Acceptance and Commitment Therapy to Improve Social Support for Veterans With PTSD

NCT04567680

October 13, 2022

Participant Name: _____ Date:_____

Title of Study: An Evaluation of Psychotherapy Treatments to Improve Social Support for Veterans with PTSD

Principal Investigator: Megan M. Kelly, Ph.D. VA Facility: Bedford VAMC

Sponsor of Study: Department of Veterans Affairs

We are asking you to choose whether or not to volunteer for a research study. This consent form will give you information about the study 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?

This study is focused on comparing two psychotherapy treatments to help Veterans with PTSD to improve their social functioning and PTSD symptoms. The psychotherapy treatments being compared are Acceptance and Commitment Therapy to Improve Social Support for Veterans with PTSD and Present-Centered Therapy. This study is being funded by the Department of Veterans Affairs. This study is taking place at the VA Bedford Healthcare System, VA Connecticut Healthcare System, and the Rocky Mountain Regional VAMC.

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

If you decide to participate in this study, you will be randomly assigned to one of the two psychotherapy treatments. This process is like flipping a coin.

During the study, you will come in for 1 study visit to determine your eligibility for this study. This visit will involve an interview and several questionnaires. This visit will take about 1-2 hours of your time. You may be able to complete some of these questionnaires online. If you are eligible for this study, you will be invited to participate in the treatment sessions that can take place in person or by video. There will be 12 treatment sessions that will take about 60 minutes each. These treatment sessions may be able to take place in person or virtually using VA-approved video-conferencing software like VA Video Connect. Sessions 4 and 8 will take an additional 30 minutes of your time to fill out questionnaires either in-person or onlineafter the treatment session.The last treatment session, session 12, will take an additional hour of your time, since you will fill out several questionnaires either in-person or online. At 3-months and 6-months after you complete treatment, we will ask you to answer several questionnaires either in-person or online at the 3-month and 6-month follow-up visits. These follow-up study visits, which can take place in-person or virtually using VA-approved video-conferencing software (like VA Video Connect), will take about 1 hour of your time. You will be given $50 the first study visit. You will be paid $20 for Sessions 4 and 8. You will be paid $50 for Session 12. You will also be paid $50 each for the 3-month follow-up visit and the 6-month follow-up visit. You will be paid by a voucher that you can take to the agent cashier or by gift card. You may receive these gift cards at your next scheduled in-person or we can mail them to you.

Pregnant women will not be able to participate.

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

We cannot and do not guarantee or promise that you will receive any benefits from this study.

Receiving psychotherapy treatment in this study may improve your levels of social support and/or PTSD symptoms.

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.

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

Participation in this research study is voluntary. If you decide to take part 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 choose not to volunteer. You may also discontinue participation at any time.

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

The person in charge of the study is Dr. Megan Kelly of the Bedford VAMC. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: 781-687-3317.

RESEARCH DETAILS

WHAT IS THE PURPOSE OF THIS STUDY?

You are invited to participate in a research study designed to compare two different types of psychotherapy treatments for improving the social support of Veterans with PTSD. You have been invited because you might have PTSD. With this research we hope to learn whether one or both of these treatments are helpful in improving the social support and PTSD symptoms of Veterans with PTSD.

HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take approximately 3.5 years. Your individual participation in the project will take 9 months.

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

Intake and Interview Procedures. If you decide to participate in this research study, you will have an in-person screening with a member of the research team and you will be asked to complete questionnaires. You can fill out these questionnaires online or in-person. We will ask you about your social

support network and interactions with other people. You will also be asked questions about possible current and past psychological or emotional difficulties and substance use. This is done because such problems are sometimes associated with social support difficulties, and because such problems may affect your efforts to improve your levels of social support. These interviews and questionnaires will take about 2 hours of your time. We will also ask for the names, contact information, and a release of information for people that you know that would help us be able to get in touch with you. If you do not meet eligibility criteria during this screening, you will be excluded from participation. If you meet eligibility criteria, you will be asked to participate in the treatment phase of the study.

Treatment Phase. You will be randomly assigned (like a flip of a coin) to one of two treatment groups (Treatment A or Treatment B). The reason you will be randomly assigned to a treatment, rather than you choosing a treatment, is so that researchers can determine which treatment works best. We expect that 75 people will be randomized in this study.

Treatment Group A: (38 participants)
If you are assigned to Group A, you will receive 12 individual therapy sessions (delivered either in-person or virtually) of an acceptance and mindfulness treatment, *Acceptance and Commitment Therapy to Improve Support for Veterans with PTSD* (ACT-SS). You will receive 12 weekly individual counseling sessions of this treatment. Sessions will focus on the use of acceptance and mindfulness-based strategies for building social support and managing PTSD symptoms. The treatment sessions will take 45 minutes of your time, and you will complete study questionnaires either in-person or online about mood, social support, community reintegration, and quality of life that take up an additional 15 minutes of your time, for a total session length of 60 minutes each week.

Treatment Group B: (37 participants)
If you are assigned to Group B, you will take part in another counseling treatment, *Present-Centered Therapy (PCT).* You will receive 12 weekly individual counseling sessions either in-person or virtually of this treatment. PCT is a commonly used treatment for PTSD. Participants are encouraged to explore their own experiences and emotions in order to make their own decisions about how they need to change. The treatment sessions will take 45 minutes of your time, and you will complete study questionnaires either in-person or online about mood, social support, community reintegration, and quality of life that take 15 minutes of your time, for a total session length of 60 minutes each week.

Follow-up appointments. A research follow-up appointment will be scheduled for 3 months and 6 months after the end of treatment for all participants. This appointment may be done in-person or virtually using VA-approved video conferencing software. At this appointment, we will ask you about social support, quality of life, community reintegration, alcohol and drug-related problems, and psychological and emotional difficulties. You will also fill out a series of questionnaires either in-person or online on PTSD, mood, quality of life, community reintegration, and social support, which will take about 15 minutes of your time. The total time for follow-up appointments will take about 1 hour. We will call you to

remind you about your appointments, including treatment and follow-up sessions.

We will ask to record your assessment and treatment sessions so that the study investigators can monitor and ensure the quality of these sessions. We will review these tapes to monitor how therapists are delivering treatment and to make sure they are delivering treatment according to each treatment's procedures. These audiotapes will be kept confidential and will be listened to only by study personnel. No audio recordings will be disclosed outside the VA.

☐ I agree to have my assessment and treatment sessions audiotaped for this study.

☐ I do not agree to have my assessment and treatment sessions audiotaped for this study.

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

The intake and follow-up interviews and questionnaires will take time to complete. We estimate it will take approximately 1-2 hours of your time for the intake assessments, between 10-15 minutes for appointments in the treatment phase of the study, one hour for Session 12, and one hour for each of the follow-up assessments. Therapy sessions will also take time, and will last about 45 minutes each during the treatment phase of the study.

You may be uncomfortable answering questions about substance use, emotional and psychosocial problems. If you are uncomfortable with any part of the interview, you may skip the question or take a break. You will have the opportunity to take breaks to minimize fatigue and discomfort. Please let the research staff know if you become too uncomfortable. You can also contact the researchers if your symptoms bother you after you go home. If needed, we will contact the psychologist on this study to evaluate you by phone or in person to see if you need any more treatment.

Also, some questionnaires include questions about whether you have had thoughts of harming yourself or others. If the research staff is concerned about your safety during the study, a study clinician may evaluate you and refer you for further evaluation and/or treatment. If a clinician determines that you are a danger to yourself or others, you may be held in a hospital against your will. These actions are to insure your safety and the safety of others.

At any point during the study, we will discharge you if we are concerned that staying in the study may cause you physical or psychological harm. If the research team discharges you from the study, we will contact your regular clinician to coordinate and provide you with the most Department of Veterans Affairs appropriate care to address these issues. If you do not have a regular clinician, we will discuss possible sources of medical care and encourage you to seek treatment.

Confidentiality of Information:

Participation in this 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.) The master list linking names to code numbers will be kept separately from the research data.

All research information will be kept in locked files 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. The Department of Veterans Affairs (VA) requires some information to be recorded in the VA electronic medical record for all veteran and non-veteran research subjects. Therefore, if you participate in this study, a medical record will be created if you do not already have one. Notes from your visits, procedures, and laboratory tests will be included in this record. In addition to the research team, and the VA staff who provide clinical services, other researchers may be granted approval to access this information in the future. Federal laws and regulations that protect privacy of medical records will apply to your VA record.

Other risks:

There is a risk that you may not be able to improve social support, reduce interpersonal difficulties, or you will experience a worsening of PTSD or other mental health symptoms during the study. However, we will monitor you very closely and will take numerous safety precautions to ensure your safety and well-being.

Unanticipated risks:

If you have any unusual or uncomfortable feelings during the study, contact the research staff. You can reach a study staff by calling a member of the research team during normal business hours. You can also come in to the Mental Health Clinic (Hours: Monday-Friday, 8:00 am-4:00 pm; Building 78, 2nd Floor; 781-687-4333). You may also come in to the Bedford VAMC Urgent Care Center during their main hours (Monday-Friday, 8:00 am-4:00 pm; Building 78, 1st Floor; 781-687-2654) or after hours. You may also call the doctor on call after hours (781-275-7500). If you become suicidal, hospitalization is possible.

Since we are concerned about your health and safety, there are some situations when we will contact your primary care physician or other clinical professional that is providing care for you, such as to inform him/her that:

- You need to be taken to Urgent Care for medical reasons
- You report suicidal thoughts or homicidal thoughts
- You are hospitalized

- You experience serious side effects that are a concern to you and/or the study team
- You experience an adverse event or reaction that occurs in the course of the study where the PCP has not already been informed
- You may be potentially harmed by continued participation in the study.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

Your participation may or may not be of benefit to you. The benefits to you include a free evaluation, free mental health treatment, and careful monitoring during treatment. You will receive counseling treatment that has been shown to be effective for treatment of mental health problems. However, we cannot and do not guarantee or promise that you will receive any benefits from this study. If you participation does not benefit you, it will be of benefit to others, as it will contribute to the effort to learn more about the treatment of Veterans with PTSD.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY? (Include if applicable)

You are free to decline entrance into or withdraw your participation in this study at any time. If you decline to participate or withdraw from the study, and you desire treatment elsewhere, you will be provided with information about alternative mental health treatment in the VA and in the community. Mental health treatments at the VA include medications and counseling. Similar treatments are available through treatments in the community. A decision not to participate in this study or to withdraw from this study will not affect your ability to participate in other VA treatment, including mental health treatment.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Participation in this research may involve a loss of privacy. However, numerous safeguards will keep electronic and hard copy data secure. Your research records will be kept as confidential as possible. All research information will be kept in locked files at all times. 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 collected. After the removal, the information could be used for future research studies without additional consent from you.

We have obtained a Certificate of Confidentiality from the Federal Government. This helps protect your privacy by allowing us to refuse to release your name or other information outside of the research study, even by a court order. The Certificate of Confidentiality will not be used to prevent disclosures to local

authorities of certain communicable diseases, physical or sexual abuse, child or elder abuse or neglect, or harm or risk of imminant harm to self or others. The Certificate does not protect you if you, someone in your family, or someone you know voluntarily releases information about you.

We will include information about your study participation in your medical record. A medical record will be created if you do not already have one. Notes from your visits, procedures, and laboratory tests will be included in this record. In addition to the research team, and the VA staff who provide clinical services, other researchers may be granted approval to access this information in the future. Federal laws and regulation that protect privacy of medical records will apply to your VA record.

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.

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 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.

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.

You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled.

For data already collected prior to the participant's withdrawal, we will continue to review the data already collected for the study but cannot collect further information, except from public records.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION (Include if applicable)

Investigators may end your participation in this study if they feel it is in your best interest, and/or if you are not complying by program rules. The reason for your discontinuation will be explained to you. If you stop participating in the study for one of these reasons, you will have the option of obtaining mental health treatment in the Mental Health Clinic, through your other health care providers, or will be referred to local mental health treatment providers. If you withdraw at any point during the study, we will still use the data that has already been collected. However, you may choose to withdraw your study data if you

indicate this to research staff. If you decide to withdraw from the counseling treatment, you may also continue to fill out questionnaires at each assessment point until the end of the study, and you will be compensated for your time and travel for your participation. If you decide to withdraw from both counseling treatment and decide not to fill out questionnaires, you will not be compensated and will be discontinued from the study.

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.

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. Megan Kelly at 781-687-3317 during the day or have the doctor on call (781-687-2000) paged after hours.**

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
No money has been set aside for compensation in case of injury as a result of participating in this study however I have been told that I would still have the right to file any legal action.

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

If you have any questions about the research, you may contact Dr. Megan Kelly at 781-687-3317.

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.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr. Kelly 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.

By signing this document below, you voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. A copy of the consent will be given to you.

Participant Name: _____ Date:_____

Title of Study: An Evaluation of Psychotherapy Treatments to Improve Social Support for Veterans with PTSD

Principal Investigator: Megan M. Kelly, Ph.D. VA Facility: Bedford VAMC

Sponsor of Study: Department of Veterans Affairs

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date