ClinicalTrials.gov Title Page

Document: Informed Consent Form

Official Study Title: Speech Perception Training: Advanced Scoring and Feedback Methods

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Informed Consent Form – Remote-Only Administration (HI)

TITLE: Speech Perception Training: Advanced Scoring and Feedback Methods

GWU IRB #011715

PRINCIPAL INVESTIGATOR: Lynne E. Bernstein, Ph.D., Dept. Speech, Language, and Hearing Sciences.
Contact: Silvio P. Eberhardt, (484) 5576593

SPONSOR
Subaward from SeeHear LLC for a project funded by National Institutes of Health (NIH)
(Lynne E. Bernstein, Ph.D., Principal Investigator at GWU)
(Silvio P. Eberhardt, Ph.D., Principal Investigator at SeeHear LLC)

INTRODUCTION
You are invited to take part in a research study being conducted by Dr. Lynne E. Bernstein of the Communication Neuroscience Laboratory, Speech, Language, and Hearing Sciences Department, George Washington University (GWU).

You are being asked if you want to take part in this study, because you are a native speaker of American English, without a history of brain trauma or learning disabilities, have hearing loss and/or difficulties understanding speech in noisy situations, and have normal or corrected-to-normal vision. You must be between 55 and 80 years old to take part in this study.

Please read this form carefully, and ask us any questions that will help you decide if you want to be in the study. Taking part is completely voluntary, and even if you decide you want to participate, you can quit at any time. You may also leave blank answers for questionnaire items, if you are for any reason not comfortable giving an answer. In a few cases, such as not providing month and year of birth, this may disqualify you from further participation.

You are one of about 270 people taking part in this study for George Washington University.

In order to participate, you must have access to and understand how to use a desktop or laptop computer with a 10-inch in diagonal screen or larger. You must be able to use audio from your computer in order to communicate with the experimenters and carry out parts of the study. If you have difficulty understanding speech with your computer's audio, you may need to use your own external loudspeaker. You must be able to use the same computer and audio setup for each session of the study. Preferably, you should be in a quiet location that is the same physical location for each session of the study. You must have a reliable internet connection capable of streaming video.

In some circumstances, your participation in the research study may be discontinued against your will. This would include situations such as: Results from various tests, such as hearing, lipreading, or vision tests being out of the range required for participation; A failure to keep appointments or to follow the directions of the research staff; If your scores during the experiment indicate that you are no longer paying attention; If conditions change such that you no longer meet the original eligibility requirements; If your computer, sound system, and/or internet connection are not adequate; Or in case of termination or cancellation of the study by the study sponsor.

If you have hearing loss, we will request that you mail, email, or fax your audiogram that you obtained most recently. If you do not have or cannot obtain an audiogram from an audiologist, please let us know. If you are a patient at the GWU Speech & Hearing Center and sign a release form to allow us access to your audiological records, we will obtain your audiogram. If your audiologist is not at GWU, and you sign a release form, we will attempt to obtain your audiogram for you.

PURPOSE

The purpose of this study is to determine how much improvement in speech perception can be gained when training is carried out with visual speech or audiovisual speech.

PROCEDURES

The total amount of time you will spend in this study is either as little as about 3 hours, if you are assigned to a no-training control group, or as many as about 11 hours if, you are assigned to a training group. Different activities will be carried out on different days. In general, between 30 and 60 minutes will be needed for each day's activities.

You will have three teleconference sessions (using Zoom, or Skype).

In your first teleconference session (about 60 minutes), you can ask questions about the study and this consent form. If you consent to participate, you may receive a vision screening test (10 minutes). The vision screening is a computer-administered test of acuity and contrast sensitivity. You will use your computer to perform a lipreading screening (12 minutes) test. The lipreading test asks you to lipread isolated sentences and type what you think the talker said. You may receive a test of awareness about common day-to-day topics (10 minutes). The test asks simple factual questions. You will be asked demographics questions (2 minutes) and questions about your hearing (5 minutes). You may leave blank answers for questions that make you feel uncomfortable. In a few cases, such as not providing month and year of birth, this may disqualify you from further participation. The experimenters will review all of your responses, and if they qualify you for participation, a sound level meter will be sent to you, and your second teleconference will be scheduled.

In the second teleconference session (about 60 minutes), you will perform listening and speech recognition tests. First, you will receive instructions for using your sound level meter (sent to you by the experimenters) to adjust the audio from your computer. Then the experimenter will administer a hearing screening with tones (8 minutes), a test of your hearing in noise with sentences (10 minutes), and a test of your hearing in noise with digits (10 minutes). Then you will perform speech recognition tests. The first test will be with isolated words. You will hear the words in noise, and half will be for listening only, and the other half will be for listening and watching the talker. You will type what you think the talker said. The second test will be with isolated sentences. You will hear the sentences in noise, and half will be for listening only, and the other half will be for listening and watching the talker. You will type what you think the talker said. Then you will receive instructions for tests to complete on your own (30 minutes). You will also be asked questions about your hearing (8 minutes). If you are assigned to training, you will also receive instructions for your training.

The tests you will be asked to complete on your own will be to lipread isolated words and type in what was said, and to lipread isolated sentences and type in what was said. You will also view nonsense words and identify the consonants in the words. After these tests, if you are assigned to training, you will be asked to train in 10 separate sessions.

If you are assigned to training, you will be asked to train for 10 sessions across at least 10 separate days, with each session taking approximately 30 to 40 minutes. Training may be with silent video

recordings, or with video and audio with noise. You will be asked to perform one of the following two types of training tasks:

(1) Viewing videos of talkers uttering sentences, and typing any words or word fragments that you think may have been said; or

(2) Learning by trial and error to associate a dozen nonsense images with a dozen videos of nonsense words, with images and videos changing each session.

After your training is complete, a third teleconference (about 60 minutes) will be scheduled. Or, if you were not assigned to training, you will participate in a third teleconference. You will repeat some or all of the activities from your second teleconference.

If you are **not** invited to participate in training, you will receive an invitation to optionally use the training system after your third teleconference. Your use of the training system will not be part of the study.

During the course of the study, you may additionally be asked to give responses to the following tests:
Vocabulary. The computer display will show you four pictures on a page, and a word will be played through a loudspeaker or headphones. After you select the picture that best indicates the meaning of the word, the computer will move on to the next word. (10 min).
List-sorting. You will be presented with a list of animals and/or foods that vary in size, and will be asked after an interval to verbally report the food or animals that you remember in order of size. (10 min).

Throughout the study, videos will be presented on your computer monitor at your comfortable viewing distance. Sounds will be presented at a comfortable listening level. Testing intervals are 10-15 minutes long; you will have the opportunity to take a break after each interval.

RISKS & CONFIDENTIALITY
Your participation in this study involves minimal risk.

You may receive loud or otherwise uncomfortable sounds, but the sounds will be presented at levels that are not loud enough to harm your hearing, and you may reduce the levels immediately if you experience discomfort. If you find the sounds uncomfortable, you may turn them off at any time.

There is a small chance that someone not on our research team could find out that you took part in the study or somehow could connect your name with the information we collect about you. The following steps are being taken to reduce these risks: After mailing your consent form and your sound level meter to you (meter is sent only if you are accepted into the study), your mailing address will be deleted. An identifier code will be used to label your data. All personal information other than your email address will be kept on paper only and will be locked in a filing cabinet. Only the laboratory personnel have access to the keys. Your email address will be kept in a repository that is separated through multiple layers of security from your data. It is necessary to store your email address, so that you can recover a lost password, and so that payment can be issued at the conclusion of the study. Your account will be deleted after one month. After all results are published, and an interval of 3-5 years has passed as required by NIH, all of your personal information will be shredded.

The records of this study will be kept private. In any published articles or presentations, we will not include any information that will make it possible to identify you as a participant. However, please

note that your records for the study may be reviewed by NIH oversight committee members, or by departments of the University that are responsible for overseeing research safety and compliance.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects 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 or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The researchers who are carrying out this study have a conflict of interest. They founded a company, SeeHear LLC, to develop commercial products to help people with hearing loss and/or speech-in-noise perception difficulties. The researchers may benefit from your participation, because your participation may improve commercial products they develop. While the researchers would like this study to succeed, they are scientists and will carry out this research project with open minds, ethically, and with the intent to publish the findings in the scientific literature.

BENEFITS
You may benefit personally from this study if the training improves your speech perception in noisy situations. Additionally, participation in this study will produce real benefits to science. Specifically, your participation will allow the researchers to gain knowledge about how to carry out speech perception training and may result in the development of improved training programs.

COMPENSATION
If you are selected to carry out training as part of the study, you will receive a $60 gift card for taking part in this study to compensate you for your time and effort. You will receive $30 gift card for taking part in this study to compensate you for your time and effort **as a participant who does not carry out training during the study**. If you do not complete all parts of the experiment, you will not be paid. You will receive a sound level meter, if you are scheduled to continue beyond the first teleconference. The meter will be yours to keep.

POLICY/PROCEDURES FOR RESEARCH RELATED INJURY
We will make every effort to prevent study-related injuries and illnesses. If you are injured or become ill while you are in the study, and the illness or injury is due to your participation in this study, you agree to seek appropriate medical care at your cost if you are participating remotely. If the injury or illness is sustained at GWU, you will receive necessary medical care at the usual charge. The costs of this care will be charged to you or to your health insurer. No funds are available from George Washington University, George Washington University Hospital, the District of Columbia government or the federal government to repay you or compensate you for a study-related injury or illness.

QUESTIONS
Talk to the research team if you have questions, concerns, complaints, or think you have been harmed. You can contact the Principal Investigator listed on the front of this form (Dr. Bernstein) at (202)994-7403. For questions regarding your rights as a participant in human research call the GWU Office of Human Research at 202-994-2715.

DOCUMENTATION OF CONSENT

Please click on one of the following boxes.

☐ YES – I consent to participate in this study.

☐ NO – I do not consent to participate in this study.

If you consent to take part in this study, an experimenter will sign two copies and mail one of them to you. The second copy will be retained by the experimenters.