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Hearing aids with tinnitus sound support reduce tinnitus severity for new and experienced hearing aid users

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Objective: This interventional study tested the hypothesis that hearing aids with a tinnitus sound support feature would reduce the impact of tinnitus for both new and experienced hearing aid users over a 12-week trial period.

Methods: A total of 19 experienced hearing aid users and 21 participants with no previous hearing aid experience completed the study. Hearing aids were fitted and dispensed with tinnitus masking sounds adjusted to individual preferences. The primary outcome measure was the Tinnitus Functional Index (TFI) score change between baseline and the end of the 12-week trial. This trial was registered on the Australian New Zealand Clinical Trials Registry, trial ID: ACTRN12621001754831.

Results: The TFI scores and secondary measures indicated significant improvements (reductions in tinnitus impact) at the end of the trial compared to the baseline for both experienced and new hearing aid users. Since no group differences were observed, pooled data are presented in this study. The median TFI total score before treatment was 49.0 (IQR = 40.0), and the median TFI total score after treatment was 26.0 (IQR = 26.0). A significant reduction ($p = 0.0001$) in the total TFI score of 24 points was observed after treatment, producing a large effect size (d = 0.60).

Conclusions: The results confirm previous findings that hearing aids assist in reducing the impact of tinnitus on daily life. The Oticon miniRITE R combination hearing aids used in this study resulted in similar improvements for both new and existing hearing aid users. This suggests that the tinnitus-reducing effects of these aids were greater than those already being used by participants.

KEYWORDS

tinnitus, hearing aid, masking, sound therapy, clinical study, combination devices

1. Introduction

The onset of tinnitus and its psychoacoustic characteristics have a strong association with hearing loss (Roberts et al., 2008; Savastano, 2008). The benefit of hearing aids (HAs) in mitigating tinnitus has been recognized for decades (Saltzman and Ersner, 1949; Bentzen, 1958; Shekhawat et al., 2013). The quality and variability in tinnitus sound therapy research using HAs have been criticized (Sereda et al., 2018; Kikidis et al., 2021). Kikidis et al. (2021) reviewed 34 studies and found that 50% of the studies had fewer than 40 participants, with a wide range of inclusion criteria and follow-up periods to measure outcomes. However, there has been a growth in the volume of research, and the weight of evidence supports

HA use for tinnitus (Shekhawat et al., 2013; Kikidis et al., 2021; Jacquemin et al., 2022). HAs are recommended for patients with persistent bothersome tinnitus and hearing loss according to the guidelines of the American Academy of Otolaryngology-Head and Neck Surgery (Tunkel et al., 2014). They are also important tools in tinnitus masking (Vernon and Schleuning, 1978; McNeill et al., 2012), tinnitus retraining therapy (Jastreboff and Jastreboff, 2000), tinnitus activities treatment (Tyler et al., 2021), and progressive tinnitus management (Henry et al., 2010). As the HA technology has improved, so have the outcomes (Trotter and Donaldson, 2008).

HAs may reduce tinnitus through the psychological benefit of assisting hearing, with less attention being paid to hearing problems and to tinnitus, through the masking of sound, and through counseling accompanying HA fitting (Coles, 1985; Møller et al., 2011). Counseling is not the primary reason for the success of HAs in reducing tinnitus. Those who receive HAs and counseling do better than those receiving only counseling (Searchfield et al., 2010; Lee et al., 2022). HA fitting without any counseling also improves tinnitus (Shekhawat et al., 2014). Psychosocial improvement in hearing handicap is not the sole reason for tinnitus reduction. HA users' improvement in their tinnitus-related quality of life was predicted by the degree of masking achieved at the fitting appointment (McNeill et al., 2012). The greatest long-term benefit was observed if total masking was achieved at the first fitting; no masking resulted in no long-term reduction in tinnitus handicap. HA use in individuals with tinnitus may also improve sleep and concentration (Zarenoe et al., 2017). Depending on an individual's tinnitus and hearing characteristics, their acute and chronic improvement may be the result of different mechanisms including improved communication, redirected attention, and reduced auditory gain (Searchfield, 2020). The behavioral benefits of the HA fitting process on attention and cognition are mirrored in distributed network changes shown in imaging following HA use for tinnitus. A positron emission tomography (PET) study compared the glycolytic metabolism after 6 months of HA use in persons with and without tinnitus (Simonetti et al., 2022). The PET study showed that metabolism increases in the frontal and temporal regions and decreases in the parietal lobe and cerebellum (Simonetti et al., 2022). Simply stated, amplified sound drives the networks of auditory and associated systems to change tinnitus positively.

Soon after wearable tinnitus maskers were developed, they were combined with amplifiers and called combination aids (Tyler and Bentler, 1987; British Society of Audiology, 2020). At present, many HAs have some form of tinnitus sound therapy as a programmable option. The value of adding therapeutic therapy sounds to amplification is uncertain (Sereda et al., 2018; Tutaj et al., 2018). The sounds generated by HAs have usually been some form of broadband noise (Kim et al., 2014), but, currently, fractal tones (Sweetow and Sabes, 2010) and synthesized ocean wave sounds (Sereda et al., 2017) have also become available. HAs can also wirelessly stream sounds from smartphone applications (via Bluetooth). Until fairly recently, the research investigating HAs and additional therapy sounds as tinnitus management tools has been limited. The benefits of combined sound and amplification and amplification alone are similar (Tutaj et al., 2018). Although different therapy sounds do not affect outcomes greatly (Barozzi et al., 2016; Henry et al., 2017), nature sounds are more pleasant to listen to than broadband noise but appear to be less effective in reducing tinnitus (Durai and Searchfield, 2017). A feasibility study, with 8 participants, of an earlier generation of the Oticon HAs tested in the present study, found broadband noise to be the most effective masker, while simulated ocean wave sounds provided distraction and/or some relaxation (Sereda et al., 2017).

This research was undertaken to further understand the effectiveness of recent HA-based sound therapy developments from one HA manufacturer and to inform clinical practice on how to optimize different forms of tinnitus sound support (TSS).

Our hypotheses were that (1) Tinnitus Functional Index (TFI) and Tinnitus Handicap Inventory (THI) scores would be similar or significantly better than baseline after fitting and 3 months of use of the study devices and (2) the clinical performance of TSS will be the same or better in comparison to the current tinnitus solution, if any (i.e., pre-study HAs).

2. Materials and methods

2.1. Ethical standards

All participants gave written informed consent for inclusion before participation in the study. The study was conducted in accordance with the Declaration of Helsinki. The protocol was approved by the Northern B Health and Disability Ethics Committee (21/NTB/233). This trial was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12621001754831).

2.2. Trial design

A pre-post interventional design with two groups (new and experienced HA users) was implemented. Participants attended three scheduled appointments at the University of Auckland Clinics, Auckland, New Zealand: baseline assessment and HA fitting (week 0), follow-up (week 3), and final appointment (week 12). Repeated outcome measures were obtained at baseline (study screening) and 12 weeks after the initial fitting appointment via online questionnaires. The study ran from 21 January 2022 until 12 December 2022.

2.3. Participants

Participants were recruited by advertising on the University of Auckland's research website and through the University of Auckland Tinnitus Research Participant Database mailing list. The inclusion criteria were as follows: adults aged 18 years or above; chronic tinnitus (at least 6 months since onset); new and experienced HA users with a slightly symmetric (16 dB HL) to moderately severe (70 dB HL) binaural symmetric (PTA4 difference

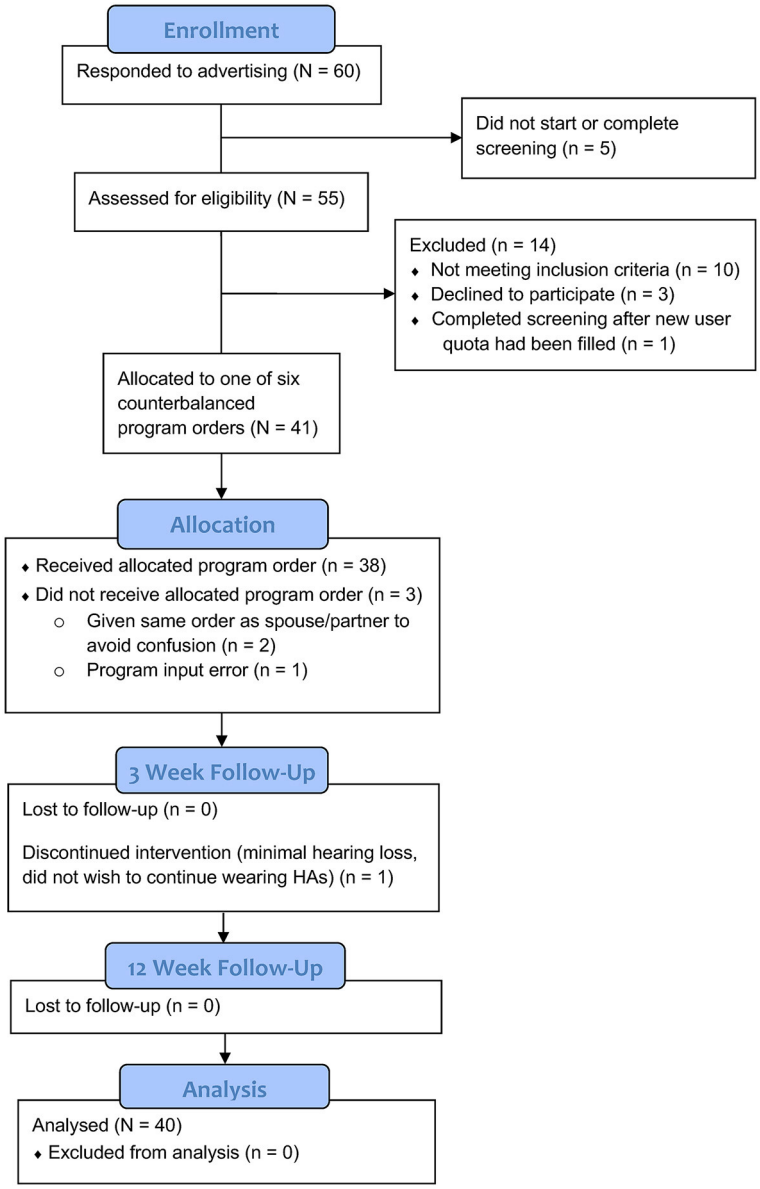

FIGURE 1
A flow diagram for participant enrollment and retention.

between ears ≤15 dB) sensorineural or mixed flat or sloping hearing loss; HA fitting level for the 60- or 85-dB speaker and domes or custom molds including all types and configurations of hearing loss; and scores in the range of "Normal to Severe" in each of the three categories on the Depression Anxiety and Stress Scale−21 Items (DASS 21) (Lovibond and Lovibond, 1995; Antony et al., 1998). The exclusion criteria were as follows: a score of "Extremely Severe" in any one of the three categories of the DASS 21 and objective, pulsatile tinnitus. The flow of participants is shown in Figure 1. The mean participant characteristics for the sample are summarized in Table 1. Audiogram data for the sample are plotted in Figures 2A, B. A total of 40 participants were included in this study, of which 21 of them were new hearing aid users and 19 were experienced hearing aid users. All but one of the experienced users had used their hearing aid for at least 6 months.

2.4. Procedures

Participants were instructed to use the provided HAs (study devices) as needed to assist hearing and help with their tinnitus. They were encouraged to use them for several hours per day at least. Participants were asked to explore all four of the programs provided. Participants received verbal counseling on the use of sound therapies for tinnitus according to their needs. All

TABLE 1 Means (standard deviations) of demographics and clinical characteristics of sample.

	All	New Users	Experienced
Measure			
Number of participants	40	21	19
Age	59.5 (12.4)	60.5 (8.4)	58.5 (16)
Sex	19 F 21 M	8 F 13 M	11 F 8 M
TFI (screen)	47.8 (22.6)	51.0 (24.7)	44.2 (20.1)
THI (screen)	41.7 (24.2)	43.2 (26.8)	39.9 (21.6)
Pitch (Hz)	4,686 (1,812)	5,059 (1,859)	4,274 (1,712)
Perceived level (dB SL)	23 (12)	23 (12)	23 (12)
TT duration	17 y 5 m	16 y 4 m	19 y 6 m
Localization			
Left ear	5	3	2
Right ear	4	4	0
Left of center	12	5	7
Right of center	6	4	2
Equal ears	11	4	7
Inside the head	2	1	1
Previous HA duration			
<6 months		n/a	1
6–12 months		n/a	0
>1 year		n/a	2
Several years		n/a	16

participants were provided with a written information sheet about tinnitus, its pathology, and management strategies.

2.4.1. Week 0: screening, assessment, counseling, and fitting

After contacting the researchers, participants were given an information sheet outlining the background and aims of the trial and details of study measurements. After providing written informed consent, participants were assigned a unique identifier code so that the data could be managed and analyzed in a de-identified manner. Participants were provided with a link to online questionnaires coded, stored, and collated using the University of Auckland's Research Electronic Data Capture (REDCap) account. De-identified data from eligible participants was inputted into the clinical data collection cloud service, SMART-TRIAL, by the researchers to enable monitoring and management by the study sponsors and funder's research team. These systems are compliant with data safety laws as well as good clinical practice.

2.4.1.1. Questionnaires

Background and screening: Participants completed the Tinnitus Sample Case History Questionnaire (TSCHQ) (Langguth et al., 2007) and the DASS 21. These participants provided eligibility data and background that could be used to help guide tinnitus counseling.

Tinnitus: The TFI (Meikle et al., 2012), which has been validated in New Zealand (Chandra et al., 2018), served as the primary tinnitus outcome measure in this trial. The TFI assesses the impact of tinnitus across various dimensions. The THI (Newman et al., 1996, 1998) served as a secondary measure.

The Client Oriented Scale of Improvement on Tinnitus (COSIT) (Searchfield, 2019) goals were established for each participant through discussion with the researcher about how tinnitus was affecting their life and what they hoped to achieve with the intervention. Participants could choose up to five personal goals to be evaluated at the end of their participation in the study.

Participants also rated on numerical scales how much of a problem their tinnitus was (0 not a problem; −5 very big problem) and the severity of tinnitus perception across five dimensions: strength, intrusiveness, discomfort, unpleasantness, and how easy it was to ignore (0 not a problem; −10 extreme problem).

2.4.1.2. Hearing and tinnitus assessment

Pure-tone audiometry (MEdRX, AVANT Stealth Audiometer, 0.25–8 kHz) was conducted in a sound-treated room (ISO 8253-1:2010) and employed the modified Hughson–Westlake procedure (Carhart and Jerger, 1959). Tinnitus psychoacoustic outcomes were measured using tinnitus testing software (MEdRX, Tinnometer). The tinnitus pitch-matching was assessed throughout the test frequency range of 0.25–16 kHz using a two-alternative forced-choice method. The measurement continued until two repeated responses were obtained.

2.4.1.3. Hearing aid fitting

The study devices, Oticon More 1 miniRITE R HAs, were dispensed and coupled to the prescribed settings provided by the Genie fitting software, individually adjusted to match the NAL-NL2 targets using a real ear measurement (REM)-based procedure, presented and recorded via an Audioscan Verifit 2 device (version 4.24.6), and programmed via a Noah Link Wireless device. This protocol was based on international state-of-the-art principles for best practices for HA fittings. HA fittings were made by a final-year University of Auckland Audiology intern under the supervision of two of the authors (GDS and PJS).

2.4.1.4. Programs and tinnitus sound support™

Four program settings were provided to all participants: (A) Amplification alone (for normal/quiet situations), (B) Enhanced noise reduction settings (for noisy situations), (C) Amplification plus TSS masking sound (quiet with masker), and (D) Enhanced noise reduction settings plus TSS masking sound (noisy with masker). Program 1 on the study device was always Amplification alone (setting A). On programs 2–4, the order of settings on B–D was counterbalanced between participants. In cases where spouses/partners were both enrolled in the study, they were given the same program in order to avoid confusion. One participant received an order that was not correctly assigned according to the counterbalancing allocation.

The TSS masking sound was delivered binaurally through the HAs. Participants were able to choose between modulated or unmodulated white, red, and pink noise or the personalized "Fit to audiogram" sound. Alternatively, three "Ocean" options were

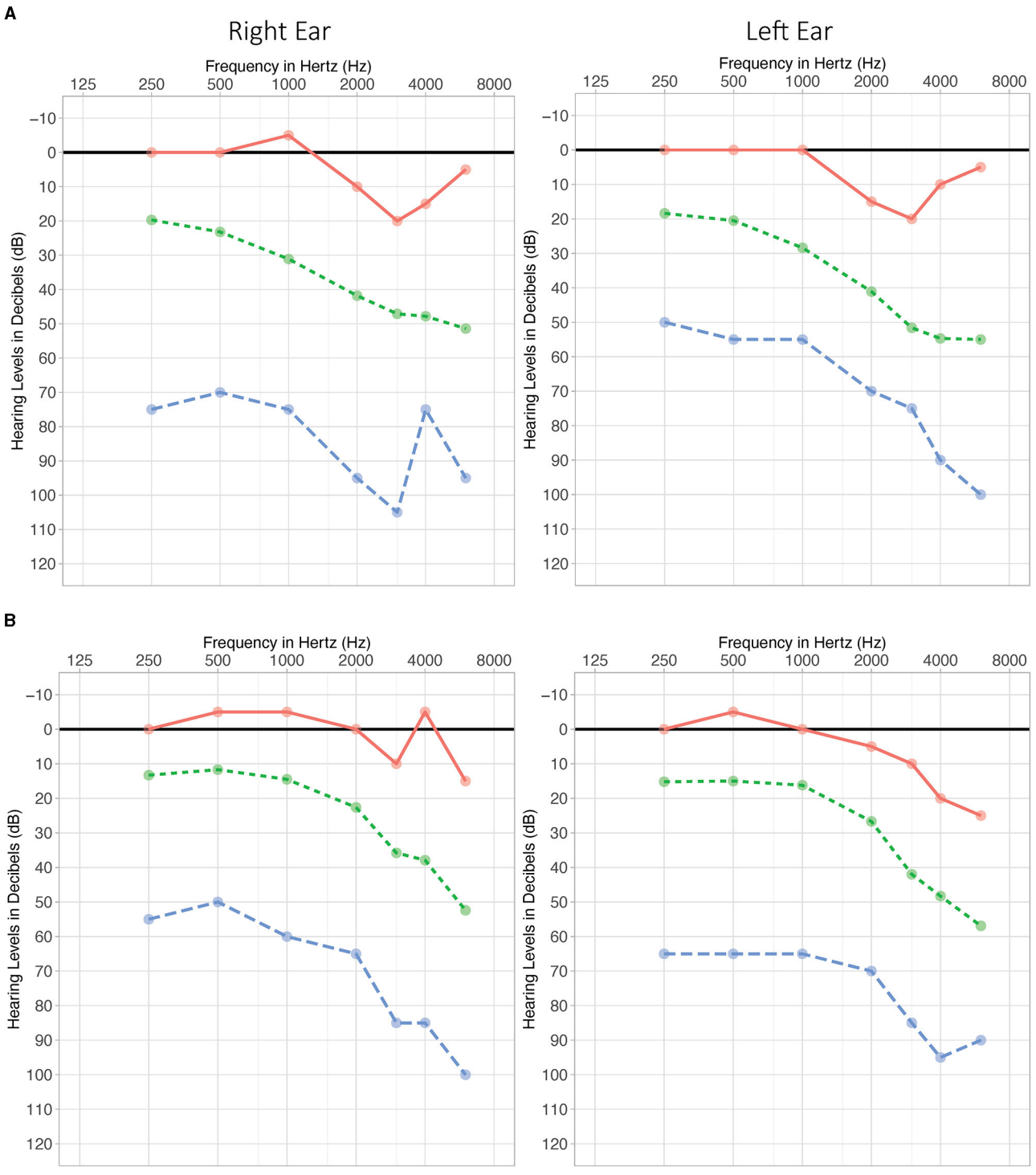

FIGURE 2
Audiogram for experienced **(A)** and new users **(B)**. Mean (green, dotted line), maximum hearing loss (blue dashed line), and minimum hearing loss (red solid line).

available (amplitude modulation of white, red, or pink noise to simulate ocean wave sounds). Default TSS levels were measured using the REM equipment. If required, the researcher then adjusted the TSS to a preferred level indicated by the participant and a second REM measure was recorded.

2.4.1.5. Counseling

Counseling was delivered by two of the authoring researchers (GDS and/or PJS), along with the audiology intern, and was based on a psycho-educational and goal-based approach (Searchfield et al., 2011) that was standardized for the study.

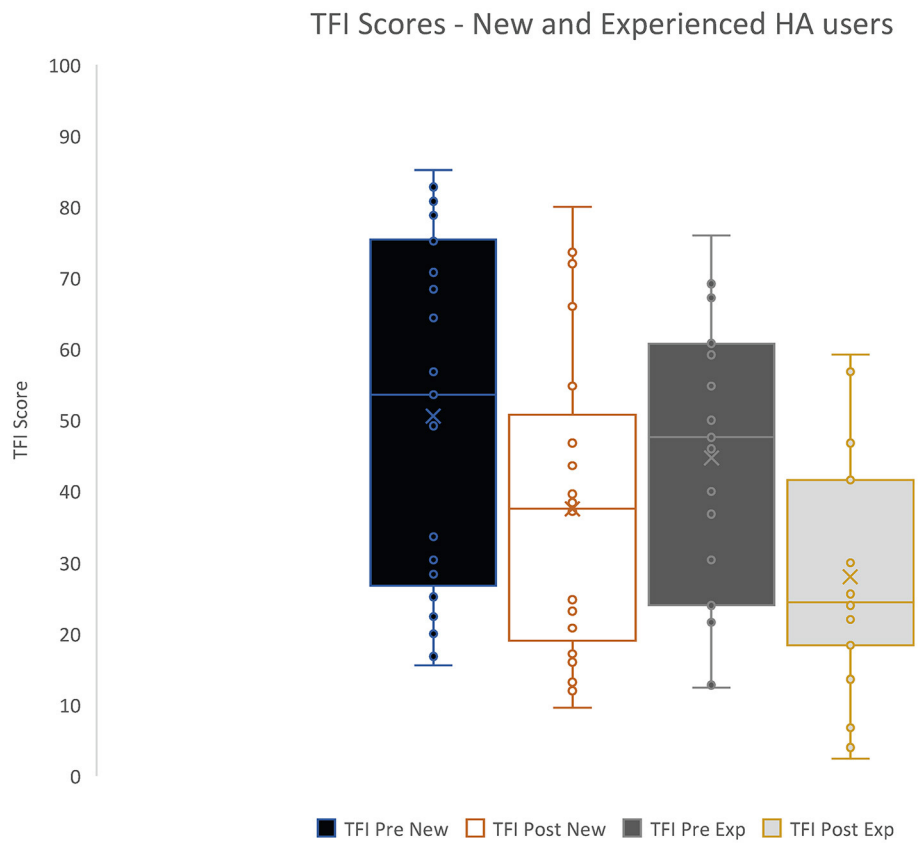

FIGURE 3
TFI scores pre- and post-intervention for new and experienced users.

2.4.2. Week 3: follow-up

A follow-up visit was scheduled for approximately 3 weeks after the initial fitting visit. This allowed participants to request adjustments to the fitting and TSS settings based on their experience with the study HAs. Participants were also able to request a change to the program order (i.e., the allocated program order could be rearranged according to the participant's preference).

2.4.3. Week 12: final visit

Twelve weeks after the fitting appointment, participants again completed the TFI, THI, DASS 21, and severity scales, as well as the COSIT outcomes form. An informal end-of-trial interview was conducted to better understand participant experiences, and any changes to fitting, programs, and TSS settings were made according to the participant's preferences.

2.5. Statistics

Power analysis (G*Power 3.1.9.4) was based on two-tailed *t*-tests. Power analyses indicated that larger sample sizes were required to detect meaningful effect sizes on the SSQ-12 (hearing-related measures outside the scope of this article) (Gatehouse and Noble, 2004; Noble et al., 2013) than for the tinnitus-related measures. Therefore, sample sizes were based on the SSQ-12 power analyses that indicated that at least 19 participants were required to be current HA users (for an effect size of 0.7, alpha = 0.05, and power = 0.8) and that at least 9 participants were required to have not used HAs prior to enrolling in the study (for an effect size of 1.15, alpha = 0.05, and power = 0.8). Therefore, the minimum sample size was estimated to be N = 28. However, during the recruitment, we aimed to enroll 40 participants to account for dropout and large variations in parameters around the test subject in tinnitus studies (e.g., severity of symptoms, psychological stress among participants, HA use and experience, hearing loss configurations).

Data analysis was conducted using the statistical programming language R. Data distribution was assessed visually using Q–Q plots and histograms and statistically using the Shapiro–Wilk normality test for each outcome measure. Most outcome measures were revealed to be non-normally distributed; therefore, the results are presented as the median and interquartile range (IQR), unless indicated otherwise. Non-parametric two-sample Wilcoxon signed-rank tests were applied to investigate differences between groups (experienced and new HA users) and measured at different time points (baseline and end of 12-week intervention period).

The movement between the severity categories based on the TFI and THI scores and pre- and post-interventions was evaluated. Bins were created to determine the number of participant scores

TABLE 2 Median, interquartile range, change scores, effect sizes and *p*-values of the TFI and TFI subscales before and after treatment with the combination aids.

Subscales	Measurement	Median (IQR)	Change score	Effect size	*p*-values
Total TFI score	Baseline	**49** (40)	**−24**	0.60 (large)	$p = 0.0001$
	Follow-up	**26** (26)			
Intrusive	Baseline	**48** (28)	**−1.6**	0.33 (medium)	$p = 0.04$
	Follow-up	**47** (31)			
Sense of control	Baseline	**60** (43)	**−13**	0.49 (medium)	$p = 0.002$
	Follow-up	**47** (28)			
Cognitive	Baseline	**40** (38)	**−18**	0.52 (large)	$p = 0.001$
	Follow-up	**22** (18)			
Sleep	Baseline	**32** (51)	**−13**	0.54 (large)	$p = 0.0009$
	Follow-up	**18** (33)			
Auditory	Baseline	**67** (35)	**−32**	0.55 (large)	$p = 0.0004$
	Follow-up	**35** (38)			
Relaxation	Baseline	**60** (44)	**−32**	0.45 (medium)	$p = 0.004$
	Follow-up	**28** (31)			
Quality Of Life	Baseline	**34** (51)	**−14**	0.54 (large)	$p = 0.0006$
	Follow-up	**20** (26)			
Emotional	Baseline	**43** (46)	**−27**	0.62 (large)	$p = 0.00005$
	Follow-up	**17** (28)			

that fell in the following category ranges. The severity categories of TFI were low = 0–18, lower moderate = 19–42, upper moderate = 43–65, and high = 66–100 (Gos et al., 2020) and THI (tinnitus handicap) were slight = 0–16, mild = 18–36, moderate = 38–56, severe = 58–76, and catastrophic = 78–100 (Newman et al., 1998; McCombe et al., 2001).

The COSIT degree of change score ranges from "With the therapy my tinnitus is…": 1, worse; 2, no different; 3, slightly better; 4, better; and 5, much better. The COSIT final score ranges from "I am annoyed by the tinnitus…": 1, almost always; 2, most of the time; 3, half of the time; 4, occasionally; and 5, hardly ever. Descriptive statistics are presented in the Results section.

Program usage time for each setting was calculated as a proportion of total usage time. Descriptions are presented in the Results section.

3. Results

3.1. TFI

Baseline and final TFI total scores for the experienced and new user groups are illustrated in a box and whisker plot in Figure 3. As no significant difference in the TFI total score was observed between the groups, scores were pooled for statistical analysis. The baseline total TFI score ranged from 12.4 to 85 points, and the final total TFI score ranged from 2.4 to 80 points (see Supplementary Figure 1 for distribution). Table 2 shows the median, IQR, median change score, and effect size of the TFI total and the subscale scores before and after treatment. The median TFI total score was 49 (IQR = 40) before treatment and 26 (IQR = 26) after treatment. A statistically significant reduction ($p = 0.0001$) in the total TFI score of 24 points was observed after treatment, with a large effect size (d = 0.60). The Auditory and the Relaxation subscales had the highest change scores of 32 points after treatment with the combination aids (Auditory: $p = 0.0004$, Relaxation: $p = 0.004$; Table 2). Significant reductions in the other TFI subscales (Intrusive, Sense of control, Cognitive, Sleep, Quality of life, and Emotional) were also observed after treatment, with the change scores ranging from 1.6 to 27 points (Table 2; Supplementary Figure 2). The largest effect sizes were observed for the Emotional, Auditory, Quality of Life, Sleep, and Cognitive scales (Table 2). The least improvement was observed for the Intrusiveness subscale, with a minimal reduction in score. However, the change was statistically significant and produced a medium effect size (Table 2).

3.1.1. Movement between TFI severity categories

Fewer participants were categorized as having upper moderate or high severity tinnitus and more as having lower moderate or low severity tinnitus after treatment than at baseline (Figure 4).

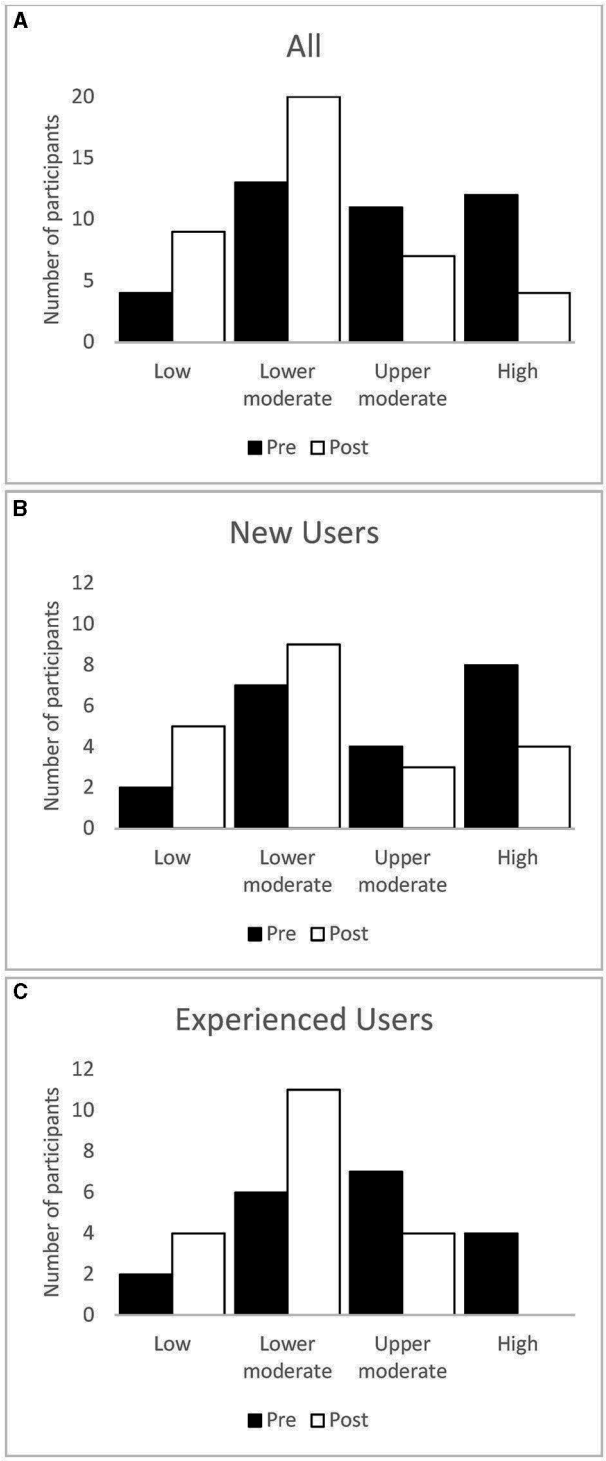

FIGURE 4
Number of participants in each TFI severity category at baseline and after the intervention period. Whole sample **(A)**, new users **(B)**, and experienced users **(C)**.

3.2. THI

Baseline and final THI total scores for the experienced and new user groups are illustrated in a box and whisker plot in Figure 5. As no significant difference in the THI total score was observed between the groups, scores were pooled for statistical analysis. The baseline total THI score ranged from 6 to 98 points, and the final total THI score ranged from 2 to 82 points (see Supplementary Figure 3 for distribution). Table 3 shows the median, IQR, median change score, and effect size of the THI total and the subscale scores before and after treatment. The median THI total score was 40 (IQR = 33) before treatment and 23 (IQR = 27) after treatment. A statistically significant reduction (p = 0.0001) total THI score of 17 points was observed after treatment, with a large effect size (d = 0.61). Significant reductions in the three subscales (Functional, Emotional, and Catastrophic response) were also observed with effect sizes ranging from d = 0.46 to 0.62 and change scores ranging from 3 to 8 points (Table 3; Supplementary Figure 4).

3.2.1. Movement between THI severity categories

Scores indicated that fewer participants were categorized as having a catastrophic or severe tinnitus handicap and more as having a moderate, mild, or slight tinnitus handicap after treatment than at baseline (Figure 6).

3.3. COSIT

The means and standard deviations for Change and Final Scores are presented in Table 4 and indicated improvements in tinnitus in relation to personal goals after treatment. Table 5 shows the proportion of the whole sample, new users, and experienced users who rated their improvement at "3–Slightly Better" or higher on at least one of their goals, on half or more of their goals, and on all their goals. The majority of participants improved on at least 50% of their goals, and 50% of the participants reported improvement on 100% of their goals. Experienced users were more likely to report improvements than new users (see Discussion for explanation).

3.4. Program use

Experienced and new users showed a similar pattern of program use. Figure 7 shows the usage pattern for the entire sample. The Amplification only setting (setting A) was the most used setting, followed by Amplification plus TSS masking sound (setting C). Enhanced Noise Reduction plus TSS (setting D) was used more than Enhanced Noise Reduction alone (setting B). Experienced users spent proportionally more time on setting A and less time on the other settings than new users.

4. Discussion

The results of this study confirm previous findings that HAs assist in reducing the impact of tinnitus on daily life. The Oticon miniRITE HAs used in this study resulted in similar improvements for both new and existing hearing aid users. This suggests that the

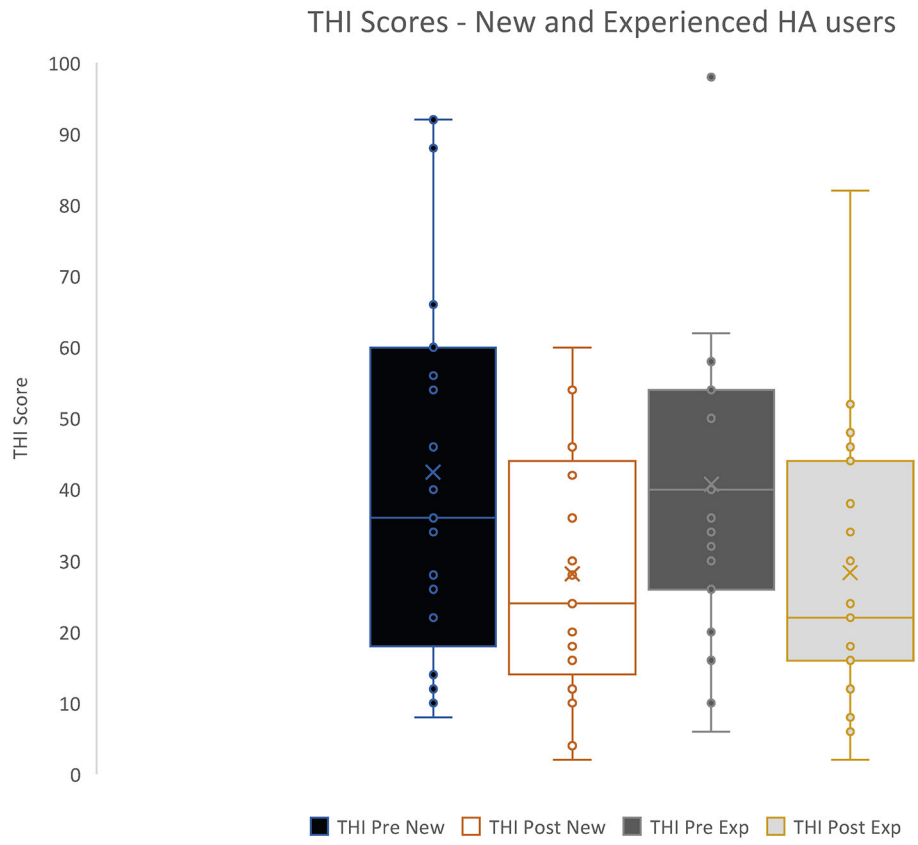

FIGURE 5
THI scores pre- and post-intervention for new and experienced users.

TABLE 3 Median, interquartile range, change scores, effect size, and *p*-values of the THI and THI subscales before and after treatment with the combination aids.

Subscales	Measurement	Median (IQR)	Change score	Effect size	*p*-values
Total THI score	Baseline	**40** (33)	**−17**	0.61 (large)	$p = 0.0001$
	Follow-up	**23** (27)			
Functional	Baseline	**22** (17)	**−8**	0.62 (large)	$p = 0.0001$
	Follow-up	**14** (15)			
Emotional	Baseline	**11** (13)	**−7**	0.46 (medium)	$p = 0.002$
	Follow-up	**4** (9)			
Catastrophic response	Baseline	**8** (6)	**−3**	0.54 (large)	$p = 0.0003$
	Follow-up	**5** (8)			

tinnitus-reducing effects of these aids was greater than those of the aids already being used by participants.

The TFI is one of the most widely used self-report tinnitus measures for documenting treatment effects as pre-post change scores (Henry et al., 2010). Studies suggest that a reduction in the total TFI score of at least 13 points is clinically meaningful (Meikle et al., 2012). The THI has been used alone or in combination with other tinnitus self-report measures for evaluating treatment effects across a wide range of treatment modalities. A change score of 20 points suggests that the treatment is clinically meaningful (Newman et al., 1998). Participants in our study completed both the TFI and the THI at two points in time, before the treatment started and 12 weeks after treatment with the combination aids. Our first hypothesis that, after 3 months of the use of the study device, the impact of tinnitus would be reduced, was confirmed; there were statistically significant reductions in total THI and TFI scores and all their subscales over the course of the study. The movement of participants from more severe to less severe categories provided further evidence for the benefit gained from the use of the study devices. Our results suggested that participants in our sample experienced improvements in emotional, auditory, quality of life, sleep, and cognitive aspects of their lives, highlighting the

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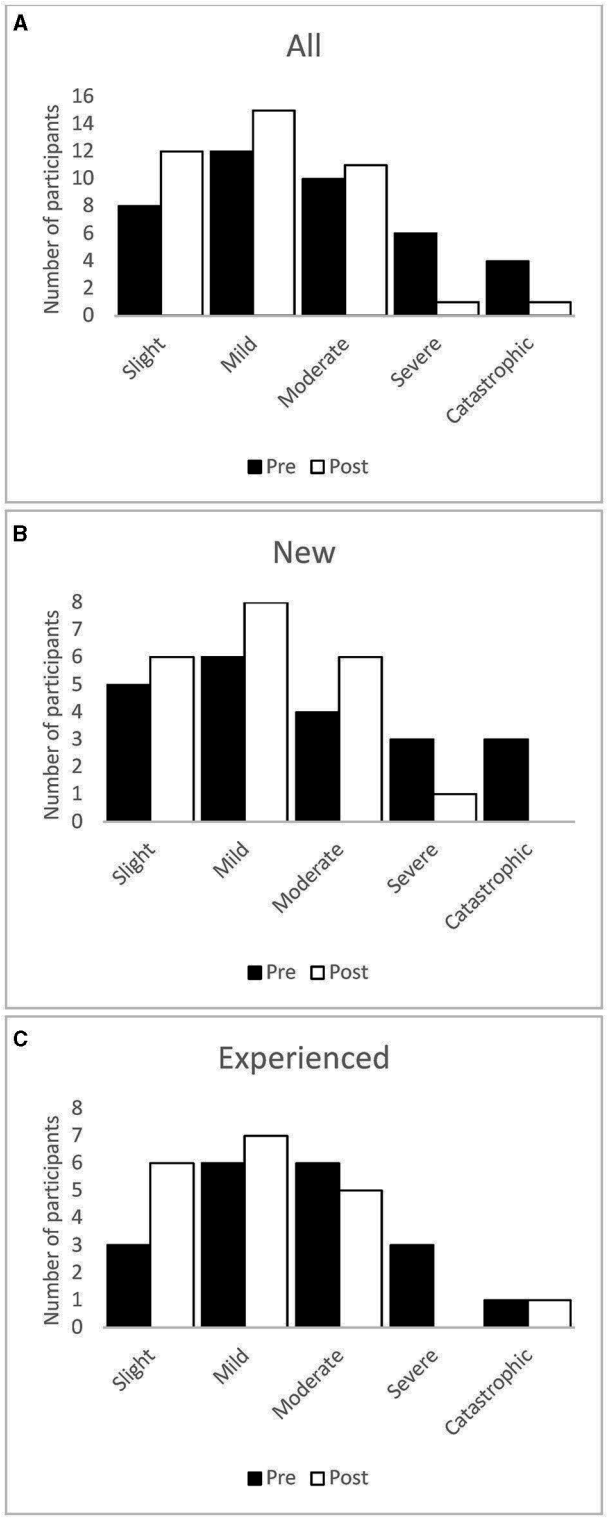

FIGURE 6
Number of participants in each THI severity category at baseline and after the intervention period. Whole sample **(A)**, new users **(B)**, and experienced users **(C)**.

wide-ranging benefits of the combination study devices in tackling this heterogeneous condition.

TABLE 4 Mean (standard deviations) COSIT change scores and final scores.

	Change	Final
Whole sample	3.25 (0.89)	3.59 (0.82)
New users	3.02 (0.92)	3.43 (0.89)
Experienced users	3.51 (0.79)	3.76 (0.71)

TABLE 5 Number and percentage of participants who reported improvement on COSIT goals.

	Group	N	%
	Whole sample	35	88
Improved on at least one goal	New users	16	76
	Experienced users	19	100
Improved on 50% of goals or more	Whole sample	31	78
	New users	15	71
	Experienced users	16	84
Improved on 100% of goals	Whole sample	20	50
	New users	7	33
	Experienced users	13	68

The COSIT results provided converging evidence that personally meaningful improvements were achieved for most participants. Interestingly, while both new and experienced HA user groups reported improvements and no statistical differences were observed between them, COSIT results and TFI/THI category movements indicated that experienced users were more likely to report improvements at the end of the trial than new users. This result was surprising because one would expect naive users to experience greater effects than those who would ostensibly be receiving some benefit from their existing devices and, therefore, would have less room for improvement. This may be the result of those with more experience having more realistic expectations. However, it also indicates that the study devices provided benefits beyond that provided by the HAs they were using prior to the study, supporting our second hypothesis that the clinical performance of the study devices would be the same or better than the current tinnitus solution (previous HAs).

Many participants reported that they were not attending as many social events or visiting loud places such as restaurants compared to their normal activities prior to the COVID-19 pandemic. This means that our examination of program use may not reflect usage under more demanding, normal circumstances.

The main limitation of this study was that no control group or control condition was included in the design. This makes it difficult to determine which elements of the intervention (tinnitus counseling, TSS, and amplification) contributed to the benefits observed. Counseling is unlikely to have accounted for the entire effect as it has been shown that HAs can provide benefits even when no counseling is provided (Shekhawat et al., 2014). In the present study, both naive and experienced users showed benefit, so it is unlikely that simple amplification of sound accounted for the entire effect; otherwise, the experienced users would be expected

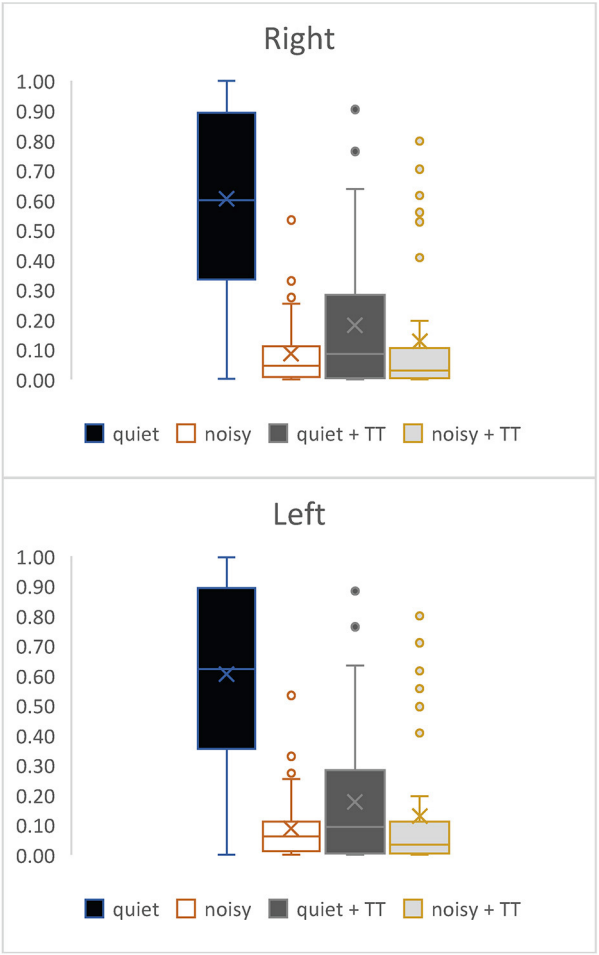

FIGURE 7
The proportion of individual program use as a function of total usage for right and left ears.

to show less pronounced effects than naive users. It is possible that amplification and/or settings may have been superior with the study devices. Indeed, Amplification alone was the most used program setting. However, the next most used program setting was Amplification plus TSS masking sound. This indicates that people used TSS as needed and that the benefit did not necessarily require constant use. It is our opinion that the effects observed were due to the combination of counseling and the technologies offered through study devices.

A no-intervention period between enrollment and baseline may have been useful to assess the stability of TFI and THI scores, as we have previously found that within-subject scores can vary dramatically over time in some people prior to any intervention (Searchfield and Sanders, 2022). If those with unstable scores between enrollment and baseline are excluded, this type of design can provide reassurance that any effects are a result of the study intervention. However, our large effect sizes and consistent improvement across the whole sample, regardless of experience, give us confidence that the benefits observed were due to the study devices rather than chance or confounding factors.

The strengths of this study included a relatively large sample size for this type of research and the inclusion of both new and experienced HA users, meaning that our findings generalize to both populations. Individual needs and preferences were considered for fitting and TSS settings, and the follow-up appointment in the third week of the study allowed for flexibility after a period of familiarization and adaptation to the devices.

Future studies could investigate the contributions of counseling, amplification, and TSS to reductions in tinnitus severity through controlled studies. While blinding is difficult in these types of studies, controls can be included through the staggered introduction of intervention components after a no-intervention period.

Data availability statement

The datasets presented in this article are not readily available because ethical permission was granted specifically for the purposes of this study. There was no approval for public data sharing. Requests to access the datasets should be directed to RN, email: reur@oticon.com.

Ethics statement

The studies involving human participants were reviewed and approved by Northern B Health and Disability Ethics Committee (21/NTB/233). The patients/participants provided their written informed consent to participate in this study.

Author contributions

GS was the principal investigator, oversaw the project, and carried out some data collection. PS carried out the bulk of data collection, administered the project, and contributed to data analysis. RN carried out the bulk of data analysis. JJ wrote the original protocol and designed the study. All authors contributed to writing and editing the manuscript.

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Conflict of interest

RN is employed by Oticon as a Senior Researcher. JJ was employed by Oticon as a Post-Market Clinical Researcher during the start of the study. GS is a founder and director of Tinnitus

Tunes and TrueSilence Therapeutics tinnitus treatment companies. The authors declare that this study received funding from Demant A/S. The funder had the following involvement in the study: study design, and data analysis.

PS and GS declared that they were editorial board members of Frontiers at the time of submission. This had no impact on the peer review process and the final decision.

Publisher's note

Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fauot.2023.1238164/full#supplementary-material

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