CONSENT TO PARTICIPATE IN RESEARCH

Cognitive Neuroscience of Reward
v07.24.2020

You are being asked to participate in a research study. The box below highlights key information about this research for you to consider when making a decision about whether or not to participate. This form will explain the study to you, including the possible risks as well as the possible benefits of participating, so you can make an informed choice about whether or not to participate in this study. Please read this consent form carefully. Ask the investigators or study staff to explain any words or information that you do not clearly understand.

Key Information for You to Consider
• You are being asked to participate in a research study about how mood and emotion affect the brain's response to reward. Participation is voluntary and it is up to you whether or not you choose to participate. • Your participation is expected to last about 2-7 hours over 1-2 study visits. • During the study you will answer questions, perform some paper and pencil/computer tests and have a brain scan (EEG, MEG, or MRI). In some studies, you will undergo a mood manipulation to increase your happiness or sadness. • There is some risk of discomfort and fatigue. Some experiments include sad videos or unpleasant negative images which could cause emotional distress. You are allowed to opt-out of any of these studies if you are concerned about this. • You may or may not receive benefit from participating. Some people may benefit from the treatment or the radiologist might notice something on your brain scan that could lead to early intervention if a problem were found. • Taking part in this study is voluntary so you can choose not to participate.

Purpose and General Information

You are being asked to participate in a research study that is being done by Dr. James F. Cavanagh, Assistant Professor at UNM, who is the Principal Investigator. This research is being done to understand how mood and emotion affect the brain's response to reward information. You are being asked to participate because you have either very high, or very low symptoms of mood and depression. Approximately 800 people will take part in this study at the Mind Research Network and the UNM Department of Psychology. This study is funded by the National Institutes of Mental Health (NIMH).

What will happen if I participate?

If you agree to be in this study, you will be asked to read and sign this consent form. Different studies will be running at different times. Participants in Study 1 will have EEG recorded in Logan Hall at UNM and they may undergo a mood or emotion manipulation. Participants in Study 2 will have MEG, EEG, and MRI

recorded at the MRN. You will be informed before you sign the consent form which Study you are assigned to. After you sign the consent form, the following things will happen:

Questionnaires: You will be asked to complete questionnaires that collect information about your medical history (such as "Are you currently taking any prescription medications?") and your feelings (such as "Do you feel depressed today?") You may refuse to answer any question at any time. These questionnaires will take about 2 hours to complete.

Tasks: You will be asked to complete a series of computer tasks that measure learning and your ability to solve problems. These tasks take about 15-25 minutes each and you will be asked to complete a varied number of tasks depending on the current study aims. In general, tasks will require you to learn to associate a specific button response (e.g. left or right) to specific images (e.g. blue square, yellow triangle) in order to get a reward (e.g. "+1!") or avoid a loss (e.g. "-1"). Different images will have different probabilities of reward or loss.

Mood and Emotion Manipulation in Logan Hall: a mood induction procedure procedure consists of watching a series of emotionally evocative videos (sad or happy theme) interspursed with the task blocks. Sad videos include clips of grief and loss after euthanization and loss of family pets (some euthanasia is shown). A positive mood-repair session will follow the task. Emotional manipulations consist of evocative pictures or emotional faces that you may be required to make value and decision judgements about. Some of these emotional images may be disturbing or very unpleasant, including starving or injured animals and children. Since some people may wish to avoid the sad mood or negative images, you have the option to select a different non-emotional task instead.

Brain wave recording (EEG) in Logan Hall: An elastic cap with sensors attached to it will be placed on your head and the sensors will be filled with a gel. You will also have sensors attached around your nose and eye area. You will sit in front of a computer while completing the computer tasks. You will be asked to make decisions about the information presented to you. The EEG takes about 2 hours.

Magnetoencephalography/Electroencephalograph (MEG/EEG) at the MRN: MEG and EEG record the magnetic activity of your brain at rest and while you work on a set of tasks (described above). It is performed while you sit in a comfortable chair in a special, magnetically shielded room. MEG does not expose you to any radiation or high magnetic fields. Electrodes will be applied to your head and sides of your face using a special conductive gel. These will be held in place with a cap or sticky tape. We use these electrodes to monitor your brain activity your eye movements, your head position, and your heartbeat. You will be seated in a comfortable chair and the chair will be raised slightly to place your head inside the MEG detector helmet. You will need to hold very still for the entire scan, which will take about 1 hour, with up to 1 hour of setup before. When the scan is over, all of the electrodes will be removed and you will have the opportunity to wash off the gel using our sink.

Magnetic Resonance Imaging (MRI) at the MRN: During the study you will undergo a brain study called MRI. For this study, you will lie down on a table and will then be placed into a long donut-shaped magnet. During the study you will hear loud rapping and knocking noises coming from the magnet. You may feel warm during this procedure. In order to obtain good pictures, it is important that you <u>do not</u> move during the procedure. Although you should not talk during the MRI procedure, you will be able to talk with the technician during breaks or in case of emergency by pressing a call button or similar device. During the scan, you may be shown pictures and words and will be asked to make decisions about the information presented in them. This takes up to 1 hour.

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 MRN in the previous six months. When your scan is read, you will receive an e-mail letting you know you can download your MRI report from the Participant Portal Homepage. If we find an abnormality that requires follow-up, we may also mail a copy of the report to you, or contact you and your doctor (with your permission) by phone to help answer questions. Our Medical Director or the research team is always available to answer any questions you may have about your scan.

Participation in this study will take a total of 2-7 hours over a period of 1-2 days. You may be asked to participate in a phone-based interview between 3-6 months after your initial session. This phone assessment will last approximately 5-15 minutes.

What are the possible risks or discomforts of being in this study?

MRI: Radio and magnetic waves associated with MRI scans are not associated with any known adverse effects. MRI is non-invasive and considered minimal risk by the FDA. However, the scanner is a large magnet, so it could move objects with iron in them in the room during the scan. This means that loose metal objects, like coin currency or key chains, are not allowed in the MRI room. If you have a piece of metal in your body such as a pacemaker, nerve stimulator, piercings or certain metal surgical implants, you will not be allowed into the MRI room and cannot have an MRI. While in the scanner, you may be bothered by feelings of claustrophobia (fear of small spaces). If you feel uncomfortable (nervous or upset stomach) in the MRI scanner for any reason, tell the research staff. The MRI also makes loud 'drum' beating noises during the study. Headphones will be provided for your safety and comfort. There is a speaker in the MRI scan room as well as a window that allows the operator to view you during data collection. This allows the assistants to hear and see you at all times to ensure that you are comfortable and to allow them to respond if you are uncomfortable. You can stop the scan at any time.

No long-term harmful effects from MRI are known. However, since the effect of MRI on early development of the fetus is unknown, if you are pregnant you should not go in the MRI. If you are a woman, have already had your first menstrual period, and there is a possibility that you may be pregnant, you will be asked to take a urine pregnancy test before being allowed to participate in the study. You are the only person who will get the results; we will not report the results of the pregnancy test to anyone else including a parent or guardian. Rarely, large tattoos can heat up during an MRI scan and cause skin irritation like a sunburn, so the MRI technologist will want to see any tattoos you have prior to the scan.

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.

MEG/EEG: There is a very small possibility that if you have sensitive skin (e.g., contact dermatitis) you may experience some skin irritation from the EEG gel or metal sensor. Throughout the sessions, assistants will be attending to you to keep you from becoming uncomfortable.

Participation in this study may produce emotional stress, inconvenience or an invasion of privacy. In particular, there is a risk of moderate to strong emotional distress after viewing the sad mood videos or negative images. In addition, there may also be side effects or risks to study participation that are unexpected and not known at this time. Every effort will be made to protect the information you give us. However, there is a small risk of loss of confidentiality. Procedures we will use to protect the information you give us are described below.

COVID-19 related risks: There is a risk for increased COVID-19 exposure due to participation in this experiment. We have many procedures in place to reduce this risk to you and our staff. Both you and the staff will follow these procedures:

1. Only individuals with clear daily symptom reports and temperature assessments (<100 F) will be allowed in the building (this applies to both you and the experimenter you're working with).
2. "Gel in": everyone uses hand sanitizer when walking into and out of room.
3. Both you and the experimenter will wear a face mask and gloves for the duration of the study. We will provide unused personal protective equipment for you.
4. Maintain social distance – stay 6 feet apart whenever possible. Face shields/plexiglass barriers may be implemented if contact closer than 6 feet is essential.
5. Speak softly.

Experimental staff have completed training on reducing exposure and they adhere to a number of protective steps, including maintaining social distancing and mask use in the lab, wiping down surfaces with appropriate disinfectant after each room use, and daily symptom and temperature assessment.

We believe that these procedures reduce the probability of disease exposure as much as possible. However, there is still a risk of exposure to COVID-19 due to participation in this study. If a staff member reports positive symptoms or tests positive for COVID-19, you will be contacted by phone if your experimental session was within 14 days of this report. We ask that you also contact your experimenter if you exhibit signs of COVID-19 within 14 days of participation.

How will my information be kept confidential?

We will take measures to protect your privacy and the security of all your personal information. Your name and other identifying information will be maintained in locked files and/or restricted databases, available only to authorized members of the research team for the duration of the study. All of the information we collect about you will be coded with a unique research subject identifier (URSI) or other subject code and will be kept on password protected computers, and stored securely in restricted and protected databases according to MRN information security policies. The record linking your name to your study ID number (which the study data is labeled with) will be kept indefinitely (forever) at the MRN in a confidential manner so that you may continue to have access to your information. De-identified data (meaning data that cannot be traced back to you) from this study may also be presented at meetings, published in journals/books, used in classrooms for training/teaching purposes, and may be shared with other researchers, which includes scientists at other universities and institutions. However, your name and other identifying information will not be used in any published reports about this study. If you initial the data-sharing consent below, your de-identified data will be deposited in open-source data repositories.

To help us protect your information, this research study has a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, the research team cannot be forced to provide your name or any identifiable research data or specimens to people who are not connected with this study, including Federal, state or local authorities, even under a subpoena. The protection offered by the certificate does not stop us from reporting information about suspected or known sexual, physical, or other abuse of a child or older person, or that you plan to harm yourself or someone else. If any member of the research team is given such information, we will make a report to the appropriate authorities.

Information from your participation in this study may be reviewed by NIMH, MRN, federal and state regulatory agencies, and by the University of New Mexico Institutional Review Board (IRB) which provides regulatory and ethical oversight of human research.

What are the benefits to being in this study?

In the course of this research, brain scans will be performed on you. These scans will be used solely for the purpose of gathering scientific information for this study. During the study, you will not be provided a medical diagnosis or treatment for any brain condition, or other health problem. However, the radiologist may notice something in the brain tissue that could lead to early intervention if a problem were found.

Your participation may help find out how mood affects the brain response to reward, contributing to a better understanding of the brain basis of major depression.

What other choices do I have if I don't participate?

Taking part in this study is voluntary so you can choose not to participate.

How will I know if you learn something new that may change my mind about participating?

You will be informed of any significant new findings that become available during the course of the study, such as changes in the risks or benefits resulting from participating in the research or new alternatives to participation that might change your mind about participating.

Are there any costs to me for participating?

You will not be charged for any of the experimental study procedures, including the MRI scan. If incidental findings from the study result in the need for further evaluation/treatment, then you or your insurance company will be responsible for any clinical evaluation/treatment that may be needed.

Will I be paid for taking part in this study?

You will be compensated either $20 or $30 per hour in cash or gift card depending on the study being run at that time. Studies with a single neuroimaging component (EEG only) are faster and easier so they are compensated at $20/hr, whereas studies with multiple neuroimaging components (EEG, MEG and MRI) are compensated at $30/hr. Some tasks may have a monetary reward component which will allow you to earn between $2 and $20 extra depending on task performance. The total amount earned for fully completed sessions will thus be between $40 and $230. If the investigators develop intellectual property and/or commercialize products or services, directly or indirectly, based on the results of the research done with your data, there are no plans to provide you with any financial compensation.

Compensation for participation in research is considered taxable income and should be reported on your income tax return. If you earn $600 or more participating in research studies, you will be sent a W-9 form to collect your tax information which will be reported to the Internal Revenue Service (IRS) as required by law. The information provided to the IRS will <u>not</u> disclose your participation in a research study; instead the income will be listed as "nonemployee compensation."

Can I stop being in the study once I begin?

Yes. You can withdraw from this study at any time.

The investigators have the right to end your participation in this study if they determine that you no longer qualify to take part, if you do not follow study procedures, or if it is in your best interest or the study's best interest to stop your participation.

What will happen if I am injured or become sick because I took part in this study?

If you are injured or become sick as a result of this study, any emergency treatment will be at your cost. Neither MRN nor UNM make a commitment to provide free medical care or money for injuries to participants in this study. This includes any COVID-19 related disease exposure.

It is important for you to tell the Principal Investigator immediately if you have been injured or become sick because of taking part in this study. If you have any questions about these issues, or believe that you have been treated carelessly in the study, please contact the Office of the IRB at (505) 277-2644 for more information.

Refusal to Sign

If you choose not to sign this consent form, you will not be allowed to take part in the research study.

What if I have questions or complaints about this study?

If you have any questions, concerns or complaints at any time about the research study, James F. Cavanagh, PhD, or his associates will be glad to answer them at 505-277-6830, Monday to Friday from 9-5. If you would like to speak with someone other than the research team to obtain information or offer input, or if you have questions regarding your rights as a research participant or about what you should do in case of any research-related harm, please contact the IRB. The IRB is a group of people from UNM and the community who provide independent oversight of safety and ethical issues related to research involving people:

UNM Office of the IRB, (505) 277-2644, irbmaincampus@unm.edu. Website: http://irb.unm.edu/

Consent

You are making a decision whether to participate in this study. Your signature below indicates that you read the information provided (or the information was read to you). By signing this consent form, you are not waiving any of your legal rights as a research participant.

OPTIONAL:
We would also like to request your permission to store all of the data that was collected in this study in The Mind Research Network Data Sharing Repository, the Patient Repository for EEG Data + Computational Tools, the NIMH's RDoC database, and other online open-source databases for future research. The stored data will include information such as your age and gender, as well as assessment and imaging data that were collected about you during the course of this study. Although the researchers will take all available precautions when de-identifying your data, it is possible that some information may be able to be linked to your name. It will be handled with the same care and confidentially as it is for the current study. Research done with information from the data repository could lead to improved diagnostic and treatment interventions for illnesses and brain disorders. If published, results will be presented in summary form only and will not include your name or other identifying information. If the investigators develop intellectual property and/or commercialize products or services, directly or indirectly, based on the results of the research done with your data, there are no plans to provide you with any financial compensation.

You have my permission to store my data in the data sharing repositories for future research. Please initial next to your choice below.
YES _____ Initials NO _____ Initials

We would like to request your permission to contact you for participation in future studies.

You have my permission to contact me about participation in future research studies. Please initial next to your choice below.
YES _____ Initials NO _____ Initials

You may be recruited from other studies which may reduce the number of tests you will need to perform for this study. Given your permission, the results of these previous tests will be shared with this study to reduce the number of times you need to perform the same tests.

I give permission to access my data from the ABQDRINQ study (UNM IRB# 11017).
YES _____ Initials NO _____ Initials

I have had an opportunity to ask questions and all questions have been answered to my satisfaction. By signing this consent form, I agree to participate in this study. A copy of this consent form will be provided to me.

_____ _____/_____
Name of Adult Participant (print) Signature of Adult Participant Date

I have explained the research to the participant and answered all of their questions. I believe that they understand the information in this consent form and freely agrees to participate.

_____ _____/ _____
Name of Research Team Member Signature of Research Team Member/Date