

Title: Testing a Neurocognitive Model of Distancing Using Transcranial Magnetic Stimulation

Duke University IRB protocol: Pro00100171

ClinicalTrials.gov Identifier: NCT03698591

Informed Consent Form

Reference Date: October 29th, 2018



Consent to Participate in a Research Study

ADULT

***Pro00100171 -Investigating Distancing with Transcranial
Magnetic Stimulation***

CONCISE SUMMARY

The purpose of this study is to examine the effects of transcranial magnetic stimulation (TMS) on emotion regulation and better understand how emotion regulation works in the brain. Eligibility requirements include no history of psychiatric or neurological disorder, passing safety screenings for TMS and magnetic resonance imaging (MRI), and meeting the age requirement of 18 to 39 years old. After completing a screening survey, eligible participants will complete two research visits over the course of about one week. At the first visit, participants will complete training for emotion regulation tasks, and structural MRI data will be collected. At the second visit, participants will receive TMS and complete emotion regulation tasks, in which they will use various techniques while observing graphic emotional stimuli. The first visit will last about 75 minutes and the second visit will last about two hours. The most significant risks of participating in this study include injury from bringing metal or restricted medical devices into the MRI scanning room and the occurrence of seizure from TMS. These risks are minimized in this study by following proper screening and safety guidelines for MRI and TMS.

You are being asked to take part in a research study about how people manage their emotions. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time deciding whether you wish to participate. As your study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

Dr. Kevin LaBar, PhD will conduct and fund the study. The funding is from the investigator himself. As the sponsor of this study, ***Dr. Kevin LaBar***, will pay Duke University to perform this research.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to examine the effects of TMS on emotion regulation and better understand how emotion regulation works in the brain.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 100 people will take part in this study Duke University Medical Center.



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WHAT IS INVOLVED IN THE STUDY?

If you agree to be in this study, you will be asked to sign and date this consent form and participate in two research visits. You will have the following tests and procedures to make sure that you are eligible:

- Medical history
- MRI and TMS safety screening
- Urine screening

The purpose of the urine test is to make sure you are not using any substance that could increase the risks of TMS as well as to test for pregnancy for those with child bearing potential.

During the first session of the study, MRI data will be collected. MRI will be used in this study to create pictures of your brain using strong magnetic fields and radio waves. MRI does not use x-rays or other radiation. After an initial screening to ensure it is safe, you will enter a large room in which a magnet is present. You will be placed on a narrow bed and then slid into a small tunnel approximately 6 feet in length and 25 inches in diameter. You will hear a loud machine-like noise. You will be able to see outside of the machine by looking at a mirror. We will communicate with you through an intercom during the study. You may be asked to respond to stimuli using button boxes placed in your hands. The MRI scans will last about 30 minutes.

It is possible that you may feel uncomfortable or confined once inside the imaging machine. This feeling usually passes within a few minutes as the investigators talk with you and the study begins. However, if this feeling persists, you can tell the investigators over the intercom and you will be removed from the machine.

Additionally during the first session, you will complete training for emotion regulation tasks. You will be asked to observe and respond to stimuli that vary in their emotional content. Stimuli may be presented by sight or sound. Stimuli may include scenes, sounds, objects, numbers, or words. Some of the stimuli may be graphic in nature. Some of the stimuli may cause you to have moderate levels of anxiety. The investigator will tell you what type of stimuli you will receive during the study, what techniques to use while observing these stimuli, and what responses you will be required to make. You may be asked to describe your experience of the tasks. This session will last about 75 minutes in total. Several days after the first session, you will complete a second session in which you will receive TMS. In this study, TMS will be used in a manner that is “investigational,” aimed at temporarily changing the way that a part of your brain works. TMS has been approved by the Food and Drug Administration (FDA) as a treatment for depression, but in this study TMS is being used to investigate the impact it can have on particular emotion regulation processes, so therefore is considered investigational. The word “investigational” means TMS is still being tested in research studies and is not approved by the FDA for these purposes. The TMS equipment produces brief electrical currents that create brief magnetic fields. When the TMS equipment is held close to the head it can induce very small electric currents in the part of the brain that is closest to the coil. These currents are similar to the currents that the cells in the brain



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produce when communicating with each other. By generating these currents with TMS, we can temporarily change how the brain functions, either making a targeted region work harder or less hard.

First, the study team will determine the proper strength of TMS for you. This personalized strength of stimulation is called the “motor threshold” and it is a measure of the excitability of a part of the brain called the motor cortex. To find this threshold, a member of the study team will place the TMS stimulator over the part of your brain that controls muscle activity in your hand. You will hear a clicking sound and feel a tapping sensation on your scalp. The stimulation will be adjusted to determine the minimum strength needed to produce a small amount of muscle activity in your hand. This procedure will take about 20 minutes.

Then, you will receive two rounds of TMS (less than one minute each). Before and after each round of TMS, you will be asked to complete emotion regulation tasks similar to the training from the first session. This session will last about two hours in total.

HOW LONG WILL I BE IN THIS STUDY?

This study will take place over the course of approximately one week. The first visit will last about 75 minutes and the second visit will last about two hours.

You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

WHAT ARE THE RISKS OF THE STUDY?

Magnetic resonance imaging (MRI) uses a magnet and radio waves to make images of the body. There are no known long-term health risks from exposure to the magnetic fields and radio waves used to make MRI brain pictures. However, it is possible that harmful effects could be recognized in the future. Strong magnetic fields pose safety risks because they attract metals such as iron. It can be dangerous for people who have medical devices, metal objects, metal debris, and certain dyes found in some tattoos in their bodies to go into an MRI machine. Therefore, we will carefully ask you about metal within your body (this includes certain dyes found in tattoos, a pacemaker, shrapnel, metal plate, or metal debris). If there is any question about potentially hazardous metal within your body, you will be excluded from participation in this research study. You will be asked to leave any metal objects in lockers provided in the MRI center. You will also be asked to remove any articles of clothing with metal inserts or clasps before entering the magnet room. In addition, the MRI scanner makes loud noises that could affect your hearing. You will be provided with earplugs or headphones in order to protect your hearing. We will also keep the examining room locked so that no one carrying metal objects can enter while you are in the scanner. Please ask the investigator if you are unsure about any instructions or questions related to the MRI procedures of this study. If you feel anxious or uncomfortable inside the MRI scanner at any



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time, you can tell the study staff over the intercom and you will be removed immediately from the MRI machine.

The most serious known risk of transcranial magnetic stimulation (TMS) is convulsions (seizure). TMS procedures are associated with a very low risk of seizures. Out of over 10,000 people given various forms of TMS to date, 16 people (less than 0.2%) have been reported to have had a seizure. TMS can produce a seizure when the magnetic pulses involved are given at high power and very close together. This study will only use levels of TMS that meet safety considerations. No seizures have occurred in appropriately screened normal volunteers with the levels of TMS used in this study. To minimize the risk of a seizure, we will medically screen you for any of the known characteristics that could lead to seizure. For example, persons with epilepsy cannot participate in this study. You will be visually monitored during the TMS for any signs of seizure or muscle twitching. In spite of these precautions, there is a chance that you will experience a seizure. Should this occur, emergency facilities are available. If you have a seizure, you may require hospital admission and follow-up neurological evaluation. Having had a convulsion may make it difficult for you to obtain medical insurance, future employment, and to drive. It is not known whether having had one convulsion will make a person more prone to have future seizures. Should you have a seizure caused by TMS in this study, we will provide you with a letter documenting that the seizure was experimentally induced.

The most commonly reported side effect of TMS is a “muscle-tension” type headache. We will make every effort to reduce any discomfort. If a headache occurs, it usually starts during or immediately after the TMS and lasts from minutes to hours after TMS. The headache usually goes away with standard over-the-counter pain medications. Neck pain may also occur. You may also experience some discomfort on your head where the TMS equipment is held. This is due to contraction of scalp muscles. Numbness of the face lasting for a short time has also been reported in rare instances that may last for several weeks after receiving the procedure. Syncope (fainting) is considered a rare side effect of TMS and has been reported in individuals who faint during blood draws. If you should experience syncope, you will be withdrawn from the study and your blood pressure will be monitored until it returns to a healthy level.

The clicking noises produced by the TMS procedure are loud enough to damage your ears. You will therefore be required to wear earplugs, provided by the experimenter. Additional side effects considered to be rare in TMS are dizziness, memory impairment, trouble concentrating, and acute mood changes. If these occur, these effects do not last long and will resolve without need for treatment. There may be other risks related to TMS that are currently unknown. The long-term effects of TMS are not known.

Some of the tasks and materials presented during the course of the study, such as negative graphic pictures, may cause you to feel uncomfortable, stressed, or anxious. However, you can choose to stop participating at any time.



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Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury. For questions about the study, a research-related injury, or other adverse effect related to the research, contact Dr. Kevin LaBar at (919) 681-0664 during regular business hours or after hours.

Additionally, there is potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. You may stop your participation in this study at any time and you will be compensated for your time given.

Female

Being a part of this study while pregnant may have a bad effect on an unborn child. Therefore, pregnant women will be excluded from the study. If you are a woman of childbearing potential, a urine pregnancy test will be done, and it must be negative before you can continue in this study. If sexually active, you must agree to use appropriate contraceptive measures for the duration of the study. Medically acceptable contraceptives include: (1) surgical sterilization (such as a tubal ligation or hysterectomy), (2) approved hormonal contraceptives (such as birth control pills, patches, implants or injections), (3) barrier methods (such as a condom or diaphragm) used with a spermicide, or (4) an intrauterine device (IUD).

Contraceptive measures such as Plan B (TM), sold for emergency use after unprotected sex, are not acceptable methods for routine use. If you do become pregnant during this study or if you have unprotected sex, you must inform your study physician immediately.

Male

Your participation in this research may damage your sperm, which could cause harm to a child that you may father while on this study. Such harm may be currently unforeseeable. If you are sexually active, you must agree to use a medically acceptable form of birth control in order to be in this study. Medically acceptable contraceptives include: (1) surgical sterilization (such as a vasectomy), or (2) a condom used with a spermicide. Contraceptive measures such as Plan B (TM), sold for emergency use after unprotected sex, are not acceptable methods for routine use. You should inform your partner of the potential for harm to an unborn child. She should know that if pregnancy occurs, you will need to report it to the study doctor, and she should promptly notify her doctor.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

This research study is not a diagnostic medical test and will be of no direct benefit to you. Medical specialists will not examine the research brain pictures. If you believe that you require a diagnostic MRI test, you should discuss your concerns with your doctor. The brain pictures obtained during this study are for research only and are not designed to search for any existing brain abnormalities. However, in the unlikely event that the technician or investigator collecting the scans notices something that appears



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abnormal, the technician will ask your permission to obtain an additional set of brain pictures that will be shown to a medically trained expert for clinical evaluation. The results of this examination will be provided to you at no charge. The decision to proceed with further examination or treatment based upon this evaluation lies solely with you. You will be responsible for any treatment that you undertake based upon this evaluation.

Although there is no direct benefit to you for participation in this study, the results of this study may be of benefit to people who suffer from emotional disorders. Additionally, we hope that the information we collect in this study will improve our knowledge about the function of the human brain.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating on, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives of the Office of Human Research Protection and the Duke University Health System (DUHS) Institutional Review Board. If your research record is reviewed by any of these groups, they may also need to review your entire medical record. If information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations. This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

The study results may be retained in your research record for at least six years after the study is completed. At that time, either the research information may be destroyed or information identifying you will be removed from such study results at DUHS.

All of the data measurements used in this study are being collected only because you are in this study. The study results will not be provided to you or sent to your physician.



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Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. For records disclosed outside of DUHS, you will be assigned a unique code number. The key to the code will be kept in a locked file in Dr. LaBar's laboratory. While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

WHAT ARE THE COSTS TO YOU?

There will be no costs to you for the research procedures.

WHAT ABOUT COMPENSATION?

You will be reimbursed \$20/hr for your participation in this study. You will be reimbursed an additional 2\$/hr for parking expenses when you pay for parking for an appointment.

WHAT ABOUT RESEARCH RELATED INJURIES?

Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or a research-related injury contact Dr. Kevin LaBar at (919) 681-0664 during regular business hours, after-hours, or weekends.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Kevin LaBar in writing and let him know that you are withdrawing from the study. His mailing address is Box 90999, Duke University, Durham, NC 27708.



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We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. Reasons why this might occur include the discovery of adverse consequences related to study procedures. If this occurs, you will be notified and your study doctor will discuss other options with you.

Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them.

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

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study, or if you have complaints, concerns, or suggestions about the research, contact Dr. Kevin LaBar at (919) 681-0664 during regular business hours, after-hours, or weekends. For questions about your rights as a research participant, or to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research, contact the DUHS Institutional Review Board (IRB) Office at (919) 668-5111.



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STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

Signature of Subject

Date

Time

Signature of Person Obtaining Consent

Date

Time