Comparing Self-Fitting Strategies for Over-the-Counter Hearing Aids: A Crossover Trial

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KEY POINTS

Question

Can self-fitting strategies - self-adjustment and in-situ audiometry - provide similar outcomes for adults with self-perceived mild-to-moderate hearing difficulties using self-fitting OTC (OTC-SF) hearing aids?

Findings

Both strategies produced equivalent overall APHAB benefit, overall IOI-HA satisfaction, speech-in-noise performance and real-ear measurements. However, self-adjustment resulted in meaningfully higher satisfaction and daily use on two IOI-HA subscales, underscoring the benefits of user participation.

Meaning

While OTC-SF hearing aids fitted through self-adjustment and in-situ audiometry both yield similar overall APHAB benefit and overall IOI-HA satisfaction, self-adjustment was found to offer additional user satisfaction and encourage more consistent use.

ABSTRACT

Importance

Less than 20% of US adults with hearing loss use hearing aids due to barriers like high cost. Over-the-counter (OTC) hearing aids offer a potential solution, incorporating self-fitting strategies via smartphone apps. Self-fitting strategies have been validated for FDA-approved OTCs compared to prescription-based approaches. However, no direct comparative analysis

exists between in-situ audiometry and self-adjustment strategies using self-fitting OTC (OTC-SF) hearing aids.

Objective

To compare self-adjustment and in-situ audiometry self-fitting strategies in OTC-SF hearing aids for adults with mild-to-moderate hearing difficulties.

Design Settings and Participants

A cross-over, within-subject pseudo-randomized controlled trial was conducted between July and November 2023. Twenty-eight participants were pseudo-randomly assigned to one of the two self-fitting strategies, and they experienced both interventions for four consecutive weeks.

Interventions

The self-adjustment group manually adjusted settings, including overall gain and spectral tilt, using Lexie B2 hearing aids, while the in-situ audiometry group utilized Lexie B2 Plus hearing aids, with an automated fitting based on in-situ tests conducted through the app.

Main Outcomes and Measures

Primary outcome: Abbreviated Profile of Hearing Aid Benefit (APHAB). Secondary outcomes: International Outcome Inventory for Hearing Aids (IOI-HA), speech-in-noise tests (DIN and QuickSIN), and real-ear measurements (REMs). Measures were completed at baseline and after the four-week field trial using each strategy.

Results

Twenty-eight participants (mean age 60.2 years SD 12) were evenly distributed by sex. Self-adjustment and in-situ audiometry strategies produced no clinically meaningful differences across various outcome measures, including overall APHAB benefit (Cohen *d* = 0.2 [95% CI, -0.2 – 0.6]) and overall IOI-HA satisfaction (Rosenthal's *r* = 0.0 [95% CI, -0.3 – 0.2]). Self-adjustment users reported higher satisfaction (Rosenthal's *r* = -0.4 [95% CI, -0.6 – -0.1]) and longer daily use (Rosenthal's *r* = -0.3 [95% CI,-0.5 – 0.0]) compared to those utilizing in-situ audiometry. No clinically meaningful differences were observed in speech-in-noise benefit and real-ear measurements.

Conclusion and Relevance

For OTC-SF hearing aids, self-adjustment and in-situ audiometry strategies resulted in similar outcomes. However, self-adjustment may produce higher satisfaction and longer daily use, highlighting the potential advantages of active user involvement in the fitting process. Further investigation is needed for long-term outcomes.

Trial registration

ClinicalTrials.gov Identifier: NCT05782153

Status: Complete

INTRODUCTION

Hearing loss is a prevalent health condition affecting millions worldwide, often left untreated.[1] Less than 20% of adults with hearing loss in the United States (US) use hearing aids due to barriers, such as the high cost.[2,3] However, the introduction of over-the-counter hearing aids (OTCs) has expanded service delivery models to improve the accessibility and affordability of hearing healthcare.[4] OTCs enable individuals with self-perceived mild-to-moderate hearing loss (or hearing difficulties) to proactively manage their hearing health without needing medical exams, prescriptions, or audiologist fittings, thus reducing some barriers to hearing aid uptake.[4]

The Food and Drug Administration (FDA) established a regulatory category for OTCs in 2022, including two sub-categories: OTCs with pre-set programs (OTC-PS) and self-fitting OTC (OTC-SF) hearing aids.[4] OTC-PS hearing aids offer standardized output profiles tailored to common hearing loss patterns. OTC-SF hearing aids are self-fit devices, adjustable via smartphone apps to customize parameters like frequency response.[4] One of these strategies is self-adjustment, which allows the user to select signal processing parameters (e.g., gain and compression) without obtaining an audiogram.[5] Another strategy is in-situ audiometry, which involves a hearing test administered through hearing aids with a smartphone app to better match the individual's hearing profile.[6]

The concept of self-fitting hearing aids was introduced over a decade ago[7] and several studies have investigated the effectiveness of self-fitting strategies, such as self-adjustment[5,8,9] and in-situ audiometry.[6,10–12] Recent studies have evaluated OTC-SF hearing aids against audiologist-fit counterparts and found comparable outcomes. For instance, Sabin et al. (2020)

employed a simple self-fitting strategy using a mobile app, where users adjusted signal processing parameters, resulting in improved self-reported sound quality comparable to the audiologist-fit group.[5] An observational study demonstrated positive outcomes for OTC-SF compared to prescription hearing aids.[13] Moreover, De Sousa et al. (2023) utilized an in-situ audiometry fitting strategy and found 6-week outcomes of OTC-SF hearing aids comparable to fitting by an audiologist-fit.[14]

Existing studies have validated OTC-SF hearing aids utilizing different self-fitting strategies against prescription-based approaches. However, a direct comparative analysis between in-situ audiometry and self-adjustment strategies used on OTC-SF hearing aids remains unexplored. Given the proliferation of available self-fitting OTCs, there is a recognized need for research comparing the efficacy of self-fitting strategies.[15] Therefore, this study aims to bridge this gap by directly comparing two self-fitting strategies in OTC-SF hearing aids - self-adjustment and in-situ audiometry - among adults with self-perceived mild-to-moderate hearing difficulties.

METHOD

Study design

A cross-over, within-subject pseudo-randomized controlled trial was conducted between July and November 2023. The Consolidated Standards of Reporting Trials (CONSORT) extension to randomized crossover trials was used in reporting this trial (Figure 1 and eTables 2-3). The trial was registered at ClinicalTrials.gov (NCT05782153), and IRB approval was obtained from the University of Pretoria Humanities Research Ethics Committee (HUM021/1122). Twenty-eight participants were randomly assigned to one of the two self-fitting strategies (self-

adjustment or in-situ audiometry) using Lexie B2 and Lexie B2 Plus Powered by Bose hearing aids. Participants sequentially experienced each intervention for four weeks before transitioning to the other, ensuring a comprehensive comparative analysis for both self-fitting strategies.

Participants

Study participation was advertised on social media platforms, and interested individuals were asked to complete a Google Form to determine their eligibility. We enrolled adult participants (>18 years) who self-reported mild-to-moderate hearing difficulties, had no active ear pathologies, and owned smartphones with data capabilities in line with the use indications for OTC-SF hearing aids. On the Google Form, participants were asked to describe their hearing (without a hearing aid) by selecting one of the following options: 1) my hearing is good, 2) I have little trouble, 3) I have a lot of trouble, or 4) I cannot hear at all. Participants were also asked to rate their hearing difficulties as slight, mild, moderate, or severe. To be included in the study, participants needed to describe their hearing as having little trouble or a lot of trouble and rate their hearing difficulties as mild or moderate. Additionally, participants were required to have a high level of English proficiency, determined through an online test (https://www.efset.org), in order to accurately comprehend and follow instructions for self-fitting the hearing aids and complete the standardized outcome measures.

Initially, 103 individuals applied via the Google Form, and the first 30 who met our eligibility criteria were enrolled. This sample size was comparable to FDA-approved studies of similar devices[4]. Participants were randomly assigned to one of the two self-fitting strategies (self-

adjustment or in-situ audiometry). Randomization was determined utilizing an AI generator (ChatGPT 3.5) and was not concealed since the primary author enrolled participants and assigned interventions accordingly. Due to a technical issue in the manufacturer's research app, the in-situ audiometry self-fitting process defaulted to a preset level rather than individualized thresholds, necessitating the disqualification of the first 9 participants. We addressed potential bias by replacing them with our pool's next 9 eligible candidates. This technical issue resulted in a departure from true randomization, leading to a pseudo-randomized design. In pseudo-randomization, participants are assigned to groups in a manner that aims to mimic randomness but can be influenced by systematic processes like technical challenges. The technical issue with the research app was addressed prior to subsequent data collection. The research app is not used commercially, minimizing the likelihood of such issues in real-life self-fitting scenarios.

Throughout the trial, two participants withdrew, resulting in 28 adults (14 males and 14 females), with a mean age of 60.2 years (SD = 12), who completed the study after providing informed consent. One participant withdrew due to financial difficulties hindering appointment attendance. Another, already a hearing aid user, withdrew as she struggled to adapt to wearing different aids for an extended period (Figure 1).

Data Collection

A qualified audiologist conducted baseline hearing assessments for all participants, which included otoscopic examination, tympanometry, pure-tone audiometry, and unaided speech-in-noise tests, such as Digits-In-Noise (DIN) and Quick Speech-in-Noise (QuickSIN). These tests

were conducted in a soundproof booth. Participants also completed the Abbreviated Profile of Hearing Aid Benefit (APHAB) in unaided conditions.

Subsequently, individual Lexie profiles were established for each participant using their email address and a secure password. Participants were instructed to download the Lexie smartphone app. During the fitting appointment, they received login credentials to connect their hearing aids via the app. The Lexie B2 and Lexie B2 plus hearing aids are FDA-cleared, rechargeable, receiver-in-the-canal OTC-SF hearing aids powered by Bose. Lexie B2 uses a self-adjustment self-fitting strategy (also referred to as a direct adjustment), whereas Lexie B2 Plus uses an in-situ audiometry self-fitting strategy. The participants were given the task of independently fitting their own hearing aids but were given the flexibility to involve a significant other or family member for support if necessary. In case they couldn't complete the process with the provided options, the researcher was available to offer help.

Participants were pseudo-randomly assigned to a self-fitting strategy. Those assigned to the self-adjustment self-fit group received a pair of Lexie B2 hearing aids, which they paired with their smartphones via Bluetooth through the Lexie app. In this approach, participants were required to manually adjust the hearing aids' settings using the Lexie app. The app interface provided a set of intuitive controls conceptualized as 'wheels,' which allowed users to modify key acoustic parameters in increments (eFigure 1), including world volume, i.e. overall gain (or amplification level) and spectral tilt (the balance of bass and treble frequencies), similar to Sabin et al. (2020).[5] The self-adjustment strategy is fully user-driven, obliging the user to decide on the hearing aid settings, guided solely by personal preference and comfort, without any pre-set starting point.

Participants in the in-situ audiometry self-fit group received a pair of Lexie B2 Plus hearing aids, which they connected to their smartphones via the Lexie app. This method utilized an automated fitting protocol based on in-situ hearing threshold assessments conducted through the hearing aids, which automatically recommended specific gain settings across different frequencies. This strategy is designed to provide a tailored fit based on the individual's unique hearing profile. However, after applying the recommended settings based on the in-situ audiometry, participants could still adjust the hearing aids' overall gain (or amplification level) and spectral tilt (the balance of bass and treble frequencies) in the app if they wanted to (eFigure 2).

Once the participants were satisfied with their settings, the audiologist performed real-ear measurements (REMs) and aided speech-in-noise testing (i.e., DIN and QuickSIN). Participants were subsequently encouraged to wear the hearing aids daily for 28 days, ensuring they did so for as much of the day as was comfortable and practical. After the 28-day period, participants returned for follow-up assessments, including the APHAB (with hearing aids), International Outcomes Inventory for Hearing Aids (IOI-HA), REMs, and aided speech-in-noise tests. Subsequently, each participant received the alternative device and fitting strategy. After the second 28-day period, the same outcome measures were re-evaluated. The primary outcome measure was the APHAB. The benefit was calculated by subtracting the aided score from the unaided score, where a higher score indicates a greater benefit. Secondary measures included the IOI-HA, speech-in-noise tests, and REMs.

Data Analysis

Data were analyzed using IBM Corporation's SPSS Statistics version 29.0 software. We used paired samples t-tests for normally distributed continuous variables and Wilcoxon signed-rank tests for non-normally distributed or ordinal variables to assess differences between self-fitting strategies within subjects. We identified significant differences with clinical relevance by examining effect size and 95% confidence intervals. Cohen's *d* was utilized for *t*-test findings with interpretation categorized 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 ($d \geq 0.8$)[16]. For the Wilcoxon signed rank test, Rosenthal's *r* was calculated as $z/\sqrt{N}$, and its interpretation included small ($r \leq 0.1$), small to medium ($0.1 < r < 0.30$), medium ($r = 0.3$), medium to large ($0.3 < r < 0.5$), and large ($r \geq 0.5$)[16]. The effect sizes would be considered clinically meaningful if they were medium or larger.

RESULTS

Baseline Assessments

The study included 28 participants (Table 1) with equal sex distribution and an average age of 60.2 years (SD 12). Half of the participants (n = 14) self-reported having a little hearing trouble, while the other half (n = 14) reported having a lot of trouble. Twenty-five percent of the participants (n = 7) reported mild hearing difficulties, while 75% (n = 21) reported moderate hearing difficulties. The mean four-frequency pure-tone average (PTA) was 32.4 (SD 14.9) and 36.8 (SD 16.3) for the left and right ears, respectively (eFigure 3). Participants had an average unaided DIN score of -8.2 (SD 1.8) and a QuickSIN score of 7.0 (SD 4.8).

Abbreviated Profile of Hearing Aid Benefit

No clinically meaningful differences were found between self-adjustment and in-situ self-fitting strategies within subjects for any APHAB subscales (EC: Rosenthal's *r* = -0.1; 95% CI, -0.4 – 0.1)(BN: Cohen *d* = -0.1; 95% CI, -0.5 – 0.2)(RV: Cohen *d* = -0.3; 95% CI, -0.6 – 0.1)(AV: Rosenthal's *r* = -0.2; 95% CI, -0.5 – 0.0) or global scores (Cohen *d* = -0.2, 95% CI, -0.6 – 0.2) after the 4-week field trial. Overall APHAB benefit from baseline did not differ meaningfully between the two self-fitting methods (EC: Rosenthal's *r* = -0.1, 95% CI, -0.4 – 0.1)(BN: Cohen *d* = 0.1, 95% CI, -0.2 – 0.5)(RV: Cohen *d* = 0.3, 95% CI, -0.1 – 0.6)(AV: Rosenthal's *r* = -0.2, 95% CI, -0.5 – 0.0)(Global: Cohen *d* = 0.2, 95% CI, -0.2 – 0.6)(Table 2 and Figure 2).

International Outcome Inventory for Hearing Aids

There was no clinically meaningful difference between the two self-fitting strategies (Rosenthal's *r* = 0.0; 95% CI,-0.3 – 0.2) for IOI-HA total scores. However, the self-adjustment self-fitting method demonstrated meaningfully longer daily use (Rosenthal's *r* = -0.3; 95% CI, -0.5 – 0.0) and higher satisfaction (Rosenthal's *r* = - 0.4; 95% CI, -0.6 – -0.1) compared to the in-situ audiometry self-fitting strategy. No meaningful differences were found for the other subscales (eFigure 4). See Table 3 and Figure 2.

Speech-In-Noise Tests

Benefit, calculated as the difference in aided from unaided scores, showed no clinically meaningful differences between self-fitting strategies in either the DIN (Cohen *d* = 0.0 [95% CI, -0.4 – 0.4]) or QuickSIN (Cohen *d* = -0.1 [95% CI, -0.4 – 0.3]) immediately post-fitting. Benefit scores after four weeks of hearing aid use also showed no clinically meaningful

differences between self-fitting strategies in DIN (Cohen *d* = 0.2 [95% CI, -0.1 – 0.6]) or QuickSIN scores (Rosenthal's *r* = -0.1 [95% CI, -0.3 – 0.2]). See Figure 2 and eTable 1.

Real-ear Measurements

For both self-fitting strategies, the average difference in output between 125-8000 Hz was within 5dB of the NAL-NL2 targets for average (65 dB SPL) and loud speech (75 dB SPL) immediately after fitting and following four weeks of using the hearing aids. The average differences for soft speech (55 dB SPL) between 125-8000 Hz slightly exceeded 5 dB (after fitting: in-situ audiometry 5.9 dB 4.4 SD, self-adjustment 6.6 dB 5.8 SD; after trial: in-situ audiometry 6.8 dB 5.7 SD, self-adjustment 6.8 dB 6.0 SD). No clinically meaningful differences were observed between average speech (65 dB SPL) immediately post-fitting (Cohen *d* = -0.2 [95% CI, -0.6 – 0.2]) or after the field trial (Cohen *d* = -0.1 [95% CI, -0.4 – 0.3]) as illustrated in Figure 3. Similar findings were observed for soft speech (55 dB SPL) immediately post-fitting (Cohen *d* = -0.2 [95% CI, -0.5 – 0.1]) and after the field trial (Cohen *d* = -0.0 [95% CI, -0.3 – 0.3]) as well as for loud speech (75 dB SPL) immediately post-fitting (Cohen *d* = -0.1 [95% CI, -0.4 – 0.1]) and after the field trial (Cohen *d* = -0.1 [95% CI, -0.3 – 0.2]). See eFigures 5 and 6.

Adjustments After In-Situ Self-Fitting Field Trial

During the field trial of the in-situ fitting process with recommended settings, participants made various adjustments to their hearing aid settings. Out of the 28 participants, 28.6% (n = 8) maintained their original world volume settings (i.e., overall gain across the frequencies), while 35.7% (n = 10) opted to increase the world volume with an average increase of 11.1 (9.7 SD) increments. However, 35.7% (n = 10) of participants decreased the world volume by an average of 8.2 (3.0 SD) increments. Moreover, 35.7% (n = 10) of participants did not alter the

spectral tilt settings. Among participants who made adjustments to the spectral tilt settings, 21.4% (n = 6) of participants opted for enhancing the treble, with an average adjustment of 11.7 (9.8 SD) increments. Conversely, 42.9% (n = 12) of participants preferred a shift towards lower bass, with an average change of 9.8 (8.0 SD) increments.

DISCUSSION

This cross-over trial directly compared two self-fitting strategies, self-adjustment and in-situ audiometry. Both methods showed no clinically meaningful differences in APHAB benefit, overall IOI-HA satisfaction, speech-in-noise performance, and real-ear measurements.

Although APHAB benefit and overall IOI-HA satisfaction were similar between self-fitting strategies, self-adjustment participants reported meaningfully higher satisfaction and longer daily use on two IOI-HA subsections. This could be due to greater control and customization with self-adjustment, allowing users to tailor hearing aid settings to their preferences without a predefined fitting based on an in-situ hearing test, potentially leading to a more comfortable perceived listening experience. However, the confidence intervals' lower bound suggests that in the broader population, these effects might not be as meaningful or may not even exist. Nonetheless, this aligns with previous research demonstrating users' preference for self-selected settings.[5,18]

Participants' adjustments during the in-situ self-fitting field trial highlight the importance of providing users with the flexibility to customize settings based on their unique needs. It is crucial to consider the diverse needs of different consumer groups, as specific self-fitting strategies may be more suitable for certain individuals.[7,18] For instance, some may prefer self-

adjustment strategies if they are comfortable with technology and desire complete control over the fitting process. However, those who are less familiar with technology or require guidance may benefit more from in-situ audiometry fitting strategies, which provide a structured approach and assist users in obtaining initial fitting parameters. In some instances, employing a combined approach could be beneficial, as it offers a comprehensive solution that addresses diverse needs and preferences.

Consistent with prior research, our study showed that self-fit users prefer a "comfort fit," which may result in higher frequency amplification levels slightly below the NAL-NL2 targets.[5,14,18] User preferences may lead to self-reported benefits but may not always result in optimal real-world performance. When evaluating hearing aid fitting strategies, it is important to distinguish between subjective user preferences and objective behavioral measures. While user satisfaction is valuable, it should be balanced with the need to ensure hearing aid settings are optimal for real-world performance, as determined by objective assessments.

The absence of clinically meaningful differences in speech-in-noise scores between self-fitting strategies for both DIN and QuickSIN tests suggests that individuals can achieve comparable speech perception in noise regardless of the self-fitting method. However, there are minimal benefits when it comes to adaptive speech-in-noise testing (eTable 1).[5,14] Speech-in-noise test performance in a lab setting may not accurately reflect real-world scenarios where speech is heard in a noisy environment. This could be due to several factors, such as the nature of the noise and speech stimuli used in tests like DIN and QuickSIN, which may not completely replicate the complexity of real-life environments, such as a restaurant with ambient noise.

Future studies should consider using fixed speech-in-noise testing instead of only adaptive speech-in-noise testing to ensure standardized and comparable assessments of speech perception benefits.

Our findings support the effectiveness of self-fitting strategies for OTC-SF hearing aids, aligning with previous studies.[5,14,17] However, our study has some limitations. The need to replace participants due to a technical issue with the research app compromised the randomization process, leading to a pseudo-randomized controlled trial. We did not include a washout period, which could have further strengthened the study's internal validity. Our sample size also limited our ability to conduct robust statistical analyses investigating correlations between outcomes and demographic variables. Additionally, the study's design limited our ability to assess the long-term outcomes of the different self-fitting strategies.

CONCLUSION

Our study is the first to show that for OTC-SF hearing aids, self-adjustment and in-situ audiometry fitting strategies both lead to positive outcomes in overall APHAB benefit, overall IOI-HA satisfaction, speech-in-noise performance, and real-ear measurements. Self-adjustment may meaningfully improve hearing aid satisfaction and daily use on two IOI-HA subscales, underscoring the value of user engagement in self-fitting. Further studies with extended follow-up and larger sample sizes are needed to assess the long-term effectiveness of these approaches individually and in combination, as well as to investigate correlations between outcomes, degree of hearing loss, age, and other relevant variables.

CONFLICT OF INTEREST DISCLOSURE

Drs. Swanepoel and Moore have a relationship with the hearX Group (Pty) Ltd that includes equity, consulting and potential royalties. Dr. De Sousa has a relationship with the hearX Group (Pty) Ltd, which includes consulting. Dr. Manchaiah has a relationship with the hearX Group (Pty) Ltd and serves as a scientific advisor. Ms Knoetze has no conflict of interest.

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ROLE OF FUNDER/SPONSOR

The funder provided the Lexie B2 and B2 plus devices and software support to complete data collection. Otherwise, the funder had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

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Ms Knoetze had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Dr Moore receives support from the NIHR Manchester Biomedical Research Centre.

DATA SHARING STATEMENT

Data will not be shared.

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Table 1. Participant Characteristics (n = 28)

Sex (n; %)	
Male	14 (50%)
Female	14 (50%)
Age	
Mean years (SD)	60.2 years (SD 12)
Self-perceived hearing difficulty (n; %)	
I have a little trouble	14 (50%)
I have a lot of trouble	14 (50%)
Self-perceived degree of hearing loss (n; %)	
Mild	7 (25%)
Moderate	21 (75%)
Mean PTA for 0.5, 1, 2, 4 kHz (SD)	
Left	32.4 (14.9)
Right	36.8 (16.3)
Unaided DIN score	-8.2 (SD 1.8)
Unaided QuickSIN	7.0 (SD 4.8)

Abbreviation: PTA, Pure-tone Average; DIN, Digits-in-Noise; QuickSIN, Quick Speech-in-Noise

Table 2. APHAB Scores for the Unaided Baseline, Post 4-week Trial and Benefit for the Self-Adjustment and In-situ Audiometry Self-fitting Strategies (n = 28)

APHAB subscale	Unaided baseline[a]	SA self-fitting[a] (post 4-wk trial)	IA self-fitting[a] (post 4-wk trial)	Effect size[c] (95% CI)	SA benefit[b] (unaided – aided)	IA benefit[b] (unaided – aided)	Effect size[c] (95% CI)
	Median (Min – Max)	Median (Min – Max)	Median (Min – Max)		Median (Min – Max)	Median (Min – Max)	
EC	29.0 (5.0 – 97.0)	11.5 (1.0 – 71.0)	11.0 (1.0 – 96.0)	Rosenthal's *r* = -0.1 (-0.4 – 0.1)	15.5 (-21.0 – 86.0)	15.0 (-19.0 – 85.0)	Rosenthal's *r* = -0.1 (-0.4 – 0.1)
BN	60.0 (11.0 – 95.0)	26.0 (5.0 – 81.0)	26.0 (1.0 – 64.0)	Cohen *d* =- 0.1 (-0.5 – 0.2)	28.5 (-20.0 – 69.0)	32.0 (-10.0 – 67.0)	Cohen *d* = 0.1 (-0.2 – 0.5)
RV	46.0 (10.0 – 83.0)	23.0 (5.0 – 56.0)	19.0 (1.0 – 52.0)	Cohen *d* = -0.3 (-0.6 – 0.1)	19.0 (-7.0 – 62.0)	22.5 (-21.0 – 60.0)	Cohen *d* = 0.3 (-0.1 – 0.6)
AV	28.0 (1.0 – 91.0)	40.0 (5.0 – 95.0)	40.0 (3.0 – 91.0)	Rosenthal's *r* = -0.2 (-0.5 – 0.0)[e]	-12.0 (-82.0 – 33.0)	-2.0 (-86.0 – 52.0)	Rosenthal's *r* = -0.2 (-0.5 – 0.0)[e]
Global[d]	45.5 (13.0 – 92.0)	20.0 (7.0 – 60.0)	19.5 (1.0 – 54.0)	Cohen *d* = -0.2 (-0.6 – 0.2)	22.0 (-14.0 – 71.0)	22.5 (-4.0 – 65.0)	Cohen *d* = 0.2 (-0.2 – 0.6)

Abbreviation: APHAB, Abbreviated Profile of Hearing Aid Benefit; EC, Ease of communication; BN, Background Noise; RV, Reverberation; AV, Aversion; SA, Self-adjustment; IA, In-situ-Audiometry

[a] A lower score indicates less communication difficulty and a higher score indicates greater communication difficulty.

[b] When calculating benefit (unaided-aided), a higher score indicates a higher degree of benefit.

[c] Effect size for normally distributed variables was calculated using Cohen's *d* and Rosenthal's *r* = z/N for nonnormal distribution.

[d] The mean score for all subscales, excluding aversiveness.

[e] The upper limit of the 95% CI is reported as 0.0 owing to rounding but is slightly greater than zero.

Table 3. IOI-HA Scores after Self-adjustment and In-situ Audiometry Self-fitting (n = 28)

IOI-HA subscale	SA self-fitting[a] (post 4-wk field trial)	IA self-fitting[a] (post 4-wk field trial)	Rosenthal's *r* (95% CI)[b]
	Median (Min – Max)	Median (Min – Max)	
Use	4.0 (3.0 – 5.0)	4.0 (2.0 – 5.0)	-0.3 (-0.5 – 0.0)[c,e]
Benefit	4.0 (3.0 – 5.0)	4.0 (3.0 – 5.0)	-0.1 (-0.3 – 0.1)
Residual activity limitation	4.0 (3.0 – 5.0)	4.0 (3.0 – 5.0)	-0.2 (-0.4 – 0.1)
Satisfaction	5.0 (3.0 – 5.0)	4.0 (2.0 – 5.0)	-0.4 (-0.6 - -0.1)[e]
Residual participation restriction	4.0 (1.0 – 5.0)	4.0 (2.0 – 5.0)	-0.1 (-0.4 – 0.1)
Impact on others	5.0 (2.0 – 5.0)	5.0 (3.0 – 5.0)	-0.2 (-0.4 – 0.1)
Quality of life	4.0 (3.0 – 5.0)	4.0 (2.0 – 5.0)	-0.1 (-0.3 – 0.2)
Total[d]	29.0 (25.0 – 33.0)	29.0 (23.0 – 34.0)	0.0 (-0.3 – 0.2)

Abbreviation: IOI-HA, International Outcomes Inventory for Hearing Aids; SA, Self-adjustment; IA, In-situ-Audiometry

[a] Benefit is rated using 5 ordinal response categories with a lower score indicating poorer outcomes and a higher score indicating better outcomes.

[b] Effect size Rosenthal's $r = z/\sqrt{N}$.

[c] The upper limit of the 95% CI is reported as 0.0 owing to rounding but is slightly greater than zero.

[d] Calculated as the sum of all 7 IOI-HA items.

[e] Clinically meaningful effect size; $r \geq 0.3$

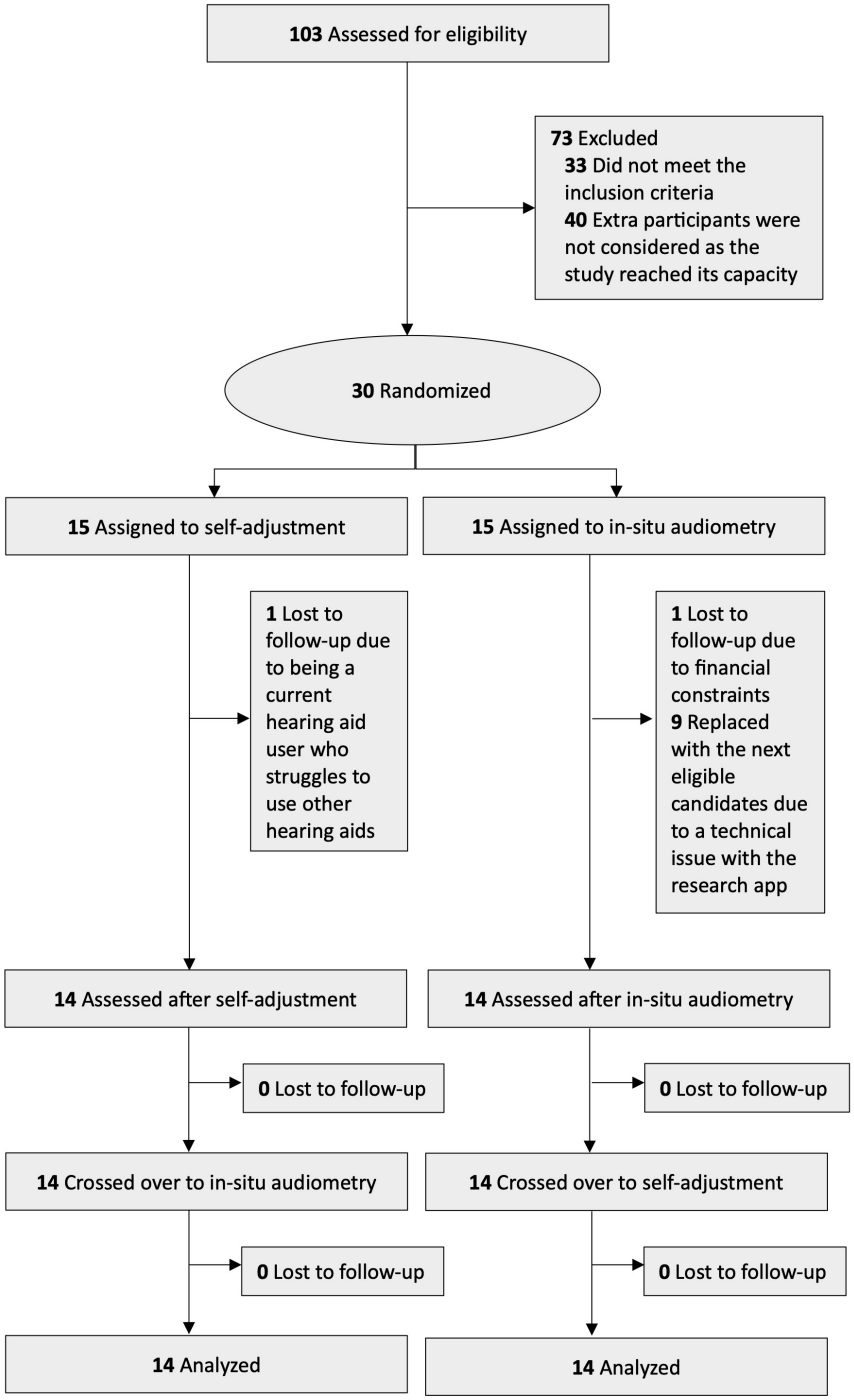

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) flow diagram

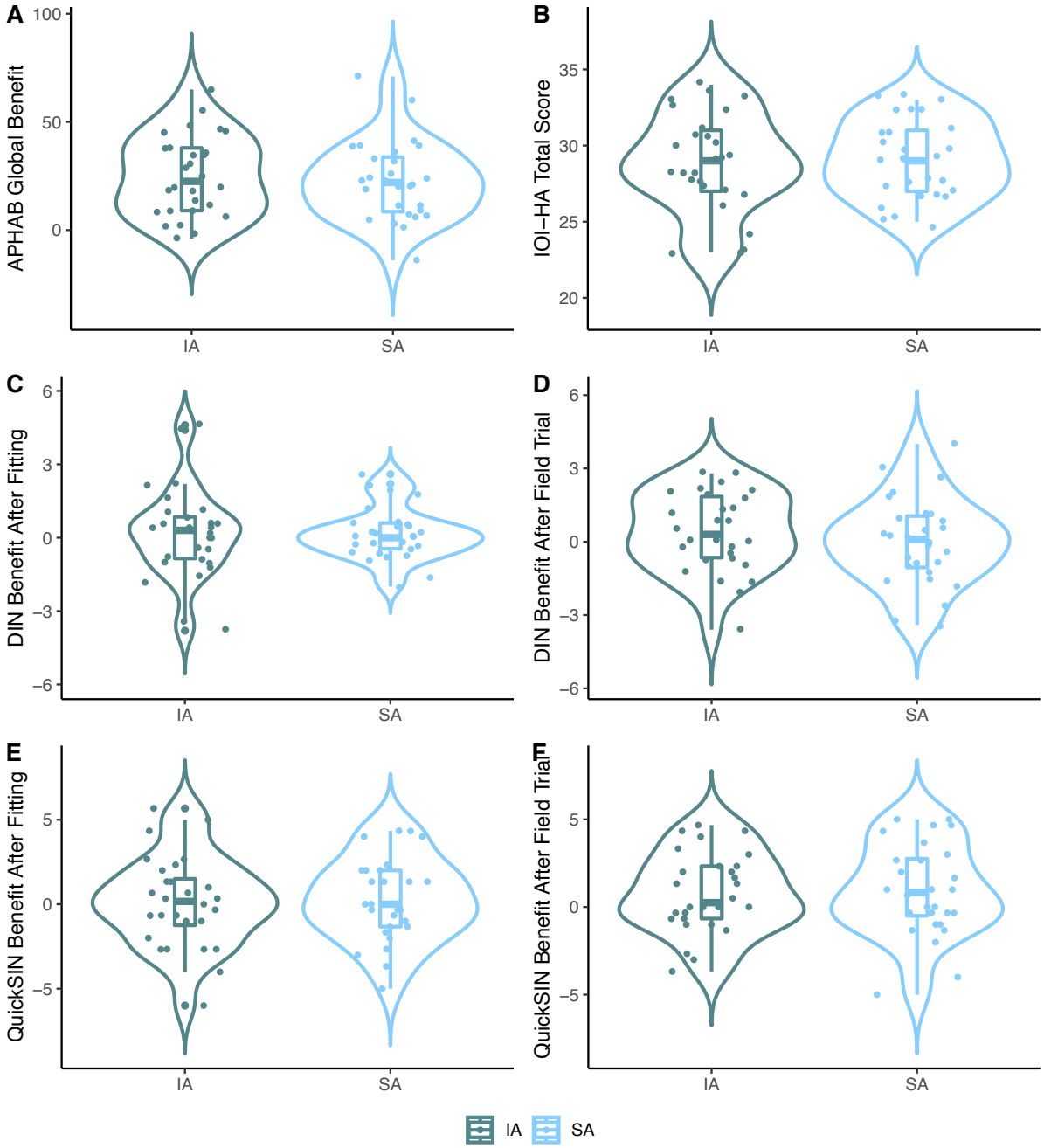

Figure 2. Outcome measures across the trial for the in-situ audiometry (IA) self-fitting and self-adjustment (SA) self-fitting. (A) Abbreviated Profile of Hearing Aid Benefit (APHAB) benefit scores ranging from 1% to 99%, with higher scores indicating better outcomes, (B) International Outcome Inventory for Hearing Aids (IOI-HA) total scores ranging from 1 to 35, with higher scores indicating better outcomes, (C) Digits-in-noise (DIN) benefit scores after fitting ranging from −22.5 to 22.5, with higher scores indicating better outcomes, (D) Digits-in-noise (DIN) benefit scores after field trial ranging from −22.5 to 22.5, with higher scores indicating better outcomes, (E) QuickSIN benefit scores after fitting ranging from −25.5 to 25.5, with higher scores indicating better outcomes, (F) QuickSIN benefit scores after field trial ranging from −25.5 to 25.5, with higher scores indicating better outcomes. Violin plots indicate kernel probability density. Boxes are IQR with median, and whiskers are 1.5 times the IQR.

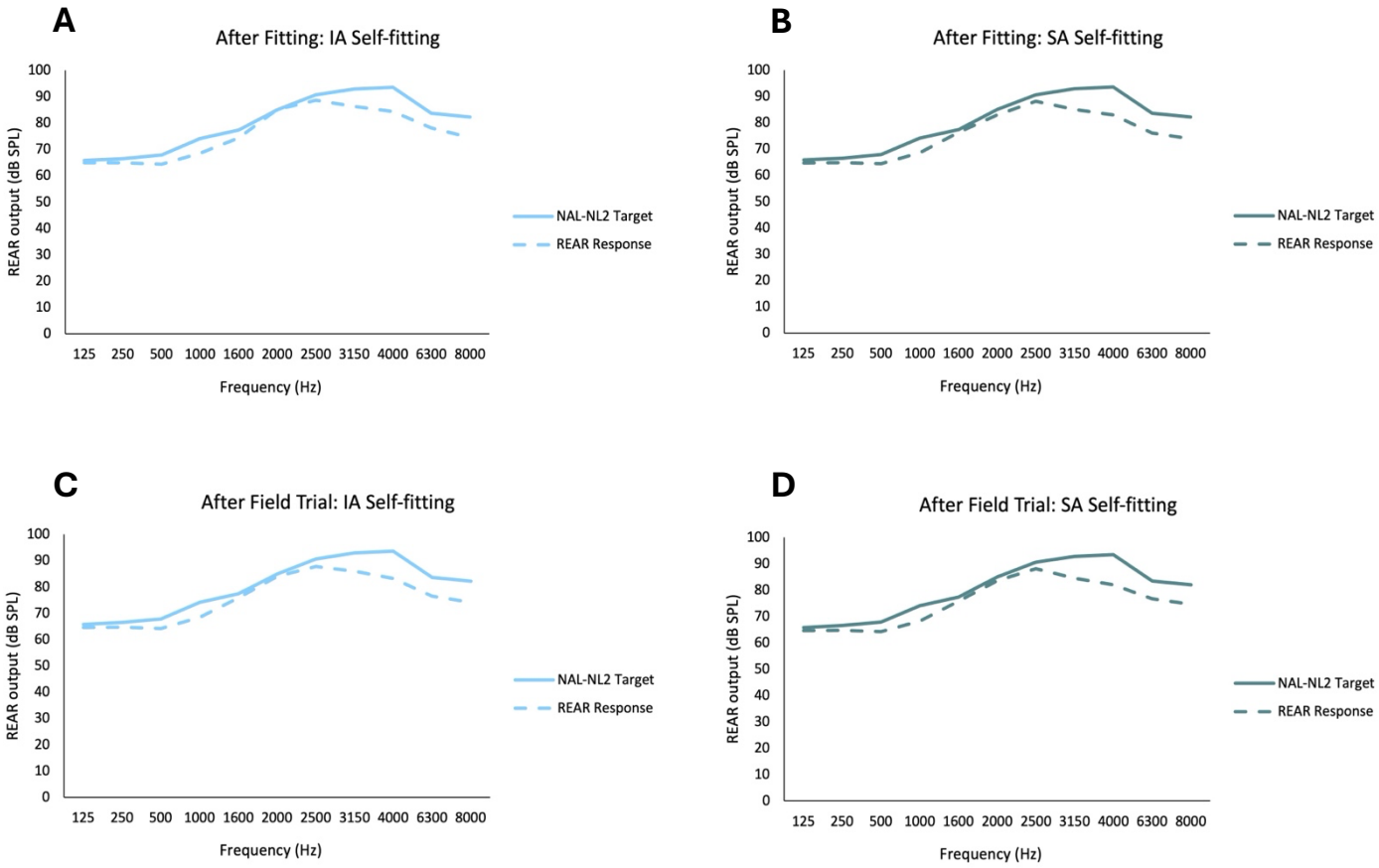

Figure 3. (A) Comparison of NAL-NL2 target and real ear output in dB SPL for the in-situ audiometry self-fitting strategy immediately after fitting, (B) Comparison of NAL-NL2 target and real ear output in dB SPL for the self-adjustment self-fitting strategy immediately after fitting, (C) Comparison of NAL-NL2 target and real ear output in dB SPL for the in-situ audiometry self-fitting strategy after field trial, (D) Comparison of NAL-NL2 target and real ear output in dB SPL for the self-adjustment self-fitting strategy after field trial. The stimulus was a 65 dB SPL International Speech Test Signal.