CONSENT FORM SUBMISSION COVER PAGE

OFFICIAL TITLE:	Motivational Interviewing to Address Suicidal Ideation for Veterans at High Risk for Suicide (MI-SI)
NCT ID NUMBER:	NCT05256940
ICF DOCUMENT DATE:	PI/SC Approval Date: 09/21/2023
	LSI Approval Date: 04/21/2025

Participant Name: _____ Date: _____

Title of Study: Motivational Interviewing to Address Suicidal Ideation (MI-SI): A Randomized Controlled Trial with Suicidal Veterans

Principal Investigator: Kyle Possemato VA Facility: Syracuse VA Medical Center, Syracuse, NY

Principal Investigator for Multisite Study: Peter Britton, PhD

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by Clinical Science Research and Development (CSR&D) at the VA Office of Research and Development. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn whether a brief three-session experimental behavioral treatment produces better outcomes than the standard care you would receive from your VA. Your participation in this research may last up to approximately one year.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

Taking part in this study may lead to knowledge that will help improve treatment outcomes for other Veterans who are dealing with similar problems. *For a complete description of benefits, refer to the Detailed Information section of this consent.*

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You will be asked to answer questions and talk about thoughts and behaviors related to suicide, depression, Post-Traumatic Stress Disorder (PTSD), substance use and other experiences that you may find upsetting. For a complete description of risks, refer to the Detailed Consent.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits, or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Peter Britton, Ph.D. at the VA Finger Lakes Healthcare System. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study you can contact the Local Site Investigator whose name and contact information is: Kyle Possemato, Ph.D.; Syracuse VA Medical Center, Syracuse, NY, 800 Irving Avenue, Syracuse, NY 13210; 315-425-4400 x53551.

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DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

By conducting this research project, we hope to learn whether a brief three-session experimental behavioral treatment produces better outcomes than high-quality care as usual.

HOW LONG WILL I BE IN THE STUDY?

Approximately 1,000 individuals across three sites will be asked to participate in the first part of this study and complete an initial interview. An estimated 500 participants will be asked to participate in the second part of the study. If you are invited to participate in the second part of the study, your individual participation will take approximately up to one year. This would involve your initial assessment, up to three therapy sessions, and a follow-up assessment at 1, 3, 6, and 12 months. This research study is expected to take approximately five years.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

- If you agree to take part in this study, you will meet with a researcher and complete a series of questionnaires and interview questions about variables related to your military experience, suicidal behavior, and mental health that will take around 30 minutes. About half of those who complete the interview will be asked to participate in the second part of the study.

- If you are asked to participate in the second part of the study, you will meet with a researcher and complete a second series of written and interview questions about depression, Post-Traumatic Stress Disorder (PTSD), substance use, sleep, motivation, and other related topics that will take about 50 minutes.

- When completing the questionnaires and interview questions, you are free to skip any questions that you do not wish to answer.

- A researcher will review your medical records to collect information that identifies you, such as your name, date of birth, address, and information about your health care use such as hospital admissions, lab tests, prescription medications, and healthcare visit information.

- Half of you will be randomized to receive an experimental treatment plus treatment as usual (i.e., any services you would get if not enrolled in the study), and half of you will receive treatment as usual alone. The process of randomization is similar to flipping a coin to see which group you will be in, so you will have a 50/50 chance of being assigned to either group.

- If you are in the experimental treatment group, you will meet with a research counselor for two 50-minute counseling sessions that will take place in the next two weeks. The sessions will include a discussion of your motivation to continue living and your plans to increase your engagement in activities that you find meaningful and rewarding. You will also be asked to complete an additional 50-minute session within a month of the second session, for a total of 3 sessions. Counseling sessions will occur in person, virtually, or by telephone depending on your preference.

- All participants will receive high-quality treatment as usual. Research staff will ensure that you receive a high-quality Safety Plan by reviewing it with you or administering it if you have not already completed one. Safety Plan reviews or administrations will occur in person, virtually, or by telephone. You will also receive a referral to a Suicide Prevention Coordinator to ensure you have access to the care you need.

- Some of your assessments will be audio recorded to ensure that researchers are scoring your responses appropriately. Counseling sessions administered as part of the study, including the experimental treatment and Safety Plans, will also be audio recorded to ensure that you are receiving high-quality care and to learn how the intervention works. To participate in the study, you must agree to being recorded. Recordings will not be shared outside of VA or outside of the study team.

- You will be contacted 1,3, 6, and 12-months after discharge to complete a virtual or telephone interview that will ask about thoughts about suicide, motivation, and other variables. Each assessment will last about 60 minutes. Researchers will have to maintain contact with you during the next year. To do so, they will ask for your contact information, the contact information of three friends and family members, and permission to contact your VA healthcare providers if needed.

- In summary, the full study includes one 30-minute interview, one 60-minute interview, and a 60-minute interview at 1, 3, 6 and 12-months. If you are randomized to the experimental treatment you will also receive two 50-minute counseling sessions within 2-weeks, and a 50-minute telephone session within the next month.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

- Complete the therapy sessions that you schedule for the study.
- Keep your study appointments. If you must miss an appointment, please contact the investigator or research staff to reschedule as soon as possible.
- Answer interview questions to the best of your ability.
- Ask questions as you think of them.
- While participating in this research study, do not take part in any other research project without approval from the investigators. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

- Any procedure has possible risks and discomforts. You will be asked to answer questions and talk about thoughts and behaviors related to suicide, depression, Post-Traumatic Stress Disorder (PTSD), substance use and other experiences that may upset you. If you experience distress at any time, we will work with you to make you feel more comfortable. If you continue to feel distressed, we will end the interview or session and help connect you to any care that may help and/or inform your VA health care providers so that they can help you.

- Although we separate your data from identifying information to maintain confidentiality, it is possible that confidentiality may be inadvertently breached.

- 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.

- Risks related to 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.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

- We do not know if you will experience any direct benefits from taking part in this research study. However, your participation may lead to knowledge that may help improve the treatment of other Veterans who are dealing with similar problems.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Any information obtained about you in this study will be treated as confidential and will be safeguarded in accordance with the Privacy Act of 1974. Information published or presented about the results of this study will be in a form that does not identify you.

Confidentiality may be broken if you are determined to be a threat to yourself or others, or report child abuse or harm. If you report that you are going to kill yourself or there is reason to believe that you are going to do so, we will break confidentiality for your protection.

There are times when we might have to show your records to other people. 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, the VA Central IRB, our local Research and Development Committee, other study monitors may look at or copy portions of records that identify you, and facility staff may require access to your account numbers for your compensation.

We will include information about your study participation in your medical record. Notes will document whether you reported suicidal ideation, a plan, or intent. Anyone who has access to the VA Computerized Patient Record System (CPRS) could find out you are a part of this study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Identifiers will be removed from data collected during the study and stored in a separate location to prevent linkage with the data. After such removal, the data could be used for future research studies or distributed to another investigator for future research studies without additional informed consent. Paper documents will be stored in locked file cabinets in locked offices, and digital information will be stored behind the VA firewall on VA servers on password protected computers. Only study staff will have access to the documents.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

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.

HOW WILL I BE COMPENSATED FOR PARTICPATING?

You will be paid $10 for completing the first interview. If you are asked to participate in the second part of the study, you will be paid an additional $60 for the baseline assessment, and each follow-up assessment. If you complete the first interview and all five assessments, you will earn a total of $310. In our experience, you will receive payment 4-12 weeks after it has been issued. Payment will be sent by the Fiscal department according to your listed preference (electronic fund transfer, voucher, or check), or will be set up if your preference is not established. Payment will require your SSN and generate a 1099 form that will be issued by the Internal Revenue Service. Information required for payment will be obtained in-person, by mail, or using DocuSign, with assistance from research personnel.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

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 is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution. You do not give up any legal rights or release the VA from any liability by signing the form.

As a veteran, you will receive medical care and treatment for injuries suffered as a result of participating in a VA research program in accordance with Federal Law* (see below). You will incur no additional charges for additional medical care and treatment that may result from injury or complications that are a direct result of your participation in this study. Money has not been set aside for pain and suffering compensation.

Should you have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY: Dr. Kyle Possemato at **315-425-4400 x53551**
AFTER HOURS: Mr. Robert Graham at 315-425-4400 ext 53348

If at any time you are feeling distressed or thinking about hurting yourself or others and need to talk to someone immediately, please call **1-800-273-TALK (8255)** and press **"1"** to be routed to the Veterans Crisis Line.

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DO I HAVE TO TAKE PART IN THE STUDY?

- Your participation is entirely voluntary, and you are not required to take part in this research study. You can refuse to participate now, or you can withdraw from this study at any time after giving your consent without affecting your healthcare/services or other rights. This will not interfere with your regular medical treatment and will incur no penalty or loss of benefits which you are otherwise entitled to as a patient. The investigator will be able to use the data already collected for the study but will not collect further information with the exception of data obtained from public records.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

Researchers reserve the right to discontinue your participation at any time if they believe that it is causing you harm.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central 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 VA Central IRB toll free at 1-877-254-3130 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input. You may also contact the local Patient Advocate at 315-425-4345

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

Sometimes during a research study, new information becomes available about the treatment that is being studied that might change a person's decision to stay in the study. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw from the study, your research doctor will arrange for your medical care to continue. If you decide to continue in the study, you might be asked to sign an updated informed consent form. Your research doctor could also decide it to be in your best interests to withdraw you from the study. If so, he or she will explain the reasons and arrange for your usual medical care to continue.

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FUTURE USE OF DATA AND RE-CONTACT

Data collected in the interviews will be stored in a locked file cabinet in a locked office. Digital data will be stored on a VA server. Audio recordings will be stored on a VA server. All data will only be accessible to the research team. Your individual data will be added to the data gathered from other people taking part in the study. Any talks or papers about this study will not identify you. You may also be contacted for a follow-up study after your participation is complete. To ensure your protection, all data will be destroyed according to VA guidelines.

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 signing this document below, you voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it. A copy of this signed consent will also be put in your medical record.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

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