SENSORY BASIS OF SPEECH MOTOR LEARNING
MAGNETIC BRAIN STIMULATION cTBS INFORMED CONSENT FORM
DEPARTMENT OF PSYCHOLOGY, MCGILL UNIVERSITY

NCT04497428

Investigator: David J Ostry, PhD, McGill University

1. TITLE OF PROJECT

Sensory Basis of Speech Motor Learning

2. REASON FOR THE STUDY

We would like you to take part in a research study designed to understand human motor skill learning, and to identify changes to the brain that accompany speech motor learning.

3. PROCEDURES

If you consent to participate, you will be asked to take part in three study visits that will occur one day apart. The first session will take place at the Magnetic Resonance Center at the Montreal Neurological Institute where you will lie in the MRI scanner and repeat words aloud while it obtains an image of your brain. This procedure will take approximately 1 hour. The second and third sessions will take place in the Department of Psychology at McGill University. The second session takes about 2 hours to complete, the third session will take 1 hour. There will be 20 participants in each of the experimental conditions in this study.

In the second and third sessions, you will participate in an experiment that is focused on how we learn to speak. You will be asked to read words presented on a computer screen. You will be assigned to one of two study groups. In one condition, you will wear headphones and hear your voice played back to you as you speak. In the second condition, you will be asked to speak while a small robotic device gently alters your jaw movements.

If you participate in the robot condition, you will wear a custom-made lightweight plastic mouth-piece that fits over your teeth and gums. This mouth-piece provides a way to connect you to the robot in order to carry out the experiment. A second plastic mouth-piece may be attached to your upper teeth. This mouth-piece will be connected to an apparatus that minimizes your head movement during the experiment. The plastic mouth-pieces are created for you individually. In order to manufacture them, we will take dental impressions of your upper and lower teeth. It takes approximately 30 minutes to do the dental impressions.

On the second visit, after the speech motor learning task, we will use a procedure known as continuous theta-burst transcranial magnetic stimulation (cTBS) in order to interfere with the retention of the newly learned motor skill. During this procedure, we will use a magnetic coil that applies pulses to your scalp and briefly stimulates the underlying brain. The main stimulation procedure lasts fifteen minutes in total. We will also record the activity in your facial muscles in response to magnetic stimulation. We will record muscle activity using surface electrodes which will be attached to your lips and face with surgical tape. There is no risk of electrical shock associated with the electrodes. The present study has been designed according to the safety guidelines for transcranial magnetic stimulation (TMS) prescribed by the International Workshop on the Safety of rTMS. On the third visit, you will once again be asked to read words presented on a computer screen.

The brain stimulation procedure is not painful but may produce brief twitches in your facial muscles.

4. CONTRAINDICATIONS

The following are contraindications for participation in this experiment:

- Pacemaker
- Aneurysm clip
- Heart / vascular clip
- Metal prosthesis
- Prosthetic valve
- Claustrophobia
- Metal fragments in body
- Personal and / or family history of epilepsy
- Antipsychotic / antidepressant/ antianxiety drugs

5. ADVANTAGES OF THE PROPOSED STUDY

You will not directly benefit from participating in this study. The study will provide us with information on the brain networks involved in motor learning that may lead to the future benefit of others.

6. DISADVANTAGES OF THE PROPOSED STUDY

If you are tested in the condition where the robot applies small forces to the jaw, a dental adhesive (temporary glue) will be used to hold the mouth-piece in place. The adhesive is temporary and the teeth are totally free of the adhesive within five to ten minutes following the experiment. You will be able to move your mouth freely and talk naturally when connected to the robot.

There is no physical discomfort apart from the sensation that the jaw is being pulled by the robot arm. There is a small possibility of injury caused by the robot. However, we have used a broad range of safety precautions to protect you as much as possible. Tooth damage is unlikely — the forces involved are substantially less than those involved in chewing. As an example, the forces needed to break a peanut are in the range of two to three times the maximum used in the present study. The mouth piece covers the teeth and gums as far back as the second molar and helps spread the small loads that are used in these tests.

We think that these risks are acceptable based on all the available information relevant to the procedures and technologies to be used. It is also based on the safety record of the laboratory personnel who have performed related procedures over the last 15 years without injury to volunteers.

There is a small risk of seizure with any form of transcranial magnetic stimulation. In the past, a small number of seizures were reported in individuals with a history of epilepsy or other neurological disorders. This is why we restrict such individuals from testing. The parameters of stimulation that we will use in this experiment fall well within the safety guidelines laid out for the use of cTBS in neurologically healthy individuals. The other main risk is fainting (syncope). There may also be risks to a fetus that are not yet known. Therefore, if you think there is a possibility you might be pregnant, you should consider not participating in this study.

7. CONFIDENTIAL NATURE OF THIS STUDY

Your results will be kept confidential. The information collected for this study will not be shared with any persons not directly involved with this study. The information collected for this study will be coded. This means that a unique identifier will replace your name and other identifying information at the earliest possible time following data collection. The McGill Institutional Review Board may access the study data to ensure the ethical conduct of this study. Your name will not be mentioned in any publication of the information we collect in this study. Your results will be stored on computers in Dr. Ostry's laboratory at McGill. Continued protection will be provided by the fact that no one other than the investigators have access to the computers used in these studies. The link to personal information will be destroyed as soon as the data have been de-identified. The data will be kept in this anonymous form indefinitely. You are free to withdraw your consent at any point until your data have been de-identified, after which it will no longer be possible to withdraw from the study.

8. DISCONTINUATION OF THE STUDY BY THE INVESTIGATOR

At any time during the testing, the investigators have the right to terminate the study for any reason.

9. WITHDRAWAL FROM THE STUDY

You are free to decide whether or not to participate, and also free to withdraw from the study at any time. You have the right to ask questions at any time. You can choose to not participate in this study, or terminate your participation in this study, at any time.

If you withdraw from this study, you have the right to withdraw your data at any point until the data have been de-identified. If the Investigator wishes to retain your data, your explicit consent must be obtained at the time of your withdrawal. You should also know that any secondary use of de-identified data would be restricted to a research protocol in the same or related area of study and would require approval of the REB (Research Ethics Board).

10. INCIDENTAL FINDINGS

The brain images obtained in these studies are not routinely examined for abnormalities. However, if any abnormalities are identified, you have the option of being provided with this information and, upon request, providing such information to your physician.

11. COMPENSATION FOR PARTICIPATION IN THE STUDY

This study involves a total time commitment of 4 hours. You will receive $150 as compensation. If you withdraw or are withdrawn from the study early, compensation will be pro-rated based on the study tasks you have completed.

12. CONTACT INFORMATION

If you have any questions about rights as a research subject and wish to discuss them with someone other than the individual(s) conducting the study, you should contact the Montreal Neurological Hospital, Patient Ombudsman at (514) 934-1934, X 48306 or Ilde Lepore, Senior Ethics Administrator, McGill University Faculty of Medicine, tel (514) 398 8302. Any other kinds of comments or concerns or assistance needed regarding participation as a research subject in the project can be addressed to the Montreal Neurological Hospital Patients' Committee, Room 354, tel. (514) 398-5358.

Please be aware that this consent form should not be signed until you have a chance to ask and receive satisfactory answers to all questions you may have. If you have any later enquiries about the study please contact the principal investigator, Dr. David Ostry — 514 398 6111.

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DECLARATION OF CONSENT

Department of Psychology, McGill University

I, _____, have reviewed the project with one of the investigators, _____.

I have been informed of the procedures, and the advantages and disadvantages of participating in the study. I freely and voluntarily consent to participate in this study.

Further, I am aware that I may seek information about each test either before or after it is given, that I am free to withdraw from the testing at any time if I desire, and that my personal information will be kept confidential. I do not waive my legal rights by signing this consent form. I will receive a copy of this consent form.

PRINT NAME _____
PARTICIPANT

SIGNATURE _____ _____ _____
PARTICIPANT ***DATE*** ***CONTACT NO.***

PRINT NAME _____
INVESTIGATOR

SIGNATURE _____ _____ _____
INVESTIGATOR ***DATE*** ***CONTACT NO.***