NCT05878080

fMRI Studies of Working Memory and Cognitive Control

6/13/2023

MOD00003490
FSU IRB Approved
13 June 2023

Permission to Take Part in a Human Research Study

Title of research study: fMRI 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.

Volunteers between the ages of 18-30 may participate in this study. Subjects must be able to tolerate small enclosed spaces and have no medical devices or implants on or in their bodies.

Subjects will be excluded from any studies if they have any history of pacemakers or pacer wires, open heart surgery, artificial heart valves, aneurysm clips, cochlear implants, braces or extensive dental work, implanted electrical or mechanical devices, tissue expanders, foreign metallic objects from explosives, shrapnel or metalwork fragments, or artificial limbs. Subjects will also be excluded if they are pregnant, claustrophobic, have tremors or cannot lie still for 1-2 hours.

It is imperative that the metal screening form is filled out fully and accurately to ensure your safety in a strong magnetic field.

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 magnetic resonance imaging (MRI) while performing a task. This will take approximately 1-2 hours. Whether or not you take part is up to you.
- Risks or discomforts include dizziness, nausea, or a metallic taste in your mouth, and claustrophobia.
- 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.

Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

Permission to Take Part in a Human Research Study

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 magnetic resonance imaging (MRI). MRI involves using an MRI scanner to observe small changes in magnetic fields produced in your brain and provides a high resolution picture of your brain anatomy as well as pictures of your brain activity over time.

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 will 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.

While performing the proposed tasks, MRI data will be collected. You will be screened by trained personnel and excluded if you meet any exclusion criteria. You will be given instructions about the task and the MRI scanning environment. If there is any concern about claustrophobia, you will be encouraged to try the mock scanner before entering the MRI scanner. The mock scanner is located next door to the MRI scanner and provides a simulated MRI environment. If you are uncomfortable with the enclosed environment (at any time), you can exit the study and receive compensation for your time. Otherwise, you will then be given a short practice session on the task either before entering the scanner, or during collection of preliminary and/or structural images. After being positioned in the scanner, we will acquire initial calibration scans. A structural image of the head and brain may be acquired before or after the functional imaging data. We will collect functional imaging data while you perform one or more tasks.

For some studies, eye tracking will be performed. This will involve positioning a camera focused over one of the eyes and recording video of eye position. Such data will be useful to monitor eye position and pupil dilation. Knowledge of eye position is important in tasks that utilize spatial stimuli (e.g. location) and when mapping out areas of the brain that respond to stimuli as a function of their position on the eyes (e.g. visual cortex).

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:

A) Frustration from poor performance on the task, fatigue, or eye-strain.

B) Probing for personal or sensitive information in surveys, interviews, or questionnaires.

Risks from MRI:

A) Magnetic field attracting ferromagnetic objects. There is a potential risk of the main magnet field attracting ferromagnetic/metallic objects towards the magnet.
B) Claustrophobia. The magnet is a small enclosed space that can induce feelings of claustrophobia.
C) Noise. The scanner makes a bothersome/loud noise during the course of data collection. This can damage hearing if measures are not taken to protect the ears.
D) Earplug risk. Risk of trauma from the earplugs in cases where participants have cerumen (earwax) accumulated in their ears.

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. 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.

Permission to Take Part in a Human Research Study

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 people to complete the 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 MRI scanner.

B) You will be asked to lie down on a narrow table/platform, which is then slid into the scanner that is about 6 feet long by 2 feet wide and open at each end.

C) Before you are placed in the scanner, an MRI coil covered in plastic will be placed around your head. Foam pads will be placed around your head to limit head movement during the session.

D) Once you are moved into the scanner, you will be asked to lie still for anywhere between 10 to 120 minutes. While MRI data are collected, the scanner will make loud noises. Some scans will acquire anatomical MRI images during which times you will be asked to lie still with no further requirements. Some scans will acquire functional MRI, during which times you may be asked to perform a task. During such times, watch the computer screen and/or listen to stimuli over headphones and limit your movements to the fingers and hands. You will be provided breaks every 5-10 minutes.

E) You will be provided oral or electronically guided instruction to perform tasks either in the scanner and/or before being placed in the scanner.

F) After scanning you may perform additional tasks similar to those performed in the scanner, or you will be asked to answer questions about your strategy for performing our tasks.

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.

Permission to Take Part in a Human Research Study

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

While there are no known permanent negative effects from exposure to a strong magnetic field, there may be some temporary effects. These temporary effects may include dizziness, nausea or a metallic taste in your mouth. Some pulse sequences can cause temporary peripheral nerve stimulation which causes mild discomfort but is not harmful. Some pulse sequences can cause heating of your body. If you experience any discomfort that you cannot tolerate, you will be given an alarm bell to notify researchers that you would like to discontinue the study. Participation in this study is voluntary and you may choose to discontinue your participation at any time.

MRI produces very loud pulsating sounds. You will be required to wear earplugs or a headset to protect your hearing.

Participation in this study may involve some additional risks or discomforts. Being in the MRI scanner where the anatomical MRI and functional MRI procedures occur can be risky for people with pacemakers or metal in their body. You will be excluded from participation in these procedures if you have a pacemaker or any metal in your body that cannot be easily removed. Some people get claustrophobic in the MRI scanner. If you have a history of claustrophobia, we will not ask you to participate in the MRI or fMRI studies. If you do not like being in the scanner for any reason, we will immediately stop the experiment. Because the MRI scanner makes loud noises, we will give you ear plugs to dampen the sound.

Risks to a fetus from MRI 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.

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. If brain imaging data are publicly shared, facial anatomical features will be removed from the data to preserve anonymity.

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.

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.

The records of this study will be kept private and confidential, to the extent allowed by law. In any publications or presentations, we will not include any information that will make it possible to identify you as a subject.

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.

Your name will never be directly associated with your study information, **UNLESS** you agree to have your scan reviewed by a radiologist, at no cost to you. (See section on Incidental Findings).

Your protected health information (PHI) created or received for the purposes of this study is protected under the federal regulations known as HIPAA. Refer to the HIPAA authorization for details concerning the use of this information. We will do our best to be sure that the personal health information you provide for this study will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your records for research, quality assurance and data analysis include:

- Certain government agencies (FDA, OHRP)
- The FSU Institutional Review Board

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?

If you need medical care because of taking part in this research study, contact the investigator and medical care will be made available. Generally, this care will be billed to you, your insurance, or other third party. Florida State University has no program to pay for medical care for research-related injury. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be billed. Funds to compensate for pain, expenses, lost wages and other damages caused by injury are not routinely available.

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.

Incidental and Secondary Findings

The MRI scan is being done to answer research questions, not to examine your brain for medical reasons. This MRI scan is not a substitute for a clinical scan (the type a doctor would order). The research scan might not show problems that may be picked up by a clinical MRI scan. However, all research MRI scans will be read by a neuroradiologist (a doctor with experience reading MRI scans) unless you have been scanned at FSU in the previous six months.

Incidental findings are potential health problems that are discovered during the course of conducting research. At Florida State University Magnetic Resonance Imaging Facility, we have all neurological research MRI scans evaluated for incidental findings, **UNLESS YOU DO NOT CONSENT TO THIS EVALUATION**.

If you consent to having your scans reviewed for incidental findings, your data will be transferred using secure encrypted methods to password-protected servers. As with all such data transfer, this ensures integrity, authenticity and confidentiality of the data in transit.

To permit the generation of your incidental findings report, your name and date of birth will be supplied to the provider of neuroradiological review services. This will also be transferred via secure encrypted methods which ensures integrity, authenticity and confidentiality of the data in transit.

The provider of neuroradiological review services may maintain your data indefinitely and may use deidentified and aggregate incidental findings data with existing and future data for statistical analysis. When your scan is read, we will mail a copy of the report to you, or contact you (with your permission) by phone to help answer questions.

Due to the very high sensitivity of MRI in detecting abnormalities, there is a risk of false-positive findings, identifying something on imaging studies that may or may not be important. This may result in anxiety and additional testing, possibly including a recommendation for clinical scans at your cost. The radiology report or other study data will not be put into your medical record unless you provide it

to your physician. If the radiology report becomes part of your personal medical record, it may or may not have an effect on getting health insurance or life insurance in the future.

Please check the appropriate box regarding your decision to have your scan reviewed for incidental findings.

☐ **I DO** consent to have my MRI scan reviewed for incidental findings.

☐ **I DO NOT** consent to have my MRI scan reviewed for incidental findings.

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
Printed name of person obtaining consent	