Combined Transcranial Magnetic Stimulation and Brief Cognitive Therapy to Reduce Suicide Behavior in High-Risk Veterans

NCT03952468

March 13, 2024

Participant Name: _____ Date: _____

Title of Study: Neuroimaging of a Combined Transcranial Magnetic Stimulation and Brief Cognitive Behavioral Therapy to Reduce Veteran Suicide

Principal Investigators: [redacted]

VA Facility: Providence 650

KEY INFORMATION ABOUT THE STUDY

This research study is about understanding and reducing suicidal thoughts and behaviors in Veterans. It is being funded by the VA's Health Services Research and Development (HSR&D) and Clinical Science Research and Development (CSR&D). We hope to learn if combining talk therapy (Brief Cognitive Behavioral Therapy, BCBT) with brain stimulation (Transcranial Magnetic Stimulation, TMS) will reduce suicide in Veterans. We are also investigating how the brain is involved in suicide using games, tests, and pictures of the brain. Additionally, we will be looking at how brains are different in those who do not currently have suicidal thoughts and behaviors.

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

Your participation will last about 12-24 months. You will have the option to participate in some or all parts of the research study. During this research study, you will be asked to answer questions about suicidal thoughts and behaviors, drug and alcohol use, and about your mental and physical health. If you participate in 1) the treatment part, you will come to the Providence VA for brain stimulation called TMS for up to 5 times per week for 15-36 sessions. These sessions will last about 15 minutes. You will also participate in 12 weekly talk therapy sessions called BCBT. These sessions will last an hour and may include weekly homework to practice skills. If you participate in 2) the brain imaging part, you will take several tests on a computer and have pictures of your brain taken at the magnetic resonance imaging (MRI) facility at the Providence VA on two different days. These visits will last about 2 hours. You will also attend up to three follow-up visits to check in on how you are doing. These visits will last about 2 hours.

Research Study Sessions	First Visit *(Today's session)*	MRI 1 *(As soon as scheduling allows after first visit)*	Treatment Visits *(Begin as soon as scheduling allows after baseline visit)*			MRI 2 *(as soon as scheduling allows after completing treatment)*	3 Follow-Up Visits *(6-, 12-, and 24- months from first treatment visit)*
Location	Providence VAMC, Inpatient Unit or Building 32	Providence VA MRI facility	Providence VAMC, Building 32 *(Therapy may be provided via video or phone if sessions cannot be provided on- site due to VA limitations).*			Providence VA MRI facility	Providence VAMC, Building 32
Time Commitment	2-3 hours	2 hours	TMS 15 mins. *(up to 5 times/week for 15-36 visits)*	BCBT 1 hour *(12 weekly sessions)*	Endpoint 2 hours *(at the last BCBT session)*	2 hours	2 hours
Description	Answer questions about your mood, and thoughts of death or suicide	Get your brain scanned and complete computer tasks	TMS treatment administered; Check-in on how you are doing and feeling	Talk therapy, complete worksheets and practice skills	Complete forms and questions asked previously	Get your brain scanned and complete computer tasks	Complete forms and questions asked previously

Providence VAHCS Institutional Review Board
Effective Date: March 13, 2024
Expiration Date: April 8, 2025

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

You have been invited to participate because you are a Veteran and have experienced recent suicidal thoughts or behaviors. It is possible you may experience fewer suicidal thoughts and may reduce suicidal attempts.

For a complete description of benefits, refer to the 'Detailed Information about the Study' section.

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

For a complete description of alternate treatment/procedures, refer to the Detailed Consent.

1) You may feel uncomfortable discussing suicide, emotions, or your mental and physical health.
2) You must travel a great distance or have other demands on your time, visits to PVAMC for this study might be inconvenient for you.
3) You find TMS uncomfortable or annoying. You may feel a tingling, tapping, or painful sensation during TMS. TMS also makes loud clicking noises that can be annoying.
4) You are uncomfortable going into an MRI scanner for an extended period of time.

For a complete description of risks, refer to the 'Detailed Information about the Study'.

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 people in charge of the research study are [redacted] (Treatment Portion: BCBT), [redacted] (Treatment Portion: TMS Therapy), and [redacted] (Neuroimaging Portion) of the Providence VA Medical Center. If you have questions, suggestions, or concerns regarding this research study or you want to withdraw from the study their contact information is: [redacted]

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DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

With this research we hope to learn the effect of combining talk therapy (Brief Cognitive Behavioral Therapy or BCBT) with brain stimulation (Transcranial Magnetic Stimulation or TMS) to see if it reduces suicide in veterans. We also are investigating if games, tests, and pictures of the brain differ in Veterans with suicidal thoughts and behaviors.

HOW LONG WILL I BE IN THE STUDY?

We are planning to recruit 130 participants, and 60 control participants. This research study is expected to take approximately 4 years to complete. Your individual participation in the project will take 12-24 months.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

Transcranial Magnetic Stimulation (TMS): Transcranial Magnetic Stimulation is a non-invasive treatment that uses a metal coil to create a pulsing magnetic field. These electromagnetic pulses are used to target specific areas of the front of the brain. The pulses coming from the coil cause electrical changes in your brain that control and regulate mood. Half the Veterans who participate will receive the magnetic energy from the TMS device, while the other group will receive no magnetic energy (also called a "sham" or placebo). Sham TMS looks and feels like the real thing but doesn't deliver magnetic energy. There is a 50/50 chance that you will be placed in the sham group and not receive actual TMS. However, you will not know which group you are in.

Brief Cognitive Behavioral Therapy (BCBT): Brief Cognitive Behavioral Therapy is a structured talk therapy. This therapy will include learning skills to help with regulating your emotions, creating plans for safety, problem solving, learning to be present, and understanding how one's thinking effects one's action. If you are engaged in suicide-focused therapy, or therapy that significantly overlaps with BCBT for suicide, you may be asked to stop that specific individual psychotherapy during the time you are having BCBT for this study. However, you will be instructed to continue with all other usual mental health care (i.e., continue prescribed mental health medications and working with your mental health providers).

Magnetic Resonance Imaging (MRI): A Magnetic Resonance Imaging (MRI) scanner takes pictures of your brain. We are taking pictures of your brain in order to compare the brains of Veterans with and without suicidal thoughts and behaviors. You will be asked to lie in the scanner for about an hour while you are either resting quietly or playing a computer game. You will be able to hear and speak to the MRI personnel/research staff while you are in the scanner.

Study Visits:

First Visit (2-3 hours): If you agree to be in this study you will complete a screening to see if the study is a good fit for you. If you are not eligible for the research study, you will only complete the screening questions. During this visit you will be asked by trained research study staff to answer questions about your mood and thoughts of death or suicide. This interview will be audio-recorded. By signing this consent, you agree to this recording. If eligible, you will also be asked to answer questions or fill out some forms about different things related to depression, how well you function, drug and alcohol use, and your

Providence VAHCS Institutional Review Board
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mental health history. If you are a woman of childbearing potential, you may be asked to complete a urine pregnancy test before TMS study procedures. If you consent to the study and complete the screening visit, but for any reason cannot be scheduled for the next study visit within two weeks, we will ask you at your next visit, or before your first treatment session, to answer some of the same questions and to fill out two of the same forms that you completed at the screening visit. This will take about 30 minutes.

MRI Visit(s): If you participate in the MRI part of this research study, you will be asked to come in for one or two MRI visits, each lasting about 2 hours. *You will come to the second MRI visit only if you also participate in the treatment portion of the research study.* You will be asked to take a breathalyzer and urine drug screen by trained study staff at the start of each visit. You will be removed from the research study if you fail the drug screens. If you do not fail the drug screen you will continue with the rest of the visit.

Behavioral Testing (approximately 60 minutes): You will be asked to respond to the numbers, letters, or symbols you see on the screen like you would if you were playing a video game.

MRI Testing (approximately 60 minutes): During this visit, you will have pictures of your brain taken with an MRI scanner. We will review MRI safety procedures with you, and we will have you remove all metal/jewelry and then change into hospital pajamas. Then, you will have a scan done on your brain. You will be asked to lie in the scanner for about an hour while you are either resting quietly or playing a computer game. You will be able to hear and speak to the MRI personnel/research staff while you are in the scanner. The scanner makes loud noises during imaging. Ear protection will be provided to reduce the noise level. If there are problems with the scanner or images are poor, we may need to collect additional MRIs and you may be scheduled for additional MRI scans.

I DO consent to participate in the MRI part of this study: _____(initials)

I DO NOT consent to participate in the MRI part of this study: _____(initials)

Treatment Visits: If you participate in the treatment part of this research study, you will be asked to come in for 12 weekly talk therapy sessions and complete 15-36 TMS sessions. It is important to keep your study appointments. If you must miss an appointment, please contact the investigator or research staff to reschedule as soon as possible.

TMS Sessions 1-36 (approximately 15 minutes): During the first session, the study physician will need to determine the correct amount of energy that will be used for your specific TMS treatments. This will be done by finding out the minimum amount of energy that will make your hand twitch by placing the TMS coil over a certain area of the brain. You will hear a clicking sound and feel a tapping sensation on your scalp during this procedure. The TMS device will be adjusted to give just enough energy through your scalp to make your hand twitch. This is called your 'motor threshold' and will be checked as needed throughout the study by the study physician.

TMS treatments will be up to 5 times per week, last up to 15 minutes, and will occur for a minimum of 15 sessions or up to 36 sessions depending on what is determined to be best for your treatment. Each day, a research staff member will ask questions about changes in your

medications, usage of alcohol or drugs, any medical events that have happened since your last visit, and how you have been feeling as well as any changes you have during this study to your current medical or mental health treatments. You will remain awake and alert throughout the treatment. At the end of each treatment session, you will be asked questions about any discomfort or unusual effects you may have experienced during the treatment. This will be provided by the trained and licensed study doctor and trained research staff.

BCBT Sessions 1-12 (about 60 minutes): You will be asked to complete 12 individual weekly 60-minute sessions with a BCBT trained therapist. These sessions will be completed in-person at the Providence VAMC. In rare circumstances (e.g., extreme weather, pandemic), these sessions may be provided via phone or video (VA approved VA Video Connect). If this happens, you will be asked to find a private space for phone/video sessions to help keep your sessions private. You will be asked to complete worksheets and practice learned skills at home. On the days you have the BCBT therapy and TMS, the TMS will occur prior to the therapy session.

The last BCBT visit, session #12, will last up to 2 hours and will take place about 3 months after your first visit with us. During this session, you will complete the last BCBT session as well as answer questions and fill out the same forms you filled out at the beginning of this study. You will be asked questions about suicide and other kinds of self-harm by a trained and licensed study therapist.

Interviews and therapy sessions will be audio recorded to see how the research staff administering the sessions and interviews are doing. You will always know if you are being recorded. Audio recording is required as part of participation in this study.

Recordings will be carefully reviewed by supervising therapist and the research team to make sure that you are receiving the best service possible. Recordings will be kept confidential and only our research team will be able to hear them.

I DO consent to participate in the treatment part of this study: _____(initials)

I DO NOT consent to participate in the treatment part of this study: _____(initials)

Follow-Up Visits (1.5 hours): If you participate in both parts of the research study, you will attend follow-up sessions at 6-, 12-, and 24-months after your first treatment visit. If you only participate in the treatment part of the study, you will attend follow-up sessions at 6- and 12- months after your first treatment visit. If you only participate in the MRI part of the study, you will attend follow-up sessions at 6-, 12-, and 24-months after your first MRI visit.

During those follow-up visits, trained research study staff will ask you questions, and you will fill out the same forms you filled out previously. Endpoint & follow-up measures can be completed over the telephone if necessary (e.g. extreme weather, pandemic, the participant no longer resides in the locality). During all assessments, including the screening session, you may refuse to answer any question that you do not feel comfortable answering. You may stop your participation at any time. You will not have to tell the study staff your reasons for ending your participation.

While participating in this research study, do not take part in any other research project without approval from 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.

VA Electronic Health Record Access: Research study staff will also review your VA electronic health record after your baseline visit, and your follow-up visits. We are interested in your health and what kinds of treatment you receive at the VA. Any data collected is for research only and will not affect the care you receive at the VA.

Use of Research Results: Identifiers, such as your name, birth date, and social security number will be removed from the data and your data will be labelled by an anonymous number (e.g. 7001). We may share your de-identified data using this anonymous number from this study (e.g. scores from interview or self-report measures, imaging data, cognitive task data) with [redacted]. We may also share your interview data, de-identified with the exception of assessment dates, (using the same anonymous study number) with the [redacted]. Only approved members of the study team will have access to recordings containing identifiable data.

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

- Please attend your study appointments. If you cannot make it, contact 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.
- Please do not take part in another research project while volunteering for this study without talking to our investigators. Doing so could invalidate the results of both studies.
- If anything changes in your mental health treatment, like a medication change or starting/stopping therapy, please let our study team know.

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

Psychological Risks: You may feel upset answering questions about suicide or your health. Mental health symptoms may temporarily worsen because of these questions. You may discuss any discomfort with one of the researchers. If you become distressed and need help, a research study staff member will put you in touch with your mental health care provider or will help you find a mental health provider.

Providence VAHCS Institutional Review Board
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Potential Risks from TMS Treatments: TMS is considered to be safe. Serious complications can occur in people who have metal in their head, such as shrapnel (pieces of bullets or metal from explosions) or implanted metallic objects such as a metal clip put in your body during surgery (such as aneurysm clips). You should not have TMS if you have ever had a seizure (also known as convulsions, fits, or epilepsy), stroke, hearing problems (such as ringing in your ears), suffer from severe frequent headaches, or have been knocked out for more than 10 minutes.

Research study staff will ask you about these and related conditions that may put you at greater risk during TMS. It is important that you tell research study staff if you have or have had any of these conditions.

The TMS coil makes loud clicking noises. This can be annoying and hurt your ears. You must wear ear plugs to protect your ears; this will reduce the noise level. Some people find ear plugs uncomfortable. When you have the TMS you may feel a tingling, tapping, or painful sensation at the treatment site during the stimulation. Most patients who have had TMS therapy usually report these sensations to be mild and find they become less over time as their body adjusts to the daily treatment procedure. Other possible side effects associated with TMS delivered to this part of the head are scalp, jaw, face, or neck discomfort, or muscle twitching in those areas, toothache, and headache. Some treatment coil adjustments may be possible to make the experience more comfortable. It is important to tell research study staff of any discomforts, so adjustments can be made.

Risk of Seizure: In ordinary clinical use, standard TMS treatments have caused a seizure in about 1 out of 1000 patients, or 1 in 30,000 treatments. The TMS treatments in this research study will be given by doctors and staff who have extensive experience with safe delivery of TMS and who are trained in steps to prevent and manage seizures. In the event that you have a seizure, appropriate medical treatment will be provided.

Risk of MRI Discomfort: You may feel nervous about being in the scanner, especially if you do not like being in small spaces. We will check in with you during the scan to make sure you are feeling okay and you may stop the session if being scanned is too uncomfortable for you. You must stay very still while in the MRI scanner, which some people find bothersome. You will be given pillows and blankets to make sure you are as comfortable as possible while you are in the scanner.

Risks related to MRI: MRI is considered to be safe. However, accidents, injuries, and even deaths have occurred. Such events are extremely rare if appropriate safety precautions are followed. Serious complications can occur in people who have metal pacemakers, metallic dust in their eyes, or certain types of metal prostheses, implants, or surgical clips. To determine whether it is safe for you to go into the scanner, it will be important that you tell research study personnel and the MRI technician about any metallic objects or devices that are in or on your body. Also, if you enter the MRI room with any magnetic cards, such as ATM and credit cards, the data on the cards may be erased by the MRI machine. The scanner also makes loud noises during imaging. Ear protection will be provided to reduce the noise level. There is a risk of tattoos heating during MRI scanning. If this happens, please tell us immediately. If you feel uncomfortable for any reason before or after the procedures, please tell the researchers. If for any reason during the procedure you want to stop, you may do so at any time.

This research study is not designed to detect problems in brain function. These research MRIs cannot take the place of a medical examination by a neurologist if one is needed. The investigators on this project are not trained to make diagnoses based on the MRI and the investigators and Providence VA Medical Center are not responsible for failure to find abnormalities in a research MRI scan. However, if we notice an MRI image that seems abnormal, we may ask a radiologist at the Providence VA Medical Center to examine the images to determine if you need to see a neurologist. If the radiologist thinks medical attention is needed, the research study staff will encourage you to contact your physician. If your physician is not a member of the Providence VA Medical Center, you will be asked to sign a release of information that will allow us to contact him or her on your behalf.

The decision to undergo further examination or treatment lies with you and your physician. Research study staff are not responsible for any examination or treatment that you undertake based upon these findings. Because the images collected in this research study are not labeled with your name, they will not be part of your VA medical record. However, if you decide to get further treatment, we will provide your PVAMC physician with a copy of the images on a CD or DVD if they request it. We may provide you with copies of these images if you wish to give them to a non-VA physician and you sign a release of information document.

Risk of worsening symptoms or lack of improvement: There is no promise that the treatment will lead to improvement of your symptoms. During the course of treatments or after finishing the final session, your symptoms may worsen. The research staff will ask you at every treatment session how you are doing, and a doctor is available to meet with you during the research study to ensure that participation in this research continues to be safe and reasonable for you.

Risk of loss of confidentiality: While every effort will be made to maintain your anonymity, it is possible that complete confidentiality will not be maintained. However, safeguards are in place to protect your confidentiality. All forms of paper data will be stored in locked offices and cabinets at the VA and will only be seen by the research study team. All electronic data is stored on protected VA computer systems. Information that might allow you to be identified will not be used in publications or reports sent to individuals outside the research study. All research study staff are trained to protect your confidentiality.

In rare circumstances, you may need to complete research visits via phone or video. If there is a session scheduled via phone or video, we may send you information (materials needed for therapy sessions and/or questionnaires used for follow-up study sessions) via mail or encrypted email. We will not include any study specific appointment information (e.g. date or time of upcoming appointments) in the materials we send out. We ask that you do not fill out or put any information into these questionnaires, as they are only meant to be used as a reference. We ask that you do not mail these materials back to us and we also ask that you do not reply to any emails we send. When completing these sessions, you will be asked to find a private space for phone/video sessions to help keep your information private. But it is still possible that others may overhear your sessions, open your email, or see your answers if you choose to fill out these questionnaires sent via mail or encrypted email directly. The research staff will work with you to try to find a private place for you to complete sessions, in order to minimize the risk that you will be overheard or have your answers seen by someone other than members of the study team.

Other risks: Although TMS and MRI are likely safe for pregnant women, the effect of these procedures on a developing fetus remains unknown. Therefore, pregnant women or women planning to become pregnant are not allowed in this research study. If you are a woman of childbearing potential, you may be

asked to complete a urine pregnancy test before you begin and while participating in the research study. Prior to the administration of each TMS session or before each MRI session you will re-affirm continued use of your designated choice of birth control. If at any time during the research study there is a chance you may be pregnant, you are agreeing to inform research study staff immediately. At that time, you will be asked to complete a urine pregnancy test. If it is confirmed that you are pregnant you will be discontinued from the research study.

If you receive monetary compensation for your participation using electronic funds transfer (EFT), there is a risk that your bank account information or social security number can be stolen or misused since funds are distributed through an electronic transfer.

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 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.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. However, it is possible that you may experience fewer thoughts of suicide or fewer thoughts of death. The potential benefits of this project to others may include enhanced knowledge about treatment options for Veterans experiencing thoughts of death or suicide.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

You may choose not to participate in this research study. If this is your decision, there are other choices such as talk therapy outside of this research study or clinical TMS is also available for certain mental health problems, and you may ask for a referral. You may discuss these options with your doctor. If you choose not to join the research study, you should continue your usual mental health and medical care and discharge plans.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

All information will be confidential to the extent of the law. Access to data will be limited to research study staff. Data will be stored in locked file cabinets and password-protected computers. Except for your contact information, your data will only be identified by a code number. As a VA patient, you have a computerized medical record and we will put notes in your record about your participation in this research study. A copy of this consent form will be scanned into the record. We will need access to your medical record for this purpose until you finish the study. Only the investigators and their staff will have access to the study records. No information will be shared outside of the VA.

All answers that you give will be kept private. The confidentiality of the information you provide to us will be maintained in accordance with the laws of the State of Rhode Island. Under the law, we must report to

the state suspected cases of child or elder abuse. If you tell us you're planning to cause serious harm to yourself or others, we will share this information with clinical staff and/or the proper authorities. Identifiers will be removed from your identifiable private information and after removal the information may be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your Legally Authorized Representative (LAR).

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.

While this study is being conducted, you will not have access to your research-related health records. This will not affect your VA healthcare, including your doctor's ability to see your records as part of your normal care. It will also not affect your right to have access to the research records after the study is completed.

The identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the you or or your Legally Authorized Representative (LAR).

Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private information. Federal laws and the federal medical or 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 these laws and the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. Other information such as HIV status, drug, alcohol or STD treatment, genetic test results or mental health treatment may be viewed or collected, if necessary or if there are interviews or surveys where you, as the research subject, provide that information to the research team.

The research team may also need to disclose or share your information to others as part of the research and study progress. Others may include the following: Food and Drug Administration, Office (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), the Government Accountability Office (GAO) the VA Institutional Review Board, and the local VA medical facility Human Research Protections Program.

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or the HIPAA Privacy Rule regulations and may be subject to re-disclosure by the recipient.

While this study is being conducted you will not have access to your research related health records.

This will not affect your VA healthcare, including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you can ask a member of the research team to give you a form to revoke your authorization in writing. Your written request will be valid when the research team receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, Jennifer Barredo and his or her research team can continue to use information about you which the research team has relied upon for the research and that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

WHAT ARE THE COST 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.

Compensation Offered for Participation: You will be compensated for your time and effort up to $425 using electronic funds transfer (EFT). You will receive up to $75 for the baseline assessment ($25 for completing the screening portion of the visit, and $50 if you consent to participate in the study and complete baseline measures), paid upon discharge. You will also receive $50 for each follow-up session you complete (6, 12, and 24 months later).

If you participate in the MRI part of the study, you will receive $75 for each MRI visit you complete (up to $150 for two visits)

If you participate in the treatment part of the study, you will receive $50 on completion of the last treatment session.

If you do not finish the research study completely, you will still be paid for your time based on the amount of study completed. To receive funds by EFT, you will have to provide your bank account number, bank routing number, and social security number on the form provided, so the funds can be sent directly to your bank account. This usually takes less than a week after we have asked the funds to be sent to you.

You may be issued an Internal Revenue Service Form 1099-MISC for the payment/s you receive in this study, which would require us to share your social security number with VA, as they will be issuing the payments. Payments may also be disclosed to others listed on the account and any unpaid debts/liens on

the account may affect the deposited funds. If you do not wish to use EFT and would prefer to receive gift cards (e.g. CVS) of the same amount, please discuss this with study staff.

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

If you are injured as a result of being in this study, the VA will provide treatment for research related injury in accordance with applicable federal regulations (38 CFR 17.85).
If you have a medical concern or get hurt or sick as a result of taking part in this research study, call:

During the day: [redacted], Dr. Jennifer Primack at [redacted], or Dr. [redacted].

After hours: Call [redacted] and ask the operator to page the psychiatrist on call.

Emergency and ongoing medical treatment will be provided as needed

DO I HAVE TO TAKE PART IN THE STUDY?

No, participation in the research study is voluntary so you have the right to withdraw at any time. Participant withdrawal will not affect your social, financial, or medical standing. You may withdraw at any time without any penalty or loss of benefits and you will still receive the same standard of care that you would otherwise have received.

If you choose to withdraw, the investigators may continue to review the data already collected for the study but cannot collect further information, except from public records, such as survival data.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION (Include if applicable)

The investigator or a research study staff member may end your participation if he/she feels it is in your best interest or believes you are not following study procedures. If you fail a drug screen at either MRI visit, you will be removed from the MRI portion of the research study. If changes in your medications, usage of alcohol or drugs, how you have been feeling, or any medical events occurring during the TMS+BCBT treatment increase the risk of these procedures you may be removed from some or all of this portion of the study, though you may still be able to take part in the MRI and follow-up visits. If your participation is terminated by the researchers, you are entitled to an explanation of the circumstances leading to that decision. To reconnect you and your mental health provider, study investigators will tell your mental health provider that you are no longer participating in this study.

Participant Name: _____ Date: _____

Title of Study: Neuroimaging of a Combined Transcranial Magnetic Stimulation and Brief Cognitive Behavioral Therapy to Reduce Veteran Suicide

Principal Investigators: [redacted]

VA Facility: Providence 650

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

Investigators: [redacted] (TMS Treatment Portion) at [redacted], [redacted] (BCBT Portion) at [redacted], or [redacted] (Neuroimaging Portion) at [redacted].

Project Coordinator: [redacted]
Administrative Research Staff: [redacted]

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 Institutional Review Board (IRB) at the Providence VA Medical Center. This is the Board that is responsible for overseeing the safety of human participants in this study. You may call Research Administration at (401) 457-3066 or the Providence VA Healthcare System Patient Advocate at (401) 457-3093 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

Yes, new findings developed during the course of the research that may affect your willingness to continue participation will be provided to you.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

[redacted] or a member of the research team has explained the research study to me. I have been told of the risks or discomforts and possible benefits of the research study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

By signing this document below, I voluntarily consent to participate in this study and authorize the use and disclosure of my health information for this study. I also confirm that I have read this consent, or it has been read to me. I will receive a copy of this consent after I sign it. A copy of this signed consent will also be put in my medical record.

I agree to participate in this research study as has been explained in this document.

Participant Name: _____ Date: _____

Title of Study: Neuroimaging of a Combined Transcranial Magnetic Stimulation and Brief Cognitive Behavioral Therapy to Reduce Veteran Suicide

Principal Investigators: [redacted]

VA Facility: Providence 650

Participant's Name	Participant's Signature	Date

Providence VAHCS Institutional Review Board
Effective Date: March 13, 2024
Expiration Date: April 8, 2025