TITLE: Investigation of direct-to-consumer hearing aids on conversation efficiency and listening effort

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STUDY TITLE:

Investigation of direct-to-consumer hearing aids on conversation efficiency and listening effort

PRINCIPAL INVESTIGATOR:

Name: Pamela Souza
Department: Communication Sciences and Disorders
Number: 847-491-2433
p-souza@northwestern.edu

CO-INVESTIGATORS:

N/A

STUDENT INVESTIGATOR (complete this section only if the project is student-initiated):

Name: Grace Szatkowski
Department: Communication Sciences and Disorders
Number: 234-706-0495
graceszatkowski2026@u.northwestern.edu

Are you an:
☐ Undergraduate Student
☒ Graduate Student or Medical Student

VERSION DATE:
12/8/2022

RELATED STUDIES:

(STU00211218) This study has a similar experimental protocol, looking at the benefits of direct-to-consumer hearing aids for adults with hearing loss and mild cognitive impairment. The proposed study listed here will not include adults with cognitive impairment.

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 Populations 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 will carry out some research activities)
☐ Research has U.S. Federal government funding via one or more direct awards or a sub-award (i.e., NIH, NSF, other federal agencies or departments)

1.0 Purpose and rationale of the study:

Hearing loss is the third most common chronic health condition in the United States, affecting individuals of any age. According to the National Institute on Deafness and Other Communication Disorders approximately 15% of all adults over age 18 in the United States have reported some trouble with their hearing, and one in eight people in the United States (about 30 million) aged 12 and older have hearing loss in both ears. However, about 28.8 million US adults who could benefit from hearing aids do not wear them.

The current model of dispensing hearing aids could be a barrier to adoption by those who could benefit from amplification. For instance, the average cost of conventional hearing aids ranges from $4000-5000 a pair, and this cost alone is often paid out of pocket due to limited insurance coverage for hearing care. Sound quality self-adjustments are highly restricted to the patient and vary based on manufacturer preferences and recommendations. Program changes are controlled by a licensed audiologist or hearing aid dispenser with the manufacturer's software for sound quality adjustments. Also, appointments are common to fine-tune the hearing aids to meet the patient's hearing needs, to replace the devices, or to repair them. These additional appointments are typically paid for out-of-pocket. The burden of upkeep, including not just the expense of office visits, but also the regular maintenance and care required for proper device functionality, may not only affect patients but their family members, loved ones, or caregivers. This is particularly true if transportation to and from appointments as well as if the availability of a caregiver or family member is limited. Thus, obtaining conventional hearing aids can carry with it the burden of affordability and reliance on the audiologist for regular maintenance. Mentioned are a few of many significant factors that could be contributing to the statistically low hearing aid adoption rates among adults who need them.

An alternative to conventional hearing aids, direct-to-consumer (DTC) hearing aids, have been

available for consumer purchase for years. Originally created as 'self-fitting' devices, these were marketed as personal sound amplification products, known as PSAPs. PSAPs were not meant to be used for hearing loss treatment, but rather more commonly as amplifiers for personal choice or recreational use such as for hunting. However, the Food and Drug Administration (FDA) issued a proposal in 2021 to make hearing care more accessible for Americans, known as the Over-the-Counter Hearing Aid Act, part of the FDA Reauthorization Act of 2017. Unlike PSAPs, DTC hearing aids in this Act would be considered a treatment option for hearing loss. Different from conventional hearing aids, these devices will not require appointments to an audiologist for adjustments. Due to their affordability and easy access, DTC hearing aids have the potential to reach more individuals with hearing loss. Despite the many potential benefits that DTC hearing aids could offer, there is little research into their use to meet unique patient listening needs and the accuracy of self-guided hearing aid fittings.

In order to better understand if DTC hearing aids may be a viable treatment option, it is important to consider patient reports. One of the most common complaints reported by patients is that listening is effortful, even when speech is loud enough. The Framework for Effortful Listening (FUEL) model developed by Pichora-Fuller and colleagues (2016), defines effortful listening as the "deliberate allocation of mental resources to overcome obstacles in goal pursuit when carrying out a task." Research has shown that despite individualizing hearing aid programming to meet amplification targets as recommended by verification measures of output gain, audibility alone cannot resolve a damaged auditory system. Cognitive influence on auditory performance is an important consideration to hearing healthcare and the future of DTC devices. The complex process of comprehending and responding to incoming auditory stimuli requires intact cognition attuned to individual listening needs and differences. To the best of our knowledge, there exists a gap in research regarding cognitive processes involved in listening, particularly effort, with DTC hearing devices.

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Currently available DTC and OTC devices that will be used for this study are listed here.

1. Bose SoundControl hearing aids: Currently listed within the U.S. Food and Drug Administration (FDA) as FDA cleared for regulatory class II as a self-fitting air conduction hearing aid in 2021.

2. Neosonic MX RIC-R hearing aids: Neosonic hearing aids been cleared and approved by the FDA as OTC hearing devices to treat mild to moderate hearing loss in adults over the age of 18 since 2022.

3. MDHearing Volt hearing aids: The MDHearing Volt has been cleared and approved by the FDA as medical devices to treat mild to moderate hearing loss in adults over the age of 18 since 2022.

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

Inclusion criteria of participant:

1. Adults ages 18-90 years
2. Speak English as their primary language
3. No vision impairment that would interfere with the ability to complete study tasks (i.e., legally blind, severe cataracts, or macular degeneration)

4. Bilateral mild to moderate sensorineural or mixed hearing loss
5. Pass a cognitive screener
6. Minimum Grade 10 education
7. Ability to attend all study visits

Inclusion criteria of communication partner:

8. Adults ages 18-90 years
9. Speak English as their primary language
10. No vision impairment that would interfere with the ability to complete study tasks (i.e., legally blind, severe cataracts, or macular degeneration)
11. Normal or corrected-to-normal hearing ability (i.e., use of hearing aids)
12. Pass a cognitive screener
13. Minimum Grade 10 education
14. Ability to attend all study visits

Exclusion criteria of participant/communication partner:

1. Clinically significant unstable or progressive medical conditions, or conditions which, in the opinion of the investigator(s) places the participant at unacceptable risk if he or she were to participate in the study
2. History of unresolved communication difficulties following another neurological problem (i.e., stroke or brain tumor), neurodevelopmental disorder (i.e., Down's syndrome), or head/neck cancer
3. Diagnosis of dementia or cognitive impairment
4. Positive history of major psychiatric disorder (i.e., schizophrenia, significant untreated depression)
5. Co-enrolled in other intervention studies targeting hearing, language, or communication strategies
6. History or current fluctuating hearing loss
7. Evidence of conductive hearing loss
8. Current active hearing aid wearer (defined as wearing hearing aid(s) at least 4 hours a day for most days within the past year)
9. Current active hearing aid wearer within 30-day trial period of purchased hearing aids from a licensed provider

For the purposes of test validation and calibration, we may also enroll a small group (n=10) of listeners with normal hearing, defined as pure-tone thresholds of 20 dB HL or less at octave frequencies between 250 and 4000 Hz. With the exception of having normal hearing, those participants will follow the inclusion and exclusion criteria described above.

We will not include any other special populations (adults unable to consent, individuals under 18 years of age, pregnant women, or prisoners or other detained individuals).

3.0 Sample Size:

A study evaluating eye gaze and communication ability with hearing loss during the Diapix Conversation Analysis (Davis et al, 2017; DOI: 10.21437/AVSP.2017-3), found a significant difference in their group of 19 dyads. Participants had hearing loss. To our knowledge, this is the only study with the most comparable methods to our study.

We will plan to collect data on 30 dyads (30 participants and 30 communication partners). We anticipate having 20 dyads by the end of our study, with 30 dyads set for room for dropouts. For visit 1 of the study, both parties will be required to attend the sessions. For visit 2, the communication partner does not need to attend. Historically less than 10% of participants drop out of studies within our lab. However, due to COVID19, we anticipate the possibility of higher-than-average dropouts.

The sample will consist of adults at least 18 years of age and older and their communication partner also be at least 18 years of age or older to participate.

4.0 Recruitment and Screening Methods:

Prior to scheduling any appointments, a brief phone screening will be conducted with the participant to obtain basic eligibility criteria (i.e., age, location, availability, language, current/previous hearing aid use). Prior to study enrollment, potential participants will agree to have their hearing and cognition completed with prior authorization via screening consent form. These preliminary screening tests will allow us to exclude ineligible participants from enrolling in the study.

Participants will be recruited from a variety of sources:

1. A within-laboratory participant pool of prospective participants that has been established by the primary investigator. Letters and emails will be sent to those who have previously agreed to be contacted for new studies.
2. Flyers and brochures posted around Northwestern University's campus, off-campus community bulletin boards, and relevant online community message boards (Nextdoor, Facebook).
3. Northwestern University Center for Audiology, Speech, Language, and Learning. Clinicians will receive a set of participant criteria. When possible, patients seen for clinic appointments that meet the criteria will be provided information about the study.
4. Postings to the investigators' websites and social media accounts.
5. Direct contact with persons interested in the study referred from outside sources.
6. Local senior and community activity centers, and local chapters of the Hearing Loss Association (HLAA).
7. Patient registries through the CNADS at Northwestern and the Communication Registry.
8. Local newspaper advertisements.

Participants who are interested in the study will contact the study coordinator via phone or email provided in the recruitment material. Prior to scheduling any appointments, a brief phone screening will be conducted to obtain basic eligibility criteria (i.e., age, location, availability, language, current/previous hearing aid use). Prior to study enrollment, potential participants will agree to have their hearing evaluated with prior authorization via screening consent form. These preliminary

screening tests will allow us to exclude ineligible participants from enrolling in the study.

5.0 Research Locations:

The main locations are Hearing Aid Lab spaces located in Frances Searle on Northwestern's Evanston Campus, private treatment rooms at Northwestern University Center for Audiology, Speech, Language, and Learning (NUCASLL); and the satellite School of Communication's research space located in Abbott Hall on Northwestern University's downtown campus. Data collection locations will be secured and kept in private, research-dedicated spaces that are accessed via key or keypad that are not accessible to the general public.

Some study visits may be conducted remotely via video conferencing software. Research staff will conduct these visits from a private space (in their home or in a research lab/clinic) that is secured from unintentional access by others not involved with the study. The virtual visits will be conducted through a School of Communication Information Technology-approved video-conferencing interface (i.e., WebEx, Zoom with password protection).

6.0 Multi-Site or Collaborative Research:

N/A

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

N/A

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
☐Secondary Data Analysis (medical record data, educational records, government, or private sector datasets, etc.)
☐Ethnographic observation
☒Physiological measurements (i.e., EEG, EKG, MRI)
☐Biospecimen collection (saliva samples, blood draws, hair samples, etc.)
☐Mobile applications/data collection devices (i.e., Fitbits, actigraphs, etc.)
☒Behavioral decision-making tasks (i.e., 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):

_Audiologic Assessment (hearing test and otoscopy), real ear measurement (hearing aid assessment)

Approach:
This is a within-subjects design and participants will wear hearing aids only during scheduled lab visits. Participants will **not** take the hearing aids outside the lab or home with them. The expected total duration of the study is 2-4 visits based on the typical timing of assessments and procedures. The range of duration of scheduling and visits will occur at times convenient for the participants. Although the study is sectioned into three visits (Eligibility, visit 1, and visit 2) participants can merge visits together (such as Eligibility and visit 1) into one visit, or split up a visit (i.e., such as changing visit 2 to two separate visits) based on the participant's schedule and convenience.

Timeline

(1) Eligibility Screening: (Approximately 60-90 minutes, in person) The Eligibility Screening will consist of inclusion questionnaires, communication questionnaires, and audiologic assessment. Both the participant and communication partner can be present for this visit and will both complete all testing for the Eligibility Screening.

If the participant and/or communication partner has had an audiologic assessment within the past year, then they are welcome to bring those results with them to their Eligibility Screening. If both the participant and communication partner have hearing assessment results from within the past year, then both of them will not be required to complete an audiologic assessment in the laboratory. If only one or neither member of the dyad has had an audiologic assessment within the past year, then the one member or both will complete an audiologic evaluation within the laboratory prior to visit 1.

Inclusion Questionnaires	**Hearing health and history questionnaire:** Participants will be asked questions regarding their hearing health history in an interview style format. If done remotely, this can be completed via phone or video chat. **MoCA:** with a score ≥24 (within normal limits): The Montreal Cognitive assessment is a cognitive screening test designed to detect mild cognitive impairment. It requires approximately 10 minutes and assesses short-term recall, visuospatial abilities, executive function, attention, working memory, language, and orientation to time and place. This may be administered remotely via phone/video chat or in-person.	***Data Collection Time: 20-30 minutes***	Questionnaires have no risk involved for the participant
Communication	**Communication Participation Item Bank**	***Data***	Questionnaires

Questionnaires	**(CPIB):** This measure was designed for hearing and communication across different communication disorders and life situations. Items probe the extent to which the participant's condition interferes with a range of interpersonal speaking situations. **Unidimensional Relationship Closeness Scale (URCS):** This questionnaire describes the relationship between the participant and their communication partner. **Speech Spatial and Quality Scales (SSQ-12):** a self-assessment of speech understanding, spatial hearing, and other qualities of sound on a scale ranging from 0 to 10, with higher scores towards 10 suggesting little to no difficulty. **Hearing Handicap Inventory for Adults (HHIA):** self-assessment scale containing 25 items of two subscales (emotional and social/situational). The assessment measures perception of emotional aspects and social limitations perceived by the individual with hearing loss.	***Collection Time: 30-40 minutes***	have no risk involved for the participant
Audiologic Assessment	**Otoscopy:** Standard clinical procedure to look into the ear to observe the eardrum and ear canal. **Audiometry (Air & Bone Conduction):** Study audiologists will complete an audiologic evaluation, including: pure-tone air conduction thresholds at 0.25, 0.5, 1, 2, 3, 4, 6, 8 kHz; pure-tone bone conduction thresholds at 0.5, 1, 2, 4 kHz; speech discrimination in quiet and in noise. If medically necessary, tympanometry, a measure of middle ear function, may be performed. This procedure would be necessary if one or more of the following conditions are met: the eardrum is not clearly visible with otoscopy (whether by scarring on the eardrum, earwax obstructing some view of the eardrum, or any other condition that makes viewing the	***Data Collection Time: 15-20 minutes***	Otoscopy, audiometry, and QuickSIN are standard clinical procedures with no risk to the participant.

	eardrum difficult), and/or if the patient complains of pressure or fullness of one or both ears, and/or if there is a conductive component on the audiogram and the eardrum appears normal. **QuickSIN:** This is a clinical auditory test that consists of low-context sentences in a background of 4 talker babble. The speech is set to an audible level and the noise is gradually increased. Research participants verbally repeat as much of the sentence as possible.		

(2) Visit 1: (Approximately 100-120 minutes) Visit One will consist of the hearing aid fitting and verification, and the Diapix Conversation Analysis both in aided and unaided conditions for the participant. The communication partner will be present and participate in the Diapix Conversation Analysis with the participant. Only the participant will be fit with hearing aids.

A pair of the listed hearing aids will be fit on participants comparing two settings; (1) a self-fit setting made by participants following the manufacturer's recommendations, and (2) an audiologist-fit setting. All participants will undergo both an initial self-fit and then complete testing with the audiologist-fit settings. Participants will be tested with or without the audiologist-fit settings at random with an equal allocation among participants within testing materials. Due to the within-subject nature of this trial, a blinded trial is not possible. However, every effort will be made to avoid comparisons of self-fit and audiologist-fit algorithms to minimize participant and researcher bias in verbal and written communication with the participants.

Hearing Aid Fitting & Verification	**Hearing Aid Fitting:** The participant will be instructed on how to insert the hearing aid into their ear(s) and will follow step-by-step instructions on a hearing aid application on a cell phone to fine-tune the hearing aid to their preferred settings. Then, the audiologist will made additional adjustments using hearing aid verification process to fine-tune the hearing aid to the participant's audiologic pure tone thresholds. **Hearing Aid Verification:** Hearing aid verification involves the use of a soft probe tip microphone into the ear canal with the hearing aid situated in the ear canal correctly. The participant will hear sentences of soft, average, and loud intensity as the software is measuring the output gain of the hearing aid	***Data Collection Time: 15-30 minutes***	Hearing aid fitting and verification are standard clinical procedures. Minimal to no risk for hearing aid fitting: patient may perceive hearing aids as louder than anticipated, and adjustments will be made to ensure the hearing aids are programmed to a comfortable listening level that is not hazardous to hearing.

	and comparing it to the recommended NAL-NL2 targets based on the participant's audiometric pure tone thresholds.		Minimal to no risk for hearing aid verification: during verification, participant will have a very soft, flexible probe tube microphone placed in the ear to measure the output of the hearing aid as it is sitting in the participant's ear. The probe tip may feel "ticklish" or may feel odd in the participant's ear canal. Efforts will be made to ensure the participant is comfortable during all procedures. Participant is welcome to take a break at any time without consequence.
Diapix Conversation Analysis	**Diapix Conversation Analysis:** Consists of derived measures including proportion of trouble sources, proportion of unsuccessful repairs, proportion of complex repairs: video and audio recording will be collected from each participant/communication partner dyad at two timepoints: pre-fitting (unaided), and wearing the hearing aid (aided). Conversation data will be collected at one of our research sites, or remotely. If conversation data is collected in a participant's home or remotely, study staff will survey the environment removing (or positioning recording equipment to avoid recording) any personally identifying or sensitive information (i.e., mail with addresses, pictures of young children or unconsented individuals, personal	***Data Collection Time: 70-90 minutes***	Minimal to no risk: Minimal risk of boredom or minimal fatigue with task. Participant is welcome to take a break at any time without consequence.

	documents) prior to recording. If in person, the study team will replace these items once data have been collected as part of the session clean-up routine. Conversation data will be collected using standardized Diapix conversation tasks. The participant-communication partner pair will be seated approximately 3-5 feet apart with a barrier between them and will be instructed to describe standardized picture stimuli from to their partner (partner is not able to see the primary speaker's picture but has a companion picture of their own). The goal of the conversation task is to have the partner use the primary speaker's description to identify up to 12 objects that are missing on their picture, but present on the primary speaker's picture. The Diapix sampling method is a standard approach for collecting conversation samples (Baker & Hazan, 2011). The Diapix pictures are freely available to the research and clinical community and can be found through the Northwestern Online Speech/Corpora Archive and Analysis Resource (OSCAAR; Kendall, 2010; http://oscaar.ling.northwestern.edu/).		

(3) Visit 2 (Approximately 60 minutes): The second visit will consist of tasks of executive functioning (Stroop Task, Flanker Task) and a physiological measurement (pupillometry) to measure listening effort during the Rapid Recall Task (RRT). Only the participant will attend visit 2.

Tasks of Executive Functioning	**Stroop Task:** This is a measure that assesses reaction time and conscious versus automatic visual processing. This test takes approximately 5 minutes to administer. Participants are instructed to read black text that indicate the names of colors, as quickly as possible. The second part of the assessment includes participants seeing colored lines, and they are instructed to name the colors on the page as quickly as they can. The third part of administration is the participant will then be given a list of color names, where they say the color of each word, not read the text itself. For example, if the word "yellow" was written in	***Data Collection Time: 10-15 minutes***	Minimal to no risk: Boredom and minimal fatigue may occur during testing. Participant is welcome to take a break at any time without consequence.

	green ink, the correct response is "green". Participants are timed for each of the three segments. **The Flanker Test:** We will administer two tasks tapping this interference control ability and compute a z-score aggregate to obtain a stable estimate. In the arrow flanker task, participants see a > or < sign, surrounded by two > or < signs on either side (i.e., >>>>>, <<><<). Their task is to focus on the middle sign and decide whether that sign is pointing to the left or the right as quickly and as accurately as possible by pressing one of the two buttons (left or right). The reaction time difference between the compatible (i.e., >>>>>) and incompatible stimuli (i.e., <<><<) will be used to index interference control ability. In the letter flanker task, participants will see either a letter G or H in the middle, surrounded by two Gs or Hs on either side (i.e., HHHHH, GGHGG). Participants' task is to focus on the middle letter and determine as quickly and as accurately as possible whether it is a G or an H. Again, the reaction time difference between the compatible (i.e., HHHHH) and incompatible (GGHGG) stimuli will be used as the index of interference control ability.		
Pupillometry & Recall Repeat Task (RRT) (Data Collection Time: 30-40 minutes)	**Pupillometry:** a measurement of pupil size, is correlated with task difficulty in a variety of research focused on cognition. Task difficulty, or listening effort, during conversation is a useful measure of how effortful auditory processing is to the participant. The participant will be asked to rest their chin on a fixed chin rest and press their forehead on a cushioned support rest. Participant will be asked to fixate on a dot during the duration of testing. Testing will be completed with the Recall Repeat Task (RRT) during pupillometry recording. Pupillometry data collection will measure dilations of the pupil and record these dilations using EyeLink software. **Recall Repeat Task (RRT):** an auditory only speech-in-noise task that assesses auditory	***Data Collection Time: 30-40 minutes***	Minimal risk to participants: Minimal to no risk include boredom with the task and minor fatigue from sitting still and maintaining a stable head position during the task. Participant is welcome to take a break at any time without consequence.

	working memory and reported listening effort by participants. The participant is presented with a list of pre-recorded sentences that they are asked to repeat back and to recall 15 seconds after repeating back a list of 6 sentences. After the participant recalls the sentences heard, they are asked to rate on a scale of 1 to 10 how effortful they found the listening situation to be and are asked to provide an estimated time of how long they are willing to spend listening to speech-in-noise condition. Responses are recorded by the examiner in the testing interface, which is not visible to the participant.		

For this study, we will not need to access any participant's pre-existing HIPAA or PHI protected medical or health information or data. Also, we will not need to access any secondary data that is not HIPAA protection or contains PHI.

We will not use mobile apps for data collection during this study.

How the student will check in with the PI:
The student (Grace Szatkowski) will be in constant communication with the primary investigator (Pamela Souza) throughout the study, and should risks arise, will contact the primary investigator.

Grace Szatkowski is a state-licensed (IL) audiologist with expertise in performing the tasks involved in this study.

9.0 Research with Vulnerable Populations

N/A

10.0 Incomplete Disclosure or Deception:

N/A

11.0 Consent Process:

Prior to enrollment, potential participants will have a hearing and cognitive test with authorization by a screening consent form. These tests will allow us to exclude potential participants from enrolling in the study who are ineligible based upon their hearing or cognitive status. If participant is eligible based upon their screening results, they will be enrolled in the study with separate consent. These 45-minute tests are built into the study design of the eligibility tasks, and do not require additional visits.

If a participant is not eligible to participate based upon the screening consent, they can authorize future contact with the consent's optional element and authorize the lab to retain the screening audiogram.

Consents may be obtained via hard copy or digitally via RedCAP, depending on participant preference. In either case, all subjects will provide their consent to study procedures to the investigator or her research assistants. An unlimited amount of time will be provided to the participant to ensure they have adequately reviewed the consent form and all questions have been addressed by study staff. Following the subject's opportunity to read the consent document, study staff will review each section with participant to clarify the study or any procedure and ensure understanding. Additionally, consent forms may be provided to a potential research participant before a study visit is scheduled so they may take extra time to review before committing to participation.

RedCAP: 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, email or video before 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.

Hard Copy: All physical consent forms are stored in a locked file cabinet drawer within the Hearing Aid lab (a locked laboratory). All participants will be offered copy of their signed consent form unless they explicitly decline a copy.

12.0 Waiver of Participant Signature on Consent Form:

N/A

13.0 Waivers and Alterations of Consent Information:

N/A

14.0 Financial Compensation:

Upon completion of study tasks, participants will be paid an hourly rate for participation ($20/hr). Payment will be made at the conclusion of each study visit. If a subject decides to withdraw from the study before its completion, s/he will still be paid $20 per hour for the time spent performing study tasks up to that point. In the event that a participant is removed from the study without their consent, compensation will be pro-rated based upon the duration the participant remained compliant with study tasks and procedures.

Participants will be compensated at the above rate in the form of cash, a Hyperwallet Virtual Card, or a physical PNC Visa provided by Northwestern University, depending on participant's preference. The card will be issued after the completion of the study visit at which point the participant will be emailed instructions for the card activation process.

Parking will be provided to all participants, whether at the Evanston or Downtown campus, in the form of validation.

15.0 Audio/Video Recording/Photography

All visits will be audio and video-recorded to determine the effectiveness of the study treatment.

Audio/video recording of testing:

- Identified with a unique identifier (no personal health information).
- Audio/video data will be stored on a dedicated server managed by the Northwestern University School of Communication Hearing Aid Laboratory (HALAB).
- Audio/video data will be uploaded directly to the HALAB Research Group server via a secure Northwestern University network.
- Audio/video data will be accessible only by trained research staff involved with this protocol.
- Audio/video data will be stored in compliance with Northwestern policies https://research.northwestern.edu/sites/research/files/policies/Research_Data.pdf.
- Data will be stored indefinitely post final data analyses OR Conversation recordings will be stored indefinitely on the HALAB Research group server.

16.0 Potential Benefits of this Research:

Although participants in this study may not directly benefit from participation, the study would provide them with the opportunity to learn about their hearing and ask questions about hearing aids without sales pressure. Participants who were unsure if they would benefit from hearing aids may find their experience informative in deciding how to manage their hearing loss. All participants in the study will have the opportunity to receive

counseling at the end of the study, done by the investigator, including listening recommendations tailored to their individual speech understanding, memory, and attention. They will have a chance to ask questions and receive information about options for their hearing loss (outside of the study).

17.0 Potential Risks to Participants:

All study procedures pose minimal risk to study participants and are not substantially different from those associated with typical hearing. Some of the study tasks can be boring, or repetitive. If a participant wishes to discontinue testing at any point, they may choose to do so without any consequence.

Some participants may find the hearing aid settings used in this study to be loud or sharp in comparison to their unaided hearing. These are all normal and expected consequences of being fit new hearing aids; many patients get used to hearing aids and find their perceived sound quality improves over time. Some adjustments can also be made to improve sound quality for the participant if the hearing aids are making them uncomfortable. Real ear measures, part of the standard of care for hearing aid fittings, involve a soft floppy tube being placed in the ear canal. Some participants may find the sensation strange or ticklish during insertion and removal, which takes less than a minute. Pupillometry, which involves the use of a chin rest, requires the head remain still in the rest for the duration of the task (about 30 minutes). Efforts will be made to ensure comfort of the participant prior to testing.

There are no anticipated physical risks associated with this study. There are no anticipated social or legal risks. Providing free parking will minimize economic risks. There are no costs associated with the study intervention itself.

Participants will be free to withdraw from the study at any point in time. If a participant withdraws from the study, all data collected up to that point can be used by the investigator unless the participant indicates they would like to have their data removed from the study. Once a participant is unable to continue with the study, compensation will end.

As part of the protocol, potential impairments not previously known to the participants may be revealed (hearing loss, cognitive changes, depression). When these do occur, the study team will provide support to the individual receiving this information. Additionally, participants will be encouraged to discuss the results of the screening measures with their family physician.

Although unlikely, participants may be withdrawn from the study if a trained experimenter determines that the participant's continuation presents immediate, clear risk to either the participant or the experimenters' physical, mental, or emotional well-being. Participants may also be withdrawn from the study if they are unable to participate fully in study activities (i.e. tolerate an effective level of amplification). Data from withdrawn participants will be retained and may be used in data analysis if the withdrawal occurred for reasons that do not affect the integrity of the collected data.

18.0 Provisions to Protect Participant Privacy and Data Confidentiality:

During the consent process, participants will be informed that their identifiable data will be used, but that their information will be stored separately from their study number in a secured location. Each participant will receive a study code that will be used for all study data. The only link between identifiable data and a study code will be on a password protected HIPAA-approved server with server security managed by Northwestern School of Communication computer staff. Any physical data containing identifiable participant information (i.e. consent documents) are kept under lock and key and are accessible only by study staff. All research staff will be trained in appropriate Human Subjects protection procedures, including confidentiality.

Participant confidentiality will be ensured by storing data without subject identifiers. Any recordings will be stored using a subject ID number in the file name. 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

Electronically stored data is accessible only to study staff via password-protected files. We will use REDCap (Research Electronic Data Capture), a secure database software that is HIPAA compliant.

19.0 Data Monitoring Plan to Ensure the Safety of Participants:

Treatment fidelity checklists will be completed for all treatment sessions. This will help ensure that the safety and welfare of participants are prioritized at all times.

Untoward events associated with the intervention will be monitored by study staff periodically and any unanticipated treatment effects will be documented in the research record. If emergency services are required, standard university policies will be followed to access care for the participant.

20.0 Long-term Data and Specimen Storage and Sharing:

No identifiable data will be shared outside of the study team. De-identified data from this study may be shared with the research community at large to advance science and health research. We will remove or code any personal information before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify participants from the information we share.

21.0 Qualifications of Research Team to Conduct the Research:

The Principal Investigator, Pamela Souza, PhD, CCC-A, FAAA, is a licensed audiologist and

an experienced researcher at Northwestern University. Her primary areas of research expertise are in aging, cognition, and hearing aids. She has worked as a clinical audiologist for over 20 years. Her primary areas of clinical expertise are in hearing aid fitting and auditory rehabilitation for older adults, including clinical experience with patients who have MCI or dementia.

Student Investigator, Grace Szatkowski, AuD, FAAA, is a licensed audiologist and PhD student at Northwestern University. Primary interests in research include cognition, hearing aids, and aging. She graduated with a Bachelor of Arts in Speech and Hearing Science in 2016 from the University at Buffalo and went on to graduate with a Doctorate in Audiology in 2021 from the University of Akron. Clinical expertise includes adult auditory rehabilitation, hearing aid fittings, and electrophysiology.

Research staff will be trained in strategies for communicating with adults who have hearing loss.