sTMS for Substance Use-disordered Veterans

NCT04336293

08/2/2023

Participant Name: _____ Date:_____

Title of Study: sTMS for Substance-Disordered Veterans: at home administration

Principal Investigator: John McGeary, Ph.D._____VA Facility: _Providence 650_

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

This is a research study that will evaluate the feasibility, acceptability, and safety of at-home use of the Wave Neuroscience NEST among Veterans with substance use disorders. The NEST device uses a technology "Synchronized Transcranial Magnetic Stimulation" (abbreviated as "sTMS") which is a method for energizing cells in the brain using magnetic fields. This treatment will be delivered through an investigational device that has not been researched among people with a substance use disorder. Thus, we are seeking participation in order to determine whether sTMS is a possible treatment option for Veterans struggling with specific substances, which include alcohol, opiates, or cocaine. This study is being funded by the Department of Veterans Affairs. By doing this study, we hope to learn about using sTMS as an alternative therapy for Veterans diagnosed with a substance use disorder.

WHAT DOES THE STUDY INVOLVE AND HOW LONG WILL IT LAST?

Following the pre-Baseline phone screening, this study includes the following 39 visits over the course of 3 months: (1) Screening/Baseline Visit – 1 visit; (2) sTMS Treatment Sessions – 30 sessions; (3) Weekly VA Visits – 6 visits; and (4) Post-Treatment Visits – 2 visits. A brief description of each session-type is provided here and is discussed further later on.

Screening/Baseline Visit: This study involves participation in research and intends to recruit up to 60 participants. The first visit is the **Screening/Baseline Visit**, during which we will see if you meet the criteria to continue in the study. If you are eligible you will undergo an informed consent process (described below). You will first talk with study staff and fill out surveys about your alcohol and drug use, feelings, and emotions. We will also conduct a blood draw, urine drug screen, electroencephalogram (EEG), and collect a DNA sample. This visit will take approximately two hours and may be split across two appointments within a 7-day window. If you meet criteria for the study, your future participation will take place over the course of 3 months. You will be randomly assigned (this is like the flip of a coin) to either "sham" (also called placebo) or "real" sTMS treatment ("real" meaning you will receive the magnetic energy from the sTMS machine, while the "sham" group will not receive the magnetic energy).

sTMS Treatment Sessions: The 30 sTMS treatment sessions will involve either a) sTMS treatment or b) placebo treatment that will not deliver any sTMS. These sessions are held Monday-Friday and will be 5 days a week. Each sTMS treatment session will take approximately 30 minutes, which is the duration of the actual sTMS treatment. You will be given a portable sTMS device and will complete these sessions in your home.

Weekly VA Visits: While you are being treated with sTMS or placebo, you will also come into the Providence VA weekly (for a total of 6 study visits) to provide urine drug screens and fill out questionnaires (these visits are brief and should take approximately 15 minutes).). The self-report questionnaires for these weekly visits may be completed in-person or remotely through a Qualtrics or REDCap survey link sent to you via email.

Post-Treatment Visits: You will come in and complete a follow up study visit within one week of the last sTMS treatment session, and a final visit one month later. These visits will take approximately one hour each.

For a complete description of study involvement, refer to the *Research Details* section.

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

You may want to volunteer to participate in this study because you will receive a psychiatric evaluation at no cost. Your participation may also help us determine whether sTMS is a feasible type of treatment for Veterans with substance use disorders.

For a complete description of benefits, refer to the Research Details section.

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

1) You may feel uncomfortable discussing your alcohol or other substance use.
2) If you have demands on your time, daily sTMS treatment sessions at home (for about 30 minutes each day) may cause an inconvenience for you.
3) There are risks of side effects while receiving sTMS. This device and therapy it provides are considered investigational, meaning that sTMS has not been approved by the United States Food and Drug Administration (FDA) for treatment of substance use disorders. The FDA has classified the sTMS device as a "significant risk device" for individuals with substance use disorders undergoing treatment sessions in their own homes.

For a complete description of risks or alternate treatment/procedures, refer to the Research Details section.

DO YOU HAVE TO TAKE PART IN THE STUDY?

No. 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 John McGeary, Ph.D. of the Providence VA Medical Center. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, his contact information is: (401) 273-7100 x16247.

RESEARCH DETAILS

WHAT IS THE PURPOSE OF THIS STUDY?

With this research, we hope to learn if sTMS is a feasible treatment option for those with substance use disorders.

HOW LONG WILL I BE IN THE STUDY?

Sixty participants will take part in this study. This research study is expected to take approximately two years. Your individual participation in the project will take up to 3 months.

WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?

This Screening/Baseline Visit and the Weekly VA Visits will take place at the Providence VA. All sTMS treatment sessions will be done in your home using a portable device that we will give you. A study staff member will be present through virtual technology during these sTMS treatment sessions to answer any questions and ask you if you're experiencing any side effects from sTMS. During the course of completing these sTMS treatment sessions, you will be asked to come into the VA once per week for Weekly VA Visits to provide a urine sample, which will be analyzed for the presence of drugs. Due to current VA restrictions on breath tests, we do not plan on conducting breathalyzers. However, if this policy at the VA changes, we may reinstate breath tests, conducting them at all in-person visits. If study staff determine that you are under the influence of substances during a study visit, the session will be terminated. This will be recorded with a note in your study file. Results of the drug screening will not be communicated to you but will be documented in your medical record. If you are determined to be under the influence of substances, we will notify the VA police, and you will be instructed to remain at the VA Campus until you are deemed safe to leave. Please note that every study visit and sTMS treatment session will be documented with a brief note in your medical chart that other authorized VA providers will be able to view.

Screening/Baseline Visit: You will first undergo measures to see if you are eligible to participate in the study. These will include questionnaires to fill out and an interview with trained study personnel. To confirm whether you are eligible to participate in the study, we will look at specific information in your medical chart, including medical history, substance screenings, and your current medication list. If you are eligible, you will complete the consenting process (i.e., going through this form with study staff and deciding if you would like to sign up for the study or not). If you would like to take this form home to consider whether you would like to participate, you may do so for 24 hours. Please note that if you decide to participate, you must sign this form in front of study staff. If you choose to take this form home and return within 24 hours, there will be no additional compensation for the Screening/Baseline Visit. You will complete a task where you look at pictures on a computer and fill out surveys about your cravings. Additionally, we will conduct several laboratory procedures, including a urine drug screen, blood draw, and DNA specimen collection. The DNA samples will be analyzed to see if genetics play a role in how people respond to sTMS treatment. If you are a woman of childbearing age, we may ask that you take a pregnancy test. This visit will take up to two hours and may be completed across two appointments within a 7-day window. You may not meet all the requirements for continuing the study. If you do not meet the criteria of the study, this will be your only visit. The study staff will inform you as to why you cannot continue in the study. If you don't meet the requirements to continue in the study, Dr. McGeary will refer you to the Collaborative Addiction and Recovery Service (CARS) at the VA by contacting the service directly.

If you meet the criteria of the study, you will be randomly placed in to 1 of 2 groups. This is like the flip of a coin. One group will receive the magnetic energy from the sTMS machine, while the other group will receive no magnetic energy from the sTMS machine (also called a "sham," or placebo). There is a 50% chance of being placed in either group. You will not be told before or during the study to which group you belong. Once you've been assigned, research staff will measure your brain waves with an electroencephalogram (EEG) by placing small metal discs with thin wires on your head. During the EEG, we will measure electrical activity in your brain and record these results on a computer. EEG results will then be sent to Wave Neuroscience (the device manufacturer) where a technician will analyze your EEG data. This analysis is only conducted once during the study and allows the sTMS machine to be calibrated to your unique brain wave pattern. Personnel at Wave Neuroscience are trained to ensure that the device is accurately and safely calibrated to your brain wave patterns. No information that could identify you will be shared with Wave Neuroscience. After the EEG, you'll be able to receive your first sTMS treatment session. See sTMS treatment section below for full details of the treatment procedures.

sTMS Treatment Sessions: Treatment Days 1-30 (Monday – Friday daily for six weeks): We will give you a portable sTMS device to administer sTMS treatment sessions in your home. Each 30-minute sTMS treatment session will be completed within the window of 8am-6pm. When administering at home, you will place the device gently on your forehead while you lay back with your eyes closed, awake, on a table or reclined in a chair for 30 minutes. The sTMS device uses a non-invasive metal coil to create a weak magnetic field at the same rate as your brain waves. Magnetic fields can move easily through human tissues like skin, hair, and bone. Before all sTMS treatment sessions, it is important that you remove all jewelry above your shoulders, as well as not have anything in your mouth (e.g., gum) that could generate facial muscle activity. We ask that you keep all metal or magnetic objects (e.g., cell phones, keys, credit cards) at least 20 inches from the sTMS headset at all times. These objects can interfere with the sTMS device and negatively impact the results of the study.

A study staff member will be present virtually throughout the duration of each in-home treatment session. If a stable video connection cannot be established treatment sessions may be re-scheduled or ended early if the video connection is lost and cannot be re-established. A licensed physician will also be available by phone during all treatment sessions in case any medical issues arise. We will observe all sessions through video technology to ensure correct use of the device and answer any questions you may have. We will ask you daily safety questions pertaining to sTMS treatment and inquire about any side effects you may be experiencing. During each sTMS treatment session, we will ask for your specific location. This is so we can contact the proper local authorities in case of a physical or mental health emergency. We also suggest that you conduct sTMS treatment sessions with another individual present in the home who is able to allow emergency services access to your location. If another individual is not present in the home at the time of sTMS treatment sessions, we ask that you unlock your door to enable entry by local authorities as to not cause unwanted property damage. By agreeing to participate in this study, you give us permission to contact these authorities in such a scenario, which waives your confidentiality as a research participant.

It is important that you return the portable sTMS device following completion of the study. We will take several measures to ensure this happens, including obtaining your address and emergency contact information. If we have not received the device from you, we will make multiple attempts to contact you via phone and will work with you to find a convinent time to retrieve the NEST device during your scheduled clinic visits at the PVAMC or possibly via a home visit. We will first inform you via mailed letter that a home visit will occur and a licensed mental health clinician will make such an outreach attempt.

Weekly VA Visits: While you are engaging in daily in-home sTMS treatment sessions, you will also be asked to come into the VA once per week (for a total of 6 times) to provide a urine drug screen. During these weekly study visits, you will fill out brief questionnaires (no more than 15 minutes) about substance use and sleep. You may elect to complete the weekly visit self-report questionnaires remotely. In this case, a Qualtrics or REDCap survey link will be emailed to you for you to complete on our own. Regardless of whenever the assessments are completed on paper or remotely through Qualitrcs/REDCap, you will still be asked to come in to the VA once per week to provide a urine drug screen.

Post-Treatment Visits (PTVs): Two Post-Treatment Visits will occur after treatment is completed. Post-Treatment Visit 1 will occur within 7 days of your last sTMS treatment session, followed by Post-Treatment Visit 2, your final visit, one month later. During these 2 visits, you will fill out questionnaires and meet with a member of the study staff who will ask you questions about your mood, substance use, any medical events, and review your current medications. You will again complete a task where you look at

pictures on a computer and fill out surveys about your cravings. We will conduct an additional urine drug screen. These visits will last about an hour.

For your convenience, we have included a table below detailing all visits and study procedures.

ACTIVITY	Pre-Baseline	Screening/ Baseline Visit	Weekly VA study visit (during 6-week treatment phase)	Daily sTMS treatment session (5/week x 6 weeks = 30 total days)	Post-Treatment Visit – 1 (after last sTMS Treatment Session)	P Tr e Vi 2 m a PT
Phone Screen (To determine eligibility)	X					
Screening		X				
Informed Consent		X				
Demographics		X				
Medical Review		X				
Structured Clinical Interview for DSM-5		X				
EEG		X				
Drug/Alcohol Cue Reactivity Task (i.e., E-Prime)		X			X	
Time-Line Follow-back		X	X		X	
Urine Toxicology Screen		X	X		X	
Blood Draw		X				
DNA Collection		X				
Pregnancy Test[a]		X				
Randomization		X				
sTMS or Sham Treatment				X		
Clinical Institute Withdrawal Assessment of Alcohol, Revised (CIWA-Ar)		X	X		X	
Substance Urge Questionnaire		X	X		X	
Patient Health Questionnaire-9 (PHQ-9)		X	X		X	
Clinician-Administered PTSD Scale (CAPS)		X			X	
PTSD Checklist for DSM-5 (PCL-5)		X			X	
The Life Events Checklist (LEC)		X				

Inventory of Depressive Symptomatology Self-Report (IDS-SR)		X			X	
Positive and Negative Affect Schedule (PANAS)		X			X	
State-Trait Anxiety Inventory (STAI)		X			X	
Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LESQ)		X			X	
Social and Occupational Functioning Assessment Scale (SOFAS)		X			X	
Pittsburgh Sleep Quality Index (PSQI)		X	X		X	
Clinical Global Impressions–Severity (CGI-s)		X			X	
CGI – Improvement (CGI-i)		X			X	
Adapted Satisfaction with Treatment Form					X	
Treatment Blinding Questionnaire					X	

a) A pregnancy test will be conducted at the screening/baseline session if you are a female of child bearing age, and may be performed at any subsequent visit if you believe you may be pregnant, or at the discretion of the PI.

b) Randomization will occur after the study team ensures that you meet all inclusion and exclusion criteria. Youwill then be randomly assigned into the sham or active sTMS treatments.

Participant reminders:

- Keep your study appointments. If you miss an appointment, please contact the investigator or study staff to reschedule as soon as you know you will miss the appointment. If you do not attend study appointments regularly, your participation in this study may be ended.
- It is important that you show up to study visits not actively under the influence of alcohol or other substances. If it is determined that you are intoxicated during a study visit, the VA police will be called. According to applicable federal regulations (38 CFR 1.218), if police are called, no legal action will be taken unless a law is being broken (e.g. disturbing the peace, disorderly conduct, damaging property, interfering with clinical care). However, if the police determine that you are incapacitated, you could be taken into “protective custody” for safety reasons, which requires either a non-incapacitated adult be available for transportation, or that you visit the ER for medical observation.
- Let a study team member know if your medications have changed, especially during the 6 weeks of sTMS treatment sessions.
- Inform study staff if you visit the emergency room or are hospitalized for any reason at a non-VA hospital.
- 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.
- 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 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. 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.

- The most common side effect of sTMS is headache. You may experience headaches regardless of whether you get sTMS or sham treatment. Over-the-counter pain medications such as acetaminophen or ibuprofen may be helpful for reducing this discomfort. The sTMS coil makes a calm, humming noise. You will have the option to wear earplugs to keep the sound out. Some people find earplugs uncomfortable. When you have the sTMS you may feel slight pressure on your forehead. This might be uncomfortable for some people.
- Participants receiving *either* sTMS or sham treatment have reported the following additional side effects: tinnitus, visual disturbances, musculoskeletal pain, skin tingling, anxiety, insomnia, gastrointestinal issues, fatigue, and respiratory infections. These side effects occurred infrequently during previous studies (less than 10% of the time within all study conditions). Importantly, there have been no significant differences between sTMS and sham treatment in terms of the frequency or severity of any side effect, indicating sTMS treatment is well tolerated.
- There may be other side effects of sTMS that we do not know about. Epileptic seizures have been reported in < 1% of patients receiving transcranial magnetic stimulation (TMS). However, there are different types of TMS. Synchronized TMS (sTMS) is the type you will receive in this study and although epileptic seizures have never been reported in previous sTMS studies, we cannot completely rule out the possibility of this event occurring. “Epileptic seizures” refers to the onset of symptoms due to sudden abnormal electrical activity in the brain. The symptoms may include sudden loss of consciousness lasting for seconds- to minutes, followed by temporary confusion. As stated above on Page 3, a study staff member will be present through virtual technology during all sTMS treatment sessions and will immediately notify 911 if you experience a loss or alteration of consciousness or any change in your baseline medical or neurological status. If possible, we suggest that another person be in your home during the sTMS treatment sessions to permit entry of emergency medical personnel, in the unlikely event you are unable to do so. If alone in your home at the time of an sTMS treatment session, we ask that you leave an entrance unlocked to prevent property damage as emergency authorities attempt to reach you.
- Serious complications could occur in people who have metal in or around their heads, such as shrapnel or implanted metallic objects (e.g., aneurysm clips, shunts, stimulators, cochlear implants, stents, or electrodes). You should not participate in sTMS if you have ever had a seizure, stroke, brain tumor, brain aneurysm, have ever lost consciousness for more than 10 minutes, or are pregnant. If you have an implanted device that is activated or controlled in any way by physiologic signals (e.g., cardiac pacemakers, implanted medication pumps, and intra cardiac lines), you should not have sTMS. Finally, those who have metal objects such as shrapnel, bullets, or bullet fragments, or magnetically activated dental implants in their bodies should not have TMS. Study staff will ask you about these conditions before you start participation in sTMS. It is important that you tell study staff if you have or have had any of these conditions. Although sTMS has been used for several years, the long-term effects of sTMS on individuals are not completely known.
- The sTMS device has been shown to occasionally stop working, including device malfunction while sessions are progress. Study staff will be available during all sessions to troubleshoot any

technical difficulties. If the device ceases to work, we will overnight ship a working device to your home.

- Risk of Lack of Improvement or Worsening Symptoms: Risks associated with participation in this trial include possible lack of benefit from the sTMS treatment. Ongoing craving for substances is also a risk. There is no guarantee that the treatment will lead to improvement of your symptoms. During the course of sTMS treatments, or after finishing the final sTMS session, there remains the risk that your substance use disorder symptoms may worsen. The research staff will ask you at every treatment session how you are doing, and the study doctor will be available at all times during the study to ensure that participation in this research continues to be safe and reasonable for you.
- Questionnaires: Some people become uncomfortable at being asked questions about their emotions and health; if, for any reason, you wish not to answer specific questions or you wish to terminate the session, you will be able to do so.
- Risk of disclosure for Qualtrics or REDCap surveys: If you opt to complete weekly visit self-report assessments online through Qualtrics or REDCap, you will be asked to provide an email address where we will send the link for the surveys. There is a chance, if anyone else has access to your email account, that they might be able to click the link and view the questions of the surveys, although your responses will not be visible. This risk can be minimized by keeping all study communications confidential and completing the surveys in private. Survey responses in Qualtrics are also time-stamped, although this information will not leave secure VA and HIPAA compliant environments (Qualtrics) and is deleted upon download to the VA network. You may also choose not to complete these assessments remotely over Qualtrics, and instead complete them in person at the VA with research staff.

- Risk of Confidentiality: There is some risk to patient confidentiality associated with participation in research clinical trials. Steps will be taken to protect privacy of your health information. Importantly, any data that is shared with the device manufacturer (Wave Neuroscience) will not contain information that could identify you as a participant. Conducting sTMS treatment sessions through virtual technology carries specific risks, such as breach of confidentiality if others are present during sTMS treatment sessions. Study staff will work with you to try to ensure you are in a private space during these sessions.
- sTMS is not recommended during pregnancy. The effect of sTMS on pregnant women and on a developing fetus is unknown, so pregnant women are not allowed in this study. This treatment may be harmful to the developing fetus. Women of child bearing potential must use a medically acceptable birth control method, in the opinion of the Investigator, during the trial, and may be tested for pregnancy at the time of admission to the study and will be required to be tested for pregnancy again later in the study if pregnancy status becomes questionable. Before you begin the investigational treatment, we will discuss with you in more detail the importance of avoiding pregnancy during the entire period of study participation. We will specifically ask you to let us know if you change your mind and decide to become pregnant during the study, or if you are not consistently using an acceptable method of birth control. If, during this study, you become pregnant, you should notify Dr. McGeary as soon as possible. Confirmed pregnancy will lead to immediate withdrawal from the study (unless a later pregnancy test shows that you are not pregnant).
- There is a risk that your bank account information or social security number can be stolen and misused if you choose to receive payment in the form of electronic funds transfer (EFT).

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 treatment as usual (i.e., the care you would usually receive outside the context of this research study) 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 treatment as usual.

Your participation in the study may be ended by the Investigator without your permission if you are a woman of childbearing age and become pregnant or if we discover a medical condition that makes sTMS unsafe for you. While there are no other specific foreseeable future situations for which your participation may be ended, your participation in the study may be ended by the researchers without your permission. If we do that, we will tell you why.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any direct benefits from taking part in this research study. However, your participation may help us determine whether sTMS is a feasible type of treatment for Veterans with substance use disorders.

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

You may choose not to participate in this study. You can receive treatment as usual outside of participation in this study. You may discuss these options with your doctor. If you choose not to join this study, you should continue your usual mental health and medical treatment care plans.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

The identifiers might be removed from the 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 or your Legally Authorized Representative (LAR). All research data will be de-identified by assigning your identifiable private information a random code number.

After the EEG is conducted, we will share these specific data with the sTMS device manufacturer, Wave Neuroscience. All identifying information will be removed from these data before it is shared. Wave Neuroscience may store this deidentified EEG data for future analyses.

We will include information about your study participation in your medical record. 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 treatment as usual and will not affect your right to have access to the research records after the study is completed.

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.

The study staff working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your

name, address, date of birth, and information from your medical records such as medical history, allergies, lab results, drug, alcohol or STD treatment, genetic test results or mental health treatment.

The study staff may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the Institutional Review Board, Food and Drug Administration, Office (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability (GAO).

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

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the study staff to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office 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, **John McGeary** and his study staff can continue to use information about you that was collected before receipt of the revocation. The study staff 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.

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.

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.

You will receive up to $225 in either gift cards or electronic funds transfer (EFT). To receive funds by EFT, you will need 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 from the VA. This usually takes less than a week after we have asked the funds to be sent to you. When using EFT, all payments will be reported directly to the Internal Revenue Service. 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 the 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. As a result, if you maintain any unpaid debts and elect for EFT, study staff cannot guarantee that distributed payments will populate in the bank account you provide. If you choose to receive payment through EFT, you will receive one $50 payment at the end of the Screening/ Baseline Visit, one $100 payment when you complete all daily sTMS treatment sessions and the post-treatment follow-up visit, and one $75 payment at the one month follow-up visit.

If you choose to receive payment through gift cards, you will receive one $50 gift card at the end of the Screening/ Baseline Visit, one $100 gift card when you complete all sTMS daily sTMS treatment sessions and the post-treatment follow-up visit, and one $75 gift card at the one month follow-up visit.

You will not be required to pay for care and services (treatment) received as a participant in this VA research project. If you do not finish the study completely, you will still be paid for your time based on what you have completed. You may be found ineligible for participation after completing the Screening/ Baseline Visit. Regardless, you will still be compensated $50 for your time.

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

The VA will provide treatment for research related injury in accordance with applicable federal regulations (38 CFR 17.85). If you want to make a legal claim against the VA or anyone who works for the VA, special laws may apply. The Federal Tort Claims Act (28 U.S.C. 1346(b), 2671-2680) is a federal law that controls when and how a person can bring a claim against the U.S. Government. If you sign this document, you are not giving up your right to make a legal claim against the United States.

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

DURING THE DAY:

Dr. John McGeary at (401) 273-7100 x16247 and

AFTER HOURS:

Dr. John McGeary by calling the main hospital (401) 273-7100 and requesting the operator page him or the psychiatrist on call

Emergency and ongoing medical treatment will be provided as needed.

DO I HAVE TO TAKE PART IN THE STUDY?

No. Your participation in this research study is completely voluntary. Refusal to take part in this study will involve no penalty or loss of benefits to which you are otherwise entitled.

If you are a VA employee or student, refusal to take part in the study will in no way influence your employment, ratings, subsequent recommendations, or academic progress as applicable. You may discontinue taking part at any time without any penalty or loss of benefits. You may withdraw and still receive the same standard of care that you would otherwise have received.

For data already collected prior to your withdrawal, the investigator 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

Your participation in the study may be ended by the researchers without your permission if we discover or you develop a medical condition that makes sTMS unsafe for you. These include pregnancy, loss of consciousness, and neurological disease. If your substance use worsens and we deem you need higher-level care, we may end your participation and refer you to substance use treatment. We also may

terminate participation if you frequently miss sTMS daily treatment sessions. While there are no other specific foreseeable future situations for which your participation may be ended, your participation in the study may be ended by the researchers without your permission. If we do that, we will tell you why.

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

You can call the Dr. McGeary (the principal investigator) at (401) 273-7100 x16247 while you are a participant or after your participation is over for the following: 1) concerns, 2) complaints, 3) problems, 4) suggestions, 5) more information, 6) questions about your rights as a research participant or 7) verifying the validity of the study and authorized contacts.

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 the IRB Coordinator at (401) 273-7100 ext. 13470, Research Administration at (401) 273-7100 ext. 13066 or the Providence VAMC 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?

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

DOES THIS STUDY INVOLVE GENETIC RESEARCH? HOW WILL MY GENETIC INFORMATION BE PROTECTED?

We will analyze your DNA sample for genetic and epigenetic differences in the context of sTMS treatment response. Samples collected will have DNA extracted and assessed for variation using microarrays in Dr. McGeary's lab at the Providence VA Medical Center. Genome wide and epigenome wide analyses will be done on collected samples. None of the results from the DNA test will be conveyed to you, your family, or your physician.

Access to data will be limited to study staff. Data will be stored in a locked file cabinet and/or on password protected computers in the study office. It will be identified by a code number and maintained separately from your personal information. Samples will be identified by a code number and stored on a dedicated shelf in a freezer. This freezer is in a locked laboratory at the Providence VA Medical Center. Your sample will be kept for a period of ten years for analyses and then it will be destroyed with bleach.

Federal laws and policies provide you with protection from discrimination by health insurance companies, group health plans, and most employers based on your genetic information. A federal law called the Genetic Information Nondiscrimination Act (GINA) generally will protect you in the following ways:

1□ Health insurance companies and group health plans may not request your genetic information obtained from this study.
2□ Health insurance companies and group health plans may not use your genetic information obtained from this study when making decisions regarding your eligibility or premiums.

3□ Employers with 15 or more employees may not use your genetic information obtained from this study when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. It also does not prohibit discrimination on the basis of already known genetic disease.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr. McGeary and/or his study staff have explained the research study to me. I have been told of the risks or discomforts and possible benefits of the 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. 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's Name	_____ Participant's Signature	_____ Date