Assessing the Effectiveness of Self- and Clinician-administered Crisis Response Planning for Suicide Risk
Consent Form

NCT: 2020B0414-B

Approved 2/25/2021

The Ohio State University Consent to Participate in Research

Study Title: Assessing the utility of the MMPI-2-RF-EX in detecting simulated underreporting of current suicide risk in veterans outside a Veterans Affairs outpatient clinical setting

Protocol Number:

Researcher: Lauren R. Khazem, PhD

Sponsor: University of Minnesota Press

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.

Purpose:
This is a two-part study.

Part 1:
The purpose Part 1 of this study is to learn more about the ability of a new self-report measure of personality and psychological functioning, the Minnesota Multiphasic Personality Inventory – 2 – Restructured Form- Expanded (MMPI-2-RF-EX), to detect under reporting of suicide risk in military veterans. Previous research indicates that veterans who are detected as under reporting their current distress or symptoms on this instrument also tend to score lower on indicators of suicide risk when compared to veterans who are not under reporting.

Part 2:
The purpose Part 2 of this study is to learn more about the effectiveness of different versions of a brief intervention focused on reducing suicide risk called the Crisis Response Plan (CRP).

The CRP is a brief, personalized plan that outlines steps for identifying your personal warning signs, coping strategies, social supports, and professional services that you may use when in crisis, have thoughts of suicide, or are distressed and has been shown to reduce thoughts of suicide and distress in military personnel. We are examining whether a version of the CRP that is administered through videoconferencing software (Zoom) is as effective as a version of the self-guided version of the CRP. In addition to randomization to a study condition in Part 1 of the study, you will also be randomized to a condition in this portion of the study:

Procedures/Tasks:
If you consent to take part in the research study, you will be randomized to one of two possible conditions in Part 1 and one of two possible conditions in Part 2. You do not have to answer any individual questions that make you feel uncomfortable if you do not want to in either part of the study.

Part 1:

Condition 1: **Standard testing**
In this condition, you will be asked to complete the MMPI-2-RF-EX and a variety of self-report measures that ask you about various aspects of your emotional, social, and psychological functioning. You will be asked to be as honest in your responses. You will be given a link to a separate survey to open in a separate browser window or tab where you will click the checkboxes nest to the numbers for MMPI-2-RF-EX items that you think are assessing suicide risk while you complete the instrument.

Condition 2: **Under reporting suicide risk**
In this condition, you will complete the same measures, including the MMPI-2-RF-EX, however you will be asked to pretend that you are having thoughts of suicide and to try to conceal these thoughts. You will be given a link to a separate survey to open in a separate browser window or tab where you will click the checkboxes nest to the numbers for MMPI-2-RF-EX items that you think are assessing suicide risk while you complete the instrument.

In both conditions, you will be emailed a secure link to our online surveys, which you are to complete in a private location free from distractions.

Please note, in order to maintain the security of the MMPI-2-RF-EX, we are required to use videoconferencing software to observe you as you complete the instrument, similar to how a test proctor may observe students during an exam. We cannot see your screen, nor are we collecting any data from you through this method. You will also be emailed a secure link to use Zoom, a secure videoconferencing platform hosted by The Ohio State University, which will be used for this purpose.

Part 2:

Condition 1: Crisis Response Plan Administered by Trained Personnel Through Zoom

In this condition, the member of the study team who observed you complete the MMPI-2-RF-EX in Part 1 (if you choose to take part in that portion of the study) will also guide you through developing your own Crisis Response Plan. Video recording software will record only this portion of the study. These videos will only be used by the study team to ensure that our team members are providing the treatment to an acceptable level of fidelity. You will also be emailed a link to complete a brief survey that will ask you about your thoughts (including thoughts of suicide), emotions, and behaviors each day for seven (7) days. We will not use videoconferencing software to watch you complete these surveys.

Condition 2: Self-guided Crisis Response Plan
In this condition, you will be provided instructions to complete your own Crisis Response Plan but no study personnel will be present or observe you through Zoom. You will also be emailed a link to complete a brief survey that will ask you about your thoughts (including thoughts of suicide), emotions, and behaviors each day for seven (7) days. We will not use videoconferencing software to watch or record you completing the Crisis Response Plan or watch these surveys.

Duration:

Part 1 of this study is anticipated to take approximately two (2) hours to complete
For Part 2: The Crisis Response Plant in Part 2 is anticipated to take approximately 35 minutes to complete, while each of the seven (7) daily surveys are anticipated to take approximately 5 minutes to complete.

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 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 the course of the study 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.

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 data will be restricted to only approved members of the research team.

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

Confidentiality:

We will work to make sure that no one sees your online responses or video files without approval. But, because we are using the Internet, there is a chance that someone could access your online responses without permission. In some cases, this information could be used to identify you.

Also, 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 or if the study team believes that you are at imminent risk of suicide. 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.

Future Research:

Your de-identified information may be used or shared with other researchers without your additional informed consent.

Incentives:

For Part 1

You will be compensated with a $50 gift card for participating in this study session with research personnel. If you are randomized to Condition 2, you are also eligible to earn an additional $20 for avoiding detection of under reporting your distress.

For Part 2

You will be compensated with a $10 gift card for each completed daily survey, which will be provided at the end of the week-long assessment period (for a possible total of $70 in the form of a gift card). Additionally, if you complete at complete least 6 out of 7 of the daily surveys will receive an additional $30 gift card.

If you complete both parts of the study, you may earn a maximum of $150 in gift cards (or $170 for those in the Condition 2 in Part 1 of the study if you successfully avoid detection of underreporting).

If you choose to no longer participate in the study after completing portions of the study, you will not lose the amount of compensation earned for study components that have already been completed.

By law, payments to participants are considered taxable income.

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 agreeing to participate, 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 participants in research.

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 Dr. Lauren Khazem at 614-366-2314 or lauren.khazem@osumc.edu

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 or hsconcerns@osu.edu.

Providing consent

I have read (or someone has read to me) this page 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 agreeing to participate.

To print or save a copy of this page, select the print button on your web browser.

Please click the button below to proceed and participate in this study. If you do not wish to participate, please close out your browser window.