Study Title: The Role of Different Prefrontal Areas in Visual Metacognition

Document Title: Consent Form

NCT: NCT04263766

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Key Information for TMS experiment clinical trial

What Am I Being Asked To Do?

You are being asked to be a volunteer in a research study. This page will give you key information to help you decide if you would like to participate. Your participation of voluntary. As you read, please feel free to ask any questions you may have about the research.

What Is This Study About and What Procedures Will You be Asked to Follow?

The purpose of this study is to understand the mechanisms behind normal perceptual processes. Your results will help us better establish the brain areas that support different perceptual processes. During the study, you will complete a visual task and we will simultaneously stimulate your brain with transcranial magnetic stimulation (TMS). Your participation in this study is expected to last between 1 and 3 hours per session (a total of 1-3 sessions).

Are There Any Risks or Discomforts you Might Experience by Being in this Study?

The most serious known risk of TMS is a seizure, which is very rare. More common risks involve transient headache and neck pain.

What Are the Reasons You Might Want to Volunteer For This Study?

You are not likely to benefit in any way from joining this study. We hope that we will learn more about the mechanisms of perception. As compensation for your time, we will compensate you $15/hour.

Do You Have to Take Part in the This Study?

It is fully your decision if you wish to be in this study or not. If you choose not to participate, or choose to participate and later determine you no longer wish to, you will not lose any rights, services, or benefits as a result of your withdrawal. The study is completely voluntary.

Consent Document for Enrolling
Adult Participants in a Research Study
at the
Georgia State University / Georgia Institute of Technology
Joint Center for Advanced Brain Imaging
831 Marietta Street
Atlanta, GA 30318

Project Title
TMS experiment clinical trial

Investigators
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Introduction
You are being asked to be a volunteer in a research study. Your participation is voluntary. Please feel free to ask questions at any time if there is anything that you do not understand. This study involves completing a computer task in which you will judge the identity of visual stimuli. You will also receive transcranial magnetic stimulation (TMS). The study will take place at the Center for Advanced Brain Imaging.

Purpose
The purpose of this study is to understand the mechanisms behind normal perceptual processes. Your results will help us better establish the brain areas that support different perceptual processes. We expect to enroll 75 people in this study.

Exclusion/Inclusion Criteria
Because task performance depends on an individual's ability to distinguish between various visual stimuli, only participants with normal or corrected-to-normal vision as well as corrected-to-normal hearing will be included. Also, to control for possible differences in brain lateralization, only right-handed participants will be included in this study. Only post-adolescent (18-40 years of age) subjects will be tested to minimize variability, statistical noise, and potential confounds in our sample. We will also be excluding people who have history of seizures, family history of epilepsy, stroke, severe headaches, metal anywhere in the head (excluding the mouth), cardiac pacemakers, or current use of medication for neurological or psychiatric conditions.

Procedures
If you decide to be in this study, your part may involve multiple visits (between 1 and 3). We expect that the majority of subjects will need to come for 2 sessions but based on initial piloting we may need to increase or decrease the number of sessions in order to ensure that sufficient amount of data is collected. Different sessions will be performed on different days separated by typically less than 1 week. Each session is expected to last about 1.5 hours (and can be between 1 and 3 hours depending on how long the TMS setup takes). You will start by completing a health and TMS screening form. We will discuss the study, and you may ask all the questions you have. You will then receive TMS either before or during the computer task.

In this study, you will receive 'repetitive transcranial magnetic stimulation' (rTMS) which for this study is an investigational procedure, aimed at temporarily changing the way that a part of your brain works. The TMS equipment consists of an electric stimulator and a wire coil. Turning the stimulator on and off produces brief electrical currents in the coil, and these currents create a short-lived magnetic field around that coil (also called a 'magnetic pulse'). The wire coil is coated in plastic in order insulate the stimulator current, it is shaped like an '8', and it is a little larger than a letter-size piece of paper. When the coil is held close to the head, and it generates a magnetic pulse, the pulse 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 neurons, a type of brain cell, produce when communicating with each other. By inducing these currents with the TMS coil, we can temporarily change the way that the underlying brain region functions, either making the region work harder or less hard. In this study, the TMS coil will be held against your head so that the magnetic pulses can be focused on an area of the brain that we think is important for performing the visual task. If this leads to performance changes, we know that this region is important for the visual task. TMS has been approved by the Food and Drug Administration (FDA) as a treatment for depression. Researchers are also studying whether TMS might help treat other conditions involving the brain.

Before applying TMS, the experimenter will need to adjust the strength of the magnetic stimulation by establishing your personal "motor threshold" – a measure of the excitability of the area of the human brain called the motor cortex. To establish this threshold, the experimenter will first place the stimulator over the part of your brain that controls the motor activity in your left hand. You will be required to sit still while you receive the stimulation. To block out the clicking noise of TMS, we will provide you with earplugs. You will hear a clicking sound and feel a tapping sensation at your scalp. The stimulator will be adjusted to give just enough energy so that the motor region of the brain sends signals to your hand muscles, to make your hand twitch. The amount of energy required to make your hand twitch is called the "motor threshold." Everyone has a different motor threshold. Once we have established your motor threshold, we will use it to adjust the intensity of stimulation. You will then either receive a period of TMS followed by the computer task, or start the computer task and receive TMS during the task. Tell the researcher if you want to quit the study or just need a break.

Risks or Discomforts
The most serious known risk of TMS is the production of a convulsion (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. All of these cases involve receiving stimulation that greatly exceeds the amount of stimulation in this study and/or participants with psychiatric conditions on medication that makes seizures more likely. No seizures have occurred in normal volunteers with the dosage of TMS used in this study.

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 coil is held. This is due to contraction of scalp muscles.

The click noises produced by the TMS procedure are loud enough to be damaging to your ears. You will therefore be required to wear earplugs, provided by the experimenter. Some repetitive TMS protocols have been shown to affect cognitive processing for up to a one hour following stimulation. However, in this study, we will only use online TMS protocols that do not have lasting effects past the period of stimulation.

Benefit of research
You are not likely to benefit in any way from joining this study. We hope that we will learn more about the mechanisms of perception.

Compensation to You
You will be compensated at the rate of $15/hour or 1 course credit/hour, whichever you may choose. If you are unwilling or unable to complete the study, you will be compensated a prorated amount according to the time that you have spent until that moment. U.S. Tax Law requires that a 1099-misc be issued if U.S. tax residents receive $600 or more per calendar year. If non-U.S. tax residents receive more than $75, mandatory 30% withholding is required. Your address and Tax I.D. may be collected for compensation purposes only. This information will be shared only with the Georgia Tech department that issues compensation, if any, for your participation.

Storing and Sharing and Future Use of Your Information
Your participation in this study is gratefully acknowledged. It is possible that your information/data will be enormously valuable for other research purposes. By signing below, you consent for your de-identified information/data to be stored by the researcher and to be shared with other researchers in a public, unrestricted database that anyone can use. Your data may also be included in the National Institute of Mental Health (NIMH) Data Archive. If you agree to allow such future sharing and use, your identity will be completely separated from your information/data. Future researchers will not have a way to identify you.

Confidentiality
The following procedures will be followed to keep your personal information confidential in this

study. To protect your privacy, your records will be kept under a code number rather than by name. Your records will be kept in locked files and only study staff will be allowed to look at them. Your name and any other fact that might point to you will not appear when results of this study are presented or published. De-identified data may be shared with other researchers and included in public databases. We will comply with any applicable laws and regulations regarding confidentiality. To make sure that this research is being carried out in the proper way, the Georgia Institute of Technology IRB may review study records. The sponsor of this study, the National Institutes of Health, has the right to review study records as well.

Requirements of Certificate of Confidentiality policy that applies to research conducted or supported by NIH involving a participant's identifiable or sensitive information

We have obtained a Certificate of Confidentiality from the National Institutes of Health to help us keep your information confidential. This Certificate provides a way that researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Costs to You

There are no costs to you, other than your time, for being in this study.

Clinical Trial Information

A description of this clinical trial will be available on www.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.

In Case of Injury/Harm

If you are injured as a result of being in this study, please contact Dobromir Rahnev, Ph.D. Neither the Principal Investigator, nor Georgia Institute of Technology, nor Georgia State University has made provision for payment of costs associated with any injury resulting from participation in this study.

Participant Rights

- Your participation in this study is voluntary. You do not have to be in this study if you don't want to be.
- You have the right to change your mind and leave the study at any time without giving any reason and without penalty.
- Any new information that may make you change your mind about being in this study

will be given to you.
- You will be given a copy of this consent form to keep.
- You do not waive any of your legal rights by signing this consent form.

Questions about the study
If you have any questions about the study, you may contact Dr. Dobromir Rahnev at rahnev@psych.gatech.edu.

Questions about Your Rights as a Research Participant
If you have any questions about your rights as a research participant, you may contact Ms. Kelly Winn, Georgia Institute of Technology Office of Research Integrity Assurance at (404) 385-2175.

Signatures
If you sign below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to be a volunteer in this study.

_____
Participant Name (printed)

_____ _____
Participant Signature **Date**

_____
Person Obtaining Consent (printed)

_____ _____
Signature of Person Obtaining Consent Date