Official Title: Open-source Hearing Aid Platform Comparisons

NCT number: NCT05693610

Document date: Approved in continuing review by IRB on 03.16.2024

INFORMED CONSENT FORM
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**Nadi, LLC / "Validating outcomes with an open-source hearing aid"**
Principal Investigator:	**Varsha Rallapalli, AuD, PhD**
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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 explained later on in this form.

An open-source speech processing platform or OSP was developed to bridge the gap between audiology research and commercial adaptation of hearing aid features, to promote innovative solutions to meet the needs of the hearing loss community. The OSP is an investigational device/platform that can replicate functions found in commercial hearing aids, and provides tools to researchers and listeners to access those functions. The purpose of this study is to validate outcomes with these OSP tools by measuring speech perception abilities in a laboratory setting with the open-source hearing aid in quiet and in noise for adults with hearing loss.

During the study, you will be asked to listen to different speech samples/sounds presented over earphones or speakers. You will be listening with laboratory hearing aids or headphones adjusted to your hearing loss. You will repeat what you heard to a study staff member or provide feedback about what you just heard. We expect that you will be in this research study for up to 3 visits of 1-2 hours each until the listening tasks are completed. The primary risk of participation is possible discomfort during an earmold impression. The main benefit is possibly understanding more about your hearing abilities and how these may influence your performance if you wear hearing aids.

Your private information collected during this study **will not be used or distributed for future research studies,** even if identifiers are removed.

A description of this clinical trial will be available on 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.

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 are an adult (18 years or older) with sensorineural (relating to the damage to the inner ear or auditory nerve) hearing loss or normal hearing.

How many people will be in this study?

We expect about 100 people to be in this research study.

What should I know about participating in a research study?

- Someone will explain the 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"?

If you decide to participate, you will come to the Hearing Aid Lab, located in room 1-451 or 1-387 of the Frances Searle building on the Evanston Campus of Northwestern. Some portions of this study may take place in a virtual sound room located in the Northwestern University Center for Speech, Language, and Learning building. A study staff member will accompany you to this building and will be with you at all times. If remote testing is necessary, remote testing will be conducted in a quiet room in your residence.

As a participant in this study, you may complete one or more of the following tests:

1. Hearing tests
    a. You will be asked questions about your hearing and health history.
    b. You will have a brief examination of your ear and ear canal with an otoscope.
    c. You may have an examination of your middle ear status using a tympanometer. You will hear a low-pitched sound and feel a mild pressure change (or tickling sensation) for a few seconds in your ear.
    d. You will be seated in a sound-treated room and we will measure how well you can hear soft tones at different pitches. The tones will be presented to you by an earphone or speaker. We may also ask you to judge the loudness of different tones. The levels of all of the sounds used in the study will be set low enough to prevent loudness discomfort.
2. Vision screening test: We will measure your vision by asking you to tell us what letters and numbers you can see on an eye chart.

3. Cognitive tests: We will measure your memory, attention, and comprehension of information. You may be asked to remember words, letters or numbers; or read a short story and answer questions about what you have read.
4. We will present some words or sentences through an earphone or speakers and determine how much of the speech you understand by asking you to either repeat you hear or what you remember later in the test. We may ask you to provide feedback about what you heard by selecting options on a computer screen or writing your answers. The speech may be difficult to hear or understand. With your permission, the listening tasks may be audio or video recorded to aid with data analysis.
5. We may present some words or sentences and ask you to rate the quality of the sound you heard or indicate your preference for sounds heard using a mouse, touchscreen or keyboard.
6. Parts of the study will involve listening through hearing aids. During the first session, we may make an earmold for you by taking an impression of your ear with soft material. A small piece of cotton or foam will 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 material and cotton/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 that we can measure the sound you are hearing through the aid. These are common procedures used in the audiology clinic.
7. In the event that an in-person study visit is not possible, some portions of the testing will be conducted remotely over the phone or by using video conferencing on your computer. In this case, we will not conduct any visual examination of the ear or tympanometry (test to determine middle ear status). If we do not have access to a valid hearing test of yours, we may ask you to complete an automated hearing test using a tablet and calibrated headphones. The tablet(s) and headphones will be provided by the lab for the duration of the experiment, using one of the following options:
    a. Curbside pickup/return,
    b. Delivered to and picked up from your doorstep by a study staff member,
    c. Mailed to you with a return box & shipping label. All devices will be thoroughly disinfected before and after use.
8. As part of the remote experiment, you may be asked to record noise levels in your room using a sound level meter application available on your cellphone/on the tablet provided to you.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include learning more about your hearing abilities.

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

During the study, you may feel bored, tired or frustrated due to the nature of the listening tasks. As our team is experienced in administering these tests, the boredness and frustration

are usually minor, if at all. Frequent breaks will be provided in order to minimize the possibility of experiencing these feelings. In addition, you can ask for a break at any time if you like. Some listeners may find the sounds processed through the hearing aid to be sharp or tinny in comparison to their unaided hearing. These are normal and expected consequences of a hearing aid fitting. 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. 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.

A possible risk for any research is that confidentiality could be compromised – that is, that people outside the study might get hold of confidential study information. We will do everything we can to minimize this risk, as described in more detail later in this form.

There may be other risks that are currently unknown.

What happens if I do not want to be in this research, or I change my mind later?

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

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

If you are performing the study visit remotely, you may pause in the middle of testing or reschedule the visit for any reason (for example, someone enters the room and disrupts testing, an urgent situation arises, etc.). You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

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

This research study is for research purposes only. The only alternative is to not participate in this study.

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

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 may also be removed 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 on the duration you remained compliant with study tasks and procedures. Once you are unable to continue with the study, compensation will end.

How will the researchers protect my information?

Data will be stored on a secured server and de-identified. 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 Health Insurance Portability and Accountability Act (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. Once enrolled in the study you will be assigned a unique numerical id, and all study data, results, publications, etc. will utilize that study number.

Who will have access to the information collected during this research study?

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.

There are reasons why information about you may be used or seen by other people beyond the research team during or after this study. Examples include:

- University officials, government officials, study funders, auditors, and the Institutional Review Board may need access to the study information to make sure the study is done in a safe and appropriate manner.
- Collaborating researchers who are involved with this study (de-identified information only).
- The research team may give information to appropriate authorities for reasons of health and safety – for example, if you indicate that you plan to harm yourself or others, or for public health reasons.

How might the information collected in this study be shared in the future?

We will keep the information we collect about you during this research study for study recordkeeping and for potential use in future research projects. Your name and other information that can directly identify you will be stored securely and separately from the rest of the research information we collect from you.

De-identified data from this study may be shared with collaborators, the research community, with journals in which study results are published, and with databases and data repositories used for research. We will remove or code any personal information that could directly identify you before the study data are shared. Despite these measures, we cannot guarantee the anonymity of your personal data.

The investigator would like to retain your contact information to contact you for future research participation. This information will not be shared with other researchers, but will only be retained for potential interest in research with the Hearing Aid Lab. We will ask for your consent to do so at the end of this form. You can be in this current research study without agreeing to future research use of your identifiable information.

The results of this study could be shared in articles and presentations, but will not include any information that identifies you unless you give permission for use of information that identifies you in articles and presentations.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also does not prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Costs

There will be no charge to you for your participation in this study.

Will I be paid or given anything for taking part in this study?

If you agree to take part in this research study, and are eligible to participate, we will pay you $15 per hour. For any in-person tests, payment will be made by cash at the end of each visit. You will be asked to sign and date a receipt verifying that you have received this payment. If you withdraw from the study after you start the research tests, you will be compensated based on the amount of time you spent in the study. For in-person visits, if you do not wish to receive cash, you may opt for any of the payment methods below.

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 and date 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.

Whom to contact about this study

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The Investigator's or study site's decision to exclude you from participation;
- Results of tests and/or procedures;

Please contact the Investigator at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00062688.

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.

_____ _____ The researcher may audio or video record me to aid with data analysis. The researcher will not share these recordings with anyone outside of the immediate study team.

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

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the investigator and study staff will use and share health data about you to conduct the study. Health data may include:

- Your name.
- Address.
- Phone number.
- Date of birth.
- Medical history.
- Information from your study visits, including all test results.

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the study staff may share health data about you with authorized users. Authorized users may include:

- Representatives of Department of Health and Human Services.
- Representatives of Nadi, LLC.
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.

- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study.
- Other research doctors and medical centers participating in this study, if applicable.
- A data safety monitoring board which oversees this study, if applicable.

Your health data will be used to conduct and oversee the research, including for instance:

- To refine and validate hearing research tools and advance OSP hardware.software to commericla grade.
- To develop and validate outcomes assessment tools to enable researchers to achieve reliable behavioral responses.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study investigator at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign and date this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant