NCT04464473

TMS Studies of Working Memory and Cognitive Control

5/18/2022

Permission to Take Part in a Human Research Study

Title of research study: ***TMS Studies of Working Memory and Cognitive Control***
Investigator: ***Derek Nee***

Key Information: Please read this consent information carefully. We provide information about the study that you should think about before deciding whether to take part. We also include special information about steps that we will take to prevent your exposure to Coronavirus when you take part in our face-to-face study activities.

Why am I being invited to take part in a research study?

We invite you to take part in this research study because we are interested in normal, healthy brain functioning in young adults. As part of that demographic, you have been asked to participate. This study will take place in-person or face-to-face. Doing this in-person will mean that you come to the Nee lab (room 408) in the Psychology Building and/or the Magnetic Resonance Imaging Facility in the College of Medicine.

We will screen you for any factors that would increase the risks associated with the study procedures.

What should I know about a research study?

Things you should know:

- The purpose of the study is to understand the mental processes involved in retaining information in mind when it is no longer available to the senses, and using retained information to guide behavior. If you choose to participate, you will undergo transcranial magnetic stimulation (TMS). You will also be asked to perform a task. These procedures will be carried out in the Magnetic Resonance Imaging Facility. This will take approximately 1-2 hours.

- Risks or discomforts include hand skin irritation or dryness, scalp discomfort, headache, neck stiffness, and in very rare instances, seizure.

- The study will have no direct benefit to you.

- Taking part in this research project is voluntary. You don't have to participate and you can stop at any time.

Why is this research being done?

The purpose of the study is to understand the mental processes involved in retaining information in mind when it is no longer available to the senses, and using retained information to guide behavior. We are conducting these experiments so that we can better understand what happens in your brain

when you do a particular task. We are using a procedure called transcranial magnetic stimulation (TMS). TMS involves using a magnetic stimulator to induce changes in brain activity.

How long will the research last and what will I need to do?

We expect that you will be in this research study for 1-2 hours per session. In some studies, you may be asked to participate in multiple sessions based on performance. If you consent, we may contact you for related studies.

In all of the testing sessions, you will be given a break approximately every 5-10 minutes. You can take more breaks if you want.

In the proposed research, we will use computer-based tasks that engage cognitive control and/or working memory. Typical paradigms will involve presenting stimuli, such as words, letters, pictures, or sounds. In tasks involving working memory, participants will be asked to retain in mind some aspect of the stimulus after it is no longer present on the monitor. In tasks involving working memory and/or cognitive control, participants will make decisions on stimuli that are based on previous instruction and previous stimuli.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way being in this study could be bad for me?

Risks for the study include hand skin irritation or dryness, scalp discomfort, headache, neck stiffness, and in very rare instances, seizure.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

There are no direct benefits for you from taking part in this research. This research is not related to any medical treatment you may be receiving. The TMS device used in this study, the MagPro X100, is to be used for investigational purposes only. We hope that the knowledge gained from this research will be useful in the future diagnosis and/or treatment of patients with psychiatric or neurological disorders.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate. Your alternative to participating in this research study is to not participate.

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Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at nee@psy.fsu.edu

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at 850-644-7900 or humansubjects@fsu.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 400 individuals to complete this study.

What happens if I say "yes" to being in this research?

If you agree and are eligible to participate in this study, we would ask you to do the following:

A) You will be outfitted with earplugs before beginning the experiment due to the loud noise of the magnetic stimulator.

B) We will use a non-invasive method called electromyography (EMG) to measure the electrical activity in your hand muscles. This involves lightly swabbing your skin with fine-grain sandpaper and alcohol, and then pasting small electrodes to the surface of your skin. (Electrodes are small, thin metal discs, about the size of a dime, that detect tiny charges resulting from electrical activity).

C) A magnetic stimulator will be placed on your head and used to determine the region of the brain that directly controls the fingers (motor cortex).

D) An electrical field will be generated by the coil that will stimulate the brain. We will move the coil around different parts of your scalp in order to locate the motor cortex. You will likely feel a gentle flick and hear an audible click. This pulse is not painful, but it can cause a twitch of your hand or face muscles. Locating the motor cortex is the first step in determining your sensitivity to stimulation so that stimulation can be tailored to you.

E) We will repeat the pulse during this initial phase to determine the strength of the magnetic stimulation required to activate hand muscles.

F) For the main part of the experiment, the coil will be located over different parts of the brain. We are comparing the effects of stimulation over these different regions to examine how the affect cognitive function. Depending on your assigned study procedures, TMS may be delivered before or during the behavioral task.

G) You may also be asked to perform an electroencephalography (EEG) assessment. If so, we will record your brain activity using EEG either at rest or while you complete tasks on the

computer. To do this, you will wear an elastic cap that holds recording sensors on your head. These sensors need to be filled with a gel, which helps the sensors accurately record brain activity at the scalp. Therefore, your hair may need to be cleaned after the task, but the gel washes out easily. The EEG recording is completely painless, nonintrusive, and safe. It is similar to EMG recording — the only exception is that EEG records electrical activity generated by the brain rather than muscles.

H) You will be provided oral or electronically guided instruction to perform either a computer-based or written task. In the computer-based tasks, you will be presented with images and/or words on a computer monitor and/or sounds through headphones or speakers. You will be asked to remember and/or make decisions about the different images, words, and/or sounds. In written tasks, you will make judgments based on words or pictures, or you will be asked to answer questions about your strategy for performing our tasks

I) One month after your last TMS procedure, you will be contacted to fill out a follow-up form. This form will ask you about any experiences you may have had since your participation.

What happens if I say "yes," but I change my mind later?

You can leave the research at any time it will not be held against you.

Is there any way being in this study could be bad for me? (Detailed Risks)

The study has the following risks:

Many people have been studied using EMG instruments without reported harm. There is a chance of skin irritation or dryness due to the sandpaper and alcohol pretreatment. If this occurs, we will provide you with an ointment to reduce skin irritation.

TMS makes a clicking sound and may cause a twitch of muscles in the hand or face when applied on the motor cortex. It is often not painful, although in some subjects it can produce a slightly painful scalp sensation, or discomfort from muscle tension.

While the Magnetic Stimulators are deemed electronically safe, TMS has been reported to induce neurological seizures in rare occasions. In neurologically healthy individuals, seizures are extremely rare and typically only occur with stimulation parameters more intense and rapid than will be used in our study.

The physical risks for single pulse, and repetitive TMS are very low. The risk would be greater for someone with an undetected brain tumor or abnormality. Based on the rates at which seizures occur in people with known brain abnormalities, we would estimate the risk to be around 1% for someone with an undetected abnormality. The researchers in the TMS laboratory have been trained to recognize signs of seizure and how to respond in such an event.

As mentioned above, the main risk from high-frequency repetitive TMS is causing an epileptic seizure. However, only 7 cases of convulsions induced by repetitive TMS in subjects without risk-factors for epilepsy have been reported, despite the fact that many thousands of subjects have been studied in the past decade world-wide. It is of note that these seizures occurred with stimulation of higher intensity and frequency than our proposed study. Nevertheless, if you experience dizziness, nausea, or feel lightheaded, please let us know and we will cease TMS.

There is a possibility of lightheadedness or dizziness. In rare cases, individuals have experienced a syncope (loss of consciousness). These symptoms are the result of a drop of blood pressure. If you experience any symptoms of lightheadedness or dizziness, please inform us right away. These will typically resolve in minutes as blood pressure is restored.

Risks associated with TMS may be increased in the presence of drug and alcohol abuse and/or dependence. Furthermore, there may be additional risks associated with depression. Risks are also increased in those with a neurological condition, and those suffering from sleep deprivation. For your safety, we ask that you disclose such risks to us and excuse yourself from participation if such circumstances apply to you.

Because the sound emitted by the stimulator is so brief, it is not perceived as being loud. This sound, however, is loud enough that it could potentially cause hearing damage. Thus, we will require that you wear ear protection during the experiment. The use of ear protection eliminates risk of hearing impairment.

There is a possibility of an onset of a headache after the study in susceptible individuals. These have been reported only rarely, and are mild and of short duration when they do occur. However, you should not participate if you have a history or migraine or other types of severe or frequent headaches. If you experience a headache at any point during the experiment, please report this immediately.

It is also possible that you will experience some neck stiffness or neck pain. This is believed to be due to the straight posture of the head and neck we will require during the experiment. If you experience neck stiffness or discomfort at any point during the experiment, please report this immediately.

If you feel any discomfort or pain at any time during the experiment, let us know and the procedures will be adjusted to alleviate your discomfort/pain or stopped altogether.

Risks to a fetus from TMS are unknown. You should not participate in this study if you are pregnant, if you think you might be pregnant, or if there has been a lapse in your birth control procedures.

During the EEG recording, there is a small possibility of mild skin irritation (redness) where the electrode contacts the skin. However, this is rare and only temporary.

Because this is a research study, there may be additional risks that we cannot identify at this time.

What happens to the information collected for the research?

All identifying information will be stored securely. Hardcopies of written forms will be kept in a locked drawer in a laboratory that remains locked with restricted access. Electronic records will be maintained in password-protected accounts. No identifying information will be publicly disseminated. Identifying information will be deleted or destroyed within 2 years of study completion.

Non-personally identifying information including, but not limited to, age, gender, ethnicity, and task performance will be kept indefinitely. Such data may be included in publicly released datasets so that other researchers can perform replication or extension analyses.

Data from this study may be submitted to the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health (NIH). NDA is a large database where deidentified study data from many National Institute of Mental Health (NIMH) studies is stored and managed. Deidentified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. Sharing your deidentified study data helps researchers learn new and important things about mental health and substance use more quickly than before.

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During and after the study, the study researchers may send deidentified study data about your health and behavior to the NDA. Other researchers across the world can then request your deidentified study data for other research. Every researcher (and institutions to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with NDA. The study data provided to NDA may help researchers around the world learn more about mental health and substance use and how to help others who have problems with mental health and substance use.
NIMH will also report to Congress and on its website about the different studies using NDA data.
You will not be contacted directly about the study data you contributed to NDA.

You may decide now or later that you do not want your study data to be added to the NDA. You can still participate in this research study even if you decide that you do not want your data to be added to the NDA. If you know now that you do not want your data in the NDA, please tell the study researcher before leaving the lab today. If you decide any time after today that you do not want your data to be added to the NDA, call or email the study staff who conducted this study, and they will tell NDA to stop sharing your study data. Once your data is part of the NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NDA, this is available on-line at http://nda.nih.gov.

If you choose to withdraw from the study, data collected up until the point of withdrawal will be subject to the policies described above.

Your name and other information that can directly identify you will be deleted from the research data collected as part of the project.

The study you are participating in may be considered a clinical trial by the definition of the National Institute of Health. Clinical trials supported by the National Institute of Health and its related branches are subject to the posting of clinical trial information at ClinicalTrials.gov. As per the above, all posted information will be non-personally identifying.

We may share your research data with other investigators without asking for your consent again, but it will not contain information that could directly identify you.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include behavior that is disruptive to the research environment and failure to perform the tasks to the best of your ability (e.g. using your phone instead of performing the task).

What else do I need to know?

In the event of an injury, experimenters are not responsible for the administration of first aid or emergency treatment. If licensed medical professionals are required, care for injuries will be billed in the ordinary manner to the research subject or their insurance company. In signing this form, you are not waiving any legal rights.

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If you agree to take part in this research study, we will pay you $15 per hour or with course credit. If you do not complete the study, you will be compensated a prorated amount in accordance with the time that you participated. This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

Permission to Take Part in a Human Research Study

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date