Evaluation of Unilateral vs Bilateral Hearing Aids for the Treatment of Age-related hearing loss

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Sponsor:	Patient-Centered Outcomes Research Institute (PCORI)
Funding Source:	Patient-Centered Outcomes Research Institute (PCORI)
Protocol Source:	PI – Department of Head and Neck Surgery & Communication Sciences
Duke IRB#:	Pro00106077

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Original Version:	3/23/2021
AMD1:	5/7/2021
AMD2:	3/22/23
AMD3:	3/5/24
AMD4:	1/24/2025

1. Protocol Title: Age-related hearing loss (ARHL)

2. Purpose of the Study:
Primary objectives:

1. To compare the hearing-aid benefit of unilateral versus bilateral fittings of commercially-available hearing aids that incorporate a dome coupling (open or closed dome as required by degree of hearing loss, or custom coupling if clinically indicated), which represents the most popular style used for mild to moderate hearing loss
2. To compare other multi-dimensional outcomes including hearing-related quality of life, hearing aid satisfaction in patient-nominated goals, ecological hearing aid outcomes, and hearing aid use.

Secondary objectives:

1. To compare performance outcomes for unilateral versus bilateral hearing aid fittings
2. To explore the differences in long-term patient reported outcomes for their final hearing aid configuration choice (months 4-30).
3. To explore patient experiences in each group (unilateral vs bilateral), and patient preference in regards to their choice of final hearing aid configuration.

3. Background & Significance: Hearing loss affects millions of Americans and is a significant public health concern in the United States.[8,9] The prevalence of hearing loss increases with increasing age.[2] In fact, data from National Health and Nutrition Examination Survey suggests that 10.5% of adults aged 55 to 64 years have hearing loss sufficiently disabling to warrant amplification. These prevalence rates increase to 25% for those 65 to 74 years and 50% for those 75+ years of age.[10] The primary complaint of listeners with hearing loss, and older listeners with hearing loss in particular, is the reduced ability to understand speech, especially in background noise such as at parties or restaurants.[11,12] This leads to difficulties with communication function in daily life.[13-17]. If left untreated, hearing loss has been shown to be associated with increased risk of dementia and cognitive decline,[18-22] increased odds of falls,[23,24] depression,[16,25,26] social isolation,[16,27,28] poor physical functioning,[29] lower levels of physical activity,[30] and reduced quality of life.[8,16,31-35] Hearing loss also is associated with underemployment and economic burden.[36-38] Hearing loss can even negatively affect significant others and care providers of affected individuals (i.e., third-party disability).[35,39-43] Hearing aids are the primary intervention option for hearing loss, especially for degrees of hearing loss in the mild to moderate range which is the range most associated with ARHL.[44,45] Hearing aids have been shown to be beneficial in terms of improved speech perception and communication function,[46-49] reduced psychosocial implications of hearing loss,[50-52] improved health- and hearing-related quality of life,[31-33,47,48] reduced impact on significant others (or reduced third-party disability),[39,53] and reduced Medicare spending.[54] Hearing aid benefit also has been shown in those with mild hearing loss.[47,55] Nascent reports suggest that treatment of hearing loss through hearing aids may even slow cognitive decline.[56-59] Long-term benefit of hearing aid use also has been demonstrated.[52,60,61] The recommendation for bilateral hearing aids for the treatment of bilateral hearing loss is considered the norm in the profession, unless there is a specific contradiction for bilateral amplification.[5,62] In fact, clinical practice guidelines state that bilateral hearing aid fittings are recommended for *most* patients with bilateral hearing loss and that one hearing aid would only be recommended in circumstances related to patient need, hearing asymmetry, or personal reasons such as cosmetics or financial.[3] The benefit of bilateral hearing aids over a unilateral hearing aid has been demonstrated in specific contexts such as with speech understanding in complex noise (e.g., spatially separated), cognitively demanding

environments (e.g., switching attention)[63], those with greater degrees of hearing loss,[64] and with outcomes related to localization and listening effort.[63,65,66] On the other hand, the literature indicates that patients with bilateral hearing loss can benefit from unilateral amplification, and at times, even more so than with bilateral hearing aids.[63,67,68] These conflicting data have contributed to the clinical dilemma surrounding the recommendation of unilateral versus bilateral hearing aid fittings for bilateral hearing loss that has been deliberated in the professional community for several years.[5,69] Nonetheless, bilateral hearing aids are almost *intuitively* recommended by audiologists for most patients with ARHL.

The gap in the evidence for unilateral versus bilateral hearing aid fittings was recently illuminated in the literature through a Cochrane report whose authors concluded that very low quality evidence exists to guide patient decisions for one or two hearing aids and that there is no hearing-specific outcome evidence to inform whether one or two hearing aids is better for the treatment of bilateral hearing loss.[4] There are several reasons for the low quality of evidence. These were highlighted in the Cochrane report[4], which was only able to identify and include four RCTs conducted in this area. For example, there was a wide range in the patient population across the studies. In the four RCT studies[5,70-72] included in the Cochrane report, the age of the participants ranged from 23-85 years with three-frequency pure-tone averages ranging from >25 dB HL to 60 dB HL. Participants across the four studies also varied in their hearing aid experience, gender, and payer source for hearing aids. The current study will focus on those 50+ years of age with age-related mild to moderate (< 60 dB HL for .5 -4 kHz)[73] bilateral hearing loss who are seeking hearing aid(s) for the first time. Small sample sizes were used in the majority of the Cochrane studies and only one performed a power analysis.[5] A wide range of hearing outcomes were used in these studies, not all of which were considered relevant. Most previous clinical trials used self-reported preference ratings or retrospective self-reports (e.g., standardized questionnaires) as the only measure of hearing aid outcomes. Inclusion of performance outcomes and degree of hearing loss also is important, as Ricketts and colleagues[74] found minimal binaural hearing aid benefit in a laboratory study in patients with milder degrees of hearing loss (<40 dB HL). Taken together, high-quality evidence demonstrating support for bilateral hearing aids over a unilateral hearing aid in most adults with bilateral age-related mild-to-moderate hearing loss is profoundly lacking.[4,5] Our proposed study aims to specifically focus on patient-reported variables as well as covariates and performance variables that are deemed important to differentiate between unilateral and bilateral hearing-related outcomes[5,62,75-77] and that are important to patient stakeholders. We seek to fill this critical gap in the literature by providing high-quality evidence comparing the benefit of unilateral versus bilateral hearing aid fittings from a randomized clinical trial. In addition, this study design will provide evidence for the determinants of *patient choice* in the decision process for amplification (focus groups), in addition to their experiences with unilateral or bilateral hearing aids, thereby increasing the generalizability of the study findings.

Every day, patients with mild-to-moderate hearing loss are faced with how to make a decision about purchasing hearing aids, and most often, clinicians intuitively recommend bilateral hearing aids. As indicated by Schilder et al. (2017), this topic is important because there is insufficient evidence regarding the amount of benefit a second hearing aid provides over one hearing aid. Nonetheless, unilateral and bilateral hearing aid use has been proven to be beneficial across a wide range of outcome domains. In addition, the cost of hearing aids often is the third highest lifetime purchase, after a home and car,[1] requiring the patient and their significant others to weigh the financial and personal benefit of pursuing hearing aids or not. The results of this study will provide high-quality objective and patient-centered evidence comparing unilateral versus bilateral hearing aid fittings in patients with ARHL through the use of a randomized controlled trial. The outcomes that will be used in the study were identified in the literature as important and will be vetted by our patient focus group to ensure they are of most interest to patients with

hearing loss and their significant others. Furthermore, the results of this study will inform hearing health strategies at the population level by demonstrating real-world influences of patient engagement and communication benefit. Specifically, in order to make appropriate clinical recommendations, information regarding how unilateral versus bilateral hearing aids affect patient directed real-world outcomes in listeners with mild-to-moderate hearing loss will be gathered. We emphasize real-world outcomes in the proposed study because (1) real-world outcomes are more likely to be relevant to public health and (2) the literature has suggested that hearing outcomes measured in the laboratory often do not translate to the real world.[78-81] To minimize recall bias, hearing aid success will be also measured in situ (i.e., in natural environment) using a novel smartphone-based Ecological Momentary Assessment (EMA) system. Recent data have indicated that the in-situ self-reports collected using a smartphone EMA system are more sensitive, and potentially more valid, than retrospective questionnaires.[82,83] The knowledge gained from this study has the real potential to change the dialogue for the recommendation of unilateral versus bilateral hearing aids. This knowledge is especially timely given the nascent federal law requiring the development of a class of over-the-counter hearing aids. The cost of the over-the-counter hearing aid is still likely to be substantial. Patients want the best value for their money, and a second hearing aid may not be incrementally better for the patient when they are confronted with the cost. Patients will soon be faced with making the best the choice of cost and functionality for themselves in their daily lives.

4. Design & Procedures: This is a randomized, parallel-group, two-phase, clinical trial (RCT) with two treatment arms including: (1) a bilateral hearing aid fitting group, and (2) a unilateral hearing aid fitting group. This RCT design will allow us to determine whether or not bilateral hearing aids are more beneficial than a unilateral hearing aid.

This study will be conducted at Duke and Vanderbilt, with Duke functioning as the coordinating center and single IRB. Our aim is to compare unilateral versus bilateral fittings of commercially-available hearing aids. Phonak® (our industry partner) agreed to extend the trial period from 45 days to 180 days to ensure subjects have adequate time to complete the study, and at a modestly reduced rate. Subjects will pay out-of-pocket for the devices and care and/or use their insurance benefits if applicable.

Phase 1:

Screening Visit: Patients undergoing routine comprehensive audiometric evaluation by a site clinical audiologist for a hearing concern will be considered for the study. The data from these routine, best practices visits will be extracted from the medical record and audiometric databases if the patient agrees to enroll in the study.

Baseline Visit: The study coordinator will screen the subject for inclusion in the study and obtain informed consent. Questionnaires including MOCA, APHAB, GHABP, HHIE, SSQ, TFI, and ECHO will be completed via REDCap electronically and the responses blinded to the remaining study staff. Participants will be asked to complete a demographic intake form that includes collection of socioeconomic data (salary, education, marital status, living arrangements). In addition, participants will be asked to answer a series of questions related to the use of facemasks during COVID19. The baseline study auditory testing (research variables) will be conducted by the research audiologist. Eligible subjects will be randomly assigned to one of the two treatment groups in a 1:1 ratio via a random-number generator. The unilateral fitting group will choose the ear in which they want fitted. If they do not have a preference, then they will be further assigned the ear in which the hearing aid will be fitted with a 1:1 ratio.

Patients will be given a purchase agreement for the hearing aids which lists the price of the hearing aids, discount received, fitting fee, and details on refunds should they want to return the hearing aids.

The study hearing aid(s), Phonak® **Audéo**™ Paradise or Lumity model, will be ordered from Phonak after the group assignment. Customary standardized education will be provided by the research audiologist regarding hearing aid expectations and the current evidence for differences in unilateral versus bilateral amplification. The research audiologist will make manufacturer and patient-specific ear measurements for tubing length, dome size, and color selection. The baseline testing of research variables can be accomplished on the same day as the consent or in a subsequent research visit. Study participants will be paid $50/research visit plus parking fees for study related time and effort.

Week 1-2 (hearing aid fitting visit): *This is a standard clinic visit.* All subjects will complete a standard, comprehensive hearing-aid fitting and the output of the hearing aid(s) verified via real-ear measurements to a prescriptive target for input ranges with speech stimuli and the maximum output of the hearing aid(s) will be verified; all measurements following standard of care practice. Subjects will be oriented on use and care of the hearing aids in the typical fashion. The manufacturer brochure will be provided as usual. ***Subsequent visit dates are based on the hearing aid fitting visit at week 1 – 2***

Week 10-11 (following hearing aid fitting visit): Ecological Momentary Assessment (EMA). During the final weeks of the 3-month trial period, we will use (EMA) techniques to gauge in-situ hearing aid benefit. We have modified the *Glasgow Hearing Aid Benefit Profile* (GHABP) to be given on a smartphone-based EMA system via REDCap to administer the GHABP in natural environments (i.e., in-situ GHABP). The system is set up to notify the subject at routine intervals throughout the day. If any of the four situations pre-defined by the GHABP (*TV listening, small conversation in quiet, conversation in noise, and group conversation*) occurred in the past 3 hours, subjects are asked to answer questions regarding them. In addition, we plan to further modify this EMA portion to include two subject-nominated listening situations that are important to them that are identified when subjects first complete the baseline version. Study participants will be paid $25 for this completion of the EMA.

Week 10-11 (following hearing aid fitting visit): Telephone visit. The study coordinator will remind the subject about the EMA completion required. They will also ask if the subject wants to stay with their current hearing aid configuration (either 1 or 2) or change the configuration at the 3-month research visit (either 0, 1 or 2 hearing aids). Subjects may be contacted by email if not able to be reached by phone.

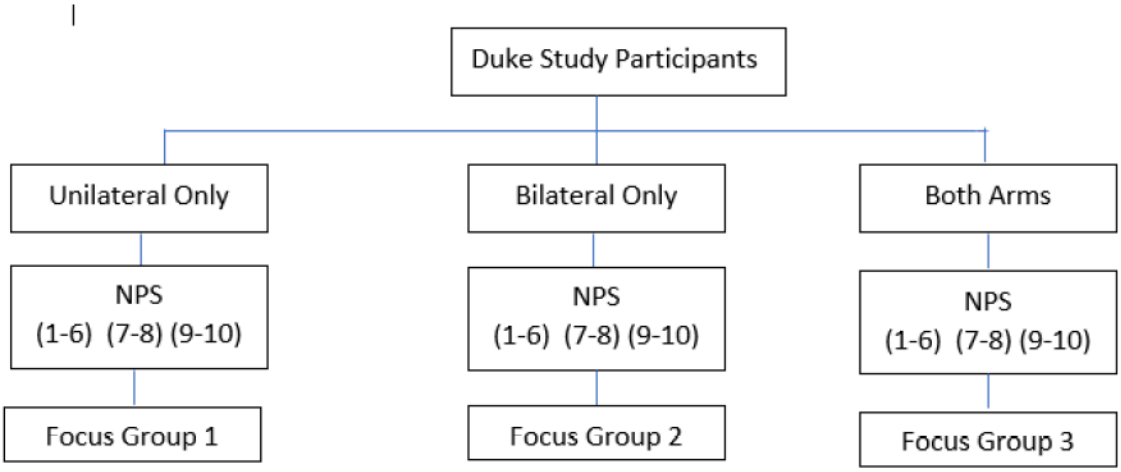
Month 3 Visit: (Three-Month Trial Period and Post-Intervention Outcomes Assessment). Three months following the ***hearing aid fitting visit (week 2 visit)***, participants will be asked to return for an in-person outcomes assessment. All subjects will be encouraged to use their assigned hearing aid configuration for the 3 months supported by Phonak (industry partner). As is standard with hearing aid trial periods for clinical patients, subjects will be allowed to visit the clinical audiologist for fine-tuning and/or hearing aid problems should they arise (number of and types of visits recorded along with data logging from the hearing aid[s]). If programming changes are made, real ear verification will be completed. The standard clinical visits will be completed by a clinical audiologist following standard of care; however, the research audiologist will enter the clinical data from these visits into the study database. Post-intervention patient-reported outcomes including APHAB, HHIE, SSQ, SADL, GHABP, COVID19 & mask questionnaire, and IOI-HA will be assessed using a REDCap link provided to the subject by the

study coordinator and aided auditory measures will be completed by the research audiologist in Research Visit 3.

Participants who choose to switch their hearing aid assignment (from 1-2, or 2-1) will have a hearing aid fitting visit for the new configuration, per standard of care.

All subjects will be offered the opportunity to return 1 or 2 hearing aids or to obtain a different hearing aid configuration at the conclusion of the 3-month trial period. Participants will receive a refund minus the fitting fee if they decide to return the hearing aid(s). These final choices will be recorded in REDCap by the research audiologist. The responses will inform the development of the focus group guide and selection of the focus group participants. Study participants will be paid $50 for this research visit plus associated parking fees as applicable.

Focus Groups: In the context of the larger trial, the specific aim is to explore subject experiences of adults assigned to unilateral vs bilateral hearing aids. Subjects from each group (unilateral vs bilateral) will be asked to participate in a focus group to discuss their experiences with unilateral vs bilateral hearing aids and factors that led to the initial choice in hearing aid fitting. A total of three focus groups will be conducted at Duke, , one with subjects who were randomized to bilateral hearing aids. One with subjects who were randomized to one unilateral, and one with a combined group of subjects from each group. Each group will have anywhere from 6-14 participants for a total of up to 40 subjects providing insight into their experiences during the RCT and final choice for hearing aid fitting. Responses to the focus group questionnaire completed during the 3 month study visit will be used to inform which participants will be invited to participate in a focus group. Invitations will be issued first by mail or email and followed up by phone. Each focus group will be scheduled for 90 minutes and will be recorded. Reminders will be sent two weeks, 1 week and 1 day prior to the scheduled group via email or text. Focus group participants will be offered a $50 incentive for their participation. To our knowledge, research to-date is limited to the use of individual interviews and checklists and has not benefitted from the value of group interaction.



Focus Group Guide: The focus groups will be semi-structured. Each will be opened with introductions (participants, facilitator, and observer), a set of participant expectations (e.g., respect for others choices, one speaker at a time, take a break when needed) and verbal acknowledgement that the discussion will be audio recorded on two devices to support data analysis (and prevent the likelihood of missing data due to technology failure or sound distortion). The discussion will start by the facilitator's introduction to the commonality across the group (hearing aid assignment and geography, recognizing the other study site). Subject experience includes both objective and subjective views and the group will be invited to describe "what happened" (objective). Allowing the discussion to unfold, the facilitator will use the group's flow to fully explore range of experiences and then the alignment of their experience with the final choice for 0, 1, or 2 hearing aids. It is expected that each group discussion will include approximately 15 minutes hearing about objective experience that will naturally transition into a 45 minute discussion on subjective experience, 10 minutes on what they would recommend to others (validating their experience data and providing targeted information for our dissemination plan), followed by a 20 minute discussion on the rationale for their final choice.

Focus Group Facilitator: Focus groups will be facilitated by Janet Prvu Bettger.

Phase 2:
In Phase 2, we will explore longer team outcomes for subjects while they are wearing their final hearing aid configuration of choice.

Week 22-23: Ecological Momentary Assessment (EMA). Subjects who kept 1 or 2 hearing aids after the 3-month trial will be asked to repeat the EMA one-week prior to the conclusion of the 6-month trial period. Study participants will be paid $25 for this completion of the EMA.

Week 22-23: Telephone visit. The study coordinator will remind the subject about receipt of EMA text messages and email link for questionnaires. The study coordinator will also ask the subject if they want to stay with the current hearing aid configuration (either 1 or 2) or change the hearing aid configuration before the end of the 6-month trial period.

Month 6 Visit: Post-Intervention Outcomes Assessment at 6 months. We will follow subjects in their final hearing aid choice for an additional 3 months by assessing patient-reported outcome measures only including APHAB, HHIE, SSQ, SADL, focus group questionnaire, COVID19 & mask questionnaire, and IOI-HA. The measures will be digitized in REDCap and the subjects will be sent an email link to complete the patient-reported outcome measures. This will allow us

to explore long-term and exlporatory outcomes on a subset of the variables. Study participants will be paid $25 to complete the measures at this 6-month time point.

Table 1. Schedule of Events

	Phase 1						Phase 2		Unscheduled Visit(s)
	Screening Visit[a]	Baseline Visit	Week 1-2	Week 10-11	Month 3 Visit	Focus Group[b]	Week 24	Month 6	
Routine Comprehensive Audiometric Evaluation	X								
HA Consultation	X								
eConsent		X							
eQuestionnaires		X			X			X	
HA Ordered		X							
Randomization		X							
Research Audiologist Evaluation		X			X				
HA fitting and/or programming[f]			X		X			X	X
Daily EMA via REDCap				X			X		
Telephone and/or email[c]				X			X		
Data Collection [d]			X		X			X	X
Retain or Return one or both HAs					X			X	
Compensation		X		X	X	X		X	

[a] Routine clinic visit must be completed within 6 months of the Baseline visit

[b] Invitation to participate in a focus group will occur sometime after the 3-month study visit, and potentially after the 6-month study visit, depending on the timing of when the focus group occurs.

[c] Reminder to complete EMA and/or questionnaires

[d] Data logging from hearing aid and REAL Ear

[f] HA fitting would be repeated per SOC if participant changed hearing aid assignment (from 1-2 or 2-1) during the trial period

5. Selection of Subjects:

Inclusion Criteria:

1. 50 years of age or older
2. Ability to read and understand English
3. Mild to moderate sensorineural hearing loss (defined by a pure-tone average at 500, 1000, and 2000 Hz of ≤55 dB HL in each ear, and the 3000 Hz and 4000 Hz threshold ≤80 in each ear), based on a hearing test obtained within the last 6 months by a licensed audiologist.
4. Symmetrical hearing loss defined by <20 dB difference between the pure-tone average of 500, 1000, and 2000 Hz between ears)
5. Interested in purchasing hearing aids, but is open minded about trying one or two hearing aids
6. No prior hearing aid use longer than 3 months (as documented via self-report)
7. Adequate literacy to complete questionnaires
8. Willing to purchase study-specific hearing aid(s)

9. Access to a smart phone (to receive text messages to link to EMA survey)
10. Has access to internet and ability to receive emails for survey completion

Exclusion Criteria:

1. Current concerns for middle ear pathology (e.g., air bone gap of ≥15 dB at 2 consecutive octave frequencies in either ear)
2. Current, unresolved concerns for retrocochlear pathology in the opinion of the PI, audiologist, or ENT provider
3. Severe tinnitus as the reason for seeking amplification
4. Co-morbid condition that would interfere with participation in the study in the opinion of the PI, audiologist, or ENT provider
5. History of fluctuating hearing loss

6. Subject Recruitment & Compensation: We anticipate enrolling a total of 350 subjects at Duke University and Vanderbilt University.

Patients will be identified from Audiology Clinics and the Hearing Aid Business Management Program. Patients who meet the inclusion and exclusion criteria listed above will be:

1. Approached for possible study participation after a member of the clinical care team asks the patient's permission to be contacted by the study team. OR
2. A letter will be sent by mail, email or my chart message to those we pre-screen PRIOR to their hearing aid consult or test & consult appointment.
3. A letter will be sent by mail, email or my chart message to those we pre-screen AFTER their hearing aid consult or test & consult appointment IF they have not made a decision to purchase hearing aids.
4. Institutional or department Facebook pages will be used to post a digital flyer and the link to the study website periodically. The study website may be provided to potential patients or they may find it on their own.

The study coordinator will then review the records of any potential subject identified, and upon determination that the patient is deemed potentially eligible for this protocol, the clinical research coordinator or PI will contact the patient. This may occur in clinic, a MyChart recruitment letter, or via phone using an IRB-approved phone script. If the patient indicates interest in study participation, the study coordinator or PI will thoroughly explain the required elements of informed consent and all aspects of the study to the subject including inclusion/exclusion criteria, risks, benefits, and alternative to study participation.

Subjects will be compensated $50.00 plus parking voucher at the Baseline and Month 3 visit, $25.00 for completing the week 10-11 EMA, week 23-24 EMA, and Month 6 questionnaire, and $50.00 for completing a focus group, for up to $225.

7. Consent Process: The principal investigator, study coordinator, or authorized key personnel will explain all aspects of the study in lay language and answer all questions regarding the study. The consent process will occur in a private room or via phone and will include eConsent which is available through REDCap. This functionality provides the ability to consent remotely or in clinic via tablets or touchscreen device. Potential subjects will have the capability to sign electronically with a stylus, mouse, or finger. Once the consent form is submitted, potential subjects will receive an email that includes a PDF attachment with a copy of the signed consent form. The PDF will be emailed to Health Information Management from REDCap for incorporation into Epic.

If the potential subject decides to participate in the study, he/she will be asked to sign and date the Informed Consent document electronically. No study procedures will be conducted without prior written informed consent.

8. Subject's Capacity to Give Legally Effective Consent: It is not anticipated that we will enroll subjects who do not have the capacity to give legally effective consent. Non-English speaking subjects will not be approached for the study.

9. Study Interventions: Please refer to Design & Procedures.

10. Risk/Benefit Assessment: There are no physical risks to subjects. All visits are conducted routinely in the clinical setting. There is the potential for loss of confidentiality. All efforts will be made to mitigate this risk. Standard clinic procedures would be to fit all people with symmetric hearing loss with two hearing aids and then return one if they only wanted one. Therefore, a potential risk may be the delay of the use of two hearing aids if you are randomized to use of one hearing aid in this study.

11. Costs to the Subject: Costs associated with routine clinic care and the hearing aids themselves will be charged to the patient following their normal payment procedure (e.g., out of pocket, insurance, or both). Phonak (our industry partner) agreed to an extended trial period to 180 days to facilitate this study. Phonak has also agreed to a reduced rate for the study hearing aids. Potential study candidates will be provided with information about different Phonak models available, along with the amounts of each to help aid their decision-making process for which one to choose. Standard, typical, clinic procedures would be to fit all people who are eligible for this study (symmetric hearing loss and open to trying two) with two hearing aids and then return one if they only wanted one. Therefore, costs to participants randomized to two hearing aids should not create a financial burden. Patients who decide to return their hearing aid(s) will get a refund minus the fitting fee.

12. Data Analysis & Statistical Considerations: ***Refer to separate Statistical Analysis Plan***

13. Data & Safety Monitoring: This is a non-therapeutic study and there is no Data Safety Monitoring Board (DSMB). Data and safety monitoring will be conducted to the extent that it ensures privacy and confidentiality.

14. Privacy, Data Storage & Confidentiality: Study records that identify subjects will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access.

Data will be collected and stored on paper and electronically. Paper documents include patient and provider questionnaires. Paper documents will be stored in a locked file at the primary care practice or in the office of the research staff at each site which is locked when not in use. Electronic data will be stored behind the Duke firewall. Only applicable study key personnel at each site will have access to the paper and electronic data.

All study data including elements of dates, name, telephone numbers and email addresses on subjects enrolled at Duke and Vanderbilt will be entered into the REDCap database managed at Duke as the Coordinating Center. Name, telephone and email addresses are required for the EMA and link to surveys via REDCap. For Duke participants, MRN will be recorded in the

database. Vanderbilt will maintain a separate log with MRN if necessary, which will not be accessible to Duke key personnel.

The Vanderbilt PI and key personnel will only have access to their study participant data via a separate data access group. Similarly, the Duke PI and key personnel will only have access to their study participant data via a data access group. However, the Data Coordinating Center team including the REDCap programmer, statistician, and Research Program Leader will have access to both site's data for management of survey invitation management, troubleshooting, and any payments managed by the coordinating center, etc.

De-identified data will be exported and shared with Vanderbilt for collaborative study analysis. Direct identifiers (other than dates) collected on Duke patients will not be shared with Vanderbilt. Direct identifiers (other than dates) collected on Vanderbilt patients will not be shared with Duke investigators or statisticians for analysis purposes. Identifiers collected and stored on Vanderbilt study participants will not be disclosed outside of Duke.

REDCap is a software tool that does not require client local software and can be accessed from anywhere on the Internet and is secured on a Duke Health Technology Services (DHTS) server. This database will be developed and maintenance performed with support of the School of Medicine (SOM) Duke Office of Clinical Research (DOCR). SOM's DOCR has partnered with the School of Medicine (SOM) to implement REDCap (developed by Vanderbilt's CTSA and currently used and supported by more than 1600 consortium partners. REDCap provides: 1) a stream-lined process for rapidly building a database; 2) an intuitive interface for collecting data (with data validation and audit trail); 3) automated export procedures for seamless data downloads to common statistical packages (SAS, SPSS, etc.); 4) branching logic, file uploading, and calculated fields; and 5) a quick and easy protocol set-up.

REDCap accounts are stored within the DTMI LDAP server hosted by the Duke Office of Information Technology (OIT). Authentication occurs via the OIT implementation of Kerberos. All connections to the system, both external and internal, occur over encrypted channels. Access to components of the system is role-based and can only be granted by administrators of the system. All collected information is stored on a database server hosted by Duke Health Technology Services (DHTS). The database server resides behind the DHTS internal firewall and access to the server is controlled via firewall rules. All collected data are backed up daily, both on the local server and by the DHTS enterprise backup system.

The study results will be retained for at least 6 years after the study is completed. After that time, research information not already in the medical record will be destroyed or identifying subjects will be removed from such study results at DUHS.

Prior to dissemination of any information in this database beyond the DUMC's secure servers or firewall, all identifiers will be stripped from the database and data will only be referenced by study-specific identification numbers. Any publications or presentations that result from this research will not identify any subjects individually, and will present data in aggregate form only.

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