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RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

Title of Study: ***"Investigating Transcranial Alternating Current Stimulation (tACS) Preconditioning Effects on Resting and Active Motor Threshold"***

NCT05503823

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This consent form, a copy of which will be left with you for your records and reference, is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, you should feel free to ask. Please take the time to read this carefully and to understand any accompanying information.

Purpose of Study

This research is being conducted to investigate whether priming the brain with tACS (transcranial alternating current stimulation) at 40 Hz or tRNS (transcranial Random Noise stimulation) for 10 minutes is able to reduce the resting motor threshold (RMT) and active motor threshold (AMT). Although we are investigating this for healthy adults, the application of such study will be for people who may need repeated transcranial magnetic stimulation (rTMS) as a treatment; those with higher RMT and AMT, priming with tACS/tRNS could be used to lower intensities while stimulating the brain for treatments. The motor threshold is the intensity at which one will have an involuntary twitch in a finger upon receiving transcranial magnetic stimulation (TMS) pulses. The RMT is measured when the hand is completely at rest and the AMT is measured with your hand slightly contracted. In general, rTMS is a technique that stimulates the brain by rapidly switching a magnetic field in a coil placed over the head. tACS and tRNS are techniques that stimulate the brain by a very small electrical current through two electrodes placed over the head.

Study Procedures

Screening

Before any stimulation, we will ask you some questions to determine your eligibility for the study explained under the *Assessment and Questionnaire* section.

In case you have taken a pain killer pill on the day of the experiment, we will have to reschedule you for another day that you have not taken any pain killer before the experiment.

Test

The study will require two sessions to Riverview Health Center for the duration of approximately 2 hours each with a minimum of 4 hours between the two sessions. The first session will be dedicated to measurements before and after tACS and the second session follows the same procedure while priming with tRNS.

Your motor threshold will be measured for the both sides of your brain 4 times. Your motor threshold (which is the minimum required intensity to activate a neuron) will be measured using a single pulse of TMS applied to the scalp. This motor threshold is measured by the minimum TMS intensity required to activate the muscles in the hand to cause an involuntary twitch in any of the fingers. The RMT is measured when the hand is completely at rest and the AMT is measured with your hand slightly contracted. You may receive a few single pulses to find your brain's motor threshold. Electromyography (EMG) will measure the muscle activity of your index finger by the placement of 3 electrodes on your hand. The resting and active motor thresholds (RMT and AMT) will be measured at baseline (before tACS/tRNS), right after tACS/tRNS, after 30 minutes of tACS/tRNS, and after 1 hour of tACS/tRNS.

Both tACS and tRNS apply a very small electric current through two electrodes placed over the head. One of the study research assistants will place the active electrode over the hand area of the primary motor cortex and the reference over the right supraorbital area.

Results

The results of the study will be provided to you upon your request by the academic supervisor of the principal investigator of the study (Dr. Zahra Moussavi) once we reach our target number of participants. Also**,** the results of the study in general will be disseminated to public once we reach our target number of participants.

Recording Devices

The electromyography (EMG) will be recorded using Brainsight 2 software and hardware. The hardware includes the Isolating Unit and the Differential Amplifier.

The blood pressure will be recorded using a standard sphygmomanometer. The blood oxygen will be recorded using an oximeter.

Assessment and Questionnaire

As we are interested to investigate adults with no cognitive impairment, we will need to run a short (maximum 10 minutes) simple test, called Montreal Cognitive Assessment (MoCA). This is a short screening assessment that tests language, memory, visual and spatial skills. A questionnaire will also be filled out by the participant to determine if they need to be excluded for their safety such as having a pacemaker or metallic implants. The participant will also be asked about confounding factors for this study such as the amount of sleep the night before and their handedness. In addition, a screening questionnaire will be presented upon both visits to monitor any use of caffeine, sleep, anxiety, and pain medications.

Benefits

A possible benefit includes contributing to a better understanding of brain activity.

Costs

You will receive no reimbursement for your participation.

Risks and Discomforts

There is a risk of seizure from TMS when applied repeatedly at high frequency in people with history of epilepsy or in people who have an increased risk of getting seizures. Although, in this study we only give a few single pulses (with a frequency of less than 1 pulse in 2 seconds), nevertheless, if you have a history of seizure, you should not participate in this study. You will be asked some questions regarding your or your family's medical history and will be excluded from the study, if you have certain conditions. Please respond completely and accurately to these questions for your safety.

You may have a mild headache following TMS application. This is believed to be due to muscle tension. In the case of a headache, you may take acetaminophen, a medication that in all prior cases of headaches induced by TMS, has promptly resolved the discomfort. Since the TMS device is an investigational instrument, there may be some other minor risks that are unknown.

The tACS and tRNS procedures used in this study are considered to be of minimal risk. These include mild pain, mild headaches or fatigue. Also, the electrodes may cause tingling, itching, burning sensation, or skin redness. There is however a risk of seizure from tACS/tRNS in people with history of epilepsy or in people who have an increased risk of getting seizures. If you have a history of seizure, you should not receive tACS/tRNS.

There are no physical risks of recording electromyography from the muscle activity.

Confidentiality

Some study data and information from the study may be sent outside of the University of Manitoba and Riverview Health Centre to other researchers, academic institutions, health care facilities, or organizations for further analysis, testing or as part of the research study.

Records containing health related information will be treated as confidential in accordance with Personal Health Information Act of Manitoba. Information gathered in this research study may be published or presented in public forums, however your name and other identifying personal information will not be revealed, data will be coded and names will not be released. Increasingly, the scientific community, the granting agencies and medical scientific journals require that data be stored and made available for secondary review and analyses. For publication purposes, your de-identified study data may be shared with other researchers from other institutions for secondary analyses or other research purposes.

All records will be kept in a locked secure area. Any information sent out of the University of Manitoba or Riverview Health Centre will not show your name or address, or any other identifiable personal information about you. However, despite efforts to keep your personal information confidential, absolute confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law.

The University of Manitoba Biomedical Research Ethics Board (BREB) may review your research records related to the study for quality assurance purposes. All records will be kept in a locked secure area and only those persons identified will have access to these records. If any of your research records need to be copied to any of the above, your name and all identifying information will be removed. No information revealing any personal information such as your name, address or telephone number will leave the Riverview Health Centre. In case of any publication of results of this study, information will be provided in such a way that you cannot be identified.

ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on http://ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Voluntary Participation/Withdrawal from the Study

Your decision to take part in this study is voluntary. You may refuse to participate or you may withdraw from the study at any time. We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study.

Results of the Project

All participants have the option of receiving a lay summary of their own assessments once we reach our target number of participants. If you wish to be informed of your results, please inform the research staff at the time of your participation or you may contact the academic supervisor of the principal investigator of the study (Dr. Zahra Moussavi, Zahra.Moussavi@umanitoba.ca).

Questions

If you require further information or if you have any problems concerning this project (for example, any side effects), you can contact Dr. Zahra Moussavi (204-474-7023). For questions about your rights as a research participant, you may contact the University of Manitoba Biomedical Research Ethics Board at 204-789-3389.

Statement of Consent

Your signature on this form indicates that you have understood to your satisfaction the information regarding participation in the research project and agree to participate as a subject. In no way does this waive your legal rights nor release the researchers, funders, or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time, and /or refrain from answering any questions you prefer to omit, without prejudice or consequence. Your continued participation should be as informed as your initial consent, so you should feel free to ask for clarification or new information throughout your participation. The University of Manitoba may look at your research records to see that the research is being done in a safe and proper way.

This research has been approved by the University of Manitoba Biomedical Research Ethics Board. If you have any concerns or complaints about this project you may contact any of the above-named persons or the University of Manitoba Bannatyne Campus at 204-789-3389**.** A copy of this consent form has been given to you to keep for your records and reference.

I agree to being contacted in relation to this study. **Yes** ☐ **No** ☐

Participant signature_____ **Date** _____

Participant printed name: _____ **(day/month/year)**

The study coordinator Part

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has knowingly given their consent

Coordinator's Signature: _____ **Date** _____

Coordinator's Printed Name: _____ **(day/month/year)**

Role in the study: _____

Relationship to study team members_____*[eg. supervisor, teacher/professor or family member.]*

Assigned Code: _____

COVID-19 Consent Appendix

Research Project Title: Investigating Transcranial Alternating Current Stimulation (tACS) Preconditioning Effects on Resting and Active Motor Threshold

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Location of study: PE-450 Administration Building
Riverview Health Centre
1 Morley Avenue, Winnipeg, MB
R3L 2P4

This document contains important information about in-person research during the COVID-19 public health crisis. COVID-19 (also called SARS-CoV2) is an illness caused by the coronavirus. Coronaviruses are most commonly spread from an infected person through: a) respiratory droplets when you cough or sneeze; b) close personal contact, such as touching or shaking hands; or c) touching something with the virus on it, then touching your eyes, nose or mouth before washing your hands.

The University of Manitoba is committed to taking measures to protect the health and safety of their campuses and the wider community. Your safety is important to us. The university has suspended most research that cannot be conducted remotely or virtually. This project requires in-person visits to Riverview Health Center. Therefore, it is important to understand that your participation in this study may increase your exposure to COVID-19.

Our project has been approved to proceed by the Research Ethics Board, our Faculty, the COVID Recovery Response Team, the COVID Recovery Steering Committee, and the University Provost. In order to gain approval, we created policies to ensure the safety of the research team and participants. These plans were reviewed and approved by the parties above. These precautions include:

- *All study research teams are wearing 3-ply reusable or disposable masks. You are also required to wear a mask.*
- *We also require all of our employees to screen themselves for symptoms daily before they come into work, and we'll screen you for symptoms the day of your visit.*
- *We will provide you with a screening questionnaire. If you answer yes to any of the questions, we will reschedule your visit. You should not attend any visits if you are not feeling well or exhibiting any symptoms of COVID-19, if you have been a close contact with someone with COVID-19 (or awaiting tests results), or have been told by a health official to self-isolate.*
- *We are following meticulous infection control practices, including disinfection, wearing gloves, and hand washing.*
- *We are limiting the number of visitors accompanying people for their study visits, and have rearranged and/or removed furniture in our waiting areas to enforce strict physical distancing practices.*
- *We're also being careful about who we ask to come for in-person study visits, and when possible are using telephone or video conferencing to reduce the number of study participants coming to our research areas at the same time.*

COVID-19 is a serious health threat and the situation is evolving rapidly. If you feel that you are from a group that is more vulnerable to COVID-19 effects (e.g., senior (over the age of 60 years), immuno-compromised), please discuss your participation with the research team before providing your consent. You are under no obligation to participate and can change your mind about participating in the research at any time and without consequence.

The University of Manitoba is closing watching the situation in Manitoba and may restrict in-person research at any time. We will continue to keep you informed as to changes that may occur to this study.

There is a possibility that during your participation in the study you could come into contact with someone with COVID-19. We are required to collect your personal contact information that we must retain in order to follow up with you and/or conduct contact tracing if you may have been exposed to COVID-19 in coming to the research site. **We cannot guarantee anonymity as the personal contact information identifies you as a participant and we may be required to disclose this information in the event of a possible exposure.** Your contact information will be kept separately from data collected through the research study to allow for de-identification of the research data. You maintain your right to withdraw from the study at any time, including your research data. If you do withdraw from the study, we will still need to continue to maintain your contact information and will only give it to the University's Environmental Health and Safety (EHS) Office and/or Manitoba Health if required for contact tracing. Please note, Manitoba Health or the University's EHS office will not have access to your research data.

If you have questions regarding this study, measures we are taking to keep all parties safe, or have any concerns, please do not hesitate to ask. You can contact any of the above named researchers or the Bannatyne Campus Research Ethics Board office at shelly.rempel-rossum@umanitoba.ca

Your signature on this form indicates that you have understood to your satisfaction the information regarding participation and the COVID-19 risk and agree to participate. In no way does this waive your legal rights nor release the researchers, sponsors, or involved institutions from their legal and professional responsibilities. Your continued participation should be as informed as your initial consent, so you should feel free to ask for clarification or new information throughout your participation.

Participant Name _____

Contact Information (phone # or email): _____

Participant's Signature _____ Date: _____