COMMUNICATION SCIENCES AND DISORDERS
ARNOLD SCHOOL OF PUBLIC HEALTH

CONSENT TO BE A RESEARCH PARTICIPANT

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NEURAL BASES OF VOCAL SENSORIMOTOR IMPAIRMENT IN APHASIA

KEY INFORMATION ABOUT THIS RESEARCH STUDY:

You are invited to volunteer for a research study conducted by Dr. Roozbeh Behroozmand. Dr. Behroozmand is an Associate Professor in the Department of Communication Sciences and Disorders, at the University of South Carolina. The University of South Carolina, National Institute of Health (NIH), and National Institute on Deafness and Other Communication Disorders (NIDCD) are sponsoring this research study. The purpose of this study is to investigate how stroke-induced damage to the brain impairs speech function. You are being asked to participate in this study because you have suffered from stroke or are part of a healthy control group for this study. This study is being done in the Speech Neuroscience Lab at the Department of Communication Sciences and Disorders at the University of South Carolina and will involve approximately 200 volunteers.

PURPOSE OF THE STUDY:

This research project is part of a broader communication disorders program to study brain mechanisms of speech function and its impairment in individuals with post-stroke aphasia and an age- and gender-matched control group. We aim to measure speech behavior concurrent with brain activity using electro-encephalography (EEG) electrodes placed on the surface of scalp and magnetic resonance imaging (MRI). Participants will be asked to perform tasks including speech vowel sound production, word/sentence reading, picture naming, identifying or matching speech sounds, and producing musical notes while different parameters of their speech (volume, pitch, formant [or quality], and timing) are altered online and fed back to ears through headphones. In addition, we seek to examine the effects of training on improving speech production. Training involves controlling the position of visual cursors on the computer screen to hit desired targets via controlling speech output. The goal of this research is to shed light on the brain areas and neural mechanisms involved in speech production and their impairment due to brain damage following stroke. The outcome of this research will help develop new technologies for diagnosis and treatment of speech disorders in stroke-induced aphasia and other neurological conditions.

ELIGIBILITY TO PARTICIPATE:
Approximately 100 individuals with aphasia due to chronic stroke (> 6 months post-stroke) and 100 healthy individuals with no history of neurological and psychiatric condition and no history of speech, language, and hearing disorder will participate in this study. All participants will be 21-80 years. You will be excluded from this study if you do not have the ability to provide informed written or verbal consent and/or do not have the ability to understand study instructions or perform speech tasks required for completion of this research study.

This form explains what you will be asked to do, if you decide to participate in this study. Please read it carefully and feel free to ask questions before you make a decision about participating.

DESCRIPTION OF STUDY PROCEDURES:
Study activities will take place in the Speech Neuroscience Lab at Discovery Building and/or the McCausland Center for Brain Imaging at the University of South Carolina. If you agree to participate in this study, you will be asked to do the following:

1. During the first session, you will be asked to fill out a questionnaire form, in order for us to collect data on your name, date of birth, contact information, gender, handedness, ethnicity, native language, language competence (if other than English), educational background, vision, hearing, background of music/voice training, scalp sensitivity and medical history. A speech-language pathologist will assess your speech, language, and hearing function and will conduct a series of memory and neuro-cognitive tests. In addition, you will be asked to complete an MRI safety screening questionnaire.

2. Following the preliminary tests, you will be prepared for speech and EEG data recording in a sound-attenuated booth located in Discovery Building. For this task, you will be comfortably seated in a chair and a microphone will be positioned near your lips to record your speech. You will also be asked to wear headphones or insert earphones will be placed in your ears canals, through which you will hear your own speech feedback through headphones. You will be asked to follow visual or sound cues or read instructions on a computer monitor to perform a variety of speech tasks including steady vowel sound vocalizations, word production, sentence reading, picture naming, speech sound matching, speech identification, and producing a musical note while different parameters of your speech (e.g. volume, pitch, formant [or quality] and timing) are altered. You may also be asked to press a button for registering your responses or triggering visual or sound outputs.

3. The brain activity signals will be recorded by placing an EEG cap with 64 electrodes on your scalp. The connectivity between scalp and electrodes will be established by gently scrubbing your scalp for each electrode and then filling each electrode with conducive gel. After speech and EEG data collection for the required number of trials, the experiment will conclude and the microphone, headphones (or insert earphones) and the EEG cap will be removed. You will be given tissues to remove any remaining gel from your scalp and hair and we advise you to rinse your hair on the same day, so that any remaining gel does not harden.

4. If you pass the MRI screening test, you will be invited to the McCausland Center at USC for MRI scanning on a different day after the EEG recording session. During this session, high-resolution anatomical scans will be obtained from your brain and your brain activity will be recorded using fMRI while you perform the same speech tasks in the scanner that you completed during the EEG recording session (see section 2 above for detailed descriptions).

5. After completing the EEG and MRI recording sessions, you will undergo maximum of three audio-visual feedback training sessions on different days. During these sessions, you will be trained to work with a computer setup to use your speech to control the position of visual objects on the computer screen to hit desired speech targets while you receive alteration in your speech feedback through headphones (volume, pitch, formant [or quality] and timing).

6. After completing the training sessions, you will be tested during a post-training session to assess your speech production. This session will involve repeating the same pre-training speech tasks under altered speech feedback while EEG signals are recorded (see section 2 above). If you have passed the MRI safety screening, you will be invited to participate for a second MRI scanning on a different day following EEG recording to complete the same speech tasks under altered speech feedback as described in sections 2 and 3 above.

DURATION:

Participation in the study involves a maximum of seven experimental session on different days. Each experimental session will last approximately 2-4 hours.

RISKS/DISCOMFORTS:

Speech recording: During the speech production and/or training tasks, you may experience slight fatigue in your vocal/speech production muscles but that should not last long. If at any time your throat feels dry or you feel tired during speech production, you will be asked to stop, take a rest and have a drink of water. You may do this as often and whenever necessary. Occasionally, individuals will have a negative reaction to neuropsychological assessment, experimental testing and/or training procedures. For example, this can be caused when individuals realize that their performance on a given task is far worse than they would have expected. We always make sure that ample time is allotted for testing and you will be allowed breaks as many times as you need.

EEG recording: EEG preparation and recording causes no harm and little to no discomfort, and has no long term side effects. Slight discomfort may be caused from the preparation of electrodes, the pressure of the cap on your scalp, or slight skin irritation from the application of the conductive gel. However, researchers are trained to minimize this discomfort as much as possible. When the cap is removed, gel may remain in your hair but can be washed out easily using water. No sensations will be transmitted; only brain waves will be recorded.

MRI scanning: Because the MRI machine acts like a large magnet, it could move metallic objects in the MRI room during your examination, which could possibly harm you. Precautions have been taken to prevent such an event from happening; loose metal objects, like pocket knives or key chains are not allowed in the MRI room. If you have a metal implant in your body, such as a fragment in your eye, aneurysm clips, ear implants, spinal nerve stimulators, or a pacemaker, you will not be allowed into the MRI room and cannot have an MRI scan. Having an MRI scan may mean some added discomfort to you. In particular, you may be bothered by feelings of claustrophobia and by the loud scanner noise during the study. Most people report, however, felling less claustrophobic during functional MRI than during a routine MRI scanning. This has to do with the visual presentation system used in fMRI studies in that the video screen gives the illusion of the scanner tunnel being larger due to 3D effects. Also, temporary hearing loss has been reported from the loud noise. This is why you will be asked to wear headphones and earplugs during MRI scanning.

Loss of Confidentiality: There is the risk of a breach of confidentiality, despite the steps that will be taken to protect your identity. Specific safeguards to protect confidentiality are described in a separate section of this document.

RESEARCH-RELATED INJURY:
In the event you are injured while participating in this research study, the principal investigator, and research staff will provide first aid with available resources and arrange for transportation to the nearest emergency medical facility, if appropriate. The University of South Carolina does not assume financial responsibilities for any medical care other than first aid.

INCIDENTAL FINDINGS:
These procedures are carried out purely for experimental purposes. The MRI scans that are acquired in this study are not the same as those acquired during a clinical examination as requested by a medical doctor; therefore, they are not useful to investigate any brain abnormalities. Furthermore, the investigators who will analyze these images are not medical doctors and are not trained to evaluate these scans. It is possible however that a brain abnormality may be noticed. If this happens, you will first be contacted the principal investigator and shown the abnormality. You will be provided with copies of the scans to take to your medical care provider. If you do not have a medical care provider, we will assist you with a referral. However, any costs associated with any medical advice, care, or treatment related to the scans will be you/your insurance carrier's responsibility. As the researchers are not medically trained, failure to detect an abnormality does not mean that you do not have a brain abnormality.

If you do NOT wish to be informed of such finding, you should NOT participate in this study.

BENEFITS:
Taking part in this study is not likely to benefit you personally. However, this research may help researchers understand about brain mechanisms involved in speech production and their impairment due to stroke. The outcome of this research may help develop speech treatment methods for patients with stroke and other neurological diseases.

COSTS:
There will be no costs to you for participating in this study other than possible costs related to transportation to and from the research site.

PAYMENT TO PARTICIPANTS:
You will be monetarily compensated for your time at the rate of $15/hour for your participation. Should you decide to withdraw from the experiment after a session has started, you will receive the payment for the time your participated in the study at $15/hour. You will need to complete a payment receipt form for cash/prepaid debit card payments, or a W9 plus a check request form for check payments to be delivered to your mailing address (approx. 2-3 weeks processing time).

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CONFIDENTIALITY OF RECORDS:
You will be identified on all research records solely by a number, ensuring confidentiality of all data. Any information that is obtained in connection with this study and that could identify you will remain confidential and will not be released or disclosed without your further consent, except as specifically required by law. If the results of this research are published or presented at scientific meetings, your identity will not be disclosed. The Institutional Review Board Office may request access to this form to ensure procedures designed to protect research participants are being properly followed. Data concerning your age, gender, handedness, task performance, etc. will be collected. All data gathered from this study will be maintained by the investigator for three-years or as required by journal, federal or state regulation.

VOLUNTARY PARTICIPATION:
Participation in this research study is voluntary. You are free not to participate, or to stop participating at any time, for any reason without negative consequences. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner. If you wish to withdraw from the study, please call or email the principal investigator listed on this form.

CONTACT PERSON(S):
I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study, I am to contact Dr. Roozbeh Behroozmand at 803-777-5055 or email r-behroozmand@sc.edu.

Questions about your rights as a research subject are to be directed to, Lisa Johnson, Assistant Director, Office of Research Compliance, University of South Carolina, 1600 Hampton Street, Suite 414D, Columbia, SC 29208, phone: (803) 777-6670 or email: LisaJ@mailbox.sc.edu.

I agree to participate in this study. I have been given a copy of this form for my own records.

If you wish to participate, you should sign below.

_____	_____
Signature of Subject / Participant	Date
_____	_____
Signature of Qualified Person Obtaining Consent	Date