Approved consent form for NMCCL.2018.0009

Brief Cognitive Behavioral Therapy Replication Trial

Approval date: 11/13/2020

NAVAL MEDICAL CENTER CAMP LEJEUNE
NC, 28547

CONSENT BY A SUBJECT FOR VOLUNTARY PARTICIPATION IN A CLINICAL INVESTIGATION
at Naval Medical Center Camp Lejeune

SUBJECT ID # _____ **DATE: _____**

Key Information for *Brief Psychological Treatment to Reduce Suicidal Behavior*

You are being asked to decide if you want to volunteer for a research study about reducing suicide risk in military personnel. You can decide if you want to participate. You can ask questions about how being in the study will affect you. If you decide to be in the study, you will be asked to sign the consent form after a researcher goes over it with you.

What is the study about and how long will it last?
The purpose of this study is to compare the effectiveness of two psychological treatments for the reduction of suicide attempts among active duty U.S. Marines. An additional component of this study is focused on examining the effects of sleep problems on suicidal thoughts and behaviors. In this study, we hope to learn the reasons why and how these treatments work. Your participation in the research will last two years.

What will you be asked to do?
While you are participating in this study you will first complete an initial interview, some self-report questionnaires, and some computerized tests. You will then participate in approximately 12 sessions of psychological treatment scheduled once or twice each week. You will be asked to complete a brief questionnaire before each treatment session. You will then complete interviews, self-report questionnaires, and computerized tests every three months for the next two years.

What are key reasons you may not want to volunteer in this study?
You may experience short term psychological distress, including thoughts of suicide or suicide attempts. A small number (less than 5%) of suicide attempts result in death. This risk exists regardless of your participation in the study. The procedures in this study are expected to decrease this risk. There is a small risk that your research records could be lost or otherwise compromised. To reduce this risk, all research staff members have been trained in data protection and confidentiality, and access to data will be restricted to only approved members of the research team.

What benefits may be expected by volunteering in the study?
You may not experience any direct benefit by volunteering in this study, but it will help us learn more about treatments that best benefit other military personnel experiencing suicidal thoughts in the future. We expect that your symptoms will decrease during the course of the study.

Do you have to agree to be in the study?
If you decide to participate 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 decide not to volunteer.

Please read this form carefully. Take time to ask the study doctor or study staff as many questions about the study as you would like. If there are any words or information that you do not understand, the study doctor or study staff will explain them to you. Reading this form and talking to the study doctor or study staff may help

you decide whether to take part or not. Before you take part in the research study, you must sign the end of this form.

1. Study Title:

You have been asked to voluntarily participate in a research study entitled "Brief Psychological Treatment to Reduce Suicidal Behavior," being conducted at the Naval Medical Center Camp Lejeune by medical researchers from Naval Medical Center Camp Lejeune, The Ohio State University and The University of Utah. The Department of Defense (DoD) is funding this study.

2. Why Is This Study Being Done?

The purpose of this study is to compare the effectiveness of two psychological treatments for the reduction of suicide attempts among active duty U.S. Marines, and to identify the reasons why and how these treatments work. An additional component of this study is focused on examining the effects of sleep problems on suicidal thoughts and behaviors.

3. Why Are You Being Asked To Take Part?

You are being asked to take part in this study because you are an active duty Marine who has reported a recent suicide attempt and/or suicidal thoughts.

This study includes only those people who choose to take part. Please take your time to make your decision and feel free to ask any questions that you might have.

4. Screening Process to Qualify for Participation in This Study

Some tests must be done, and some information must be collected before the Investigator can confirm that you meet the qualifications to become a subject in this study. This is called the "Screening Process." These tests will include an interview.

5. What Is Involved In This Study?

If you choose to take part in this study, you will first complete an initial interview, some self-report questionnaires, and some computerized tests. You will then participate in approximately 12 sessions of psychological treatment scheduled once or twice each week. You will be asked to complete a brief questionnaire before each treatment session. You will then complete interviews, self-report questionnaires, and computerized tests every three months for the next two years.

You will be randomly assigned into one of two treatment groups. This means you will be assigned into one of these groups by chance. Often a computer program is used to make the assignments. Neither you, your doctor, nor the investigator will be able to choose the group to which you are assigned. Both of the treatment groups involve a total of 12 treatment sessions scheduled once or twice each week. Patients who have received both treatments have reported significant reductions in suicidal thoughts and psychological symptoms. These two treatments differ from each other with respect to the specific procedures and techniques used. The purpose of this study is to determine if one treatment works better than the other, or if they are equal to each other with respect to outcomes.

- The first group is called **Present Centered Therapy (PCT).** This treatment has been shown to reduce depression, PTSD symptoms, and suicidal thoughts.
- The second group is called **Brief Cognitive Behavioral Therapy (BCBT).** This treatment has also been shown to reduce depression, PTSD symptoms, and suicidal thoughts.

If you take part in this study, you will have the following tests and procedures:

- Interviews focused on suicidal thoughts and behaviors.
- Questionnaires focused on your symptoms, life experiences, and personality traits.
- Computerized tests focused on decision-making and reaction time.
- Methods focused on assessing your heart rate and physical stress response.

The following are the experimental procedures that are being tested in this study:

- Comparing the specific procedures and strategies used in each treatment.

The following are routine procedures that will be done if you decide to participate in this study:

- Completing questionnaires focused on your symptoms.

The following procedures are part of regular medical care that may be done even if you do not join the study:

- Asking you to report suicidal thoughts and behaviors during treatment.
- Creating plans to increase your safety.

All of the interviews and therapy sessions will be audio recorded using a digital audio recorder. The purpose of recording these interviews and sessions is to allow the researchers to ensure the research staff members are conducting the interviews correctly and providing the treatments appropriately. **Audio recordings will be maintained for 3 years after the end of the study.**

Regardless of the treatment condition you are assigned to, you will also be asked to participate in an additional component of the study that involves examining your sleep, physical activity, food and water logs (if you complete them, which is not required or expected), weight and heartrate, in addition to completing brief surveys using your smart phone. As part of this portion of the study, you will be given a Fitbit device to wear throughout the day that will measure your heartrate, physical activity, and sleep patterns at various points throughout a 24-hour day**. Operational security may prevent you from wearing the Fitbit device.** In addition, you will be asked to answer brief questions about your sleep patterns, thoughts, feelings, and behaviors on a daily basis by using a smart phone application. Data from your Fitbit device and your responses to questions from your smart phone will be shared directly with the research team and stored in a secure database.

6. How Many People Will Take Part In This Study?

A total number of 210 subjects are expected to participate in this study. Of these 210 subjects, 100 will be asked to take part in the additional component of the study involving providing data through wearing a Fitbit device and answering daily questions through their smart phone.

7. How Long Will You Be In This Study?

Your participation in this research project will be for a period of two years. If you choose to participate in the additional component of the study described above, you will also provide additional information for 28 days while also participating in the overall study.

You may stop participating in this study at any time. However, if you decide to stop participating, we encourage you to talk to the investigator and your regular healthcare provider first.

8. When Should You Not Take Part?

In order to participate in this study, you must be an active duty U.S. Marine. There are no known conditions or medications that would make it unsafe for you to take part in this study. If you expect to leave military service (e.g., retirement, separation), deploy, or change station within the next 90 days, you should not take part in this study.

9. What Are The Risks Of The Study?

The following are risks and side effects related to the treatments we are studying. These risks and side effects are part of regular medical care that exist even if you do not join the study:

Likely

- Short-term psychological distress: Filling out surveys, answering questions about difficult experiences in life, and talking about these events during treatment might increase some your symptoms and increase your risk of feeling emotionally uncomfortable in the short term. This increase is usually not severe, however, and does not last long.

- Suicide attempts: Prior research has shown that, following a suicide attempt, up to half of patients in treatment make another suicide attempt. If a suicide attempt occurs within the first year of treatment, on average a patient will attempt suicide 2.5 times. We therefore anticipate that up to half of the participants enrolled in this study (i.e., up 105 individuals total) could attempt suicide during the two-year follow-up assessment period, although the procedures in this study are expected to decrease this risk. Monitoring of suicide attempts will occur by tracking hospitalization records, reviewing your medical records, and interviews with you at each study visit.

Rare

- Death: A small number (less than 5%) of suicide attempts result in death. The procedures in this study are expected to decrease this risk.

While in the study, you are at risk for these risks and side effects. You should discuss them with the investigator and your regular healthcare provider. Other treatments (e.g., group therapy, medications, hospitalization) may be given to make the risks less serious and make you more comfortable. Although we expect these risks to decline soon after the start of treatment, in some cases these risks can last for long periods of time.

The following are risks that are part of the research study that exist if you join the study:

Rare

- Breach of Confidentiality: There is a small risk that your research records could be lost or otherwise compromised. To reduce this risk, all research staff members have been trained in data protection and confidentiality, and access to date will be restricted to only approved members of the research team.
  Disclosure of illegal activities: Disclosure of a violation of military regulation or laws that involves risk to life or mission may need to be reported to Commanding Officers, which may affect participants' military careers.

There also may be other risks that are unknown and that we cannot predict.

For more information about risks and side effects, ask the investigator or contact one of the following individuals:

- Jonathan Dettmer: 910-450-4700 or jonathan.r.dettmer.mil@mail.mil
- Dr. Craig Bryan: 614-366-2314 or craig.bryan@osumc.edu

10. Are There Benefits To Taking Part In This Study?

If you agree to take part in this study, there may or may not be direct benefit to you. There is no guarantee that you will personally benefit from taking part in this study. We hope the information learned from this study will benefit other military personnel experiencing suicidal thoughts in the future.

11. Are There Alternatives To This Study?

You may choose to not participate. You will then receive standard medical treatment that may or may not include any one of the procedure(s) or treatment(s) that are part of the planned research study. You may also choose to only participate in the part of the research study examining the differences between two treatments without taking part in the additional part of the study that involves wearing the Fitbit device and answering brief daily surveys using your smart phone.

12. What About Confidentiality?

We plan to hold all health information in strict confidence, but we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Authorized personnel from the Institutional Review Board, Department of the Navy, Department of Defense, The Ohio State University and/or the University of Utah may have access to your research file for authorized purposes, including verification that your rights have been safeguarded.

If you agree to participate in this study, your interviews and therapy sessions will be audio recorded using a digital recorder that will be placed on a table or desk in between you and the research staff member. Recordings will be stored on the digital recorder. Before the end of the day, the staff member will transfer this recording from the digital recorder to their computer hard drive. The audio file will then be uploaded over the internet to a secured, password-protected, encrypted database at the University of Utah that can only be accessed by approved members of the research team. After the audio recording has been uploaded, staff members will delete the audio file from their computer and the audio recorder so they can be reviewed by researchers at The Ohio State University on a weekly basis. These researchers will provide feedback to the interviewers and therapists to ensure they continue conducting interviews and providing treatments correctly. **As described above, audio recordings will be stored for 3 years after completion of the study.**

There is a possibility that identifiers (like your name or date of birth) might be removed from your identifiable private information and the information 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.

Privacy Act Statement

In accordance with the Privacy Act of 1974 (Public Law 93-579), this notice informs you of the purpose of this form and how it will be used. Please read it carefully.

1. Authority. Public Law 104-191; E.O. 9397 (SSAN); DoD 6025.18-R.
2. Purpose. Medical research information will be collected to enhance basic medical knowledge or to develop tests, procedures, and equipment to improve the diagnosis, treatment, or prevention of illness, injury, or functional impairment. This form is to provide the Naval Medical Center Camp Lejeune/TRICARE Health Plan with a means to request the use and/or disclosure of your protected health information.
3. Use. To any third party or the individual upon authorization for the disclosure from the individual for: personal use; insurance; continued medical care; school; legal; retirement/separation; or other reasons.
4. Disclosure. Voluntary. Failure to sign the authorization form will result in the non-release of the protected health information. This form will not be used for the authorization to disclose alcohol or drug abuse patient information from medical records or for authorization to disclose information from records of an alcohol or drug abuse treatment program. In addition, any use as an authorization to use or disclose psychotherapy notes may not be combined with another authorization except one to use or disclose psychotherapy notes.

   HIPAA: Release Authorization

   a. You have the right to revoke this authorization at any time. Your revocation must be in writing and provided to the facility where the research is being conducted. You are aware that if you later revoke this authorization, the research facility may have used and/or disclosed your protected information on the basis of this authorization.
   b. If you authorize your protected health information to be disclosed to someone who is not required to comply with federal privacy protection regulations, then such information may be re-disclosed and would no longer be protected.
   c. You have a right to inspect and receive a copy of your own protected health information to be used or disclosed, in accordance with the requirements of the federal privacy protection regulations found in the Privacy Act and 45 CFR 164.524.
   d. The Military Health System (which includes the TRICARE Health Plan) may not condition your treatment in MTFs/DTFs, payment by the TRICARE Health Plan, enrollment in the TRICARE Health Plan or eligibility for TRICARE Health Plan benefits on failure to obtain this authorization. (i.e. The MHS may not alter, deny, or make your legal entitlement to benefits a condition of your participation in this study or your decision to provide consent to use your protected health information).
   e. Representatives of the Department of Defense (DoD) may receive disclosed protected health information

(PHI).

By signing this consent, you are authorizing NMC Camp Lejeune to obtain and release the information as described in this consent form. You have the right to refuse to sign this permission form.

5. Disclosure. All information contained in this Consent Statement or derived from the medical research study described herein will be retained permanently at Naval Medical Center Camp Lejeune and salient portions thereof may be entered into your health record. You voluntarily agree to its disclosure to agencies or individuals identified in the preceding paragraph. You have been informed that failure to agree to such disclosure may negate the purposes for which the research study was conducted.

13. What If You Get Injured?

If you suffer any injury as a result of your participation in this study, medical treatment is available at Naval Medical Center Camp Lejeune. All medical care, including medical treatment for injuries related to this study and medical care unrelated to this study, will be evaluated and provided in keeping with the benefits to which you are entitled under applicable regulations.

14. Will You Get Paid For Participation?

You will receive a $25 Amazon gift card for each follow-up assessment that you complete. Because there is a total of eight (8) follow-up assessments, you could potentially receive up to $200 total in Amazon gift cards during the course of this study. If you choose to participate in the additional component of the study that involves wearing a Fitbit device and answering brief surveys through your smart phone, you will also receive $2 each day for recording and sharing information about your sleep and data from your Fitbit device and up to an additional $9.50 per day that you complete brief surveys using your smart phone (up to $266 total). You may also keep the Fitbit device that you are given**. Given that the Fitbit is considered a gift and not compensation, all Joint Ethics regulations must be followed, and we recommend that you contact your command's legal counsel with any questions.** DoD policy requires you to be off-duty in order to receive these incentives. Off-duty refers to days and times during which you are not scheduled for work or expected to be engaged in work or job duties. All treatments related to this study will be provided in accordance with applicable regulations. **You will be permitted to keep the Fitbit whether or not you complete the study, which is considered a gift and not a form of compensation.**

15. What Are Your Rights As A Participant?

Your participation in this project is voluntary, and your refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled under applicable regulations. If you choose to participate, you are free to ask questions or withdraw from the project at any time without prejudice to your future care. No study information will be released to any participants in this study. Any new significant findings developed during the course of the research, which may affect your willingness to participate further, will be explained to you. Please notify Jonathan Dettmer at 910-450-4700 or Dr. Craig Bryan at 614--366-2314 to ensure an orderly termination process.

If you withdraw, you will no longer receive treatments that are part of the study, unless these are also part of your normal treatment. Your withdrawal will involve no loss of benefits to which you are otherwise entitled. If you withdraw from this study, your data will be included in the data analysis for this project.

16. Can Your Participation In This Study Be Terminated?

The investigator may terminate your participation in this project for the following reasons:

- If the researchers believe that continued participation could be dangerous or harmful to you.
- If you lose the right to receive medical care at a military treatment facility.
- If military mission requirements require you to stop participating.

17. Who Can You Call If You Have Questions Or Concerns About This Study?

If you have any questions regarding this research project, you may contact Jonathan Dettmer at 910-450-4700 or Dr. Craig Bryan at 614--366-2314.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov,* as required by 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.

If you feel you have suffered an injury as a result your participation in this research project or if you have any questions regarding your rights as a research subject at Naval Medical Center Camp Lejeune, you can contact the Research Administration Officer at (910) 450-3460, the Chair, Institutional Review Board at Naval Medical Center Camp Lejeune at (910) 450-4048, or the Head, Clinical Investigation Department at (910) 449-2769

SIGNATURES

Investigators must use the following steps in order to orient the potential subject to the purpose of the research and why they might wish to participate:

- **Step One:** The Investigator must explain the study to the potential subject verbally, providing all pertinent information (purpose, procedures, risks, benefits, alternatives to participation, etc.), and must allow the potential subject ample opportunity to ask questions.

- **Step Two:** Following this verbal explanation, the potential subject should be provided with a written consent form and afforded sufficient time to consider whether or not to participate in the research. "Sufficient time" can range from hours to days, depending on how long it reasonably takes to evaluate the procedures, risks, potential benefits, and alternative treatments.

- **Step Three:** After allowing the potential subject time to read the consent form, the Investigator should meet with the potential subject and answer any additional questions he or she may have.

SUBJECT STATEMENT

By signing below, you are indicating that you were given enough time to read this study consent form, all of your questions about this research project were adequately answered and a copy of this consent form was given to you for future reference. Most importantly, by signing this consent form, you are indicating that you voluntarily agree to participate in this research study.

Subject's Signature	Date (DD/MMM/YY)	Typed/Printed Name
		Sponsor Status

By initialing here, you are indicating that you understand your interviews and therapy sessions will be audio recorded and reviewed by the researchers:

_____

By initialing here, you are indicating that you give consent to participate in the additional component of the study that involves examining your sleep, physical activity, and heartrate through a Fitbit device, in addition to completing brief surveys using your smart phone.

_____

INVESTIGATOR STATEMENT

You have explained to the above individual the nature and purpose of the study, the potential benefits and possible risks associated with the study, and the alternatives to participation in this study. You have answered any questions that were raised. You have explained the above to the subject on the date stated on this consent form. Consent was obtained prior to participation in the study.

Investigator performing consent process and obtaining written signature.

Investigator's Signature	Date (DD/MMM/YY)	Typed/Printed Name
		Grade or Rank