Improving Treatment Outcomes for Suicidal Veterans with PTSD

NCT04690582

10/19/2021

The Ohio State University Consent to Participate in Research

Study Title:	**Enhancing the effectiveness of cognitive processing therapy among military veterans with PTSD**
Principal Investigator:	**Craig J. Bryan, PsyD, ABPP**
Sponsor:	**The Boeing Company**

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.

- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at OSU, your decision will not affect your grades or employment status.

- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.

- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study

The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

You are being asked to be a participant in a research study that seeks to improve the effectiveness of a well-established treatment for PTSD called cognitive processing therapy (CPT). This research is being done to determine if small changes to CPT can result in faster reductions in suicide ideation among veterans who have suicidal thoughts at the start of treatment and prevent the onset of new suicide ideation among veterans who do not have suicidal thoughts at the start of treatment. The specific treatment procedures that you receive will be determined randomly, which is similar to flipping a coin. This will help us to determine if one procedure may be more helpful and better suited for people receiving CPT .

The study will involve questionnaires, an interview, and psychological (non-medication) treatment that will be provided either face-to-face or over the internet, depending on your

preference and location. The total time that you will be involved in this study is at least 29 hours over the next year: at least 12 hours for treatment, 12 hours for treatment practice worksheets, 4.5 hours for surveys completed on your smart phone during a two-week period of time, and at least 0.5 hours (30 minutes) for follow-up surveys. You will receive $50 compensation for each follow-up survey that you complete, up to $100 maximum.

1. Why is this study being done?

This research is being done to improve the effectiveness of an existing treatment for PTSD called cognitive processing therapy (CPT). We will determine if small changes to CPT result in faster reductions in suicide ideation and PTSD symptoms among veterans who are diagnosed with PTSD.

2. How many people will take part in this study?

Approximately 1250 people may be enrolled in this research at The Ohio State University.

3. What will happen if I take part in this study?

This research will be performed at The Ohio State University's Department of Psychiatry and Behavioral Health.

To participate in this study, you will need to meet with a mental health professional for 1 hour per day for 14 consecutive days. Therapy sessions will be held either online or face-to-face, depending on your preference. During these 14 days, you will be asked to complete surveys up to 4 times per day. These surveys can be completed on your phone and will take less than 5 minutes to complete. Six (6) and 12 months after you complete treatment, you will be asked to complete questionnaires online. Each of these questionnaires will take less than 15 minutes to complete. **No drug or substance of any kind will be given during the course of this research study**.

All of the procedures described below will be performed by qualified, clinically trained personnel and arranged at your convenience. If you volunteer to participate in this study, please keep in mind that you have the right to refuse to answer any question that you may not wish to answer.

As a participant, we will ask you to do the following things:

<u>Part 1: Psychological Treatment and Assessment, Approximately 16.5 hours</u>
If you are eligible for the study, we will schedule you to begin meeting with a mental health professional for daily therapy sessions. Therapy sessions will be scheduled for 1 hour per day. You can choose to attend therapy sessions in person or via an approved online communication platform. At the end of each therapy session, you will receive an assignment to complete a series of worksheets to practice the skills learned during

that day. These practice assignments typically require 1-2 hours of time to complete. You will be asked to review your completed worksheets at the beginning of each session.

In this study, you will receive cognitive processing therapy (CPT), a psychological (nonmedication) treatment that has been shown to significantly reduce the symptoms of PTSD. Previous research has shown that more than 80 of 100 people who receive CPT benefit from the treatment, and approximately 53 of 100 people who receive CPT no longer have PTSD afterwards.

In addition to CPT, you will participate in 1 of 2 possible procedures designed to help you identify and use strategies for reducing emotional distress during stressful situations. These procedures are often called "safety plans" or "crisis plans," and are widely used by mental health professionals to help their patients. Both types of plans involve identifying signs of emotional distress, personal strategies you can take to manage your distress, sources of social support, and contact information for crisis services. Depending on the type of plan that you receive, you might also identify steps to increase the safety of your environment or identify meaningful and positive things in your life. Previous research suggests that both types of procedures reduce suicidal thoughts and behaviors. The specific procedure that you receive will be determined randomly, which is similar to flipping a coin. This will help us to determine if one procedure may be more helpful and better suited for people receiving CPT.

While receiving treatment, you will also be asked to complete a brief survey on your smartphone 4 times per day for 14 consecutive days (2 weeks). These surveys will be sent to you every day at randomly selected times between 8AM and 11PM. Each survey will take less than 5 minutes to complete, and will ask you to report what you are doing, how you are feeling, and who you are with.

Part 2: Follow-Up Assessments, Approximately 30 minutes

Research staff will contact you approximately 6 months and 12 months after completing treatment to complete several questionnaires that will ask you about your feelings, thoughts, moods, impulses, substance use, and behavior. These questionnaires will take less than 15 minutes to complete.

4. How long will I be in the study?

The total time that you will be involved in this study is at least 29.5 hours over the next year. Your participation will be over at the completion of Part 2, unless you choose to end your participation before that time. Here is a brief timeline of the study:

Psychological Treatment	12 hrs
Psychological Treatment Practice Assignments (During treatment)	12-24 hrs

Phone Surveys (During Treatment)	5 mins per survey, 20 mins per day
Follow-Up Assessment #1 (6 Months)	15 mins
Follow-Up Assessment #2 (12 Months)	15 mins

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

The known or expected risks are:

Interviews and Questionnaires

The interviews and questionnaires are administered as a research procedure in the context of this study to fully describe the people who take part in this study. Please note that some of the questions may be of a personal and/or sensitive nature, and that you may become bored or fatigued completing the interviews and questionnaires. The collection of such data poses a potential risk of loss of confidentiality around sensitive information such as psychiatric status, history of substance abuse, etc. Interviews will be conducted by experienced staff who will maintain confidentiality and all data from interviews and questionnaires will be coded so as to conceal your identity. If any of the interview questions make you feel uncomfortable, you do not have to answer them. If you are identified as having a potentially imminent risk, the researcher will conduct a more thorough assessment, including possible evaluation by a clinical mental health provider on the study team for possible hospitalization and/or notification of emergency services for the purposes of a rescue.

Psychological Treatment

The treatment that you will receive does not require you to describe or talk about any of the traumas that you have experienced, but it does require you to think about how the trauma(s) have affected you, your relationships, and other parts of your life. A small number of people (around 1 in 4) who receive CPT describe a short-term increase in symptoms during the first 2-3 sessions of treatment. This increase in symptoms typically reduces soon thereafter, and continues to reduce over the following sessions. For some people, this temporary increase in symptoms can increase thoughts and urges about suicide. To manage this risk, you will be asked to develop a safety or crisis plan, both of which have been shown to help people to manage suicidal thoughts and urges. You will

also receive assistance and support from your assigned therapist, who has experience with CPT and helping people to manage these symptoms.

7. What benefits can I expect from being in the study?

Although we cannot guarantee that you will directly benefit from participation in this research, you may benefit from receiving the treatments offered in this study, which have been shown to significantly reduce PTSD symptoms, depression, suicidal ideation, and other problems in life for most (though not all) people who receive it. You may also benefit from completing our assessments and a structured diagnostic interview for psychiatric conditions. Such information could provide useful information that could be used to pursue optimal types of treatment or therapy. You may also experience increased self-awareness by tracking your mood on a regular basis while receiving treatment.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled. You may choose receive the treatments offered in this study, or other treatments that are not used in this study, from a licensed mental health professional.

9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Your data will be protected with a code to reduce the risk that other people can view the responses.

We will work to make sure that no one sees your survey responses without approval. But, because we are using the Internet and smartphones, there is a chance that someone could access your responses without permission. In some cases, this information could be used to identify you. Your data will be protected with a code to reduce the risk that other people can view the responses.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If new information is provided to you, your consent to continue participating in this study may be re-obtained.

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.

Please talk to your study team, or contact the Office of Responsible Research Practices at 614-688-8641, if you have questions.

10. Will my de-identified information be used or shared for future research?

Yes, your information may be used or shared with other researchers without your additional informed consent.

11. What are the costs of taking part in this study?

The costs to you for participating in this research may include travel costs and time. You may also incur costs for internet access or smartphone data use.

12. Will I be paid for taking part in this study?

By law, payments to participants are considered taxable income.

You will receive compensation in the amount of $50 for each completed follow-up assessment, which will be completed online. If you complete both of the follow-up assessments, you will be compensated a total of $100.

The payments will be given to you as check, gift card, or reloadable debit card after each assessment.

Activity	**Payment**
Follow-Up Assessment #1 (6 months)	$50
Follow-Up Assessment #2 (12 months)	$50
Total	Up to $100

13. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

14. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

15. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact

Craig J. Bryan, PsyD, ABPP
The Ohio State University, College of Medicine
Department of Psychiatry and Behavioral Health
1670 Upham Drive, Columbus, OH
Phone: 614-366-1027

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact HIPAA Privacy Officer The Ohio State University Wexner Medical Center, Suite E2140, 600 Ackerman Road, Columbus, OH 43210 or at 614-293-4477.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Dr. Craig Bryan at 614-366-1027.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form**.**

Printed name of participant	**Signature of participant**
	AM/PM
	Date and time

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time