Feasibility and Acceptability of Using Low-Gain Hearing Aids for Bothersome Tinnitus

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Title

Feasibility and Acceptability of Using Low-Gain Hearing Aids for Bothersome Tinnitus

Investigators

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Specific Aims/Purpose

The study team will obtain pilot data evaluating Veterans with normal hearing thresholds through 4 kilohertz (kHz) and bothersome tinnitus to determine if low-gain hearing aids for tinnitus is an acceptable and feasible approach to addressing bothersome tinnitus, and to provide preliminary data on the impact of providing mild amplification on perceived tinnitus handicap and perceived hearing handicap in the population being studied. This pilot study will also include interviews of clinical audiologists who both are and are not fitting mild amplification for tinnitus on patients with normal hearing. This study is the essential first step toward fully investigating the premise that low-gain hearing aids are effective for individuals who have bothersome tinnitus but who otherwise are not hearing aid candidates.

The project has two Specific Aims.

Aim 1: Measure the reduction in tinnitus handicap when mild amplification through receiver-in-the-canal hearing aids is provided to Veterans with bothersome tinnitus and normal hearing thresholds through 4 kHz.

Aim 2: Document the opinions, procedures, and rationale used clinically to make decisions regarding fitting mild amplification for tinnitus on Veterans with bothersome tinnitus and normal hearing thresholds.

Hypothesis: This pilot study is not hypothesis driven.

Scientific Rationale and Significance

Tinnitus affects 10-15% of the adult population[1]. Of this population, approximately 80% do not seek tinnitus-specific clinical services[2, 3]. For the remaining 20%, however, tinnitus impacts their lives—most broadly with respect to sleep disturbance, impaired concentration, and/or emotional reactions[4]. Those 20% are the most in need of clinical services. Approximately 80% of all people with tinnitus (not just those looking for help with tinnitus) also have hearing loss[5]. However, people with tinnitus and normal hearing can also be very bothered by their tinnitus. A recent summary of evidence-based tinnitus clinical practice guidelines from The United States, Germany, The Netherlands, Sweden, and Denmark all recommend use of hearing aids, "but only when clinically meaningful hearing loss is also present"[6] (p. 9). Tinnitus clinical practice guidelines are based on available evidence from well-designed trials. Currently there are no trials of hearing aids for tinnitus in people with normal hearing sensitivity. Because of this, the guidelines from the United States, Germany, and the Netherlands caution that there is insufficient evidence to support the use of hearing aids for tinnitus in people with normal hearing, and Germany's guidelines recommend against the practice[6].

Despite the current tinnitus practice guidelines, there are increasing reports from the field that audiologists are providing mild amplification through hearing aids for bothersome tinnitus to patients who have normal hearing sensitivity. Clinicians are informally reporting beneficial outcomes from the practice, and at least one clinician has presented the procedures and outcomes of this practice at a professional conference[7]. Further evidence that clinicians are warming up to the idea of fitting hearing aids for the purposes of addressing tinnitus when

hearing is not a problem comes from a three-round Delphi review of hearing professionals from the United Kingdom[8]. Of the 28 panelists who were interviewed, 82% agreed that “hearing aids should be offered for patients with a mild loss and bothersome tinnitus even if they did not report hearing difficulties”[8] (p. 7).

There is some limited, published, evidence that patients with normal hearing thresholds are willing to use mild amplification, and that is safe to do so. A study was conducted in which 19 subjects with normal hearing threshold were fit with hearing aids adjusted to provide mild amplification[6]. The amplification was being provided for the purposes of addressing reported hearing handicap. Seventeen subjects completed the trial period and their hearing thresholds were tested at the beginning and end of the trial with no change in thresholds. Of the original 19 subjects, one dropped out the study because he found the hearing aids to be too loud, and one was dropped from the study because he lost one of the hearing aids. Of the 17 who remained in the study, data logging indicated that they were wearing the hearing aids approximately 1-4 hours per day. Hobson et al[9] concluded, based on their review of numerous studies, that hearing aids used for tinnitus management did not present any safety concerns.

There is considerable evidence that providing amplification through hearing aids for people with hearing loss can be beneficial in reducing functional effects of tinnitus[10-13]. Statistically validated tinnitus outcomes instruments are all vulnerable to influence from improvements in hearing function, which makes it difficult to separate the effects of improved communication from improvements in function that are independent of hearing problems. In a summary of use of hearing aids and sound generators for tinnitus in people with hearing loss, Hoare et al[14] acknowledged that “It is uncertain what benefit from hearing aids results from a change in reactions to tinnitus as opposed to improvement in hearing function” (p. 68). We do however have reasons to believe that hearing aids may be helpful for tinnitus even when there is no hearing problem to be addressed. Hoare et al suggested three possible mechanisms whereby hearing aids could be beneficial for tinnitus for reasons not related to improved hearing function: (1) Amplifying external sounds reduces the contrast between tinnitus and the ambient sound environment, thereby making the tinnitus less salient. (2) Amplification may facilitate refocusing attention onto external sounds. (3) Amplification enriches the sound environment, restoring afferent input to the central auditory system and reducing the opportunity for neuroplastic changes that may contribute to tinnitus generation. In addition, two studies have supported the premise that hearing aids may provide benefit for bothersome tinnitus that is similar to ear-level sound generators: (1) Parazzini et al[15] compared the use of hearing aids to sound generators when delivering tinnitus retaining therapy[16]. Despite the lack of significant hearing loss in the speech-frequency range, both sound generators and hearing aids provided identical and significant improvement. (2) Folmer and Carroll[17] showed that hearing aids and sound generators both achieved significant improvement, whereas control subjects (not using devices) did not benefit. One potential benefit of using hearing aids to provide sound stimulation for tinnitus is that the sound provided from hearing aids would be unlikely to make it more difficult to communicate, which may not be the case with ear level sound generators.

The procedures used to provide mild amplification as reported at the 2017 JDVAC[7] are consistent with those described via personal communication with various other clinicians, i.e., the hearing aids provide approximately 5-10 decibels (dB) of gain as verified by real-ear measurements. Several clinicians mentioned they were using National Acoustic Laboratories Non-linear 2 (NAL-NL2) prescriptive targets for normal thresholds, which approximates 5-10 dB of gain. Other clinicians report they are providing 5-6 dB of gain. Each of these methods for choosing target gain results in similar outcomes. Most clinicians who were informally queried also reported that they ensure that the maximum output of the hearing aids is minimized, and that there is no amplification for 80 dB inputs. All clinicians reported using open-fit receiver-in-

canal hearing aids. These informally collected guidelines are in accordance with the fitting strategy used in a study of hearing aids fit on people who had normal hearing but reported hearing difficulties[18]; amplification in those cases was adjusted to 5-10 dB of insertion gain from 1 kilohertz (kHz) through 4 kHz for soft and conversational inputs, with no amplification at loud inputs.

The use of hearing aids for individuals with bothersome tinnitus and normal hearing is reported by many audiologists to be successful. Audiologists use varying methods to determine the success of the practice, including patient reports of satisfaction, tinnitus outcome instruments, and hearing outcome instruments. However, no systematic study of the feasibility, acceptability, or efficacy of this approach has been conducted. It is essential to show evidence supporting such practice in order to justify the continued use (and expense) of fitting these devices to patients who otherwise do not qualify to receive hearing aids. This is especially important in Veterans whose quality of life suffers from tinnitus, which is the most prevalent service-connected disability[19], and for the Veterans Health Administration. The anecdotal nature of the existing evidence suggests the need for pilot data to determine if a randomized controlled trial (RCT) is warranted and, if so, how to conduct the study. Data from this pilot study will provide critical information regarding recruitment rates of Veterans with normal hearing thresholds through 4 kHz and bothersome tinnitus, compliance and acceptability of the procedures with the target population, and will help to determine if existing tinnitus and hearing outcome instruments are appropriate for use with the target population.

Department of Veterans Affairs (VA) audiologists who have adopted the practice of fitting low-gain hearing aids to Veterans with normal hearing and bothersome tinnitus have each developed procedures for identifying appropriate candidates, fitting the devices, and evaluating outcomes. Their collective experiences comprise a valuable source of data. We therefore plan to survey these audiologists to obtain this information.

Preliminary Studies

Our team, led by Dr. James Henry (Co-Investigator on this proposal) has completed two RCTs evaluating combination instruments (hearing aids with a built-in sound generator) for bothersome tinnitus in non-hearing-aid users who were candidates for hearing aids based on their hearing loss[10, 11]. For both studies, participants used combination instruments either with the sound generator activated or deactivated. For one of the trials, a third group used deep-fit, extended-wear hearing aids[11]. Outcomes for each study were assessed pre- and post-treatment using the Tinnitus Functional Index (TFI)[20]. Both RCTs revealed comparable findings: every device studied resulted in decreased tinnitus handicap as measured by the TFI. No significant differences in outcomes were observed between groups.

A caveat should be noted concerning these two RCTs: All participants had both hearing loss and bothersome tinnitus. People will often respond to questions about effects of tinnitus with respect to their hearing loss[21]. For some of the participants, baseline to post-treatment improvement on a tinnitus outcome questionnaire would have resulted from improved hearing. Hearing loss, therefore, confounded the results of these studies, and it is impossible to know how much of the improvement in effects of tinnitus was actually a reduction in hearing difficulties.

This pilot study will specifically look at the use of hearing aids to address bothersome tinnitus in Veteran patients who have hearing within normal limits through 4 kHz based on a conventional audiogram. As already described, such utilization of ear-level devices has anecdotal evidence, but no controlled trials evaluating their efficacy for this purpose. This study will obtain initial data with this population of Veteran patients to determine the feasibility and acceptability of this approach. It is anticipated that results will be positive, which will lead to a

future RCT to fully evaluate such an approach to tinnitus management in this under-served population.

Research Design and Methods

Hearing Aid Study

Assessment Visit (Visit 1). After qualifying over the telephone, individuals will be scheduled for an appointment (Visit 1) at the NCRAR to undergo an assessment to determine study candidacy. Following informed consent, participants will complete standard audiologic testing (air and bone conduction hearing thresholds, speech audiometry, immittance audiometry, and hearing aid assessment). During the audiologic exam, any physical issues that would interfere with the participant wearing hearing aids will be identified, and may result in exclusion from participation. If participants meet all criteria, and they are willing to participate, they will be enrolled in the study. Once enrolled, participants will complete the Tinnitus Functional Index (TFI)[20], the Hearing Handicap Inventory (HHI), and Tinnitus Questionnaire Baseline.

Enrolled participants (N=20) will be fit with commercially available receiver-in-canal (RIC) hearing aids with optional sound generator and streaming at the first study visit. Participants will be fit using manufacturer-provided ear-domes. Using the NAL-NL2 formula[22], real-ear measures, in addition to patient feedback, will be used to verify and adjust the amplification settings. The hearing aids will be adjusted to be acoustically transparent for loud sounds (no loud sounds will be amplified), while providing mild amplification based on NAL-NL2 targets for soft and moderate inputs. The instruments will have data-logging capability, i.e., the number of hours the devices are used per day will be logged for later retrieval by the audiologist. Tinnitus counseling will occur immediately following the fitting and adjustment of the instruments.

All participants will receive scripted tinnitus counseling, which was used in our two previous hearing aid studies[10, 11]. The counseling, which describes how sound can be used to improve comfort with tinnitus, will follow pp. 31-64 in the flip-chart counseling book *Progressive Tinnitus Management: Counseling Guide*[23], and will require about 15 minutes.

Follow-up Visit (Visit 2). Two to 3 weeks after the fitting, participants will return for a follow-up appointment (Visit 2). The tinnitus counseling will be reviewed for all participants. The research audiologist will check the performance of the hearing aids, retrieve the data-logging information, and provide any necessary instructions to participants to ensure they are using the devices properly. If needed, adjustments will be made to the gain settings of the hearing aids.

Final Visit (Visit 3). Approximately 3 months after Visit 1, participants will return for their final visit (Visit 3). Hearing and speech testing will be repeated at this visit. Hearing testing at the final visit will include only testing of air conduction thresholds. Participants will also complete the TFI and other outcome measures, and answer a series of open-ended questions (Exit Interview). Questions will be asked to determine their subjective impressions of using the devices (general impressions of the devices, if they helped their tinnitus, when they were/were not helpful, and other comments). A final hearing aid check will be completed at this time, and data-logging information will be retrieved. Participants will be allowed to keep their devices, if desired.

Payment. Participants will be paid $20 for each study visit. Candidates who screen fail at the assessment appointment will still be paid $20 for coming in.

Outcome Measures. The primary outcome measure will be the TFI, which has been validated for measuring changes in tinnitus impact (*responsiveness*) resulting from intervention[20]. The 25-item TFI provides an index score from 0-100, with higher numbers reflecting greater tinnitus impact. The developers of the TFI provided data supporting a

minimum TFI score reduction of approximately 13 points as being generally meaningful to an individual patient.

The QuickSIN™ assesses speech understanding in noise[24]. Participants will listen to sentences at six signal-to-noise ratios (SNRs) presented binaurally in the sound field from a single loudspeaker located at 0 degrees azimuth. An 'SNR loss' is computed with a lower score indicating better performance. The SNR loss is the dB SNR relative to the SNR required for normal hearing individuals to repeat back 50% of the key words correctly. The QuickSIN will be conducted for unaided listening and aided listening at visits one and three. Two lists will be presented and an average score will be computed for each listening condition.

The HHI assesses hearing handicap and will be used to measure the impact of the devices on auditory hearing handicap. The 25-item Hearing Handicap Inventory for Adults (HHIA)[25] will be completed by individuals age <65 and the Hearing Handicap Inventory for the Elderly (HHIE)[26] will be completed by individuals age 65 years and older. The HHIA and HHIE differ in three questions. Participants answer 'No,' 'Sometimes,' or 'Yes' to a series of statements. Scores are summed across responses with total scores ranging from 0 (no hearing handicap) to 100 (maximum hearing handicap). The HHI will be administered at visits one, two, and three.

The International Outcome Inventory for Hearing Aids (IOI-HA)[27] is a seven-item questionnaire that assesses hearing aid outcomes on seven dimensions: Use, Benefit, Residual activity limitation, Satisfaction, Residual participation restriction, Impact (of hearing impairment) on others, and Quality of life. Responses are provided on a 5-point scale. Total scores range from 7 to 35, with higher scores indicating better outcome. The IOI-HA is used routinely in VA clinics to assess hearing aid recipients. This questionnaire will be administered at Visit 3 only.

Statistical Analysis. All quantitative and qualitative data will be provided to the data manager, who is responsible for developing and maintaining study databases and records. The data manager will perform double entry of the questionnaire data to check for and remediate any errors. The primary goal of Aim 1 will be to provide a preliminary evaluation of benefit of low-gain amplification for all participants. The primary outcome measure for estimating benefit of low gain hearing aids for tinnitus will be the TFI. Secondary outcome measures, including the HHIA and the QuickSIN test, will be used to evaluate any changes in perceived hearing handicap, and speech understanding resulting from the intervention. These outcomes will be evaluated at baseline (pre-randomization) and at two follow-up time points post-intervention (i.e., after fitting hearing aids). A linear mixed-model approach will be used to analyze outcome data[28]. This approach will model an overall baseline mean, along with a mean at each follow-up time point. The same model set up will be used for each outcome measure (TFI, HHIA, and QuickSIN). Contrasts between the follow-up mean estimates and baseline mean will indicate the level of benefit given by the treatment.

Usage of and reactions to wearing the hearing aids will be assessed with both qualitative (exit interview) and quantitative (usage via data-logging) measures. Qualitative analyses of exit interview responses will summarize patient experiences using the devices (e.g., comfort level with wearing the hearing aids, as well as comfort with the amplification, whether there was any sense of stigma from wearing hearing aids, etc.), and self-assessment of benefit. These analyses will follow a similar approach to those described for Aim 2 below. Comparison of the interview responses with actual usage data will provide some validation to self-reported compliance.

VA Clinician Interviews

The Principal Investigator (PI) will email approximately 200 VA audiologists via the National Audiology listserv with the following text:

Please do not "reply all."

Do you fit hearing aids on Veterans with normal hearing thresholds (25dB HL or better) from .25 kHz through 4 kHz for the purposes of improving quality of life with bothersome tinnitus?

Are you interested in being interviewed about the practice of fitting hearing aids on Veterans with normal hearing thresholds (25dB HL or better) from .25 kHz through 4 kHz for the purposes of improving quality of life with bothersome tinnitus? We are interested in interviewing clinicians who do and do not fit hearing aids for tinnitus on Veterans with normal hearing thresholds through 4K kHz.

Audiologists who choose to participate will reply to the Principal Investigator with their responses to the above questions. From those willing to be interviewed, approximately 15 audiologists will be selected to complete the telephone interview.

Telephone interviews with VA audiologists will be performed by Drs. Zaugg (PI) and Manning (Co-I), under the supervision of Dr. Tuepker (consultant). At the beginning of each call, a consent script will be read to the participating audiologist and oral consent will be obtained before the interview commences. Interviews with audiologists who are fitting low-gain hearing aids will follow an interview guide including questions on how Veterans are identified as good candidates for low-gain hearing aids, what guidelines are used for fitting the hearing aids, what results they tend to see, and how they measure outcomes (if at all). Interview questions for audiologists who are not fitting low-gain hearing aids will include why they do not perform this practice and what their opinions are about other clinicians engaging in the practice. Interviews will be audio-recorded for later reference.

The interviewers will take notes during the phone interviews, using the interview guide as a template. Following the interview (as close in time as possible), the interviewer will compose a summary of the interviewees' responses to each question, using the summary template (see below). The audio recording will be used to inform these summaries if needed to aid recollection, and/or to confirm any unclear responses. These interview summaries will be used for a rapid qualitative analysis (recordings will not be transcribed due to time and staffing constraints).

Statistical Analysis. Responses to the email survey question will be stored in a database. The responses will be tallied and summarized. No formal analyses are planned for survey data. Qualitative data will be extracted from interview summaries and analyzed by Dr. Newell (Co-I). Analyses for Aim 2 will employ rapid qualitative analysis strategies to analyze clinician interview summaries. The steps involved in this analysis include: (1) a domain name will be assigned to each question in the interview guide; (2) a summary interview template will be created; (3) the template will be tested and assessed for usability and relevance; (4) after consistency has been established across the summarizers (i.e. the interviewers), the summary template will be completed for all interviews; (5) the content of the summary templates will be transferred into a matrix of domain x respondent, organized by whether the clinician has fit low-gain amplification for tinnitus or not. Steps 1-2 will be completed before interviews commence. Step 3 will occur when the first few interviews have been completed and use of the summary template may be evaluated. Step 4 will continue as interviews occur. Step 5 will complete the rapid data analysis. The matrix produced by step 5 will allow quick perusal of the content of any domain to get a sense of variation in responses and to identify any gaps in the information collected. Additionally, as interview responses are processed, meaningful or powerful quotations will be identified and recorded.

Project Timeline

Table 1. Two-year timeline for study activities, by aim.

Activity	Year 1				Year 2			
Aim 1	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Obtain IRB approval								
Subject Recruitment								
Fitting of hearing aids								
Data collection								
Quantitative analyses								
Qualitative data analysis								
Aim 2	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Create interview guide								
Assign domain names and draft summary template (steps 1-2 of qualitative analysis)								
Survey Audiology email list								
Select and contact clinicians, schedule interviews								
Interviews								
Test summary template (step 3)								
Complete summary template for all interviews (step 4)								
Complete rapid qualitative analysis (step 5) and write-up								

Study Population

Hearing Aid Study

Approximately 20 participants will be enrolled. To account for potential screen failures, a total of up to 40 candidates will be consented for the study. Participants will be Veterans, recruited from the VA Portland Health Care System (VAPORHCS) and from the surrounding community, and will likely represent the gender and ethnic makeup of Portland and the surrounding area. They can be any gender, any age, any ethnic group, and any race. Special efforts will be undertaken to enroll minorities and women—VA offices that address minority and women's concerns will be contacted directly to inform them about the study. Non-Veterans will be enrolled if necessary to achieve the target number.

Inclusion criteria: Inclusion criteria will include: (1) a score of 5 or greater on section A the Tinnitus and Hearing Survey during the telephone screening; and (2) air conduction hearing thresholds of 25 dB HL or better from .25 kHz through 4 kHz bilaterally as measured at the first study visit; (3) must not be a current hearing aid user; and (4) capable of consenting and participating (including ability to communicate in English).

Exclusion Criteria: Exclusion criteria will include: (1) an air conduction hearing threshold greater than 25 dB HL from .25 kHz through 4 kHz; (2) significant conductive hearing loss—defined as an air-bone gap of 15 dB at more than two frequencies in one ear, or an air-bone gap greater than 20 dB at any one frequency; (3) suspicion of secondary (somatic) tinnitus, or Meniere's disease (either of which can be ruled out with an examination by an appropriate physician); (4) currently a hearing aid user; or (5) any mental, emotional, or health conditions that would preclude full study participation.

VA Clinician Interviews

Approximately 200 VA audiologists will receive the survey email from the study PI. Up to approximately 15 audiologists will be identified from the survey email responses and scheduled for telephone interviews. Lacking any more exact information on the gender and ethnic makeup of VA employees, we expect that representation of women and minorities in our sample will roughly align with US population data. We will collect basic demographic information from all participants. No children will be involved in any part of the study.

Subject Identification/Recruitment

Hearing Aid Study

Recruitment and Screening. Participants will be Veterans recruited from the VA Portland Health Care System (VAPORHCS). Patients with bothersome tinnitus who have been seen for an appointment in the clinic will be identified through the medical record. Whenever possible, existing audiograms will be screened to ensure that candidates with normal hearing through 4 kHz are selected. Alternately, International Classification of Disease, Tenth Edition (ICD-10) diagnosis codes from the medical record will be used to identify those with normal hearing. Letters will be sent to these study candidates. These letters will indicate that candidates may opt out of further contact regarding the study by calling study staff or returning a form. Those who do not opt out may be contacted approximately 2 weeks after receiving the letter. If this does not identify sufficient numbers of potential participants, a broader data pull of Veterans with tinnitus will be collected, and those with diagnosis codes indicating hearing loss will be filtered out. If necessary, we will also pull data for Veterans who have a diagnosis of sensorineural hearing loss to search for candidates who only have hearing loss above 4 kHz.

If these methods fail to identify enough study candidates, participants in past studies at the NCRAR will be used to recruit the remainder needed to fulfill our enrollment goal of 20 participants. These past study participants have indicated their interest and have given permission to be contacted to participate in future research opportunities. Their contact information and basic audiometric test results reside in the NCRAR Subject Data Repository (IRB #2874). Should the need arise, a data use agreement will be signed and approved between the study Principal Investigator (PI) (Zaugg) and the repository director. Following approval of the Data Use Agreement (DUA), names, contact information and audiometric data will be released from the repository to the study team. Audiometric test results included in the repository will serve to identify candidates who are likely to qualify for the project. Some candidates in the repository are not Veterans, if the data repository is used for recruitment we may recruit non-Veterans. Our primary recruitment focus will be Veterans, however if we are unable to recruit a sufficient number of Veterans we will also recruit civilians.

Identified candidates will be contacted via letter or phone call with information about the research study and will have the opportunity to be telephone-screened to determine if they qualify for participation in the project. Telephone screening will include the Tinnitus and Hearing Survey (THS), which was designed to distinguish tinnitus-specific from hearing-specific complaints[29]. Items in Section A of the THS include things like trouble concentrating on reading (which would clearly not be rooted in trouble hearing). A minimum score of 5 on the tinnitus portion (Section A) of the THS will be used as the initial qualification of bothersome tinnitus. Having a score of at least 5 will ensure that the person experiences some tinnitus-specific problems that are not hearing-related and that there is room to improve for problems not related to hearing. Candidates screened over the telephone with scores of 5 or more on Section A will be scheduled for the Assessment Visit.

VA Clinician Interviews

Recruitment. Audiologists who choose to participate in the email survey will reply to the Principal Investigator with their responses to the survey questions. From those willing to be

interviewed, approximately 15 audiologists will be selected to complete the telephone interview. Approximately two-thirds of the audiologists interviewed will be those who are conducting the practice, and approximately one-third of the audiologists interviewed be those who are not conducting the practice. Before scheduling the telephone interview, study personnel will confirm that the respondent is in fact a VA clinical audiologist.

Informed Consent & HIPAA Authorization

Hearing Aid Study

Documentation of informed consent will be acquired at the beginning of the first appointment. The candidate will sit in a room (usually sound booth or control room) with a member of the study team to review the information provided in the informed consent form. Once the candidate understands the content of the informed consent form, the candidate may sign the written consent form and a Health Insurance Portability and Accountability (HIPAA) acknowledgement form to indicate their agreement to participate in all study procedures. Testing will begin after informed consent has been documented. Additionally, as part of the informed consent process the subject will have the opportunity to agree to add their data to the Audiology and Rehabilitation Research Data Repository (MIRB #3750, P.I. James A. Henry, Ph.D.) for future research and recruitment.

VA Clinician Interviews

An information sheet describing the study along with its risks and benefits will accompany the email survey sent to approximately 200 VA audiologists, via the National Audiology listserv. The information sheet will inform the recipients of the email of the purpose of the study and what will be done with the information received. Anyone who does not consent, need not reply to the email. Clinicians interested in participating will be scheduled for a telephone appointment. At the beginning of the phone call, the interviewer will confirm that the participant received the information sheet and will read a spoken consent script. If the clinician wishes to participate, then an audio-recording will be made of the participant giving spoken acknowledgement of consent to be interviewed and giving spoken consent to be audio-recorded during the interview. After an audio-recording of acknowledgment of consent has been made, then the interview questions (which will be audio-recorded) will begin.

Risks and Side Effects:

Hearing Aid Study

It is possible that faulty equipment might present sounds at too high a level, although this has never happened in the research team's experience over many years of testing, and the equipment and software are typically designed so that such errors would be extraordinarily unlikely. Nonetheless, participants will be encouraged to alert the experimenter if any sound is uncomfortably loud and to feel free to remove or turn off the sound-producing devices at any time if they so wish.

VA Clinician Interviews

For participants in telephone interviews, risks are limited to emotional reactions that could result from responding to the interview questions, and potential loss of privacy due to collection of identifiable information. The study provides for protections against this risk as described below. No sensitive or health information will be obtained during the study.

Participant Safeguards:

General

Provision is made, and will be stated explicitly during the Informed Consent process, for a participant in either Aim to terminate a session or withdraw from the study entirely at any time and for any reason. Should any unforeseen medical emergency arise, medical care is available

at nearby hospitals. All procedures, forms, advertisements, and protocols will be reviewed and monitored by the VAPORHCS IRB.

Records will be maintained at the NCRAR and the records will be restricted to approved study personnel. Any public presentation or description of the results of the research project, including publication in scholarly journals or texts, will refer to individual subjects by assigned numbers and not by name. The potential risk that Protected Health Information (PHI) could be divulged to persons outside of the study will be minimized through the coding of all databases, forms, files, and questionnaires. The only link to identifying information will be in a code book that will remain locked in the Data Manager's office. Electronic data will be stored in a database on the VA server, with user account password required to access the server, and access restricted to approved team members. Only the people listed on the consent form (information sheet) and scope of work form as study team members will have access to such information. PHI will not be revealed in any published reports.

Hearing Aid Study

All audiometric and speech testing, and hearing aid fitting will be conducted by certified audiologists (investigators Zaugg and Manning). Participants will be able to ask questions of the audiologists throughout their participation.

VA Clinician Interviews

Although the risks for participants in telephone interviews are very unlikely, participants will be told they do not have to answer any interview questions that cause them discomfort. They will also be told that they can terminate their participation at any time for any reason, without consequence. A psychologist will be made available for counseling should the need arise.

Recordings of telephone interviews will be captured on a digital recorder. Digital audio recorders will be kept in a locked drawer when not in use. Digital files of recorded telephone interviews will be transferred to the VAPORHCS server. Here they will be saved in a location only accessible to approved study team members.

Benefits

The participants in the hearing aid study may benefit if the low-gain amplification helps them to be less bothered by their tinnitus. Even though all individual participants may not personally benefit, the results of this study may lead to a future larger study, which could in turn provide evidence to support the expanded use of low-gain amplification for bothersome tinnitus. All participants in clinician interviews will be VA staff and clinicians. Although no direct benefit to the VA staff or clinicians is expected, responses will inform a future study that may lead to evidence to support the spread of this practice in VA clinics. In this case, more Veterans with normal hearing thresholds and bothersome tinnitus could benefit from the research.

Protected Health Information:

HIPAA identifiers will include names, geographical subdivisions smaller than a state, dates (date of birth—DOB—and study contact dates), telephone numbers, emails, and social security numbers (SSNs). This information is the minimum necessary to contact subjects, enroll them in the study, and carry out the study protocol. Phone numbers and address are needed to ensure that subjects may be reached for follow-up visits and other study-related communication. Full SSN and DOB are needed to verify records exist in CPRS for subjects or enroll any subjects in CPRS who do not already have a record there for the purpose of entering study-related notes.

Resources Available

Necessary equipment for this project is available at the National Center for Rehabilitative Auditory Research (NCRAR), VA Portland Health Care System (VAPORHCS), where the

Principal Investigator (PI), Dr. Zaugg, and the core research team have offices and research space allocated for their usage in a variety of ongoing projects. A double-walled booth and adjacent control room are dedicated to the PI's projects.

Audiometric test equipment includes a GSI audiometer and middle ear analyzer. Multiple computers are available for use in the lab, including one that is networked with access to the VAPORHCS server and to the Internet. Several different kinds of earphones are available, including the ER3 earphones that came with the audiometer. Two Larson Davis sound level meter systems are available. The hearing aid laboratory has a Fonix 7000 Hearing Aid Test System, Starmed Otolab Professional Finishing System, and an AuraCare hearing aid cleaning and modification station. Other equipment in the lab may be used on an as-needed basis. For example, additional audio test and measurement equipment is available to verify the output of the hearing aids

Data storage, analysis, and preparation of manuscripts and presentations will be performed digitally using a combination of hardware and software systems already in place at the NCRAR. The VAPORHCS will maintain backups and data security for the project in compliance with the VA federally-mandated responsibility for oversight of all data collected as part of research conducted at a VA facility. No direct costs will be incurred by the use of this system. The procedures will be overseen and approved by the VAPORHCS Institutional Review Board.

Costs To Subjects

A Veteran participant will not be required to pay for care and services (treatment) received as a subject in a VA research project. Some Veterans are also required to pay co-payments for medical care and services provided by VA that are not part of this study (e.g., normal hospital and prescription expenses that are not part of the research study, any treatment that is standard clinical treatment). The study may include non-Veterans, who will incur no costs. The VA audiologists in Aim 2 will incur no costs.

Subject Compensation

The research participants in Aim 1 will receive $20 for each appointment, an amount consistent with our other studies, which will cover typical travel costs associated with attending the appointments. The VA audiologists participating in clinician interviews will not receive compensation.

Privacy and Confidentiality

Subjects' information used for this study will be kept confidential as required by law. The results of their participation in this study may be used for publication or for scientific purposes, but the results will not include any information that could identify them. Their identity will not be disclosed unless they give specific, separate consent or if required by law. Current VA regulations require us to keep study records indefinitely.

At the end of their study participation, subjects from Aim 1 will be allowed to keep the hearing aids used during the study. In order to maintain the product warranty on the hearing aids once ownership passes to the subject, the subjects' name and device serial numbers must be disclosed to the hearing aid manufacturer, Widex, upon their completion of the study. This information will be provided by telephone or fax (fax transmissions will be scheduled on both ends to ensure that the fax transmission is immediately received by the intended party); it will not be disclosed by email. Subjects may decline to release their name and device serial numbers, however they will be informed that they will not have a warranty on their hearing aids in that case.

Information and/or Specimen Management

Electronic data will be kept in a database that resides behind the VA firewall. Hardcopy data and records (including ICFs, etc.) will be stored in in a locket file cabinet in a locked office (Building 103/104 P5F-153).

Data and Safety Monitoring Plan (DSMP)

1. *What safety information will be collected, including serious adverse events and unanticipated problems involving risk?* The safety information collected will include serious adverse events reported by participants, unanticipated problems involving risk, and leaving the study before the protocol is complete. Hearing will be evaluated at baseline, and again at the final visit to document any change in hearing. (A change in hearing due to study participation is not expected.)

2. *How the safety information will be collected, e.g., case report forms, at study visits, by telephone, etc.* The study data will be collected and recorded by a study audiologist, trainee, and/or research coordinator/assistant. The data will be entered into a research database stored on the VAPORHCS server. Serious events are not expected, and thus, if they occur, would likely be reported to the study team by the participant.

3. *The frequency of data collection, including when safety data collection starts.* Information will be collected at each study visit, and if anything comes up between visits.

4. *The frequency or periodicity of review of cumulative safety data (e.g., at a Data Safety Monitoring Board quarterly meeting, by the PI weekly, etc.).* Summary reports of study data will be generated for discussion at weekly meetings. Safety information will be reported to the PI as it is collected.

5. *Who will have oversight over the safety data?* Principal Investigator

6. *Describe the individual or group that will monitor the data and safety of the protocol and provide general description of the expertise of the person/membership and/or board/group as a whole.* Principal Investigator

7. *Which conditions would trigger an immediate suspension of the research? For example, efficacy proven, halted by DSMB due to unforeseen safety data, etc. (if applicable).* It is not expected that any event will occur that would trigger an immediate suspension of the research. If unexpected events do occur, the PI may decide, to halt the study due to unforseen saftety problems.

If any feedback is received from research participants indicating they may have experienced harm because of study participation, the incident will be immediately reported to the IRB. All electronic study data will be backed up on the VA secure server. Interview recordings and summaries will also be backed up on the server. Digital recorders and hard copy data (e.g., subject charts, and interview field notes) will be kept in a locked cabinet within a locked office. All analysis datasets will be deidentified. In the unlikely event of a breach of confidentiality, the incident will be reported to the IRB within the required timeframe and any resulting actions required and/or recommended by the IRB, Information Security and Privacy Offices will be taken promptly.

Step-by-Step Guidance on Conducting the Study

Hearing Aid Study

Recruitment

- Send recruitment letters to potential candidates identified via a CDW data pull.
- Post ads at the VAPORHCS (e.g., audiology, primary care, women's health clinics) and in the surrounding community
- Contact previous participants in NCRAR research studies

Telephone Screening

- Screen candidates over the phone using screening script, including administration of the Tinnitus and Hearing Survey (THS)
- If eligible, gather information from candidate and schedule initial appointment

Initial Appointment

- Administer informed consent
- Conduct conventional audiometric testing in sound-attenuated suite
- Exclude candidates if they reveal significant conductive hearing loss—as defined above. Tympanometry may be used to confirm middle ear function
- Ensure candidates have no active middle-ear disease and that hearing thresholds are within acceptable levels (25 dB HL or better at audiometric frequencies from .25-4 kHz)
- Candidates who fail to meet any of the inclusion criteria are considered screen fails and are not enrolled in the study. They are paid $20 for attending the visit and do not complete the rest of the study visit procedures.
- Candidates who meet all inclusion criteria are enrolled in the study.
- Subjects complete the following questionnaires and assessments: Tinnitus Baseline Questionnaire, Tinnitus Functional Index (TFI), Hearing Handicap Inventory, QuickSIN testing
- All participants will receive hearing aids. Hearing aids will be programmed using the NAL-NL2 formula (Keidser, Dillon et al. 2012). Real-ear measures, in addition to participant feedback, will be used to verify and adjust the amplification settings.Hearing aids may be adjusted if necessary. Participants will be asked to use the hearing aids daily.
- Participants are paid $20 for attending the appointment

2-3 Week Follow-up Visit

- Tinnitus counseling will be reviewed for all participants.
- The research audiologist will check the performance of the hearing aids, retrieve the data-logging information, and provide any necessary instructions to participants to

ensure they are using the devices properly. If needed, adjustments will be made to the gain settings of the hearing aids.

- Participants will fill out the TFI, HHI, and IOI-HA.
- Participants are paid $20 for completing the visit.

3 Month Follow-Up Visit

- Participants will return 3 months after baseline to complete the study.
- A hearing evaluation of air conduction thresholds will be repeated to document any hearing change (or lack thereof).
- Subjects complete the following questionnaires and assessments: Tinnitus Functional Index (TFI), Hearing Handicap Inventory, IOI-HA, and QuickSIN testing
- Subjects then complete an exit interview regarding their experience with the hearing aids
- The research audiologist will again check the performance of the hearing aids, retrieve the data-logging information, and answer any questions. If needed, adjustments will be made to the gain settings of the hearing aids. Participants will be allowed to keep the hearing aids following this visit.
- Subjects are paid $20 at this visit.

Schedule of Tests/Outcomes

Measure	Screen	Baseline	2-3 weeks	3 months
Tinnitus and Hearing Survey (THS)	X			
Inspect ear canal and ear drum		X	X	X
Tympanometry		X		X
Hearing test		X		X
Hearing aid assessment and fitting		X		
Real Ear testing		X		X
Speech in Noise test (QuickSIN)		X		X
Tinnitus Baseline Questionnaire		X		
Tinnitus Functional Index (TFI)		X	X	X
Hearing Handicap Inventory (HHI)		X	X	X
International Outcome Inventory for Hearing Aids (IOI-HA)			X	X
Tinnitus Counseling		X	X	
Exit Interview				X
Total Time	15 min	3 hrs	1.5 hrs	2 hrs

VA Clinician Interviews

Recruitment.

- Send survey via email to the VA Audiology email list to ask if they:
    - fit low-gain hearing aids on Veterans with bothersome tinnitus and normal hearing

- are willing to participate in a brief telephone interview

Telephone Interview Scheduling

- Interviewees will be selected from those email survey respondees who volunteer for interviews
- Those selected will be contacted by email or phone to schedule the telephone interview

Telephone Interviews

- The information sheet will be sent to the participant prior to the interview
- At the beginning of the interview phone call, the interviewer will confirm that the participant received the information sheet, and will read a spoken consent script. An audio-recording will be made of the participant giving spoken acknowledgement of consent to be interviewed and giving spoken consent to be audio-recorded during the interview. After an audio-recording of acknowledgment of consent has been made, then the interview questions (which will be audio-recorded) will begin.
- Interview questions will cover clinician attitudes on providing hearing aids for people with bothersome tinnitus and normal hearing.
- A notetaker will be present with the interviewer to take notes during the interview.

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Appendix – Supporting Documents List

Tinnitus Baseline Questionnaire
Tinnitus Functional Index (TFI)
Tinnitus and Hearing Survey (THS)
Hearing Handicap Inventory (HHI)

International Outcome Inventory for Hearing Aids (IOI-HA)
Exit Interview – Hearing Aid Participants
Clinician Interview Guide