SENSORY BASIS OF SPEECH MOTOR LEARNING

PAIRING OF SOMATIC INPUTS AND SPEECH SOUNDS IN SPEECH MOTOR LEARNING

June 6, 2019

CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT

YALE UNIVERSITY SCHOOL OF MEDICINE – HASKINS LABORATORIES

Study Title: Sensory Basis of Speech Motor Learning
Principal Investigator: David J Ostry
Phone Number: (203) 865 6163
Funding Source: NIH

Specific Aim 3.1: Pairing of Somatic Inputs and Speech Sounds in Speech Motor Learning

Research Study Summary:

We are asking you to join a research study. The purpose of this research study is to understand how auditory and somatosensory sensory information jointly contribute to speech motor learning. The study procedures will include: behavioral testing. Three study visits are required. The visit will take two and a half hours in total. There are some risks from participating in this study. The primary risk is an allergic reaction to surgical tape that is used on the face. The study will have no benefits to you. Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits. If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Take as much time as you need before you make your decision. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

Invitation to Participate and Description of Project

You are invited to participate in a research study designed to understand speech motor learning. We hope that by better understanding speech motor learning we will be better able to design therapeutic procedures for speech learning deficits. If you participate, you will be asked to take part in three sessions that will take place at Haskins Laboratories. The purpose of the study is to learn more about the processes involved in learning to speak

Description of Procedures

If you decide to participate, there will be three sessions, the first lasting approximately 90 minutes and the second and third about 30 minutes each. You will be asked to do the following tasks:

1) The task involves listening to speech sounds that will be played through headphones. As you listen to the speech sounds a small robotic device may gently stretch your facial skin. The skin stretch involves small plastic tabs which are attached to your cheeks using double-sided tape, which in turn are connected to the robotic device.

2) Speech perception tests will be conducted during all three sessions. The second session with be one day after the first. The third session will be one week later.

Risks and Inconveniences

There is no physical discomfort associated apart from a slight tug to the facial skin. There is a possible allergic reaction to the adhesive tape used on the cheek.

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.

Benefits

Knowledge gained from this study may provide information to the scientific and educational community that would further the understanding of speech motor learning and its disabilities.

Economic Considerations

You will receive $20 / hour monetary compensation for your participation in the experiment.

Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institute for Deafness and Communicative Disorders which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

Any identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission or as permitted by U.S. or State law. Examples of information that we are legally required to disclose include abuse of a child or elderly person, or certain reportable diseases. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

We understand that your information is personal, and we are committed to protecting the privacy of that information. If you decide to be in this study, the researcher will get information that identifies you. This may include information that might directly identify you, such as your name. This information will be de-identified at the earliest reasonable time after we receive it, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator will keep a link that identifies you to your coded information, and this link will be kept secure and available only to the PI or selected members of the research team. The link to your personal information will be kept for 6 years, after which time the link will be destroyed and the data will become anonymous. The data will be kept in this anonymous form indefinitely. No names will appear in any publication or be mentioned in any public place in connection with this project.

Information about you which might identify you may be used by or given to:

- Department of Health and Human Safety (DHHS), representatives from Yale University and the Human Investigation Committee (the committee that reviews, approves, and monitors research on human subjects), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- Study personnel, including the PI (Dr. David J Ostry), and other investigators

By signing this form, you authorize the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing is to ensure that the information relating to this research is available to all parties who may need it for research purposes.

In Case of Injury

If you are injured while on study, seek treatment as soon as you are able. Haskins Laboratories does not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available. You do not give up any of your legal rights by signing this form.

Voluntary Participation and Withdrawal

You are free to choose not to take part in this study. This will not affect your relationship with Haskins Laboratories or the Yale School of Medicine. However, you will not be able to enroll in this research study and will not receive study procedures as a study participant if you do not allow use of your information as part of this study.

If you are a subject, you are free to stop and withdraw from this study at any time during its course. If you sign this authorization, you may change your mind at any time, but the researchers may continue to use information collected before you changed your mind to complete the research. To withdraw, you can call or email a member of the research team at any time and tell them that you no longer want to take part. This will cancel any appointments in the future.

This authorization to use and disclose you information will never expire unless and until you change your mind and revoke it.

The researchers may withdraw you from participating in the research if you are not compliant with the experimental tasks.

Questions

Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Principal Investigator, David J Ostry at (203) 865 6163.

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

Authorization and Permission

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of my involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

By signing this form, I give permission to the researchers to use [and give out] information for the purposes described in this form. By refusing to give permission, I understand that I will not be able to be in this research.

Name of Subject:_____

Signature:_____

Date:_____

_____ _____

Signature of Person Obtaining Consent Date