any payment for participating in this study.

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

If you have any questions, complaints, or concerns about the research or other related matters, you may contact Dr. James Pittman at James.Pittman@va.gov or 858.552.8585 x7787.

If you have any questions or concerns about your rights as a research subject, the validity of a research study, or research personnel you can contact the Research Compliance Officer at 858-642-3817, VA Research Service at 858-642-3657, VA Regional Counsel at 858-642-1540, or the VASDHS Institutional Review Board at 858-642-6362. This is the Board that is responsible for overseeing the safety of human participants in this study.

HOW WILL MY PRIVATE INFORMTION BE PROTECTED?

Participation in this study may involve a loss of privacy, but information about you will be handled as confidentially as possible. The following steps are taken to minimize the risk to confidentiality. Electronic data will be stored on a secure research drive on our VA network, accessible only to VA research personnel associated with the proposed study. Electronic records will include a password-protected key linking participant numbers with subject names. Paper records will be coded by participant number only and will not include names. All paper records will be kept in locked cabinets in a locked room. A special custom-tailored database system will be developed for this project to ensure the highest possible data reliability. Data entry programs will include double data entry, item prompts, skip patterns, range checks, and logical validity routines. Copies of audio, video, and transcription files from staff qualitative interviews will be stored on the VA secure server behind the VA firewall. Interviews will be audio and video recorded, and transcribed using MS Teams. The privacy setting on MS Teams will be set to private self-service. Any presentations or publications from this information will not identify you.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

You have been informed that you do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled.

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Dr. Pittman, or an approved study staff member, has explained the study to me. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

By signing this document below, I voluntarily consent to participate in this study. I also confirm that I have read this consent, or it has been read to me. I will receive a copy of this consent after I sign it.

I agree to participate in this research study as has been explained in this document.

_____ _____
Participant's Signature Date

_____ _____ _____
Signature of Researcher obtaining consent Name (print) Date

A copy of this document will be provided to the research participant.

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Health Information Portability and Accountability Act (HIPAA)

This study will not collect staff participant PHI.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

You have been asked to participate as a subject in medical research.
You have the right to know:

1) The nature and purpose of the study.
2) The procedures in the study and any drug or device to be used.
3) Discomforts and risks reasonably to be expected from the study.
4) Benefits reasonably to be expected from the study.
5) Alternative procedures, drugs, or devices that might be helpful to you and their risks and benefits.
6) Availability of medical treatment should complications occur.
7) You may ask questions about the study or the procedure.
8) You may quit the study at any time without affecting your future care at the VA.
9) You should be given a copy of the signed and dated written consent form for the study.
10) Your consent to participate must be given freely, without being obtained through deceit, force, or coercion.

If you have any questions or concerns about your rights as a research subject please contact the VASDHS Research Compliance Officer at (858) 642-3817 or RCO@vapop.ucsd.edu. You may leave an anonymous comment at the VASDHS research compliance hotline at 858-642-6311.

REF: California HSC 24170-24179.5

A copy of this document will be provided to the research participant.