Official Title: Reducing Suicide Risk in Older Veterans with Mental Health Disorders Using Problem Solving Therapy

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Reducing Life Stress in Older Veterans

Informed Consent

Are you participating in any other research studies? ☐yes ☐no

CONCISE SUMMARY

- The purpose of this study is to examine a new treatment to relieve stress and increase hope in older Veterans. Your consent for participation in the research is being sought. Your participation in the study is voluntary.

- All study activities are by phone. If you chose to participate in the study, you will be asked to complete a 1 ½ - 2 hours of mood and memory testing before starting and after completing the treatment.

- All participants will receive the usual treatment, a standard of care to help you manage crisis situations. Though this treatment is considered a standard of care for crisis situations, other treatments for mental health conditions and stress are also available at VA and in the community. These include medications and other forms of psychotherapy. These other treatments will not be provided in this study. You will have a fifty percent chance of receiving the usual treatment only, and a fifty percent chance of receiving both the usual treatment and the new treatment. Both treatments teach useful strategies to manage stress; they do not involve medication. You will have 6 sessions of treatment lasting up to 60 minutes each. Additionally, after completing the treatment, you will be asked to complete three 30-min follow-up tests related to mood at 1-month, 3-months, and 6-months.

- Reasonably foreseeable risks or discomforts include boredom answering questions or experiencing negative emotions due to questions on the test, although this experience is usually fleeting. Benefits are not guaranteed; however, all participants receive a standard treatment that is routinely provided to help Veterans in crisis. The study pays up to $220.

- If you are also assigned the new treatment, you may also become more informed about your mood and learn ways to help relieve stress and increase hope that you may not have been aware of previously.

- Alternatives to participating in this study include, not participating and receiving referrals to other VA clinics or community provider for treatment.

PURPOSE OF RESEARCH

You are invited to participate in a research study of a new treatment for stress in older adults. We hope to learn for whom this treatment provides the most advantage and to get feedback from older adults about what they like or dislike. You were selected as a possible participant because you recently reported symptoms of stress that could potentially benefit from treatment during the screen.

Number of participants and location. This study is looking for older adults (55 years old or older) experiencing stress. The study is through VA Palo Alto Health Care System, Palo Alto Division, but all study activities are by phone. We expect to enroll 75 research study subjects at the VA Palo Alto site and 75 subjects at another VA site, for a total of 150 subjects.

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled. You have the right to refuse to answer particular questions.

DURATION OF STUDY INVOLVEMENT

There are 6 weekly treatment sessions to be completed in 6-8 weeks (up to an hour each plus 20-30 minutes of testing at the end of each session) and two testing sessions for about 2 hours each before the first session and after the last session. There is an additional 30-60 minute activity at the end of the first testing session. There is also a brief follow up assessment that takes 20-30 minutes at 1-month, 3-months, and 6-months after you complete the treatment.

PROCEDURES

If you decide to participate, Dr. Beaudreau and her research study collaborators will describe procedures to be followed, including their purposes, how long they will take and their frequency.

- You will first be asked to complete about 2 hours of testing before the first treatment session and after the last treatment session. Testing involves answering questions about stress, mood, and other life experiences and completing tests of memory and thinking. In addition, at the end of the first testing appointment, you will be asked to complete a 30-60 minute activity related to the treatment.
- All participants will receive the usual treatment (standard of care). Though this treatment is considered a standard of care for crisis situations, other treatments for mental health conditions and stress are also available at VA and in the community. These include medications and other forms of psychotherapy. These other treatments will not be provided in this study. Half of participants will also be randomly assigned to receive a new treatment (research condition) in addition to the usual treatment. This new treatment is what is considered experimental in this study. After you complete the initial testing session, you will find out which treatments you have been assigned. Again, treatment assignment is random.
- Treatment will involve attending 6 sessions lasting up to 60-minutes each week with the trained interventionist and reading and practicing the skills. You will have 6-8 weeks to complete these 6 weekly sessions. Additionally, you will be asked to complete three brief questionnaires (approximately 20-30 minutes) during each treatment session, and at 1-month, 3-months, and 6-months after the treatment is completed. At the end of the 6th session, you will have an opportunity to share your experience of the treatment. Completion of the study is estimated at 31 weeks (7 ½ months).
- Testing session before starting and after completing treatment will be audiotaped to check the scoring of the tests. Treatment sessions may be recorded for quality assurance of the sessions. Recordings will be immediately uploaded to the VA secure network and deleted from the recording device. Recordings are not saved to the network with any identifying information. Instead, we save the file with a participant number that is randomly assigned. All recordings are deleted once the scoring or quality assurance of the therapy session is completed. Only the investigator and the research team will have access to the audio recordings. Under no circumstances will anyone else listen to the audio without your written permission.

  Do you give your permission to be audiotaped?

  - ☐ Yes, I give my permission to be audiotaped
  - ☐ No, I do not give my permission to be audiotaped

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Complete testing as instructed.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.
- Ask questions as you think of them.

While participating in this research study, you should not take part in any other research project without approval from the Protocol Director. This is to ensure that the current treatment, but not other factors, affect treatment outcome.

WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are **free to withdraw** your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for any disease and you will not lose any benefits to which you would otherwise be entitled.

If you withdraw from the study, no negative consequences are anticipated other than losing from the potential benefits of completed treatment.

If you withdraw from the study:

- You should tell the investigators or study staff as soon as possible. You can do this by phone by calling Dr. Sherry Beaudreau at [redacted].
- If you withdraw and are willing, you have the option to give feedback regarding reasons for your discontinuing in the study which can help us improve the study.

- If you withdraw from treatment and are willing to participate in testing, you can do this and get reimbursed $50 for 1.5 to 2 hours of testing and $10 for each 30-minute follow up testing visit 1-month, 3-months, and 6-months later.

The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons: Failure to follow the instructions of the Protocol Director and/or study staff, if the Protocol Director decides that continuing your participation could be harmful to you, if you need more intensive treatment than is included in this study, if the study is cancelled, for other administrative reasons, or for other unanticipated circumstances.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions. Your participation in this study may involve risks that are currently unforeseeable due to the investigational nature of this study. However, if any new risks become known in the future you will be informed of them. The following explains the precautions we are taking and the risks involved in these procedures:

- The responses to questions concerning illegal drug use could be self-incriminating and harmful to you if they became known outside the study. As explained in the confidentiality statement on page 6 of the consent, we do not intend to disclose this information.
- It is possible that, based on information gained from this study, the investigators may be required to report information (e.g., information relating to immediate risk of suicide, or physical or sexual abuse) to the appropriate authorities.
- Because the new treatment is experimental, it is possible that if you are assigned to receive it that it may involve risks to you, which are currently unforeseeable.
- There are virtually no risks involved in the memory testing measurements other than the anxiety that can be associated with any test. Some of the mood tests can be associated with the experience of negative emotion, although this experience is usually fleeting. It is possible that you might become tired or frustrated by some of our testing. You may find answering the questionnaires annoying, boring, or repetitive. If this happens, please tell us and we will take a break or skip a particularly difficult test.
- Repeated evaluations of mood and mental status may be slightly frustrating or produce fatigue and boredom.

- It is possible that answering questions about your mood might cause some discomfort or potentially increase your feelings of hopelessness

In the event that you experience any emotional distress, you may contact Dr. Sherry A. Beaudreau at [redacted] or staff at [redacted] during regular business hours or call the VA Telecare [redacted] at all other times.

POTENTIAL BENEFITS

We cannot and do not guarantee or promise that you will receive any benefits from this study. While no benefits can be guaranteed, we expect that you may benefit from this study by becoming more informed about your mood and learning options to help improve your mood that you may not have been aware of previously. Additionally, your participation has the potential to benefit older Veterans for whom we hope to give these treatments in the future. Your participation may help us to learn more about the best way to help older adults manage stress without medication.

ALTERNATIVES

You do not have to participate in this research study in order to receive treatment for any medical condition. Your study doctor will discuss any alternatives with you before you agree to participate in this study. The treatment has support for use in older adults. Participants will have the opportunity to receive a referral to another VA clinic or community provider for treatment. One alternative to participating in this study is to not participate.

PARTICIPANT'S RIGHTS

Your participation is voluntary. You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

ClinicalTrials.gov

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.

CONFIDENTIALITY

Identifiers might be removed from identifiable private information and, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you. We will keep your name and all the information you tell us in this study as confidential as possible. We may publish the results of this study for others to read about, but you will not be identified in any articles about the study by name, social security number, address, telephone number, or any other direct personal identifier. Also, other federal agencies as required, such as the VA Office of Research Oversight and the VA Office of the Inspector General may have access to your information.

Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

How will my health information be used in the study?

This is a research program to examine a psychological treatment for stress in older adults. Information we collect about you will be added to information about other people and analyzed to help researchers and clinicians better understand how well the treatment helps older adults reporting stress and if it helps some people more than others. Results from this study will be presented as conference proceedings, in a peer-reviewed journal and in a grant application to obtain additional funding in this area. Results may include individual descriptions of the presenting concerns, pre/post treatment testing, and treatment process and outcome. These descriptions will not include patient identifiable information.

What Personal Health Information Will Be Used or Shared?

The following health information, linked to you by your name, will be used for this research:

- Medical history and physical examination information
- Progress notes
- Discharge summary
- Survey/Questionnaire responses
- Mental health (not psychotherapy) notes
- Psychological test results
- Drug abuse Information
- Alcoholism or alcohol use information
- Hospitalizations during the course of the study
- Audio recordings of assessments and therapy sessions

- Signed consent form
- Your social security number for processing payment; it will not be used for any other purpose.

Who May Use or Share Your Health Information?

By signing this document, you allow the following individuals and entities to obtain, use and share your health information for this research study:

- The Program Director/Principal Investigator (Sherry A. Beaudreau, PhD) and members of the VA research team.
- Departments within the VA Health Care System responsible for the oversight, administration, or conduct of research.
- The Stanford University Administrative Panel on Human Subjects in Medical Research and other Stanford University Officials responsible for the oversight, administration, or conduct of research.

- No health information will be disclosed to others unless you sign a release of information requesting that the general results of their testing or therapy be disclosed to an outside, non-VA provider. The consequences of signing the release would be discussed with you. For your protection, it would be recommended that the release of information have a set expiration date of two months into the future or sooner.

Who May Receive and Use Your Health Information

The investigators may share your health information with the following individuals as part of this VA research study.

- *VA and Stanford/VA-affiliated collaborators on our Palo Alto research team, including Co-Investigators [redacted] and [redacted] and* research data analyst, [redacted], will have access to data collected for this study.
- Our biostatistician, [redacted], is a Stanford University investigator and may work with de-identified data from this study for the purpose of data analysis.
- The Office for Human Research Protections in the U.S. Department of Health and Human Services.
- Your personal physician may receive some data collected for this study, if you request (in writing) that we send information to them.
- Other outside individuals or entities hired by the VA Palo Alto Health Care System to do certain work in support of the VA Health Care System.
- The other VA site enrolling Veterans for this study (VA Syracuse/Canandaigua in New York).

We will protect your health information as required by all laws, however health information shared with others may no longer be protected by Federal laws or regulations and might be shared by the parties above.

Do I have to sign this form?

No. Signing this form is voluntary. The VA may not condition treatment, payment, enrollment or eligibility for benefits based on signing this form. If you decide not to sign the form, you will not be able to take part in this study or receive any research-related treatment.

If I sign now, can I decide later not to continue in the study?

Yes. You are free to take back your permission and stop being in the study. The investigators will not collect any more information about you after you take back your permission, but they can continue to use your information that was collected before you took back your permission.

Your request to take back your permission must be done in writing. Either give your written request to the investigator or send it by mail to: Sherry A. Beaudreau, Ph.D., [redacted]

Does My Permission for the use my Personal Health Information Expire?

Yes. Your information cannot be used forever. Your permission related to the use and sharing of your health information expires when this research study is completed or December 31, 2095.

HIPAA regulations require you to give separate written permission (signature) for the use of your protected health information.

_____ _____

Signature of Participant Date

Printed Name of Participant

FINANCIAL CONSIDERATIONS

Payments. You will be paid up to $220 to participate in this research study. You may need to provide your social security number to receive payment.

If you withdraw from treatment and are willing to participate in testing, you can do this and get reimbursed $50 for 1.5 to 2 hours of testing and $10 for each 30-minute follow up testing visit 1-month, 3-months, and 6-months later.

If you withdraw from treatment and are not willing to participate in testing, your payment will be prorated based on the completed procedures.

Costs. There will be no cost to you for participation in this study. You may incur some minor expenses (minutes on some phone plans) if you participate in this study that will not be covered. All evaluations and treatment pertinent to this study (memory testing; treatment) will be performed at no charge to you.

However, medical care and services provided by the VA that are not part of this study (e.g., normal hospital and prescription expenses which are not part of the research study) may require co-payments if your VA-eligibility category requires co-payment for VA services.

Financial Sponsorship. VA Clinical Services Research & Development is providing financial support and/or material for this study. All therapists providing treatment and assessors conducting the assessments are employees of the VA Health Care System. The Sierra Pacific Mental Illness Research, Education, and Clinic Center (MIRECC) is providing space for this study. Assessors are supervised and trained in conducting the assessments by the Program Director/Principal Investigator (Dr. Sherry A. Beaudreau). Interventionists in the study are trained in the delivery of the treatment and supervised by Dr. Beaudreau. The Project Director ([redacted]) and Co-Investigator ([redacted]) also provide supervision to assessors and interventionists..

Consultative or Financial Relationships. None of the study investigators have consultative or financial relationships relevant to the study sponsor.

COMPENSATION for Research Related Injury

If you are injured as a direct result of being in this study, medical treatment will be available. If you are eligible for veteran's benefits, the cost of such treatment will be covered by the VA. If not, the cost of such treatments may still be covered by the VA depending on a number of factors. In most circumstances, the treatment must be provided in a VA medical facility. No other form of compensation for injuries is available. However, by signing this form you have not released the VA from liability for negligence.

CONTACT INFORMATION

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr. Sherry Beaudreau, at [redacted]. You should also contact her at any time if you feel you have been hurt by being a part of this study.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at [redacted]. You can also write to the Stanford IRB, Stanford University, [redacted].

Appointment Contact: If you need to change your appointment, please contact the study team at [redacted].

Alternate Contact: If you cannot reach the principal investigator, please contact the Project Director, [redacted].

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

May we contact you (by phone or letter) about related studies that may be of interest to you?

☐ Yes. I would like to be contacted for future research opportunities.

☐ No. Do not contact me about future research opportunities.

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Signing your name means you agree to be in this study and that you will receive a copy of this signed and dated consent form.

_____ _____

Signature of Participant Date

_____

Print Name of Participant

_____ _____

Signature of Person Obtaining Consent Date

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Print Name of Person Obtaining Consent

HIPAA regulations require the participant to give separate written permission (signature) for the use of their protected health information.

Person Obtaining Consent HIPAA Authorization confirmation:

☐ Confirm the participant signed the VA HIPAA Authorization section of this consent form.