A Randomized Clinical Trial Testing the Effectiveness of Telemental Health for Suicidal Patients

Informed Consent

IRB Protocol Number: 2020B0396

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IRB Protocol Number: 2020B0396 IRB Approval Date: 1/25/2021 Version: 1 The Ohio State University Consent to Participate in Research

Study Title: A randomized clinical trial testing the effectiveness of telemental health for suicidal patients
Principal Investigator: Justin C. Baker, PhD & Craig J. Bryan, PsyD, ABPP
Sponsor: None

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate.

Your participation is voluntary.
Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate. If you decide to participate, you will be asked to sign this form and will receive a copy of the form.

Purpose: You are being asked to be a participant in a research study that seeks to compare the effectiveness of two psychological (non-medication) treatments to reduce suicidal thoughts and behaviors when delivered remotely using an online, video conferencing system. This research is being done to determine if one of the treatments works better than the other. The specific treatment that you receive will be determined randomly, which is similar to flipping a coin. This will help us to determine if one of the treatments is more helpful and better suited for people who have recently thought about suicide or made a suicide attempt.

Procedures/Tasks: This research will be performed by research therapists employed within The Ohio State University's Department of Psychiatry and Behavioral Health. All therapeutic encounters will occur online via an easy to navigate video conferencing platform.

To participate in this study, you will need to meet with a mental health professional for approximately 12 consecutive sessions that occur either once or twice per week. Additional sessions may also be added if clinically warranted as collaboratively determined between you and your research therapist. Each of the appointments will last 1 hour, and will be held online. Sessions will be video recorded and reviewed by supervising psychologists to ensure fidelity of the treatment being delivered. Before each of these 12 appointments, you will be asked to complete a survey that asks about your thoughts, feelings, and behaviors. These surveys can be completed online and will take less than 5 minutes to complete. You will also be asked to complete interviews and questionnaires in 3 months, 6 months, 9 months, and 12 months following the end of treatment. Each of these interviews and assessments will take less than 30 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:

Part 1: Psychological Assessment, Approximately 1.5 hours
We will ask you to complete an interview and several questionnaires that ask you about your feelings, thoughts, moods, impulses, substance use, and behavior. The interview and questionnaires will take about 1.5 hours to complete.

Part 2: Psychological Treatment (Online), Approximately 12 hours
We will schedule you to meet with a mental health professional for weekly therapy sessions. Each therapy session will be scheduled for 1 hour using a video conferencing platform. You will need to have access to a stable internet connection and an internet-enabled computer or smartphone for these sessions. At the end of each therapy session, you may receive an assignment to practice the skills learned during that session. These practice assignments typically require 1-2 hours of time to complete. You will be asked to review your practice assignments at the beginning of each session.

In this study, you will receive a psychological (nonmedication) treatment that has been shown to significantly reduce the symptoms of depression, suicidal thoughts, and other problems in life. The specific treatment that you receive will be determined randomly, which is similar to flipping a coin. We also will not tell you the name of the treatment that you are receiving. This will help us to determine if one procedure may be more helpful than the other.

Part 3: Follow-Up Assessments, Approximately 30 minutes each
Research staff will contact you approximately 3 months, 6 months, 9 months, and 12 months after completing treatment to complete an interview and 5 questionnaires that will ask you about your feelings, thoughts, moods, impulses, substance use, and behavior. These assessments can be completed by phone or an online video conferencing system, and will take less than 30 minutes to complete.

Duration: The total time that you will be involved in this study will be approximately 17-19 hours over the next year. Your participation will be over at the completion of Part 3, unless you choose to end your participation before that time. Here is a brief timeline of the study:

Psychological Assessment 90 mins
Psychological Treatment (once per week for 12 weeks)* 12 hrs (1 hr per week for 12 weeks)
Follow-Up Assessment #1 (3 Months) 30 mins
Follow-Up Assessment #2 (6 Months) 30 mins
Follow-Up Assessment #3 (9 Months) 30 mins
Follow-Up Assessment #4 (12 Months) 30 mins
*Additional sessions may be added as collaboratively agreed upon by the research therapist and participant.

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.

Risks and Benefits:

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 make effort to maintain confidentiality and all data from interviews and questionnaires will be stored in a secure and confidential manner. If any of the interview questions make you feel uncomfortable, you do not have to answer them.

Psychological Treatment
The treatment that you will receive may require you to think about stressful events from your life. A substantial minority of people (around 1 in 4) who receive these treatments experience increased emotional distress and/or become upset when talking about these events. The increase in distress is similar to what you would experience when talking about a stressful event with a family member, friend, or trusted person, and typically does not last longer than a few minutes. For some people, this temporary increase in symptoms can increase thoughts and urges about suicide. To manage this risk, you will be asked to use skills and strategies learned in therapy to reduce associated psychiatric symptoms and suicidal urges. You will also receive assistance and support from your assigned therapist, who has experience working with helping people experiencing intense stress and suicidal thoughts.

The potential benefits are:

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 symptoms of 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.

Confidentiality:

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. 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;
• The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
• The sponsor, if any, or agency (including the Food and Drug Administration for FDA-regulated research) supporting the study.

To minimize the risk of confidentiality breach, research staff will receive rigorous training in confidentiality and privacy procedures. Your name, date of birth, etc., will be stored separate from your data. Video recordings that will be utilized for the purposes of fidelity monitoring will be stored on HIPAA compliant servers. We will use recommended security procedures and strategies for maximizing confidentiality and minimizing the risk of third-party intrusion during Zoom-based research activities. Your data will be tracked using a sequential numeric ID system generated specifically for you (e.g., 1001, 1002, 1003...). Survey data will be stored in a deidentified manner using your IDs instead of potential identifiers.

Please remember that there is an exception to protecting subject privacy and confidentiality if child, elder, and/or disabled adult abuse or neglect of an identifiable individual, or the threat of imminent self-harm or harm to others is disclosed. If such information is disclosed, the researchers may be obligated to inform the appropriate authorities. In the case of imminent self-harm or harm to others, the researchers may refer you to an appropriate medical facility for further assessment of treatment needs and possible inpatient hospitalization.

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

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

Incentives:

By law, payments to participants are considered taxable income.

You will receive compensation in the amount of $50 for each completed follow-up assessment. While you do not need to answer every survey item to receive compensation, you do need to review each item through the end of the survey to receive compensation. There will be no prorated incentive amount for partial completion should you chose to terminate an individual follow-up assessment prematurely. Additionally, if for example you do not complete follow-up assessment #2, you will still be eligible to participate in follow-up assessment #3 and receive full compensation upon completion of the assessment. If you complete all 4 of the follow-up assessments, you will be compensated a total of $200.

The payments will be given to you as check or Amazon.com gift card after each assessment.

Activity	Payment
Follow-Up Assessment #1 (3 months)	$50
Follow-Up Assessment #2 (6 months)	$50
Follow-Up Assessment #3 (9 months)	$50
Follow-Up Assessment #4 (12 months)	$50
Total Up to $200	

Participant Rights:

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.

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.
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.

Contacts and Questions:

For questions, concerns, or complaints about the study, or you feel you have been harmed as a result of study participation, 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.

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.

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1) I voluntarily agree to participate in this study. ◯ Yes ◯ No

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2) Full Name of Subject _____

3) Signature

_____

4) Date and time

_____

AUTHORIZED AGENT (when applicable)

5) Printed name of person authorized to consent for subject (when applicable)

_____

6) Signature of person authorized to consent for subject (when applicable)

_____

7) Relationship to the subject

_____

8) Date and time

_____

INVESTIGATOR/RESEARCH STAFF

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.

9) Printed name of person obtaining consent

_____

10) Signature of person obtaining consent

_____

11) Date and time

_____