Department of Veterans Affairs

VANJHCS RESEARCH CONSENT FORM

VANJHCS IRB OFFICE USE ONLY
VANJHCS
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APPROVED

Version #: 1 ***Version Date: 02/13/2020***

Title of Study: Suicide Prevention for Patients with Chronic Pain

Principal Investigator: Lisa McAndrew, Ph.D. IRB#: 01507

Subject Name: _____ **Date:** _____

CONCISE SUMMARY

This is a research study to find out how helpful Problem-solving Treatment is in improving problem-solving skills, managing thoughts of suicide, and reducing impairment caused by pain. To enroll in this study, Veterans report thoughts of suicide and experiences chronic pain. Veterans have been screened for the above prior to enrolling into this study and will be randomized to one of two arms of the study: **Problem-solving Treatment or Attentional control**.

You are being asked to participate in this study because you are a support person (e.g., significant other, caregiver, spouse, partner, family member, friend) of a Veteran who is also enrolled into this study.

In this study, you will be asked to complete two questionnaire packets that will ask about your opinion on the problem-solving skills of the Veteran you provide support to. You will be asked to complete one questionnaire packet at the beginning of the study and one at the end of the study. You can opt out of participating in the study at any time and the Veteran you provide support to can still participate.

Read the information below and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you do decide to take part in this study, your signature on this consent form will show that you received all the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

The PI of this study is Lisa McAndrew, PhD and the research is being supported by the National Institute of Mental Health (NIMH). Up to 60 Veterans and up to 60 support people will take part in this study.

BACKGROUND & PURPOSE

Patients with chronic pain often have a greater risk of experiencing thoughts of killing themselves. Problem-solving Treatment (PST) has been effective in treating chronic pain by strengthening problem-solving skills, and some studies have found that Problem-solving Treatment can also help with addressing thoughts of suicide. With this research study, we hope to learn how helpful Problem-solving Treatment is in improving problem-solving skills, managing thoughts of suicide, and reducing impairment caused by pain. We will be comparing results to Veterans who are receiving Attentional control. Attentional control is a control condition which means it is not a replacement for standard mental health treatment. Problem-solving Treatment is also not a replacement for standard clinical care (including mental health care).

DURATION OF THE RESEARCH

This research study is expected to take about 2 years. If we find Problem-solving Treatment works, we will increase the amount of time we conduct the study. Your individual participation in the project will take place over the course of about 12 weeks.

PROCEDURES

If you decide to take part in this study, this is what will happen:

1. You will complete the informed consent process, which includes reviewing the informed consent document and Health Insurance Portability and Accountability Act (HIPAA) form with a study team member. This process will take place over the phone with a study team member. During this time, you will review the informed consent and HIPAA form with the study team member and will be asked to sign both.

2. After you complete the informed consent process, you will be asked to fill out a questionnaire packet. Completing this questionnaire packet can be done either over the phone, over the internet through Qualtrics, or mailed back to us in a prepaid envelope. You are free to skip any questions that you prefer not to answer.

3. A follow-up assessment will be completed approximately 12 weeks after you complete the first questionnaire packet. Completing this questionnaire packet can be done either over the phone, over the internet through Qualtrics, or mailed back to us in a prepaid envelope. You are free to skip any questions that you prefer not to answer.

POSSIBLE RISKS OR DISCOMFORTS

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

1. Emotional Stress: It is possible that some participants could find some of the questions in the questionnaire packets upsetting. If you are experiencing emotional distress, you may contact the **National CRISIS LINE** at **1-800-273-8255**. Someone will be available to talk to you 24 hours a day, every day of the year.

    - You may also call the **NJ War Related Illness and Injury Study Center (WRIISC)** and ask to speak with a mental health provider who is part of our study team at **1-800-248-8005**. Mental health providers are typically (but not always) available Monday – Friday 8am to 4 pm eastern standard time.

2. Loss of Confidentiality: There is a risk that study information (data) could be connected to your

name. This is called "loss of confidentiality." Data collected from the study, including audio recordings of sessions, will be maintained on the VA server with access limited to the study team. The methods and procedures used for data storage and security are consistent with those adopted by VA NJHCS. If you complete your questionnaires online, there are additional risks of loss of information. Similarly, completing the online computer testing has additional risks of loss of information. You may choose to complete your questionnaires on paper and you may also choose to not complete the online computer testing to reduce this risk.

POTENTIAL BENEFITS

There are no direct benefits to you from your taking part in this research study. However, the information we get from this study might help us better understand how best to treat chronic pain and active thoughts of suicide.

CONFIDENTIALITY

All information collected for this study will be kept confidential.

1. Taking part in this study will involve collecting information, including private information about you and data. Private information may include the following: age and address. Data may include the following: answers from the questionnaires you complete.

   The methods and procedures used for data storage and security are consistent with those adopted by VA. This information will be protected in the following ways:

   - You will be assigned a unique identification number. All data is coded with this unique identification number. There is an electronic "link" that connects your name and the unique identification number. The "link" will permanently reside in a password protected electronic file on the VA secure server created by the IRM in East Orange, NJ. All data from the questionnaires and recordings will be inputted to a database with your unique subject number. No personal information, e.g. your name, will be inputted with your data. Only members of the study team will have access to this "link," the shared network folder, and its electronic files.

   - If you decide to complete your questionnaires on the Qualtrics website, your data will be temporarily stored on the secured Qualtrics server. This data will be identified only with your unique identification number, which you will be assigned (no identifiable information of yours is entered). The data will be transmitted to us through encryption methods that are VA approved. This data will then be uploaded onto our secured shared network folder within the secure VA server created by the IRM in East Orange, NJ.

- All paper copies will be kept in a locked cabinet in a locked office. Only members of the study team will have access to these cabinets.

2. Some of the data analysis will be completed by our collaborator at Rutgers University School of Public Health.

3. Information about you will be combined with information from other people taking part in the study. We will write about the combined data we have gathered. Any talks or papers about this study will not identify you.

4. There are times when we might have to show your study records to people outside the research team. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, our local IRB, our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you.

5. An exception to confidentiality is when the law mandates us to do so. Under the following circumstance we are required to break confidentiality and contact someone outside the treatment team:
   - If you are at risk to harm yourself or someone else
   - If a child, elder, or dependent adult is at risk of harm or abuse

6. 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 study results. You can search this Web site at any time.

COSTS TO PARTICIPANTS AND PAYMENT

Costs to Participants*:*
You will not be charged for any treatments or procedures that are part of this study.

Tax law may require the reporting of the amount of payment you received for participating in research to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally, this reporting would take place if you received payments that equal $600 or more in a calendar year. You would be responsible for the payment of any tax that may be due on this additional income.

Payment Offered for Participation: You will not be compensated for your participation.

MEDICAL TREATMENT AND COMPENSATION FOR INJURY

Every reasonable safety measure will be used to protect your well-being. If you are injured as a result of taking part in this study, the Veterans Biomedical Research Institute will provide necessary medical treatment at no cost to you unless the injury was due to your not following the study procedures.

If you should have a medical concern or get hurt or sick because of taking part in this study, call:

DURING THE DAY:

- Dr. Lisa McAndrew or Ms. Nicole Anastasides
  Phone: **973-676-1000, ext. 1-201167**

- WRIISC Main Phoneline: **1-800-248-8005**

AFTER HOURS:

- You can contact your local Emergency Room

- Crisis Line: Phone: **800-273-8255**
  Available 24 hours a day, every day of the year.

Emergency and ongoing medical treatment will be provided as needed.

You do not give up any of your legal rights and you do not release VBRI from any liability by signing this form.

PARTICIPATION IS VOLUNTARY

It is up to you to decide whether to take part in this study. Your participation in this study is voluntary. If you decide to take part, you may still withdraw at any time. If you do not wish to be in this study or leave the study early, the Veteran you provide support to will not lose any benefits to which he/she is entitled and your decision not to take part will not affect the relationship the Veteran has with his/her doctor or other staff, and it will not affect the usual care that he/she receives.

If you decide to withdraw from the study prior to completion, data already collected prior to your withdrawal may still be reviewed and analyzed.

RIGHT OF INVESTIGATOR TO TERMINATE PARTICIPATION

The Principal Investigator may stop you from taking part in the study at any time if she believes that it is in your best interest and/or the best interest of the study.

PERSONS TO CONTACT ABOUT THIS STUDY

If you have any questions, complaints or concerns about your rights as a study participant, you should contact the **Patient Representative at 973-676-1000 ext. 1- 203399**.

If you want to make sure this is a valid VA study, you may contact the VANJHCS Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the **VANJHCS IRB at 973-676-1000 ext.1- 202778** if you have questions, complaints or concerns about the study or if you would like to obtain information.

Dr. Lisa McAndrew and Study Coordinator
Phone: **973-676-1000 ext. 1- 201167**

PAYMENT TO INVESTIGATORS

Lisa McAndrew, PhD is being paid by the **National Institute of Mental Health (NIMH)** to conduct this study.

SIGNIFICANT NEW FINDINGS

Important new findings found during this study which may change your willingness to continue in the study will be given to you.

FUTURE USE OF DATA AND RE-CONTACT

With your permission, the funding agency for this study (NIMH) would like your data or health information to be reused later for additional research purposes. If you agree, your data will be submitted to the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health (NIH). NDA is a large database where deidentified study data from many National Institute of Mental Health (NIMH) studies is stored and managed. Deidentified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. Sharing your deidentified study data helps researchers learn new and important things about mental health more quickly than before.

During and after the study, the study researchers will send deidentified study data to the NDA. Other researchers across the world can then request your deidentified study data for other research. Every researcher (and institutions to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy.

You can still participate in this research study even if you decide that you do not want your data to be added to the NDA. If you know now that you do not want your data in the NDA, please checkmark "NO" below and tell the study staff member you are speaking with. If you decide any time after today that you do not want your data to be added to the NDA, call the study staff who conducted this study, and they will tell NDA to stop sharing your study data. Once your data is part of the NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NDA, this is available on-line at http://nda.nih.gov.

Please read the statement below and check one box.

- I give my permission for the data collected from my participation in this study, including health information, to be submitted to the NDA at NIH.

  Verbally indicate YES or NO.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms._____ has 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 verbally agreeing to participate, you voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you.