

VANJHCS IRB OFFICE USE ONLY
VANJHCS IRB
MAY 18 2020
APPROVED

Version #: 2

Version Date: 05/01/2020

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, you must be a Veteran that reports thoughts of suicide and experiences chronic pain. You have been screened for the above prior to enrolling into this study. You will be randomized to one of two arms of the study: **Problem-solving Treatment** or a **comparison condition that is called Attentional Control**. Attentional control is a control condition that is used to compare the effect of problem-solving. It includes time spent with a counselor but does not contain many of the treatment elements of problem-solving treatment. Neither group is a replacement for clinical care.

In this study, you will be randomized (like flipping a coin) into one of two groups: **Problem-solving Treatment** or **Attentional control**. One group will receive 12 sessions of remote-delivered Problem-solving Treatment and the other group will receive 12 session of remote-delivered Attentional control. Attentional control is a control condition which means it is not a replacement for standard clinical care (including mental health treatment). Problem-solving Treatment is also not a replacement for standard clinical care (including mental health treatment). Problem-solving Treatment and Attentional control can be delivered through the VA's Video Connect (VVC) technology or by telephone. Sessions will last ~1 hour and may be recorded.

You will also be asked to complete questionnaire packets at 4 different timepoints: at the beginning of the study, after the 4th session, post treatment (after the 12th session of either Problem-solving Treatment or Attentional control), and 6 months after the treatment is completed.

The greatest risk of participating in this study is the possibility of increased emotional stress from the sessions and/or the questionnaires and loss of confidentiality.

If you gave us permission at screening, we will also reach out to your support person (e.g., significant other, caregiver, spouse, partner, family member, friend) to ask their opinion of your problem-solving skills. You can opt out of identifying a support person and still participate in the study. You can also still participate in the study if your support person does not want to provide his/her opinion of your problem-solving skills.

If you are interested in learning more about this study, please continue reading below.

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.

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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 clinical care (including mental health treatment). Problem-solving Treatment is also not a replacement for standard clinical care (including mental health treatment). We strongly encourage you to continue with the care you are already receiving from your providers and you can begin any new treatment you would like while participating in this study.

DURATION OF THE RESEARCH

This research study is expected to take about 2 years. If we find Problem-Solving Treatment works, we may increase the amount of time we conduct the study and the number of participants. Your individual participation in the project will take place over the course of about 9 months.

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. After reviewing these documents, you will be asked if you verbally agree to participate in this study.
2. We will collect the contact information (name, phone number, and mailing address) of your primary care and mental health providers. This information may be obtained and confirmed either from your medical record or through a form you will complete. We are getting this information so we may let your primary care and mental health providers know about your participation in this study. This will enable your providers to let us know of any health concerns s/he may have about your participation. We highly encourage you to reach out to your providers to discuss your participation in the study. We may also contact your primary care or mental health provider if we have any medical or safety concerns about you during the study.

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3. 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. You will also be asked to complete online computer testing through Millisecond Inquisit Web, which will be done from your home.
4. You will be “randomized” into one of two study groups: Problem-solving Treatment or attentional control. Like flipping a coin, you will have about a 1 in 2 chance of being randomized into either group. About half of the study participants will receive Problem-solving Treatment and the other half of study participants will receive attentional control. Neither group is a replacement for standard clinical care (including mental health care). Each weekly session will take place at a time of your choosing.

Throughout the course of the study, study providers will check-in with you weekly regarding your thoughts of suicide. During your participation in the study, we will enter notes into your electronic medical record and you can continue to receive all standard of care treatments or any new treatments recommended by your healthcare providers.

- If you are in the **Problem-solving Treatment group**, you will have 12 weekly Problem-solving Treatment sessions either through VVC or over the phone with a Study Provider. Each session will last about an hour and may be recorded. You will be provided a workbook and during your time with the Study Provider, you will be taught a 5-step planful problem-solving approach we call S-O-L-V-E. Steps of S-O-L-V-E include: 1. State the problem and goals; 2. Option identification; 3. List pros and cons of options; 4. Visualize the steps; 5. Evaluate success. The study provider may make changes to the treatment (e.g., change the order information is presented) if it is in your best interest.

During the sessions, you will also be asked to follow some basic rules (e.g., not having anyone else in the room, not driving, and shutting off other telephones so there will be no distractions). You will be able to receive any care you are currently receiving from any VA or non-VA providers or make any changes to your care you would like to make.

- If you are in the **attentional control group**, you will have 12 weekly attentional control sessions either through VVC or over the phone with a Study Provider. Each session will last about an hour and may be recorded. During your time with the Study Provider, you will have the opportunity to discuss any concerns you may have, which could include stressors or successes you experience, etc. You will be provided discussion starter forms that you may use, which will be mailed to you. Sessions are designed to be supportive. You will not discuss problem-solving or behavioral change techniques during these

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sessions. Attentional control is not the same as standard mental health treatment or usual care which includes problem-solving and behavioral change. If you are interested in receiving standard mental health treatment during your participation in this study, you may do so.

- There are other treatment options available to help manage chronic pain and thoughts of suicide, like cognitive-behavioral therapy. Please contact your medical care providers if you are interested in learning more about such options.

During the sessions, you will also be asked to follow some basic rules (e.g., not having anyone else in the room, not driving, and shutting off other telephones so there will be no distractions). You will be able to receive any care you are currently receiving from any VA or non-VA providers or make any changes to your care you would like to make. We recommend all Veterans with suicidal ideation receive treatment to reduce suicide risk.

Voice Recordings: Only with your permission, Study Providers may audio record sessions for research purposes only. You may decide to change your mind about allowing audio-recording the session at any time. The information will be accessed by the PI and her research study team. Audio recordings will be downloaded and stored on a secure shared network folder created by the Information Resource Management (IRM) in East Orange, NJ. Any audio recording devices will be stored in a locked filing cabinet; the audio recordings will be stored on a secure shared network folder and then disposed of as per VA's policy.

I have read and understand the above statement and I consent to the use of my voice as specified for the above-described purpose(s).

_____ Initials

5. Follow-up assessments will be completed at 3 additional time points for both treatment groups:
 - After the 4th session of either problem-solving treatment or attentional control, you will be asked to fill out a questionnaire packet
 - Post treatment (after the 12th session of either problem-solving treatment or attentional control), you will be asked to fill out a questionnaire packet and complete the same computer testing you completed at the beginning of the study
 - 6 months after your last session of either problem-solving treatment or attentional control, you will be asked to fill out a questionnaire packet
6. If you gave us permission at screening, we will also reach out to your support person (e.g., significant other, caregiver, spouse, partner, family member, friend) to ask their opinion of

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problem-solving skills. Support person participation is limited to completing questionnaires at 2 different timepoints: at the beginning of the study and after you complete your 12th session. You can opt out of identifying a support person and still participate in the study.

- We may also collect information from your medical record about your diagnoses, treatments, tests and medications.
- You can refuse to participate in any portion of the study and still take part in the rest of the study.
- You will interact with Study Coordinators, Research Assistants, and Study Providers.
- Each session will take place weekly at a time of your choosing.

PARTICIPANT RESPONSIBILITIES

During your participation in the research, we ask that you do the following:

- Keep your study appointments. If you miss an appointment, please contact the investigator or research staff to reschedule as soon as you know you will miss the appointment.
- Tell the investigator or research staff if you believe you might be pregnant.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Tell the investigator or research staff if you change your mind about staying in the study.
- While participating in this research study, do not take part in any other research project without approval from the investigators. This is to protect you from possible injury. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this research, as well as that of the other studies.

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. It is also a possibility that some participants may find the Problem-solving Treatment or attentional control sessions upsetting.
 - If you are experiencing emotional distress, you may contact the **National VA CRISIS LINE** at **1-800-273-8255**. Someone will be available to talk to you 24 hours a day, every day of the year.

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- 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.
 3. As part of Problem-solving Treatment, you may decide to make changes to your daily activities (e.g., starting a new diet, doing physical activity, increase social activities). If and how you make these changes is your choice. There could be risks associated with any changes you make to your daily life. You should consult with your primary care provider or other medical provider to minimize any risks and address any concerns you may have about changes you may wish to make. We may also contact your health care provider.
 4. There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.
 5. Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

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. It is possible you may experience improvement in pain, disability, and suicide ideation.

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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, address, health information, (e.g., diagnoses, symptoms), treatment recommendations, your voice, and your social security number. Data may include the following: answers from the questionnaires you complete, the online computer testing, and recordings from sessions with your study provider.

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.
- When you complete the online computer testing through Millisecond Inquisit, your data will be temporarily stored on the secured Millisecond servers. This data will be identified only with your unique identification number, which you will be assigned (no identifiable information of yours is entered). Once transferred to us, 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.

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2. Some of the data analysis will be completed by our collaborator at Rutgers University School of Public Health.
3. We may include information about your study participation in your VA medical record; a note of this consent form will be placed in your electronic VA medical record.
4. 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.
5. There are times when we might have to show your records to people outside the research team. For example, someone from the Office of Human Research Protections or other federal, state, or international regulatory agencies, our local IRB, our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you.
6. 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
7. 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. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not 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.

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Payment Offered for Participation: You will be compensated for your participation in this study up to a total of \$250 for completing and returning questionnaires as follows:

- Baseline questionnaire = \$50
- 4th-week mid treatment questionnaire = \$50
- Post-treatment (12-week) questionnaire = \$75
- 6-month follow-up questionnaire = \$75

You will sign a voucher giving us permission to pay you. You may be asked for your social security number on these vouchers, so you can be paid. Due to limitations in the Financial Management System, payments made to you through Austin Financial Services Center generate an Internal Revenue Service Form 1099 regardless of amount. You may mail to us the voucher with the completed questionnaires in the pre-paid envelopes provided. You should receive a check in about 6-8 weeks. If you are at the VA NJHCS in person, you may receive cash. If you have direct deposit setup, you may receive payment directly to the account you specified.

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 VA 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 Phonenumber: **1-800-248-8005**

AFTER HOURS:

- VA NJHCS Emergency Room
Phone: **973-395-7236 or 973-676-1000, ext. 1-201222**
- You can also contact your local VA Emergency Room
- VA 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.

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You do not give up any of your legal rights and you do not release the VA 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, you will not lose any benefits to which you are entitled. If you don't take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctor or other staff, and it will not affect the usual care that you receive as a patient.

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

This study is sponsored by the **National Institute of Mental Health (NIMH)**.

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

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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.

YES NO _____ Initials

With your permission, we may also contact you in the future to invite you to take part in additional studies in the future. Please read the statement below and check one box.

- I give my permission for the Principal Investigator (Lisa McAndrew, PhD) or a member of her study team to contact me to ask me to take part in additional studies in the future.

YES NO _____ Initials



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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.