Transcranial alternating current stimulation to boost the efficacy of motivational interviewing
Consent to Participate in Research
09/20/2020

Purpose of the research: You are being asked to participate in a research project that is being done by Jon M. Houck, Ph.D., and his associates, from the Mind Research Network. The purpose of this research is to test whether noninvasive brain stimulation can affect psychotherapy sessions for alcohol use. You are being asked to join because you are an adult who drinks alcohol above the low-risk level. Up to 94 participants will take part in this study.

This consent form contains important information about this project and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision about whether or not to participate. Your participation in this research is voluntary. Before you can be enrolled in the study we will give you a short questionnaire to make sure that you understand what you will do in the project.

Key Information for You to Consider
• You are being asked to participate in a research study about how brain stimulation affects psychotherapy for alcohol use. Participation is voluntary and it is up to you whether you choose to participate. • Your participation is expected to last a total of four hours over 30 days, including one visit to the Mind Research Network. • During the study you will answer questions, perform some paper and pencil/computer tests, and have two brain scans (MEG and MRI). • There is some risk of skin irritation, stress, emotional distress, claustrophobia, and possible loss of privacy. • You may or may not receive benefit from participating. Some people may benefit from the psychotherapy, or the radiologist might notice something on your MRI that could lead to early intervention if a problem were found.

COVID-safe practices

As long as the New Mexico State of Public Health Emergency declared in Executive Order 2020-004 remains in effect, this study will use procedures intended to reduce the risk of transmitting COVID-19. When we schedule your visit and again when you arrive at the Mind Research Network building, we will ask you questions about COVID-19 symptoms. We will also check your temperature using a touchless thermometer. If you have a temperature above 100°F or have any COVID-19 symptoms we will reschedule your visit for another day.

Any friends or family members who come with you to a visit must wait outside of the building. Use of masks is required; if you do not have a mask or if your mask is not sufficient, one will be provided for you. A social distancing limit of 6' will be followed whenever possible except when necessary for data collection, for example when we are getting you ready for a scan or helping you into a scanner. We will use additional personal protective equipment like face shields or plexiglass barriers when we need to remain within 6' of you. Please contact Dr. Houck immediately (jhouck@mrn.org/(505) 272-2869) if you test positive for COVID-19 or develop symptoms of COVID-19 within 14 days of your visit to the Mind Research Network.

What you will do in the project:

Group assignment: There are three different groups ("conditions") in this study. If you are eligible for the study, you will be randomly assigned either to a waiting list group, to an active brain stimulation group, or to a placebo brain stimulation group. Placebo stimulation means that you would go through all the same procedures as the active brain stimulation group, but with no electrical current. Randomization means you will be assigned to a group based on chance, like a flip of a coin. If you are assigned to the waiting list group, you will not receive either kind of brain stimulation or any neuroimaging. If you are assigned to one of the brain stimulation groups, neither you nor your experimenter will know whether you will be receiving active brain stimulation or placebo brain stimulation.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This web site will not include information that can identify you. At most, the website will include a summary of the results. You can search this web site at any time.

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 two hours.

Transcranial Alternating Current Stimulation (TACS): TACS is a low electrical current that slightly changes the way the brain works for a short period of time. TACS applied to the head does this by giving a very weak electrical current through your scalp and into your brain. Electrodes will be placed on your scalp using a special conductive gel. The electrodes are kept in place with a cap or sticky tape. The electrodes will give a very weak electrical current for 30 minutes, which may briefly result in a tingling and/or itching feeling at the electrode sites.

Heart recording (ECG): sensors will be placed on your body near your collarbone and the sensors will be filled with a gel. The sensors will be used to measure your heart beats during your interview.

Interview: You will have a brief discussion with a trained interviewer. If you are assigned to one of the brain stimulation groups (either active or placebo), this interview will happen during your TACS session. This discussion will be audio recorded, and will include topics such as your concerns about your alcohol use, reasons to change or not to change, and your future desires for your alcohol use. This study is not a treatment program – what you choose to do after the interview will be up to you. If you tell us that you want information about treatment for substance use, we will provide information for several nearby treatment options.

Magnetoencephalography (MEG): MEG records the magnetic activity of your brain at rest and while you work on a set of tasks. 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 and near your collarbone using a special conductive gel. These will be held in place with a cap or sticky tape. We use these electrodes to monitor 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 45 minutes. During the scan, you may be shown pictures and words and will be asked to make decisions about the information presented in them. When the scan is over, all of the electrodes will be removed and you will have the opportunity to wash off the gel using the sink.

Magnetic Resonance Imaging (MRI): During the study you will undergo a brain study called MRI. An MRI will be done at your baseline visit. If the MRI results are unclear, you may be asked to have an additional MRI done. 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 do not 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 about 30 minutes.

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. The MRN Medical Director or the research team is always available to answer any questions you may have about your scan.

Follow-up questionnaires: About a month after your first visit, we will ask you to complete some questionnaires again. You can complete the questionnaires at home/online, or you can come back and complete them in person. These questionnaires will take about one hour.

Risks:

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

TACS: We will be using a weak electrical current called TACS to non-invasively stimulate your brain (or your arm). At the TACS dose used in this study, no long-term harmful effects are known. TACS has been safely administered to many people for the last several decades. Most participants report only mild, transient tingling at the stimulation site. In a few cases, people have reported minor skin damage or irritation at the electrode site. In rare cases, the skin damage resembles a burn, much like sunburn, that may result in a scab or skin discoloration (resembling a suntan) at the electrode site that can last several days. If any of these are observed, we will postpone or terminate your participation in the study.

In addition to the tingling feeling at the start of TACS, there may also be a warming sensation on the scalp. You will be encouraged to tell us about any pain or discomfort at the electrode sites throughout the TACS procedure. If you tell us that the warming sensation becomes a burning sensation, the TACS procedure will be stopped. If there are any signs of redness or irritation of the scalp, the TACS will also be stopped. There is the chance of receiving a small shock and a sensation of a short light flash if TACS is stopped suddenly. To help keep this from happening we will ask you to keep as still as possible during the experiment. Also, if the electrodes are placed where they are uncomfortable in any way, please ask the research assistant to move the electrodes; do not try to do this by yourself.

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,certain metal surgical implants, or a bullet, BB, or shrapnel, 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, participants who are pregnant 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.

As long as the State of Public Health Emergency declared in Executive Order 2020-004 remains in effect in New Mexico, there will be a risk of contracting COVID-19 as a result of participating in this study. When you participate in this study you will have close contact with members of the research team and may also have incidental contact with other members of the public when you travel to and from your visit to MRN. If anyone you encounter has COVID-19, you may be at risk for catching it. MRN has procedures that should reduce this risk, like the use of symptom checks, hand sanitizer, and personal protective equipment, but this risk cannot be eliminated.

There are risks of stress, emotional distress, inconvenience and possible loss of privacy and confidentiality associated with participating in a research project. The study may involve risks to you that are currently unforeseeable.

Benefits: A potential benefit to this study is talking with a trained interviewer about your alcohol use. This has been shown to reduce alcohol use in previous studies with similar populations. A reduction in alcohol use may provide health benefits to you. Your participation may also help us to find out how to improve psychotherapy for alcohol use, which would benefit society.

Confidentiality of your information:

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 special study code number and will be kept on password protected computers, and stored securely in restricted and protected databases. If you have an MRI, at the end of the study the record linking your name and other identifying information to your study code will be made unavailable to the research team; however, it will be kept indefinitely (forever) at the MRN in a confidential manner so that you may continue to have access to your MRI information. Data from this study that does not contain any identifiers such as your name, date of birth, etc., may be presented at meetings, published in journals/books, used in classrooms for training/teaching purposes, and may be used and shared with other researchers for future research purposes, 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.

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 in any Federal, state or local proceedings unless you agree that we can share it. However, we still must report information to local authorities if we learn about child abuse or neglect, or intent to harm yourself or others. Disclosure will also be necessary upon request from the Department of Health and Human Services (DHHS) or other federal agencies for audits or program evaluations.

The University of New Mexico Institutional Review Board (IRB) that oversees human research, the sponsor, and/or the FDA may be permitted to access your records. Your name will not be used in any published reports about this project.

You should understand that the researcher is not prevented from taking steps, including reporting to authorities, to prevent serious harm of yourself or others.

Use of your information for future research:

All identifiable information (e.g., your name, date of birth) will be removed from the information or samples collected in this project. After we remove all identifiers, the information or samples may be used for future research or shared with other researchers without your additional informed consent.

Payment: In return for your time and the inconvenience of participating in this project, you will be paid $40 for completing the questionnaires, $20 for the interview, $20 for completing the follow-up questionnaires, $20 for the MEG, and $15 for the MRI, for a total of $115. If you do not complete the study, you will be paid based on how much you finished. For example, if you complete the questionnaires, the interview, and half of the follow-up questionnaires, you would be paid $70 ($40 + $20 + ½ of $20). Compensation is considered taxable income. Amounts of $600 or more will be reported by MRN to the Internal Revenue Service (IRS).

Right to withdraw from the research: Your participation in this research is completely voluntary. You have the right to choose not to participate or to withdraw your participation at any time without penalty. Also, 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 including the use of hand sanitizer and personal protective equipment, or if it is in your best interest or the study's best interest to stop your participation. If you withdraw or are withdrawn from the research, all data we have collected from you will be retained.

If you have any questions, concerns, or complaints about the research, please contact:

Jon M. Houck, The Mind Research Network, Albuquerque, NM 87106. (505) 272-2869. jhouck@mrn.org

If you have questions regarding your rights as a research participant, or about what you should do in case of any research-related harm to you, or if you want to obtain information or offer input, 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/

Research related injury: If you are injured or become sick as a result of this study, any emergency treatment will be at your cost. MRN makes no commitment to provide free medical care or money for injuries to participants in this study.

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.

CONSENT

You are making a decision whether to participate in this research. Your signature below indicates that you have read this form (or the form was read to you) and that all questions have been answered to your satisfaction. By signing this consent form, you are not waiving any of your legal rights as a research participant. A copy of this consent form will be made available to you.

I agree to participate in this research.

_____	_____	_____
Name of Adult Participant	Signature of Adult Participant	Date

Researcher Signature (to be completed at time of informed consent)

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

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