

Title: Investigating The Role of Noise Correlations in Learning

NCT Number: NCT06673303

Document Date: September 30th, 2024



BROWN UNIVERSITY
CONSENT FOR RESEARCH PARTICIPATION

[Version 11, September 30th, 2024]

Project Title: Cognitive and Molecular Challenges to Statistical Inference Across Healthy Aging.

Project Sponsors: Brown University and the National Institute on Aging

Principal-Investigator: Matthew R Nassar, Ph.D.

KEY INFORMATION:

You are invited to take part in a Brown University research study. Your participation is voluntary.

- **PURPOSE:** The study examines how learning, memory and decision making change with age and to better understand the reason.
- **PROCEDURES:** You will be asked to complete several computerized tasks and you may be asked to complete these tasks lying still in an MRI scanner or when wearing a stretchy cap with electrodes attached (EEG). You may be asked to complete brief surveys, medical and mental health history questions, and demographic questions either in person or on the computer, as well as take hearing, visual, or cognitive screening tests. During some tasks, we may track your eye movements using an eye-tracker.
- **TIME INVOLVED:** The study will involve X sessions, each lasting approximately 1-3.5 hours of your time. In some cases 2 sessions might occur one after another requiring up to 4 hours of time in a given day.
- **COMPENSATION:** You will receive \$10/hour for behavioral testing, \$15/hour for EEG testing, and \$25/hour for brain imaging (MRI). Some computerized tasks offer performance bonuses of up to \$20 per session. Studies that involve at least 3 sessions will also pay an additional \$20 upon completion of all sessions.
- **Travel reimbursement:** If you incur any financial expenses in order to arrive at Brown for the study, we can reimburse you based on your form of transportation. Details see below.
- **RISKS:** You might get tired while doing the tasks or have some discomfort from sitting still and minimizing your movement, but you will be given breaks throughout the session. If this experiment involves an eye tracker, you may experience some discomfort from the chin rest, but you may take breaks to alleviate this. You may experience slight skin irritation from the electrodes used to measure brainwaves. You may be uncomfortable answering some medical history questions. MRI is generally considered to be safe but does impose serious risks to certain individuals (such as those with metal implants or pacemakers, or those with claustrophobia). For this reason, you will only be asked to participate in the MRI portion of the study if our safety screening indicates that it does not impose any serious risks to you. The addendum provides additional information about potential risks associated with MRI.
- **BENEFITS:** There are no direct benefits to you from participating in this research study.

What will I be asked to do?

Matthew Nassar, PhD, is the Principal Investigator of this study, but you may be working most directly with his research staff. This study is a clinical trial that employs multiple methods including behavioral

testing, eye-tracking, magnetic resonance imaging (MRI) to measure brain activity and electroencephalography (EEG) to measure brainwaves. You will be asked to participate in a type of experiment that employs one or more of these methods.

Procedures

Only the procedures that will be used in this study have been marked with an “X” in the table below and marked with an “X” in the body of the document.

This Study	Procedure Name
<input type="checkbox"/>	Behavioral Tasks
<input type="checkbox"/>	Electroencephalography (EEG)
<input type="checkbox"/>	Magnetic Resonance Imaging (MRI)
<input type="checkbox"/>	Questionnaires and cognitive/perceptual assessments
<input type="checkbox"/>	Eye-Tracking
<input type="checkbox"/>	Physiological measures

☐ Behavioral Tasks

This study will require you to perform one or more cognitive tasks. These tasks might, for example:

- (a) involve viewing symbols on a computer screen and attempting to remember them;
- (b) have you “choose” one symbol over the other, according to instructions given by the computer and the experimenter;
- (c) have you predict an upcoming symbol or to report what you see or hear;
- (d) Provide you with feedback regarding your performance of the task and you will be able to use this feedback to improve performance;
- (e) Have you complete the task by pushing a button on a keyboard, mouse, or other more specialized input device;
- (f) Have you report your response directly with eye movements that will be recorded with an eye-tracker (a high resolution video camera that, with calibration, can track the location of your gaze).

The research staff will answer any questions that you have regarding the rules or instructions for the specific tasks that you will be asked to complete.

☐ Electroencephalography (EEG)

While completing the behavioral tasks, you may be asked to allow EEG data to be recorded. This involves wearing a stretchy electrode cap that looks like a swimmer’s cap that is connected by wires to a computer and can allow us to record electrical activity from your brain and muscles. There are a number of sensors in the cap and some additional sensors will be placed on your face and head. In order to record the signals your skin will need to be thoroughly cleaned and some gel will be applied to the sensors so that they can work properly. During this application the skin on your face and scalp will be rubbed gently by a stick similar to a Q-tip. This process takes about 45 minutes and is generally painless. Following the experiment, you will be given the opportunity to wash your hair to remove any remaining gel.

☐ Magnetic Resonance Imaging (MRI)

Before anyone is allowed to enter the MRI scanner, we take strict precautions to ensure that no harm can come to them as a result of the strong magnetic forces that their body is exposed to as a result. You will therefore complete a screening form to indicate whether your body contains any metallic medical devices or equipment, including heart pacemakers, metal prostheses, implants or surgical clips. You also will be asked whether you have had any prior injury from shrapnel or grinding metal, and whether your eyes have been exposed to metallic dust or metallic shavings. If you are cleared to enter the scanner, before entering the MRI room you will be asked to remove all metal objects (including jewelry, watches, and eyeglasses), empty your pockets, and remove any eye shadow. In addition, if your clothing has more than a minimal amount of metal content, you may be asked to change into a hospital gown or other suitable garment.

Once you enter the scanner room you will be asked to lay on a table and your body will be slid into a large horizontal tube. You will be asked to lie as still as possible during this time. Foam cushions will be used to help keep your head still. To reduce the noise of the scanner, you will be fitted with earplugs or headphones.

During the first part of the scan, pictures will be taken of the shape of your brain. Next, additional images will be obtained using the high-speed function of the scanner. While these images are being taken, you will perform some of the behavioral tasks described above, viewing the task screen using a mirror placed over your head. You will indicate your responses using a device placed near your hand (e.g., a keypad).

You may spend up to 1 hour in the scanner, with an extra 30 minutes before and/or after the scan for preparation, training, and additional tasks.

☐ Questionnaires and cognitive/perceptual assessments

You will be asked to complete questionnaires or cognitive assessments either on your own (using paper and pencil or computer) or administered by a member of our research staff. These procedures could involve testing different aspects of your vision, including color vision, near and far vision, and peripheral vision. They could also involve testing your ability to solve problems or make decisions, and in some cases they will ask you about aspects of your personality or emotions.

☐ Eye Tracking

While completing the behavioral tasks, your eye position may be monitored using an eye tracker (a camera capable of measuring slight deviations in your gaze position).

☐ Physiological Measures

During some MRI scans, we will collect simultaneous physiological measures, such as SpO2 via a finger pulse oximeter, respiration via a breathing belt, Pulse Ox, and/or heart rate.

Compensation

You will receive \$10/hour for behavioral testing, \$15/hour for EEG testing, and \$25/hour for MRI procedures. Some computerized tasks offer performance bonuses of up to \$20 per session. Studies that involve more than 3 sessions will also pay an additional \$20 upon completion of all sessions. If you withdraw from this study before completing it you will still be compensated for your time.

Travel reimbursement

If you incur any financial expenses in order to arrive at Brown for the study, we can reimburse you based on your form of transportation.

Buses and trolleys: \$6 (RIPTA 1 day pass)

Uber/taxi: double the amount of ride receipt (round trip)

Driving: 57.5 cents per mile (standard mileage rate) + \$1.25 per hour (Providence meter rate)

Duration

The total number of sessions will be X.

The reason for multiple visits relates to the need for screening procedures, the time required to learn and perform the tasks, and the time necessary to record MRI and EEG data.

Each behavioral session will last 1-2 hours.

Each MRI session will last for 1-2 hours.

Each EEG session will last 1-3.5 hours.

In some cases you may be asked to schedule MRI and EEG or behavior session back-to-back, such that the total duration for the combined session is 2-4 hours.

Potential Risks and Discomforts

Questionnaires and cognitive/perceptual assessments

In some cases you may be asked questions that might make you feel uncomfortable, for example about the frequency with which you experience obsessive or intrusive thoughts, depression, and anxiety.

Behavioral Tasks

The tasks involved in these experiments can require some mental effort, and you may therefore experience some fatigue during the experiment. However, for those studies, you will receive ample time for rest periods and/or stretch breaks. It is also possible that some questions on the surveys may make you uncomfortable. However, if that is the case, you are free to skip these types of questions. If this experiment involves an eye tracker, you may experience some discomfort from a head and chin rest, but you may take breaks during the experiment to alleviate this.

Electroencephalography (EEG). There is a small possibility that you may experience some tenderness or reddening of the skin where the EEG sensors are placed. If at any time you feel uncomfortable, however,

you may request to stop the experiment. Removing the electrode cap and facial electrodes after the experiment might produce some discomfort, too, similar to removing a Band-Aid.

MRI

MRI uses large magnet fields. There are no known or foreseeable risks or side effects associated with scanning procedures except for those people who have electrically, magnetically or mechanically activated implants, or metal in or on their bodies.

Although the vast majority of data suggests that it is perfectly safe for embryos or fetuses to be scanned, there is still much that remains unknown. For this reason, we believe that it is safer to err on the side of caution and not allow anyone who suspects they might be pregnant to participate in MRI scanning. If you are pregnant or you feel that there is any chance that you may be pregnant, you should not participate in this study at this time. You do not need to tell us why you have chosen not to participate.

Please review provided document that describes the potential Risks and Discomforts for MRI.

Covid-19

Due to the coronavirus public health emergency, the U.S. government issued a Declaration under the Public Readiness and Emergency Preparedness (PREP) Act. This Declaration may apply to this study if it involves procedures or other actions that are related to or in response to coronavirus. If it applies, this Declaration limits your right to sue the researchers, healthcare providers, study sponsors, manufacturers, distributors, and potentially others that are involved with this study. However, the U.S. government has a program that may provide compensation to you or your family if you experience serious physical injuries or death related to procedures or other actions taken in this study. To find out more about the 'Countermeasures Injury Compensation Program,' please visit <https://www.hrsa.gov/cicp>.

Potential Benefits

Although this research will not be of any direct benefit to you, the results will be used to understand the biological and computational basis for behavior. This information may contribute to a better understanding of how specific medications will affect behavior that could eventually help to ensure that patients with behavioral or psychiatric disorders receive the treatment that is right for them.

Possible Alternatives

The alternative to participate in this research study is not to participate.

Confidentiality

All information will be confidential. Any reports of publications will not identify individual participants by name or initials. Paper data collected will be stored and locked in the investigator's file. Electronic records of participation that include identifiable information will be encrypted and stored under password protection and accessible only to lab personnel. In the case that a participant indicates to the experimenter that they would like to be contacted about possible participation in future studies including studies from other labs at Brown, name and contact information may also be shared and used

for this purpose. Electronic experimental data will be anonymized and stored on lab computers in the absence of identifiable information. Additionally, the personnel for this study will retain your contact information and potentially contact you to request further personal information in relation to this study for up to one year post-participation.

Rights

The participation in this experiment is voluntary. Your decision whether or not to participate will not affect your future relationship with Brown University. If you decide to participate, you are free to withdraw your consent and to discontinue your participation at anytime without penalty of loss of benefits to which you are otherwise entitled.

Further Questions

If you have questions about the research, please contact Dr. Matthew Nassar at nassarlab@brown.edu or at matthew_nassar@brown.edu. If you have questions about your rights as a research subject, please contact the Brown University Human Research Protection Program, at (401) 863-3050, or IRB@brown.edu.

Your signature

By signing this form, I affirm that I have read the information contained in the form, that the study has been explained to me, that my questions have been answered, and that I agree to take part in this study.

PARTICIPANT (print): _____

SIGNATURE: _____ DATE: _____

PERSON EXPLAINING THE STUDY (print): _____

SIGNATURE: _____ DATE: _____

The Participant must also sign the MRI-related Addendum to this Consent Form if the study involves MRI procedures

Place initials below to indicate whether you would like to be contacted for participation in future studies:

_____ I **would** like to be contacted to participate in future studies

_____ I **would** like to be contacted to participate in future studies from other labs at Brown

_____ I **would not** like to be contacted to participate in future studies

If you **would** like to be contacted for future studies, please provide your preferred method of contact and contact information below:

Email: _____

(and/or) Phone: _____