INFORMED CONSENT FORM

Study Title:
Efficacy of Low-frequency Repetitive Transcranial Magnetic Stimulation on Rehabilitation of Aphasia

Study Design : Randomized Controlled Trial

Research Center : İstanbul Medipol University, Speech, Language and Swallowing Therapy and Research Center (MEDKOM)

Document Date : 28.06.2022

Informed Consent Form

This study titled "Efficacy of Low-frequency Repetitive Transcranial Magnetic Stimulation on Rehabilitation of Aphasia" aims to investigate effectiveness of repetitive transcranial magnetic stimulation (rTMS) in rehabilitation of people with aphasia. The study has been approved by the Institutional Review Board of Istanbul Medipol University.

rTMS is used to stimulate brain regions to modulate their working patterns. There is some evidence for effectiveness of rTMS in improving language performance in aphasia. In this study, the participants will be randomly assigned to two intervention groups. Both groups will receive the same rTMS procedures except for the location of stimulation in the brain. This way, we aim to compare rTMS application to different brain areas. We will use several language and cognitive assessment tests and an eyetracking experiment throughout the study to assess language outcomes in our participants. The language and cognitive assessments we will conduct are pen-and-paper tests. The eyetracking study involves listening to sentences and looking at pictures on a computer screen, while the camera of the eyetracker keeps track of your eye movements.

rTMS has been shown to be safe when participants are properly screened. The most serious side effect of rTMS is its possibility to trigger an epileptic seizure especially in people with a history of epilepsy. Also, it is advised for people with head implants including cochlear implants, skull plates or deep brain stimulation systems not to undergo rTMS as these implants might be affected by the strong magnetic field created by the device. Therefore, if you have a history of a seizure or carry such an implant, please report it to the clinician and do not participate in this study. Other less serious side effects of rTMS include temporary headaches or neck pain.

The study will be conducted in İstanbul Medipol University, Speech, Language and Swallowing Therapy and Research Center (MEDKOM). rTMS will be administered for 20 minutes daily for a total period of 10 days over two weeks.

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will be offered the treatment that is routinely offered in this clinic/hospital for aphasia, and we will tell you more about it later. You may change your mind later and stop participating even if you agreed earlier.

If you participate in this research, you will have the following benefits: rTMS intervention and language assessments will be offered at no charge to you. Although you may benefit from the

rTMS intervention offered to you, there is no guarantee. Also, your participation is likely to help us find out more about effectiveness of rTMS in aphasia, and develop better treatments in the future. You will not receive monetary compensation for your participation. Any information collected from you will be kept confidential.

You may contact the research team if you have any further questions or if you encounter any side effects throughout the study (contact details of the research team are provided to the participant).

I have read the information above, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research. A copy of this form has been given to me.

Participant's

Name:

Address:

Date and signature:

(If any) Legal representative's

Name:

Address:

Date and signature:

Researcher's

Name:

Title / Position:

Address:

Phone:

Date and signature: