Improving Anxiety Treatment Engagement and Effectiveness in Primary Care-Mental Health Integration: Multi-site Hybrid I RCT of a Brief Veteran-Centered Anxiety Intervention

NCT04829240

October 3, 2022

Participant Name: _____ **Date:** _____

Title of Study: Improving Anxiety Treatment Engagement and Effectiveness in Primary Care-Mental Health Integration: Multi-site Hybrid I RCT of a Brief Veteran-Centered Anxiety Intervention

Principal Investigator: Robyn L. Shepardson, Ph.D. **VAMC:** Syracuse

Consent Version Date: (08/18/2022)

KEY INFORMATION

What key information do you need to know?
This study is testing a brief, non-medication treatment for anxiety specifically designed for Veterans in primary care. It involves a total of 6 assessment sessions and up to 6 treatment sessions with an integrated behavioral health provider in primary care. You may benefit from this study by learning more about anxiety symptoms and ways to manage anxiety better using healthy coping skills. You could earn up to $200 for completing all study assessments. This study is confidential and completely voluntary. The results of this study may help us improve the services offered to Veterans in primary care.

PURPOSE OF THE STUDY

You are being asked to take part in a research study at the Syracuse VA Medical Center (VAMC) because you are a primary care patient reporting current symptoms of anxiety. Our research team is conducting this study to improve the treatment of anxiety in the primary care setting. We have developed a brief anxiety treatment, Veterans Anxiety Skills Training, that is intended to help Veterans better understand and manage symptoms of anxiety. The purpose of this study is to test the effectiveness of this treatment compared to primary care treatment as usual. This study is funded by VA Health Services Research and Development.

DESCRIPTION OF THE PROCEDURES AND APPROXIMATE DURATION OF THE STUDY

A total of 178 Veterans from the Syracuse VAMC, Western New York VAMCs, and area VA Community-Based Outpatient Clinics (CBOCs) are expected to participate in this study, which lasts approximately 7 months. Approximately 90 Veterans will be enrolled locally at the Syracuse VAMC and CBOCs.

If you agree to participate in this research study, you will be asked to complete 6 total assessment sessions and attend up to 6 treatment sessions in primary care at the Syracuse VAMC/CBOCs. Here is what you can expect if you decide to participate in this study:

During the rest of today's session, which will take approximately 90 minutes, you will be asked to complete a few questionnaires regarding anxiety, mood, quality of life, and mental health treatment history, such as:

a) Demographics, medication, and treatment history
b) Stress, anxiety, and depressed mood, including thoughts of death and suicide
c) General wellbeing, functional impairment, quality of life, coping skills
d) Substance use
e) Sleep and behaviors

Participant Name: _____ **Date:** _____

Title of Study: Improving Anxiety Treatment Engagement and Effectiveness in Primary Care-Mental Health Integration: Multi-site Hybrid I RCT of a Brief Veteran-Centered Anxiety Intervention

Principal Investigator: Robyn L. Shepardson, Ph.D. **VAMC:** Syracuse

Consent Version Date: (08/18/2022)

If you complete today's session, you would receive $40 to thank you for your time.

We are comparing the brief anxiety treatment to primary care treatment as usual for anxiety. Each participant will be randomly assigned to a treatment. Using a procedure like a flip of a coin, you will have a 1 in 2 chance of receiving the brief anxiety treatment or receiving primary care treatment as usual.

The brief anxiety treatment will involve up to 6 sessions (about 30 minutes each) over 16 weeks with an integrated behavioral health provider to learn skills to help you better cope with symptoms of anxiety. The treatment as usual condition will involve meeting with an integrated behavioral health provider who specializes in treating concerns such as stress, anxiety, and depression, at your primary care clinic.

If you are randomized to the brief anxiety treatment:

> You will be asked to attend up to 6 individual sessions (approximately 30 minutes each) in primary care at the Syracuse VAMC/CBOCs. These sessions can be in-person, conducted via the telephone, or conducted using the VA Video Connect (VVC) telehealth system as needed. This treatment does not involve taking any medications. Instead, in this treatment, you meet with a provider to learn skills to help you better cope with anxiety. The anxiety treatment being evaluated in this study has been developed specifically for Veterans and for the primary care setting. These sessions will be audiotaped for supervision and research purposes.

If you are randomized to the treatment as usual condition:

> The treatment as usual condition will involve making an appointment with an integrated behavioral health provider, who specializes in treating concerns such as stress, anxiety, and depression, at your primary care clinic. These sessions can be in-person, conducted via the telephone, or conducted using the VA Video Connect (VVC) telehealth system as needed. These sessions will be audiotaped for research purposes. You and the provider can collaboratively decide whether and when you would like to meet again during the following 16 weeks.

For all participants:

Depending on your VA patient category and means test, your insurance carrier may be responsible to pay for you and you maybe be responsible to make a co-payment for the sessions with an integrated behavioral health provider (i.e., for either the brief anxiety treatment sessions or the treatment as usual sessions) that would be administered as part of your standard clinical care if you were not a research subject.

Participant Name: _____ **Date:** _____

Title of Study: Improving Anxiety Treatment Engagement and Effectiveness in Primary Care-Mental Health Integration: Multi-site Hybrid I RCT of a Brief Veteran-Centered Anxiety Intervention

Principal Investigator: Robyn L. Shepardson, Ph.D. **VAMC:** Syracuse

Consent Version Date: (08/18/2022)

Research staff conducting the assessment sessions will not know whether you are assigned to the brief anxiety treatment or the treatment as usual condition. This helps them treat everyone the same and not give special treatment to one group or another.

Three brief telephone assessments will occur approximately every 4 weeks during the study, at 4, 8, and 12 weeks from now. This involves research staff calling you on the phone so you can complete 2 short questionnaires about anxiety and mood. Each brief telephone assessment will take about 10 minutes, and you will receive $10 as compensation for your time for each of these assessments that you complete.

A post-treatment assessment session would take place approximately 16 weeks from now. This assessment may be conducted in-person, over the telephone, or using VVC as needed. This involves completing questionnaires about anxiety, mood, quality of life, coping skills, and mental health treatment engagement. This assessment will take 90-120 minutes and you would receive $50 as compensation for your time if you complete it.

A final follow-up assessment session would take place approximately 28 weeks from now, or about 3 months after the post assessment. This assessment may also be conducted in-person, over the telephone, or via VVC as needed. This involves completing similar questionnaires about anxiety, mood, quality of life, and mental health treatment engagement and will take approximately 30 minutes to complete and you would receive $40 as compensation for your time if you complete it.

If you complete all 6 assessments, you would earn an additional $40. Overall, the total possible compensation for the entire study, including today's initial assessment, the 3 brief telephone assessments, the post-treatment assessment, and the final follow-up assessment is $200. All payments will be pro-rated if you withdraw, such that if you complete half of an assessment, you would receive half of the payment. You will be paid via either direct deposit (electronic funds transfer), prepaid debit card, or check.

We will remind you about all study assessments, which will be scheduled at your convenience. Based on your preference, research staff may call, text, or email you appointment reminders. Staff will not text or email any personal health information because these methods of communication are not secure.

We ask permission to obtain the following information about you from your VA medical records: demographics; medications; diagnoses; treatment utilization (dates, diagnoses, and recommendations from primary care, emergency room, and mental health visits [including drug/alcohol treatment] from 12 months before today through 12 months after the 16-week post assessment); and screening results (food, housing, interpersonal violence). Your privacy will be carefully protected (see details below). Both your own reports at follow-up and the information we get from your medical records are important ways of evaluating longer-term outcomes of the treatment.

Participant Name: _____ **Date:** _____

Title of Study: Improving Anxiety Treatment Engagement and Effectiveness in Primary Care-Mental Health Integration: Multi-site Hybrid I RCT of a Brief Veteran-Centered Anxiety Intervention

Principal Investigator: Robyn L. Shepardson, Ph.D. **VAMC:** Syracuse

Consent Version Date: (08/18/2022)

Since this study involves asking you further information about your mood and issues pertaining to your safety, we want you to know that at any time if we are concerned about your safety, we will discuss it with you if possible, or seek help from your primary care provider or emergency services if necessary. At the discretion of the principal investigator, participants may be taken out of this study due to unanticipated circumstances, such as extreme distress. In other words, we may withdraw you from the study should we judge your participation not to be in your best interest.

At any time, you can choose to discontinue the entire study, including assessment sessions and the treatment sessions. You can also choose to discontinue the treatment sessions but complete any or all of the assessment sessions.

During the study, voice recordings will be obtained from you while you are: in treatment sessions. This is for the following purpose(s): supervision of study therapists and understanding treatment processes (brief anxiety treatment condition) and understanding what interventions were used and treatment processes (treatment as usual condition). This will help us evaluate how and why the treatments are effective.

NOTE: The information requested in this consent form is solicited under the authority of title 38, United States Code. The execution of this information consent form does not authorize disclosure of the materials specified above except for the purpose(s) stated. The specified material may be used within the VA for authorized purposes, such as education of VA personnel or for VA research activities. It may also be disclosed outside the VA system as permitted by law. If the material is part of a VA system of records, it may be disclosed outside the VA as stated in the 'Routine Uses' in the "VA Privacy Act Systems of Records" published in the Federal Register. A copy of the 'Routine Uses' is available upon request to the administrative office of the VA facility involved. You do not have to consent to have your picture or voice taken, recorded, or used. Your refusal to grant your consent will have no effect on any VA benefits to which you may be entitled.

Dr. Robyn Shepardson is a primary care psychologist who is involved as an investigator in this research study. As both a psychologist and a research investigator, she is interested in both your medical care and the conduct of this research study. Before agreeing to participate in this research study, or at any time during your study participation, you may discuss your care with another doctor or psychologist who is not associated with this research study. You are not under any obligation to participate in any research study offered by your primary care psychologist.

Participant Name: _____ **Date:** _____

Title of Study: Improving Anxiety Treatment Engagement and Effectiveness in Primary Care-Mental Health Integration: Multi-site Hybrid I RCT of a Brief Veteran-Centered Anxiety Intervention

Principal Investigator: Robyn L. Shepardson, Ph.D. **VAMC:** Syracuse

Consent Version Date: (08/18/2022)

DESCRIPTION OF THE DISCOMFORTS, INCONVENIENCES, AND/OR RISKS

Every effort has been made to minimize potential risks associated with your participation in this research study. Most individuals will experience little, if any, risks from their participation in this study. It is possible that answering questions about your anxiety level and mood during assessments or treatment sessions might cause some discomfort or distress or increase feelings of hopelessness. You may experience fatigue from completing the questionnaires or mild discomfort during tasks associated with the anxiety treatment; however, you may complete it at your own pace and take a break if needed. In addition, there may be unknown or unforeseen risks associated with study participation.

In the event that you experience any emotional distress, you may contact Dr. Robyn Shepardson at [redacted] during regular business hours (Monday-Friday 8:00 am – 4:00 pm) or call the VA Telecare at [redacted] at all other times.

FOR STUDY PARTICIPANTS WHO ARE VETERANS:

As a veteran subject you will not be required to pay for any treatment received as a research participant, which is being done solely for the purpose of this research study. However, your insurance carrier will be billed for all routine care and clinical procedures, if applicable. If you are in a "priority group # 6, 7 or 8 veteran category" you are subject to making a co-payment for all non-research related medical care as indicated by a means test. Your doctor should be able to provide you with this information or refer you to the appropriate individual for any questions you may have.

As a veteran, you will receive medical care and treatment for injuries suffered as a result of participating in a VA research program in accordance with Federal Law*** (see below)**. You will incur no additional charges for additional medical care and treatment that may result from injury or complications that are a direct result of your participation in this study. Money has not been set aside for pain and suffering compensation.

In case there are any medical problems or questions, or in the event of illness or injury that you believe to be related to the study, you can also call Dr. Robyn Shepardson at [redacted]

***Federal Law Advisory - VA Disability Compensation Benefits**: As a veteran-participant, you may be entitled to VA disability compensation benefits for "additional disability" incurred or aggravated as a direct result of your participation in this study (*see* 38 U.S.C. Sec. 1151; 38 C.F.R. Sec. 3.358). If you believe you have incurred additional disability as a result of your participation in this study, please contact your Veterans Service Officer for more information regarding your right to file for VA disability benefits.

Participant Name: _____ **Date:** _____

Title of Study: Improving Anxiety Treatment Engagement and Effectiveness in Primary Care-Mental Health Integration: Multi-site Hybrid I RCT of a Brief Veteran-Centered Anxiety Intervention

Principal Investigator: Robyn L. Shepardson, Ph.D. **VAMC:** Syracuse

Consent Version Date: (08/18/2022)

ANTICIPATED BENEFITS RESULTING FROM STUDY PARTICIPATION

While no direct benefits can be guaranteed, we expect that you may benefit from this study by learning more about anxiety symptoms and ways to manage anxiety better using healthy coping skills. Taking part in this study may not personally help you, but your participation may lead to knowledge that will help us improve anxiety treatment options in primary care to help other Veterans.

ALTERNATIVE PROCEDURES/OTHER TREATMENT AVAILABLE

You can receive treatment in primary care or outpatient mental health instead of participating in this study if you prefer. If you choose not to participate in this study, there are several alternative treatments available to you through the VA. Treatment options may include assessment and evaluation, counseling, educational group therapy, medication, or a referral for therapy at the outpatient behavioral health clinic.

You are not required to take part in this research study. Your participation is entirely voluntary. You can refuse to participate now or you can withdraw from this study at any time after giving your consent without affecting your healthcare/services or other rights. In addition, you can choose not to answer any questions without prejudice or penalty. This will not interfere with your regular medical treatment, and will incur no penalty or loss of benefits to which you are otherwise entitled to as a patient.

CONFIDENTIALITY AND PRIVACY

Any information obtained about you in this study will be treated as confidential and will be safeguarded in accordance with the Privacy Act of 1974. Information published or presented about the results of this study will be in a form that does not identify any particular participant. In order to monitor compliance with federal regulations and for purposes of monitoring the accuracy and completeness of the research data, records identifying you may be inspected by representatives of the sponsor or sponsors of this study, the Syracuse VA Medical Center Institutional Review Board (Syracuse IRB), Internal Compliance Auditors, the Office of Human Research Protections (OHRP), VA Office of Research Oversight (ORO), Veterans Affairs contracted agency for accrediting VA Human Research Protection Programs and the Department of Health and Human Services (DHHS). If this study involves articles regulated by the Food and Drug Administration (FDA), the FDA may choose to inspect records identifying you as a subject in this investigation. By signing this document, you consent to such inspection. The results of this study may be published but your identity and records will not be revealed unless required by law.

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

Participant Name: _____ **Date:** _____

Title of Study: Improving Anxiety Treatment Engagement and Effectiveness in Primary Care-Mental Health Integration: Multi-site Hybrid I RCT of a Brief Veteran-Centered Anxiety Intervention

Principal Investigator: Robyn L. Shepardson, Ph.D. **VAMC:** Syracuse

Consent Version Date: (08/18/2022)

This study is confidential. To protect your privacy, your name or other identifying information (e.g., last 4 of SSN) will NOT be recorded on study questionnaires. Rather, an identification number will be assigned to you. The master tracking log linking your name to your identification number will be stored securely and separately from your study data.

The only place we will store your name is on this consent form/HIPAA authorization and the master tracking log. All study information will be kept in locked files and secure computer networks accessible only to our research staff. Research personnel are carefully trained to maintain the confidentiality of the information collected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

We take your privacy and confidentiality very seriously, but there are some limits to confidentiality. One situation where confidentiality may be broken is if you report wanting/planning to harm yourself or others or if you report child abuse/neglect. If this is disclosed to treatment providers or research staff, we would be legally and ethically required to report this information to the appropriate parties in order to protect your safety or the safety of others.

RESEARCH RESULTS

In the event new information becomes available that may affect the risks and/or benefits associated with this study or your willingness to participate in it, you and your physician will be notified so you can make a decision whether or not to continue your participation in this study.

All paper data will be stored in locked file cabinets in the secure research offices of the Center for Integrated Healthcare. All electronic data will be stored on a secure VA computer network. Only IRB-approved VA research staff will have access to the study data. The principal investigator will have possession of all study data and will maintain it until it is eventually destroyed in accordance with the IRB regulations and the VHA Records Control Schedule.

What will happen to your information (data) at the end of the study?

If results of this study are reported in medical journals or at scientific meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent.

At the end of the study your VA information will be retained in your research record in accordance with Veterans Health Administration (VHA) and Federal Records Control Schedule policies.

Participant Name: _____ **Date:** _____

Title of Study: Improving Anxiety Treatment Engagement and Effectiveness in Primary Care-Mental Health Integration: Multi-site Hybrid I RCT of a Brief Veteran-Centered Anxiety Intervention

Principal Investigator: Robyn L. Shepardson, Ph.D. **VAMC:** Syracuse

Consent Version Date: (08/18/2022)

How will your information be used in the future?

Your information collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

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 signing this form, 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 (completing questionnaires/interview questions, audio recordings of treatment sessions). They will also collect other information including your name, address, date of birth, and information from your medical records such as diagnoses, health screening results, and medical and mental health treatment history including drug/alcohol 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 VA Health Services Research and Development Data Safety Monitoring Board, Institutional Review Board, Food and Drug Administration (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability Office (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.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. 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.

If you revoke this authorization, Dr. Robyn Shepardson and her research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

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

Participant Name: _____ **Date:** _____

Title of Study: Improving Anxiety Treatment Engagement and Effectiveness in Primary Care-Mental Health Integration: Multi-site Hybrid I RCT of a Brief Veteran-Centered Anxiety Intervention

Principal Investigator: Robyn L. Shepardson, Ph.D. **VAMC:** Syracuse

Consent Version Date: (08/18/2022)

CONTACT INFORMATION

If you have questions about this study or to report a research-related injury, you can contact: Dr. Robyn Shepardson at [redacted].

If you have general questions about giving consent or your rights as a participant in this study or you would like to speak with an individual who is unaffiliated to this specific research study to discuss problems, concerns, and questions; obtain information or offer input you may call the Chairman of the Syracuse VAMC Institutional Review Board or the Human Research Protection Program Administrator, [redacted] or the Syracuse VA Patient Advocate at [redacted].

STATEMENT OF PERSON AGREEING TO PARTICIPATE IN THIS RESEARCH STUDY

I have read (___) this consent form or have had it read to me (___). (Check one).

Research staff have explained the study to me, and all of my questions have been answered. 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 told my rights as a research subject, and I voluntarily consent to participate in this study. I have been told what the study is about and how and why it is being done. All my questions have been answered. If I do not take part in this study, my refusal to participate will involve no penalty or loss of rights to which I am entitled.

I agree to authorize voice recordings to be made of my treatment sessions while I am participating in this research study. I authorize the disclosure of these voice recordings to all parties mentioned in the HIPAA section above. I understand that the said voice recordings are intended for the purpose of supervision of therapists and understanding what interventions were used for the duration of this study.

I have been told that I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled. **I may withdraw consent and discontinue participation at any time, without prejudice to my care, by informing Dr. Robyn Shepardson of my decision to withdraw**. I also have been told that my participation also may be stopped by the study sponsor, study doctor, FDA, OHRP, ORO, or the Syracuse IRB, *without my consent*.

If any important information is found during this study that may affect your wanting to continue your participation in this study, you will be told about it right away.

Participant Name: _____ **Date:** _____

Title of Study: Improving Anxiety Treatment Engagement and Effectiveness in Primary Care-Mental Health Integration: Multi-site Hybrid I RCT of a Brief Veteran-Centered Anxiety Intervention

Principal Investigator: Robyn L. Shepardson, Ph.D. **VAMC:** Syracuse

Consent Version Date: (08/18/2022)

You will receive a copy of this consent form and the original will be placed in the investigator's research files. Additional copies will be filed in your medical chart and in the Syracuse VAMC's RCO Office.

NOTE: CONSENT FORM SHOULD NOT BE SIGNED IF THE APPROVAL STAMP IS MISSING.

SUBJECT'S STATEMENT: I, the undersigned, hereby agree to participate as a subject in this research study and authorize the use and disclosure of my health information for this study.

Subject's Signature	**Subject's SSN (last 4 only)**		
Subject's Name (Printed)	**Telephone Number**	**Date**	**Time**