Permission to Take Part in a Human Research Study

Title of Research Study: Characterizing Variability in Hearing Aid Outcomes Among Older Adults

Investigator: *Pamela Souza, PhD, CCC-A*

Supported By: This research is supported by the National Institues of Health

Key Information about this research study:

The following is a short summary of this study to help you decide whether to be a part of this study. Information that is more detailed is listed later on in this form.

The purpose of this study is to further our understanding of what factors contribute to differences in hearing-aid benefit among older adults. During this study, you will be asked to listen to different sounds and/or speech samples. These sounds will be presented over headphones or speakers. If speakers are used, we may ask you to listen using a hearing aid we've programmed in the lab. You will then be asked to repeat what you heard back to the examiner or tell us what you think about what you just heard. We expect that you will be in this research study for 4 visits of 1-2 hours until the listening tasks are completed. The primary risk of participation is some possible discomfort during an earmold impression should one be necessary. The main benefit is posibbly understanding more about your hearing abilities and how those may influence your performance if you wear hearing aids.

Due to COVID-19, elements of the study may take place remotely. If equipment is needed, we can schedule a curbside pick up at the lab or bring the equipment to you directly. In some cases, it may be possible to ship the study equipment.

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Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you have a sensorineural hearing loss or normal hearing.

How many people will be studied?

We expect about 300 people will be in this research study.

What should I know about participating in a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

What happens if I say "Yes, I want to be in this research"?

During your first visit, we will establish your eligibility to take part in the study. As part of this testing we will:

(1) Measure your vision by asking you to tell us what letters and numbers you can see on an eye chart.
(2) Ask you questions about your hearing and medical history.
(3) Measure your memory, attention, and comprehension of information. You may be asked to remember words, pictures, letters or numbers; or read a short story and answer questions about what you have read.

During subsequent visits (up to 4 visits total) we will:

(4) Measure how well you can hear soft tones at different pitches. We may also ask you to indicate whether you can hear a difference between different tones or noises and to judge the pitch or loudness of different tones. The levels of all of the sounds used in the study will be set low enough to prevent loudness discomfort.
(5) Present some words or sentences and determine how much of the speech you understand by asking you to either repeat back what you hear, or select the sound you heard using a mouse or keyboard.
    a. If this testing is performed remotely, we may need to audio record your responses for later scoring. These recordings will only be listened to by lab members, and the files will be stored using a de-identified tracking number.
(6) Present some words, sentences or music and ask you to rate the quality of the sound you heard using a mouse or keyboard.
(7) Ask you to complete questionnaires that ask how well you can hear in different listening situations. Some parts of the testing may involve listening through hearing aids. If you do not already have a hearing aid earmold we may make one for you by taking an impression of you ear with a soft material during the first session. A small piece of cotton or foarm wil be placed in the ear canal before the soft material is inserted. The impression material must remain in your ear for about 3 minutes, after which the impression and cotton or foam block will be removed. We will adjust the hearing aid so that it is appropriate for your hearing. To adjust the hearing aid, we may place a small plastic tube in your ear during the study procedures so we can measure the sound your are hearing throught the aid.

For parts of this experiment, we may place the small plastic tube in your ear to record the output of the hearing aid in response to some sounds mixed with noise, presented at different levels. You will be requested to minimize movements for short amounts of time (~90 seconds) while we obtain these recordings. We may either provide a laboratory hearing aid adjusted to your hearing or use your own hearing aid (if you own one and with your permission; no adjustments will be made) for making these recordings. The total duration of this recording process may take 20-30 minutes and you may take as many breaks as needed. We prefer that you remain seated with the plastic tube and hearing aid in your ear during these breaks because reinserting/changing the position of the plastic tube may result in an inaccurate recording.

Is there any way being in this study could be bad for me?

If an earmold impression is taken, you may experience some temporary discomfort or a ticklish feeling as the cotton or foam block is placed into your ear canal. You may also notice that the impression material is slightly cold, or experience a feeling of pressure while the impression material is in your ear. Rarely, there can be some minor abrasions to the skin of the ear canal. You may find it uncomfortable to minimize movements during the hearing aid recordings. These procedures are routinely used when fitting hearing aids or creating custom earplugs and the risks in this study are no higher than the risks that would be experienced in an audiology clinic.

What happens if I do not want to be in this research?

Participation in research is voluntary. You can decide to participate of not to participate.

What happens if I say "Yes", but I change my mind later?

You can leave the research at any time and it will not be held against you.

If you decide to leave the research, all study data collected until the point where you withdraw can be used.

If you are performing the study visit remotely, you may pause in the middle of testing or reschedule the visit for any reason (e.g. someone enters the room and disrupts testing, an urgent situation arises, etc.)

What happens to the information collected for the research?

If you decide to participate in this study you will be assigned a study code that will be used to identify you in all data. No Protected Health Information or otherwise identifiable data (name, date of birth, etc) will be

associated with your study data. The only link between your name and your study code are stored on a password protected HIPAA approved server with server security managed by Northwestern School of Communication computer support staff.

Any data collected on a tablet will be erased and stored on the secure server after you complete the test. No identifiable information will be collected or stored on the tablet at any point before/during/after the tests.

Efforts will be made to limit the use and disclosure of your personal information, including research study records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution, the representatives from the National Institute of Deafness and Communication Disorders, and the PI's collaborators and study staff at the University of Colorado. Once enrolled in the study you will be assigned a unique numerical id, and all study date, results, publications, etc. will utilize that study number.

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 or documents 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 or documents 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 harm to self or others) 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 National Institutes of Health which are 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.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of harm to self or others.

Data Sharing: De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

An exception to our promise of confidentiality is when law or policy permits us in good faith to report evidence of child [or elder] abuse or neglect.

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Can I be removed from the research without giving my OK?

The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal include the inability to adhere to the prescribed study schedule and tasks. You also may be removed from the study if the investigator believes participation in the study will place you at an unacceptable risk. In the event that you are removed from the study without your consent your compensation will be pro-rated based upon the duration you remained compliant with study tasks and procedures. Once you are unable to continue with the study, compensation will end.

What else do I need to know?

Compensation: If you agree to take part in this research study, we will pay you $15/hour in cash at the end of each study visit.

Due to concerns regarding infection control during the COVID-19 pandemic, if you agree to take part in the virtual visits/remote testing, we will pay you $15 per hour in the form of a Hyperwallet Virtual Card, which will be accessible to you usually within 1-2 days after the study visit. You will be emailed instructions for

how to activate the card. You will be asked to sign an online receipt verifying that you have received this payment. If you decide to withdraw from the study before its completion, you will be paid at the above rate for the time spent performing study tasks up to that point. If you do not have access to email, you may receive a check or a physical gift card for the amount that you are owed.

A description of this clinical trial is available at http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, please contact the research team. You can contact the individual in charge of this research study: Dr. Pamela Souza at Northwestern University, at 847-491-2433 (Monday through Friday from 9 am to 5 pm) or by email at p-souza@northwestern.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree	I disagree	
_____	_____	The researcher may contact me in the future to see whether I am interested in participating in other research studies by the principal investigator of this study.
_____	_____	The researcher may use my own hearing aids to obtain recordings.

Your signature documents your permission to take part in this research.

_____ _____
Signature of participant Date

_____
Printed name of participant

_____ _____
Signature of person obtaining consent Date

_____
Printed name of person obtaining consent