TO YOU WANT TO PARTICIPATE IN A RESEARCH PROJECT ABOUT BRAIN STIMULATION AND ATTENTION?

Institution of Psychology at UiT - The arctic University of Norway

Conducted by:

Steffen Aasen (saa054@uit.no) and Ragnhild Drevland (rdr006@uit.no)

Under supervision of:

Associate professor Gábor Csifcsák (gabor.csifcsak@uit.no) | Professor Matthias Mittner (matthias.mittner@uit.no)

AIM OF THE PROJECT AND WHY YOU ARE ASKED

This is a request for you to attend a research project where we will be studying the effect of brain stimulation on attention. This will provide us with more insight into the relation between different brain regions, and how we can influence attention in grown adults.

In this project we will be using rTMS (repetitive transcranial magnetic stimulation) which is a safe procedure to stimulate the brain from outside of the skull using magnetic fields. As a participant you will conduct an attentional task and answer a few questions that will be asked while conducting this task. This study requires that you attend two sessions in total, with at least one week gap between each session. Both sessions will be identical except for that on one session you will receive real rTMS stimulation (which influences the brain), and the other session you will receive fake rTMS stimulation (have no effect on the brain). The order for real/fake stimulation will be random, you will not be told when you will receive real or fake stimulation. One session is expected to last about 140 minutes.

We are looking for right-handed healthy adults between 18 and 50 years.

- You should have good or corrected eyesight, be righthanded, have no psychological/neurological diseases currently or in the past (e. g. major depression, bipolar disorder, epilepsy, migraine, severe head injury, brain surgery), not pregnant, no history of epilepsy in the family (first-degree relatives), not taking any medication targeting the central nervous system (e. g. antidepressants, antiepileptics), no metal implants (e.g., pacemaker, cochlea implant), no electronical devices in the body.
- ➤ It is important that you get enough sleep the day before the session, have eaten enough, are not under the influence of any psychoactive drugs (e.g., alcohol, narcotics), do not have a hangover.
- You are allowed to consume caffeine (e.g., coffee, energy drink), and nicotine (e.g., cigarettes, snus) according to your usual routines.

WHAT DOES THE PROJECT MEAN TO YOU?

In this project we will obtain and register information about you. We will gather information such as name, e-mail, phone number, dominant hand, age, and gender. Personal information and contact information will be collected for us to remind you of your next session and in case of other needs. We will collect information about your responses on the attentional task and the questions given during the task, and answers given on

questionnaires after the experiment. All the collected information will be treated confidentially, only the project group will have access to the data before anonymization.

Both sessions will have this procedure:

- ➤ You will be asked to join in our lab at the Institute of Psychology at UiT Arctic University of Norway. At arrival you will be asked to read and sign an informed consent. You will also be asked to fill out a checklist for inclusion criteria before each session. The data collected will last for about 140 minutes each session. One of our researchers will give you instructions while attending the session. You will be given instructions on the task you will conduct and be asked to fill out a schema showing that you understand the task.
- You will receive earplugs that will be used during stimulation to reduce noise from the stimulator, the stimulator will produce some clicking noises. Before stimulation you will be asked to remove any metal objects that is close to the head like earrings, hand watch, glasses, jewelry or piercings. Wearing too much eye make-up might cause some uncomfortable sensations during stimulation, therefore you will be asked to remove any eye make-up before the stimulation. When stimulated you will wear a "subject tracker" around your head making it possible to localize the stimulation spot.
- ➤ Then you will start with the attentional task. This task consists of four blocks that lasts about 10 minutes each. While conducting this task you will be asked to answer where your attention was during the task. Stimulation will be given between these task-sessions (between each block). Every bout of stimulation lasts around 40-190s.
- After the task you will be answering some questions related to your thoughts about the study and the task, and questions about possible side effects as a result of stimulation.
- After the last stimulation you will be asked to stay in the experimental area in case of epileptic seizures for a total of 30 minutes. 15 of these minutes will go to the task and questionnaire, and 15 minutes will be waiting time.

PROS AND CONS

- > The benefit from participating in this project is that you get to observe how brain studies are conducted, and you contribute to the field of research. You will also receive a gift card worth 500kr for your participation at both sessions.
- This type of brain stimulation gives a very small risk of having an epileptic seizure. This happens rarely in healthy adults. To minimize this risk our procedure for stimulation and our exclusion criteria are based on updated and recent documentation given by international guidelines. The researchers will have practice in handling epileptic seizures.
- As a participant in this study, you might experience some mild side-effects such as mild headache, itching, neck pain, tingling, and uncomfortable sensation at the stimulation site. This will disappear within 24 hours after stimulation. If the side-effects don't disappear contact Gábor Csifcsák (see contact information on the last page) or contact the emergency department.

VOLUNTARY PARTICIPATION AND OPPORTUNITY TO WITHDRAW YOUR CONSENT

- ➤ It is voluntary to attend in this project.
- If you want to participate you will be signing a declaration of consent on the last page and you will receive a time for participation and come to our lab.
- You have the right to end the data collection at any given time and to withdraw your consent of participation without giving any reason for your choice. In this case all the collected data from you will

- not be used in any way. This would have no negative consequence for you if you chose to not participate or wish to withdraw.
- You have a right to insight to the information collected from you, this information will be given to you within 30 days.
- You can demand that information about your health will be deleted.
- > The access to destruction, deletion or insight of the data does not apply if the material or information is already published. This access can also be limited if the information is already analyzed or if the material is processed.
- If you later want to withdraw or have any questions about the project you can contact the project managers (see contact information on the last page).

WHAT WILL HAPPEN TO YOUR PERSONAL DATA?

- All the information collected of you will only be used for the purpose of this project, as described previously.
- Extensions in the use and storage time can only happen after approval from REK (regional ethics committee) and other relevant authorities.
- You have the right to know which information that is registered about you and will be given the opportunity to correct possible mistakes in the information.
- You also have the right to gain insight into the safety measures in treatment of your information. You can complain about this treatment of your information to The Norwegian Data Protection Authority (DPA) and the data protection official at the institution.
- All the collected data will be gathered anonymously and will only be marked with a unique code. The key that connects this code to the personal information will be stored in a locked drawer available only to project manager and the project staff.
- > You have the right to gain access to your data (performance on the attentional task, answers on the questionnaires) by request, this requires that you remember your date of attendance and your participation code.
- > The collected data will be used as a purpose to publish our results in a scientific journal. The collected data will be presented on a group level, not on an individual level. This means that no individual data will be presented in scientific publications or university assignments, only results attained from the whole group of participants will be presented.
- Publication is necessary in research. All publication will happen so that each participant cannot be recognized, but we are obliged to tell you that it cannot be excluded.
- Your anonymized data will be shared with other researchers and published open and available to everyone. This is to contribute to scientific development in this research domain.

SHARING OF DATA AND TRANSFER TO DATA ABROAD

By agreeing to participate in the study, you are also consenting to that your coded information about your performance on a task, self-report of attention, side-effects, questionnaires, and stimulation protocol can be transferred to another country as a part of research collaboration and publication. We will be using Open

Science Framework (osf.io) which is a platform with the intention to share scientific research data and promote transparence and an open scientific network.

- > By signing the informed consent, you agree to that data from you as a participant will be shared with other researchers. Other researchers can use this data to gain more insight to attentional processes and the dynamics between the brain regions involved.
- The legislation in the country where the information is stored is what's applicable.

INSURANCE

The Product Liability Act applies to this project.

ECONOMY

You will be compensated for your time in form of a gift card at Jekta Storsenter in Tromsø with a value of 500 NOK. Resources for this research project is financed by The Research Council of Norway and UiT (The Arctic University of Norway). Researchers and research managers do not have any conflict of interest.

APPROVALS

The Regional Committee for medical and health research have conducted a research ethical assessment and approved this project. [285811]

UiT and the project leader Matthias Mittner is responsible for the personal privacy in this project.

CONTACT INFORMATION

If you have questions regarding this study and want to withdraw you can contact:

Ragnhild Drevland (rdr006@uit.no) or Steffen Aasen (saa054@uit.no)

If you are experiencing any side-effects lasting longer than 24 hours, please contact:

Co-supervisor, Gabor Csifcsak

gabor.csifcsak@uit.no

+47 776 46 776

If you have any questions regarding privacy of the project you can contact the data protection official at the institution:

Data protection official at UiT, Joakim Bakkevold

personvernombud@uit.no

Project leader:

Professor, Matthias Mittner

Matthias.mittner@uit.no

+ 47 776 46 371

CONCENT

I hereby acknowledge that I understand all information described above and give by consent to participate in this study.

I understand that it is my right to withdraw or end the study whenever I want without having to address a reason for my choice. In this case all data about me that has already been collected will be destroyed, and no data will be used in any way.

All data will be collected and kept anonymized and be available for the people responsible for this study. The results of this study will only be presented in scientific publications or at a university thesis on group level.

I understand that the collected data in this study will be collected for its research purpose and not to establish any clinical diagnosis. Thereby I will not ask for any diagnostic interpretations.

I CONSENT TO PARTICIPATING IN THE RESEARCH PROJECT AND THAT MY PERSONAL DATA CAN BE USED AS DESCRIBED ABOVE

| Place | Date |
|-----------------------|-----------------------------------|
| | |
| | |
| Participant signature | Participants name in block letter |
| | |
| | |
| Researcher signature | Researchers name in block letters |