



Department of Veterans Affairs
VA Boston Healthcare System

Information for Physicians and Speech/Language Pathologists who plan to refer chronic stroke patients with aphasia (any type of aphasia) to this research project

Transcranial Magnetic Stimulation (TMS) to Improve Speech and Naming in Aphasia

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The principal aim of the present study is to evaluate whether suppressing the activity of certain brain areas in the right hemisphere, for a short amount of time may result in a paradoxical improvement of naming in patients who have long-standing aphasia after a left hemisphere stroke. The hypothesis underlying this aim is that activity of certain brain areas in the right hemisphere in patients with persistent aphasia after a stroke, contributes to sustain the speech disorder. Suppression of this activity in the right hemisphere, may therefore release the rest of the brain of a negative input and improve naming behavior.

Stroke Patients who are eligible to enter the study:

Age 45 - 80 years; single stroke on left side of the brain (no previous strokes or stroke on the right side of the brain); at least 6 months after stroke onset; patient is right-handed and a native speaker of English.

It is preferred that the patient lives in the Boston metropolitan area, or in Massachusetts. However, for this research project, patients from elsewhere are eligible for the study and will be able to stay for the duration of the study at the General Clinical Research Center (GCRC) at the Beth Israel Deaconess Medical Center (BIDMC), Boston. The GCRC is funded by NIH to support clinical research. There is no cost to the patient for overnight stays.

This repetitive Transcranial Magnetic Stimulation (TMS) project has approved Informed Consent Forms issued from the VA Boston Healthcare System, Human Studies Subcommittee and the Committee on Clinical Investigations, Beth Israel Deaconess Medical Center, Boston.

The patient will be paid for participation in the project. If the patient is interested in more detailed information on the research project, we can meet with the patient and family, and provide a copy of these Informed Consent Forms.



Process for referral to this research project, and what is involved with participation:

1. Referral from a Speech/Language Pathologist, or Neurologist who is familiar with the patient, to Ethan Treglia, M.S., CCC-SLP, Telephone: 857-364-2631 or email: etreglia@bu.edu
OR Margaret Naeser, Ph.D. Telephone: 857-364-4030 or email: mnaeser@bu.edu
2. Dr. Naeser or someone from her lab meets with the patient (and a family member) for about an hour, to explain the procedures involved.
3. If the patient agrees, and he/she signs the Informed Consent Form, a few appointments are made:
 - a. Appointment for Baseline Language testing (parts of the Boston Diagnostic Aphasia Exam and Boston Naming Test) with Ethan Treglia, M.S., CCC-SLP, in Dr. Naeser's lab, Boston VAMC, Room D12-87. This appointment lasts about 1 hour.
 - b. Appointment for a MRI brain scan (3-dimensional MRI scan) at the Boston University Center for Biomedical Imaging (BU CBI). This MRI scan appointment takes about one hour.
 - c. Three short (15-minute) appointments in Dr. Naeser's office at the Boston VAMC, Room 12D-87, for Baseline Naming testing.

Baseline Naming is tested with ten separate lists, 20 pictures per list (Snodgrass Vanderwart pictures - simple ones such as duck, apple, sofa, etc.). This is performed using a laptop computer screen. The first visit consists of training the patient to become familiar with naming the pictures shown on a computer screen. Two Test lists of 20 pictures are also administered. Four other Test lists of 20 pictures each, are administered on two later visits. Each list takes only 4 minutes to complete. There are different pictures on each of the ten Test lists.

Each picture is shown for 10 seconds and the patient's speech is tape-recorded. If the patient cannot name the picture in 10 seconds, that is OK, and the next picture is automatically shown on the computer screen.

4. If the patient can name an average of at least 3 of the 20 pictures across the ten lists, that patient is appropriate to enter the study.

Phase 1.

The patient makes 3 visits to the Transcranial Magnetic Brain Stimulation Laboratory, Beth Israel Deaconess Medical Center, Boston, for 5 repetitive Transcranial Magnetic Stimulation sessions. During a TMS session, the patient sits in a comfortable armchair.

The TMS session consists of the placement of a hand-held figure-of-eight shaped coil over the side of the head. The coil is about the size of a telephone receiver. The exact placement is determined from the 3-dimensional MRI scan that is imaged on a computer screen in the TMS lab. A different region in the brain is stimulated at each of the treatment sessions.



The magnetic coil will discharge a magnetic pulse once per second for 10 minutes. It feels like a small, quick tap on the head. Our patients have not complained of any discomfort. The area of the brain cortex, which is treated, is about a half-inch square (1cm x 1cm).

The one-pulse-per-second stimulus will suppress the activity of the cortical area targeted for a few minutes. There are four cortical areas that are examined: right pars triangularis, anterior portion; right pars triangularis, posterior portion; right pars opercularis; right motor cortex mouth area (based on MEP for left, first dorsal interosseus muscle).

The rationale for the brain areas chosen for treatment with TMS is taken from our previous functional magnetic resonance imaging (fMRI) research.

The patient's ability to name pictures is tested *immediately before*, and *immediately after*, the TMS treatment using the same laptop computer that was used in Dr. Naeser's office at the Boston VAMC during the initial Baseline Naming testing. The effect will last for only approximately 8 minutes, when the TMS stimulation is performed for only 10 minutes.

During Phase 1, there are 3 visits to the Beth Israel Hospital TMS lab, and 2 different cortical areas are stimulated at each visit, with a 45-minute break in between. Each of these visits lasts about 2 hours.

The patient will be paid \$50 after completion of Phase 1.

If there is a positive change in naming ability, for one of the brain regions stimulated in Phase 1, then the patient may enter Phase 2.

Phase 2.

During Phase 2, the brain region that produced the most improvement in naming pictures during Phase 1, is then treated 20 minutes a day, for 5 days a week, for two weeks. Thus, during Phase 2, the patient receives at least 10 TMS treatment sessions and each treatment lasts a longer time, 20 minutes. Each appointment during Phase 2, however, is only about one hour.

We expect the longer treatment sessions of 20 minutes (over two weeks) may produce improvement in naming that may last up to two months, but we do not know.

Some of the treatments during Phase 1 or Phase 2 may be sham treatments. All patients will, at some time, receive a full series of the 20-minute TMS treatments that are real, and not sham. At the end of the patient's participation in the study, the patient will be told which treatment sessions were real, and which sessions were sham.

Naming and Language tests are again administered by Ethan Treglia, M.S., CCC-SLP in Dr. Naeser's lab, Boston VAMC, within a week after the last TMS treatment in Phase 2, and again at 2 months later.

The patient will be paid \$60 after completion of Phase 2.



Please contact Ethan Treglia, M.S., CCC-SLP or Dr. Naeser at the above-listed telephone numbers and/or emails for referral of an aphasia patient to this project.

As mentioned above, the patient is welcome to stay a few days or weeks, if necessary, at the BIDMC General Clinical Research Center (GCRC) at no cost to the patient or the insurance company, while participating in this research project. This will provide closer oversight of the patient during participation in the study.



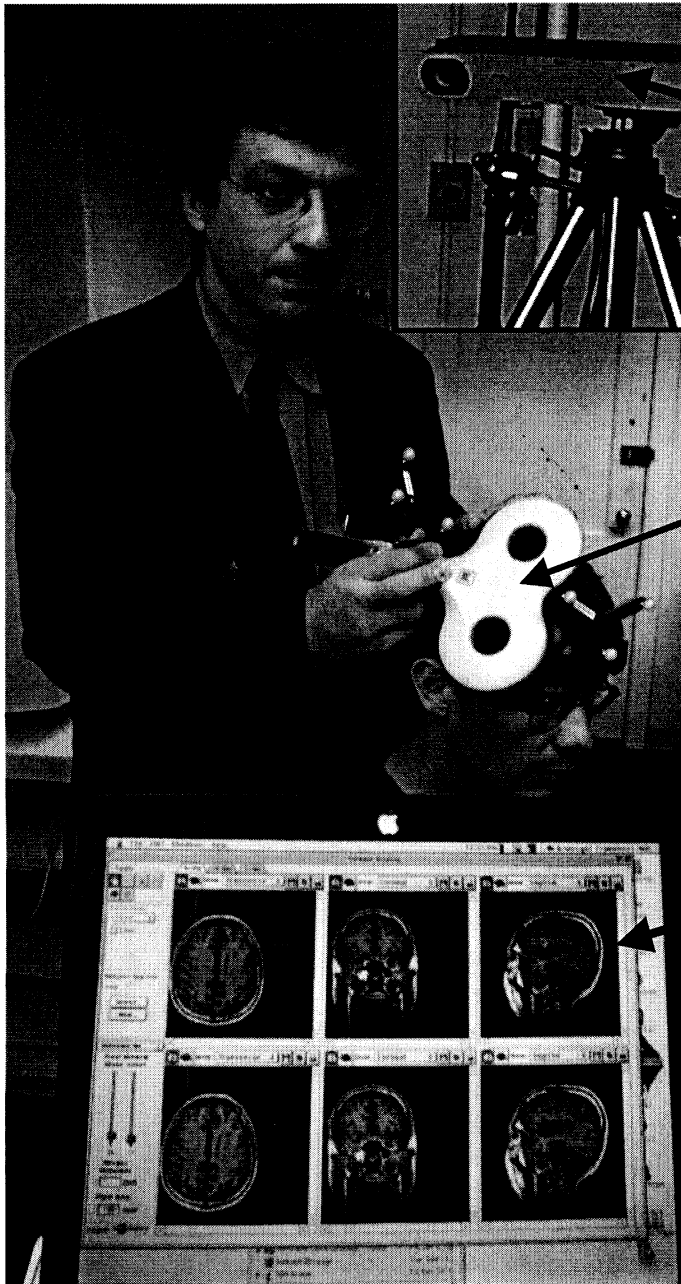


Figure 1:

Infra-red camera:

detects the position of subject's head.

Transcranial Magnetic Stimulation (TMS) coil:

treats the brain cortex and is painless and non-invasive

Brain MRI: helps to position the TMS coil.

