SENSORY BASIS OF SPEECH MOTOR LEARNING

SENSORY WORKING MEMORY AND SPEECH MOTOR ADAPTATION

June 15, 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

Aim 2.1: Sensory Working Memory and Speech Motor Adaptation

Research Study Summary:

We are asking you to join a research study. The purpose of this research study is to understand the relationship between short-term sensory memory and speech motor learning. The study procedures will include: behavioral testing. One study visit is required. The visit will take 90 minutes in total. There are some risks from participating in this study. The primary risk, although highly improbable, is injury as a result of the robotic device used in the experiment. 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 one session 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 one session lasting approximately 90 minutes in which you will be asked to do the following tasks:

1) You will be asked to read words presented on a computer screen. During this procedure, you will either wear headphones and hear your voice played back to you as you speak or you will be asked to speak while a small robotic device gently alters the movement path of your jaw.
2) If you participate in the robot condition, you will wear a custom-built lightweight plastic mouth-piece that fits comfortably over the teeth and gums of your lower jaw. This

mouth-piece provides a way to connect you to the robot in order to carry out the measurements. A second plastic mouth-piece may be attached to your upper teeth. This mouth-piece will be connected to a head positioning system that will be used to minimize 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.

3) We will conduct a test of auditory memory in which you will be asked to listen to a set of sounds or digits through headphones and then tell us whether a test sound (or digit) which is presented afterwards is one of the ones that you heard first.
4) We will also conduct a test of tactile memory in which small plastic tabs will be taped to your lips with two-sided tape. A small robotic device that is connected to the tabs with thin wires will slightly pull on the skin of your lips in a series of different directions. Afterwards a further "test stretch" will be applied by the robot and you will have to indicate whether or not it was one of the previous stretch directions.

Risks and Inconveniences

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 jaw freely and talk naturally when in contact with the robot.

There is no physical discomfort apart from the sensation that the jaw is being pushed 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.

In experiments involving facial skin stretch, there is no physical discomfort 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, emergency help will be provided including transport to the emergency room if needed. Haskins liability insurance will cover the cost of emergency medical 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

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

Aim 2.2: Ventrolateral Prefrontal Cortex 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 the role of prefrontal areas of the brain in speech motor learning. The study procedures will include: brain scans, behavioral testing, and non-invasive magnetic brain stimulation. Three study visits are required. These visits will take six hours in total. There are some risks from participating in this study. The primary risk is fainting. 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

We invite you to take part in a research study designed to understand speech motor learning. We hope that by better understanding speech motor learning in healthy people, we will be better able to design therapeutic procedures for speech learning deficits. If you participate, you will be asked to take part in two sessions that will take place at Haskins Laboratories and one further session at the Yale University Magnetic Resonance Research Center. The purpose of the study is to learn about the brain areas involved in learning to speak.

Description of Procedures

If you decide to participate, there will be three sessions lasting approximately six hours in total in which you will be asked to do the following tasks:

1) Magnetic resonance imaging: The first session of the experiment takes place at the Yale University Magnetic Resonance Research Center in The Anlyan Center (TAC) during which we will record images of your brain. While in the scanner, we will ask you to listen to words presented through earphones and repeat them aloud. We will also ask you to simply rest in the scanner while we take a picture of your brain that we will use in later parts of the study. The entire imaging procedure takes approximately 45 minutes. A

member of the research team will accompany you to the brain imaging center and will stay with you for the duration of this phase of the study.

2) The portion of the study at Haskins Laboratories will take place after the MRI session on two different days. On each day we will first use magnetic brain stimulation that is applied to the surface of the scalp using a stimulating coil to reduce, for approximately one hour, the activity in an area of the brain associated with short term sensory memory. The brain stimulation procedure, which is known as known as continuous theta-burst stimulation (cTBS) is not painful and you will not notice any of its effects.
3) Afterwards, on one day, we will conduct a test of auditory memory in which you will be asked to listen to a set of sounds or digits through headphones and then tell us whether a test sound (or digit) which is presented afterwards is one of the ones that you heard first.
4) On that same day, we will also conduct a test of tactile memory in which small plastic tabs will be taped to your lips with two-sided tape. A small robotic device that is connected to the tabs with thin wires will slightly pull on the skin of your lips in a series of different directions. Afterwards a further "test stretch" will be applied by the robot and you will have to indicate whether or not it was one of the previous stretch directions. These two procedures take approximately 90 minutes in total.
5) On a separate day, which also starts with the brain stimulation procedure, you will be asked to read words presented on a computer screen. During this procedure, you will either wear headphones and hear your voice played back to you as you speak or you will be asked to speak while a small robotic device gently alters the movement path of your jaw.
6) If you participate in the robot condition, you will wear a custom-built lightweight plastic mouth-piece that fits comfortably over the teeth and gums of your lower jaw. This mouth-piece provides a way to connect you to the robot in order to carry out the measurements. A second plastic mouth-piece may be attached to your upper teeth. This mouth-piece will be connected to a head positioning system that will be used to minimize 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.

Risks and Inconveniences

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 jaw freely and talk naturally when in contact with the robot.

There is no physical discomfort apart from the sensation that the jaw is being pushed 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.

In experiments involving facial skin stretch, there is no physical discomfort apart from a slight tug to the facial skin. There is a possible allergic reaction to the adhesive tape used on the cheek.

Magnetic resonance (MR) is a technique that uses magnetism and radio waves, not xrays, to take pictures and measure chemicals of different parts of the body. The United States Food and Drug Administration (FDA) has set guidelines for magnet strength and exposure to radio waves, and we carefully observe those guidelines.

You will be watched closely throughout the MR study. Some people may feel uncomfortable or anxious. If this happens to you, you may ask to stop the study at any time and we will take you out of the MR scanner. On rare occasions, some people might feel dizzy, get an upset stomach, have a metallic taste or feel tingling sensations or muscle twitches. These sensations usually go away quickly but please tell the research staff if you have them. There are some risks with an MR study for certain people. If you have a pacemaker or some metal objects inside your body, you may not be in this study because the strong magnets in the MR scanner might harm you. Another risk is the possibility of metal objects being pulled into the magnet and hitting you. To lower this risk, all people involved with the study must remove all metal from their clothing and all metal objects from their pockets. We also ask all people involved with the study to walk through a detector designed to detect metal objects. It is important to know that no metal can be brought into the magnet room at any time. Also, once you are in the magnet, the door to the room will be closed so that no one from outside accidentally goes near the magnet.

We want you to read and answer very carefully the questions on the MR Safety Questionnaire related to your personal safety. Take a moment now to be sure that you have read the MR Safety Questionnaire and be sure to tell us any information you think might be important.

This MR study is for research purposes only and is not in any way a complete health care imaging examination. The scans performed in this study are not designed to find abnormalities. The principal investigator, the lab, the MR technologist, and the Magnetic Resonance Research Center are not qualified to interpret the MR scans and are not responsible for providing a health care evaluation of the images. If a worrisome finding is seen on your scan, a radiologist or another physician will be asked to review the relevant images. Based on his or her recommendation (if any), the principal investigator or consulting physician will contact you, inform you and your parents of the finding, and recommend that you seek medical advice as a precautionary measure. The decision for additional examination or treatment would lie only with you and your physician. The investigators, the consulting physician, the Magnetic Resonance Research Center, and Yale University are not responsible for any examination or treatment that you receive based on these findings. The images collected in this study are not a health care MR exam and for that reason, they will not be made available for health care purposes.

This experiment will also use a procedure known as transcranial magnetic stimulation (TMS) and in particular a variant known as continuous theta-burst stimulation (cTBS). 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 itself takes one minute and is applied twice separated by a 10 minute break. There is no risk of electrical shock. The brain stimulation procedure is not painful but may produce brief twitches in your facial muscles or in your arm. The present study has been designed according to the safety guidelines for TMS prescribed by the International Workshop on the Safety of rTMS.

The following conditions are considered risk factors for transcranial magnetic stimulation. Your participation is not allowed if any of these conditions applies to you:

1) Pacemaker
2) Aneurysm Clip
3) Heart/Vascular Clip
4) Prosthetic Valve
5) Metal Prosthesis
6) Cochlear Implant
6) Pregnancy
7) Personal and/or family history of epilepsy or other neurological disorders
8) Antipsychotic / antidepressant/ antianxiety drugs

For TMS, there is a small risk of seizure. 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 TMS in neurologically healthy individuals. The other main risk is fainting (syncope). There is also a potential risk of TMS to a fetus.

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 $50 / hour monetary compensation for your participation in the three session 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, emergency help will be provided including transport to the emergency room if needed. Haskins liability insurance will cover the cost of emergency medical 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

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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