Official title: Evaluating the Neurocomputational Mechanisms of Explore-Exploit Decision Making in Older Adults

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University of Arizona
Consent to Participate in Research

Study Title: The explore-exploit dilemma in human decision making: behavioral and pupillometric, electroencephalographic, fMRI and TMS experiments

Principal Investigator: Robert Wilson

Sponsor: Robert Wilson, NIH

Summary of the research

This is a consent form for participation in a research project. Your participation in this research study is voluntary. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether to participate.

The goal of this study is to investigate how people tradeoff information and reward when making decisions and how this decision-making process changes with age. If you take part in this study, you will come to the lab for either two or five experimental sessions, depending on your eligibility.

Sessions 1 & 2: The first two sessions are behavioral sessions lasting 2-3 hours each. In these behavioral sessions you will complete a series of behavioral tests. Depending on your performance on these tests, you may be invited back to take part in the remaining three sessions.

Session 3: The third sessions is an MRI session lasting approximately 2 hours. In this session we will image activity in your brain while you perform a decision-making task.

Sessions 4 & 5: The final two sessions involve transcranial magnetic stimulation (TMS). This procedure involves stimulating your brain with an electromagnet for approximately 40 seconds. After stimulation is complete you will then perform a decision-making task. Each session will take up to 2 hours.

The risks from taking part in this study are low and are outlined in detail further down this consent form. In brief:

- There is no risk from the behavioral studies.
- The risks from MRI involve the high magnetic field which can interact with metallic implants (e.g., pacemakers). Proper screening minimizes these risks.
- The risks from TMS come from the stimulation of the brain. In theory, seizure is possible following TMS, but this is rare and has almost never occurred since stricter exclusion criteria were established. It is also possible to develop a headache after TMS, which can be treated with over-the-counter medications such as Advil. It is also possible to

experience lightheadedness if you are not properly fed and hydrated before taking part in the experiment.

Why is this study being done?

The purpose of this study is to learn how humans tradeoff information and reward when making decisions and how this decision-making process changes with age.

What will happen if I take part in this study?

Before the study begins, you will be asked to complete a short online questionnaire and telephone interview to assess your eligibility to participate. If you are eligible you will come into the lab for two sessions of initial testing on two different days. In the second session, you will also complete a short survey about any pain you may have experienced in the past 3 months. Depending on your performance and/or eligibility for magnetic resonance imaging and transcranial magnetic stimulation, you may be invited back for three more experimental sessions on different days. Thus, if you participate in this study, you will complete either the first two or all five of the following experimental sessions.

Sessions 1 and 2 – Behavioral sessions. In sessions 1 and 2 you will come into the lab for approximately 3 hours of cognitive and behavioral testing each session. These tests involve completing tasks either verbally, on pen and paper, or on a computer. There is no risk associated with any of these tests.

Depending on your performance on these initial behavioral tests we may invite you back to take part in the following three experimental sessions.

Session 3 – MRI session. The scanning session will be very similar to a routine clinical MRI scan of the brain. You will be asked to lie down on a table. Foam pads will be placed around your head to limit head movement during the study. The table will then be slid into the magnet. While in the scanner, you will be asked to lie still for approximately one hour, during which time several scans will take place. At times, you will be asked to perform the experiment task. In general, it will require you to observe stimuli presented on a screen. You will be asked to observe and/or respond to these stimuli by pressing a button. The whole session will last approximately two hours, including about 30 minutes of preparation and about 90 minutes inside the scanner. Occasional breaks of 1 to 2 minutes will be provided, during which you will remain in the scanner.

Sessions 4 & 5 – Transcranial Magnetic Stimulation (TMS) sessions. The TMS operator will first calibrate the TMS machine to establish an appropriate “dose” of stimulation. To do so, we will gently place the TMS coil on the surface of your head directly above the region of the brain that is responsible for hand motions. The TMS coil will then deliver single pulses that incrementally get stronger until a level is reached that causes your hand to twitch. The “strength of the dose” required to make your hand twitch is called the “motor threshold” and it varies for each individual. We will identify two separate motor thresholds; 1) Resting Motor Threshold

(acquired at rest), and 2) Active Motor Threshold (acquired while participant gently pinches their thumb and pointer finger together). These "motor threshold" measures will then be used to calibrate the machine for the TMS protocols. Importantly, in addition to observing your hand visually, we will also attach sensors to the skin on your hand. These sensors will detect any activity in your muscles, which will yield a more accurate measurement for your personal "motor thresholds".

During the TMS protocol, we will apply what is known as continuous theta burst stimulation for 40 seconds at 80% AMT. After TMS is applied you will perform a behavioral task.

How long will I be in the study?

Each behavioral session lasts between 2 and 3 hours. The MRI session lasts approximately 2 hours. The TMS sessions last up to 2 hours each.

Thus, if you complete the two behavioral sessions you will be in the study for 4-6 hours across two sessions on different days. If you qualify for all five sessions of the study, you will be in the study for approximately 10-12 hours across five different days.

How many people will take part in this study?

Approximately 240

Can I stop being in the study?

Your participation is voluntary. You do not need to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The University of Arizona. If you are a student or employee at the University of Arizona, your decision will not affect your grades or employment status.

What risks or benefits can I expect from being in the study?

Behavioral sessions: There are no physical risks associated with the behavioral studies, which simply involve answering questions and making decisions.

The cognitive task that we give you in the first session might reveal a low score. It is important to know that this cognitive test is not diagnostic. However, if you want to discuss your score, you can speak with Principal Investigator Dr. Robert Wilson. He can be reached at bob@email.arizona.edu or via the research assistant who is managing your enrollment in the study. If desired, you may wish to contact your primary care provider for more comprehensive testing.

MRI session: The risks involved are minimal and are limited to the risks present during routine MRI examinations. When near an MRI scanner, there is a potential for the powerful magnetic

field to attract ferromagnetic metallic objects toward the magnet. For this reason, you will be carefully screened for previous exposure to metallic fragments or clips that may be inside your body. Similarly, you will be asked to place all metallic and magnetic objects in your possession (e.g. keys, credit cards) in a locker outside the magnet room.

While you are lying in the scanner, you will often hear beeping and knocking noises, some of which may be loud, that are produced by the scanning equipment. Disposable earplugs will be provided to diminish the noise.

You will always be able to communicate with the scanner operator throughout the study. Before and after individual scans, there will be breaks during which you will be able to talk with the operator through an intercom system. During a scan, the equipment noise will make it difficult to use this intercom, but you will also have at all times a signal ball that you can squeeze to let the operator know that you would like speak to them. If you ever squeeze this, the operator will immediately stop the scan, and you will be able to use the intercom once again. If at any time you feel uncomfortable or unwilling to continue, no matter what the reason, you can request to immediately stop the study, and the operator will remove you from the scanner. Because you will not be physically restrained in the scanner, you could even pull yourself out if necessary; however, we ask that you instead use the intercom or squeeze bulb to tell us to remove you.

The bore of the magnet is a small space and some people may feel claustrophobic. Most participants rapidly grow accustomed to the space, but please let us know if you feel uncomfortable, and remember that you can always choose to leave the scanner at any time.

Although there is no known or anticipated risk to a fetus, you will not be allowed to participate in the study if there is any possibility you are pregnant. Beyond the risks described above, there are no known long-term physical risks associated with fMRI studies.

The head coil, which we will place around over your face when we put you in the scanner, uses pulses of radio waves to scan your brain. This is completely safe. However, if the head coil is touching your face it is possible that the heat of the coil may cause mild burns. There is no risk of burns if the head coil is not touching your face. When we place you in the scanner, we will make sure that your face is not touching the head coil. If, however, you move in the scanner and the head coil does touch your face please let us know immediately over the intercom or by using the squeeze bulb.

If in the course of this research scanning protocol we observe an anomaly in one or more of the MRI images, you will be informed of the observation. An anomaly does not necessarily indicate the presence of any disorder. Because our MRI scans are for research purposes only, they may be inadequate for the purpose of clinical diagnosis. Additionally, as researchers, we are not trained to clinically interpret MRI data. However, we feel it is important to inform you of any observations, as we cannot rule out the possibility that this anomaly may require medical advice. All information collected as part of this study will be made available to you for further examination by a medical professional. If you prefer not to be informed of anomalous findings, you must choose not to participate in the study.

TMS sessions: Seizure is a theoretical risk with TMS. TMS procedures are associated with a very low risk of seizures. Out of over 10,000 people given various forms of TMS over the last two decades 16 people (~ 0.1%) have been reported to have had a seizure. Eight occurred before safety parameters were established in 1997. Of the other eight reports, six occurred either when the safe rTMS parameters were exceeded or other safety guidelines ignored, and the actual occurrence of a seizure has been questioned in the other two (i.e., convulsive syncope or pseudoseizure may have occurred). In a workshop convened by the National Institute for Neurological Disorders and Stroke (NINDS) in 1996, researchers in the field agreed upon a set of rTMS consensus safety guidelines, including recommended stimulation parameters and contra-indications (Wasserman, 1998), and these consensus guidelines have been recently updated (Rossi et al., 2009). Widespread adherence to the 1996 guidelines has resulted in the virtual elimination of inadvertent seizures in rTMS studies (Rossi et al., 2009).

This study will only use levels of TMS that are within current safety guidelines, which have been formulated after careful review of thousands of participants/patients receiving TMS. Levels of TMS that fall within the safety guidelines have not been associated with seizure in appropriately screened individuals. No seizures have occurred in normal volunteers with the dosage of TMS used in this study. To minimize this risk, you will be medically screened 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 unexpected 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 protocol, we will provide you with a letter documenting that the seizure was experimentally induced.

While only experienced by a minority of participants, the most commonly reported side effect of TMS is a "muscle-tension" type headache. 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 (e.g., Advil). Neck or scalp 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. 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.

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, which will be provided by the experimenter to minimize this risk.

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 should resolve without need for treatment.

It is possible that if you are not properly fed and hydrated before taking part in the experiment that you may experience lightheadedness. If this occur, these effects do not last long and should resolve after eating food and drinking water, which we have available in the lab.

There may be other risks that are currently unknown. There are no known long-term effects of TMS at this time.

Data privacy: There is also a risk of potential loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

Although we have tried to avoid risks, you may feel that some questions [or procedures] we ask you to do may be stressful or upsetting. If this occurs, you can stop participating immediately.

You will not receive any benefit from taking part in this study.

Will I be paid for participating in the study or experience any costs?

You will be paid $20/hour for each session. Compensation for participation in a research study is considered taxable income for you. If your compensation for this research study or a combination of research studies is $600 or more in a calendar year (January to December), you will receive an IRS Form 1099 to report on your taxes. Please note, if you are an employee of UArizona, any compensation from a research study is considerable taxable income.

For any compensation or reimbursement you receive, we are required to obtain identifiable information such as your name, address, and Social Security number for financial compliance purposes.

Will my study-related information be kept confidential?

The information that you provide in the study will be handled confidentially. However, there may be circumstances where this information must be released or shared as required by law. In particular, your records may be reviewed by the following groups**:**

- The University of Arizona Institutional Review Board or Office of Responsible Research Practices;
- Other federal, state, or international regulatory agencies;
- The sponsor of the study, if any, may review the research records for monitoring purposes

Researchers will view your anonymous experimental data for coding and analytic purposes, but they won't link the experimental data to your identity for any purposes.

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.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Will my study-related information be used for future research?

Results will be kept to allow us to investigate new questions related to the purpose of this research. Once identifiers have been removed from your data, the information could be distributed to another investigator, or publicly archived, for future research. Re-consent will not be obtained from you if test records and results are used for future research. Consent forms will be stored in the Psychology Building for six years.

There may be an opportunity to participate in other research conducted by our and/or our collaborator's group. In some studies, invitation for other studies may depend on scores in neuropsychological testing.

Please check this box if you want to be contacted to participate in future research conducted by our or our collaborator's team.

Please check this box if you do NOT want to be contacted to participate in future research.

Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact Robert Wilson at bob@email.arizona.edu.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact

the Human Subjects Protection Program Director at 520-626-8630 or online at https://research.arizona.edu/compliance/human-subjects-protection-program.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Robert Wilson at bob@email.arizona.edu.

Signing the consent form

I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

Printed name of subject	Signature of subject	Date