# Targeting Functional Improvement in rTMS Therapy

NCT04016402

NCT03851380

March 27, 2019

Participant Name: _____ Date:_____

Title of Study: __Targeting Functional Improvement in rTMS Therapy_____

Principal Investigator: _Noah S Philip, MD_____ VA Facility: _Providence 650_____

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

This study is about learning how transcranial magnetic stimulation (TMS) works to help depression. It is being funded by the Department of Veterans Affairs (VA) and VA Rehabilitation Research & Development Center for Neurorestoration and Neurotechnology. By doing this study, we hope to learn the best way to use TMS in the clinic and understand how it makes depression better.

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

This study uses a magnetic resonance imaging (MRI) scanner to obtain pictures of your brain and its activity. In this study, you will have MRI scans before, during and after you receive TMS treatment. In addition, you will be asked questions about your symptoms and daily activities. Your participation in this research will include six 2-hour study visits, spread over four to six weeks.

You will participate in this study as you receive TMS therapy. The TMS therapy procedures are not part of this study, and are not included in this consent.

| Clinical Activity | Pretreatment | | TMS treatment sessions | | | Post-Treatment |
|---|---|---|---|---|---|---|
| Study Session | Screening Visit | MRI #1 | MRI #2 | MRI #3 | MRI #4 | MRI #5 |
| Location | Providence VAMC | Brown MRI Research Facility<br>185 Meeting Street, Providence RI<br>or Providence VA MRI scanner | | | | |
| Time commitment | 1-2 hours | 2 hours | 2 hours | 2 hours | 2 hours | 2 hours |
| Description | Screening interview and questionnaires | MRI scanning (1 hour)<br>Study Questionnaires and MRI preparation (up to 1 hour) | | | | |

**WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?**Your participation will help us understand the best ways to treat people with transcranial magnetic stimulation (TMS).

**WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?**There are risks associated with getting MRI scans, but these can be safely managed by taking appropriate precautions.



PVAMC IRB #00001402
IRB NUMBER: IRB-2019-003
IRB APPROVAL DATE: 03/27/2019
IRB EXPIRATION DATE: 03/12/2020

Participant Name: _____ Date:_____

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Principal Investigator: _Noah S Philip, MD_____ VA Facility: _Providence 650_____

**DO YOU HAVE TO TAKE PART IN THE STUDY?**

- Participation in this study is completely voluntary.
- 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 Dr. Noah Philip 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 extension 2369.

## RESEARCH DETAILS

**WHAT IS THE PURPOSE OF THIS STUDY?**

This study has two purposes:

- The first purpose is to test how the device used in TMS (called a coil) is placed, and to make sure coil placement is in the best spot.
- The second purpose is to measure how the brain changes when people are treated with TMS therapy. This requires looking at the brain, which is done with an MRI scanner.

**HOW LONG WILL I BE IN THE STUDY?**

This study will enroll a total of 45 participants over four years. Your individual participation in this study will take up to 6 weeks. Your participation will begin before you start your TMS therapy at the Providence VA Medical Center and continue until soon after your TMS therapy ends. If you agree to participate, this study will include a visit to see if you are eligible to participate, and five study visits that include questionnaires and MRI scans.

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

You will participate in this study as you receive TMS therapy. The TMS therapy procedures are not part of this study. You will receive TMS therapy as part of your regular care. TMS therapy procedures and clinical questionnaires are not included in this consent form. Only research procedures are included as follows:

**Study Visit 1**: If you agree to participate, you will first undergo screening procedures. These will include questionnaires to fill out and an interview with trained study staff members. The total time for this screening visit is approximately two hours. During this screening you will be asked about your psychiatric symptoms, including depression, and about your daily activities and function. If you are eligible, you will be scheduled for an MRI scan. All MRI scans may occur at either the Brown MRI Research Facility, which is located at 185 Meeting Street in Providence

RI, or the Providence VA MRI scanner. The first scan will be scheduled a few days before you start your TMS treatments.

**Study Visit 2**: On the day of the first MRI scan, you will receive a brief orientation to the facility and be asked to fill out several safety forms. You may be asked to practice some of the tasks that you will perform in the scanner. After the training, you will have a MRI scan done on your brain. Most of the time during the scan you will be looking at a cross on the screen. For about 10-20 minutes you may be asked to do a task, such as remembering certain numbers, letters or pictures, you learned before you got into the scanner.

During the scan itself, you will lie on a table that slides into a horizontal cylinder slightly wider than your body. You will be asked to lie still inside the MRI.The MRI makes loud tapping noises as it acquires images and you will be given ear plugs to wear during the scan to reduce the sound. You will be monitored and able to hear and speak to MRI personnel at all times. The time inside the MRI scanner will be no longer than one hour. You may be at the MRI facility for up to two hours total.

No MRI scanning procedures will be experimental; all MRI scanner settings are established and safe, although most of the MRI images obtained would not be part of normal clinical care.



MRI scanner

**Study Visits 3-5**: After the first MRI scan, you will begin your TMS therapy as scheduled. During the course of your TMS therapy, you will be scheduled to complete three additional MRI scans at approximately weekly intervals. Research staff will assist with scheduling them at a time that works well for you. These scans will follow the same procedure as the first scan. In the same visit as the scans, you will be asked to complete questionnaires about your psychiatric symptoms, and your daily activities and function. The time to complete both the MRI scans and the questionnaires may be up to 2 hours for each visit.

**Study Visit 6**: You will be scheduled to have one more MRI scan within a week of completing your TMS therapy. The procedure for this scan will be the same as the other scans. You will

also be asked to complete questionnaires during this visit. The total time to complete both the MRI scans and the questionnaires may be up to 2 hours total.

**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.

Risks associated with MRI: MR imaging is generally considered to be safe, but accidents, injuries and even deaths have occurred during MRI procedures. Such adverse 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. Dental fillings are not a problem.
- MRI is also potentially dangerous for anyone wearing metal objects, including jewelry, piercings, watches, hair holders, eyeglasses or metal on clothing, as well as some eye shadow that sometimes contains metallic substances.
- Some intrauterine devices (IUDs) are not MRI compatible; if you have an IUD please let study staff know.
- Some people experience a 'closed-in' feeling due to the relatively restricted space within the MRI machine.
- Although MRI is considered safe for pregnant women, the potential risks of MRI on developing fetuses and embryos are not known. Therefore, if you are pregnant or are trying to become pregnant, you should not participate in this study. Investigators may ask you to complete a pregnancy test.
- In addition, if you enter the MRI room with any magnetic cards, such as ATM and credit cards, you will risk having the data on the cards erased by the MRI machine.

For these reasons, a researcher or technician will review safety information with you before the scan. In order to determine whether it is safe for you to undergo the scanning procedure, it will be important that you tell study personnel and the MRI technician about any metallic objects or devices in, or on, your body. If there is any question about the presence of metal in your body, you may be requested to have an X-ray to determine this; the X-ray will become part of your medical record.

Risks associated with Questionnaires and study questions:

- Some people become uncomfortable at being asked questions about their psychiatric symptoms.

- 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.

Risks of TMS and clinical care: TMS procedures and the clinical care you receive while you participate in this research protocol are not part of this study. Risks associated with TMS and other clinical care procedures are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of TMS or any aspect of your clinical care.

Risks of using electronic funds transfer (EFT): If you choose to use EFT to receive compensation for your participation in this study, there is a risk that your bank account information or social security number can be stolen and misused.

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.

**WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?**

There are no direct benefits to you through participating in this study. However, the information learned in this study may help us improve TMS therapy in the future.

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

You may choose not to participate in this study. If this is your decision, you can still receive TMS therapy at the Neuromodulation clinic.

**HOW WILL MY PRIVATE INFORMATION BE PROTECTED?**

Every effort to maintain confidentiality will be made. You will not be identified in any reports or publications that may result from this study. The confidentiality of the information you provide will be maintained on a secure research server. Identifiable information gathered during the course of this study will not be shared outside study personnel except where permitted by law.

Any information that could be used to identify you (e.g. name, contact information, birthdate) will be removed from the data. After your identifying information is removed, the data we collect in this study can be used for future studies without asking for your consent again.

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 normal care 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 research team 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 and record other information including your name, sex, race, date of birth, education, address and information from your medical records. Medical history, current and past treatments (e.g., medications, psychotherapy) allergies, lab results, HIV status, drug, alcohol or other substance use, your depression history and its treatment may also be recorded.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include other collaborating VA researchers including the Palo Alto VA, Institutional Review Board, Food and Drug Administration (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability Office (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 research team 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, Dr. Noah Philip and his or her research team can continue to use information about you 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 not expire, but you can revoke it at any 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.

**WHAT COMPENSATION IS OFFERED FOR PARTICIPATION IN THE STUDY?**

After each of the 6 study visits, you will be compensated for your time and effort and to assist with your travel expenses:

- You will receive $40 for completing the screening visit.
- You will receive $20 for each session you answer study questionnaires.
- You will receive $100 for each study MRI scan.
- Total compensation for is up to $640.
- If you are unable to continue in the study or withdraw for any reason, your compensation will be for the study sessions you attend. There is no other extra compensation.

You may choose to receive the payment in the form of gift cards (e.g. CVS) or through Electronic Funds Transfer (EFT). 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. If you receive $600.00 or more in study payments in a calendar year, this will be reported to the Internal Revenue Service (IRS) and you will receive a Form 1099-MISC. You will need to provide your social security number for this purpose.

If you choose to have compensation in gift cards research staff will give them to you after the study visit.

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

If you are injured as a result of this study, the VA will provide treatment for research related injury in accordance with applicable federal regulations (38 CFR 17.85).

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. Noah Philip at (401) 273-7100 ext. 2369
After hours: Call (401) 273-7100 and ask the operator to contact Dr. Noah Philip.

Emergency and ongoing medical treatment will be provided as needed.

**DO I HAVE TO TAKE PART IN THE STUDY?**

- No. Participation in this study is completely voluntary. 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 participate.
- Your decision to participate or not participate in this study will not affect your treatment, at the Providence VA Medical Center, including TMS therapy.
- If you choose to participate in the study, you may withdraw at any time. MRI scans and questionnaires completed before you withdraw may still be reviewed, but no new data will be collected.
- If you choose to withdraw from participation in the study, your treatment at the Providence VA Medical Center will not be affected. Compensation will be for the number of sessions that you complete.

**RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION**

The investigator or a study staff member may end your participation in this study if he or she feels it is in your best interest or believes you are not following study procedures. If your participation is terminated by the research staff, you will be provided with an explanation of the circumstances leading to that decision.

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

- If you have questions about the research, you may contact Noah Philip at (401) 273-7100 ext. 2369.
- 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. 3470, or Research Administration at (401) 273-7100 ext. 3066
- If you have questions, complaints or concerns about the study or if you would like to obtain information or offer input, you can contact the Providence VAMC Patient Advocate at 401-457-3093.

**WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?**

You will be informed of any new findings learned during the course of this research study that may affect your willingness to continue to participate.

**AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY**

- Dr. Noah Philip or a member of his study staff has explained the research study to me.
- I have been told of the risks or discomforts and possible benefits of the study.

Participant Name: _____ Date:_____

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- 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's Name | _____ Participant's Signature | _____ Date |



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IRB APPROVAL DATE: 03/27/2019
IRB EXPIRATION DATE: 03/12/2020