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Long-Term Outcomes of Self-Fit vs Audiologist-Fit Hearing Aids

Karina C. De Sousa, PhD; Vinaya Manchaiah, PhD; David R. Moore, PhD; Marien A. Graham, PhD; De Wet Swanepoel, PhD

IMPORTANCE With rising interest in over-the-counter (OTC) hearing aids as an alternative to traditional audiologist-fit devices, understanding their long-term efficacy is crucial. However, given the novelty of the US Food and Drug Administration category of OTC hearing aids, minimal evidence currently supports their long-term efficacy.

OBJECTIVE To compare the long-term self-reported outcomes at 8 months of self-fit OTC hearing aids to the same hearing aids fit by audiologists.

DESIGN, SETTING, AND PARTICIPANTS Building on a previous randomized clinical trial, this follow-up comparative effectiveness research study reassessed a number of the original participants that were not lost to follow-up. Participants were initially divided into those with self-fit OTC hearing aids and those with audiologist-fit devices. Approximately 8 months after fitting, participants completed self-reported questionnaires. Missing data were addressed through multiple imputation. The original noninferiority trial was conducted at the University of Pretoria in South Africa from April 2022 to August 2022. The current analysis took place between July 7, 2023, to November 20, 2023.

INTERVENTIONS In the original trial, participants in the self-fit device group received a pair of OTC hearing aids and independently fit them with remote support as needed. The audiologist-fit device group received the same hearing aids fit by a certified audiologist using best practices.

MAIN OUTCOMES AND MEASURES The main outcomes were self-reported hearing aid benefit, measured using the Abbreviated Profile of Hearing Aid Benefit (APHAB) and the International Outcome Inventory for Hearing Aids (IOI-HA).

RESULTS Of 64 participants in the trial, 44 participants were included in the extension study (21 [47.7%] in the audiologist-fit group; 23 [52.3%] in the self-fit group). The mean (SD) age of these participants was 63.0 (13.2) years, and 21 (47.7%) were male. At the long-term follow-up, self-fit and audiologist-fit groups showed no significant differences in the APHAB global score (mean difference, 0.02 [95% CI, −7.1 to 7.1]; Cohen *d*, 0.01 [95% CI, −0.5 to 0.5]) or the IOI-HA total score (mean difference, 1.5 [95% CI, −1.4 to 4.4]; Cohen *d*, 0.3 [95% CI, −0.2 to 0.8]). From 6 weeks to 8 months, no clinically meaningful group-time interaction was found between groups for the APHAB global score (Cohen *d*, 0.1 [95% CI, −0.2 to 0.3]), but a significant interaction for the IOI-HA total score was found (Cohen *d*, −0.6 [95% CI, −0.8 to −0.3]), with the self-fit group generally performing better.

CONCLUSION This comparative effectiveness research study demonstrated that self-fit OTC hearing aids can offer comparable long-term benefits to audiologist-fit hearing aids for individuals with mild to moderate hearing loss.

Supplemental content

Author Affiliations: Author affiliations are listed at the end of this article.

Corresponding Author: Karina C. De Sousa, PhD, Department of Speech-Language Pathology and Audiology, University of Pretoria, c/o Lynnwood Rd and Roper St, Pretoria 0002, Gauteng, South Africa (karina.swanepoel@up.ac.za).

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Amid the pervasive prevalence of adult hearing loss, the medical community is increasingly placing emphasis on proactive advocacy and earlier hearing interventions. Over-the-counter (OTC) hearing aids, available directly to consumers without professional consultation or fitting, have been anticipated for years, offering an alternative to the traditional route of acquiring them through hearing health care professionals. The goal behind this category of hearing aids is to enhance the availability and affordability of hearing care in the US, a critical move considering the high prevalence of adult hearing loss and the noticeable underutilization of hearing aids, which is a meager 20% of US adults with hearing loss.[1]

Earlier studies on self-fit OTC hearing aids predominantly focused on 3 areas: the consumer's ability to adjust the acoustic characteristics, the outcomes of the self-fit method, and user satisfaction with devices.[2] A crossover trial by Sabin and colleagues in 2020[3] explored the validation of self-selected gain and sound quality preferences using a prototype device. The group that self-adjusted their devices reported better sound quality than the group using the same device with parameters set by a clinician. In the same study, no significant differences between groups were found when the hearing aid was fit according to clinical best practice, compared to the self-fit condition.[3] Convery et al[4] investigated how well users could self-fit hearing aids, revealing that nearly 68% of participants could do so successfully. However, the same study shed light on the fact that prior technological experience plays a role in determining self-fit success. Humes et al[5] conducted a double-blind, placebo-controlled, randomized clinical trial assessing the effect of the service delivery model and purchase price on hearing aid outcomes. The study indicated improved hearing-related results across audiology best practices and consumer-driven groups, with the former presenting slightly higher satisfaction.[5] Though encouraging, previous studies neither used commercial devices nor assessed long-term effectiveness beyond the initial weeks, emphasizing the need for further comprehensive investigations to establish the efficacy and effectiveness of self-fit hearing aids.

We recently conducted a noninferiority randomized clinical trial comparing the effectiveness of OTC hearing aids approved by the US Food and Drug Administration (FDA) that were self-fit with remote support to the same hearing aids that were fit by an audiologist.[6] After wearing the hearing aids for 6 weeks, no significant differences were found in any outcome measure (ie, self-reported hearing aid benefit and satisfaction, speech in noise performance). Therefore, this study showed that self-fitting OTC hearing aids could be effective for mild to moderate hearing loss.[6]

Given the novelty of self-fitting OTC hearing aids, significant industry concerns remain regarding their sustainability and long-term efficacy, particularly in the absence of ongoing, hands-on support from hearing health care professionals.[7] Long-term follow-up is necessary to evaluate if users of self-fit hearing aids continue to experience satisfactory benefit and satisfaction over time. It also helps assess how the lack of professional guidance affects their long-term success and overall satisfaction. As an extension of our previous randomized clinical trial,[6] this comparative effectiveness research aims to explore long-term self-reported benefit and satisfaction of self-fit OTC hearing aids compared to audiologist-fit hearing aids.

Key Points

Question Can self-fit over-the-counter (OTC) hearing aids provide equal long-term benefit compared to the same hearing aid fit by an audiologist according to best practices?

Findings In this comparative effectiveness research study of 44 participants, no significant differences were found between the self-reported benefit of a self-fit OTC hearing aid and audiologist-fit hearing aid 8 months after fitting per the Abbreviated Profile of Hearing Aid Benefit (mean difference, 0.02; Cohen *d*, 0.01) and International Outcome Inventory for Hearing Aids (mean difference, 1.5; Cohen *d*, 0.3).

Meaning These findings suggest that self-fit OTC hearing aids may be an effective long-term intervention option for people with mild to moderate hearing loss.

Methods

Study Design and Participants

This investigator-initiated extension study was approved by the Humanities Research Ethics Committee at the University of Pretoria. All participants enrolled in the original trial were contacted by email or by phone to invite them to participate in the extension study and all provided written informed consent. The original noninferiority trial was implemented at the University of Pretoria in South Africa from April 2022 to August 2022. The current analysis took place between July 7, 2023, to November 20, 2023.

Participants were randomly assigned to 2 groups, a self-fit device group and an audiologist-fit device group (NCT05337748). The self-fit group received FDA-certified, self-fitting OTC hearing aids (Lexie Lumen), representing a reasonable selection from the current market offerings. They fit the devices independently, with no professional guidance. The audiologist-fit group received the same hearing aids fit by 1 of 3 audiologists using typical best practices, which included real-ear measurements to ensure the devices' output matches the prescribed gain for the individual's hearing loss, personalized fine-tuning of the device, and professional orientation to educate users on device maintenance and optimization for daily use. Both groups received the devices free of charge.

A 2-week trial after fitting was conducted in which no hearing aid adjustments were made for either group. Group members with audiologist-fit devices could request fine-tuning at the first follow-up 2 weeks after fitting (2), whereas participants with self-fit devices could choose to reach out to remote support. The final evaluation occurred after an additional 4-week field trial (6 weeks after fitting, T2). At the conclusion of the original 6-week trial, participants retained their hearing aids. In terms of requests for follow-up support after the trial, all participants were asked to direct their queries through the remote support channel. This study incorporated a 1-time trial extension, aiming to evaluate long-term

hearing aid use and self-reported benefits approximately 8 months after fitting (T3). Three attempts were made to establish contact; if these were unsuccessful, the data were categorized as lost to follow-up.

Data Collection and Main Outcomes

In line with the 6-week randomized clinical trial, the primary outcome was self-reported hearing aid benefit, measured using 2 standardized questionnaires, the Abbreviated Profile of Hearing Aid Benefit (APHAB)[8] and the International Outcome Inventory for Hearing Aids (IOI-HA).[9] The APHAB is a 24-item tool designed to assess the perceived benefits and problems with hearing aid use, which are ultimately defined in 4 subscales, namely ease of communication, background noise, reverberation, and aversiveness.[8] The APHAB is used before hearing aid use and after hearing aid use to determine the effectiveness of the hearing aids in different listening environments. Ranges for APHAB are 1% to 99%, in which a lower score indicates less communication difficulty and a higher score indicates greater communication difficulty. The IOI-HA is a shorter 7-item questionnaire designed to evaluate the impact of hearing aids on the quality of life and satisfaction of users.[9] Benefit was rated using an ordinal response scale of 1 to 5, with a lower score indicating worse outcomes and a higher score indicating better outcomes. Both questionnaires have various subscales, but the primary outcome in this analysis was the global score for the APHAB and the total score for the IOI-HA. The APHAB was conducted at the following time points: baseline (T0), 2 weeks after fitting (T1), and 6 weeks after fitting (T2) in the original trial, while the IOI-HA was conducted at T1 and T2. For this extension study, the same questionnaires were sent remotely to participants using a remote survey platform (Qualtrics) at T3. In the follow-up study, we opted not to conduct speech recognition testing as our previous study revealed no significant differences in benefit between the groups in this measure, and we aimed to maximize participant retention by using less burdensome online self-report questionnaires.

Statistical Analysis

Missing information from nonresponses to the questionnaires at T3 was imputed using the multiple imputation function of SPSS statistical software, version 28.0 (IBM). Despite the data not being missing at random, we used multiple imputation as it has been shown to yield less biased results than listwise deletion, even under the conditions of not being missing at random, by leveraging dependencies on observed variables and reducing the impact of missingness on unobserved information.[10,11] This approach allows for more comprehensive use of the available data, enhancing the validity of our analysis compared to methods like listwise deletion. Five sets of imputed data were produced, ensuring a robust model effect estimate with CI coverage of at least 95%.[12] To compare groups at the clinical trial time points from baseline (T0) to T2 and concluding time point (T3), independent *t* tests were used. A generalized estimating equation assessed variations over time, including the influence of repeated measures. This model covered primary effects of time, treatment groups, and interaction of time-by-treatment. Participants were categorized into 2 groups based on a median field wear time of 234 days to determine the effect of field wear time on the APHAB and IOI-HA scores using the Mann-Whitney test. For all analyses, significant clinical variances considered effect size and 95% CIs. Variances were considered clinically meaningful when the effect size was medium or larger. Cohen *d* was interpreted as small ($d \leq 0.2$), small to medium ($0.2 < d < 0.5$), medium ($d = 0.5$), medium to large ($0.5 < d < 0.8$), and large ($d \geq 0.8$).[13]

Results

Participants and Follow-Up Support Requests

Of 64 participants in the trial, 44 participants were included in the extension study (**Figure 1**). Eleven participants (34.4%) in the audiologist-fit group from the original trial were lost to follow-up, and 9 participants (28.1%) in the self-fit group from the original trial were lost to follow-up. The mean (SD) age of these participants was 63.0 (13.2) years, and 21 (47.7%) were male. Self-reported outcome measures were repeated to determine long-term effectiveness between 174 to 338 days following the end of their participation in the 6-week trial (mean [SD], 240 [41] days). A summary of all participant characteristics can be found in eTable 1 in Supplement 1, along with the outcomes presented across age and gender (eMethods and eTables 2-5 in Supplement 1). Only 1 participant in the self-fit group requested follow-up support with intermittent static from the hearing aid. Additionally, 1 participant in the audiologist-fit group requested support with gain adjustments.

Long-Term Outcomes

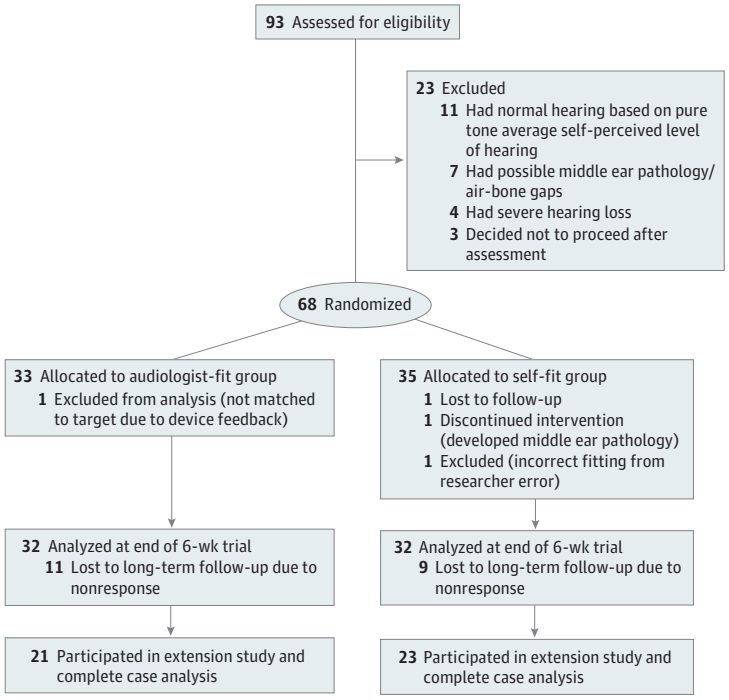
At the extended 8-month follow-up (T3), no clinically meaningful difference was found between the self-fit and audiologist-fit group for the APHAB global score (mean difference, 0.02 [95% CI, −7.1 to 7.1]; Cohen *d*, 0.01 [95% CI, −0.5 to 0.5]) or the IOI-HA total score (mean difference, 1.5 [95% CI, −1.4 to 4.4]; Cohen *d*, 0.3 [95% CI, −0.2 to 0.8]). Likewise, none of the APHAB subscales (**Table 1**) or IOI-HA domains had clinically meaningful differences between the groups, having an effect size (Cohen *d*) of less than 0.5. Considering the varied timing of long-term follow-up assessments among participants, they were stratified into 2 groups based on a median duration of 234 days of field wear time. This stratification compared the APHAB and IOI-HA scores, which ultimately indicated no clinically meaningful differences related to the duration of follow-up.

Effectiveness Over Time

Across the 3 aided time points (T1, T2, and T3), there was no significant group-time interaction (Cohen *d*, −0.02 [95% CI, −0.3 to 0.2]). Furthermore, from 6 weeks (T2) to 8 months (T3), there was no clinically meaningful interaction for group and time (audiologist-fit vs self-fit) for the APHAB global score (Cohen *d*, 0.1 [95% CI, −0.2 to 0.3]; **Figure 2**), nor any of the APHAB subscales (Cohen $d < 0.4$; eFigure 1 in Supplement 1), signifying sustained performance for both groups after the original 6-week trial.

On the IOI-HA total score, a clinically meaningful group-time interaction effect was found across all 3 aided time points

Figure 1. Participant Flow Diagram



This figure shows the flow of participants through the original randomized clinical trial and those remaining participants included in the follow-up comparative effectiveness research 8 months after fitting.

Table 1. Abbreviated Profile of Hearing Aid Benefit (APHAB) Scores Between Audiologist-Fit Device and Self-Fit Device Groups

APHAB subscale[a]	Time point	Mean (SD) score		Cohen *d* (95% CI)[b]
		Audiologist-fit	Self-fit	
Ease of communication	T0	36.1 (23.4)	43.5 (27.6)	−0.3 (−0.8 to 0.2)
	T1	19.0 (20.2)	15.6 (18.2)	0.2 (−0.3 to 0.7)
	T2	18.4 (20.8)	14.7 (17.6)	0.2 (−0.3 to 0.7)
	T3[c]	27.9 (17.0)	31.8 (15.5)	−0.2 (−0.7 to 0.3)
Background noise	T0	54.8 (16.8)	58.1 (19.6)	−0.2 (−0.7 to 0.2)
	T1	34.0 (17.8)	24.1 (14.3)	0.6 (0.1 to 1.2)
	T2	27.4 (19.3)	21.9 (13.7)	0.3 (−0.2 to 0.8)
	T3[c]	13.9 (8.9)	16.9 (13.3)	0.3 (−0.2 to 0.8)
Reverberation	T0	54.8 (18.7)	47.1 (18.3)	−0.1 (−0.6 to 0.4)
	T1	30.0 (17.6)	23.6 (16.4)	0.4 (−0.1 to 0.9)
	T2	26.5 (16.5)	20.7 (16.3)	0.4 (−0.1 to 0.9)
	T3[c]	20.0 (10.1)	21.1 (12.6)	0.1 (−0.4 to 0.6)
Aversiveness	T0	34.4 (23.6)	37.4 (25.8)	−0.1 (−0.6 to 0.4)
	T1	38.3 (23.6)	33.1 (24.1)	0.2 (−0.3 to 0.7)
	T2	26.6 (23.7)	33.4 (26.7)	−0.3 (−0.8 to 0.2)
	T3[c]	17.9 (14.3)	16.0 (12.8)	0.2 (−0.4 to 0.6)
Primary outcome measure				
Global[d]	T0	45.5 (16.6)	49.2 (19.6)	−0.2 (−0.7 to 0.3)
	T1	27.7 (16.2)	21.1 (14.4)	0.4 (−0.1 to 0.9)
	T2	24.1 (16.7)	19.1 (14.1)	0.3 (−0.2 to 0.8)
	T3[c]	21.9 (12.7)	20.8 (10.2)	0.0 (−0.5 to 0.5)

Abbreviations: T0, baseline; T1, 2 weeks; T2, 6 weeks; T3, 8 months.

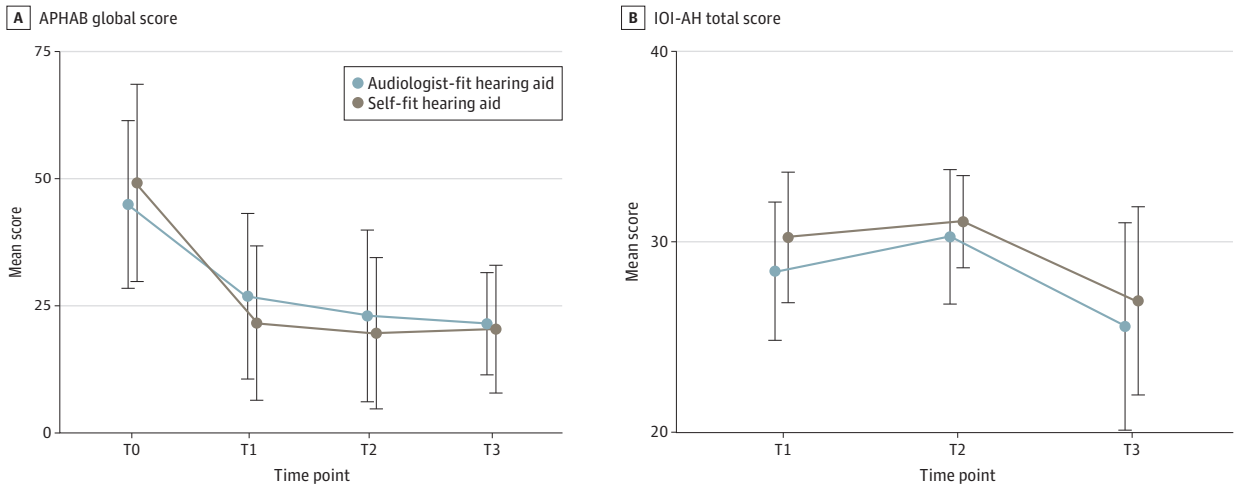
[a] The APHAB is a 24-item tool designed to assess the perceived benefits and problems with hearing aid use, defined in 4 subscales: ease of communication, background noise, reverberation, and aversiveness. Scores range from 1% to 99% with higher values indicating greater performance problems.

[b] For all analyses, variances were when considered clinically meaningful when the effect size was medium or larger. Cohen *d* was interpreted as small ($d \leq 0.2$), small to medium ($0.2 < d < 0.5$), medium ($d = 0.5$), medium to large ($0.5 < d < 0.8$), and large ($d \geq 0.8$).

[c] Values are mean and SD estimates from multiple imputation.

[d] Global score indicates mean scores across all subscales excluding aversiveness.

Figure 2. Main Outcome Measures



A, The mean Abbreviated Profile of Hearing Aid Benefit (APHAB) global score is displayed at baseline (T0), 2 weeks (T1), 6 weeks (T2), and 8 months (T3) for the audiologist-fit hearing aid group and self-fit hearing aid group. Error bars indicate SDs. A lower APHAB score indicates better performance.

B, The mean International Outcome Inventory for Hearing Aids (IOI-HA) total score is displayed at 2 weeks (T1), 6 weeks (T2), and 8 months (T3) for the audiologist-fit hearing aid group and self-fit hearing aid group. Error bars indicate SDs. A higher score indicates better performance.

(T1, T2, and T3; Cohen *d*, −0.5 [95% CI, −0.7 to −0.3]), though not evident in the separate domains (Cohen *d* < 0.4). Generally, the self-fit group performed better than the audiologist-fit group, and significantly so at 2 weeks (T1; Cohen *d*, 0.5 [95% CI, 0.02 to 1.0]), as reported in the original trial.[8] From 6 weeks (T2) to 8 months (T3), the time-group interaction effect was meaningful (Cohen *d*, −0.6 [95% CI, −0.8 to −0.3]), with the self-fit group generally performing better than the audiologist-fit group (Figure 2). This interaction pattern was particularly evident in the IOI-HA domain of satisfaction with a clinically meaningful effect (Cohen *d*, −0.5 [95% CI, −0.8 to −0.3]), but not for the rest of the domains (Cohen *d* ≤ 0.3) (**Table 2**; eFigure 2 in Supplement 1).

Although no meaningful difference was seen between the groups at 8 months, a clinically meaningful decrease in self-reported benefit from 6 weeks (T2) to 8 months (T3) in IOI-HA total score was found for both the self-fit group (Cohen *d*, 1.1 [95% CI, 0.6 to 1.7]) and audiologist-fit group (Cohen *d*, 1.0 [95% CI, 0.5 to 1.6]) (Figure 2). In the audiologist-fit group, this decline was seen in all domains, except for residual participant restriction. The same domains showed a decline in the self-fit group, in addition to impact on other domains (eFigures 1-2 in Supplement 1).

Discussion

This comparative effectiveness research study demonstrates that self-fit OTC hearing aids provide comparable long-term, self-reported benefit to professionally fit hearing aids for adults with mild to moderate hearing loss. These results contribute to the growing body of literature supporting the feasibility and effectiveness of OTC hearing aids.[3,5,6,14] The FDA's formal regulations for this category of hearing aids were established only a year ago.[15] Health care professionals have expressed considerable concerns about the effectiveness of OTC devices. A recent study, which surveyed 730 hearing health care professionals in the US on their view of OTC hearing aids, found that 78.3% believed these devices would not provide the same benefit as professionally fit prescription hearing aids,[7] which are thought to offer more precise adjustments for enhancing sound quality, speech understanding in various environments, and ongoing professional support to help people adapt to these devices. However, the results of our original trial[6] and this extension study support similar benefit for a self-fit OTC hearing aid to an audiologist-fit device according to clinical best practice.

Studies examining long-term hearing aid outcomes are limited. Gatehouse (1992)[16] and Cox and Alexander (1992)[17] found accumulating enhancement in subjective and objective benefit over the initial months of hearing aid use, an effect referred to as hearing aid acclimatization. This study found sustained self-reported benefit for both groups in the APHAB global score between 6 weeks and 8 months. However, researchers observed a small decrease in both groups in IOI-HA total scores over the same time. One longitudinal study of 134 older adults examined changes in subjective benefit of wearing professionally fit hearing aids.[18] The self-report measures included the Hearing Aid Satisfaction Survey and the Glasgow Hearing Aid Benefit profile, measured at 1 month, 6 months, and 12 months after fitting and extended to 2 years after fitting for a subgroup. Although mean changes across all benefit measures were minimal over time, self-report measures showed a significant decline in benefit at 6 months and 1 year after fitting.[18] However, another larger-scale study examining satisfaction (Glasgow Hearing Aid Benefit profile) and use (self-report) of professionally fit hearing aids in older adult listeners at 1 to 2 years after fitting showed only a very slight decline in satisfaction with little change in use.[19] Consistent with this study, overall hear-

Table 2. International Outcome Inventory for Hearing Aids (IOI-HA) Scores for Audiologist-Fit Device and Self-Fit Device Groups

IOI-HA domain[a]	Time point	Mean (SD) score		Cohen *d* (95% CI)[b]
		Audiologist-fit	Self-fit	
Use	T1	3.9 (0.8)	4.4 (0.7)	−0.7 (−1.1 to −0.2)
	T2	4.1 (0.7)	4.4 (0.6)	0.4 (−0.9 to 0.1)
	T3[c]	3.2 (1.4)	3.7 (1.2)	−0.2 (−0.7 to 0.3)
Benefit	T1	4.0 (1.0)	4.3 (0.7)	−0.4 (−0.9 to 0.1)
	T2	4.3 (0.9)	4.5 (0.6)	−0.3 (−0.8 to 0.2)
	T3[c]	4.2 (0.6)	4.0 (1.3)	0.1 (−0.4 to 0.6)
Residual activity limitation	T1	4.0 (0.8)	4.3 (0.6)	−0.4 (−0.9 to 0.1)
	T2	4.2 (0.7)	4.3 (0.6)	−0.1 (−0.6 to 0.4)
	T3[c]	3.4 (1.3)	3.6 (1.5)	−0.1 (−0.6 to 0.4)
Satisfaction	T1	4.5 (0.7)	4.3 (1.1)	0.1 (−0.4 to 0.6)
	T2	4.6 (0.5)	4.7 (0.8)	−0.1 (−0.6 to 0.4)
	T3[c]	3.2 (1.3)	3.5 (1.3)	−0.1 (−0.6 to 0.4)
Residual participation restrictions	T1	3.8 (1.1)	4.0 (1.3)	−0.2 (−0.7 to 0.3)
	T2	4.2 (1.1)	4.0 (1.2)	0.2 (−0.3 to 0.7)
	T3[c]	3.3 (1.5)	3.5 (1.5)	−0.1 (−0.7 to 0.3)
Impact on others	T1	4.2 (1.3)	4.5 (1.0)	−0.3 (−0.8 to 0.2)
	T2	4.3 (0.7)	4.6 (0.7)	−0.4 (−0.8 to 0.1)
	T3[c]	4.2 (0.9)	4.3 (1.1)	−0.2 (−0.7 to 0.3)
Quality of life	T1	4.2 (0.9)	4.3 (0.7)	−0.2 (−0.7 to 0.3)
	T2	4.5 (0.8)	4.5 (0.6)	−0.1 (−0.6 to 0.4)
	T3[c]	4.0 (0.9)	4.3 (0.7)	−0.1 (−0.6 to 0.4)
Primary outcome measure				
Total score[d]	T1	28.5 (3.6)	30.2 (3.4)	−0.5 (−1.0 to −0.0)
	T2	30.2 (3.5)	31.0 (2.4)	−0.3 (−0.8 to 0.2)
	T3[c]	25.6 (5.4)	26.9 (5.0)	−0.1 (−0.7 to 0.3)

Abbreviations: T1, 2 weeks; T2, 6 weeks; T3, 8 months.

[a] The IOI-HA is a 7-item questionnaire designed to evaluate the impact of hearing aids on the quality of life and the satisfaction of users. Total scores range from 1 to 35 with higher scores indicating a higher degree of benefit.

[b] For all analyses, variances were when considered clinically meaningful when the effect size was medium or larger. Cohen *d* was interpreted as small ($d \leq 0.2$), small to medium ($0.2 < d < 0.5$), medium ($d = 0.5$), medium to large ($0.5 < d < 0.8$), and large ($d \geq 0.8$).

[c] Means and SDs are pooled estimates from multiple imputation.

[d] Total score is the sum of the individual scores of all domains.

ing aid benefit tended to be retained across extended use, while satisfaction may decline slightly over time.

The differing long-term outcomes observed in the APHAB and IOI-HA within both groups in this study could be attributed to the distinctive focus, underlying constructs, and measurement parameters of the 2 instruments. The APHAB is designed to evaluate the perceived benefits and problems associated with hearing aid use in everyday life, primarily in terms of ease of communication, background noise management, and reverberation.[8] Longer-term stability suggests that users continue to perceive these functional benefits from their hearing aids in these areas. The IOI-HA, on the other hand, encompasses broader implications and the impact of hearing aid use, including psychosocial aspects. These constructs include satisfaction (ie, pleasurable emotional experience), residual activity limitations, impact on others, and quality of life.[9] The decrease in IOI-HA scores in this study may reflect long-term challenges in domains that are not captured by the APHAB. In both groups, the domains of use, activity limitation, satisfaction, and quality of life showed a slight decline in long-term, self-reported benefit. As time progressed, participants from both groups could have adjusted their expectations and become more cognizant of their device's limitations generally, which was a common trend between the groups rather than being specific to the fitting method used. This observation highlights the need for sustained, long-term support for both OTC and prescription hearing aid users, as they experience challenges over extended periods.

Limitations

This study was limited in that data that were lost to follow-up in long-term outcome measures presented a risk for potential attrition bias. Participants who continued in the long-term follow-up may have also differed in self-reported benefit and hearing aid use from those who dropped out. Another limitation was that the study focused on only 1 OTC hearing aid model, specifically within the self-fit category. Notably, the OTC market encompasses an increasingly diverse range of products, with varying levels of technology, features, and fitting processes. The exclusion of other OTC hearing aids meant that the study did not account for the diversity of options. Lower classes of devices could have produced outcomes with different levels of benefit and user satisfaction. Additionally, this study did not include behavioral speech in noise testing as in the original trial. Finally, sample sizes, although larger than most previous studies, were still small. These factors suggest that further re-

search using a wider variety of devices and larger sample sizes is needed to confirm the generally positive results obtained here.

Conclusions

This comparative effectiveness research study confirmed the long-term outcomes of self-fitting OTC hearing aids for individuals with mild to moderate hearing loss. These results demonstrate that self-fitting OTC devices can provide outcomes comparable to audiologist-fit hearing aids over an extended period. Given the low uptake and use of hearing aids, even among those with adequate access to audiological resources, these results are promising for persons with mild to moderate hearing loss seeking more accessible and affordable hearing care.

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Author Affiliations: Department of Speech-Language Pathology and Audiology, University of Pretoria, Pretoria, South Africa (De Sousa, Manchaiah, Swanepoel); Virtual Hearing Lab, Collaborative Initiative Between the University of Colorado and the University of Pretoria, Aurora, Colorado (De Sousa, Manchaiah, Swanepoel); Department of Otolaryngology–Head and Neck Surgery, University of Colorado School of Medicine, Aurora (Manchaiah, Swanepoel); UCHealth Hearing and Balance, University of Colorado Hospital, Aurora (Manchaiah); Department of Speech and Hearing, Manipal College of Health Professions, Manipal Academy of Higher Education, Manipal, India (Manchaiah); Communication Sciences Research Center, Cincinnati Children's Hospital Medical Center and University of Cincinnati, Cincinnati, Ohio (Moore); Manchester Centre for Audiology and Deafness, University of Manchester, Manchester, United Kingdom (Moore); Department of Science, Mathematics and Technology Education, University of Pretoria, Pretoria, South Africa (Graham).

Author Contributions: Dr De Sousa had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Concept and design: De Sousa, Manchaiah, Moore, Swanepoel.
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Supervision: Manchaiah, Swanepoel.

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