An eHealth intervention to increase depression treatment initiation and adherence among veterans referred for mental health services (CDA 18-189)

NCT05990075

June 27, 2023

Department of Veterans Affairs	VA RESEARCH CONSENT FORM Social and Behavioral Research

Title of Study:	An eHealth intervention to increase depression treatment initiation and adherence among veterans referred for mental health services		
Principal Investigator:	**Dr. Vanessa Panaite, PhD**	**VAMC:**	**Tampa-673**

Informed Consent to Participate in Research: Social and Behavioral Research
University of South Florida, the IRB of record for the James A. Haley Veterans' Hospital

Information to Consider Before Taking Part in this Research Study

IRB Study # 001008

Researchers at the James A. Haley Veterans' Hospital study many topics. Our goal is to find better ways to help treat patients. To do this, we need the help of people who agree to take part in a research study.

STUDY OVERVIEW:

1. **WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?**
   We are inviting you to volunteer for a research study being funded by the Department of Veterans Affairs about mental health care utilization at the VA. This initial overview is to give you key information to help you decide whether to participate. We have included detailed information after this overview. You can also ask the research team questions. Taking part in this study is completely voluntary.

2. **WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?**
   The purpose of the study is to gain a better understanding of mental health care utilization, including factors that aid or interfere with use of mental health services. As part of this study you may also be asked to test a new system designed to help patients waiting to start mental health care. This system will be providing coping strategies, information about services and tools, and ways to monitor your well-being to determine if additional help is needed. To best understand factors impacting how services are utilized, you are being invited to participate in any one of the activities listed below as part of our research study:

   - You may be asked to complete a survey about your past or current experience with using mental health services.
   - You may be asked to complete an interview about the features of a new system that we are developing to help patients stay engaged with mental health services.
   - You may be asked to participate in brief surveys (about 10-15 minutes each) delivered over text over the course of one to several weeks depending entirely on your preference designed to help you reflect on your ongoing well-being.

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By doing this study, we hope to learn how to help patients stay more easily engaged with the mental health services they elect for themselves or their providers recommend to them.
Your individual time spent participating in the project will be 1-2 hours per 1 interview and/or 1 survey and 10-15 minutes for up to daily brief surveys and self-reflections for 1 to several weeks depending on your preference. All study activities will be done remotely from the comfort of your home.

Finally, we will also be accessing your medical records for up to 12 months which will not require your effort. This will be done by the study team to understand your engagement with VA services and any barriers you may encounter in this process.

3. WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?
You may want to participate to find out about ways to become more engaged in your mental health care. There may be no direct benefits to you. Your participation may benefit other patients in need of mental health services that struggle to stay connected to receive full services as we will learn more about factors that facilitate and deter patients from engaging with mental health care. For a complete description of benefits, refer to the Detailed Consent Section.

4. WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?
The current study is considered low risk, in that most questions are generally not distressing or are no more distressing than questions you may be asked during your annual primary care visit. However, some questions, such as those asking about your experience with mental health services, may bring up distress from remembering past events. For a complete description of risks, refer to the Detailed Section of the Consent and/or Appendix.

Volunteering in this study is not meant to replace mental health services. The alternative to being in the current study is to not volunteer. For a complete description of alternate treatment/procedures, refer to the Detailed Section of the Consent.

5. DO YOU HAVE TO TAKE PART IN THE STUDY?
If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

6. WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?
The person in charge of the study is Vanessa Panaite, PhD (Principal Investigator, PI) at the Tampa VA. This person is called the Principal Investigator. If you have questions, suggestions, or concerns

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regarding this study or you want to withdraw from the study her contact information is: vanessa.panaite2@va.gov; 813-768-2193.

After you read this form, you can:

- Take your time to think about the information that has been provided to you.
- Have a friend or family member go over the form with you.
- Talk it over with another health care provider.

It's up to you. If you choose to be in the study, then you can freely give your consent to take part in the study. If you do not want to take part in this study, you should not proceed with any study related activities.

DETAILED RESEARCH CONSENT SECTION

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to find out what factors aid or interfere with use of mental health services among patients that elect or are referred by their providers. To best understand these factors, we are asking participants to help us through interviews and surveys over the course of days and weeks depending on your preference. We are also wanting to test a system that combines helpful information about tools and services that could be used for your mental health with self reflection to provide support after referral before starting mental health treatment.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

About 300 people will take part in this study at James A. Haley Veterans' Hospital**.**

HOW LONG WILL I BE IN THE STUDY?

If you are invited to complete a one time interview or survey that will be up to 2 hours of your time. If you are invited to test our new system, the length of time you are in the study will be entirely up to you. This part can be anywhere between one and several weeks.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

Participation in this study is entirely remote, such that all interviews and surveys are completed over the phone either with the PI or a research assistant or online and over text through your phone. One time interviews are about 1 hour and you will be asked questions about your experiences over the phone. One time surveys are about 1-2 hours and it will be completed online through a link you will receive either in your email or in a text.

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All brief surveys and self-reflections will be completed over texts received from the VA Annie app and online. Specifically, each day you elect to be in the study you will receive brief questions over text on your phone and a final text containing a link for a very brief survey. When you click on the link, the survey will activate, and you will be able to respond to a series of questions. This survey will take about 10-15 minutes. When the last survey is completed or you decide to terminate the study, an exit interview will be completed to better understand your experience so we can learn how to improve. We will be monitoring study data collection daily. You are free to skip any of the study activities or stop your participation in the study at any time.

Finally, we will also be accessing your medical records for up to 12 months which will not require your effort. This will be done by the study team to understand your engagement with VA services and any barriers you may encounter in this process.

To complete the study as originally designed, please:

- Keep your study appointments.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- While participating in this research study, do not take part in any other research project without approval from the investigators. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

Photographs, audiotaping, or videotaping: There will be audio recording of you during the interview as part of this study. The audio file won't contain personally identifiable information and it will be stores behind VA firewals in a password protected folder.

If a patient reports suicidal ideation but is not deemed at imminent risk (such as reporting intent and means to hurt self or others), they will be provided with resources both in the community and the VA that they can use if needed and encouragedto reach out to their providers.

If you report abuse of a child, elder, or other vulnerable individual, the study staff must report this abuse to the appropriate authorities (Department of Children and Families, child protective services, or adult protective services). If patients are deemed at imminent risk of harm to self or others, patients will consent to being connected to the VA Crisis Line and their information will be sent to their primary care

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or mental health providers as verified with patients at the beginning of the interview. This information will not be linked to your survey and interview data provided for this study.
The PI will always be available during study related activities such as interviews.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?
Any procedure has possible risks and discomforts. This is considered a minimal risk study, in that the risks and discomforts are similar to those encountered in daily life or usual care encountered in your primary care office. The procedures in this study may cause all, some, or none of the risks listed.

- All questions will be familiar if you ever talked about your mental health to a provider before. It is possible to experience transient distress from reflecting on your daily experiences.
- You are always free to stop participation at any time during the study.
- If you need hospitalization or emergency intervention at any time during the study whether it is due to your participation in the study or otherwise, you will be automatically withdrawn from the study for you to be fully focusing on your needed care.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?
This study does not offer any treatments and therefore does not offer any direct benefits to participants. The information collected from you if you are a participant in Part 1 or 2 would help the PI and future investigators, as well as mental health providers better understand barriers and facilitators that help patients stay engaged in mental health care. This could possibly improve care for patients in the future. Overall, there are no direct/personal benefits to you from your taking part in this research study. However, the information we get from this study might help others with your conditions.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?
All identifiable information collected for recruitment purposes will not be linked to the interview and survey data provided for this study. Your responses will be deidentified for the purposes of the study and identified by a study ID which will not be linked to your identifiable information. Personally identifiable information will not be shared outside of this study without your consent. All data provided for thisstudy will be kept confidencial.

The information you provide through surveys and interviews and information collected from your chart will be deidentified and could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

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In order to text with you, you will be registering with the VA Annie App, a secure app utilized by VA clinician for communication with patients. In order to send you survey links, your email address will be provided to VA approved Qualtrics (a secure online survey platform). Data provided through these means will not contain personally identifiable information.

All data you provide through surveys, texts, interviews through audio recordings, and that we collect from your medical chart will be recorded in deidetified databases secured in password protected folders behind the VA firewall.

Any presentations or papers about the study will not identify you. Your data will be combined with the data of other people taking part in the study.
There are certain situations when we are obligated by law to disclose information to authorities, such as disclosures of immediate harm to self or others, or disclosure of information you may know about child or elderly abuse.

Health Information Portability and Accountability Act (HIPAA)
There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By providing your verbal consent and authorization, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as diagnoses or mental health treatment.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the VA CSP Site Monitoring; Auditing and Review Team (SMART); CSPCC's Human Research Committee (HRC); **USF** Institutional Review Board (IRB), Food and Drug Administration, Office (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability (GAO).

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

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You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Principal Investigator of the study at this facility.

Principal Investigator: Vanessa Panaite, PhD
James A. Haley Veterans' Hospital
13000 Bruce B. Downs Blvd.
Tampa, FL 33612-4745

You can also ask a member of the research team to give you a form to revoke the authorization. The study team will contact the Release of Information Office. Your request will be valid when the Release of Information Office receives it.

If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you giving this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

A description of this clinical trial will be available on 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.

Informed Consent Process for Online Survey Based Research
It is possible that unauthorized individuals could gain access to your responses. Confidentiality will be maintained to the degree permitted by the technology used. No guarantees can be made regarding the interception of data sent via the Internet. However, your participation in this online survey involves risks similar to a person's everyday use of the Internet. If you complete and submit an anonymous survey and later request your data be withdrawn, this may or may not be possible as the researcher may be unable to extract anonymous data from the database.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?
You will not be charged for being a part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study. You will incur text and online data usage charges per your phone carrier for use of your phone for this study.

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Will you be paid for taking part in this study?
If you participate in the online survey: Participants will receive $20 for completing the survey that could take about 1 hour to complete.

If you participate in the phone interview: Participants will receive $20 for completing the phone interview that could take about 1 hour to complete.

If you participate in testing our system: Participants will receive $5 for completing bursts of texts and surveys (or $2 if you only complete the text burst but opt out of the survey option at the end of each text burst).

Payment for participation is done through Visa or Gift Cards.

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

You are participating in a research project approved by a Research and Development Committee and conducted under the supervision of one or more VA employees. Every reasonable safety measure will be used to protect your well-being. If you are injured because of your participation as a research subject in this research study, the VA medical facility will provide you with necessary medical treatment.

If you need emergency care:

- **Go to your nearest hospital or emergency room right away. Call 911 for help.** It is important that you tell the doctors at the hospital or emergency room that you are participating in a research study. If possible, take a copy of this consent form with you when you go.
- Call the person in charge of this study as soon as you can. They will need to know that you are hurt or ill. Call Dr. Vanessa Panaite at 813-768-2193.

If you need emergency care in a private hospital, have a friend or family member contact the VA immediately at (877) 881-7618, and your doctor so that they can coordinate care with a private hospital. If an eligible veteran requires admission to a non-VA hospital as a result of an emergency, the Department of Veterans Affairs will not be responsible for the cost incurred unless the Department of Veterans Affairs is involved immediately.

<u>If it is not an emergency</u>, and you get hurt or begin to feel bad: Go to your regular doctor. Tell your doctor that you are taking part in this study. If you can, take a copy of this consent form with you.

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If you believe you have a medical concern related to this study or have been hurt or became sick because of something that is done during the study, you should call 911 with an emergency and then the person listed below.

DURING THE DAY FOR NON EMERGENCY SITUATIONS:
Dr. Vanessa Panaite, PhD
Telephone number: 813-768-2193

AFTER HOURS:
Tampa VA: 813-972-2000

Emergency and ongoing medical treatment will be provided as needed.

Compensation for Research-Related Injuries

Financial compensation for research-related injuries, lost wages, discomfort or disability may be available. You do not give up any of your legal rights and you do not release the VA from any liability by agreeing to participate in this study.

DO I HAVE TO TAKE PART IN THE STUDY?
Participation in this study is voluntary. If you decide not to participate this will involve no penalty or loss of benefits to which you are otherwise entitled.

If you are a VA employee, refusal to take part in the study will in no way influence your employment, ratings, subsequent recommendations, or progress. You may discontinue taking part at any time without any penalty or loss of benefits.

Withdrawal from the study will have no impact on your well-being or your welfare. Data already collected prior to your withdrawal will be retained as part of the final data but we will not collect further information, except from public records, such as survival data.

You can revoke your interest in participating in the study in writing, at any time. To withdraw from the study, you must write to the Principal Investigator of the study at this facility.

Principal Investigator: Vanessa Panaite, PhD
8900 Grand Oak Circle, Room 132B
Tampa, FL 33612-4745

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RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

Even if you want to participate in the study, there may be reasons we will need to discontinue if:

- We find out it is not safe for you to stay in the study, or the questions are too distressing for you.
- You are hospitalized or need emergency intervention.

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

Should you have any questions, complaints, and concerns about the research or related matters please feel free to contact the PI Dr. Vanessa Panaite at *813-768-2193*.

If you have questions 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 (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the USF IRB at (813) 974-5638 or contact the USF IRB by email at RSCH-IRB@usf.edu if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.
If you would like to contact someone independent of the research study, or cannot reach the research staff, you may contact the James A. Haley Veterans' Hospital Research Compliance Officer at 813-903-4274.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

New findings developed during the research that may affect your willingness to participate will be provided to you. Overall results of the study will be disseminated in aggregate form at the end of the study through publications or presentations, however your name will not appear on any of these public documents.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms._____ _____ has 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.

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By proceeding with study activities, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information for this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent to the address you provided.

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

Signature of Person Obtaining Informed Consent/Research Authorization		
_____ Name	_____ Signature	_____ Date

Subject's Name: _____

Subject's Last 4 digits of SS# required: _____