Official Title: Open-source Hearing Aid Platform Comparisons

NCT number: NCT05693610

Document date: Approved in continuing review by IRB on 03.16.2024

STUDY TITLE:

Validating outcomes with an open-source hearing aid.

PRINCIPAL INVESTIGATOR:

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VERSION DATE:

6.16.2022

Check any **applicable** boxes in the table below – you will be asked for further detail on these topics later in the protocol form:

Indicate Vulnerable Population(s) to be Enrolled	☐ Children ☐ Cognitively Impaired Adults ☐ Pregnant Women (IF the research activities will affect the pregnancy or the fetus) ☐ Prisoners (or other detained/paroled individuals)
International Research (check this box if you will collect data from individuals located outside the United States)	☐
Research involving external collaborators (some research activities will be carried out by individuals not employed by Northwestern or NU affiliates)	☐
Research has U.S. Federal government funding via direct award or a sub-award (e.g., NIH, NSF, other federal agencies or departments)	☒ NIH (R44DC020406)

1.0 Purpose and rationale of the study:

Hearing loss (HL) is an invisible disability affecting 360 million people worldwide. In the United States, 75% of individuals over the age of 70 have HL [1]. The consequences of

untreated HL and its downstream effects have been a topic of active clinical research and include reduced quality of life, increased risk of falls, cognitive decline, dementia, and Alzheimer's, [2]–[5]. Despite tremendous advances in modern digital hearing aids (HAs) [6] and the potential health benefits of their use, only one in three individuals with HL owns a HA [1]. Two of the most cited reasons for low HA adoption are the lack of perceived benefit in real-world environments (e.g., noisy environments such as restaurants) and limited access due to high cost [7]–[10]. Overcoming these HA adoption hurdles has been stymied by the proprietary nature of commercial hearing aids, which make it nearly impossible for audiology researchers to understand and evaluate the innerworkings of commercial HAs in real-world conditions. Moreover, signal processing implementations across HA manufacturers can be very different for a given technology [11], [12] making it a challenge to compare across devices and prescribe the best implementation suitable for an individual listener. To circumvent these proprietary constraints, researchers often resort to laboratory simulations of HAs [13]–[16] that may be restricted to certain forms of signal processing. The drawback of this approach is the inadequate representation of the features in a commercial HA (e.g., open-ear acoustics, microphone location, etc.) that often interact with the signal processing [17]. Alternatively, to capture effects of wearable HAs, researchers may use commercial devices as a "black box" and rely on external metrics as proxies to characterize the effects of signal processing [18], [19]. Unfortunately, this approach can reduce the scientific rigor of experiments because of the inability to precisely describe and manipulate signal processing in the HA. In order to advance hearing healthcare and enable HA innovations that could improve quality and cost, thus increasing adoption of hearing aids, audiology researchers need validated open-source HA platforms that mimic commercial HAs in form and function.

The open-source speech processing platform (OSP) was developed in response to call from National Institute on Deafness and Other Communication Disorders (NIDCD) for new open-source platforms [20], [21].The OSP serves the following functions: 1) provides researchers complete control for long-term stability for experiments, 2) Researchers can configure the hearing aid processing features and investigate interactions among these features, 3) OSP provides an integrated research environment on a single platform to streamline and support an efficient research workflow. The purpose of this project is to advance the academic proofs of concepts for researcher tools successfully completed with previous R21/R33 and R01 funding into working audiology researcher tools (Aim 1), outcomes assessment tools (Aim 2) and ecological momentary assessment (EMA) tools (Aim 3 [not included in this behavioral study]) to address the need for an open-source HA with a full range of signal processing capabilities and complete researcher control.

Specific Aims pertaining to the behavioral study are 1) Refine and validate hearing research tools and advance OSP hardware/software to commercial grade (for researchers). This aim will investigate interactions among OSP parameters such as spatial processing, compression release times, noise managenment, etc. 2) Develop and

validate outcomes assessment tools to enable researchers to present acoustic stimuli and log users' responses, along with other information such as reaction time, number of stimulus repetitions to achieve reliable behavioral responses.

The study is a within-subjects design that allows for comparison of outcomes within the same participant. Experiment 1: We will compare baseline performance(unaided) and performance with the OSP (aided) for adults with hearing loss. We will measure performance in the laboratory using common clinical tests of speech understanding in noise as well as noise acceptance. We will test aided performance with different hearing aid settings. The hearing aid settings may vary with regard to compression and noise management. Statistical analyses will use a repeated measures model to control for correlation between outcomes for the same participant.

Experiment 2: To validate the capability of the OSP to assess listener outcomes, we will also compare aided speech discrimination ability in quiet and in noise for two test modes: OSP assessment tool (stimulus presentation controlled by participant & responses collected directly from the participant on the OSP) versus conventional (stimulus presentation controlled on an external program by experimenter & paper-and-pencil responses provided by participant). Statistical analyses methods will quantify agreement, correlation, and association (linear regression) between outcomes from the two test modes.

In both experiments, each participant will be presented with all the test conditions (hearing aid settings or test modes) in a laboratory setting. The order of presentation of the test conditions will be randomized and counterbalanced across participants.

2.0 Enrollment Criteria (who can be in your study and who would not be eligible to participate in your study):

Inclusion Criteria:

- >= 18 years of age; any sex
- Sensorineural hearing loss with pure-tone thresholds between 25-85 dB HL at octave frequencies between 250 and 3000 Hz
- Speak English as their primary language
- Normal or corrected-to-normal vision (<=20/50)
- Participants will be in good health (self-report)

Exclusion Criteria:

- Clinically significant unstable or progressive medical conditions
- Participants who score < 23 on the cognitive screening test (Montreal Cognitive Assessment)
- Evidence of conductive hearing loss or middle ear issues
- Significant history of otologic or neurologic disorders
- Non English-speaking or non-native English speaking

For the purposes of test validation and calibration, we may also enroll a small group (n=50) of listeners with normal hearing, defined as pure-tone thresholds of 25 dB HL or less at octave frequencies between 250 and 3000 Hz. With the exception of having normal hearing, those participants will follow the inclusion and exclusion criteria described above.

The study will not recruit special populations such as adults unable to consent/cognitively impaired, minors, prisoners, or other detained individuals.

3.0 Sample Size:

The proposed study will recruit 100 participants (based on power analysis) with bilateral symmetric sensorineural HL in the mild to severe range, over a 2-year period. Each experiment will recruit approximately 40 participants (additional 10 account for pilot testing and attrition).

Experiment 1 (Aim 1)

We assume type I error rates of 2.5% for tests of contrasts between repeated measures within individuals. We anticipate N=40 participants will suffice to detect moderate effects of d=0.5 with 80% power. Effects of this size translate to 0.71 dB points for QuickSIN and 2.6 for ANL. These are smaller than critical differences identified for QuickSIN (2.7 dB) [22] and ANL (6 dB) [23]. A smaller sample size would provide 80% power to detect larger effects (see Table A), though even if we fall short of our recruitment and data collection goals, we will still be well-powered to detect meaningful effects in Aim-1.

Table A. Sample sizes & effect sizes for Aim-1

Sample Size	Difference (d)	QuickSIN Diff.	ANL Diff.
30	0.59	0.82	4.12
35	0.54	0.76	3.79
40	0.50	0.71	3.53

Experiment 2 (Aim 2)

We will report 95% confidence intervals for the ICC and Pearson correlations, which will have similar widths (see Table B). A sample size of N=40 would allow for narrow confidence intervals for large ICCs and correlations; and ICC≥0.87 or correlation >0.87 would have a 95% confidence interval width <0.15. Smaller ICCs would have larger confidence interval widths; an ICC or correlation of 0.7 would have a 95% confidence interval width of 0.33.

Table B. Pearson correlations, ICC, and corresponding confidence interval (CI) widths for Aim-2			
Correlation	**Cor. CI**	**ICC**	**ICC CI**
0.5	0.48	0.5	0.47
0.7	0.33	0.7	0.33
0.8	0.24	0.8	0.23
0.9	0.13	0.9	0.13

4.0 Recruitment and Screening Methods:

Recruitment process:
The proposed study will recruit 100 adults (18 years or older) over a two-year period. Participants will be primarily recruited from an existing database in the lab that has over 300 adults with hearing loss who are interested in study participation and agreed to be contacted for future research. The lab also has access to a Communication Research Registry, a confidential database for individuals interested in continuing research participation within the Northwestern School of Communication. Additional recruitment will take place through the department's audiology clinic, local audiology clinics, local community, local senior centers, and local Hearing Loss Association of America (HLAA) chapter. Recruitment methods will include flyers and brochures to the department and local audiology clinics, local senior centers, and the local HLAA chapter; advertisements in local social media boards and newspapers; flyers on bulletin boards throughout the Northwestern campus.

Screening methods:
Prior to enrollment in the study, potential participants will go through a screening process. The screening procedure will take approximately 60-80 minutes. The following tests may be conducted to verify eligibility for research inclusion:

Test	Description/Purpose	Exclusion Criteria
Case history	Written administration; questions re: onset/nature of hearing loss, hearing aid use, otologic and medical history; CEDRA questionnaire [24]	Significant history of otologic/neurologic disorders
Otoscopy	Visual examination of pinna, ear canal, and ear drum	Significant impaction of wax, active discharge; exclusion will be determined in

		conjunction with tympanometry when appropriate
Tympanometry	Test to determine middle ear status	B-type tympanogram suggesting unhealthy middle ear status
Audiogram*	Air conduction (250 Hz to 8000 Hz) and bone conduction (500 Hz to 4000 Hz) testing to determine degree and type of hearing loss	Evidence of conductive hearing loss (air-bone gap > 10 dB HL); Hearing loss > 85 dB HL at any frequency between 250-3000 Hz
Monosyllabic word recognition	Percentage of phonetically-balanced words repeated in quiet at a comfortable loudness.	Evidence of significant asymmetry between ears [25]
Montreal Cognitive Assessment (MoCA) [26]	Cognitive screening test that assesses orientation to time and place, short-term memory, and ability to follow simple commands	The scope of this study does not include cognitive impairments, therefore, we will exclude participants with a score lower than 23 [27] (suggests dementia)
Vision Screening	Screen for normal or corrected-to-normal vision using a letter/number chart	Normal/corrected-to-normal vision is required because the study involves selection of response options seen on a computer/tablet screen. MoCA (above) involves identifying/copying visual objects. We will exclude subjects who fail vision screening.

Interested participants will be contacted by the research staff via phone/email as preferred by the potential participant. At this time, the participant will be provided with basic information regarding study procedures and inclusion criteria. The lab manager will be the primary point of contact to coordinate all recruitment and scheduling, and Dr. Rallapalli (PI) will be available as needed.

*For participants recruited from outside our lab pool or any participant who does not have a valid audiogram, we may adopt the following procedures:

a) Request the participant to provide a copy of their existing audiogram (if available) completed by an audiologist outside of our lab. The participant will be asked to upload a copy of their hearing test via REDCap. If a participant is unable to access REDCap, they can send a copy of their hearing test via fax or to an encrypted email address.
b) We may obtain air conduction thresholds using a validated remote automated test (e.g., GSI AMTAS Flex [28]) delivered to the participant via a tablet and calibrated headphones. The participant will be asked to complete the test in a quiet room with minimum distractions. The automated hearing test is HIPAA-compliant and FDA-registered.

Additional explanation:
All participants must be native speakers of English because our outcome measures include speech recognition of English sentences or words. Therefore,

proficiency in English is required for the validity of the results. Our study population is adults with hearing loss. Therefore, we will include individuals with sensorineural hearing loss with pure-tone thresholds between 25-85 dB HL at octave frequencies between 250 and 3000 Hz. This meets the criteria for a mild to severe hearing loss. This is the typical range of hearing loss for which individuals seek hearing aids, and the range for which hearing aids can provide sufficient gain. Participants should have no significant history of otologic or neurologic disorders as these disorders are beyond the scope of the study. The participant must have normal or corrected-to-normal vision because the cognitive screening and experiment involve visual tasks. The participants should be in general good health (based on self-report). Exclusion criteria include conductive hearing loss and middle ear issues (e.g., active discharge, significant wax impaction) as these conditions may preclude the use of a hearing aid. Participants who do not pass the cognitive screening test (< 23 on the Montreal Cognitive Assessment [26], [27]) will also be excluded because cognitive impairments may confound the results and are beyond the scope of this study.

5.0 Research Locations:

The proposed work will be conducted within the Hearing Aid Lab (Director: Dr. Pamela Souza) and in a virtual sound room (ViSoR) at Northwestern University. The lab is a 600 square foot space that includes an 8’ x 8’ double-walled IAC sound booth. The lab also has a meeting area with a large desk and chairs for case history-taking, cognitive assessments, and counseling, a participant waiting area with educational materials on hearing loss resources and support, and a secure file storage area. The research may also be conducted in a separate 10’ X 7’ sound-treated space (Frances-Searle room 1-387) that is part of the Hearing Aid Lab.

The virtual sound room (ViSoR) is within the Northwestern University Center for Audiology, Speech, Language and Learning (NUCASLL) in a building adjacent to the Hearing Aid Lab. The research staff involved in this study have access to this room.

Participant research visits may be conducted remotely. Remote participation allows a more diverse group of people to participate, especially those with limited or intermittent access to transportation, mobility challenges, or health concerns where that can be addressed by limiting in person contact, especially in light of covid 19. Remote visits may be conducted using Northwestern IT-approved (and HIPAA-approved) video conferencing or phone. The research staff will conduct these visits from a private room in their apartment and no one else will be present during the research study. The research staff may also conduct these virtual visits from the hearing aid lab or an office space. Participants will

perform the remote testing from their respective places of residence/a quiet place of their convenience. The virtual visits will be conducted either through Zoom or Microsoft Teams or WebEx applications. The platform used will be determined by participant preference.

6.0 Multi-site Research (research that involves external collaborating institutions and individuals):

The current study is a behavioral research study being conducted to validate outcomes with an open-speech platform. This study is being conducted under a subaward to Northwestern University (subaward PI: Dr. Rallapalli), and the main SBIR grant will be awarded to Dr. Harinath Garudadri (Nadi, LLC).

All the human subjects research work proposed here will be conducted at a single-site, i.e., at Northwestern University. Communication of results and findings will only be done with de-identified data. When sharing information, de-identified data will be exchanged via secure FTP. In addition to be being de-identified, all data will be stored in a secure password protected database or on REDcap, and will only be accessible to study staff at Northwestern University.

7.0 International Research (where data collection will occur outside the United States and U.S. territories, including online activities): NA

8.0 Procedures Involved:

Please check the boxes for all applicable data collection procedures you plan to use:
☐One-on-one interviews
☐Focus Groups
☐Questionnaires/surveys
☐Analysis of secondary data (medical record data, educational records, government or private sector datasets, etc.)
☐Ethnographic observation
☐Physiological measurements (e.g., EEG, EKG, MRI)
☐Biospecimen collection (saliva samples, blood draws, hair samples, etc.)
☐Mobile applications/data collection devices (e.g., Fitbits, actigraphs, etc.)
☒Behavioral decision making tasks (e.g., puzzles, interactive games, etc.)
☐Physical activities such as walking and other forms of exercise
☐Other procedures (briefly list types of procedures here if not covered by the check-boxes above): _____

The proposed research will measure aided speech perception outcomes for hearing-impaired listeners under laboratory conditions, with a combination of hearing aid

settings in quiet and noisy conditions. The study will use the OSP to provide various combinations of hearing aid signal processing. Test procedures including stimuli and outcome measures are described below.

Data collection for each experiment will include the following steps per participant:

Session	Aim 1 (Exp. 1)	Approx. Duration	Aim 2 (Exp. 2)	Approx. Duration
Session 1	Candidacy assessment	60-80 mins	Candidacy assessment	60-80 mins
	Baseline/Unaided outcome measurement (QuickSIN, ANL)	30 mins	Earmold impression (if needed)	15-20 mins
	Earmold impression (if needed)	15-20 mins		
Session 2	Earmold + OSP Fitting	45-60 mins	Earmold + OSP Fitting	45-60 mins
	Aided Outcome measurement (QuickSIN, ANL)	60 mins	Aided Outcome measurement (MRT)	60 mins

Session 2 may take place ~7-10 days after session 1 to allow for time taken for the custom earmold order to be received.

Open-source speech processing platform (OSP):

The OSP will be used to provide amplification to the participant. The OSP mimics the functionality of a hearing aid in that it will process sound in real-time. The OSP has wearable earpieces or calibrated headphones to deliver the processed sound to the ears. However, unlike a commercial hearing aid, the processing takes places via a computer simulation of a hearing aid (portable or fixed) rather than within the housing that rests on the participants ears and also contains the microphones. The OSP allows flexible adjustments beyond what is available in commercial hearing aids, and ensures adequate scientific rigor. Different signal processing features in the hearing aid, including spatial processing and noise reduction will be varied across test conditions. Clinically realistic settings will be used. The amount of amplification with the hearing aid will be customized for each listener based on a validated prescription. The hearing aids will be fit to a foam/ear tip or a custom earmold. These are standard clinical procedures as described below.

The OSP will be used for the duration of the experiment in a lab setting under the supervision of the experimenter. The OSP will be returned the experimenter at the end of a session.

Stimuli:

Recorded speech materials (words, sentences, or passages) will be presented. These speech materials will be combined with speech-shaped noise or multi-talker babble at varying levels (including no noise), and the intensity of the stimuli will be adjusted to represent typical conversational speech (65 dB SPL) or a comfortable level for the listener.

Earmold impression: First, the ear is visually inspected with an otoscope (lighted magnifying scope). Then a cotton/foam block and soft impression material are placed in the ear. The material is left to set for about 3 mins after which it is removed along with the cotton/foam block and is used to order an earmold for later testing. This is a standard clinical procedure.

Loudness discomfort levels: Participants will be played sounds at progressively louder levels and asked to verbally indicate the maximum point of listening comfort. Loudness discomfort levels will be measured at 0.5 and 3 kHz and used in combination with patient report. This is a standard clinical test used to verify that stimuli levels are not uncomfortably loud.

Hearing aid fitting: The ear is visually inspected using an otoscope. A small soft plastic tube is inserted into the ear canal and is used to measure the sound output of the hearing aid. The hearing aid + earmold are placed in the ear. The participant is seated in front of a speaker and sound is played from it. The sounds may be speech or noise with similar frequency content to speech, at levels ranging from soft to conversational to loud speech (50-80 dB SPL). In order to verify that the hearing aid is not uncomfortably loud, a stream of loud beeps (85-90 dB SPL) are played for 2-3 secs. Alternatively, the hearing aid fitting may be completed in a test box with a standard coupler instead of the participant's ears. These are standard clinical procedures used to adjust the hearing aid so that the programming settings are appropriate for the participant's hearing loss.

<u>Outcome measures:</u>
Speech recognition: The recorded speech materials that have been electronically processed and mixed with multi-talker babble or speech-shaped noise, will be presented through earphones or speakers. The speech material and noise may be presented through single or multiple speakers and from different locations in the test room. The participant will listen through the hearing aids or headphones for the duration of the experiment. The participant's task would be to either repeat the speech or select it from a list of choices on a computer monitor or provide a written response.

QuickSIN: The test measures speech recognition ability in noise. Participants will listen to and repeat recorded sentences mixed with noise. Scoring is determined by the number of words repeated correctly. Scores range from 0 to 25.5 dB SNR loss (a lower score indicates better speech recognition ability in noise). The task is expected to take 10-15 minutes for each test condition and up to 30 minutes per session. The task

duration includes time for instructions and practice. The outcome measure will be completed under experiment 1.

Modified Rhyme Test (MRT): The test is a measure of word-discrimination ability. Participants will select a word out of a choice of six rhyming words. The words may be in quiet or mixed with background noise and will be presented through the hearing aid/speakers/earphones. Participants may be asked to record their responses on paper or via button/mouse click on a computer or tablet screen. Scores will be based on percentage of words identified correctly (range: 0-100%). A higher score indicates better word-discrimination ability. Scores for phonetic-level errors and reaction times for responses may also be reported with the OSP assessment tool. The task is expected to take 30 minutes for each test condition and up to 60 minutes per session. The outcome measure will be completed under experiment 2.

Acceptable Noise Level Test (ANL): Participants will indicate the level of noise that is acceptable while listening to running speech. Scoring is determined based on the difference between the listener's most comfortable level for speech and the highest background noise level they are willing to accept. A smaller score indicates better noise acceptance. The task is expected to take 10-15 minutes for each test condition and up to 30 minutes per session. The task duration includes time for instructions and practice. The outcome measure will be completed under experiment 1.

Preference and sound quality: Sound quality and listener preferences are critical component of successful hearing aid outcomes. Multiple dimensions of sound quality may be assessed using rating scales. Participants will listen to speech or sentences that have been electronically processed, and rate each sentence for overall quality, pleasantness, clarity, noisiness, loudness, and preference. Alternatively, participants may be presented with pairs of electronically processed speech (words, sentences or paragraphs) and they may be asked to select whichever one they prefer. The speech may be presented in quiet or mixed with different levels and types of pre-recorded noise (such as multiple talkers, babble, and other environmental noise). Ratings will be provided using a graphical user interface on a tablet or computer monitor (using a touchscreen, keyboard or mouse). The task may take upto 60 minutes and may be conducted in a separate session (e.g., session 3) if needed.

The participant may be provided with a tablet or computer monitor to control (using a touchscreen, keyboard or mouse) the presentation of the stimuli via a graphical user interface. The participant will be recorded repeating the speech so that their responses may be scored later by the experimenter (also see section 15). The participant will be guided with on screen instructions and may reach the experimenter via an intercom at any time.

Acoustic measurements: After the completion of experiment by the participant, de-identified hearing aid fitting data may be retrieved from the hearing aid in order to

record output on an acoustic manikin or a sound level meter within the same test conditions as the behavioral experiment. The recorded output will be used to measure signal fidelity across conditions and relate acoustic measurements with speech intelligibility. This part of the experiment does not directly involve the participant and will only be conducted with de-identified materials.

Additional procedures for remote data collection: If the participant is provided a tablet and calibrated headphones for automated audiometry, the following procedures will be used. The participant will be provided with detailed instructions on the phone or through a HIPAA-compliant video conferencing platform. The participant will be requested to complete the testing in a quiet location, with minimum distractions. In order to monitor the surrounding noise levels during the testing, the participant may be asked to record the noise levels in their room using a publicly available sound level meter application (e.g., Decibel X, NIOSH SLM). Obtaining a record of the noise level during the testing is important as high background noise may obscure the results of an audiogram.

No identifiable information will be placed on the tablet at any stage of the experiment. Completed data from each participant will be retrieved from the tablet (and erased) and housed on a secure server, before providing the tablet to the next participant.

The remote testing equipment (tablet(s) and calibrated headphones) will be provided to the participant using one of the following methods (depending on convenience):

a) The participant may pick up the equipment from a research staff member from the curbside/parking lot by the Frances-Searle building. The participant may also return the equipment to the research staff member at the same location, upon completion of the experiment.
b) The equipment may be delivered to and picked up from the participant's residence by a research staff member.
c) The equipment may be mailed to the participant with a return box and shipping label.

Communication regarding the details of pickup and return of the equipment (including preferred method and date/time/location) will take place over the phone or via email. A record of the agreed upon details will be maintained by the research staff. The participant will be sent a reminder 24 hours before the scheduled time, either via email or phone (depending on the participant's preferred method of contact). A tracking number will be associated with any shipments and the package will be insured. In the event that the participant does not return the equipment by the agreed upon time/date, we will follow up with reminder emails or phone calls to determine the cause for delay and to provide them with alternative options for returning the equipment within a reasonable time frame. Participants will not be charged and financial compensation will not be withheld in the event of loss or damage to any equipment.

9.0 Research with Vulnerable Populations: NA

10.0 Incomplete Disclosure or Deception: NA

11.0 Consent Process:

Prior to enrollment in the study, potential participants will have a hearing, vision, and cognitive test with authorization by a screening consent form. These tests will allow us to exclude potential participants who are ineligible based on their hearing, vision, or cognitive status from enrolling in the study. These tests will be built into the first visit tasks and will last 60-80 minutes. If the participant is eligible based on the screening process, he/she will be consented for the experimental procedures using a separate form. If a participant is not eligible based on screening, they will have the option to authorize future contact and authorize the lab to retain the screening audiogram and cognitive test results. Consenting will take place in the Hearing Aid Lab, prior to any research procedure taking place. All consent forms are stored in a locked file cabinet within the Hearing Aid lab (locked lab). The potential participant will be provided unlimited amount of time to review the consent forms and ask any clarifying questions. Following the participant's opportunity to review the consent form, the researcher will review each section with the participant to clarify any study procedure and ensure understanding. All participants will be offered a copy of their signed consent form with the option to decline. The researcher will document the consent process and the participants' receipt of/decline of a signed copy on a study flow sheet. Both participant and staff will initial the flow sheet to verify that the consent form was provided or that a copy was declined. Please note that during the consent process, the researcher will explain to the participant that their identifiable information will be kept confidential and will not be used.

Virtual consent may be obtained as an alternative (e.g., remote participation). Participants will be consented using one of two procedures, determined by participant preference:

Option 1: The participant will be consented electronically using REDCap. The participant will be required to "sign" by typing their name and enter the date. The participant will be able to review the consent form as many times as they need to, go back and forth through sections, and take their time before providing their consent. They may save their progress on the form and return to it at a later time if needed. The participant may contact a study team member as needed to provide any clarifications regarding any part of the consent form via phone or email or video before the deciding to provide their consent. All information required for informed consent will be available on the eConsent forms. Consent forms for this study do not have any associated external material

or hyperlinks. In order to ensure the identity of the signer, the REDCap consent form can only be accessed by the email address that it is sent to (i.e., the email address provided by the participant). In addition, the participant will be provided with a predetermined passcode via phone or video. At the time of accessing the electronic consent form, the participant must enter the passcode which will be internally compared with the stored version entered by the study team member. The participant will be granted entry only if the passcode matches. The participant will have the option of saving a copy of their signed eConsent forms as PDFs. A study team member will review the submitted eConsent form and electronically sign and date as confirmation.

Option 2: The participant will be sent a consent form via encrypted email, which they will sign and date, scan/take a photo of, and email back to the research staff. The participant may contact a study member as needed to provide any clarifications regarding any part of the consent form via phone or email or video before the deciding to provide their consent. The staff member will review the submitted consent form and sign and date as confirmation. The participant will be sent a scanned copy of the signed consent form for their records.

12.0 Waiver of Participant Signature on Consent Form: NA

13.0 Waivers and Alterations of Consent Information: NA

14.0 Financial Compensation:

Upon completion of the study tasks, the participant will be paid an hourly rate for participation ($15/hour). Payment will be made in cash at the conclusion of each session. If the participant decides to withdraw from the study before its completion, he/she will be paid $15/hour for the time spent. There is also dedicated parking space for research participants (at no charge) and an accessible entrance to the lab building.

Participants may be given the option of being compensated at the above rate in the form of a Hyperwallet Virtual Card provided by Northwestern University. The card will be issued at the completion of the study visit at which point the participant will be emailed instructions for the card activation process. For participants who do not have access to email, they will also be given the option of being issued a check or a physical gift card for the amount that they are owed. Financial compensation will not be withheld in the event of loss or damage to any experimental equipment.

15.0 Audio/Video Recording/Photography

Audio and video recordings may be obtained during the screening tests and the listening tasks. The purpose of the audio/video recordings is to ensure accuracy

(a second scorer may listen to the recordings and correct any potential errors). The recordings will contain only non-identifiable information and will be destroyed 3 years after the completion of the study. Audio and video recordings will not be obtained during earmold impressions and hearing aid fitting.

16.0 Potential Benefits of this Research:

Participants in this study may not directly benefit from the experiment. The importance of this research lies in the potential to generate innovative and evidence-based solutions to increase access to hearing healthcare. Therefore, participants with hearing loss seeking hearing aids may benefit in the long-term. Many participants are interested in hearing aid research as an opportunity to get information and ask questions about hearing aids without sales pressure. All participants will have the opportunity to receive counseling at the end of the study, by the investigators or the research coordinator, all of whom are also trained and certified audiologists. Counseling, if and when provided, will include listening recommendations tailored to their individual speech understanding and memory. Participants will have the chance to ask questions and receive information about options for their hearing loss (outside the study).

17.0 Potential Risks to Participants:

All study procedures pose minimal risk to participants. There is potential that the study task might be boring or repetitive, and therefore if a participant wishes to discontinue testing at any point, they may choose to do so without any consequence. Listeners who receive poor scores on the MoCA may be disappointed to learn of their performance. Some listeners may find the sounds processed through the OSP to be sharp or tinny in comparison to their unaided hearing. These are normal and expected consequences of any hearing aid fitting. Loudness discomfort levels will be measured and presentation levels will be monitored to ensure that levels never become uncomfortable.

When the earmold impression is taken, participants may experience some temporary discomfort or a ticklish feeling as the cotton/foam block is placed into the ear canal. Participants 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.

The hearing aids and earmolds will only be used for the duration of the experiment. The participant is free to remove the hearing aids and/or leave the test booth at any time. Participants are encouraged to take breaks and can discontinue the study at any time without penalty. If the investigator determines

participation in the study places a participant at unacceptable risk, enrollment or study tasks will not proceed.

Participant confidentiality will be ensured by storing data without subject identifiers. Data files are password protected and can only be accessed by authorized lab members. Hard copy data are stored in locked file cabinets within a restricted-access laboratory space. All study staff complete training in ethical procedures for working with human subjects and in HIPAA regulations.

If a research participant decides to withdraw or discontinue study procedures, all data collected up to that point can be used by the investigator unless the participant indicates that they would like to have their data removed from the study. In the event that a participant is removed from the study without their consent, compensation will be pro-rated based on the duration the participant remained compliant with study tasks and procedures.

In the event that a participant is compensated using the Hyperwallet Virtual Card, an account will need to be created using the participant's name and email address, which will link their name to the study. This creates a small additional risk of breach of confidentiality.

18.0 Provisions to Protect Participant Privacy and Data Confidentiality:

All experimental procedures will be conducted in the Hearing Aid Lab at Northwestern University. The data for this study will include audiometric thresholds, age, cognitive measures, speech perception scores, hearing aid fitting data, and acoustic measurements. Participant responses recorded through the computer interface will be coded and will not contain any identifiable information. All data will be de-identified prior to analysis. De-identification will take place by assigning a particular code to all data pertaining to one subject. The link between the subject code and the subject name will be stored in a password-protected file on a HIPAA-approved server managed by Northwestern School of Communication computer support staff. This information will also be stored on the secure REDCap database. Participant identifiers will be stored electronically on REDCap in a separate instrument than the study data. REDCap will also be used to track study data. All research staff will receive appropriate Human Subjects protection training and training regarding confidentiality. Data are only accessible by the study staff via password-protected files. Discussion regarding subject confidentiality will also be included during regular lab meetings.

19.0 Data Monitoring Plan to Ensure the Safety of Participants:

All experimental procedures will be conducted in the Hearing Aid Lab or the virtual sound room at Northwestern University. The data for this study will

include audiological data, age, cognitive measures, and speech perception scores, hearing aid fitting data, and acoustic measurements. Participant responses recorded by the experimenter through the computer interface will be coded and will not contain any identifiable information. Any audio-recording done for the purpose of scoring will also be de-identified and will be deleted at the end of the experiment. All data will be de-identified prior to analysis. De-identification will take place by assigning a particular code to all data pertaining to one subject. The same subject code will be used in the hearing aid programming software. The link between the subject code and the subject name will be stored in a password-protected file on a HIPAA-approved server managed by Northwestern School of Communication computer support staff. All research staff will receive appropriate Human Subjects protection training and training regarding confidentiality. Data are only accessible by the study staff via password-protected files. Discussion regarding subject confidentiality will also be included during regular lab meetings.

The proposed research uses a very low-risk intervention (i.e., hearing aids). The investigator will be responsible for ensuring participants' safety at the time of experimentation. If the investigator determines that participation in the study places a participant at an unacceptable risk, enrollment or study tasks will not proceed. The participants will use the OSP only for the duration of the experiment. Therefore, the use of the OSP will always be monitored by the experimenter. A trained audiologist is responsible for making the ear impressions and completing the OSP fitting. All testing will be conducted by an investigator, an audiologist, the research study coordinator, or a research assistant. The research assistant will be supervised by an investigator or the research study coordinator. The investigator as well as the research study coordinator are trained and licensed audiologists and have several years of experience in conducting hearing assessments, hearing aid fitting, and research with adults and are therefore qualified for monitoring the study.

20.0 Long-term Data and Specimen Storage and Sharing: N/A

21.0 Qualifications of Research Team to Conduct the Research:

Our team has extensive experience in human research and all members are CITI (Collaborate Institutional Training Initiative) certified:

- Varsha Rallapalli is a research assistant professor who has significant experience in human research and is also a trained and licensed audiologist and a researcher with over ten years of human research experience. Her research expertise is in the area of speech perception, modeling, and hearing aids.

- Kendra Marks is a research study coordinator in the Hearing Aid Lab. She is a trained and licensed audiologist and has over ten years of experience in hearing testing, hearing aid fitting, and counseling patients with hearing loss as well as significant experience in human research.

- Research assistant on the study who will assist with data collection and analysis will be a graduate student in audiology who is receiving training in assessment and rehabilitation of hearing-impaired individuals. The research assistant will also be CITI certified.

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