Tinnitus Management: Randomized Controlled Trial Comparing Extended-Wear Hearing Aids, Conventional Hearing Aids, and Combination Instruments

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Abstract

Background: Whereas hearing aids have long been considered effective for providing relief from tinnitus, controlled clinical studies evaluating this premise have been very limited.

Purpose: The purpose of this study was to systematically determine the relative efficacy of conventional receiver-in-the-canal hearing aids (HA), the same hearing aids with a sound generator (HA+SG), and extended-wear, deep fit hearing aids (EWHA), to provide relief from tinnitus through a randomized controlled trial. Each of these ear-level devices was a product of Phonak, LLC.

Research Design: Participants were randomized to HA, HA+SG, or EWHA and wore bilaterally fit devices for about 4 months. Fittings, adjustments, and follow-up appointments were conducted to comply with company guidelines and to ensure that all participants attended appointments on the same schedule. At 4–5 months, participants returned to complete final outcome measures, which concluded their study participation.

Study Sample: Participants were 55 individuals (mean age: 63.1 years) with mild to moderately-severe hearing loss who: (a) did not currently use hearing aids; (b) reported tinnitus that was sufficiently bothersome to warrant intervention; and (c) were suitable candidates for each of the study devices.

Data Collection and Analysis: The primary outcome measure was the Tinnitus Functional Index (TFI). Secondary outcome measures included hearing-specific questionnaires and the Quick Speech in Noise test (QuickSIN). The goal of the analysis was to evaluate efficacy of the EWHA and HA+SG devices versus the HA standard device.

Results: There were 18 participants in each of the HA and EWHA groups and 19 in the HA+SG group. Gender, age, and baseline TFI severity were balanced across treatment groups. Nearly all participants had a reduction in tinnitus symptoms during the study. The average TFI change (improvement) from baseline was 21 points in the HA group, 31 points in the EWHA group, and 33 points in the HA+SG group. A "clinically significant" improvement in reaction to tinnitus (at least 13-point reduction in TFI

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score) was seen by 67% of HA, 82% of EWHA, and 79% of HA+SG participants. There were no statistically significant differences in the extent to which the devices reduced TFI scores. Likewise, the hearing-specific questionnaires and QuickSIN showed improvements following use of the hearing aids but these improvements did not differ across device groups.

Conclusions: There is insufficient evidence to conclude that any of these devices offers greater relief from tinnitus than any other one tested. However, all devices appear to offer some improvement in the functional effects of tinnitus.

Key Words: acoustic stimulation, hearing, outcomes, randomized controlled trial, research, tinnitus

Abbreviations: AAO-HNSF = American Academy of Otolaryngology – Head & Neck Surgery Foundation; ANOVAs = analyses of variance; CBT = cognitive-behavioral therapy; CPG = Clinical Practice Guideline; EWHA = extended-wear hearing aid; HA = hearing aid; HA + SG = hearing aid with a sound generator; HHI = Hearing Handicap Inventory; HHIA = Hearing Handicap Inventory for Adults; HHIE = Hearing Handicap Inventory for the Elderly; IOI-HA = International Outcome Inventory for Hearing Aids; MoCA = Montreal Cognitive Assessment; NCRAR = National Center for Rehabilitative Auditory Research; QuickSIN = Quick Speech in Noise; RCT = randomized controlled trial; RIC = receiver-in-the-canal; SD = standard deviation; SE = standard error; SG = sound generator; SNR = signal-to-noise ratio; SSQ12 = 12-item version of the Speech, Spatial, and Qualities of Hearing; TFI = Tinnitus Functional Index; THI = Tinnitus Handicap Inventory; TRT = tinnitus retraining therapy; VAPORHCS = VA Portland Health Care System

INTRODUCTION

About 10–15% of the adult population experiences chronic tinnitus (Hoffman and Reed, 2004), of whom about one in five has a problem that would warrant tinnitus-specific clinical services (Davis and Refaie, 2000). Hearing aids (HAs) have long been a mainstay tool for providing relief from tinnitus (Saltzman and Ersner, 1947; Surr et al, 1985; Melin et al, 1987). However, controlled clinical studies evaluating the effectiveness of hearing devices for tinnitus management are limited (Shekhawat et al, 2013).

We defer to Cochrane reviews as a standard to inform evidence-based care for medical conditions. These rigorous systematic reviews rely on randomized controlled trials (RCTs) as their source material. Cochrane reviews have addressed methods of tinnitus intervention, with one review concluding that cognitive-behavioral therapy (CBT) can improve quality of life and depression scores (Martinez-Devesa et al, 2010). Another review concluded that sound therapy can be beneficial when combined with counseling, but sound therapy "on its own" has not been shown to provide significant benefit (Hobson et al, 2010).

A recent Cochrane review evaluated studies that addressed the use of HAs for tinnitus management (Hoare et al, 2014). Only one study met the requirements for inclusion, which was an RCT that compared the use of open-ear HAs to ear-level sound generators (SGs) for management of tinnitus (Parazzini et al, 2011). All participants were marginal HA candidates who received educational counseling based on tinnitus retraining therapy (TRT) (Jastreboff and Hazell, 2004). Outcomes were assessed at 3, 6, and 12 mo using the Tinnitus Handicap Inventory (THI) (Newman et al, 1996). Each group showed a reduction in mean THI scores of ∼30 points (on a scale of 0–100). This Cochrane review concluded, "Whilst hearing aids are sometimes prescribed as part of tinnitus management, there is currently no evidence to support or refute their use as a more routine intervention for tinnitus" (Hoare et al, 2014, p. 2).

Evidence-based guidelines for the clinical management of tinnitus did not exist until the American Academy of Otolaryngology/Head & Neck Surgery Foundation (AAO-HNSF) published their Clinical Practice Guideline (CPG) (Tunkel et al, 2014). Developing the CPG involved an exhaustive search of the peer-reviewed literature to identify appropriate RCTs for making evidence-based recommendations for clinical practice. The available Cochrane reviews were highly influential in this effort. Among the recommendations in the AAO-HNSF CPG, clinicians should recommend an HA evaluation for patients with chronic, bothersome tinnitus and hearing loss. Their only recommendation for tinnitus-specific "intervention" was CBT for patients with chronic, bothersome tinnitus. Based on the AAO-HNSF CPG and the Cochrane reviews, it is concluded that evidence-based intervention for bothersome tinnitus includes HAs (if warranted to address hearing loss) and CBT.

The beneficial effects on tinnitus from the use of HAs may be due to (a) amelioration of communicative difficulties caused by hearing loss but attributed to tinnitus (Ratnayake et al, 2009); (b) alleviation of stress associated with difficult listening situations (Del Bo and Ambrosetti, 2007; Hoare et al, 2014); (c) increase in ambient sound that can mask tinnitus or make it less noticeable (Vernon, 1988); and (d) stimulating impaired portions of the auditory system that have been deprived of sound, possibly reversing tinnitus-related cortical reorganization (Moffat et al, 2009).

Since 1976, externally generated sound has been used as a clinical technique to provide tinnitus masking (Vernon, 1976). Initially, Vernon used "tinnitus maskers" (ear-level SGs), and soon thereafter pioneered the use of combination instruments (amplification and SG combined in a single unit) (Vernon, 1982). He noted that broadband noise produced "only a partial reduction in the tinnitus: it is still perceivable but in a suppressed form" (Vernon, 1988, p. 101). He further reported that when masking was suggested for patients, combination instruments were recommended 67% of the time (and tinnitus maskers, 21%). Combination instruments are also an important component of treatment with TRT (Jastreboff and Hazell, 1998). The primary purpose of combination instruments or HAs for either masking or TRT is to mitigate effects of tinnitus, with improved audibility considered a secondary benefit.

All of the major HA manufacturers currently produce combination instruments. Due to technological limitations, patients who previously were fit with combination instruments often did not receive amplification that optimally addressed their hearing loss. Today, however, combination instruments merge state-of-the-art HAs with an acoustic signal that, depending on the brand and model, may be broadband, band shapeable, amplitude adjustable, amplitude and frequency modulated, and/or fractal (Henry, Frederick, et al, 2015). Research is needed to evaluate whether combination instruments provide greater benefit to patients with bothersome tinnitus than the use of HAs alone. This question was first addressed prospectively by dos Santos et al (2014), who evaluated 49 patients using a blind randomized clinical trial. Both groups experienced a significant reduction in tinnitus annoyance as assessed using the THI (Newman et al, 1998). The difference between groups, however, was not statistically significant. Henry, Frederick, et al (2015) recently completed an RCT comparing HAs to combination instruments for tinnitus management. The motivation for that study was to determine if an SG added to a traditional HA would improve efficacy for tinnitus management. All participants received initial counseling using components of Progressive Tinnitus Management (Henry et al, 2010a). Both groups showed significant improvement based on Tinnitus Functional Index (TFI) (Meikle et al, 2012) outcomes at 3 mo, but the difference between groups was not statistically significant. It should be noted that findings of both of these studies were not available when the Cochrane review evaluating the use of HAs for tinnitus management (Hoare et al, 2014) and the AAO-HNSF CPG (Tunkel et al, 2014) were in preparation.

The present study essentially replicated the previous study (Henry, Frederick, et al, 2015), although the devices used in the present study were from a different manufacturer. In addition, extended-wear hearing aids (EWHAs; Phonak, LLC, Warrenville, IL) were evaluated in this study. The inclusion of EWHAs was based on observations from clinical audiologists that many patients using EWHAs commented that their tinnitus became much less bothersome after receiving the devices that are worn 24 hr per day, 7 days a week. This might be because EWHAs provide increased stimulation of impaired portions of the auditory system that have been deprived of sound, possibly reversing tinnitus-related cortical reorganization (Wienbruch et al, 2006). Also, a decrease in the strength of the tinnitus signal by sound therapy can facilitate the process of habituation (Thompson and Donegan, 1987). Considering results from the previous two studies (dos Santos et al, 2014; Henry, Frederick, et al, 2015), and the rationale for using EWHAs to provide relief from tinnitus, we hypothesized that all of these devices would be beneficial, based on TFI scores, for reducing effects of tinnitus.

METHODS

The primary purpose of this study was to determine the relative efficacy of EWHAs, conventional receiver-in-the-canal (RIC) HAs, and RIC hearing aid with a sound generator (HA + SG) to provide relief from tinnitus. A no-treatment control group was not included in the study, since all participants had sufficient hearing loss to benefit from amplification. Because all interventions involved amplification devices, it was necessary to evaluate HA performance and satisfaction associated with these devices—relief from tinnitus should not come at the cost of poor amplification or HA satisfaction. The study was conducted at the National Center for Rehabilitative Auditory Research (NCRAR) located at the VA Portland Health Care System (VAPORHCS), and was approved by the VAPORHCS Institutional Review Board.

HAs

The extended-wear, deep seated device (Lyric; Phonak) is a single-channel, analog, digitally programmable wide dynamic range compression circuit device that is worn 24/7 and can remain in the ear canal for months at a time (up to device battery life) before requiring replacement. Candidacy for an extended-wear device can be limiting for the general population and is based not only on hearing loss, but also on ear size and shape, medical conditions, and lifestyle. The manufacturer-defined fitting range makes the device generally suitable for mild to moderately severe hearing loss. Hearing care professionals receive specialized training from the manufacturer to evaluate and size ear canals—measuring length and diameter of the ear canal, assessing the geometry, anatomical features, and overall health of the canal to ensure a comfortable fit as well as candidacy. This assessment requires magnification

and illumination of the canal, using high-magnification microscopy, loupes, and/or video otoscope magnification, to familiarize the clinician with and visualize the canal shape and features to ensure correct insertion depth and device size. The device must be inserted by an appropriately trained hearing health-care professional, but may be removed by the user if necessary using a special removal tool. The device has limitations as compared to conventional digital circuits. One of the limitations of this device is that the fitting parameters are transferred to the device via a magnetic impulse, and this communication is one way (cannot read-out fitting). This limits verification of fitting parameters stored on the devices once fit. Additionally, due to the deep fit, real-ear verification was not recommended by the manufacturer at the time of this study, thus limiting verification of fit to functional gain measurements in the sound field. The software allows the clinician to adjust overall gain, minimally alter the compression kneepoint, adjust low-frequency cut (compensation for insertion loss and over-amplification of low frequencies), and minimally adjust the shape of the frequency response. The limited controls make this device less suitable for those with steeply sloping hearing loss (≥30 dB/octave). Users are able to turn the device on and off, place the device in "sleep" mode (sleep mode makes the device "acoustically transparent" by providing a small amount of amplification to compensate for insertion loss), and adjust the volume, using a remote control (SoundLync wand; Phonak). When this study began, the Lyric 2 was available, but shortly thereafter, the Lyric 3 replaced the Lyric 2. The first four participants randomized to the extended-wear group used the Lyric 2, and the Lyric 3 was used with all remaining participants. The Lyric 2 and Lyric 3 were identical in size and shape, but the Lyric 3 contained an updated signal processor, improved encapsulation against moisture, and new giant magnetoresistance, which replaced the reed switch used for communication between the device and the remote control. For the remainder of this article, the Lyric device will be referred to as EWHA.

The comparison devices were from the Audéo Q line of RIC hearing instruments (Audéo Q90 312-T; Phonak). The Q90 was chosen for use in the study because it was the manufacturer's model that incorporated an SG. The Q90 was a 20-channel digital wide dynamic range compression instrument with numerous signal processing and other features such as automatic directional microphones, noise reduction, feedback management, wind management, data logging (tracks device usage) and, most importantly for this study, the option of an SG for tinnitus relief. The SG had three sound options: white noise, pink noise, and a spectrally shaped sound based on the user's hearing loss. All three sound options could be spectrally altered in terms of frequency bandwidth and volume. The maximum output level of the SG

was 85 dBA. The RIC devices had the option of three maximum power outputs (112, 126, or 129) and three dome types (open, closed, and power). All participants in this study had mild to moderately severe hearing loss, thus only the standard receivers (maximum power output = 112) were used. The dome selected was that which was most appropriate for the individual's hearing loss.

Outcome Measures

The primary outcome measure was the TFI, which has been validated for measuring changes in tinnitus impact ("responsiveness") resulting from intervention (Meikle et al, 2012). The 25-item TFI provides an index score from 0 to 100, with higher numbers reflecting greater tinnitus impact. A score of ≥25 indicates, on average, a significant problem with tinnitus, with possible need for intervention. The developers of the TFI provided data supporting a minimum TFI score reduction of ∼13 points as being generally meaningful to patients. The TFI was completed by participants using paper and pen.

HA Performance and Satisfaction

We also measured HA satisfaction and performance to assess HA outcome among tinnitus sufferers who would also benefit from HAs. These measures included the Quick Speech in Noise (QuickSIN), Hearing Handicap Inventory for the Elderly/Adults (HHIE/HHIA) as appropriate, 12-item version of the Speech, Spatial, and Qualities of Hearing (SSQ12) questionnaire, International Outcome Inventory for Hearing Aids (IOI-HA), and a semistructured exit interview developed specifically for this study.

QuickSIN

The QuickSIN (Killion et al, 2004) assesses speech understanding in noise. Participants listen to sentences at six signal-to-noise ratios (SNRs) presented binaurally in the sound field from a single loudspeaker located at 0° 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 was conducted for unaided listening and aided listening. Two lists were presented, and an average score was computed for each listening condition.

Hearing Handicap Inventory

The Hearing Handicap Inventory (HHI) assesses hearing handicap and was used to examine whether the devices decreased auditory hearing handicap. The

25-item HHIA (Newman et al, 1990) is completed by individuals aged <65 yr and the HHIE (Newman and Weinstein, 1988) is completed by individuals aged ≥65 yr. 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 was completed by participants using computerized format.

SSQ12

The SSQ12 (Gatehouse and Noble, 2004; Noble et al, 2013) is a 12-item questionnaire that assesses three dimensions of auditory function: speech understanding, spatial hearing, and quality of sound. Responses are given on an 11-point scale ranging from 0 (not able to do this at all) to 10 (able to do this perfectly). Responses to all items are averaged, thus total SSQ12 scores range from 0 to 10. The SSQ12 was completed using a computerized format.

IOI-HA

The IOI-HA (Cox and Alexander, 2002) is a seven-item questionnaire that assesses HA 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 was completed using a paper and pen format.

Recruitment and Screening

Fifty-five participants were targeted for randomization. This number was based on an interim power analysis conducted after the first 21 participants had been randomized. No statistical tests of efficacy were conducted in the interim analysis, but rather the predicted probability of statistically significant results (i.e., power) for different total recruitments was computed based on methods of "stochastic curtailment" (Spiegelhalter et al, 2004). This is a method of computing the probability of detecting a given effect, conditional on all of the data collected through the first 21 participants. For a total of 55 participants, this analysis gave better than 87% power to detect a significant contrast between the EWHA device and the HA device, and better than 80% power to detect a significant contrast between HA + SG and HA. Results of that initial analysis were used by the study evaluators and the sponsor to decide to continue the study up to a total recruitment of 55 participants.

Candidates were recruited primarily from advertisements placed in the local newspaper and its associated online Web site. In addition, flyers were posted in various locations at the VAPORHCS. We also recruited from previous research participants at the NCRAR who provided written permission to be contacted for future research projects. All interested candidates initially contacted a member of the research team who performed a telephone screening. To pass the screening, callers were required to report both a suspected hearing loss and bothersome tinnitus. More specifically, the 10-item Tinnitus and Hearing Survey (Henry, Griest, et al, 2015) was administered over the phone, requiring a minimum total score of 4 on the tinnitus section A. In addition, they needed to speak fluent English, not have worn HAs for the past 6 mo, and report being in good mental, emotional, and health conditions to comply with full study participation. Further, the EWHA has manufacturer-defined medical and lifestyle contraindications (e.g., radiation to head or neck, scuba diving, skydiving) that would preclude wearing the EWHA; candidates were screened with the Contraindications Phone Screen (Supplemental Appendix S1, supplemental to the online version of this article). Eligible candidates were invited to attend an appointment for consenting and further screening; nine candidates obtained medical clearance for medical contraindications before the appointment (seven were for diabetes, one for immune system deficiency, and one for both diabetes and blood thinners). Table 1 provides a list of measures and procedures conducted during the telephone screening and the five laboratory visits.

Table 1. Test Measures and Procedures

Measure/Procedure	Telephone Screening	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
THS	X					
Medical history/lifestyle screener	X					
TFI		X				X
MoCA		X				
Comprehensive hearing evaluation (case history, immittance testing, pure-tone and speech audiometry, UCLs)		X				
Lyric sizing		X				
Randomization			X			
HA fitting			X			
QuickSIN			X			X
Functional gain testing			X	X	X	X
HHI			X			X
SSQ12			X			X
IOI-HA			X			X
Tinnitus counseling			X			
HA check				X	X	X
Exit interview						X

Note: THS = Tinnitus and Hearing Survey; UCL = uncomfortable loudness level.

Initial Assessment (Visit 1)

Before any assessment, candidates completed informed consent, which was administered by a member of the study team. Candidates then performed inclusion/exclusion assessments. First, they completed the TFI and Montreal Cognitive Assessment (MoCA) (Nasreddine et al, 2005). Inclusion requirements were a TFI score of ≥20 and an MoCA score of ≥26 (maximum 30). The TFI inclusion criterion was changed from a score of >25 to a score of >20 partway through the study to broaden the pool of potential participants. However, all participants that were finally enrolled had a TFI score of >25 (range = 25.6–95.6). Second, they underwent standard audiological testing (pure-tone air and bone audiometry and word recognition testing) and an HA assessment to determine if their degree of hearing loss was within the aidable range to be fit with the study devices. Lifestyle contraindications that would preclude wearing the EWHA were reiterated, and it was specified that the head could not be submerged underwater while wearing the EWHA unless using swimplugs. Finally, an anatomical examination of each candidate's ear canals was completed to determine suitability for bilateral EWHAs. Cerumen management was conducted at this time if necessary, which was the case for 37 of the 55 participants (67%). Candidates who met the preceding inclusion criteria then had their ear canal length measured and underwent the EWHA sizing, placement, and tolerance assessment. If candidates could not be fit bilaterally with both types of HAs, they were not eligible to participate. Further, participants meeting the AAO-HNS recommendations for physician referral before HA fitting were required to obtain a medical clearance before being permitted to participate in the study (AAO-HNS, 1993; 1994). This resulted in 11 referrals due to the presence of asymmetric hearing loss (defined as a between-ear difference in thresholds of ≥15 dB at two or more consecutive frequencies, and/or ≥15 dB asymmetry in word recognition scores) or an air–bone gap of >10 dB at two or more frequencies. These individuals were given a form to be completed by their primary care physician or an otolaryngologist before further evaluation.

Fitting Appointment (Visit 2)

Within ~4 weeks of the initial assessment, eligible candidates returned to the laboratory and were randomized into one of three groups: (a) EWHA, (b) HA, or (c) HA + SG. A simple randomization allocation was used. The random allocation sequence was generated using computer software. Allocation concealment was achieved using sequentially numbered, opaque, sealed envelopes, which were opened by study staff to randomize and enroll participants. Following randomization, participants completed the unaided QuickSIN using standard procedures (binaural sound field, at prescribed presentation levels based on pure-tone averages) (Killion et al, 2004), the HHI, and the SSQ12. They were then fit bilaterally with the HA to which they had been randomized. EWHA devices were fit to the manufacturer's fitting formula (only option) and verified with listening checks and aided threshold measures (used to calculate functional gain). Due to the limitations of a deep-seated device, verification of the fitting could not be ascertained with real-ear measurements and, although functional gain has significant limitations, it was determined a better option than no verification of the EWHA fit. Adjustments were made to the initial fit if verification indicated insertion loss at any tested frequency. Participants were provided with a remote to control volume, on/off, and sleep mode. HA and HA + SG devices were fit to National Acoustic Laboratories non-linear 2 targets, used the automatic program (no user was given multiple programs while enrolled in the study), volume control was enabled, and verified with real-ear measurements to be within ±5 dB at frequencies up to 4000 Hz.

Participants in the HA + SG group were counseled that when the SG signal was switched on, their tinnitus should be "barely audible." All participants reported that they could hear the SG signal and that they were able to set the level as instructed.

All participants underwent functional gain testing, as this was the only way to verify gain of the EWHA (analog, single-channel instrument). This involved aided and unaided sound field threshold testing using frequency modulated tones centered at 0.5, 1, 2, 3, and 4 kHz as well as speech recognition thresholds. Ear-specific information was obtained by plugging the nontest ear with an earplug or by placing the EWHA in the "off" mode, causing it to act similarly to an earplug.

Participants randomized to the HA + SG group were instructed to choose which one of three sounds (white noise, pink noise, and spectrally shaped noise) provided the greatest sense of immediate relief from their tinnitus. Nine participants chose the white noise (47%), seven chose the pink noise (37%), and three chose the spectrally shaped noise (16%). The intensity of the sound was adjusted to the perception of the tinnitus being "barely audible" above the noise and deemed tolerable to the participant. The spectral settings were not adjusted, as this study was not "pitch matching" the tinnitus. Once enabled, the SG provided constant sound while the HA was powered on. The SG settings remained fixed for the study duration. Participants had the option to further individualize the devices at the final visit, but measures were taken to limit and equate device options between the groups while enrolled in the study.

Counseling took place following device fitting and adjustment. HA orientation and informational counseling involved use of a device-specific PowerPoint (Microsoft Corp., Redmond, WA) presentation to ensure that standardized information was provided. Content included information about use, care, troubleshooting, and maintenance of the device; communication tips, both with and without amplification; safety issues; goals and realistic expectations of amplification; and overall adjustment to amplification. HA and HA + SG participants practiced insertion and removal; learned how to adjust the volume, change the batteries, and distinguish right/left devices; and verified cell and/or landline phone compatibility. EWHA participants learned how to adjust the volume, change the listening modes (on/off/sleep), and remove the devices if necessary. They also watched a video demonstrating these device-specific manipulations produced by the manufacturer.

All participants received the same scripted counseling to describe briefly how sound can be used to make tinnitus less problematic. The counseling followed pages 31–64 in a flip-chart counseling guide (Henry et al, 2010a). Participants also received a copy of a tinnitus self-help workbook (Henry et al, 2010b) to read on their own (their use of the workbook was not tracked). The research audiologists were available to answer questions or address concerns at any time during study participation.

Participants were telephoned within two business days of the fitting appointment to ensure that the devices were comfortable and working properly. If there were any problems, participants were asked to return to the NCRAR at their earliest convenience to meet with a study audiologist. In the event that an HA or HA + SG device was not functioning to specifications properly, it was replaced. Only one of these participants had a device replaced due to battery-drain issues. If an EWHA device malfunctioned (dead battery, device output became weak, or communication malfunction with the remote), it too was replaced. All of the four participants who were fit initially with the Lyric 2 had at least three device malfunctions. Seven of the participants fit with the Lyric 3 had at least one device malfunction (one participant had one malfunction, four had two malfunctions, and two had three malfunctions). If an EWHA was causing any pain, participants were instructed to remove the device before the visit. If an EWHA participant's ear showed irritation at any study visit, a period of rest was recommended, and the participant returned for an additional visit for the fitting of a new device.

Follow-Up Appointments (Visits 3 and 4)

One to 3 weeks after fitting, participants returned for their first scheduled follow-up appointment. An audiologist checked the performance of the devices and asked a series of scripted questions (Supplemental Appendix S2) to determine if any adjustments or counseling was necessary. Programming adjustments were made based on reported sound comfort, sound quality, feedback issues, and acclimatization to the amplification. All adjustments were verified by real-ear measurements (HA or HA + SG) or aided thresholds (EWHA). For programming adjustments verified by real ear, reasonable efforts were made to maintain a match to target while addressing the individual's complaint.

Additional re-instruction on use, care, and maintenance was provided as necessary to ensure devices were being used properly. Participants also returned for a 2-mo follow-up visit (8–10 weeks after fitting), at which time they completed the QuickSIN (aided and unaided conditions). Further, because EWHA devices have an estimated lifespan of between 2 and 4 mo, participants in the EWHA group had their devices replaced to preclude battery failure. Participants in the HA and HA + SG groups were provided with a supply of batteries. All participants were told to contact the audiologist at any time if they were in need of additional batteries or had other concerns.

Final Appointment (Visit 5)

Four to 5 mo after fitting, participants returned for their final appointment. They completed the TFI, QuickSIN, HHI, SSQ12, and IOI-HA. They then underwent an exit interview and were given the option of keeping the devices they had used during the study. If a participant wished to keep the devices, he/she was given the opportunity to have the device settings adjusted to his/her preference, and EWHA participants had their devices replaced again. This ended their participation in the study.

In lieu of payment, participants in the HA and HA + SG groups were allowed to keep their devices. EWHA participants were offered a subscription to receive replacement devices for 1 yr at no cost through a local provider.

Data Analysis

The goal of the analysis was to evaluate efficacy of the EWHA and HA + SG devices versus the HA standard device. A total of 55 participants were randomized with equal probability to each device type, and returned to measure improvement in tinnitus symptoms. The primary outcome measure used in this analysis was the TFI. Secondary analyses of changes in each TFI subscale were also conducted.

Reaction to tinnitus was measured by the TFI at baseline (prerandomization) and postintervention. A conventional approach to analyzing longitudinal data of this type uses change scores, given by the difference

between baseline and follow-up, with the idea that the change score naturally adjusts for baseline response (Bland and Altman, 1994). The change score approach, however, is not generally recommended, as it is susceptible to regression to the mean, such that treatment groups that happen to have larger than average baseline means will show a decrease in outcome even in the absence of any real treatment effect. Model-based approaches including analysis of covariance (Bland and Altman, 1994), and linear mixed models (Fitzmaurice et al, 2004) are more appropriate for analyzing longitudinal data while adjusting for baseline responses. Another, more subtle, argument against the change score approach is that it implicitly assumes that the population baseline response varies among groups. This is categorically impossible, since participants were all randomized "after" baseline measurements were taken. All participants had to be from the same population at baseline.

A linear mixed model was fit to the data from TFI scores to evaluate differences in TFI improvements across treatment groups. Specifically, we modeled the population mean response μ as a linear combination of time and group indicators, denoted by $I(\cdot)$, and regression coefficients β such that:

$$
\begin{aligned}
\mu = {} & \beta_B \cdot I(\text{time} = \text{baseline}) \\
& + \beta_A \cdot I(\text{time} = \text{follow-up and group} = \text{HA}) \\
& + \beta_L \cdot I(\text{time} = \text{follow-up and group} = \text{EWHA}) \\
& + \beta_T \cdot I(\text{time} = \text{follow-up and group} = \text{HA} + \text{SG})
\end{aligned}
\tag{1}
$$

According to this model, the baseline population mean response for all groups is β_B, the follow-up mean response for the HA group is β_A, the follow-up mean response for the EWHA group is β_L, and the follow-up mean response for the HA + SG group is β_T.

The extent to which the EWHA improves the reaction to tinnitus compared to the HA device is estimated by $(\beta_L - \beta_B) - (\beta_A - \beta_B) = \beta_L - \beta_A$. Similarly, the extent to which the HA + SG device improves symptoms over the HA is given by $(\beta_T - \beta_B) - (\beta_A - \beta_B) = \beta_T - \beta_A$. Negative values of each contrast indicate that the EWHA device (or HA + SG) offers "greater" tinnitus relief than the HA device. The null hypothesis of no true difference between the EWHA and HA (or between HA + SG and HA) is tested using relevant contrasts between the estimated regression coefficients from fitting the model in Equation 1.

It is important to note that the model described in Equation 1 explicitly includes the natural assumption that baseline population mean response is the same across groups. This model structure is regularly used in analyzing longitudinal clinical trial data (Fitzmaurice et al, 2004). This model was fit assuming Gaussian residuals and a random intercept to model correlation among repeated measures. Residual analysis showed no gross

deviations from Gaussian errors assumption. Likelihood displacement statistics were generated to evaluate possible influential observations on the fitted model.

Secondary outcome measures were analyzed using analyses of variance (ANOVAs). The significance level for each ANOVA was set to $p < 0.05$. Significant main effects and interactions were examined further by post hoc testing using Bonferroni corrections for multiple testing.

RESULTS

The observed data, collected between April 2014 and July 2015, are shown in Table 2. A total of 55 participants were randomized and completed follow-up testing. Only one participant (E041), a male in the EWHA group, did not provide any follow-up data. Otherwise, the data are complete, and a total of 109 observations (baselines and follow-ups) were used in this analysis. Table 3 shows baseline participant features by intervention group. There were 18 participants in each of the HA and EWHA groups and 19 in the HA + SG group. Baseline mean right- and left-ear audiograms are shown in Figure 1 (mean baseline audiometric thresholds were symmetrical for all groups).

Baseline Data

Table 4 shows the mean baseline audiometric and word recognition data for participants in each intervention group separately, along with baseline performance on the HA outcome measures (QuickSIN, HHI, SSQ12) and the results of ANOVAs comparing the three intervention groups. The data illustrate that participants had mild to moderately severe hearing loss, good word recognition, a mild SNR loss, and significant perceived hearing handicap, and that there were no significant between-group differences on any of these baseline measures.

Tinnitus Outcomes

Each participant's TFI scores by group and over time are shown in Figure 2, along with the time- and group-specific means (± 1 standard error [SE]) shown as a star. Individual participants' responses are connected by lines. It is seen from Figure 2 that by and large nearly everyone had a reduction in tinnitus symptoms during the study, as indicated by the lines with negative slopes. The average change in TFI from baseline (shown in each panel) was -21 in the HA group, -31 in the EWHA group, and -33 in the HA + SG group. Also shown in each panel is the percentage of participants with at least a 13-point improvement (reduction) on the TFI, which was identified as a clinically significant improvement in reaction to tinnitus (Meikle et al, 2012). Sixty-seven percent of HA participants had a clinically

Table 2. Observed Data

Participant ID	Gender	Treatment Group	Age at Baseline (yr)	Baseline TFI	Follow-Up TFI
E001	Male	HA + SG	68	71.2	18.0
E002	Male	HA	65	64.4	34.8
E003	Male	HA + SG	64	69.6	61.2
E004	Male	HA	63	64.4	50.8
E005	Female	EWHA (Lyric 2/Lyric 3)	61	62.4	25.6
E006	Male	EWHA (Lyric 2/Lyric 3)	81	46.8	0.0
E007	Male	HA + SG	63	90.0	5.2
E008	Male	HA	61	66.4	36.0
E009	Female	EWHA (Lyric 2/Lyric 3)	67	81.2	0.0
E010	Male	HA	60	52.8	6.4
E011	Female	EWHA (Lyric 2/Lyric 3)	33	64.4	78.8
E012	Male	HA + SG	69	52.4	70.4
E013	Male	HA + SG	66	91.6	16.8
E014	Female	EWHA (Lyric 3)	68	59.2	8.4
E015	Male	EWHA (Lyric 3)	66	63.2	11.2
E016	Female	HA	66	62.0	29.6
E017	Male	HA	65	73.2	80.4
E018	Male	HA + SG	60	39.2	32.4
E019	Female	HA	65	50.8	48.8
E020	Male	HA + SG	60	95.6	30.4
E021	Male	EWHA (Lyric 3)	64	57.2	33.2
E022	Male	HA	56	60.0	51.2
E023	Male	EWHA (Lyric 3)	67	32.8	50.8
E024	Male	HA + SG	58	59.6	8.4
E025	Male	HA	50	56.4	34.4
E026	Female	HA + SG	60	49.6	24.4
E027	Male	EWHA (Lyric 3)	61	50.8	23.2
E028	Male	HA	75	68.0	59.2
E029	Male	EWHA (Lyric 3)	71	61.2	23.6
E030	Female	HA + SG	75	31.2	9.6
E031	Male	EWHA (Lyric 3)	63	74.4	64.8
E032	Male	HA	58	48.0	38.8
E033	Male	HA + SG	63	26.4	8.8
E034	Male	EWHA (Lyric 3)	80	36.0	11.6
E035	Male	HA	65	50.8	26.4
E036	Male	HA + SG	67	37.2	2.4
E037	Female	HA	48	46.8	34.0
E038	Male	HA	70	45.2	10.0
E039	Male	EWHA (Lyric 3)	66	52.0	15.4
E040	Female	HA + SG	64	58.8	37.2
E041	Male	EWHA (Lyric 3)	48	43.6	—
E042	Male	HA + SG	54	54.8	34.0
E043	Male	HA	73	39.2	22.0
E044	Male	EWHA (Lyric 3)	72	38.0	24.0
E045	Male	HA + SG	56	61.6	2.4
E046	Male	HA + SG	66	49.2	15.2
E047	Male	EWHA (Lyric 3)	58	65.6	21.6
E048	Male	HA	53	58.0	15.6
E049	Female	HA	54	71.2	56.4
E050	Male	EWHA (Lyric 3)	69	59.6	18.8
E051	Female	HA + SG	68	38.8	44.4
E052	Male	HA + SG	68	60.0	21.2
E053	Male	HA	52	52.0	18.0
E054	Male	EWHA (Lyric 3)	63	25.6	7.2
E055	Male	HA + SG	67	48.4	9.2

Table 3. Participant Summary

		HA (N = 18)	EWHA (N = 18)	HA + SG (N = 19)	All (N = 55)
Gender					
Female	N	4	4	4	12
	%	22.2	22.2	21.1	21.8
Male	N	14	14	15	43
	%	77.8	77.8	78.9	78.2
Age at baseline (yr)	Mean	61.1	64.3	64.0	63.1
	Minimum	48	33	54	33
	Maximum	75	81	75	81
Baseline TFI score	Mean	57.2	54.1	57.1	56.2
	Minimum	39.2	25.6	26.4	25.6
	Maximum	73.2	81.2	95.6	95.6

significant improvement compared to 82% of EWHA participants and 79% of HA + SG participants.

Relevant contrasts based on the statistical model are shown in Table 5. One participant, E011, a female receiving the EWHA device, had a likelihood displacement-influence diagnostic statistic that was nearly double that of the next most influential subject. This participant's data, corresponding to the increasing dashed line in Figure 2, reduced the estimated efficacy of the EWHA device by ~3 points on the TFI scale. In light of this effect, results are shown both with and without this influential participant in Table 5.

Recall that negative values of each contrast (rows in Table 5) indicate that the EWHA device (or HA + SG) offers "greater" tinnitus relief than the HA device. p Values in Table 5 were adjusted for multiple testing using a simulation approach (Hsu and Nelson, 1998).

The EWHA devices reduced TFI scores by ~11.2 points more than the HA devices, though this result is not statistically significant at the 0.05 test level ($p = 0.141$). Similarly, the HA + SG reduced TFI scores by ~12.5 points more than the HA devices, though again this is not statistically significant ($p = 0.079$). The EWHA and HA + SG devices provided similar tinnitus relief (contrast = 1.3 points, $p = 0.97$). Removal of participant E011 resulted in a greater efficacy of the EWHA compared to the HA device (-14.5), which was statistically significant at $p = 0.035$.

Table 6 shows the mean change scores for each of the eight subscales of the TFI, separately by group. In all cases, these means showed a reduction, which indicates improved scores. These ranged from -8.7 points (Sleep subscale for HA) to -48.9 points (Auditory subscale for HA + SG). Of note is the finding that participants in the
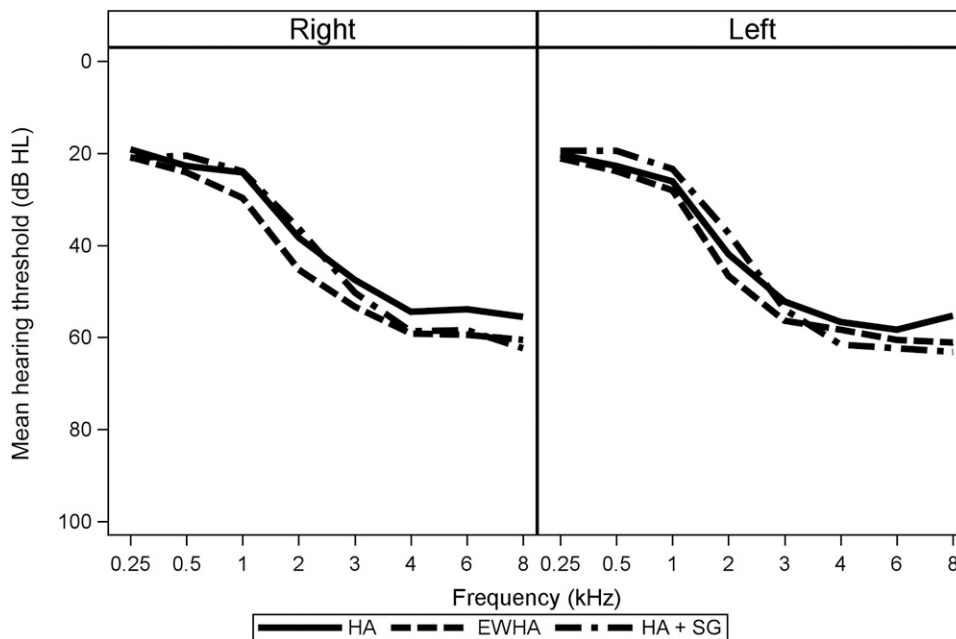

Figure 1. Baseline mean audiograms, shown separately for the three groups.

Table 4. Mean (SD) Baseline Audiometric and Speech Performance for Participants in Each Intervention Group along with Results of ANOVAs for between-Group Comparisons

Test Measure	HA (n = 18)	EWHA (n = 18)	HS + SG (n = 19)	Between-Group Comparison
4-FPTA (dB HL)				
Left	36.9 (8.0)	39.2 (6.4)	35.5 (8.7)	$F = 1.108$, $p = 0.338$
Right	34.9 (9.0)	39.6 (6.6)	34.9 (10.0)	$F = 1.762$, $p = 0.182$
Word recognition (%)				
Left	86.7 (8.6)	90.0 (7.0)	90.1 (8.4)	$F = 1.080$, $p = 0.347$
Right	92.0 (6.0)	89.6 (7.7)	92.2 (7.9)	$F = 0.753$, $p = 0.476$
QuickSIN (dB loss)	4.1 (3.5)	3.8 (2.1)	3.5 (2.4)	$F = 0.215$, $p = 0.807$
HHIE (points, range 0–100)	51.7 (14.0)	48.0 (16.0)	50.6 (18.5)	$F = 0.243$, $p = 0.785$
SSQ12 (points, range 0–10)	5.1 (1.6)	5.4 (1.4)	4.7 (1.9)	$F = 0.854$, $p = 0.432$

Note: 4-FPTA = four-frequency (0.5, 1, 2, and 4 kHz) pure-tone average.

HA group showed 2–3 times less benefit on the Sleep scale, and 1.5–2 times less benefit on the Relaxation scale than participants in the other two groups.

HA Outcomes

Table 7 shows benefit scores for each intervention group separately on the QuickSIN, HHI, and SSQ12, along with between-intervention group comparisons. Benefit on the QuickSIN, HHI, and SSQ12 was computed as follows. A lower score on the QuickSIN indicates better performance, therefore aided benefit was computed by subtracting the QuickSIN aided score at Visit 5 from the unaided QuickSIN score at baseline. Likewise, a lower score on the HHI indicates less hearing

handicap, so again, HHI benefit was computed by subtracting HHI score at Visit 5 from HHI score at baseline. Conversely, a higher score on the SSQ12 indicates fewer reported problems, thus SSQ12 benefit was computed by subtracting baseline SSQ12 score from SSQ12 score at Visit 5. The positive benefit scores in Table 7 indicate that individuals in each group showed behavioral (QuickSIN) and subjective (HHI and SSQ12) benefit from their HAs, but that the benefit obtained did not differ by type of HA.

According to QuickSIN norms (QuickSIN manual) the 90% critical difference for comparison of two conditions when using two test lists per condition (as used here) is 2.2 dB; 47.4% of participants in the HA + SG group exceeded this value, as did 35.3% in the EWHA
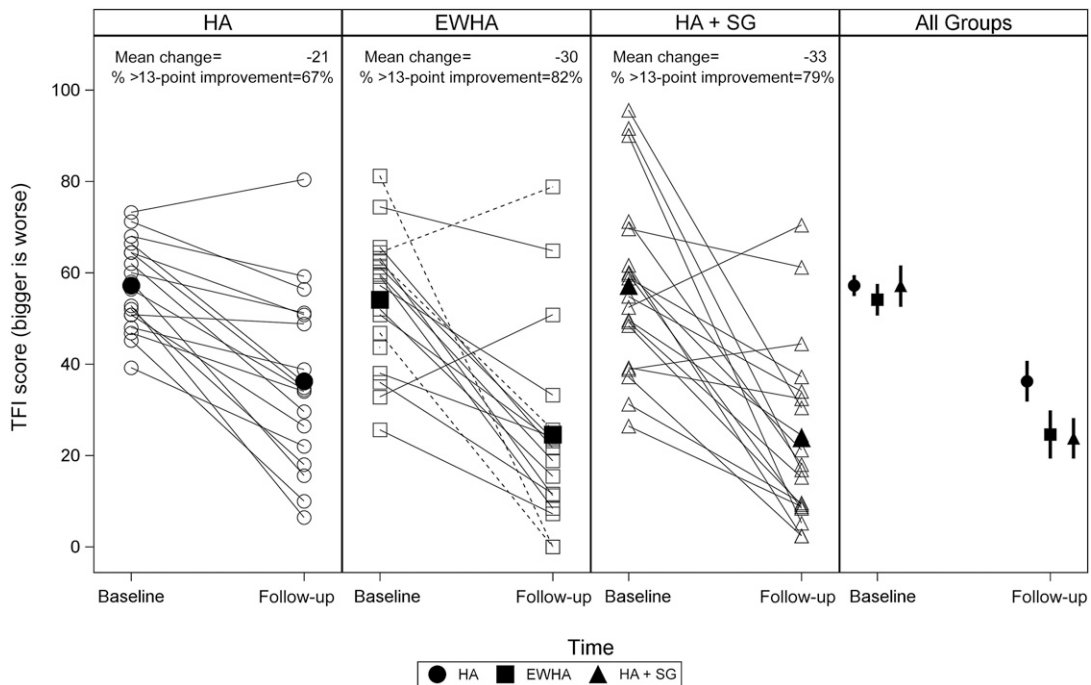

Figure 2. Observed TFI scores (*y* axis) by time point (*x* axis) shown as black circles. Each participant's response is connected by a single line. The dashed lines indicate the first four EWHA participants who received Lyric 2 devices (subsequent EWHA participants received Lyric 3).

Table 5. Estimated Differences in Relief (Based on TFI Scores) from Tinnitus between Each Device

Contrast	All Data			Data without E011		
	Estimate	SE	Adjusted p	Estimate	SE	Adjusted p
EWHA minus HA	−11.18	5.86	0.141	−14.49	5.73	0.035
HA + SG minus HA	−12.48	5.70	0.079	−12.48	5.49	0.063
EWHA minus HA + SG	1.30	5.79	0.970	−2.01	5.66	0.929

Note: Results are shown both with and without potentially influential participant E011.

group and 27.8% in the HA group. Further, the mean benefit for individuals in the HA and HA + SG conditions exceeded this value, but the mean benefit for individuals in the EWHA did not. Thus, despite there being no significant between-group difference, there is an indication that those in the EWHA group obtained less benefit for speech in noise than did individuals in the other two groups. Likewise for the HHI, the critical difference on the HHI is 19.2 points (Newman and Weinstein, 1989). The mean benefit for individuals in the HA and HA + SG groups exceeded this value, but did not for individuals in the EWHA group. Further, 68.4% of participants in the HA + SG group exceeded this value, as did 66.7% in the HA group and 44.4% in the EWHA group. No equivalent data are available for the SSQ12, although, once again, individuals in the HA and HA + SG conditions reported more benefit on the SSQ than did those wearing the EWHA. Combining the behavioral and reported results, there is an indication that the HA and HA + SG devices showed better overall objective and subjective auditory outcomes than the EWHAs.

Also shown in Table 7 is group mean total IOI-HA score for each intervention group separately. The total IOI-HA scores are very similar for each group with nonsignificant between-group differences. However, when scores on each item were examined separately, group differences become apparent. Specifically, on item 4 (Satisfaction) the group mean EWHA score was 3.2 (standard deviation [SD] = 1.6) while the group mean HA and HA + SG scores were 4.5 (SD = 0.7) and 4.4

Table 6. Observed Mean Change in Each Subscale of the TFI

TFI Subscale	Mean Change		
	HA	EWHA	HA + SG
Auditory	−41.5	−40.6	−48.9
Cognitive	−16.7	−27.6	−21.9
Control	−20.6	−34.7	−37.7
Emotional	−19.8	−22.7	−33.7
Intrusive	−21.1	−28.5	−31.2
Quality	−21.0	−27.4	−32.1
Relaxation	−18.1	−28.6	−38.2
Sleep	−8.7	−30.8	−23.5

Note: Negative values indicate reduction of symptoms described by each subscale.

(SD = 1.3), respectively. Likewise, on item 8 (Quality of life) the group mean EWHA score was 3.2 (SD = 1.3) while the group mean HA and HA + SG scores were 3.9 (SD = 0.7) and 4.2 (SD = 1.0), respectively. This indicates that individuals in the EWHA group perceived lower satisfaction and less benefit to their quality of life from the device than individuals in the other two intervention groups.

Exit Interview

The only exit interview question that pertained to tinnitus is reported here. Participants were asked, "Did they [the hearing aids] help your tinnitus?" Of the 55 participants, 33 (60%) responded "yes," 14 (25%) "no," and 8 (15%) were "unsure." Of the 33 "yes they helped" responses, HA had 9 (50% of HA group), EWHA had 10 (56% of EWHA group), and HA + SG had 14 (74% of HA + SG group).

It should be noted that, during the last visit, nine of the participants reported they would not continue wearing their devices following the conclusion of the study. All of these individuals were in the EWHA group.

DISCUSSION

This RCT evaluated the relative efficacy of EWHAs, traditional HAs, and HA + SG combination instruments to provide relief from tinnitus. Participants were screened, both over the telephone and in the laboratory, to ensure that they met all of the inclusion criteria. These criteria were particularly stringent because, in addition to being HA candidates with bothersome tinnitus, all participants had to be eligible to be fit with all three test devices. The study population, then, does not represent a typical clinical population.

The primary outcome measure was the TFI. Almost every participant showed a reduction in tinnitus symptoms during the study with ~80% of EWHA and HA + SG participants, and ~70% of HA participants, showing a clinically significant improvement in reaction to tinnitus, and between 50% and 74% of participants reporting the devices helped with their tinnitus. Although none of the differences observed between groups was significantly different, it is clear that overall each of these devices was associated with reduced negative reactions to tinnitus.

Table 7. Between-Group Comparison of HA Benefit Assessed by the QuickSIN, HHI, and SSQ12

HA Benefit Scores	HA (n = 18)	EWHA (n = 18)	HA + SG (n = 19)	Between-Group Comparison
QuickSIN (dB)	1.8 (2.8)	1.0 (2.1)	1.9 (2.5)	$F = 0.690$, $p = 0.506$
HHIE (points, range 0–100)	24.9 (16.1)	17.3 (22.0)	30.6 (23.6)	$F = 1.878$, $p = 0.163$
SSQ12 (points, range 0–10)	2.3 (1.6)	1.2 (2.1)	2.7 (2.3)	$F = 2.644$, $p = 0.081$
IOI-HA (points, range 7–35)	28.8 (3.6)	27.7 (5.6)	29.5 (4.6)	$F = 0.659$, $p = 0.522$

Note: Values are mean benefit (SD).

The secondary outcome measures were used primarily to confirm each device was providing benefit as an HA and to assess whether nontinnitus HA outcomes were similar across groups. The data indicated that all three devices provided HA benefit for listening to speech in noise but that the HA and HA + SG devices provided twice as much benefit as the EWHA device (2 dB SNR versus 1 dB SNR). Similarly, in terms of perceived HA benefit (HHI, SSQ12, IOI-HA), participants who wore the HA and HA + SG devices reported more benefits than those who wore EWHA devices. Again, these participants do not represent a typical clinic population. Notably, participants were interested in receiving HAs, but some who were randomized to EWHA would not have chosen that particular device.

During the last visit, EWHA participants were asked if they turned their devices "on and off at times." Responses to this question are of particular interest because the original premise of this study was that EWHA devices might be especially helpful for tinnitus because they provide amplification ("sound enrichment") for most or all of each day. (It should be noted that EWHA participants were not instructed to leave their devices on all night long, which was in keeping with clinical protocol.) Of the 18 EWHA participants, only one responded that the devices were never turned off, leaving 16 who reported that they turned them off at times (one did not respond). Of these 16, 10 specifically mentioned "during sleep," and 11 mentioned "during noise" (five mentioned both "sleep" and "noise"). We do not know if those who reported (at the last visit) turning them off during sleep put them in the "sleep" mode or turned them completely off. We did, however, ask them about this at their first follow-up visit (1–3 weeks after fitting) (Supplemental Appendix S2). At that time 11 of the 18 EWHA participants reported putting them in "sleep" mode, and 2 reported turning them off.

HA and HA + SG participants were not asked if they turned their devices on and off, because the more relevant question for them would be how many hours per day did they wear their devices. This question was addressed at the first follow-up visit through the HA and HA + SG data-logging feature. The usage data were downloaded at that visit, revealing that the HA participants used their devices an average of 9.5 hr per day (SD = 3.0; range = 3–14) and the HA + SG participants used theirs an average of 8.8 hr (SD = 3.7;

range = 4–15). The HA and HA + SG participants on average did not wear their devices almost two-thirds of the day, which cannot be directly compared to full-time EWHA usage (with the majority of EWHA participants turning the devices off or to "sleep" mode during sleep). It seems possible that wearing HA or HA + SG devices more hours per day, and leaving EWHA devices turned on all the time, might have resulted in better tinnitus outcomes. Nonetheless, results suggest that EWHAs performed at least as well as traditional HAs and combination devices for managing effects of tinnitus.

The TFI includes eight subscales, and Table 6 shows the mean changes for each of the subscales for each of the three groups. Each number is negative, reflecting consistently fewer negative effects due to tinnitus. Some findings from these subscales are noteworthy: (a) The EWHA and HA + SG groups provided greater improvement than the HA group on all of the subscales except Auditory. (b) By far, the overall greatest improvement was seen in the Auditory subscale, which may reflect the fact that people often confuse hearing problems with tinnitus problems (Henry, Griest, et al, 2015; Ratnayake et al, 2009). These results support the general contention that HAs are helpful for tinnitus, which could at least be partially explained if people think that tinnitus is the cause of their hearing problems (i.e., if hearing problems are reduced by wearing HAs, that improvement may be viewed as a reduced tinnitus problem). (c) The HA + SG showed an 8–9 point greater improvement in the Auditory subscale relative to the two HA-alone groups. (d) The Sleep reduction for the HA group was minimal, which would be expected because people do not wear traditional HAs while sleeping. The improvement with Sleep was over three times as much with the EWHA, which would lend credence to the original hypothesis that EWHAs would be especially beneficial for reducing tinnitus reactions if the devices are worn while sleeping. However, countering this argument is the fact that some of the EWHA participants turned their devices off or to "sleep" mode during sleep time. The HA + SG also showed benefit on the Sleep scale, which might be because use of the SG during the day had some kind of carryover effect during sleep.

The first four participants randomized to the EWHA group were fit with Lyric 2 devices. Lyric 3 devices then

became available and all subsequent EWHA participants were fit with the Lyric 3. Also, those already wearing the Lyric 2 had their devices replaced with the Lyric 3 when they became available. In general, the participants wearing Lyric 2 experienced many more device failures than the Lyric 3 participants. Lyric 2 failures occurred in a variety of ways: (a) device would stop working, (b) sound quality would change or become weak, (c) device would stop responding to the Sound-Lync wand, and (d) device was not programmable upon delivery. The failure rate for the four Lyric 2 participants ranged from 50% to 70%, with an average failure rate of 62.5%. In contrast, the overall failure rate for the Lyric 3 was 17.5%. Device failure caused significant inconvenience for participants because of the need to attend extra appointments to replace the device(s). Further, when a device is removed the ear sometimes needs "rest" resulting in additional appointments.

Because of the higher-than-usual failure rate for the Lyric 2, we looked at the data for these four participants (dashed lines in Figure 2) to see if their outcomes differed from the Lyric 3 participants. Of the four Lyric 2 participants, three showed improved TFI scores and one had a TFI score that increased. The mean TFI change for these four participants was a reduction of 37.6 points. Of the 14 Lyric 3 participants, 1 did not provide a postintervention TFI score. For the remaining 13 Lyric 3 participants, 12 showed improved TFI scores and 1 had a TFI score that increased. The mean TFI change for these 13 Lyric 3 participants was a reduction of 27.8 points. The improvement in mean TFI scores was ~10 points "better" for the four participants who initially received Lyric 2 devices. It is therefore concluded the Lyric 2 failures did not reduce the overall effectiveness of the devices for tinnitus management.

Controlled trials evaluating the efficacy of HAs for tinnitus management are rare, and the recent Cochrane review that addressed the use of HAs for tinnitus management (Hoare et al, 2014) identified only one RCT that met their criteria. It thus seems paradoxical that HAs have been advocated for tinnitus management since the middle of the last century (Saltzman and Ersner, 1947) and yet have received such little formal study to verify mostly anecdotal information. Shekhawat et al (2013) addressed this concern and conducted a "scoping review" of all relevant studies. They concluded, "Clinicians should feel reassured that some evidence shows support for the use of hearing aids, but there is still a need for stronger methodology and RCTs in future research. Further research is needed to understand how hearing aids can be optimized for tinnitus relief" (p. 759).

The present study and the two previous studies mentioned earlier (dos Santos et al, 2014; Henry, Frederick, et al, 2015) were RCTs that compared outcomes between HAs and combination devices for tinnitus management.

Whereas these three studies used devices from different manufacturers, results were comparable. In all three studies, both HAs and combination devices resulted in significant improvement in the primary tinnitus outcome measure. In the present study and the Henry, Frederick, et al (2015) study, combination devices showed greater effectiveness, although not significantly so. In the dos Santos et al (2014) study, HAs showed greater effectiveness, although not significantly so. The consistency between these studies lends credence to these results with respect to generalizability across different makes and models of HAs and combination devices. Further, these three studies are the first to directly compare the use of HAs to combination devices under controlled conditions. Although it seems that adding an SG to an HA imparts additional benefit for tinnitus relief, further study is needed to determine whether there are individual differences in the extent to which this is helpful and thus to learn whether certain individuals are more "suitable candidates" for combination devices than others.

The present study had several limitations. First, a no-treatment control group was not included because all participants had hearing loss that would benefit from amplification and thus not providing treatment was considered unethical. As a result it is not possible to ascertain the extent to which the positive outcomes might be due to a placebo effect. Second, only self-report data are available regarding how long participants in the EWHA group turned their devices on and off, and thus we do not know the extent to which these participants were receiving 24-hr-a-day amplification. Third, it was not possible, at the time of the study, to make real-ear measurements for the EWHAs, thus it was not possible to compare the groups in terms of the extent to which HA target outputs were met. Fourth, numerous technical problems were encountered with the EWHAs. This likely influenced subjective ratings of outcome; however, as noted above, the TFI outcome scores of those individuals who encountered the most problems were better than those individuals who encountered fewer problems.

CONCLUSION

In sum, the EWHA and HA + SG showed consistently better results for tinnitus outcomes, although the differences observed were not statistically significant. The HA outcome data suggest greater behavioral and subjective benefit for the HA and HA + SG devices than the EWHA device, although the study was not powered to make this assessment, nor did the participants represent typical patients seeking HAs. In general, this study supports the premise that amplification, with and without an SG, is beneficial for relief of tinnitus for individuals who have hearing loss.

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Lyric Contraindications Phone Screen

Medical Contraindications

Please answer yes or no the following questions about your medical history:

	Yes	No
Have you EVER had radiation therapy to the head or neck?		
Do you have a bleeding disorder (i.e. hemophilia A/B, Von Willebrand, etc.)?		
Do you have chronic ear pain?		
Have you had problems with frequent ear pain in the past? (are you sensitive to having things in your ears such as earplugs)		
Do you have active or chronic problems with ear infections or fluid in the ears (not including earwax)?		
Have you had problems with unresolved ear infections or fluid in the ears in the past?		
Do you currently have tubes in your ears or a hole in your eardrum?		
Do you have any history of chronic outer, middle, or inner ear disease/disorder?		

Lifestyle Contraindications

Please answer yes or no to the following questions about your lifestyle:

	Yes	No
Do you plan to swim underwater over the next 6 months?		
If yes, do you use earplugs when you swim underwater?		
Do you anticipate needing an MRI over the next 6 months?		
Do you plan to participate in skydiving or scuba diving over the next 6 months?		

*If the answer is YES to any of the above **Lifestyle and Medical Contraindications** questions (for the swimming question individual must answer YES and NO to earplug follow-up question), the individual is not a candidate for the Lyric hearing aid and does not qualify for the study.*

Medical Clearance Required

Please answer yes or no to the following questions about your medical history:

	Yes	No
Do you have diabetes?		
Do you take any blood thinners?		
Have you had chemotherapy within the last 6 months?		
Do you have any immune system deficiencies (i.e. AIDS, cancer)?		
Do you have an implantable medical device (i.e. pacemaker, deep brain stimulation, hydrocephalus shunt, etc.)?		
Is the patient under the age of 21?		

*If the answer is YES to any of the above **Medical Clearance Required** questions, the individual must obtain medical clearance from a physician prior to participating in the study.*

Cerumen Management Recommendation

	Yes	No
Do you have a history of wax build up in the ears? *-the hearing aid is affected by excessive wax build-up, causing it to malfunction/stop working, if they regularly get wax removed (> every 3 months), they just are not a good candidate for the Lyric*		

*If the answer is YES to the above **Cerumen Management Recommended** question, it is highly recommended that the individual have his/her ears cleaned by a professional prior to the screening visit.*

Visit 3 (2 Week Follow-up)

1. Did you have any ear discomfort after you were fit with the hearing aid? [   ] Yes   [   ] No

    a. If yes; Has that discomfort gone away?

2. Are you currently having any pain? [   ] Yes   [   ] No

    a. If yes; On a scale of 1 to 10 how would you rate the pain, with 10 being unbearable and 1 being just a sense of awareness of the hearing aid in your ear; Rating_____

    b. (**For Lyric patients**) if pain is unbearable, remove Lyric and inspect the health of the ear canal.

        b.i.   If hematoma; allow minimum of 10-14 days before inserting another device

        b.ii.   Reschedule for a re-fit

3. Have you had any feedback? [   ] Yes   [   ] No

    a. If yes; probe about when and how often it occurs.

    b. Make programming adjustments to the hearing aids to eliminate feedback.

4. How is the volume of the hearing aid?

    [   ] too soft   [   ] slightly soft [   ] comfortable [   ] slightly loud [   ] too loud

    a. If yes; counsel on acclimatization period and adjusting to hearing new sounds.

    b. For loudness concerns that cannot be addressed through counseling, adjust programming to meet patient concerns.

5. How do you like the sound quality of the hearing aids?

    a. If needed make programming adjustments if sound quality is poor.

6. (**For Audeo users**) Are you having any trouble cleaning the hearing aid, changing the battery or inserting/removing the hearing aid? [   ] Yes   [   ] No

    a. If yes; re-instruct.

7. Are you having any difficulty changing the volume or turning on/off (sleep mode for Lyric) on your hearing aid? [   ] Yes   [   ] No

     a.   If yes; re-instruct.

8. (**For Audeo users**) For about how many hours each day are you wearing the hearing aids?

     a.   Pt report:_____ _____hrs/day

     b.   Data logging: _____hrs/day

9. (**For Lyric users**) Do you ever turn the hearing aids off? [   ] Yes   [ ] No

     a.   If yes, in what situations:_____

10. (**For Lyric users**) What setting do you use at night? [   ] Sleep   [   ] Off   [   ] On

11. Do you have any concerns about the hearings aids that you'd like to discuss? [   ] Yes   [ ] No

     a.   If yes; note concerns and address them.