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HEARING HELP-SEEKING, HEARING AID UPTAKE AND OUTCOMES IN ADULTS: BARRIERS, ENABLERS AND OVER-THE-COUNTER HEARING AIDS

by

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A thesis submitted in partial fulfillment of the requirements for the degree

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Romans 11:36

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PLAGIARISM DECLARATION

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I declare that this thesis is my own original work. Where secondary material is used, it has been carefully acknowledged and referenced in accordance with the university requirements.

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05 August 2024

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ETHICS STATEMENT

The author, whose name appears on the title page of this thesis, has obtained, for the research described in this work, the applicable research ethics approval.

The author declares that she has observed the ethical standards required in terms of the University of Pretoria's Code of Ethics for Researchers and the Policy Guidelines for Responsible Research.

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ABSTRACT

Title: Hearing Help-Seeking, Hearing Aid Uptake and Outcomes in Adults: Barriers, Enablers and Over-the-Counter Hearing Aids

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Hearing loss is a growing global health concern, with its prevalence increasing worldwide. In adults, unaddressed hearing loss can lead to various negative consequences, including reduced quality of life, cognitive decline, and economic disadvantages. Timely intervention with hearing aids can mitigate these consequences. However, despite their availability and effectiveness, help-seeking behaviors and hearing aid uptake have been notably low. In the past decade, significant efforts have been made to improve access to hearing healthcare, including establishing various types of direct-to-consumer (DTC) hearing devices, such as over-the-counter (OTC) hearing aids in the United States. Despite these advancements, the number of people seeking help for hearing difficulties and hearing aid uptake remains low. This may be due to various audiological and non-audiological factors that hinder or facilitate help-seeking behavior and the uptake of hearing aids. This project, therefore, explored factors influencing help-seeking behavior for hearing difficulties and the uptake of hearing aids, in addition to evaluating self-fitting OTC (OTC-SF) hearing aids for usability and effectiveness.

Study I analyzed factors influencing hearing help-seeking and hearing aid uptake in adults with hearing loss through a literature review. Using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, 42 articles from January 2011 to February 2022 were reviewed. Factors included 70 audiological and 28 non-audiological for help-seeking and 159 audiological and 66 non-audiological for hearing aid uptake. Hearing aid uptake had strong predictors, such as hearing sensitivity, while others showed conflicting results, such as self-reported health. Hearing help-seeking had clear non-predictive factors,

such as education, and conflicting factors, such as self-reported health. New factors included cognitive anxiety associated with increased help-seeking and hearing aid uptake and urban residency and access to financial support with hearing aid uptake. Most studies were rated low evidence (67%) and fair quality (86%). The findings suggest further research to understand conflicting factors and factors with limited evidence to effectively promote help-seeking and hearing aid uptake among adults with hearing loss.

Study II explored the main reasons for hearing aid uptake from a user perspective and provided recommendations for others with hearing difficulties. A cross-sectional survey gathered responses to an open-ended question, which were analyzed using qualitative content analysis. The study sampled 642 adult hearing aid users from the Hearing Tracker website and Lexie Hearing databases in the US. Participants cited reasons for hearing aid uptake in three domains: (a) personal impact, (b) social difficulties, and (c) auditory difficulties, encompassing 11 main categories and 48 sub-categories. Recommendations for others included eight main categories, such as timely help and affordability, with 32 sub-categories. The decision to take up hearing aids was influenced by intrinsic factors such as readiness to change and extrinsic factors such as financial availability. The most frequent recommendation was not to delay seeking hearing help. These findings may inform strategies to improve hearing aid adoption.

Study III explored user perspectives on the relationship between hearing aid cost and uptake, along with cost-related recommendations for others with hearing difficulties, among prescription and OTC hearing aid users. A secondary analysis of a cross-sectional survey to an open-ended question were analyzed using the qualitative content analysis. Study participants included 241 adults, 179 prescription hearing aid users from the Hearing Tracker website and 62 OTC users from the Lexie Hearing United States database. Three domains were identified: (a) perceived enablers to hearing aid uptake related to cost, (b) perceived barriers, and (c) cost-related recommendations. Both groups cited high costs and lack of insurance coverage as major barriers. Prescription users noted external financial support as an enabler, while OTC users emphasized the affordability of OTC devices. Prescription users recommended seeking professional support, whereas OTC users advised researching hearing aids before purchasing. The study concludes that cost and insurance coverage are primary barriers to hearing aid adoption, suggesting that initiatives should address these financial challenges to enhance accessibility. Further research is needed on the relationship between cost and uptake, particularly for OTC users and those requiring financial assistance.

Study IV compares the usability and performance of six OTC-SF hearing aids for individuals with mild-to-moderate hearing loss. In a cross-sectional study, 43 adults were pseudo-randomly assigned to self-fit two of the six devices using manufacturer instructions and smartphone apps. Usability was assessed through fitting time, Hearing Aid Skills and Knowledge (HASK) scores, ease of the self-fitting process, and the Post-Study System Usability Questionnaire (PSSUQ). Performance was evaluated using the Judgement of Sound Quality (JSQ) test, and speech-in-noise benefit was assessed through the Digits-In-Noise (DIN) and Quick Speech in Noise (QuickSIN) tests. Results showed fitting times ranged from 14.4 minutes (HP Hearing PRO) to 27.1 minutes (Lexie Lumen), with varied HASK scores, the highest being Soundwave Sontro (8.9/10) and the lowest HP Hearing PRO (6.8/10). While self-fitting ease and PSSUQ scores were similar across devices, sound quality ratings varied, with Lexie B2 scoring highest and HP Hearing PRO lowest. Speech-in-noise benefit did not significantly differ. Participants generally found the devices user-friendly, though issues with Bluetooth connectivity, handling, insertion, and sound quality were noted. These findings can aid consumers and healthcare professionals in choosing OTC-SF hearing aids, highlighting the need for further research on long-term usability and selection processes.

Study V compared in-situ audiometry and self-adjustment strategies for OTC-SF hearing aids in adults with mild-to-moderate hearing difficulties. Conducted as a cross-over, within-participant pseudo-randomized controlled trial, it involved 28 participants (mean age 60.2 years). Participants used both strategies for four weeks: self-adjustment with Lexie B2 hearing aids and in-situ audiometry with Lexie B2 Plus hearing aids. The primary outcome was the Abbreviated Profile of Hearing Aid Benefit (APHAB), with secondary outcomes including the International Outcome Inventory for Hearing Aids (IOI-HA), speech-in-noise tests (DIN and QuickSIN), and real-ear measurements (REMs). Results showed no clinically meaningful differences in APHAB benefit or overall IOI-HA satisfaction. However, self-adjustment users reported higher satisfaction and longer daily use. Both strategies produced similar results in speech-in-noise benefit and REMs. The findings suggest that self-adjustment may offer higher user satisfaction and engagement, indicating the potential benefits of active user involvement in the fitting process. Further research is needed to assess long-term outcomes.

From these studies, it is evident that numerous factors, both audiological and non-audiological, influence the help-seeking behavior and uptake of hearing aids among adults with hearing loss. While advancements such as OTC hearing aids have improved accessibility, significant barriers, especially financial constraints, impede widespread adoption. The user perspectives highlighted in these studies underscore the importance of timely intervention, affordability, and the effectiveness of both self-adjustment and professional support in promoting hearing aid uptake. Continued research is essential to address these barriers and optimize strategies for enhancing hearing healthcare accessibility and user satisfaction.

KEYWORDS

Hearing help-seeking

Hearing aid uptake

Hearing aid adoption

Hearing aids

Over-the-counter (OTC) hearing aids

Direct-to-consumer (DTC) hearing devices

Usability

Performance

Self-fitting strategies

ABBREVIATIONS

AIADH: Amsterdam Inventory for Auditory Disability and Handicap

APHAB: Abbreviated Profile of Hearing Aid Benefit

APP: Application

BTE: Behind-The-Ear

CPHI: Communication Profile for the Hearing Impaired

CONSORT: Consolidated Standards of Reporting Trials

DIN: Digits-In-Noise

DTC: Direct-To-Consumer

ECHO: Expected Consequences of Hearing Aid Ownership

EF SET: EF Standard English Test

FDA: Food and Drug Administration

HA: Hearing Aid

HASK: Hearing Aid Skills and Knowledge

HBM: Health Belief Model

HBQ: Health Belief Questionnaire

HHI: Hearing Handicap Inventory

IA: In-situ Audiometry

INFOQUAL = Information quality

INTERQUAL = Interface quality

IOI-HA: International Outcome Inventory for Hearing Aids

IQR: Interquartile Range

ITE: In-The-Ear

JSQ: Judgment of Sound Quality

NAL-NL2: National Acoustic Laboratories' Non-Linear fitting procedure version 2

NIH: National Institute of Health

OCEBM: Oxford Centre for Evidence-Based Medicine

OTC: Over-The-Counter

OTC-SF: Self-Fitting Over-The-Counter

OTC-PS: Pre-set Over-The-Counter

PICOST: Population Intervention Comparison Outcome Study Design Timeline

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

PROSPERO: International Prospective Register of Systematic Reviews

PSAP: Personal Sound Amplification Products

PSSUQ: Post-Study System Usability Questionnaire

PTA: Pure Tone Average

QuickSIN: Quick Speech in Noise

REM: Real-Ear Measurement

SA: Self-Adjustment

SD: Standard Deviation

SF: Self-Fitting

SPSS: Statistical Package for the Social Sciences

SRT: Speech Recognition Thresholds

SWiM: Synthesis Without Meta-Analysis

SYSUSE: System usefulness

TPB: Theory of Planned Behavior

US: United States

WHO: World Health Organization

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CHAPTER 1

INTRODUCTION

1.1 Background

Hearing loss is a growing global health concern, with its prevalence increasing worldwide (World Health Organization, 2021). Currently, over 1.5 billion people are affected by some degree of hearing loss, with at least 430 million experiencing disabling hearing loss that necessitates rehabilitation (World Health Organization, 2021). Projections estimate that by 2050, over 700 million people will suffer from disabling hearing loss (World Health Organization, 2021). Unaddressed hearing loss can lead to various negative consequences, including social isolation, loneliness, depression, and reduced quality of life (Deal et al., 2019; Golub et al., 2019; Huddle et al., 2017; Nordvik et al., 2018; Olusanya et al., 2014; Shukla et al., 2020). Additionally, it increases the risk of cognitive decline (Livingston et al., 2020). The Lancet Commission on Dementia Prevention, Intervention, and Care identified unaddressed hearing loss as one of the top modifiable risk factors for dementia (Livingston et al., 2020).

Beyond health impacts, adults with hearing loss often face economic disadvantages, including higher unemployment rates and lower income levels (Emmett & Francis, 2015; Jung & Bhattacharyya, 2012). The global economic burden of unaddressed hearing loss exceeds $980 billion annually, encompassing healthcare costs, societal expenses, educational support, and lost productivity (World Health Organization, 2021). Prompt and appropriate interventions can significantly mitigate or even avoid these negative consequences (World Health Organization, 2021).

Hearing aids are the most common form of rehabilitation for individuals with hearing loss (Brodie et al., 2018). Timely intervention with hearing aids can improve communication, cognition, and health-related quality of life (Chisolm et al., 2007; Ferguson et al., 2017; Livingston et al., 2020). However, despite their availability and effectiveness, help-seeking behaviors and hearing aid uptake remain notably low (Orji et al., 2020). On average, people wait nine years before seeking help for their hearing difficulties (Simpson et al., 2019).In a study conducted in the United States, only 20% of adults with hearing complaints reported seeing a physician for their hearing problems in the last five years (Mahboubi et al., 2018). Similarly, low levels of hearing help-seeking have been reported in studies from other countries, particularly in low- and middle-income countries (Mukari & Wan Hashim, 2018; Schönborn et al., 2020). Globally, the uptake of hearing aids remains low, with less than 11% of individuals with disabling hearing loss acquiring hearing aids (Bisgaard et al., 2021). Longitudinal population-based studies revealed that the 5- and 10-year incidence rates of hearing aid adoption are approximately 8.5% and 36%, respectively (Fischer et al., 2011; Gopinath et al., 2011). These low adoption rates may be attributed to limited access to hearing healthcare services and the high cost of hearing devices.

In the past decade, significant advancements have been made toward improving access to hearing healthcare (Blazer et al., 2016). These advancements include the development of mobile health applications (apps) for promoting, screening, diagnosing, treating, and supporting individuals with hearing loss (Frisby et al., 2021). Additionally, tele-audiology services have become more widespread, offering home-based otoscopy, online hearing screenings, and remote hearing aid fittings (D'Onofrio & Zeng, 2022). Computational audiology has also emerged, utilizing algorithms and data-driven modeling techniques for advanced clinical applications (Wasmann et al., 2021).Furthermore, technological innovations in hearing aids have led to more affordable and accessible direct-to-consumer (DTC) hearing device options such as hearables, personal sound amplification products (PSAPs), and over-the-counter (OTC) hearing aids (Manchaiah et al., 2017).

A landmark development in this context is the establishment of the OTC hearing aid category by the U.S. Food and Drug Administration (FDA). This regulatory change allows adults with perceived mild-to-moderate hearing loss to purchase OTC hearing aids online or from stores without requiring a hearing assessment, prescription, or fitting adjustment by a licensed hearing healthcare professional (Food and Drug Administration, 2022). Despite these advancements, the number of people seeking help for hearing difficulties and hearing aid uptake remains low. This may be due to various audiological and non-audiological factors that either hinder or facilitate help-seeking behavior and the uptake of hearing aids.

1.2 Barriers and enablers to hearing help-seeking and hearing aid uptake

In exploring barriers and enablers to hearing help-seeking and hearing aid uptake, various reviews have shed light on multifaceted factors (Jenstad & Moon, 2011; Knudsen et al., 2010; Meyer & Hickson, 2012; Ng & Loke, 2015). A comprehensive review by Knudsen et al. (2010) identified 31 factors influencing hearing help-seeking, hearing aid uptake, use, and satisfaction, categorized into personal, demographic, and external factors. The findings highlighted that motivation by others to seek help for hearing loss had a positive association with help-seeking, while self-motivation did not show the same effect. Additionally, positive attitudes towards hearing aids were linked to higher uptake rates. Greater acceptance of hearing loss and poorer hearing sensitivity were also positively associated with both help-seeking and hearing aid uptake. Interestingly, age and gender did not correlate with any of the outcomes, but self-reported hearing disability positively influenced all four outcomes. The most recent review by Meyer and Hickson (2012) explored factors influencing both hearing help-seeking and hearing aid uptake. They concluded that individuals are more likely to seek help for their hearing problems and/or adopt hearing aids if they have moderate to severe hearing loss, self-reported hearing-related activity limitations or participation restrictions, are older, perceive their hearing as poor, see more benefits than barriers to amplification, and perceive their significant others as supportive of hearing rehabilitation.

Since these previous reviews, there has been an increasing number of investigations aiming to better understand the factors affecting help-seeking and hearing aid uptake (For example: Humes & Dubno, 2021; Pronk et al., 2017; Sawyer et al., 2020; Singh & Launer, 2018). Therefore, there is a need to consolidate the latest evidence to capture the current landscape and understand the audiological and non-audiological factors that either hinder or facilitate help-seeking behavior and the uptake of hearing aids. Moreover, previous reviews have mainly focused on quantitative studies rather than qualitative studies. While a few qualitative studies offer important insights on barriers and enablers to adopting hearing aids, there is little information available on the reasons for adopting hearing aids, particularly from the perspective of the hearing aid user. Additionally, previous reviews have identified factors that need further exploration, such as the cost of hearing aids, since it has been observed to affect hearing aid uptake in clinical practice but with limited evidence (Jenstad & Moon, 2011; Knudsen et al., 2010; Meyer & Hickson, 2012; Ng & Loke, 2015).

1.3 Cost as a barrier to hearing aid uptake

The high cost of hearing aids has been proposed as one of the key barriers to the uptake of hearing aids, often outweighing the perceived benefits of improved hearing and impacting their decision to adopt these devices (Jilla et al., 2020). The average cost of prescription hearing aids in the United States (US) is $5,000 per pair, typically paid out-of-pocket due to limited coverage by most health insurance plans (Jilla et al., 2020). Data from the 2016 American Community Survey revealed that three out of four Americans with functional hearing loss cannot afford hearing aids at this price point (Jilla et al., 2020). Moreover, purchasing hearing aids at this cost would push 4% of the US population into poverty for the year (Jilla et al., 2020). Additionally, Mahmoudi et al. (2018)found that hearing aid users in the US incur significantly higher total annual healthcare and out-of-pocket expenses compared to non-users. Findings from the MarkeTrak 2022 consumer survey indicate that higher income levels and third-party coverage are associated with increased hearing aid uptake (Windmill, 2022). Interestingly, the survey highlights that enhanced third-party coverage serves as a more significant motivator for hearing aid uptake than merely reduced costs (Windmill, 2022). These studies highlight the high cost of hearing aids as a significant factor in the low adoption of hearing aids.

Various qualitative studies have also emphasized that the high cost of hearing aids remains a significant barrier to uptake (Chandra & Searchfield, 2016; Ekberg et al., 2017; Laplante-Lévesque et al., 2010; McKee et al., 2019; Hesselton et al., 2022). However, there is a perceived benefit in lower costs associated with alternative service delivery models, such as DTC hearing devices, which could potentially alleviate this barrier (Hesselton et al., 2022). Notably, these studies have primarily focused on prescription hearing aids due to the timeframe of the research. With the recent FDA approval of OTC hearing aids, there is a gap in understanding user perspectives within the OTC service-delivery model on this issue. Therefore, further research on the relationship between the cost and uptake of OTC hearing aids compared to prescription hearing aids is important. Such studies can inform policies and regulations to enhance hearing aid accessibility and adoption rates.

1.4 Over-the-counter hearing aids

The emergence of OTC hearing aids presents a promising alternative uptake, potentially improving affordability and access to hearing healthcare for individuals with perceived mild-to-moderate hearing loss (Food and Drug Administration, 2022). OTC hearing aids reduce perceived barriers such as cost and accessibility and serve as a cue to action for individuals who prefer to self-manage their hearing health. The FDA defined two sub-categories for OTC hearing aids, namely 1) OTC hearing aids with standardized output profiles (i.e., pre-set programs; OTC-PS) and 2) self-fitting OTC (OTC-SF) hearing aids, which allow users to program their hearing aids with a self-fitting strategy and customize their hearing aid settings according to their needs and preferences (Food and Drug Administration, 2022).

Recent studies have shown that OTC-SF hearing aids are as beneficial and satisfactory as audiologist-fitted hearing aids for those with mild-to-moderate hearing loss. Sabin et al. (2020) validated an OTC-SF method using a Bose prototype, with users reporting better sound quality and no significant differences in clinical outcomes compared to audiologist-fitted hearing aids. De Sousa et al. (2023) found comparable short-term benefits and satisfaction between OTC-SF and audiologist-fitted hearing aids. Swanepoel et al. (2023) observed no difference in outcomes between users of prescription hearing aids and OTC-SF aids.

The market has seen many OTC hearing aids with various self-fitting strategies, but research on their usability and performance is limited. No studies have compared the self-fitting process among different OTC-SF hearing aids, highlighting a significant research gap. Additionally, no study has directly compared different self-fitting strategies (e.g., self-adjustment vs in-situ audiometry) within the OTC-SF devices, further emphasizing the need for research in this area. Understanding usability and performance is essential for empowering consumers, guiding healthcare professionals, and establishing industry standards.

1.5 Study rationale

The existing reviews have identified various barriers and enablers to hearing help-seeking and hearing aid uptake. However, these reviews were conducted more than ten years ago. In the last decade, there have been significant advancements in hearing healthcare, including the introduction of OTC hearing aids, which have the potential to improve access and affordability in hearing healthcare. Therefore, there is a need for a thorough review of the latest evidence to understand the current landscape and the audiological and non-audiological factors that hinder or facilitate seeking hearing help and adopting hearing aids.

While there are clear quantitative predictors for hearing aid uptake, there is limited qualitative research exploring personal and contextual factors. Most existing research has focused on identifying reasons why individuals do not take up hearing aids, emphasizing the barriers. However, there has been less emphasis on understanding the reasons why people choose to adopt hearing aids—the enablers of uptake. Understanding these positive factors is crucial, as it can help develop strategies to encourage more individuals to seek help and benefit from hearing aids.

Previous reviews have identified factors that require further investigation, such as the cost of hearing aids. The cost of hearing aids has been reported as a major obstacle, yet the relationship between cost and uptake has not been thoroughly investigated in recent studies. OTC hearing aids, in particular, look promising as they might lower costs and increase accessibility, addressing one of the key barriers identified in earlier research. However, the impact of these devices on hearing aid uptake has not been explored. Additionally, there is limited evidence regarding the usability and performance of OTC hearing aids available in the market. In summary, this research project aimed to answer the question: What factors influence help-seeking behavior for hearing difficulties and the uptake of hearing aids, and what are the performance and usability of different OTC-SF hearing aids?

To answer the main research question, the following five research objectives with their respective research questions were addressed in five separate studies:

- Study I: To systematically review and summarise the evidence concerning the audiological and non-audiological factors that influence hearing help-seeking and hearing aid uptake in adults with hearing loss based on the research evidence published during the last decade.
  1) What audiological factors hinder or facilitate hearing help-seeking and hearing aid uptake in adults?

2) What non-audiological factors hinder or facilitate hearing help-seeking and hearing aid uptake in adults?

3) What new factors influencing hearing help-seeking and hearing aid uptake have emerged?

- Study II: To explore the main reasons for hearing aid uptake and recommendations to others with hearing difficulties in a sample of adult hearing aid users in the US.
  1) What are the main reasons for hearing aid uptake among adult hearing aid users?
  2) What recommendations do hearing aid users offer to others with hearing aid difficulties?

- Study III: To explore user perspectives on the relationship between hearing aid cost and hearing aid uptake and recommendations related to cost in a sample of prescription and OTC hearing aid users.
  1) What is the relationship between hearing aid uptake and hearing aid cost in prescription and OTC hearing aid users?
  2) What cost-related recommendations do hearing aid users offer to others with hearing aid difficulties?

- Study IV: To compare the usability and performance of several FDA-approved OTC-SF hearing aids available to consumers.
  1) How do usability and performance measures differ across different OTC-SF hearing aids?

- Study V: To compare self-adjustment and in-situ audiometry self-fitting strategies in OTC-SF hearing aids for adults with mild-to-moderate hearing difficulties.
  1) What are the differences in hearing aid outcomes between self-adjustment and in-situ audiometry self-fitting strategies in OTC-SF hearing aids?

CHAPTER 2

METHOD

2.1 Research objectives

2.1.1 Study aim

The main aim of this study was to 1) investigate factors influencing hearing help-seeking and hearing aid uptake and 2) evaluate the usability and effectiveness of OTC-SF hearing aids.

To achieve the main aim, this study was divided into five research objectives, each constituting a research project that was submitted as an article to accredited peer-reviewed journals.

2.1.2 Research objectives

- Study I: To systematically review and summarise the evidence concerning the audiological and non-audiological factors that influence hearing help-seeking and hearing aid uptake in adults with hearing loss based on the research evidence published during the last decade.
- Study II: To explore the main reasons for hearing aid uptake and recommendations to others with hearing difficulties in a sample of adult hearing aid users in the United States.
- Study III: To explore user perspectives on the relationship between hearing aid cost and hearing aid uptake and recommendations related to cost in a sample of prescription and OTC hearing aid users.
- Study IV: To compare the usability and performance of several FDA-approved OTC-SF hearing aids available to consumers.
- Study V: To compare self-adjustment and in-situ audiometry self-fitting strategies in OTC-SF hearing aids for adults with mild-to-moderate hearing difficulties.

2.2 Ethical considerations

This research project received institutional review board approval from the Humanities Research Ethics Committee at the University of Pretoria, with protocol numbers

HUM008/0822 (Appendix A) for Studies I to III and HUM021/1122 (Appendix B and C) for Studies IV and V.

2.2.1 Protection from Harm

Participants should not be exposed to any form of physical or psychological harm (Leedy & Ormrod, 2016). Minimal risks were involved when participating in this study. Prior to their involvement, participants were provided with informed consent letters clearly stating their right to withdraw from the study at any time without facing any negative consequences (Appendix D and E). This was also verbally communicated to the participants. Additionally, the benefits of participating in the study far outweighed any potential risks. Specifically, participants in studies IV and V received a free hearing assessment and a pair of OTC hearing aids.

2.2.2 Voluntary and Informed Consent

Participants must be informed about the nature of the study and give written permission to participate (Leedy & Ormrod, 2016). In studies II, III, IV and V, participants had to give written informed consent before data collection began (see Appendix D, E and I). The informed consent letters were also explained verbally to the participants, and they were given the chance to ask questions to ensure they understood the study.

2.2.3 Right to Privacy

Researchers should always respect the participant's right to privacy by keeping the nature and quality of the participant's performance strictly confidential (Leedy & Ormrod, 2016). De-identified survey responses were analyzed for studies II and III. For studies ll, lll, lV, and V, each participant was allocated a numeric code to replace their name to ensure confidentiality. No personally identifying information was disclosed in the event of publication. The researcher was the only person with access to the data sheets containing participant information. Contact details of participants were solely used by the researcher to provide additional information about the studies and to schedule appointments. The contact details were kept strictly confidential, and only the researcher had access to them. All of the above measures were taken to ensure compliance with the Protection of Personal Information Act and to protect the personal information of the participants.

2.2.4 Release of Research Findings

The results of the five separate studies were submitted to accredited, peer-reviewed journals for publication. Participants were informed that articles submitted to scientific journals would not include personally identifying information (see Appendix D and E).

2.2.5 Data Storage

According to the University of Pretoria guidelines, data must be securely stored for at least 10 years. The data will be stored electronically and in hard copy at the Department of Speech-Language Pathology and Audiology, University of Pretoria.

2.3 Study I: Review of Factors Influencing Help-seeking and Hearing Aid Uptake

2.3.1 Research design

This study utilized a systematic review to identify, evaluate, and summarize relevant studies' findings to make the available evidence more accessible to decision-makers (Gopalakrishnan & Ganeshkumar, 2013). The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines were followed in the performing and reporting of this systematic review (Page et al., 2021). The Population Intervention Comparison Outcome Study Design Timeline (PICOST) framework was used to select the eligibility criteria for this study and can be found in the table below (Table 2.1).

Table 2.1 Eligibility Criteria for Study I

Study characteristic/ Domain	Inclusion criteria	Exclusion criteria
Population	Adults (18 years and older) with hearing difficulties	Adults without hearing difficulties and children (younger than 18 years)
Intervention/Exposure	Not applicable	Not applicable
Comparison	The review will include studies in all settings and contexts	No exclusions
Outcome	Hearing help-seeking (e.g., consulting professionals, performing online hearing screening) and hearing aid uptake (conventional hearing aids)	Studies focusing on hearing aid use and hearing aid benefit/ satisfaction alone as well as studies dealing with amplification devices other than conventional hearing aids e.g., cochlear implants, middle-ear implants, bone-anchored hearing aids and assistive listening devices

Study designs	Quantitative studies with any study design	Qualitative studies
Timeline	Studies published after 01 January 2011	Studies published before 01 January 2011
Other: Publication type	Studies published in peer-reviewed scientific journals	Non-peer reviewed publications, discussion papers, dissertation/ thesis, conference papers
Other: Language	Studies published in English	Studies published in languages other than English

2.3.2 Research procedures

The following procedures were conducted to complete this systematic review:

a) Two reviewers independently searched for relevant articles in electronic databases, including CINAHL, PsycINFO, and Medline.

b) The search was performed using the key terms based on two key concepts, as illustrated in Table 2.2.

Table 2.2 Key concepts and keywords for database search (Study I)

Concept 1: Condition		**Concept 2: Outcome**
hearing OR “hearing loss” OR “hearing impair*” OR “hearing diff*” OR “hearing disability” OR “hearing problem” OR “hard of hearing” AND “hearing aid” OR “hearing device” OR amplification OR “audiological rehabilitation*” OR “aural rehab*” OR “auditory rehab*”	**AND**	“help seeking” OR help OR advice OR uptake OR adopt* OR acqui* OR purchase OR refusal OR reject* OR adherent OR nonadherent OR candidate OR applicant

c) Articles were exported from the databases into Rayyan (https://www.rayyan.ai/).

d) Duplicate articles were identified and removed by the Rayyan software.

e) Thereafter, studies were screened based on their titles and abstracts regarding the inclusion criteria, while the researchers were blinded to each other’s decisions. If a decision could not be made based on the abstract, the full-text article was retrieved and reviewed.

f) Full-text PDF versions of the articles that met the inclusion criteria were inspected closely to extract the relevant data.

g) The reference lists of the identified publications were checked for additional studies to be included in the review. Additionally, searches were run on Google Scholar and Google Search to identify any other studies that should have been retrieved for inclusion.

h) Microsoft Excel (2019) was used for data extraction and management. A specific form was used to summarize the information obtained from the articles. It included the following elements: Publication (e.g., reference, authors, title, country of study, date of publication), study design (e.g., aim, study design, data collection method, data analysis method), population (e.g., sampling method, sample size, age of participants, gender of participants), factor(s) examined (audiological and non-audiological factors) and outcomes (e.g., key findings, associations). The primary reviewer extracted all the data, and the second reviewer cross-checked 20% of the data using a random number generator to ensure completeness and accuracy.
i) The National Institute of Health (NIH) quality assessment tools were used to assess the quality of the studies included in the review (National Institute of Health, 2021). The NIH tool does not provide specific parameters to rate the quality as good, fair or poor. Therefore, we used parameters as specified in another systematic review where they rated a score of 0-4 as poor, 5-10 as fair, and 11-14 as good (Bagias et al., 2021). Each study's level of evidence was determined according to the Oxford Centre for Evidence-Based Medicine (OCEBM Levels of Evidence Working Group, 2011). The primary reviewer conducted the quality assessment and determined the level of evidence. The second reviewer cross-checked 20% using a random number generator to ensure reliability.
j) If a disagreement had arisen at any stage, it was discussed. If necessary, other research team members were involved to resolve the disagreement and make a final decision.

2.3.3 Statistical analysis and data processing

Data synthesis was conducted using a narrative approach, as described by Campbell et al. (2020), to identify, characterize, and summarize available research evidence on audiological and non-audiological factors influencing hearing help-seeking and hearing aid uptake. The primary reviewer conducted the synthesis, and the final results were reported as agreed upon by the rest of the research team members.

2.4 Study ll: Reasons for Hearing Aid Uptake in the US: Qualitative Analysis of Survey Responses

2.4.1 Research design

This study used a retrospective design to determine the main reasons why adults with hearing loss take up hearing aids and their recommendations to others with hearing difficulties. The supervisors already collected the data using a cross-sectional survey, and permission was given to analyze the data retrospectively (Appendix F).

2.4.2 Research procedures

a) The Lamar University Human Subjects Review Board granted ethical clearance for the cross-sectional study (Appendix G).
b) An online questionnaire was designed using the Qualtrics Platform with open-ended and structured questions regarding hearing aids (Appendix H). The questionnaire was distributed to hearing aid user(s) from the Hearing Tracker website (www.hearingtracker.com) and user(s) from the Lexie Hearing (www.lexiehearing.com) United States database.
c) Participants were required to give informed consent electronically (Appendix I) before they completed the questionnaire and were included if they were adults (18 years and older) with hearing loss who had been or were current unilateral (fitted with a hearing aid in one ear) or bilateral (fitted with hearing aids in both ears) hearing aid users.
d) An open-ended question was used to obtain information about reasons for taking up a hearing aid and recommendations to others with hearing difficulties. The responses were exported to Microsoft Excel (2019), where data screening was conducted to prepare the raw data for data analysis.
e) This study analyzed 727 de-identified responses from the open-ended question regarding reasons for hearing aid uptake and recommendations to others who also have hearing difficulties.

2.4.3 Statistical analysis and data processing

De-identified demographic data was coded in Microsoft Excel (2019) and then transferred to Statistical Package for the Social Sciences (SPSS) version 28 for statistical analysis. The analysis involved descriptive statistics such as frequency, mean, standard deviation, and range. Mann-Whitney U and Chi-square tests were utilized to determine significant differences among groups regarding demographic and audiological variables. Furthermore, 727 responses were qualitatively analyzed in Microsoft Excel (2019) using qualitative content analysis (Graneheim & Lundman, 2004; Knudsen et al., 2011). This approach, suitable for open-ended questions, focuses on categorizing explicit data to provide a descriptive overview. An inductive approach was employed, deriving generalizations from specific instances. Patterns within responses were identified, leading to the development of sub-categories and broader categories.

The researcher iteratively read through responses, then condensed them into meaning units and applied codes. These codes were further organized into sub-categories and categories. The process involved constant revisiting and refining of the coding and categorization scheme to ensure all relevant patterns were identified, facilitating a comprehensive understanding of the data.

2.5: Study lll: Perspectives on Hearing Aid Cost and Uptake: Prescription vs. OTC Users

2.5.1 Research design

A retrospective design was used to describe the relationship between hearing aid cost and uptake, as well as cost-related recommendations to others with hearing difficulties. The study supervisors already collected the data as part of a larger research project using a cross-sectional survey, and permission was given to analyze the data retrospectively (Appendix F).

2.5.2 Research procedures

a) The Lamar University Human Subjects Review Board granted ethical clearance for the cross-sectional study (Appendix G).
b) An online questionnaire was designed using the Qualtrics Platform with open-ended and structured questions regarding hearing aids (Appendix H). The questionnaire was distributed to hearing aid user(s) from the Hearing Tracker website (www.hearingtracker.com) and user(s) from the Lexie Hearing (www.lexiehearing.com) United States database.
c) Participants were required to give informed consent electronically (Appendix I) before they completed the questionnaire and were included if they were adults (18 years and older) with hearing loss who had been or were current unilateral (fitted with a hearing aid in one ear) or bilateral (fitted with hearing aids in both ears) hearing aid users.

d) An open-ended question was used to obtain information about reasons for taking up a hearing aid and recommendations to others with hearing difficulties. The responses were exported to Microsoft Excel (2019), where data screening was conducted to prepare the raw data for data analysis.

e) This study analyzed 727 de-identified responses to the open-ended question regarding hearing aid cost and cost-related recommendations.

2.5.3 Statistical analysis and data processing

The 727 de-identified responses were screened in Microsoft Excel (2019) to identify responses to the open-ended question related to hearing aid cost and cost-related recommendations. Qualitative content analysis was used to examine and interpret the data to identify patterns, themes, and relationships (Graneheim & Lundman, 2004; Knudsen et al., 2011). Knudsen et al. (2011) described coding and categorization as critical components of qualitative data analysis. Coding involves assigning labels or tags to specific segments of the data, while categorization involves grouping these codes into broader categories. The authors emphasized that the coding and categorization process should be iterative and involve ongoing reflection and revision to ensure that the emerging categories accurately capture the data. The researcher read the data multiple times to develop an understanding of its content and to identify meaningful units of text. Using an inductive approach (i.e., bottom-up), the researcher assigned specific codes to the meaning units and organized them into broader categories and domains.

2.6 Study lV: Usability and Performance of Self-Fitting OTC Hearing Aids

2.6.1 Research design

This study used a cross-sectional design to compare the usability and performance of six OTC-SF hearing aids, including the HP Hearing PRO, Jabra Enhance Plus, Lexie B2 Powered by Bose, Lexie Lumen, Soundwave Sontro, and Sony CRE-C10 hearing aids.

2.6.2 Research participants

To be eligible to participate in the study, participants needed to be:

- 18 years or older

- Suspect that you have mild to moderate hearing loss or have previously been diagnosed with mild to moderate hearing loss
- Should not have a history of recurrent ear infections or other middle ear pathologies
- Have a high level of proficiency in English
- Own an Android or iOS smartphone with access to mobile data

2.6.3 Research equipment and materials

Table 2.3 describes the equipment and materials used in this study.

Table 2.3 Study lV: Equipment and materials

Materials and apparatus	Use
EF Standard English Test (EF SET)	Participants were required to complete an online English proficiency test to ensure a high level of proficiency (EF SET, n.d.) to accurately comprehend and follow instructions for self-fitting the hearing aids and complete the standardized outcome measures.
Welch Allyn Pocketscope with reusable specula	The otoscope was used to visually inspect the ear canals and tympanic membranes.
GSI G1 Clinical Audiometer (model no 1761) with GSI speakers and TDH-50P Telephonics headphones	The audiometer and headphones were used to conduct conventional pure-tone air conduction audiometry. The speakers were used to perform aided speech-in-noise testing (DIN and QuickSIN).
Maico diagnostic touchTymp tympanometer	The tympanometer was used to determine middle ear functioning.
Samsung smartphone with DIN and QuickSIN applications	Aided speech-in-noise tests (DIN and QuickSIN) were conducted after each fitting in a sound-proof booth at 70 dB HL. Speech-in-noise benefit was assessed by subtracting the aided scores from the unaided scores.
iPhone X	Participants self-fit their assigned OTC-SF hearing aids using an iPhone X and the manufacturer-provided instructions on the accompanying smartphone application.
HP Hearing PRO with accompanying smartphone application (HP Hearing)	Earbud-style rechargeable self-fitting OTC hearing aids using an in-situ audiometry self-fitting strategy.
Jabra Enhance Plus with accompanying smartphone application (Jabra Enhance)	Earbud-style rechargeable self-fitting OTC hearing aids using an in-situ audiometry self-fitting strategy.
Lexie B2 Powered by Bose with accompanying smartphone application (Lexie)	Receiver-in-the-canal rechargeable self-fitting OTC hearing aids using a self-adjustment self-fitting strategy.
Lexie Lumen with accompanying smartphone application (Lexie)	Behind-the-ear non-rechargeable self-fitting OTC hearing aids using an in-situ audiometry self-fitting strategy.
Soundwave Sontro with accompanying smartphone application (otoTune)	Receiver-in-the-canal non-rechargeable self-fitting OTC hearing aids using an in-situ audiometry self-fitting strategy.
Sony CRE-C10 hearing aids with accompanying smartphone application (Sony Hearing Control)	Completely-in-the-canal non-rechargeable self-fitting OTC hearing aids using an in-situ audiometry self-fitting strategy.
Audioscan Verifit1 or MedRx system	REMs were conducted by the audiologist after each fitting for average speech (65 dB SPL), soft speech (55 dB SPL), and loud speech (75 dB SPL) using the International Speech Test Signal (ISTS).
Ease of Self-fitting Process	After each self-fitting, participants were asked to rate the ease of the self-fitting process using a 5-point Likert scale, with one being very easy and five being very difficult. The question was: “How easy was the self-fit process?” Additionally, they were

	asked to complete an open-ended question that was phrased as follows: "Tell us about your overall experience." The researcher also took field notes during each fitting.
Hearing Aid Skills and Knowledge (HASK)	The researcher assessed the participants' hearing aid skills and knowledge using selected items from the HASK test (Saunders et al., 2017) immediately after self-fitting. These items included distinguishing left from right, inserting the right hearing aid, inserting the left hearing aid, changing the volume, and switching the hearing aids on and off. Each item was given a score out of two points. Participants who did not know the information or could not complete the task received zero points. Those who were aware of the information but required assistance from the researcher received one point. Participants who demonstrated knowledge and performed the task correctly received two points. The total score was out of 10 points, with possible scores ranging from 0 to 10.
Post-Study System Usability Questionnaire (PSSUQ)	Participants completed version 3 of the PSSUQ to measure their post-use usability of the OTC-SF hearing aids (Lewis, 2002). The PSSUQ comprised 16 standardized questions, following a 7-point Likert scale and a not-applicable option. The overall result is determined by averaging the scores across the 7-point scale. The possible scores range from 1 to 7, with lower scores indicating higher post-use usability. The PSSUQ consists of three sub-scales, namely system usefulness (SYSUSE; possible scores range between 1 to 7, information quality (INFOQUAL; possible scores range between 1 to 7, and interface quality (INTERQUAL; possible scores range between 1 to 7).
Judgement of Sound Quality (JSQ)	To assess the sound quality of the OTC-SF hearing aids, we used specific items from the Judgement of Sound Quality (JSQ) rating scale (Gabrielsson et al., 1988). Given the potential challenges in evaluating certain items, such as fullness and spaciousness, especially immediately after fitting the OTC-SF hearing aids, we focused on easily understandable and reliable items for rating. These items included the overall impression (i.e., very bad to very good) and clarity of sound (i.e., very unclear to very clear). Participants rated sound quality on a scale of zero to ten (11-point Likert scale), with higher scores indicating better sound quality.

2.6.4 Research procedures

Participants were asked to attend two sessions at the University of Pretoria at no cost. Each session took approximately two hours, scheduled at a time convenient to the participant.

2.6.4.1 Session 1 (Study IV)

- English proficiency test

For this test, participants were asked to conduct the online 15-minute EF SET English proficiency test (EF SET, n.d.). The test involved selecting one of a number of responses to English phrases. The instruction was to select the response that was most appropriate to the sentence.

- Otoscopy

For this examination, the participant was seated upright while the audiologist visually inspected the ear canal by placing an otoscope (ear light) in the ear.

- Pure tone audiometry

For this test, the participant was seated in a soundproof booth. Headphones were placed on the ears. The participant was asked to respond to a series of soft sounds (at different pitches) by pressing a button. This was done to measure the participant's hearing sensitivity.

- Unaided speech perception testing

The QuickSIN and DIN tests were performed in the sound field using the speakers in the soundproof booth. For the QuikSIN, a list of sentences was presented in noise. Participants were requested to say the sentences that were heard. For the DIN, participants were asked to listen to the digits presented and say the digits in the order that it was heard. If they were uncertain, they were instructed to guess.

2.6.4.2 Session 2 (Study IV)

- Hearing aid fitting

After participants had been assigned to different conditions, they completed the self-fitting of two of the five devices (Lexie, Sontro, HP, Sony, and Jabra devices) using the instructions provided by the manufacturers. The self-fit process was timed.

- Questionnaires

After each fitting, participants completed a self-reported questionnaire, the PSSUQ, and the JSQ.

- Real ear measurements

After each fitting, real ear measurements were performed. For this standard clinical test, a small thin tube (probe microphone) was inserted in the ear canal along with the hearing aid. This test measured the exact sound levels presented by the hearing aid. For this test, the participant was only requested to stay seated while speech sounds were presented via the equipment's speaker.

- Aided speech-in-noise testing

After each fitting, participants wore the hearing aids and completed speech-in-noise testing (QuickSIN and DIN).

2.6.5 Statistical analysis and data processing

We used IBM SPSS v28.0.1.0 for data analysis. Initial examination revealed non-normality ($p < .05$) across all variables via Shapiro-Wilk's test. Descriptive statistics, including mean, median, standard deviation, and range, were computed to summarize the data comprehensively. To compare OTC-SF hearing aids' usability and performance, we applied the Kruskal-Wallis test, followed by Dunn's (1964) procedure for pairwise comparisons to adjust for multiple comparisons. Qualitative feedback from open-ended questions and researcher field notes provided insights into participants' experiences. Inductive thematic analysis, as per (Braun & Clarke, 2006), was utilized to uncover patterns directly from the data without predefined frameworks. The primary researcher coded the data, with cross-checking by co-authors experienced in thematic analysis to ensure reliability. Inconsistencies were resolved through discussion until a consensus was reached.

2.7 Study V: A Crossover Trial Comparing Self-Fitting Strategies for OTC Hearing Aids

2.7.1 Research design

This study used a comparative within-subjects cross-over controlled trial to compare the existing self-fitting strategy of the Lexie Powered by Bose hearing aids (i.e., self-adjustment) to a newly developed in-situ audiometry fitting strategy. Patients' perspectives and preferences will be determined qualitatively. Additionally, real ear measurements (REM) and speech-in-noise testing will be compared between the two fitting strategies.

2.7.2 Research participants

To be eligible to participate in the study, participants needed to be:

- 18 years or older
- Suspect that you have mild to moderate hearing loss or have previously been diagnosed with mild to moderate hearing loss
- Should not have a history of recurrent ear infections or other middle ear pathologies
- Have a high level of proficiency in English
- Own an Android or iOS smartphone with access to mobile data

2.7.3 Research equipment and materials

Table 2.4 describes the equipment and materials used in this study.

Table 2.4 Study V: Equipment and materials

Materials and apparatus	Use
EF SET	Participants were required to complete an online English proficiency test to ensure a high level of proficiency (EF SET, n.d.) to accurately comprehend and follow instructions for self-fitting the hearing aids and complete the standardized outcome measures.
Welch Allyn Pocketscope with reusable specula	The otoscope was used to visually inspect the ear canals and tympanic membranes.
GSI G1 Clinical Audiometer (model no 1761) with GSI speakers and TDH-50P Telephonics headphones	The audiometer and headphones were used to conduct conventional pure-tone air conduction audiometry. The speakers were used to perform aided speech-in-noise testing (DIN and QuickSIN).
Maico diagnostic touchTymp tympanometer	The tympanometer was used to determine middle ear functioning.
Samsung smartphone with DIN and QuickSIN applications	Aided speech-in-noise tests (DIN and QuickSIN) were conducted after each fitting in a sound-proof booth at 70 dB HL. Speech-in-noise benefit was assessed by subtracting the aided scores from the unaided scores.
Lexie B2 Powered by Bose with accompanying smartphone application (Lexie)	Receiver-in-the-canal rechargeable self-fitting OTC hearing aids using a self-adjustment self-fitting strategy.
Lexie B2 Plus Powered by Bose with research application	Receiver-in-the-canal rechargeable self-fitting OTC hearing aids using an in-situ audiometry self-fitting strategy.
Audioscan Verifit1 or MedRx system	REMs were conducted by the audiologist after each fitting for average speech (65 dB SPL), soft speech (55 dB SPL), and loud speech (75 dB SPL) using the International Speech Test Signal (ISTS).
Abbreviated Profile of Hearing Aid Benefit (APHAB)	The APHAB (Cox & Alexander, 1995) is a 24-item self-assessment inventory in which patients report the amount of trouble they are having with communication or noises in various everyday situations. Benefit is calculated by comparing the patient's reported difficulty in the unaided condition with their amount of difficulty when using amplification. The APHAB produces scores for 4 subscales: Ease of Communication (EC), Reverberation (RV), Background Noise (BN), and Aversiveness (AV).
International Outcomes Inventory for Hearing Aids (IOI-HA)	The IOI-HA (Cox & Alexander, 2002) is a seven-item standardized questionnaire designed to measure the outcomes of hearing aid use from the user's perspective. Developed by an international working group, the IOI-HA aims to provide a simple, yet comprehensive tool for assessing the benefits and effectiveness of hearing aids across different populations and settings.

2.7.4 Research procedures

Participants were asked to attend three sessions at the University of Pretoria at no cost. Each session, which took approximately two hours, was scheduled at a time convenient to the participant.

2.7.4.1 Session 1 (Study V)

- English proficiency test

The test involved selecting one of several responses to English phrases (EF SET, n.d.). The instruction was to select the response that was most appropriate to the sentence.

- Otoscopy

For the examination, the participant was seated upright while the audiologist visually inspected the ear canal by placing an otoscope (ear light) in the ear.

- Pure tone audiometry

For the test, the participant was seated in a soundproof booth. Headphones were placed on the ears. The participant was asked to respond to a series of soft sounds (at different pitches) by pressing a button. This was done to measure the participant's hearing sensitivity.

- Unaided speech perception testing

The QuickSIN, DIN, and word recognition testing were performed in the sound field using the speakers in the soundproof booth. For the QuikSIN, a list of sentences was presented in noise. Participants were requested to say the sentences that were heard. For the DIN, participants were asked to listen to the digits presented and say the digits in the order that they were heard. If they were uncertain, they were instructed to guess. For the word recognition testing, words were presented in quiet, and participants were asked to repeat the words.

- Hearing aid experience questionnaire

Using the APHAB, the participant was asked to answer a series of Likert-style questions or statements related to their hearing with and without a hearing aid. The questionnaires were uploaded electronically, and participants completed them in the session using a tablet provided by the researchers.

- Hearing aid fitting

Participants were fitted with the Lexie B2 Powered by Bose hearing aids either using the self-fit strategy or the in-situ audiometry fitting strategy (depending on which group they were in). The self-fit process was timed, and participants were asked to rate how easy it was using a Likert scale.

- Real ear measurements

For the standard clinical test, a small thin tube (probe microphone) was inserted into the ear canal along with the hearing aid. This test measured the exact sound levels that were presented by the hearing aid. For this test, the participant was only requested to stay seated while speech sounds were presented via the equipment's speaker.

- Aided speech-in-noise testing

Participants completed speech perception testing (QuickSIN, DIN, and word recognition testing) while wearing the hearing aids. Participants were asked to wear the hearing aids for 28 days for approximately 6 hours per day.

2.7.4.2 Session 2 (Study V)

After four weeks, participants were asked to return for session 2.

- Hearing aid experience questionnaires

Participants were asked to complete the APHAB and the IOI-HA questionnaires to determine hearing aid benefit and satisfaction.

- Hearing aid fitting

Participants were fitted with the same hearing aids using the alternative fitting strategy (i.e., those who were fitted using the self-fit strategy were now fitted using the in-situ audiometry and vice versa). The self-fit process was timed, and participants were asked to rate how easy it was using a Likert scale.

- Real ear measurements and aided speech perception testing

Real ear measurements and aided speech-in-noise testing were performed again.
Thereafter, participants were asked to wear the hearing aids for another 28 days for approximately 6 hours per day.

2.7.4.3 Session 3 (Study V)

After four weeks, participants were asked to return for session 3.

- Hearing aid experience questionnaires

Participants completed the APHAB as well as the IOI-HA to determine hearing aid benefit and satisfaction after hearing aid fitting.

Participants were then able to keep the Lexie B2 Powered by Bose hearing aids and smartphone application to use for free.

2.7.5 Statistical analysis and data processing

We analyzed the data using IBM Corporation's SPSS Statistics version 29.0 software. Paired samples *t*-tests were applied to normally distributed continuous variables, and Wilcoxon signed-rank tests were used for non-normally distributed or ordinal variables to compare self-fitting strategies within subjects. We determined clinically meaningful differences by examining effect size and 95% confidence intervals. Cohen’s d was used for t-test results, with interpretations 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 ($d \geq 0.8$). For the Wilcoxon signed-rank test, Rosenthal’s r was calculated as $z/\sqrt{N}$, with interpretations including 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 ($r \geq 0.5$). Effect sizes were deemed clinically meaningful if they were medium or larger.

CHAPTER 3

FACTORS INFLUENCING HEARING HELP-SEEKING AND HEARING AID UPTAKE IN ADULTS: A SYSTEMATIC REVIEW OF THE PAST DECADE

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3.1 Abstract

This systematic review examined the audiological and non-audiological factors that influence hearing help-seeking and hearing aid uptake in adults with hearing loss based on the literature published during the last decade. Peer-reviewed articles published between January 2011 and February 2022 were identified through systematic searches in electronic databases CINAHL, PsycINFO and MEDLINE. The review was conducted and reported according to the PRISMA protocol. Forty-two articles met the inclusion criteria. 70 (42 audiological and 28 non-audiological) hearing help-seeking factors and 159 (93 audiological and 66 non-audiological) hearing aid uptake factors were investigated with many factors reported only once (10/70 and 62/159, respectively). Hearing aid uptake had some strong predictors (e.g., hearing sensitivity) with others showing conflicting results (e.g., self-reported health). Hearing help-seeking had clear non-predictive factors (e.g., education) and conflicting factors (e.g., self-reported health). New factors included cognitive anxiety associated with increased help-seeking and hearing aid uptake and urban residency and access to financial support with hearing aid uptake. Most studies were rated as having a low level of evidence (67%) and fair quality (86%). Effective promotion of hearing help-seeking requires more research evidence. Investigating

factors with conflicting results and limited evidence is important to clarify what factors support help-seeking and hearing aid uptake in adults with hearing loss. These findings can inform future research and hearing health promotion and rehabilitation practices.

Keywords: Hearing loss, Hearing aid, Help-seeking, Uptake, Adoption, Systematic review

3.2 Introduction

Unaddressed hearing loss can have severe negative consequences with pervasive effects across the life course (Huddle et al., 2017; Nordviket al., 2018; Olusanya, Neumann, & Saunders, 2014). If addressed in a timely and appropriate manner, the adverse consequences of hearing loss can largely be avoided or mitigated (World Health Organization, 2021). Hearing aids are most commonly used to rehabilitate hearing loss and can improve listening abilities as well as health-related quality of life (Ferguson et al., 2017). However, a significant proportion of people with hearing loss do not seek help for their hearing problems and do not acquire hearing aids (Orji et al., 2020). Research has shown that people wait 9 years on average to seek help for their hearing loss (Simpson, Matthews, Cassarly, & Dubno, 2019). In a national study in the United States, 32% of adults with hearing difficulty reported never having seen a physician about their hearing problems and 28% never had a hearing test (Mahboubi, Lin, & Bhattacharyya, 2018). Studies from other countries, especially in the low- and middle-income countries, have similarly reported low levels of hearing help-seeking. In Malaysia, only 29% of adults who had self-perceived hearing loss sought professional help (Mukari & Wan Hashim, 2018). A study done by Schönborn et al. (2020) in South Africa reported that only 14% of people who failed an app-based digits-in-noise (DIN) hearing test followed up with an audiologist. Worldwide, the hearing aid uptake numbers has been low with fewer than 11% of people with disabling hearing loss acquiring hearing aids (Bisgaard, Zimmer, Laureyns, & Groth, 2021). Moreover, longitudinal population-based studies revealed that the 5- and 10-year incidence rates of hearing aid adoption by people who exhibited hearing loss at baseline were approximately 8.5% and 36%, respectively (Fischer et al., 2011; Gopinath et al., 2011).

In the last decade, there have been significant efforts to improve access to hearing healthcare services (Blazer, Domnitz, Liverman, & Medicine, 2016). They include mobile health applications for promotion, screening, diagnosis, treatment and support for hearing loss (Frisby, Eikelboom, Mahomed-Asmail, Kuper, & Swanepoel, 2021), tele-audiology services like home-based otoscopy, online hearing screenings and remote hearing aid fittings (D'Onofrio & Zeng, 2022) as well as computational audiology (Wasmann et al., 2021). Computational audiology can be used to expand telehealth by incorporating clinical expertise into algorithms that can be employed on devices used by patients in underserved areas (Wasmann et al., 2021). Furthermore, a technological revolution in hearing aids has led to more affordable and accessible options such as direct-to-consumer (DTC) hearing devices (Manchaiah et al., 2017). Despite these efforts, hearing help-seeking and hearing aid uptake remain low. This may be explained by a wide range of audiological and non-audiological factors influencing hearing help-seeking and hearing aid uptake.

Various reviews have investigated the factors affecting hearing help-seeking and hearing aid uptake (Jenstad & Moon, 2011; Knudsen, Oberg, Nielsen, Naylor, & Kramer, 2010; Meyer & Hickson, 2012; Ng & Loke, 2015). A comprehensive review by Knudsen et al. (2010) investigated factors influencing hearing help-seeking, hearing aid uptake, use and satisfaction. The authors identified 31 factors (personal, demographic and external factors) relating to the outcomes. Motivation by others to seek help for hearing loss showed a positive association with help-seeking as opposed to being self-motivated. Hearing aid uptake was positively affected by attitudes towards hearing aids. Greater acceptance of hearing loss and poorer hearing sensitivity had a positive effect on both help-seeking and hearing aid uptake. Furthermore, age and gender did not show any relationship with any of the outcomes but that self-reported hearing disability positively influenced all four outcomes. The most recent review by Meyer and Hickson (2012) that explored the factors influencing both hearing help-seeking and hearing aid uptake concluded that people are more likely to seek help for their hearing problems and/or adopt hearing aids if they have moderate to severe hearing loss and self-reported hearing-related activity limitations or participation restrictions, are older, perceive their hearing as poor, consider there to be more benefits than barriers to amplification and perceive their significant others as supportive of hearing rehabilitation. Meyer and Hickson (2012) also mentioned that the influence of some factors requires further investigation, for example ethnicity, education and employment, due to a limited number of studies and/or conflicting results within the literature. Since previous reviews, there has been an increasing number of investigations to better understand factors affecting help-seeking and hearing aid uptake (e.g., Humes & Dubno, 2021; Pronk et al., 2017; Sawyer, Armitage, Munro, Singh, & Dawes, 2020; Singh & Launer, 2018). This systematic review, therefore, aims to review and summarise the evidence concerning the audiological and non-audiological factors that influence hearing help-seeking and hearing aid uptake in adults with hearing loss based on the research evidence published during the last decade.

3.3 Methods

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines were followed in performing and reporting of this review (Page et al., 2021). The review protocol was registered on the International Prospective Register of Systematic Reviews (PROSPERO)(CRD42022312208).

3.3.1 Search Strategy

The primary reviewer (MK) searched for relevant articles in electronic databases including CINAHL, PsycINFO and MEDLINE. The search was conducted using key terms: (hearing OR "hearing loss" OR "hearing impair*" OR "hearing diff*" OR "hearing disability" OR "hearing problem" OR "hard of hearing") AND ("hearing aid" OR "hearing device" OR amplification OR "audiological rehabilitation*" OR "aural rehab*" OR "auditory rehab*" AND "help seeking" OR help OR advice OR uptake OR adopt* OR acqui* OR purchase OR refusal OR reject* OR adherent OR nonadherent OR candidate OR applicant). Limiters included language (only studies published in English were considered) and publication period (only studies published after January 01, 2011 were considered). A final search was done on June 01, 2022, but no additional studies were found during this search.

3.3.2 Eligibility Criteria

The Population Intervention Comparison Outcome Study Design Timeline (PICOST) framework was used to select the inclusion and exclusion criteria for the review:

- Population: Studies including adults (18 years and older) with hearing loss (either self-reported hearing difficulties or confirmed hearing loss based on a hearing screening or assessment) were included. Studies including adults without hearing loss or children (younger than 18 years) were excluded.

▪ Intervention/Exposure: The intervention for hearing help-seeking referred to an action towards seeking help for hearing loss (i.e., making an appointment to consult with a hearing healthcare professional). With regards to hearing aid uptake, the intervention was obtaining conventional air conduction hearing aids.

▪ Comparison: The review included studies in all settings and contexts.

▪ Outcome: Studies focusing on hearing help-seeking (e.g., consulting professionals, performing online hearing screening) and hearing aid uptake were included. When studies focused on multiple outcomes (e.g., hearing help-seeking, hearing aid uptake, hearing aid use and satisfaction/benefit), we only extracted and reported on the outcomes relevant to this review (i.e., hearing help-seeking and hearing aid uptake). Studies focusing on hearing aid use and hearing aid benefit/ satisfaction alone were excluded as were studies dealing with amplification devices other than conventional hearing aids (e.g., cochlear implants, middle-ear implants, bone-anchored hearing aids and assistive listening devices).

▪ Study Design: Quantitative studies with any design were included. Qualitative studies were excluded from this review to be in line with the previous reviews by Knudsen et al. (2010) and Meyer and Hickson (2012) for comparative data. Knudsen et al. (2010) also excluded qualitative studies and Meyer and Hickson (2012) mostly focused on quantitative studies (20 out of the 22 included studies were quantitative).

▪ Timeline: Studies published between 01 January 2011 and 02 February 2022 were included.

▪ Other: Studies published in peer-reviewed scientific journals were eligible for inclusion. Non-peer reviewed publications, discussion papers, dissertations/theses and conference papers were excluded. Only studies published in English were included in the review.

3.3.3 Selection Procedure

The study selection was carried out by two researchers (MK and BM) independently. Articles were exported from the databases into Rayyan (https://www.rayyan.ai/). The Rayyan software was used for screening of studies and to record decisions. Firstly, duplicate articles were removed. Thereafter, studies were screened based on their titles and abstracts with regard to the inclusion criteria while the researchers were blinded to each other's decisions. The full-text article was retrieved and reviewed if a decision could not be made based on the abstract. Subsequently, the reference lists of the identified publications were checked for additional studies to be included in the review. There were disagreements in 20% of the articles.

Disagreements were resolved by discussion and involving other research team members (VM and DWS). The full-text PDF versions of the articles that met the inclusion criteria were inspected closely to extract the relevant data.

3.3.4 Data Extraction

Microsoft Excel was used for data extraction and management. A specific form was used to summarize the information obtained from the articles. It included the following elements: Publication (e.g., reference, authors, title, country of study, date of publication), study design (e.g., aim, study design, data collection method, data analysis method), population (e.g., sampling method, sample size, age of participants, gender of participants), factor(s) examined (audiological and non-audiological factors) and outcomes (e.g., key findings, associations, the direction of effect). The primary reviewer (MK) extracted all the data and the second reviewer (BM) cross-checked 20% of the data using a random number generator to ensure completeness and accuracy. There were disagreements in 14% of the articles, mostly relating to the study designs and sampling methods. These were resolved by discussion and involving other research team members (VM and DWS).

3.3.5 Risk of Bias (Quality) Assessment and Determination of Level of Evidence

The National Institute of Health (NIH) quality assessment tools were used to assess the quality of the studies included in the review (National Institute of Health, 2021). The NIH tools are specific to certain study designs and were designed to assist reviewers in focusing on concepts that are important in determining a study's internal validity (National Institute of Health, 2021). Reviewers could respond with "yes", "no", or "cannot determine/not reported/not applicable" to each item on the tool. In the end, every "yes" represented 1 point. The reviewers added up the points to determine the total score and decide whether the study should be rated as good, fair or poor quality. To prevent bias, the NIH tool does not provide specific parameters to rate the quality as good, fair or poor since each study should be assessed on its own. However, we used parameters as specified in another systematic review as a guide on how to rate the quality, where a score of 0-4 was rated as poor, 5-10 as fair and 11-14 as good (Bagias, Sukumar, Weldeselassie, Oyebode, & Saravanan, 2021). The level of evidence was determined according to the Oxford Centre for Evidence-Based Medicine Levels of Evidence based on each study's design (OCEBM Levels of Evidence Working Group, 2011).

We used the OCEBM hierarchy of evidence (level 1 being the highest level of evidence) as it was created for researchers to easily identify the likely best evidence. The primary reviewer (MK) conducted the quality assessment and the determination of the level of evidence. The second reviewer (BM) cross-checked 20% using a random number generator to ensure reliability. There were disagreements in 5% of the articles, mostly relating to the participation rate. These were resolved by discussion and involving other research team members (VM and DWS).

3.3.6 Data Synthesis

Due to the high heterogeneity of included studies, the synthesis without meta-analysis (SWiM) reporting guidelines as described by Campbell et al. (2020) were used to identify, characterize, and summarize available research evidence on audiological and non-audiological factors influencing hearing help-seeking and hearing aid uptake. Vote counting based on direction of effect was selected as the synthesis method (Campbell et al., 2020). The synthesis was conducted by the primary reviewer (MK) and was approved by the rest of the research team (BM, VM and DWS).

3.4 Results

3.4.1 Search and Study Selection

The search identified 637 records on CINAHL, 781 on MEDLINE and 282 on PsycINFO. After removing 518 duplicates, 1182 records were screened based on their titles and abstracts. Full texts of 46 articles were assessed for eligibility. Of these, eight were excluded (three had an inappropriate study design, two had the wrong publication type and three were focused on an inappropriate outcome, e.g., hearing aid use). Four additional studies were identified through reference checking. Therefore, a total of 42 studies were included in the review (see Figure 3.1).

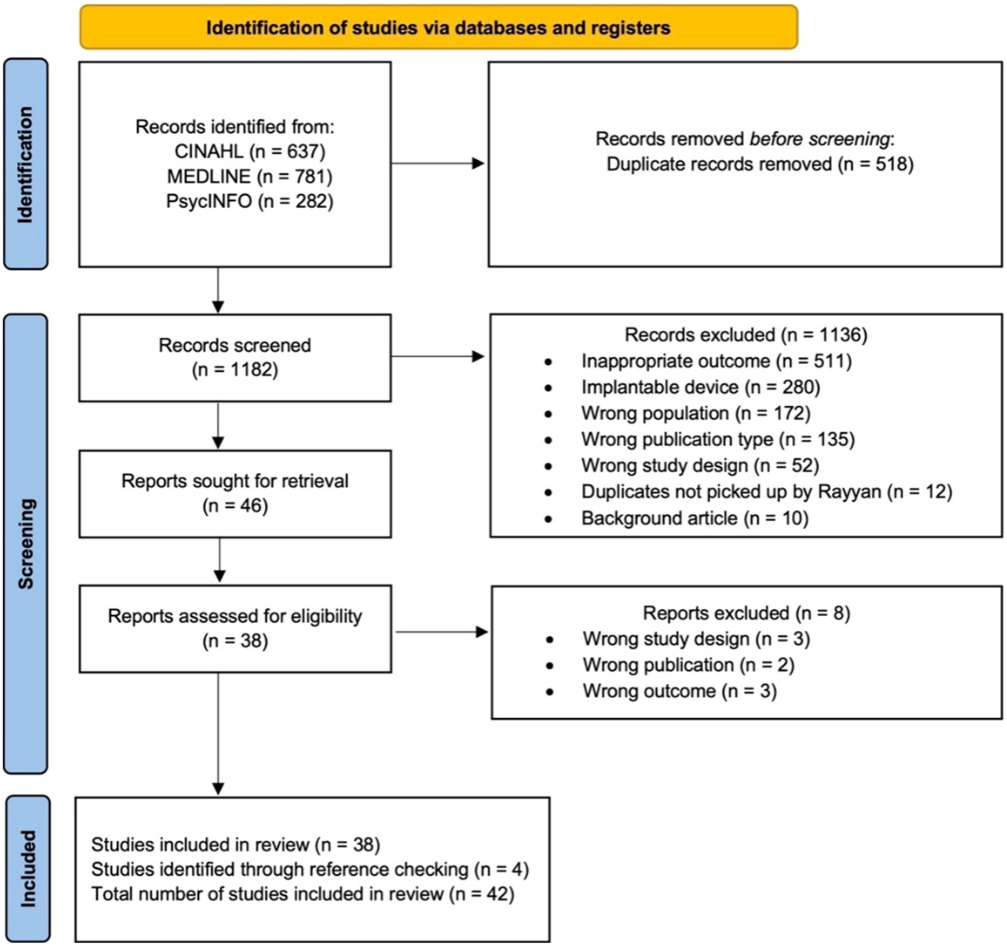

Figure 3.1 PRISMA Flow Diagram of the Selection Process.

3.4.2 Study Characteristics

Table 3.1 summarizes the key characteristics of the included studies (n=42). Sixteen studies were conducted in the Americas (38%), nine in Australia (21%), eight in Europe (19%), five in Asia (12%) and four in the United Kingdom (10%). Most studies were cross-sectional or cohort studies except for one true experimental study (Adorni, Manzi, Crapolicchio, & Steca, 2021) and one cluster randomized controlled trial in which groups of individuals were randomized (Pronk, Meijerink, Kramer, Heymans, & Besser, 2019). Thirty studies (71%) were prospective and twelve were retrospective (29%). Convenience (26% of the studies) and purposive (14% of the studies) sampling were the most used sampling methods. Both these are non-probability sampling techniques. A convenience sample is drawn from a population that is easily accessible to the researcher, whereas a purposive sample is intentionally selected based on the characteristics of the participants that are relevant to the study (Etikan, Musa, & Alkassim, 2016). The sample size ranged from 32 to 60,964 participants. Participant ages ranged from 20 to 77 years. Of the 38 studies that reported the mean age of participants, the average was 68 years. Thirty studies investigated factors influencing hearing aid uptake, four studies investigated factors influencing hearing help-seeking and eight studies investigated factors influencing both. All factors investigated for their potential influence on hearing help-seeking and hearing aid uptake are presented in Tables 3.2-3.5, but only the factors showing at least one positive or negative association are described in the text.

Table 3.1 Key characteristics of included articles (n=42)

Authors	Year	Country	Study design	Sampling method	N	Age (Mean ± SD unless otherwise reported)	Hearing help-seeking	Hearing aid uptake	Level of evidence	Quality rating
Cho et al.	2022	Korea	Cross-sectional survey (P)	NR	1464	70.4 ± 12.2		✔	4	Fair
Weycker et al.	2021	USA	Cohort (P)	NR	579	56.0		✔	3	Fair
Adorni et al.	2021	Italy	True-experimental (P)	Snowball	209	33.9 ± 13.0		✔	2	Fair
Humes & Dubno	2021	USA	Cross-sectional survey (P)	Community sample: convenience Clinic samples: NR	764	Community: 68.6 ± 6.1 Clinic- No HA: 74.5 ± 7.0 Clinic- HA: 75.7 ± 6.7	✔	✔	4	Fair
Van Leeuwen et al.	2021	Netherlands	Cohort (P)	Convenience	218	Across two cohorts: 48.9 ± 10.0 to 49.7 ± 11.1		✔	3	Fair
Tran et al.	2021	USA	Cross-sectional survey (P)	Convenience	1376	54.7 ± 17.4		✔	4	Fair
Maidment & Wege	2021	England	Cross-sectional (R)	N/A	17172	Median: 77.0		✔	4	Fair
Nixon et al.	2021	Australia	Cohort (P)	NR	85	70.2 ± 5.2		✔	4	Fair
Humes	2021	USA	Cohort (P)	Convenience	139	Adherents 74.7 ± 7.7 years Non-adherents 72.7 ± 7.0		✔	3	Fair
Chua Wei De	2021	Singapore	Cross-sectional (R)	N/A	109	Median: 76.0		✔	3	Fair
Angara et al.	2021	USA	Cross-sectional survey (R)	N/A	5230	Range: 20.0-70.0+		✔	4	Fair
Sawyer et al.	2020	England	Cross-sectional (R)	N/A	2845	72.1 ± 9.1	✔	✔	4	Poor
Pronk et al.	2019	Netherlands	Cluster randomized controlled trial (P)	NR	267	66.9		✔	2	Fair
Simpson et al.	2019	USA	Cohort (P)	Snowball	857	Adopted: 69.1 ± 8.6 Not adopted: 70.2 ± 10.6		✔	3	Fair
Mukari & Hashim	2018	Malaysia	Cohort (P)	Stratified cluster random	301	68.4 ± 6.0	✔		3	Fair
He et al.	2018	China	Cross-sectional (R)	Probability proportional	1503	74.5 ± 6.6		✔	4	Fair

Singh & Launer	2018	Canada	Cohort (R)	N/A	24842	75.4 ± 13.5		✔	4	Fair
Chan et al.	2017	USA	Cross-sectional survey (P)	NR	336	Urban: 66.3 Rural: 66.7		✔	4	Fair
Sciacca et al.	2017	Australia	Cross-sectional (P)	Audiologists: Convenience Patients: Purposive	62	71.6 ± 9.1		✔	4	Fair
Pronk et al.	2017	Netherlands	Cross-sectional (P)	Convenience	377	72.6 ± 8.0	✔		4	Fair
Singh & Launer	2016	UK	Cohort (R)	N/A	60964	Alone: 70.4 ± 12.4 With other: 74.5 ± 11.6		✔	4	Fair
Ridgway et al.	2016	Australia	Cohort (P)	NR	216	69.6 ± 10.5		✔	3	Fair
Saunders et al.	2016	USA	Cohort (P)	NR	167	69.3 ± 7.5		✔	3	Fair
Otavio et al.	2016	Brazil	Cross-sectional (P)	NR	32	71.4 ± 12.1		✔	4	Fair
Ridgway et al.	2015	Australia	Cohort (P)	NR	253	69.9 ± 10.5		✔	3	Fair
Moschis et al.	2015	USA	Cross-sectional survey (P)	Purposive	477	58.8 ± 7.1		✔	4	Poor
Benova et al.	2015	England	Cross-sectional survey (R)	N/A	8780	Between 50.0-64.0: 46.4% Between 65.0-74.0: 29.7% 75.0+: 23.9%	✔		4	Fair
Cobelli et al.	2014	Italy	Cross-sectional survey (P)	Purposive	243	69.5 ± 8.3		✔	4	Fair
Meyer et al.	2014	Australia	Cross-sectional (R)	N/A	307	73.0 ± 7.2	✔	✔	4	Fair
Ham et al.	2014	Australia	Cross-sectional survey (P)	NR	251	72.0 ± 7.0	✔	✔	4	Poor
Kelly-Campbell & Parry	2014	USA	Cross-sectional (P)	Purposive	35	Adopters: 64.2 ± 5.1 Non-adopters: 62.0 ± 2.8		✔	4	Good
Saunders et al.	2013	USA	Cross-sectional survey (P)	Convenience	223	Male: 61.1 ± 14.1 Female: 57.7 ± 14.0	✔	✔	4	Fair
Öberg et al.	2012	Sweden	Cross-sectional survey (R)	N/A	346	77.0	✔	✔	4	Fair

Robertson et al.	2012	USA	Cross-sectional (R)	N/A	144	Across three groups: 65.7 ± 2.9 to 67.6 ± 5.5		✔	4	Fair
Meyer et al.	2011	Australia	Cohort (P)	Stratified cluster random	193	67.6 ± 12.3	✔		3	Fair
Fischer et al.	2011	USA	Cohort (P)	NR	718	70.5		✔	3	Fair
Meister et al.	2014	Germany	Cross-sectional survey (P)	Convenience	204	65.2 ± 9.9	✔	✔	4	Fair
Gopinath et al.	2011	Australia	Cohort study (P)	Purposive	1371	Non-owner: 67.1 ± 7.3 Owner: 73.5 ± 7.0 User: 73.6 ± 6.9		✔	3	Fair
Kelly et al.	2011	USA	Cross-sectional (P)	Non-consulters: Convenience Consulters: Purposive	93	Non-consulters: 72.8 ± 4.3 Consulters: 70.6 ± 4.7 Consulters 2: 73.1 ± 6.2	✔	✔	4	Poor
Laplante-Lévesque et al.	2012	Australia	Cross-sectional (P)	Convenience	153	Median: 70.0		✔	4	Fair
Chang et al.	2016	Taiwan	Cross-sectional survey (P)	Convenience	599	72.1 ± 5.8		✔	4	Fair
Tahden et al.	2018	Germany	Cross-sectional (R)	N/A	211	HA non-user: 70.6 ± 5.1 HA user: 72.1 ± 6.1		✔	4	Fair

3.4.3 Hearing Help-Seeking

Forty-two audiological factors (see Table 3.2) and 28 non-audiological factors (see Table 3.3) influencing hearing help-seeking were investigated in the twelve studies that focused on this topic. The number of significant factors (i.e., factors that either showed a positive or negative association) per category is shown in Figure 3.2 and these are discussed below. Significant factors that have not been reported in previous reviews are marked by an asterisk in Tables 3.2 and 3.3. Non-significant factors (i.e., factors that showed no association) are also shown in Tables 3.2 and 3.3. For more detail, see Supplementary Material 1 (Appendix J). Additionally, evidence from previous reviews, as reported by Knudsen et al. (2010) and Meyer and Hickson (2012), is compared to evidence from the present systematic review in Table 3.6.

Table 3.2 Audiological factors influencing hearing help-seeking

Category and factors	No. of studies	Positive association	Negative association	No association
Hearing Sensitivity				
Worst ear PTA (1, 2, 4 kHz)	1	1	-	-
Better ear PTA (0.5, 1, 2 kHz)	1	-	-	1
Better ear PTA (0.5, 1, 2, 4 kHz)	2	1	-	1
Hearing screening				
Hearing screening (1 and 3 kHz)	1	1	-	-
Reason for hearing screening	1	-	-	1
Self-reported Hearing Difficulties and Beliefs				
Perceived hearing loss	1	-	-	1
Self-reported hearing disability	1	1	-	-
Tinnitus	1	-	-	1
Otorrhea	1	-	-	1
Hearing Beliefs Questionnaire:				
Susceptibility	1	1	-	-
Severity	1	-	-	1
Benefits	1	-	-	1
Barriers	1	-	1	-
Self-efficacy	1	-	-	1
Cues to action	1	1	-	-
Communication Difficulties				
Self-assessment of communication	1	1	-	-
Communication Profile for the Hearing Impaired:				
Performance - social	1	-	1	-
Performance - work	1	-	1	-
Performance - home	1	-	1	-
Performance - problem awareness	1	-	1	-
Environment - communication need	1	-	-	1
Environment - physical characteristics	1	-	-	1
Environment - attitudes of others	1	-	-	1

Environment - behaviors of others	1	-	-	1
Strategies - maladaptive behaviors	1	-	-	1
Strategies - verbal strategies	1	-	-	1
Strategies - nonverbal strategies	1	-	-	1
Personal adjustment - self-acceptance	1	-	-	1
Personal adjustment - acceptance of loss	1	-	-	1
Personal adjustment - anger	1	-	-	1
Personal adjustment - displacement of responsibility	1	-	-	1
Personal adjustment - exaggeration of responsibility	1	-	-	1
Personal adjustment - discouragement	1	-	-	1
Personal adjustment - stress	1	-	-	1
Personal adjustment - withdrawal	1	-	-	1
Personal adjustment - denial	1	-	1	-
Expectations and Perceived Benefits from Hearing aids				
Attitude towards hearing aids: Benefits scale	2	2	-	-
Attitude to hearing aids	1	-	-	1
Attitude towards hearing aids: Negative support scale	1	-	-	1
Basic handling scale	1	-	-	1
Considered hearing aids before*	1	1	-	-
Other				
Noise exposure	1	-	-	1

Note: PTA = Pure Tone Average
*Significant factors that have not been reported in previous reviews relevant to the specific outcome

Table 3.3 Non-audiological factors influencing hearing help-seeking

Category and factors	No. of studies	Positive association	Negative association	No association
Demographics				
Age	5	2	-	3
Age participant felt	1	-	-	1
Male sex (vs. female)	6	3	-	3
Ethnicity	2	-	-	2
Marital status	1	-	-	1
Education	3	-	-	3
Area of residence	2	-	-	2
Living situation	1	-	-	1
Retired	1	-	-	1
Socioeconomic Status				
Socioeconomic position	1	-	-	1
Wealth	1	-	-	1
Perceived income	1	-	-	1
Pension	1	-	-	1
Health, Cognition and Mental Health				
Self-reported health*	3	1	1	1
Number of diseases	1	-	-	1
Cognitive performance*	2	1	-	1
Cognitive anxiety*	1	1	-	-
Mental health	2	-	-	2
Social pressure, Stigma and Social Activities				
Social pressure	2	2	-	-
Stigma	1	1	-	-
Number of social activities*	1	-	1	-
Number of leisure activities	1	-	-	1
Attitudes and Behavioral Control				
Attitude to ageing	1	-	-	1
Attitude towards behavior*	1	1	-	-
Behavioral control*	1	1	-	-
Other				
Source of recruitment	1	-	-	1
Technology	1	-	-	1
Recall hearing screening result*	1	1	-	-

*Significant factors that have not been reported in previous reviews relevant to the specific outcome

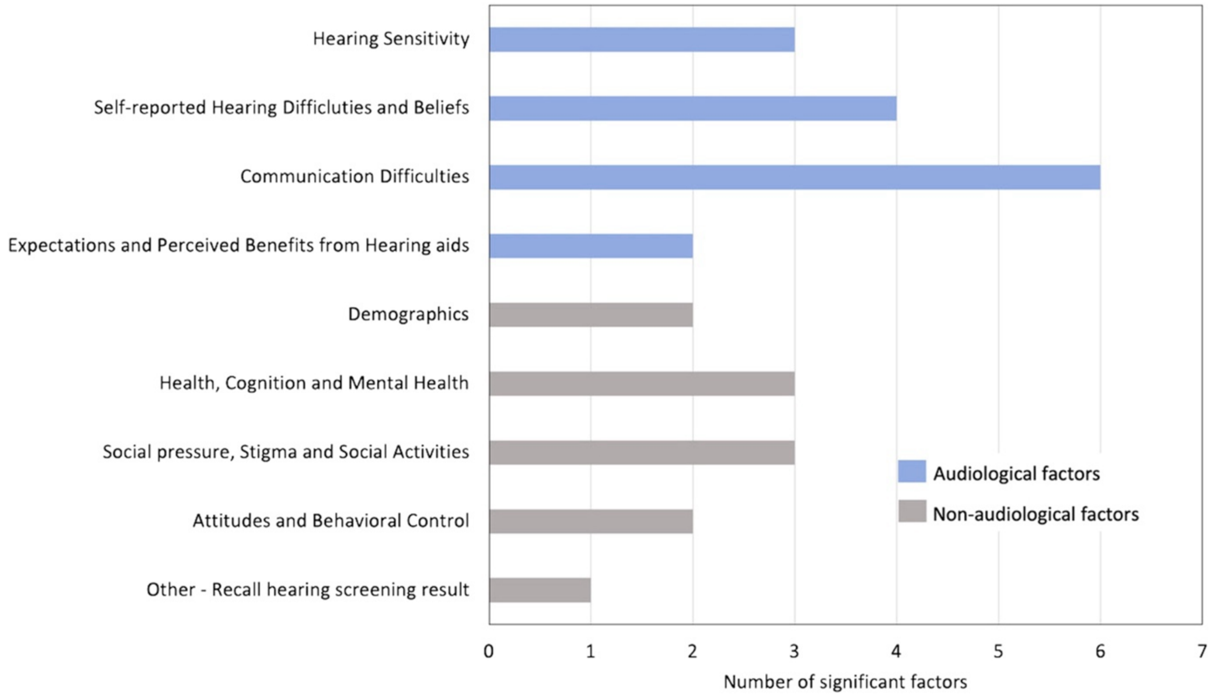

Figure 3.2 Number of Significant Factors Identified Within Studies That Influence Hearing Help-Seeking for Each Category of Audiological or Nonaudiological Factors.

Audiological Factors

Hearing Sensitivity

Hearing sensitivity measured using pure tone audiometry was found to be positively associated with hearing help-seeking in two studies, while two studies did not show any association. Pronk et al. (2017) reported that females (and not males) were more likely to enter a hearing aid evaluation period if they had greater hearing loss severity (determined by the worst ear pure-tone average (PTA) at 1, 2 and 4 kHz). Meyer et al. (2014) reported that people were more likely to seek help if they had greater hearing loss severity (determined by better ear PTA at 0.5, 1, 2 and 4 kHz) relative to people who did not seek help. Additionally, Sawyer et al. (2020) reported that people were more likely to seek help if they had greater hearing loss according to a hearing screening test at 1 and 3 kHz.

Self-reported Hearing Difficulties and Beliefs

Greater self-reported hearing disability was found to be a significant predictor of entering a hearing aid evaluation period in one study (Pronk et al., 2017). A study by Saunders et al. (2013) assessed hearing beliefs within the constructs of the Health Belief Model (HBM). They found that people were more likely to seek help for their hearing loss if they had higher perceived susceptibility to hearing loss, lower perceived barriers to hearing rehabilitation and higher cues to action. Cues to action referred to the participant's experience of cues (intrinsic or extrinsic) prompting him/her to take action (e.g., the participant knew where to get a hearing test).

Communication Difficulties

Perceived communication difficulties were found to be positively associated with hearing help-seeking in two studies. Meyer et al. (2014) reported that older adults were more likely to seek help if they acknowledged their communication difficulties due to their hearing loss. Humes and Dubno (2021) found that people were less likely to seek help if they had better communication performance (in social settings, at work and at home), less awareness of communication problems and greater denial using the Communication Profile for the Hearing Impaired (CPHI).

Expectations and Perceived Benefits from Hearing Aids

Two studies reported that the expected benefits of hearing aids were positively associated with hearing help-seeking. Pronk et al. (2017) found that people were more likely to enter a hearing aid evaluation period if they had more expected benefits of hearing aids. Similarly, Meyer et al. (2014) found that older adults were more likely to seek help for their hearing loss if they perceived there to be many benefits of hearing aids. People were also more likely to seek help for their hearing loss if they had considered hearing aids before in one study (Meyer et al., 2011).

Non-audiological Factors

Demographics

While three studies did not find any associations, Sawyer, Armitage, Munro, Singh, and Dawes (2020), as well as Saunders, Frederick, Silverman, and Papesh (2013), reported increasing help-seeking with increasing age. Three studies (Öberg et al., 2012; Saunders et al., 2013; Sawyer et al., 2020) reported that males were more likely to seek help for their hearing loss than females, although three studies reported no association between sex and help-seeking.

Health, Cognition, and Mental Health

Two studies revealed mixed findings of self-reported health and its association with hearing help-seeking. Sawyer et al. (2020) found that people in later categories of help-seeking (e.g., "told a health professional about hearing loss") had poorer self-reported health. On the other hand, Meyer, Hickson, Lovelock, Lampert, and Khan (2014) found that people were more likely to seek help if they had better self-reported health. Similarly, two studies reported mixed findings on cognitive performance and its association with hearing help-seeking. Sawyer et al. (2020) reported that people were more likely to seek help if they had better cognitive performance, although Öberg et al. (2012) did not show any association. A study by Kelly, Neimeyer, and Wark (2011) concluded that people actively seeking consultation for their hearing loss have higher cognitive anxiety than those who are not seeking help or those who already received assistance. Cognitive anxiety can be defined as a transient state where a person struggles to interpret situations meaningfully and judge their implications (Viney & Westbrook, 1976).

Social Pressure, Stigma and Social Activities

Social pressure as exerted by significant others, for example, was found to be positively associated with hearing help-seeking in two studies. Pronk et al. (2017) reported that people were more likely to enter a hearing aid evaluation period if they experienced greater social pressure. Meister, Grugel, and Meis (2014)used a survey based on the Theory of Planned Behavior (TPB). They also reported the construct “subjective norm,” (i.e., social pressure) to be positively associated with hearing help-seeking, specifically in the initial stages. Females were more likely to seek help if they experienced hearing aid stigma in one study (Pronk et al., 2017). According to one study, people were more likely to tell a health professional about their hearing loss if they participated in fewer social activities (Sawyer et al., 2020).

Attitudes and Behavioral Control

One study reported that those who sought help for their hearing problems were positively affected by the TPB constructs “attitude towards behavior” and “behavioral control” (Meister et al., 2014). Attitude towards behavior refers to whether a person is in favor of doing the behavior and behavioral control relates to whether a person feels in control of the action (Meister et al., 2014).

Other

A study by Meyer et al. (2011) found that people were more likely to seek help if they could accurately recall their hearing screening results.

3.4.4 Hearing Aid Uptake

Ninety-three audiological factors (Table 3.4) and 66 non-audiological factors (Table 3.5) influencing hearing aid uptake were investigated in the thirty-eight studies that investigated this topic. The number of significant factors (i.e., factors that either showed a positive or negative association) per category can be seen in Figure 3.3 and these are discussed below. Significant factors that have not been reported in previous reviews are marked by an asterisk in Tables 3.4 and 3.5. Non-significant factors (i.e., factors that showed no association) are also included in Tables 3.4 and 3.5. For more detail, see Supplementary Material 1 (Appendix J). Additionally, evidence from previous reviews, as reported by Knudsen et al. (2010) and Meyer and Hickson (2012), is compared to evidence from the present systematic review in Table 3.7.

Table 3.4 Audiological factors influencing hearing device uptake

Category and factors	No. of studies	Positive association	Negative association	No association
Hearing Sensitivity				
Hearing screening (1 and 3 kHz)	1	1	-	-
Worst ear PTA (1, 2, 4 kHz)	1	1	-	-
Better ear PTA (0.5, 1, 2, 4 kHz)	11	9	-	2
Better ear PTA (0.5, 1, 2 kHz)	1	-	-	1
PTA (0.5, 1, 2, 4 kHz above 25 dB HL)	2	2	-	-
Mean binaural PTA (0.5, 1, 2 kHz)	1	1	-	-
Mean binaural PTA (0.5, 1, 2, 4 kHz)	1	1	-	-
High-frequency PTA (3, 4, 6, 8 kHz and 2, 3, 4, 6, 8 kHz)	2	2	-	-
Low-frequency PTA (0.25, 0.5, 1 kHz)	1	-	-	1
Degree of hearing loss (e.g. severe to profound)	1	1	-	-
Erber's area (includes hearing thresholds poorer than 35 dB in the frequency range below 1000 Hz)*	1	1	-	-
Bilateral hearing loss*	1	1	-	-
Duration of Hearing Loss and Age of Diagnosis				
Age of hearing loss onset	2	2	-	-
Hearing loss duration	5	3	-	2
Self-reported Hearing Difficulties and Beliefs				
Self-reported hearing difficulties	9	7	-	2
Self-reported hearing disability (e.g. HHI)	11	6	-	5
Difficulty when someone whispers*	1	1	-	-
Hearing disability perceived by others	1	-	-	1
Hearing difficulties perceived by others*	1	1	-	-
Disturbance to daily life	1	-	-	1
Uses closed captions*	1	1	-	-
Tinnitus	3	-	-	3
Vertigo	1	-	-	1
Hearing beliefs questionnaire:				
Susceptibility	2	1	-	1
Severity	2	1	-	1
Benefits	2	2	-	-
Barriers	2	-	1	1
Self-efficacy	2	1	-	1
Cues to action	2	2	-	-
Speech Perception				
Signal-to-noise ratio loss*	2	2	-	-
Speech recognition threshold*	2	1	-	1
Word recognition score	1	-	-	1
Word recognition in quiet	1	-	-	1
Low-context sentence recognition in babble*	1	-	1	-
High-context sentences in babble	1	-	-	1
Connected Speech Test	1	-	-	1
Acceptable Noise Level	1	-	-	1
Audiology Appointment, Assessment and Consultation				
Self-referred for hearing test*	1	1	-	-
First hearing aid consultation institution*	1	1	-	-
Hearing aid recommendation	1	-	-	1

Recent hearing test*	2	2	-	-
Participant's recommendation of dispenser services	1	-	-	1
Consulted audiologist*	1	1	-	-
Consulted ear, nose and throat doctor	1	-	-	1
Consulted hearing aid dispenser*	1	1	-	-
Referral source	1	-	-	1
Later time of the day (vs. earlier)*	1	-	1	-
Day of the week	1	-	-	1
Attending appointment with other	1	1	-	-
Language	1	-	-	1
Health literacy	1	-	-	1
Medical language*	1	1	-	-
Flesch–Kincaid reading grade level of audiologist talk*	1	-	1	-
Audiologists' number of sentences	1	-	-	1
Communication Difficulties				
Communication partner assignment	1	-	-	1
Perceived communication program effectiveness	1	-	-	1
Perceived suitability of the individual program*	1	-	1	-
Communication self-efficacy*	1	-	1	-
Perceived likely adherence	1	-	-	1
Perceived suitability of group program	1	-	-	1
Other people's recommendation of the communication programs	1	-	-	1
Communication Profile for the Hearing Impaired:				
Performance - social	2	-	2	-
Performance - work	2	-	2	-
Performance - home	2	-	2	-
Performance - problem awareness	2	2	-	-
Environment - communication need	2	-	-	2
Environment - physical characteristics	2	-	-	2
Environment - attitudes of others	2	-	-	2
Environment - behaviors of others	2	-	-	2
Strategies - maladaptive behaviors	3	-	-	3
Strategies - verbal strategies	3	1	-	2
Strategies - nonverbal strategies	3	2	-	1
Personal adjustment - self-acceptance	3	1	-	2
Personal adjustment - acceptance of loss	3	1	-	2
Personal adjustment - anger	2	-	-	2
Personal adjustment - displacement of responsibility	2	1	-	1
Personal adjustment - exaggeration of responsibility	2	1	-	1
Personal adjustment - discouragement	2	-	-	2
Personal adjustment - stress	3	-	-	3
Personal adjustment - withdrawal	3	-	1	2
Personal adjustment - denial	2	-	1	1
Belief, Expectation and Understanding of Hearing aids				
HearSupport received*	1	1	-	-
Understanding HA function*	1	1	-	-
Hearing aid handling*	2	1	-	1
Desire for hearing aids	2	-	-	2
Concerns about hearing aid cost and practices	1	-	-	1
Attitude towards hearing aids: Benefits scale	1	1	-	-
Attitude towards hearing aids	2	2	-	-
Attitude towards hearing aids: Negative support scale	1	-	1	-

Expected Consequences of Hearing Aid Ownership:				
Positive effects	1	1	-	-
Negative effects	1	-	-	1
Service and cost	1	1	-	-
Personal image	1	1	-	-

Note: PTA = Pure Tone Average, HHI = Hearing Handicap Inventory

*Significant factors that have not been reported in previous reviews relevant to the specific outcome

Table 3.5 Non-audiological factors influencing hearing device uptake

Category and factors	No. of studies	Positive association	Negative association	No association
Demographics				
Age	25	8	1	16
Duration in old-age roles	1	-	-	1
Number of transitions experienced	1	-	-	1
Male sex (vs. female)	20	3	1	16
White race (vs. other)	4	2	-	2
Education	12	4	-	8
Country of birth	1	-	-	1
Urban area of residence (vs. rural)*	2	2	-	-
Living situation	3	-	-	3
Marital status	5	1	-	4
Household size	1	-	-	1
Job	2	-	-	2
Job control	1	-	-	1
Psychological job demand*	1	1	-	-
Need for recovery after work	1	-	-	1
Retired	1	-	-	1
Socioeconomic Status				
Socioeconomic status	5	3	-	2
Household income*	2	1	-	1
Income	2	-	-	2
Poverty income ratio	1	-	-	1
Pension*	1	1	-	-
Hearing Healthcare Funding and Health Insurance				
Eligibility for subsidized hearing services	1	-	-	1
Applied for subsidized hearing services*	1	1	-	-
Government assistance*	1	1	-	-
Senior Mobility Fund*	1	1	-	-
Health insurance*	2	1	-	1
Health				
Self-reported health	4	2	2	-
Chronic health conditions	1	-	-	1
Self-reported diabetes*	1	-	1	-
Self-reported hypertension*	1	-	1	-
Self-reported dementia	1	-	-	1
Self-reported history of stroke*	1	-	1	-
Number of diseases	1	-	-	1
Cognition and Mental Health				
Cognition	3	-	-	3
Cognitive reasoning: similarities*	1	1	-	-
Cognitive anxiety*	2	2	-	-
Mental health	2	-	-	2
Distress	1	-	-	1
Attention	1	-	-	1
Psychomotor function	1	-	-	1
Executive function	1	-	-	1
Visual learning	1	-	-	1
Working memory	1	-	-	1
Loneliness scale	1	-	-	1

Social network	1	-	-	1
Anxiety	1	-	-	1
Depression	1	-	-	1
Memory	1	-	-	1
Affect and personality	1	-	-	1
Emotional response	1	-	-	1
Motivation, Support, Subjective Norms and Trust				
Autonomous motivation*	2	2	-	-
Autonomous support	1	-	-	1
Controlled motivation	1	-	-	1
Subjective norm	2	2	-	-
Trust	1	-	-	1
Attitude X trust	1	-	-	1
Subjective norm X trust*	1	1	-	-
Attitudes towards Behavior and Control				
Behavioral control*	1	1	-	-
Attitude towards behavior*	1	1	-	-
Locus of control	1	-	-	1
Readiness for Change				
Precontemplation	3	1	-	2
Contemplation	3	2	-	1
Action	3	1	-	2
Committed action	1	-	-	1
Other				
Self-efficacy	1	-	-	1
Technology commitment	2	1	-	1

*Significant factors that have not been reported in previous reviews relevant to the specific outcome

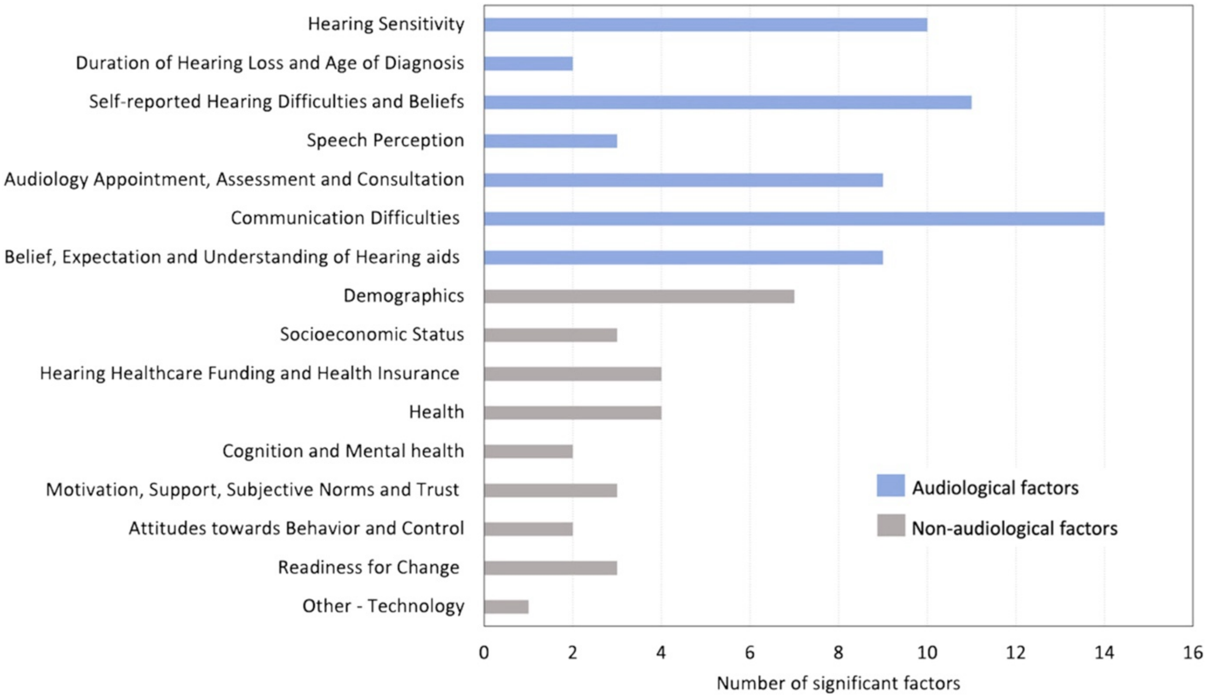

Figure 3.3 Number of Significant Factors Identified Within Studies That Influence Hearing Aid Uptake for Each Category of Audiological or Nonaudiological Factors.

Audiological Factors

Hearing Sensitivity

Twenty studies found a positive association between greater hearing loss (i.e., poor hearing sensitivity measured using the pure tone audiometry) and hearing aid uptake, while four studies showed no association. These studies used various measures to define hearing sensitivity (e.g., better ear pure tone average (PTA) at 0.5, 1, 2 and 4 kHz)(see Table 3.5). A study by Robertson, Kelly-Campbell, and Wark (2012) reported that participants were more likely to purchase hearing aids if their audiograms fell within Erber's area (hearing thresholds poorer than 35 dB HL in the frequency range below 1000 Hz). One study found that people were more likely to adopt hearing aids if they had bilateral, as opposed to unilateral hearing loss (Angara et al., 2021).

Duration of Hearing Loss and Age of Diagnosis

Two studies reported positive associations between the age of hearing loss onset and hearing aid uptake. Chan et al. (2017) reported that age of hearing loss onset was correlated with time to hearing aid acquisition, older people acquiring hearing aids more quickly than younger people, and Moschis, Lee, Mathur, Rigdon, and Fatt (2015) concluded that the older the person at the time of diagnosis, the more likely they were to purchase a hearing aid. Three studies reported that people were more likely to take up hearing aids if they had a longer hearing loss duration (Cho et al., 2022; Moschis et al., 2015; Saunders et al., 2016), although two studies reported no association.

Self-reported Hearing Difficulties and Health Beliefs

Seven studies reported a positive association between poor self-reported hearing difficulties and hearing aid uptake (For example: Angara et al., 2021; Fischer et al., 2011), while two studies showed no association. A study by Gopinath et al. (2011) also reported that people were more likely to adopt hearing aids if they reported having difficulty hearing when someone whispered. One study reported that people were more likely to adopt hearing aids if they used closed captions or if their hearing difficulties were perceived by others (Weycker et al., 2021). Six studies reported a positive association between self-reported hearing disability and hearing aid uptake, although five studies reported no association. Five studies used various versions of the Hearing Handicap Inventory (HHI) (Fischer et al., 2011; Gopinath et al., 2011; Saunders, Frederick, Silverman, Nielsen, & Laplante-Lévesque, 2016; Simpson et al., 2019; Weycker et al., 2021) and one study used the Amsterdam Inventory for Auditory Disability and Handicap (AIADH) (van Leeuwen et al., 2021). Two studies investigated hearing beliefs within the constructs of the health belief model (Saunders et al., 2016, 2013). Saunders et al. (2013) found that people were more likely to adopt hearing aids if they had higher perceived susceptibility to hearing loss, higher perceived benefits of hearing and rehabilitation, lower perceived barriers to hearing rehabilitation, and higher cues to action. Saunders et al. (2016) found that people were more likely to adopt hearing aids if they had higher perceived severity of hearing loss, higher perceived benefits of hearing and rehabilitation, higher perceived self-efficacy regarding hearing rehabilitation, and higher cues to action.

Speech Perception

Two studies found that people were more likely to adopt hearing aids if they had a higher signal-to-noise ratio loss, which represented the dB increase in signal-to-noise ratio required by the participant to understand speech in noise compared to people with normal hearing, measured using the Quick Speech in Noise (QuickSIN) test (Kelly-Campbell & Parry, 2014; Robertson et al., 2012). Two studies reported mixed findings on speech recognition thresholds (SRT) and its association with hearing aid uptake. Robertson et al. (2012)found that people who purchased hearing aids had higher SRTs than those who did not purchase hearing aids, although van Leeuwen et al. (2021) reported no association. The SRTs were measured for each ear using monitored live voice and the Central Institute for the Deaf W-1 spondaic word list (Hirsh et al., 1952). A study by Simpson et al. (2019) reported that people were more likely to adopt hearing aids if they had the poorest low-context sentences-in-babble scores.

Audiology Appointment, Assessment and Consultation

Two studies reported on the association between a recent hearing test and hearing aid uptake. Angara et al. (2021) and He et al. (2018) found that people were more likely to adopt hearing aids if they had received a hearing assessment. A study by Saunders et al. (2016) reported that people were more likely to obtain hearing aids if they self-referred for a hearing test. One study reported that people were more likely to adopt hearing aids if they had their first hearing aid consultation at a hearing aid centre instead of a hospital (Cho et al., 2022). A study by Moschis et al. (2015) concluded that people were more likely to take up hearing aids if they had a consultation with either an audiologist or hearing aid dispenser. One study found that people were less likely to take up hearing aids if their appointment was scheduled at 12 pm and 4 pm compared to earlier in the day (Singh & Launer, 2018). A study by Singh and Launer (2016) reported that people were more likely to adopt hearing aids if they attended an audiology appointment with a significant other. Two studies reported on the relationship between the healthcare professional's language and hearing aid uptake. Adorni et al. (2021)concluded that people were more likely to obtain hearing aids if the family doctor used medical language. On the other hand a study by Sciacca, Meyer, Ekberg, Barr, and Hickson (2017) found that patients were less likely to obtain hearing aids if the audiologists' language was at higher reading grade level measured using the Flesch–Kincaid readability formula.

Communication Difficulties

A study by Laplante-Lévesque et al. (2012) investigated the predictors of the uptake of hearing aids and communication programs. They found that people were more likely to complete communication programs and less likely to adopt hearing aids if they perceived greater suitability of the individual communication program. In addition, people were less likely to adopt hearing aids if they reported greater communication self-efficacy (Laplante-Lévesque et al., 2012). Two studies used the CPHI to investigate the relationship between communication profile and hearing aid uptake. Humes (2021) and Humes and Dubno (2021) found that people were more likely to obtain hearing aids if they had poorer communication performance (in social settings, at work and at home), more awareness of communication problems and better use of non-verbal communication strategies as assessed using the CPHI. Humes and Dubno (2021) also reported that people who decided to obtain hearing aids were more accepting of their hearing loss but allocated more responsibility for difficulties to their communication partners, whereas Humes (2021) found that people who decided to obtain hearing aids had better use of verbal communication strategies, lower self-acceptance of hearing loss, less exaggeration of responsibility, less withdrawal and less denial of communication difficulties.

Belief, Expectation and Understanding of Hearing Aids

According to one study, people who received a support program (HearSupport) were more likely to take up hearing aids (Pronk et al., 2019). A study by He et al. (2018) reported that people were more likely to adopt hearing aids if they understood hearing aid function. Two studies reported on hearing aid handling and its relationship with hearing aid uptake. Meyer et al. (2014) found that successful hearing aid owners perceived that they could better manage the basic functions of their hearing aids, although Pronk et al. (2019) reported no association. Two studies reported that people were more likely to adopt hearing aids if they had a positive attitude toward hearing aids (Cobelli, Gill, Cassia, & Ugolini, 2014; Meyer et al., 2014). A study by Meyer et al. (2014) concluded that people were more likely to take up hearing aids if they perceived more benefits of hearing aids and experienced more support for hearing aids from significant others. One study reported that people who did not take up hearing aids had lower expectations for hearing aids according to the Expected Consequences of Hearing Aid Ownership (ECHO) scale (Humes, 2021). This assessed the positive effects of hearing aids, service and cost as well as personal image (Humes, 2021).

Non-audiological Factors

Demographics

While 16 studies reported no association, eight studies reported that people were more likely to adopt hearing aids if they were older (Angara et al., 2021; Gopinath et al., 2011; Maidment & Wege, 2021; Saunders et al., 2016, 2013; Sawyer et al., 2020; Singh & Launer, 2016, 2018). Conversely, Chang et al. (2016) reported that people were more likely to accept a hearing aid if they were younger in an older cohort (65 – 90 years of age). While 16 studies found no association, Angara et al. (2021), Chang et al. (2016) and Öberg et al. (2012) found a positive association between sex (being male) and hearing aid uptake, whereas Simpson et al. (2019) found that females were more likely to adopt hearing aids. Two studies by Angara et al. (2021) and Simpson et al. (2019) reported that people were more likely to take up hearing aids if they were white people, whereas two studies reported no association. While 8 studies showed no association, four studies (Angara et al., 2021; Cho et al., 2022; Fischer et al., 2011; Weycker et al., 2021) found that people were more likely to take up hearing aids if they had a higher education. Two studies by Chan, Hixon, Adkins, Shinn, and Bush (2017) and He et al. (2018) reported that people were more likely to adopt hearing aids and to adopt them more quickly if they were urban residents compared to rural residents. Whereas four studies reported no association, one study concluded that people were more likely to obtain hearing aids if they were married compared to single (van Leeuwen et al., 2021). One study by van Leeuwen et al. (2021) found that males were more likely to take up hearing aids if they perceived higher psychological job demand (i.e., the psychological requirements for an employee's tasks).

Socioeconomic Status

Four studies reported that people were more likely to take up hearing aids if they had higher socioeconomic status or household income (Cho et al., 2022; Laplante-Lévesque et al., 2012; Simpson et al., 2019; Tahden et al., 2018), although three studies did not report any association. A study by Meyer et al. (2014) reported that older adults were more likely to obtain hearing aids if they received a pension.

Hearing Healthcare Funding and Health Insurance

According to four different studies, people were more likely to adopt hearing aids if they applied for subsidized hearing services (Laplante-Lévesque et al., 2012), received government assistance (Cho et al., 2022), senior mobility fund (Chua Wei De, 2021) or had health insurance

(Tran et al., 2021). A study by Angara et al. (2021), however, reported no association between health insurance and hearing aid uptake.

Health

As with hearing help-seeking, mixed findings were reported regarding self-reported health and its association with hearing aid uptake in four studies. Öberg et al. (2012) and Tahden et al. (2018) found that people were more likely to own a hearing aid if they had better self-reported health. In contrast, Nixon, Sarant, Tomlin, and Dowell (2021) and Sawyer et al. (2020) found that people were more likely to take up hearing aids if they had poorer self-reported health. Two studies reported on comorbidities and their relationship with hearing aid uptake. People were less likely to adopt hearing aids if they had self-reported diabetes (Maidment & Wege, 2021), hypertension (Maidment & Wege, 2021) or a history of stroke (Gopinath et al., 2011).

Cognition and Mental Health

A study by Meyer et al. (2014) reported that people were more likely to obtain hearing aids if they had better cognitive reasoning skills. Two studies by Kelly-Campbell and Parry (2014) and Kelly et al. (2011) reported that people were more likely to take up hearing aids if they experienced higher cognitive anxiety.

Motivation, Support, Subjective Norms, and Trust

According to two studies by Ridgway, Hickson, and Lind, (2015, 2016), people were more likely to take up hearing aids if they had autonomous motivation. Two studies reported a positive relationship between the "subjective norm" construct of the TPB (i.e., social pressure) and hearing aid uptake (Cobelli et al., 2014; Meister et al., 2014). Cobelli et al. (2014), however, reported a significant interaction between subjective norm and trust, indicating that when trust in the health professional was high, subjective norm was not significantly related to hearing aid uptake. When there was a lower level of trust in the health professional, subjective norm was strongly related to hearing aid uptake.

Attitude towards Behavior and Control

In one study, hearing aid uptake was positively affected by the "attitude towards behavior" and "behavioral control" constructs of the TPB (Meister et al., 2014).

Readiness for Change

Three studies used the University of Rhode Island change assessment to investigate readiness for change. Saunders et al. (2016) found that those who took up hearing aids had lower pre-contemplation scores (problem denial), higher contemplation scores (problem awareness and evaluation of the pros and cons of change) and higher action scores (devoting time and energy to behavior change). Pronk et al. (2019) and Laplante-Lévesque et al. (2012), however, did not report any association between hearing aid uptake and pre-contemplation or action scores. Similar to Saunders et al. (2016), Laplante-Lévesque et al. (2012) also found that people who took up hearing aids had higher contemplation scores (i.e., they acknowledged their hearing loss and compared the pros and cons of intervention uptake), although Pronk et al. (2019) did not report any association.

Other: Technology Commitment

Two studies reported on the influence of technology commitment on hearing aid uptake. Tahden et al. (2018)reported that people were more likely to own hearing aids if they had a technology commitment, although Ham, Bunn, Meyer, Khan, & Hickson (2014) reported no association. Technology commitment included technology competence, acceptance, control, and usage habits of media devices.

Table 3.6 Combined evidence from previous reviews, including Knudsen et al. (2010) and Meyer and Hickson (2012), and the current systematic review (2011-2022) on factors influencing hearing help-seeking

Audiological factors						
Factor	**Previous reviews (<2012)**		**Current systematic review (2011-2022)**		**Combined**	
	No. of studies	**Results**	**No. of studies**	**Results**	**No. of studies**	**Results**
Attitudes towards hearing aids	1	0	1	0	2	0, 0
Attitudes towards own hearing loss	1	- (coping style)	No data		1	-
Self-reported hearing problems (and/or activity limitation,	5	+, +, +, +, +	2	+ (self-reported hearing disability), 0	7	+, +, +, +, +, +, 0

participation restriction)				(self-perceived HL)		
Hearing sensitivity	5	+, +, +, +, 0	5	+, +, +, 0, 0	10	+, +, +, + , +, +, +, 0, 0, 0
Age of hearing loss onset	1	+ (before 65 years)	No data		1	+
Acknowledge hearing loss	1	+	1	+ (Self-assessment of communication)	2	+, +
Hearing screening	1	+	1	+	2	+, +
			Non-audiological factors			
Age	4	+, 0, 0, 0	5	+, +, 0, 0, 0	9	+, +, +, 0, 0, 0, 0, 0, 0
Male sex (vs. female)	4	0, 0, 0 , 0	6	+, +, +, 0, 0, 0	10	+, +, +, 0, 0, 0, 0, 0, 0, 0
Education	1	+	3	0, 0, 0	4	+, 0, 0, 0
Motivation	2	+ (others) + (client, health professional and family)	2	+, + (both social pressure)	4	+, +, +, +
General practitioner	1	-	No data		1	-
Personality*	1	+ (lower neuroticism, lower openness, pragmatic and routine orientated, higher internal locus of control)	No data		1	+

Note: Four studies from the Meyer and Hickson (2012) review were excluded from the table, including Carson (2005) and Wallhagen (2010) because they are qualitative studies as well as Kochkin (2007) and Kochkin (2009) because they are not peer-reviewed papers. "+" indicates a positive association between the factor and the outcome, "–" a negative association, "0" no association. *Factors including multiple outcomes.

Table 3.7 Combined evidence from previous reviews, including Knudsen et al. (2010) and Meyer and Hickson (2012), and the current systematic review (2011-2022) on factors influencing hearing aid uptake

Audiological factors						
Factor	**Previous reviews (<2012)**		**Current systematic review (2011-2012)**		**Combined**	
	No. of studies	**Results**	**No. of studies**	**Results**	**No. of studies**	**Results**
Attitudes towards hearing aids	1	+	2	+, +	3	+, +, +
Attitudes towards own hearing loss*	3	+ Acceptance of hearing loss + Distress + Problem awareness - Denial of problems - Self-acceptance - Maladaptive behavior	No data		3	+ Acceptance of hearing loss + Distress + Problem awareness - Denial of problems - Self-acceptance - Maladaptive behavior
Expectations*	2	0, + (impact on quality of life and would not be negatively perceived by others)	1	+ Positive effects 0 Negative effects +Service and cost + Personal image	3	0, + (impact on quality of life and would not be negatively perceived by others), + Positive effects + Service and cost + Personal image 0 Negative effects
Self-reported hearing problems (and/or activity limitation, participation restriction)	5	+, +, + , +, +	25	+, +, +, +, +, +, +, 0, 0 (self-reported hearing difficulties) +, +, +, +, +, +, +, +, +, +, +, 0, 0, 0, 0, 0 (self-reported hearing disability)	30	+, 0, 0, 0, 0, 0, 0, 0
Hearing sensitivity	5	+, +, +, +, -	22	+, +, +, +, +, +, +, +, +, +, +, +, +, +, +, +, +, +, 0, 0, 0, 0	27	+, -, 0, 0, 0, 0
Age of hearing loss onset	1	0	2	+, +	3	+, +, 0
Duration of hearing loss	1	0	5	+, +, +, 0, 0	6	+, +, +, 0, 0, 0
Speech reading	1	0	No data		1	0
Hearing screening	1	+	1	+	2	+, +

Willingness to use HAs	1	+	No data		1	+
Non-audiological factors						
Age	4	+, +, 0, 0	25	+, +, +, +, +, +, +, +, -, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0,	29	+, +, +, +, +, +, +, +, +, +, -, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0
Male sex (vs. female)	4	0, 0, 0, 0	20	+, +, +, -, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0	24	+, +, +, -, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0
Socio-economic status	4	+, 0, 0, 0	5	+, +, +, 0, 0	9	+, +, +, +, 0, 0, 0, 0, 0
Living arrangement	4	+, 0, 0, 0	3	0, 0, 0	7	+, 0, 0, 0, 0, 0, 0
Education	5	+, - (higher education), 0, 0, 0	12	+, +, +, +, 0, 0, 0, 0, 0, 0, 0, 0	17	+, +, +, +, +, -, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0
Social interaction	1	0	No data		1	0
Cost concerns	1	-	No data		1	-
Marital status	2	0, 0	5	+, 0, 0, 0, 0	7	+, 0, 0, 0, 0, 0, 0
Health	1	0	4	+, +, -, -	5	+, +, -, -, 0
General health attitude	1	0	No data		1	0
Technology	1	- (internet and email)	2	+, 0	3	+, -, 0
Personality*	1	+ responsibility for communication problems + locus of control and ego strength in females	1	0	2	+ responsibility for communication problems + locus of control and ego strength in females, 0
White race (vs. other)	1	+	4	+, +, 0, 0	5	+, +, +, 0, 0

Note: Four studies from the Meyer and Hickson (2012) review were excluded from the table, including Carson (2005) and Wallhagen (2010) because they are qualitative studies as well as Kochkin (2007) and Kochkin (2009) because they are not peer-reviewed papers. "+" indicates a positive association between the factor and the outcome, "–" a negative association, "0" no association. *Factors including multiple ouctomes.

3.4.5 Level of Evidence

The level of evidence according to the OCEBM for each study is indicated in Table 3.1. Twenty-eight cross-sectional studies (67%) were classified as level four evidence, 12 cohort studies (29%) as level three evidence and two studies (one true experimental study and one cluster randomized control trial)(5%) as level two evidence.

3.4.6 Quality Assessment

The NIH quality assessment tool was used to assess the quality of each study included in the review. Quality ratings are shown in Table 3.1. Thirty-six studies (86%) were rated fair quality, two (5%) good quality and four (10%) poor quality. The quality assessment showed a few poor areas. Firstly, only 7% of the studies gave a sample size justification, power description or variance and effect estimates. Secondly, most studies were cross-sectional and therefore 74% of the studies did not measure the exposure(s) (i.e., audiological or non-audiological factors) before the outcomes (hearing help-seeking and/or hearing aid uptake) but instead measured it at the same time. For the same reason, most studies (86%) did not measure the exposure(s) more than once. Thirdly, 79% of the studies used self-report measures to determine the outcomes (hearing help-seeking and/or hearing aid uptake). Lastly, none of the studies reported blinding.

3.5 Discussion

This systematic review examined audiological and non-audiological factors influencing hearing help-seeking and hearing aid uptake in adults with hearing loss based on literature published between January 2011 and February 2022. Identified studies investigated 70 (42 audiological and 28 non-audiological) hearing help-seeking factors and 159 (93 audiological and 66 non-audiological) hearing aid uptake factors with many reported only once (10/70 and 62/159 respectively). Some of the key identified audiological and non-audiological factors will be discussed below.

3.5.1 Audiological factors

As opposed to hearing help-seeking, audiological factors influencing hearing aid uptake have been widely studied (see Tables 3.6 and 3.7). However, some new factors emerged in the present review, including the health professional's language usage. Adorni et al. (2021) found that medical language compared to everyday language was more effective in persuading people to obtain hearing aids. Authors suggest that everyday language might come across as inappropriate and unprofessional, leading to mistrust in the health professional. Sciacca et al. (2017) found that patients were less likely to obtain hearing aids if the audiologists' language was at a higher Flesch–Kincaid reading grade level. They concluded that reduced understanding might limit the patient's involvement in decision-making and cause them to be less willing to take up hearing aids. Therefore, hearing healthcare professionals should consider accessible use of medical language, that still keep the dialogue clear and understandable. Two studies also found that understanding hearing aid function affected hearing aid uptake positively. Additionally, a cluster randomized controlled trial by Pronk et al. (2019) showed that receiving a program (HearSupport) that includes information on hearing aid handling positively affected hearing aid uptake. This emphasizes the importance of counseling regarding hearing aid function and handling even before the patient has made the decision to take up hearing aids.

Like the present review, Meyer and Hickson (2012) as well as Knudsen et al. (2010) found that evidence on hearing sensitivity in relation to help-seeking is less clear compared to hearing aid uptake. In total (including studies from the current review and previous reviews), 10 studies have investigated the influence of hearing sensitivity on hearing help-seeking (Table 3.6), whereas 27 studies investigated the influence of hearing sensitivity on hearing aid uptake (Table 3.7). In the present review, three studies found positive associations between poorer hearing sensitivity and hearing help-seeking, while two studies did not find any associations. The severity of hearing loss was one of the strongest predictors of hearing aid uptake, as also reported by Meyer and Hickson (2012), whether it was measured by PTA (20/24 studies showed positive associations), speech perception testing (4/10 studies showed positive associations) or self-report (7/9 studies showed positive associations). In line with earlier reviews by Knudsen et al. (2010) and Meyer and Hickson (2012), self-reported hearing disability was also a strong predictor of hearing aid uptake (Table 3.7). Six studies found a positive association between greater self-reported disability using standardized tools and hearing aid uptake, whereas five did not find any association. As recommended by Humes and Dubno (2021), measuring self-reported hearing disability in addition to pure tone audiometry during the initial assessment can provide valuable information regarding hearing aid candidacy.

For help-seeking previous reviews identified factors like self-reported hearing disability, hearing beliefs and communication profile as important (Knudsen et al., 2010; Meyer & Hickson, 2012). In the present review, greater self-reported hearing disability was reported to be a significant predictor of entering a hearing aid evaluation period by Pronk et al. (2017).

Using the Health Belief Questionnaire (HBQ), Saunders et al. (2013)found that help-seekers had higher perceived susceptibility to hearing loss, lower barriers to hearing rehabilitation and higher cues to action compared to non-help seekers. Humes and Dubno (2021) used the CPHI and concluded that older adults with self-awareness of hearing loss were more likely to seek help. Consistent with Meyer and Hickson (2012), two studies found positive associations between perceived benefits of hearing aids and help-seeking. People who considered hearing aids before seeking help were also more likely to seek help for their hearing problems (Meyer et al., 2011). Similarly, Meyer et al. (2014)concluded that participants who perceived more benefits of hearing aids and experienced their significant others being more supportive of hearing aids were more likely to take up hearing aids. People with positive attitudes towards hearing aids were found to be more likely to adopt hearing aids in two studies, as also reported by Knudsen et al. (2010).

3.5.2 Non-audiological factors

Several new non-audiological predictors not previously reported in systematic reviews were identified, including cognitive anxiety for both hearing help-seeking and hearing aid uptake (Kelly-Campbell & Parry, 2014; Kelly et al., 2011). People with hearing loss are at increased risk of cognitive anxiety because they cannot anticipate communication breakdowns due to missing conversations, and seeking treatment may help decrease this anxiety (Kelly et al., 2011). Being aware of the signs of cognitive anxiety, as described in Kelly et al. (2011), can potentially assist hearing healthcare professionals in determining readiness for intervention.

Two studies also demonstrated for the first time that urban residents were more likely to purchase hearing aids and to purchase them more quickly than rural residents (Chan et al., 2017; He et al., 2018). Rural residents typically have less access to hearing healthcare services, less education and lower socioeconomic statuses than urban residents, which also influences hearing aid uptake (Chan et al., 2017). This highlights the importance of more accessible hearing healthcare services in rural areas.

Having access to financial support (whether receiving an income or funding from a third party) clearly affected hearing aid uptake in the present review. Three studies showed positive associations between higher socioeconomic status and hearing aid uptake. A higher household income, receiving a pension, applications for subsidized hearing services, government funding and having health insurance were all linked to hearing aid uptake in six studies.

Comorbidities considered as risk factors for hearing loss, like diabetes, hypertension and history of stroke, were all negatively associated with hearing aid uptake (Kuo, Shiao, Wang, Chang, & Lin, 2016; Nawaz et al., 2021; Samocha-Bonet, Wu, & Ryugo, 2021). This may be because people with chronic illnesses may have a more limited capacity to manage their hearing loss due to time, money and other potential constraints. Thus, hearing healthcare professionals should focus on high-risk populations by, for example, performing hearing screenings to ensure that they receive the appropriate treatment.

Key non-audiological factors reported in previous reviews were also confirmed by the current review. As shown in an earlier review (Knudsen et al., 2010), age and sex were the most studied factors in the present review (see Tables 3.6 and 3.7). Knudsen et al. (2010) concluded that age and sex show no relationship with hearing help-seeking or hearing aid uptake. In the present review, older age, which is linked to increasing hearing loss prevalence and severity (World Health Organization, 2021), was associated with hearing help-seeking, although three of the five studies did not report a significant association. Older age generally resulted in hearing aid uptake but not in all studies. In an older adult cohort (65 – 90 years of age), hearing aid uptake was greater for those closer to 65 years of age (Chang et al., 2016). Thus, it is important to consider the age range of participants in a study that aims to investigate the effect of age on other variables.

Generally, males (who are more likely to have hearing loss; Hoffman, Dobie, Losonczy, Themann, & Flamme, 2017) were also more likely to seek help for their hearing problems, although some studies (3/6) showed no association. The majority of studies (16/20) did not report different associations across sex but in three studies males were more likely to adopt hearing aids while in one study females were more likely. As in previous reviews (Knudsen et al., 2010; Meyer & Hickson, 2012), the present review demonstrates a positive association between social pressure and hearing help-seeking (Table 3.6). Hearing aid uptake was also positively affected by social pressure in two studies. Although autonomous motivation, suggesting that hearing aid uptake is largely/partly a self-determined behavior, was also positively associated with hearing aid uptake in two studies.

Based on previous studies, stigma is generally considered as a barrier to help-seeking (Meyer & Hickson, 2012). Pronk et al. (2017) however reported greater hearing aid stigma to be a positive predictor for entering a hearing aid evaluation period, but only for females. The limited and inconsistent evidence on the effect of stigma requires further investigation.

Contradictory or limited results were reported for factors concerning health, cognition and mental health. A fair-quality study reported a positive association between better self-reported health and hearing help-seeking (Meyer et al., 2014), but a second fair-quality study did not find any association (Öberg et al., 2012), whilst a third poor-quality study found a negative association (Sawyer et al., 2020). Considering study quality, it is more likely that better self-reported health is associated with increased hearing help-seeking. Self-reported health and hearing aid uptake was negatively associated in two studies (both fair quality), while two other studies (one fair quality and one poor quality) found positive associations. Cognitive performance and hearing help-seeking showed no association in a fair-quality study (Öberg et al., 2012) compared to a positive association in a recent poor-quality study (Sawyer et al., 2020). More evidence on the influence of general health, cognition and other aspects of mental health is required.

3.6 Conclusion

A range of hearing help-seeking and hearing aid uptake factors have been investigated with several reported only once (10/70 and 62/159) for help-seeking and hearing aid uptake. Most reviewed research has focussed on hearing aid uptake (70%) as opposed to hearing help-seeking (30%), which reflects the need to better understand help-seeking as the first step to acquiring hearing aids as also mentioned by Meyer and Hickson (2012). Expanding our understanding of hearing help-seeking is especially important with the rapidly changing landscape in hearing aid service delivery models, including Over-the-Counter (OTC) hearing aids. The present review identified several predictors that have not been identified in systematic reviews before, including cognitive anxiety for both help-seeking and hearing aid uptake and urban residency for hearing aid uptake. Age and sex were not predictive of hearing help-seeking or hearing aid uptake in most studies. However, a few reports indicated that older people and males were more likely to seek help or to take up hearing aids. Social factors like social pressure appear important for hearing help-seeking. Perceived potential benefit of amplification was linked to hearing help-seeking and positive attitudes to hearing aids and an understanding of their function was predictive of hearing aid uptake. Access to financial support was a strong predictor of hearing aid uptake but not of hearing help-seeking. Severity of hearing loss and greater self-reported hearing disability were two of the most important predictors of hearing aid uptake.

More research is required where evidence is limited, for example, the influence of stigma on help-seeking. Additionally, further investigations are required where mixed findings were reported, for instance the relationship between self-reported health and help-seeking/hearing aid uptake. Other factors to investigate are hearing aid cost and counseling style, since they have been observed to affect hearing aid uptake in clinical practice but with limited evidence. A limitation of the synthesis methods used in this study (i.e., direction of effect and vote-counting) was that they did not provide information on the magnitude of the effects. Overall, studies of higher quality and stronger evidence (e.g., randomized controlled trials) are required for both hearing help-seeking and hearing aid uptake. A systematic review and synthesis of qualitative studies to obtain further insights into the factors influencing hearing help-seeking and hearing aid uptake may be helpful. A better understanding of factors influencing hearing help-seeking and hearing aid uptake can inform public health and clinical initiatives to promote hearing help-seeking and hearing aid uptake. This review highlights the need for further investigations to explore specific factors with limited or conflicting results.

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Supplemental Material

Supplemental material for this article is available online.

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CHAPTER 4

REASONS FOR HEARING AID UPTAKE IN THE UNITED STATES: A QUALITATIVE ANALYSIS OF OPEN-TEXT RESPONSES FROM A LARGE-SCALE SURVEY OF USER PERSPECTIVES

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4.1 Abstract

Objective: This study aimed to explore the main reasons for hearing aid uptake from a user perspective and recommendations to others with hearing difficulties.

Design: A cross-sectional survey design was used. Responses to a single open-ended question were analyzed using qualitative content analysis.

Study sample: Participants (n=642) included adult hearing aid users sampled from the Hearing Tracker website community and Lexie Hearing user databases in the United States.

Results: Participants had a mean age of 65.4 years (13.7 SD) and included 61.8% males, 37.7% females, 0.3% non-binary, and 0.2% preferred not to say. Reasons for hearing aid uptake were categorized into three domains (personal impact, social difficulties, and auditory difficulties), containing 11 main categories and 48 sub-categories. User recommendations to others with hearing difficulties constituted eight main categories (timely help, trial period, support,

affordability, technology, direct-to-consumer hearing aids, adjustments, and advocacy) and 32 sub-categories.

Conclusions: The decision to take up hearing aids included intrinsic factors like readiness to change and extrinsic factors such as the availability of finances. The most frequent recommendation to others was not to delay seeking hearing help and to get hearing aids. Our findings may support strategies to facilitate behavior change for improved hearing aid uptake.

Key Words

Hearing loss, Hearing aids, Hearing aid uptake, Hearing help-seeking

4.2 Introduction

More than 1.5 billion people worldwide experience hearing loss, of whom at least 430 million experience disabling hearing loss that will require rehabilitation (World Health Organization, 2021). Due to the growing population, it is estimated that by 2050 over 700 million people will suffer from disabling hearing loss (World Health Organization, 2021). People frequently delay seeking help for their health issues (Cornally & McCarthy, 2011; Doll et al., 2021), especially for hearing problems (Simpson et al., 2019). If not addressed, hearing loss can have severe consequences, including communication difficulties, social isolation and reduced quality of life (Nordvik et al., 2018; Shukla et al., 2020). Moreover, untreated hearing loss is associated with cognitive decline (Lin et al., 2023; Livingston et al., 2020). The Lancet Commission on Dementia Prevention, Intervention, and Care identified unaddressed hearing loss as a potentially modifiable risk factor in mid-life for developing dementia (Livingston et al., 2020). A recent study showed that hearing intervention can reduce cognitive decline by 48% in at-risk older adults over three years (Lin et al., 2023).

The majority of people with hearing loss can benefit from hearing aids (Ferguson et al., 2017). However, hearing aid adoption around the world has been low. In the United States (US), hearing aid ownership among older adults was estimated to be 18.5% in 2018 (Reed et al., 2021). A study by Orji et al. (2020) showed that 83% of people who could benefit from hearing aids are not using them. Similarly, Bisgaard et al. (2021)estimated the global hearing aid coverage using data on hearing aid sales and found that fewer than 11% of people with disabling hearing loss are hearing aid users. The reasons for the poor penetration of hearing aids are multifaceted, as outlined below.

The decision to seek help and take up hearing aids can be influenced by a person's readiness to change (Manchaiah et al., 2017). According to the transtheoretical model, health behavior change involves moving through different stages, including pre-contemplation (unaware or resistant to change), contemplation (considering change), preparation (planning for change), action (actively modifying behavior), maintenance (sustaining new behavior) and termination (fully ingrained change, optional stage) (Prochaska & Velicer, 1997). A study by Laplante-Lévesque et al. (2013) describes how the stages of change can be applied to audiological rehabilitation. Later stages of change indicate a greater likelihood of seeking help and taking up hearing aids (Manchaiah et al., 2017). A study by Schönborn et al. (2020) reported that adults in a later stage of change were more inclined to follow up with a hearing healthcare professional after they failed an app-based digits-in-noise (DIN) hearing screening test. Similarly, Ratanjee-Vanmali et al. (2020) found that patients who continued seeking hearing healthcare (e.g., obtaining hearing aids and support services) were in a later stage of change (action stage) compared to patients who did not seek hearing healthcare. Understanding readiness to change is important for health care professionals to support and inform uptake of hearing aids.

Nevertheless, as highlighted earlier, many factors can influence a person's readiness to take up hearing aids (Jenstad & Moon, 2011; Knudsen et al., 2010; Knoetze, Manchaiah, Mothemela, et al., 2023; Meyer & Hickson, 2012; Ng & Loke, 2015). Self-stigma, for example, has been identified as a barrier that may prevent people with hearing loss from obtaining hearing aids (Wallhagen, 2009). In a qualitative study by Wallhagen (2009), stigma was related to alterations in self-perception, ageism and vanity. Participants reported that the meaning of hearing loss and hearing aids changed the way they perceive themselves and their partners, as well as how others view them (Wallhagen, 2009). Furthermore, participants reported that hearing aids would make them appear old or unattractive (Wallhagen, 2009). The cost of hearing aids has also been reported as a barrier to hearing aid uptake, even in high-income countries like the US (Fischer et al., 2011). However, it's important to acknowledge that in countries, such as Norway and the United Kingdom, where the government provides free hearing aids, a considerable portion of the population still don't acquire hearing aids (Kirkwood, 2015). Therefore, it is essential to examine the various factors that may be preventing or enabling people to acquire hearing aids, taking into account the complex nature of this issue.

Rolfe and Gardner (2016) recruited 22 adult hearing aid users and conducted semi-structured interviews with thematic analysis to identify barriers to hearing aid uptake. Three themes were identified representing barriers to intervention uptake, including the journey from realization to readiness, combatting social stigma and accessing appropriate services (Rolfe & Gardner, 2016). Zheng et al. (2022) also used semi-structured interviews with thematic analysis to identify barriers to hearing aid uptake in a group of 12 adults who had seen Ear, Nose and Throat (ENT) specialist doctors but did not take up hearing aids. Barriers included a desire for a cure for hearing loss, a lack of perceived need for hearing aids and negative impressions and misconceptions about hearing aids (Zheng et al., 2022). However, a study by Engelund (2006) proposed that the focus should not be on why people do not seek treatment but rather on why people do seek treatment. Engelund (2006)concluded that in order for people to act on their hearing problem, they need to go through four stages of a complex process to recognize their hearing loss, including attracting attention, becoming suspicious, sensing tribulation and jeopardizing fundamental self.

The attracting attention stage refers to when a person with hearing loss does not experience hearing problems, but others who are close to the person start noticing his/her hearing problems. The becoming suspicious stage involves noticing some hearing difficulty. These two stages could explain what happens during the transtheoretical model's pre-contemplation stage. The sensing tribulation stage refers to when a person starts becoming more aware of his/her hearing problems and experiences emotional reactions, e.g. embarrassment. Finally, the jeopardizing fundamental self involves having a sense of lost control and having the need to seek help. According to Engelund (2006), a person needs to be at the end of the sensing tribulation or jeopardising fundamental self stages in order to reach the transtheoretical model's contemplation stage.

The decision to take up hearing aids remains complex. Quantitative research has identified clear predictors for hearing aid uptake, such as poor hearing sensitivity and self-reported hearing disability (Jenstad & Moon, 2011; Knudsen et al., 2010; Knoetze, Manchaiah, Mothemela, et al., 2023; Meyer & Hickson, 2012; Ng & Loke, 2015). Similarly, a qualitative study using semi-structured interviews and thematic analysis found that participants (n = 32) were more likely to take up hearing aids if their self-reported hearing problem had worsened over time (Gallagher & Woodside, 2018). Another study by Poost-Foroosh et al. (2011) included 23 participants (13 adults who received a hearing aid recommendation and 10 audiologists) and used concept mapping to identify factors in the client-clinician interaction that influence hearing aid uptake. They concluded that empowering patients through client-centred interaction might improve hearing aid uptake (Poost-Foroosh et al., 2011).

Although a few qualitative studies provide important insights on hearing aid uptake barriers and enablers, little is known about the reasons for hearing aid uptake, specifically from the hearing aid user's perspective. Hearing aid users typically find themselves in later stages of change (e.g., the transtheoretical model's maintenance stage), where they have already recognized the need for hearing aids and taken steps to adopt them. The perspectives and experiences of hearing aid users can potentially support individuals in earlier stages of change (e.g., the transtheoretical model's contemplation stage) who are open to the idea of hearing aids to progress through the stages and facilitate their decision to take up hearing aids. This information is also important to inform and support hearing healthcare professionals and service-delivery models to implement strategies that can foster readiness to change, i.e. readiness to adopt and maintain behavior change (Prochaska & Velicer, 1997), in this case, willingness to take up hearing aids. Furthermore, existing qualitative studies on the topic of hearing aid uptake have used relatively small sample sizes. This study, therefore, explored the main reasons for hearing aid uptake and recommendations to others with hearing difficulties in a large sample of adult hearing aid users in the US.

4.3 Method

4.3.1 Study Design

The study was part of a larger project that aimed to investigate hearing aid experiences of adult hearing aid users that included a combination of structured and open-ended questions.

The current study was limited to the analysis of responses to a single open-ended question pertinent to the current study's aim of exploring reasons for hearing aid uptake and recommendations to others from a user perspective. Institutional Review Board (IRB) approval was obtained for this study from Lamar University's Human Subjects Review Board (Ref: IRB-FY21-248) and further ethical clearance for data analysis was obtained from the Faculty of Humanities Research Ethics Committee, University of Pretoria (Ref: HUM008/0822). The Equator network Checklist for Reporting Results of Internet e-Surveys (CHERRIES; Eysenbach, 2004) was used to report the methods and results of the study and
domain 3 of the consolidated criteria for reporting qualitative research (COREQ; Tong et al., 2007) was used to report the analysis of the study (see Supplementary Material 1 and 2 - Appendix K and L).

4.3.2 Questionnaire

Items for the questionnaire were identified through an iterative process by focusing on the current research identifying factors that could contribute to hearing aid experiences. The questionnaire went through two stages of review. Four audiologists piloted the questionnaire. Their suggestions were addressed and the final questionnaire was imported into Qualtrics (Qualtrics, Provo, UT) and was reviewed by team members to ensure functionality. No randomization of the items was used, and respondents were unable to change their responses once submitted. No personally identifiable data were collected.

The final questionnaire comprised of 33 closed-ended questions and 4 open-ended questions. The estimated time to complete the questionnaire was 20 min. The questionnaire consisted of five sections that included 1) structured questions regarding demographic and hearing aid related information, 2) open-ended questions regarding hearing aid experiences, 3) International Outcomes Inventory for Hearing Aids (IOI-HA; Cox & Alexander (2002)), 4) information regarding general health, well-being and social network and 5) additional demographic information.

Due to the large sample and amount of data, the current study focused on responses from section 1 and the first open-ended question in section 2. The open-ended question was formulated by a multidisciplinary team, including audiologists (DS and VM) and social psychologists (Jamie Pennebaker and Ryan Boyd). The decision to adopt hearing aids is multifaceted, often incorporating personal, social, and economic considerations. Therefore, the question was designed with extended writing prompts to provide some context and validation for the feelings that hearing aid users may have experienced (e.g., embarrassment), potentially helping them feel more comfortable in sharing their true experiences and feelings. The utilization of extended writing prompts is a commonly used method in psychology research (see other examples: Boyd et al., 2021; Robinson et al., 2016; Stanton et al., 2015). The social psychology experts ensured that the question appropriately captured the complexities of human decision-making processes. Furthermore, the length and complexity of the question were consistent with their recommendation to allow participants the space to describe their journey holistically. The question was worded as follows:

For many people, getting and wearing a hearing aid is a major life decision. They often say that getting a hearing aid is embarrassing and makes them feel or look old. Others worry about the cost or what others will say. How did you deal with these issues when you decided to buy a hearing aid? What motivated you to get hearing aids? Was there a single reason or event that convinced you or were there many reasons? Please provide as much detail as possible about the reason(s) why you decided to get hearing aids. What would you recommend to others who are starting to have hearing problems?

4.3.3 Data Collection

The larger study used purposive sampling to recruit participants. Participants were only included if they were adults (18 years and older) with hearing loss who had been or were current hearing aid users. Participants included hearing aid users from the Hearing Tracker website (www.hearingtracker.com) and users from the Lexie Hearing (www.lexiehearing.com) US database. The Hearing Tracker website is an online forum for consumers where they can share their personal opinions and experiences with hearing aids through unsolicited reviews (Swanepoel et al., 2023). Hearing aid users from the Hearing Tracker community had received traditional in-person hearing care services through healthcare professionals. These services were either obtained from private hearing aid clinics, public health or discount warehouses. Users from the Lexie Hearing US database purchased self-fitting, behind-the-ear (BTE), over-the-counter (OTC) Lexie Lumen hearing aids online, along with the accompanying app (Swanepoel et al., 2023).

A link to the open questionnaire was sent out via email to the Hearing Tracker database and to the Lexie hearing aid users during October and November 2021. The link took participants to an informed consent form and participant information sheet. Participants had to give electronic informed consent before they could complete the online questionnaire. For the Hearing Tracker users, responses to the open-ended questions were required to be at least 20 words long. There was no minimum word count for the Lexie users. Participation was voluntary and no incentives were offered to participants. Furthermore, it is noteworthy that 58 hearing aid users in the Hearing Tracker group received their hearing aids for free (e.g., from the U.S. Department for Veterans Affairs) and all users in the Lexie Hearing group purchased their hearing aids. Information pertaining to the average logged completion time was not made available to the researchers as part of the final dataset. It is noteworthy that users self-selected themselves to respond to the survey. The response rate could not be estimated as the information was not available about how many people in each of the databases received and opened the online survey.

4.3.4 Data Analysis

A total of 1,094 responses (827 from Hearing Tracker and 267 from Lexie Hearing) were exported to Microsoft Excel (2019), where data screening was conducted to prepare the raw data for data analysis. The following responses were excluded: Participants who did not provide informed consent (n = 26), participants who had implantable devices (e.g., cochlear implants)(n = 3), participants who had personal sound amplification systems (PSAPs)(n = 14), participants who did not answer the open-ended questions (n = 338), participants who reported that they had childhood hearing loss and had been fitted with hearing aids during childhood (n = 40). Additionally, responses were excluded if they were duplicated (n = 9) or irrelevant (i.e., responses unrelated to the question, responses related to hearing aid outcomes or responses related to barriers to hearing aid uptake only) (n = 22). Therefore, a total of 642 responses (415 from Hearing Tracker and 227 from Lexie Hearing) were analyzed.

De-identified demographic data were coded in Microsoft Excel (2019) and transferred to Statistic Package Social Sciences (SPSS) version 28 for statistical analysis. Results were analyzed using descriptive statistical measures in terms of frequency, mean, standard deviation and range. The Mann-Whitney U and Chi-square analysis were used to determine if there were significant differences between groups in terms of demographic and audiological variables. Furthermore, 642 responses were analyzed in Microsoft Excel (2019) using qualitative content analysis (Graneheim & Lundman, 2004; Knudsen et al., 2011).

Content analysis was found to be suitable due to the nature of the responses obtained from open-ended questions, which can vary widely in terms of detail and depth. As described by Knudsen et al. (2011), qualitative content analysis pertains to the categorization of manifest content (the explicit and visible aspects of the data) and aims to provide a descriptive overview of the data. An inductive approach, which is a bottom-up approach, was used in this study (Elo & Kyngäs, 2008). This involves generating generalizations or theories based on observations of specific instances. The researcher started analyzing specific responses and identified patterns within the data, and these patterns were used to develop broader sub-categories and categories. This approach is useful when exploring new or under-researched topics, as it allows for the generation of new insights and understandings based on the specific data being collected.

The primary researcher read through the responses numerous times to get an idea of the whole. Thereafter, the responses were divided into condensed meaning units and labelled using codes, after which the codes were grouped into sub-categories and eventually into categories (Graneheim & Lundman, 2004). The iterative process of qualitative content analysis involves a constant revisiting and refining of the coding and categorization scheme. This means that as the analysis progresses, the researcher may go back and revise their codes or create new categories based on emerging patterns within the data. This process allows for a more nuanced and comprehensive understanding of the data and ensures that all relevant patterns are identified. The coding was conducted by the primary researcher and 50% of the coding was cross-checked by an experienced qualitative researcher (EB). Any discrepancies were resolved by discussions with a third researcher (VM). Data saturation was reached after

73% of the responses (i.e., n=468) were analyzed, i.e., no new codes or categories emerged from the dataset after reaching this point. Participants did not provide feedback on findings.

4.4 Results

4.4.1 Participant and Response Characteristics

Table 4.1 provides details of the participants' demographics. Participant ages ranged from 22 to 93 years, with a mean age of 65.4 years (13.7 SD). Lexie users (63.7 years; 12.4 SD) were significantly younger compared to users from Hearing Tracker (66.4 years; 14.2 SD). Participants included 61.8% males, 37.7% females, 0.3% non-binary, and 0.2% preferred not to say. There was no significant difference between the two groups in terms of gender distribution (see Table 4.1). The duration of hearing loss ranged from 0 to 74 years, with a mean duration of 18.6 (16.3 SD). Lexie users had a significantly shorter duration of hearing loss (14.4 years; 14.1 SD) compared to users from Hearing Tracker (20.9 years; 16.9 SD). Lexie users had a significantly longer duration of hearing loss before hearing aid purchase (8.4 years; 11 SD) compared to Hearing Tracker users (6.6 years; 11 SD). In terms of self-reported hearing difficulty (i.e., hear everything, sometimes don't hear, regularly don't hear, and almost never hear), more than half of users (52%) reported that they regularly don't hear. There was a significant difference in self-reported hearing difficulties between the two groups, with Lexie users reporting less severe hearing difficulties (see Table 4.1).

Overall, 41.3% of participants, including all Lexie users, purchased hearing aids online. Furthermore, 36.8% purchased hearing aids from a private hearing clinic or university, 11.7% purchased hearing aids from a discount warehouse, and 9.3% reported getting hearing aids from other places (e.g., the Veterans Affairs). A very small percentage (0.6%) purchased hearing aids from a pharmacy hearing center or (0.3%) were fitted with hearing aids by a hearing professional at their house. Most participants (92.2%) were bilateral hearing aid users. Hearing Tracker users included significantly more unilateral users (9.9%) compared to Lexie users (4%)(Table 4.1).

Table 4.1 Comparison of demographic and audiological variables between Hearing Tracker and Lexie users

	All users (642)	Hearing Tracker users (415)	Lexie users (227)	Group difference analysis (Mann-Whitney U or Chi-square analysis: Z or X^2 value; p-value)
Age (mean; SD)	65.4 (13.7)	66.4 years (14.2)	63.7 years (12.4)	z = -3.713; p < .001*
Gender (n; %)				X^2 = 2.682; p = .262
Male	397 (61.8%)	247 (59.5%)	150 (66.1%)	
Female	242 (37.7%)	166 (40%)	76 (33.5%)	
Other	3 (0.5%)	2 (0.5%)	1 (0.4%)	
Duration of hearing loss in years (mean; SD)	18.6 (16.3)	20.9 (16.9)	14.4 (14.1)	z = -5.688; p < .001*
Duration of hearing loss before HA purchase in years (mean; SD)	7.2 (11)	6.6 (11)	8.4 (11)	z = -4.126; p < .001*
Self-reported hearing difficulty (n; %)				X^2 = 14.397; p = .002*
Almost never hear	139 (21.7%)	108 (26%)	31 (13.7%)	
Regularly don't hear	335 (52.2%)	203 (48.9%)	132 (58.1%)	
Sometimes don't hear	163 (25.4%)	102 (24.6%)	61 (26.9%)	
Hear everything	5 (0.8%)	2 (0.5%)	3 (1.3%)	
Hearing aid purchase (n; %)				X^2 = 499.584; p < .001*
Online	265 (41.3%)	38 (9.2%)	227 (100%)	
Private clinic or university	236 (36.8%)	236 (56.9%)	-	
Discount warehouse	75 (11.7%)	75 (18.1%)	-	
Others (e.g., Veterans Affairs)	60 (9.3%)	60 (14.5%)	-	
Pharmacy hearing center	4 (0.6%)	4 (1%)	-	
Fitted by hearing professional at home	2 (0.3%)	2 (0.5%)	-	
Bilateral or unilateral users (n; %)				X^2 = 7.148; p = .008*
Bilateral	592 (92.2%)	374 (90.1%)	218 (96%)	
Unilateral	50 (7.8%)	41 (9.9%)	9 (4%)	

Note: *Significant difference between Hearing Tracker and Lexie users; p < .05
Duration of hearing loss before HA purchase was calculated excluding four outliers from the Hearing Tracker group
SD = Standard deviation, HA = Hearing aid

Results from the qualitative content analysis are tabulated in Tables 4.2-4.5, as outlined in the next section. The frequency of meaning units reported in each domain, category or sub-category is shown in brackets in the tables.

4.4.2 Reasons for Hearing Aid Uptake

Three domains emerged, containing 11 categories and 48 sub-categories. The domains for hearing aid uptake reasons included personal impact, social difficulties and auditory difficulties, as described below (see Figure 4.1).

Domain 1: Personal Impact

Personal impact included five categories presented in Table 4.2 with their respective sub-categories. Several participants indicated that they obtained hearing aids because they did not feel self-conscious about wearing hearing aids. This occurred either because they were not concerned about their appearance with hearing aids or they felt that the hearing aids were not visible, for example, *"Wearing hearing aids never concerned me. I actually ordered a red-colored BTE pair so people would notice them and understand that I was hard of hearing" (P102, 82, male)*. Some participants reported taking up hearing aids because of having access to finances, as they mentioned that they had finances available or received hearing aids from a third party (e.g., health insurance). A number of participants got hearing aids for free, e.g., as a gift or from a non-profit organization. Listening fatigue was reported as a primary reason for hearing aid uptake in regard to auditory-related impact, for example, *"straining to hear was tiring" (P205, 70, male)*. Participants also reported fearing the consequences of untreated hearing loss, particularly mental decline, as a motivating factor for hearing aid uptake.

The ability to work in general was also described as a primary reason for hearing aid uptake. Some participants specifically mentioned that they struggled to participate in meetings at work, for example, *"I was having a very difficult time hearing during meetings. I often misinterpreted what was being said so responded with comments and conversation that was off track from the discussion" (P198, 62, female)*. Teachers and musicians also reported that they had to get hearing aids due to the nature of their jobs. Learning at school or university was another reason for hearing aid uptake. Most participants reported quality of life as the main driver for hearing aid uptake in terms of emotional impact. Participants who reported frustration as the motivating factor for hearing aid uptake either referred to the frustration experienced by themselves or the frustration experienced by their friends/family. Some participants also described experiencing external pressure to take up hearing aids. The external pressure was either positive (e.g., a family member encouraging a participant to buy a hearing) or negative (e.g., a boss telling a participant they need to get hearing aids to keep their job).

Table 4.2 Personal impact factors contributing to getting a hearing aid (n = 596 meaning units)

Category	Sub-category	Meaning unit examples (participant ID, age in years, gender)
Barriers removed (241)	Appearance not a concern (126)	*I did not worry about the looks (P11, 72, male)*
	Hearing aids not visible (28)	*They are very discreet (P6, 42, female)*
	Provided by a third-party (34)	*I got the cheapest ones that were fully covered by insurance (P2, 50, female)*
	Availability of finances (29)	*I could afford to consider it (P3, 46, male)*
	Free hearing aid (7)	*I was gifted a pair of Kirkland hearing aids (P66, 74, female)*
	Readiness to change (12)	*It was time to get them. (P234, 76, male)*
	Accepted hearing loss (5)	*I had to go through the grieving process of losing my hear (P42, 68, female)*
Auditory-related impact (53)	Listening fatigue (29)	*I was tired of not being able to hear. (P69, 71, female)*
	Tinnitus (6)	*My ears keep ringing (P537, 64, male)*
	Balance difficulties (1)	*I can't keep my balance (P468, 25, female)*
	Consequences of untreated hearing loss (11)	*Not hearing can lead to other health issues and mental decline (P127, 61, female)*
	Auditory deprivation (4)	*To be sure I didn't lose brain activity in hearing center (P120, 67, female)*
	Realising it is a long-term condition (2)	*Deafness will endure to the end of my days! (P133, 78, female)*
Impact on education/work (146)	Ability to learn (7)	*I was starting graduate school and wanted to hear better in class (P273, 70, male)*
	Ability work (94)	*it was impacting my work (P26, 57, male)*
	Participating in meetings (28)	*would miss critical information in business meetings. (P28, 63, female)*
	Working as a teacher (13)	*I'm a college professor and needed one for my job. (P39, 68, female)*
	Working as a musician (4)	*I am a professional vocalist and it was imperative for me to hear music clearly (P54, 56, female)*
Emotional impact (110)	Reduced quality of life (56)	*It was a quality of life issue for me. (P132, 71, male)*
	Frustration (27)	*I was more and more frustrated (P35, 64, female)*
	Embarrassment (14)	*It was embarrassing in the least (P148, 78, male)*
	Unable to function (7)	*I could no longer function without them (P53, 56, male)*
	Lower mood and self-esteem (6)	*I had self-esteem issues initially (P290, 24, male)*
Social support and encouragement (46)	Family members (27)	*My wife has suggested a hearing aid for years. (P55, 78, male)*
	Friends with hearing aids (6)	*After talking to a co-worker who has hearing aids (P49, 58, male)*
	Work colleagues (5)	*My boss said I needed to get them (P235, 71, female)*
	Medical professionals (5)	*A medical doctor suggested that I get hearing aids. (P131, 78, male)*
	Others (3)	*I was on a plane trip and the person sitting next to me said: You really need to go get your hearing checked. (P425, 64, male)*

Note: Numbers in brackets are the frequency of the meaning units reported in each category or sub-category

Domain 2: Social Difficulties

Three categories of social difficulties were identified, following a hierarchical structure, including communication, social interactions and social withdrawal (see Table 4.3). One of the main reasons for hearing aid uptake was communication difficulties and social interactions, especially with family members, such as their partner, children or grandchildren, for example, *"I didn't want to miss out on communication with my grandchildren. I was fearful that if they had repeat what they said that they would stop interacting with me"(P247, 64, female)*. Struggling to interact in group settings, e.g., in restaurants or at public gatherings and socializing with friends, were further reasons for hearing aid uptake. The impact their hearing loss had on their relationships was also a motivating factor for hearing aid uptake, for example, *"and social relationships were impacted as well" (P324, 73, male)*. Realizing that they were withdrawing socially from events such as parties or shows was a further factor leading to obtaining hearing aids. Participants thus took up hearing aids to feel more comfortable in social situations. Specific speech perception difficulties that motivated participants to take up hearing aids included annoyance of not understanding speech, needing to ask for repetition and missing conversation.

Figure 4.1 Domains and categories identified regarding reasons for hearing aid uptake

Table 4.3 Social difficulties contributing to getting a hearing aid (n = 489 meaning units)

Category	Sub-category	Meaning unit examples (participant ID, age in years, gender)
Communication (310)	Communication difficulties in general (101)	*Unable to communicate normally with others (P10, 25, male)*
	Difficulty understanding speech (76)	*I didn't always understand what was said. (P66, 74, female)*
	Asking for repetition (75)	*was saying "what?" too often (P11, 72, male)*
	Impacting conversation flow (58)	*I was missing conversations. (P48, 73, female)*
Social interactions (137)	Family members (103)	*I had trouble hearing my wife (P85, 58, male)*
	Friends (16)	*Do not subject friends and family to having to repeat themselves. (P45, 77, female)*
	Group conversations (18)	*I wanted to hear better when out with a group (P270, 78, female)*
	Impact on relationships (19)	*Once others around me thought I was being rude because I was not responding (P450, 52, female)*
Social withdrawal (42)	Socialization difficulties (23)	*Socializing became difficult (P133, 78, female)*
	Social isolation (20)	*I realized my increased isolation (P88, 74, female)*

Note: Numbers in brackets are the frequency of the meaning units reported in each category or sub-category

Domain 3: Auditory Difficulties

Three categories emerged, namely hearing difficulty, contextual difficulties, and hearing-based entertainment (see Table 4.4). Participants mentioned seeking hearing aids because they desired clarity as they struggled to hear everything. They also reported auditory difficulties (difficulty hearing sounds or perceiving speech) in specific contexts as the main reason for hearing aid uptake, particularly hearing in background noise, for example, *"Couldn't follow conversations in areas with background noise" (P365, 78, female)*. Participants also mentioned difficulty hearing over the phone and hearing environmental sounds like birds chirping. Hearing the television, radio or music difficulties were further reasons for hearing aid uptake.

Table 4.4 Auditory difficulties contributing to getting a hearing aid (n = 337 meaning units)

Category	Sub-category	Meaning unit examples (participant ID, age in years, gender)
Hearing difficulty (214)	General hearing difficulty (202)	*Wanted to hear better (P29, 75, male)*
	Clarity desired (12)	*I wanted to hear more clearly (P280, 39, male)*
Contextual (57)	In background noise (25)	*Issues with conversations at a table in a noisy restaurant (P86, 81, male)*
	At home (5)	*I was having trouble hearing in my own home. (P101, 61, female)*
	Using the phone (14)	*Could not hear or use phone (P174, 75, female)*
	Environmental sounds (9)	*Couldn't hear the wind in the trees or the birds chirping (P236, 55, male)*
	For personal safety (4)	*It was more about a safety issue (P310, 58, female)*
Entertainment (66)	Watching television (50)	*Having to turn up the TV (P35, 64, female)*
	Listening to music (11)	*Wanting to hear music better (P352, 41, male)*
	Listening to radio (5)	*I noticed the volume of my car radio (P258, 73, female)*

Note: Numbers in brackets are the frequency of the meaning units reported in each category or sub-category

4.4.3 Recommendations to Others with Hearing Difficulties

Regarding recommendations to others with hearing difficulties, 8 categories and 32 sub-categories were identified as presented in Table 4.5 and Figure 4.2. Participants either recommended getting hearing aids or at least getting a hearing test. A further recommendation was to do a hearing aid trial and do enough research before purchasing hearing aids, e.g., watching YouTube videos regarding hearing aids. The sub-categories *adjustment time* and *persist* were closely related. Participants in the sub-category *adjustment time*recommended allowing enough time to get used to wearing hearing aids, for example, *"It is physically and emotionally exhausting for the first few weeks while your brain adjusts" (P42, 68, female)* while the sub-category *persist* included recommendations to wear the hearing aids as much as possible in order to adjust, for example, *"start using the hearing aids from day one, even if it doesn't sound right" (P275, 81, male)*. In terms of support, the majority of participants from Hearing Tracker mentioned that it is important to find the right hearing healthcare professional. For some participants, this meant finding a suitable audiologist and for others it meant seeing an ENT specialist. Participants further recommended involving family or joining a support group like the Hearing Loss Association of America.

Recommendations to shop for cheaper hearing aids or to consider finance options were also common, for example, *"research for best prices" (P232, 68, male)*. Some participants recommended purchasing hearing aids with specific features like rechargeable batteries or Bluetooth. In terms of direct-to-consumer (DTC) hearing aids, participants either recommended getting DTC hearing aids because they are more accessible and affordable or not getting DTC hearing aids because they do not work as well as hearing aids that are recommended by a hearing healthcare professional. Participants further mentioned that getting hearing aid adjustments can be helpful. They either reported getting many adjustments in order to be satisfied with hearing aids or specifically getting the hearing aids adjusted for different environments. For others to attend to communication needs, they recommended making people aware of your hearing loss or hearing aids, for example, *"Wear a pin that says please face me so I can hear you" (P243, 68, female)*.

Table 4.5 Recommendations to others who have hearing difficulties reported by 642 participants (n = 503 meaning units)

Category	Sub-category	Meaning unit examples (participant ID, age in years, gender)
Timely help (181)	Get hearing aids (74)	*Get the hearing aids (P2, 50, female)*
	Don't delay (60)	*I recommend not waiting (P21, 71, female)*
	Get tested (46)	*Get your hearing checked (P32, 70, male)*
	Online hearing screening (1)	*Ability to get a valid audiogram *easily* is improving now through self-help access on the internet (P340, 65, male)*
Trial period (97)	Do research (23)	*I read everything I could find on the subject. (P42, 68, female)*
	Adjustment time (19)	*Give yourself a lot of time to adapt to wearing the hearing aid. (P30, 44, female)*
	Change the hearing aid style (18)	*At first I wanted small and comfortable, but as my hearing loss progressively got worse, I saw the benefit in having a BTE. (P176, 62, female)*
	Hearing aid trial (11)	*The long trial period also really helped. (P33, 73, female)*
	Persist (10)	*Getting to point where aid(s) feel right may take time and patience. (P78, 61, male)*
	Trial a range of devices (8)	*Try multiple brands (P96, 92, male)*
	Don't rush the decision (6)	*Take your time. (P4, 34, female)*
	Ask questions (2)	*I would suggest any first time users to ask more questions (P185, 77, male)*
Support (71)	Seek the right professional (24)	*See a licensed and skilled hearing healthcare professional (P176, 62, female)*
	Find a suitable audiologist (23)	*I would recommend to find a good audiologist (P51, 80, female)*
	Quality service (15)	*Their service is beyond reproach (P137, 81, male)*
	Join a support group (3)	*get involved with other people knowing that you're not alone (P310, 58, female)*
	See an Ear-Nose-and-Throat specialist (3)	*I will always recommend others see an ENT (P24, 64, male)*
	Involve family (3)	*Support of family is important (P132, 71, male)*
Affordability (56)	Seek affordable options (56)	*Shopped for the best value. (P32, 70, male)*
Technology (48)	Get the latest technology (15)	*Purchase the most current technology you can afford. (P312, 63, female)*
	Get Bluetooth hearing aids (14)	*Bluetooth has made a huge difference (P163, 80, male)*
	Realistic expectations (6)	*Just realize that your hearing will never be as it was (P336, 75, female)*
	Use assistive listening devices (6)	*I also use an assistive listening device (P129, 65, female)*
	Use communication tactics (4)	*I also read lips while talking with someone (P132, 71, male)*
	Get rechargeable hearing aids (2)	*rechargeable aids are great (P77, 67, male)*
	Use telecoil (1)	*I have been an outspoken advocate for telecoil technology (P292, 83, male)*
DTC hearing aids (21)	Get DTC hearing aids (18)	*I found a way to get aids that I could adjust myself…less costly and not at all difficult* (P342, 82, male)
	Don't get DTC hearing aids (3)	*Not buy over the counter or online (P226, 83, female)*
Adjustments (13)	Get adjustments (10)	*Many adjustments with aids (P111, 67, male)*
	Adjust for different environments (3)	*Make a list of situations that you struggle in and go for adjustments (P4, 34, female)*
Advocacy (16)	Make people aware (11)	*Let them know you're a hearing aid user (P290, 24, male)*

	Forget what others think (5)	*Forget about what others think about using hearing aids (P275, 81, male)*

Note: Numbers in brackets are the frequency of the meaning units reported in each category, sub-category or code, DTC=Direct-to-Consumer, ENT=Ear, Nose and Throat specialist, HOH=Hard of Hearing

Figure 4.2 Categories identified regarding recommendations to others with hearing difficulties

4.5 Discussion

This study explored the main reasons for hearing aid uptake and recommendations to others with hearing difficulties using qualitative content analysis of responses from 642 hearing aid users. Reasons for hearing aid uptake were categorized into three domains (personal impact, social difficulties, and auditory difficulties), containing 11 main categories and 48 sub-categories. Recommendations to others with hearing difficulties constituted eight main categories (timely help, trial period, support, affordability, technology, direct-to-consumer hearing aids, adjustments, and advocacy) and 32 sub-categories.

The majority of the categories identified in this study have been reported as factors influencing hearing aid uptake in quantitative studies (Jenstad & Moon, 2011; Knudsen et al., 2010; Knoetze, Manchaiah, Mothemela, et al., 2023; Meyer & Hickson, 2012; Ng & Loke, 2015). However, when considering the sub-categories, this study provided more insights with more specific and detailed reasons for hearing aid uptake reported. For example, communication difficulties have been identified as a predictor for hearing aid uptake (Humes & Dubno, 2021). Still, in this study, participants described specific speech perception difficulties that motivated hearing aid uptake, such as asking for repetition. Unlike other qualitative studies on this topic, this study reported a wide range of reasons for hearing aid uptake, some of which have not been reported before. Most research in healthcare is focused on why people do not seek help or take up interventions. For example, studies in the field of psychology tend to focus on why people avoid treatment for mental illness (Muhorakeye & Biracyaza, 2021; Radez et al., 2021). Like the aforementioned, most studies in audiology have focused on reasons people do not seek help/take up hearing aids. However, it may be more effective to promote hearing aid uptake by focusing on the factors that motivate a person to take up hearing aids, as reported by the hearing aid users in the present study, as opposed to focusing on the barriers. Although our sample of hearing aid users may not be representative of all potential hearing aid users, we believe that the insights gained from our sample of hearing aid users can still be useful for informing interventions to support those in earlier stages of change who are open to the idea of using hearing aids to progress through the stages and facilitate their decision to take up hearing aids.

A key takeaway from this study is that some people do not only take up hearing aids to improve their hearing but also to improve their general well-being. Reasons for hearing aid uptake could be identified in all three core well-being dimensions, namely socio-emotional well-being, cognitive well-being and physical well-being (Vercammen et al., 2020). For example, some participants reported taking up hearing aids to improve their quality of life (socio-emotional well-being), prevent auditory deprivation (cognitive well-being), or for personal safety (physical well-being). This is encouraging as it is in line with the recent call for action to change the narrative of hearing health to be framed within the broader context of healthy living (Saunders et al., 2021). It highlights the need for hearing healthcare professionals to broaden their perspective on hearing health and the potential benefits of hearing aids on various dimensions of well-being. Therefore, hearing healthcare professionals should incorporate discussions on well-being and quality of life in their consultations and highlight the positive impact of hearing aids on quality of life.

Although many personal impact factors contributed to taking up hearing aids, most participants reported hearing aid uptake because of having access to finances and not feeling self-conscious. These two factors are typically reported as barriers to hearing aid uptake (Fischer et al., 2011; Wallhagen, 2009) and removing these barriers may increase an individual's motivation to progress through the stages of change and take up hearing aids. In line with Rolfe and Gardner (2016), some participants in the present study felt less self-conscious because their hearing aids were discreet, whereas others were not concerned about their appearance with the hearing aids. Hearing healthcare professionals should increase visibility and public acceptance of hearing loss and hearing aids to support lower stigma and improve hearing aid uptake, as suggested by Rolfe and Gardner (2016). Hearing loss must be treated as a component of overall health, and hearing healthcare professionals should promote hearing assessment and treatment to destigmatize hearing loss, as also recommended by Wallhagen (2009). Moreover, it is important for hearing healthcare professionals to consider the social representation of hearing aids (whether hearing aids are viewed as acceptable or not), as this may vary from country to country (Chundu et al., 2021). Cross-cultural differences need to be considered to develop culturally sensitive health campaigns that can improve perceptions about hearing aids (Chundu et al., 2021). Furthermore, cost as a barrier to hearing aid uptake should be addressed. Participants frequently reported taking up hearing aids because of the availability of finances or financial support. A recent systematic review by Knoetze, Manchaiah, Mothemela, et al. (2023) also revealed that having access to financial support (e.g., receiving funding from a third party) can positively affect hearing aid uptake. The availability of affordable hearing aid options or financial assistance could therefore improve hearing aid uptake.

Hearing aid uptake was motivated either intrinsically when participants felt ready to seek help for their hearing difficulties or extrinsically due to social support and encouragement, as also indicated by Rolfe and Gardner (2016). Similarly, a recent systematic review (Knoetze, Manchaiah, Mothemela, et al. 2023) reported that hearing aid uptake was positively associated with social pressure, although autonomous motivation also positively affected hearing aid uptake suggesting a largely self-determined behavior. Therefore, external motivation can have a positive impact on hearing aid uptake, but for an individual to take action and adopt hearing aids, they need to be intrinsically motivated to change. Raising awareness regarding the benefits of hearing aids, such as improving psychosocial functioning (Oosthuizen et al., 2022), reducing listening fatigue (Holman et al., 2021), and reducing the risks of cognitive decline (Livingston et al., 2020) are important priorities for hearing healthcare professionals. This could support intrinsic motivation to obtain hearing aids since these were reported to contribute to hearing aid uptake. The transtheoretical model suggests that various factors, such as the perceived benefits of behavior change, influence an individual's readiness to change. Therefore, people who recognize and value the potential benefits of hearing aids might be more likely to show readiness to change and take up hearing aids.

It is well known that hearing loss can cause social difficulties, including social isolation, which can lead to other mental health problems (Shukla et al., 2020). Thus, it was expected that social difficulties, such as communication difficulties, social interactions and social withdrawal, would be reported as motivating factors for hearing aid uptake. A study by Humes and Dubno (2021) reported similar findings and concluded that people with poorer communication performance and increased awareness of communication problems were more likely to seek help and take up hearing aids. Similar to what participants reported in this study, communication partners can also experience communication difficulties, social restrictions and less relationship satisfaction because of their partners' hearing loss (Kamil & Lin, 2015; Manchaiah et al., 2012). Therefore, it may be helpful for hearing healthcare professionals to involve communication partners like family members in discussions about interventions (Kamil & Lin, 2015; Manchaiah et al., 2012). This will extend a patient-centered care approach to a family-centered care approach, which can address the communication needs of the patient and their family (Nerina et al., 2013). In previous qualitative studies, hearing aid users also reported that social support from family/friends encouraged them to use their hearing aids more often (Dawes et al., 2014; Lockey et al., 2010).

In the auditory difficulties domain, similar to Gallagher and Woodside (2018), participants predominantly reported taking up hearing aids because of self-reported hearing difficulty. Some participants specified the context, for example, difficulty hearing sounds or perceiving speech in background noise, at home or over the phone. Poor hearing sensitivity, whether it is self-reported or measured using pure tone audiometry, has previously been identified as a strong predictor of hearing aid uptake (Knoetze, Manchaiah, Mothemela, et al., 2023; Knudsen et al., 2010). This emphasizes the importance of hearing screening for hearing healthcare professionals to increase awareness of hearing loss and potentially improve hearing aid uptake (Rolfe & Gardner, 2016). Participants also mentioned taking up hearing aids for entertainment purposes, like watching TV. A study by Strelcyk and Singh (2018) showed that hearing aids could alleviate listening difficulties while watching TV. They also found that hearing aid users watched TV for approximately 6 hours longer than non-users (Strelcyk & Singh, 2018). It is important to note that some people might not use hearing aids regularly but only use them for entertainment purposes, such as watching TV, and still describe themselves as satisfied hearing aid users (Laplante-Lévesque et al., 2011). When providing counselling regarding intervention options, it may be helpful for hearing healthcare professionals to incorporate the potential benefits of hearing aids for specific situations or purposes (e.g., for entertainment), as some people take up hearing aids mainly for this reason.

In a previous analysis of the same data, we compared the user perspectives related to reasons and recommendations for hearing aid uptake between Lexie and Hearing Tracker users (Knoetze, Manchaiah & Swanepoel, 2023). This analysis showed that the Lexie users, who were significantly younger and potentially more socially active, were more likely to adopt hearing aids due to difficulties in social interactions with friends. Lexie users also reported listening fatigue as a reason for hearing aid uptake more often. On the other hand, Hearing Tracker users, who were significantly older, mentioned the consequences of untreated hearing loss, particularly related to cognitive decline and dementia, as a motivating factor for hearing aid uptake more frequently. This could be due to their age and the guidance from hearing healthcare providers during clinical consultations. Therefore, raising awareness about the benefits of hearing aids, including reducing listening fatigue and cognitive decline, can encourage the adoption of hearing aids in both groups.

To our knowledge, this was the first study to document hearing aid users' recommendations to others with hearing difficulties. Literature on recommendations to others with similar health problems is also limited in other health areas. The present study reported several recommendations to others with hearing difficulties covering the entire patient journey, including pre-fitting recommendations, e.g., seeking hearing help to post-fitting recommendations, e.g., getting hearing aid adjustments. These recommendations seem to be aligned with typical hearing healthcare professional recommendations and may suggest that people who accept and repeat clinical recommendations from a hearing healthcare professional are more likely to take up hearing aids. Hearing Tracker users were more likely to recommend not to delay seeking help and more likely to suggest getting a hearing test (Knoetze, Manchaiah & Swanepoel, 2023). This could be attributed to the fact that Lexie users were not required to take a hearing test. Hearing Tracker users also had poorer self-reported hearing difficulties and longer duration of hearing loss, which may contribute to their emphasis on timely help. Additionally, Hearing Tracker users were more likely to recommend changing the hearing aid style, which is understandable considering the wider variety of options available for prescription users compared to Lexie users who only had the option of behind-the-ear hearing aids. More research in this area is required as this information can assist hearing healthcare professionals and service-delivery models to better appreciate what hearing aid users value and what may improve hearing aid uptake.

4.5.1 Study Limitations

While our study was the first to report reasons for obtaining hearing aids from a user perspective, it has some limitations. Firstly, there is a potential sampling bias due to participant recruitment and self-selection. Secondly, Lexie participants were verified hearing aid users, as they had to purchase Lexie hearing aids, whereas Hearing Tracker participants could not be independently verified, as we relied on their self-reported hearing aid usage in the larger study. Thirdly, the complexity of the open-ended question, with multiple sub-questions, may have led to selective responses. Fourthly, Lexie participants were not assigned a minimum word count requirement, resulting in some concise responses with limited contextual information. Lastly, our sample consisted of individuals who had already taken up hearing aids and may not represent all potential hearing aid users, especially those who are strongly opposed to using hearing aids or who face significant barriers to accessing hearing aids. Nonetheless, our study provides valuable insights into why individuals choose to take up hearing aids and can inform interventions aimed at improving hearing aid uptake among those who are at the stage of change where they are open to the idea of using hearing aids. While our study does not directly relate to the readiness literature due to retrospective questioning, it indirectly contributes by exploring the underlying motivations for hearing aid uptake.

4.6 Conclusions

The hearing aid user perspective on reasons for hearing aid uptake have been drawn from a much larger sample compared to previous qualitative studies. Most factors motivating hearing aid uptake were intrinsic, suggesting that it is primarily a self-determined behavior. Hearing healthcare professionals should, therefore, be aware of a person's readiness for change for successful intervention uptake. However, some important extrinsic factors reportedly influence hearing aid uptake, such as the availability of finances and social support. These factors should be taken into account by hearing healthcare professionals to support change as well as used when developing public health approaches to promote hearing aid uptake. The most frequent recommendation to others was not to delay seeking hearing help and to get hearing aids. Earlier detection of hearing loss through screening programs could support hearing help-seeking and hearing aid uptake. Overall, the study results suggest that the process of and reasons for obtaining hearing aids are highly personal and are due to diverse reasons. In retrospect, hearing aid users tend to appreciate the benefits of getting hearing aids early in their hearing care journey, as evident from their recommendations to others. Hearing healthcare professionals should broaden their perspective on hearing health and emphasize the benefits of hearing aids, such as improving psychosocial functioning, reducing listening fatigue, reducing the risks of cognitive decline, and enhancing the overall quality of life. There is a need for future research to develop strategies that can facilitate change and encourage hearing aid uptake among those who are hesitant towards using hearing aids.

Disclosure statement

The relationship between author De Wet Swanepoel and the hearX Group, which owns Lexie Hearing, includes equity, consulting, and potential royalties. The other authors have declared that no other competing financial or nonfinancial interests existed at the time of publication.

Data availability statement

The data analysed during the current study are available from the corresponding author upon reasonable request.

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CHAPTER 5

PERSPECTIVES ON HEARING AID COST AND UPTAKE FOR PRESCRIPTION AND OVER-THE-COUNTER HEARING AID USERS

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5.1 Abstract

Purpose

This study explored user perspectives on the relationship between hearing aid cost and uptake, as well as cost-related recommendations for others with hearing difficulties, in a sample of prescription and over-the-counter (OTC) hearing aid users.

Method

A secondary analysis was conducted on a cross-sectional survey using qualitative content analysis to analyze responses related to the cost of hearing aids. The study included a total of 241 adult participants, comprising 179 prescription hearing aid users from the Hearing Tracker website and 62 OTC hearing aid users from the Lexie Hearing US database.

Results

Prescription users had a mean age of 66.7 years (SD 13.2), including 62.0% males, 37.4% females, and 0.6% non-binary individuals. OTC users had a mean age of 63.0 (SD 13.4), with 48.4% males and 51.6% females. Three overarching domains were identified: perceived

enablers to hearing aid uptake related to the cost, perceived barriers to hearing aid uptake related to the cost, and recommendations to others with hearing difficulties related to the cost, with 14 categories recognized for prescription users and 12 for OTC users. Both groups identified the high cost of hearing aids and lack of insurance coverage as significant barriers to uptake. Many prescription users reported external support (e.g., financial support and health insurance coverage) as an enabler, while OTC users frequently mentioned the affordability of OTC devices. The most common recommendation among prescription users was to seek professional support, whereas OTC users recommended researching hearing aids before making a purchase.

Conclusions

Cost and insurance coverage consistently emerge as primary barriers to hearing aid adoption for both prescription and OTC users. To foster greater accessibility, initiatives should target these financial obstacles. Additional research is warranted on the relationship between hearing aid cost and uptake, especially among OTC users and those seeking financial assistance.

Keywords

Hearing loss, Hearing aids, Hearing aid uptake, Cost, Affordability

5.2 Introduction

Hearing loss is widespread, affecting nearly 20% of the global population (World Health Organization, 2021). Hearing aids are the most common management option for hearing loss (Brodie et al., 2018). While hearing aids can improve the listening ability and quality of life of those with hearing loss (Ferguson et al., 2017), only a small proportion of adults with acquired hearing loss seek help for their hearing difficulties and obtain hearing aids globally (Bisgaard et al., 2021). According to the most recent (2011-12, 2015-16, 2017-20) National Health and Nutrition Examination Survey (NHANES) in the United States (US), 85% of persons with audiometric or self-reported hearing loss never tried hearing aids or were not current hearing aids users (Humes, 2023). This underscores the need for a deeper understanding of factors influencing hearing aid uptake.

The average cost of prescription hearing aids in the US is $5,000 a pair, which is usually an out-of-pocket expense since most health insurance plans do not cover hearing aids (Jilla et al., 2020). This cost is a bundled price, covering the physical devices, services and support, such as fittings, adjustments and follow-up appointments. However, some audiologists may opt for unbundling, where services are priced separately from the devices. The data from the 2016 American Community Survey showed that three out of four Americans with functional hearing loss could not afford hearing aids at this price (Jilla et al., 2020). Furthermore, purchasing hearing aids at this price would add 4% of the US population into poverty for the year (Jilla et al., 2020). In addition, a study by Mahmoudi et al. (2018) found significantly higher total annual healthcare and out-of-pocket spending by hearing aid users in the US compared to non-users. Our recent systematic review has also demonstrated that having access to financial support positively affects hearing aid uptake in several studies (Knoetze et al., 2023b). Moreover, the MarkeTrak 2022 consumer survey showed that higher income levels and third-party coverage were related to increased hearing aid uptake (Windmill, 2022). The survey also found that increased third-party coverage was a bigger motivator for hearing aid uptake than simply lowered costs (Windmill, 2022). Overall, these studies highlight the high cost of hearing aids as one of the important contributing factors to the low uptake of hearing aids.

Recent changes in regulatory standards for hearing aids in the US may contribute to reducing the affordability barrier. On the 17th of October 2022, the Food and Drug Administration (FDA) issued a final rule, which now enables adults with self-perceived mild-to-moderate hearing difficulties to purchase over-the-counter (OTC) hearing aids online or from stores without a hearing assessment, hearing aid prescription or fitting adjustment by a licensed hearing healthcare professional (Food and Drug Administration, 2022). A few recent studies have demonstrated that OTC hearing aids could provide benefit and satisfaction that are comparable to prescription hearing aids that are fitted in person by hearing healthcare professionals (Swanepoel et al., 2023; De Sousa et al., 2023). While the price of OTC hearing aids is generally lower than prescription hearing aids, ranging from $200 to over $2,000 per pair, the more expensive OTC devices may still be a significant expense for some individuals (Manchaiah et al., 2023).

Our systematic review indicated that while some studies suggest that the high cost of prescription hearing aids may prevent people from obtaining them, there is still limited evidence regarding this matter (Knoetze et al., 2023b). This may be attributed to a scarcity of research specifically exploring the direct impact of cost on hearing aid uptake, with existing studies typically encompassing multiple factors and methodologies rather than solely examining the relationship between cost and hearing aid adoption. Moreover, there are few qualitative studies on this topic. Qualitative research can provide valuable insights into complex issues by capturing the diverse experiences and perspectives of individuals (Austin & Sutton, 2014).

Previous qualitative studies (Chandra & Searchfield, 2016; Ekberg et al., 2017; Heselton et al., 2022; Laplante-Lévesque et al., 2010; McKee et al., 2019) suggest that the high cost associated with hearing aids poses a significant barrier to their uptake, while the perceived benefit of lower costs associated with alternative service delivery models, such as online hearing aids, presents a potential solution to this barrier. These qualitative studies examining the relationship between hearing aid cost and uptake have focused solely on prescription hearing aids primarily due to the timeframe of the research. However, with the recent FDA approval of OTC hearing aids, there is a gap in evidence regarding user perspectives from the OTC service-delivery model on this topic. Additionally, studies on the relationship between the cost and uptake of OTC hearing aids compared to prescription hearing aids are also important areas of exploration. This may help to inform policies and regulations surrounding hearing aids and may allow for greater accessibility to hearing aids. Therefore, the study explored user perspectives on the relationship between hearing aid cost and uptake, as well as cost-related recommendations for others with hearing difficulties, in a sample of prescription and over-the-counter (OTC) hearing aid users.

5.3 Method

Ethical approval for this study was obtained from Lamar University's Human Subjects Review Board (Ref: IRB-FY21-248) and from the Faculty of Humanities Research Ethics Committee, University of Pretoria (Ref: HUM008/0822).

5.3.1 Study Design

This preliminary study was based on a secondary analysis of a cross-sectional survey (Knoetze et al., 2023a). Secondary analysis and reuse of qualitative data have become more common in research, allowing for further exploration beyond the original study's scope (Bishop & Kuula-Luumi, 2017; Denzin & Lincoln, 2011). The original study analyzed 642 responses to an open-ended question in an online questionnaire to explore user perspectives on reasons for hearing aid uptake and recommendations to others with hearing difficulties using qualitative content analysis.

A multidisciplinary team consisting of audiologists (authors DS and VM) and social psychologists (Jamie Pennebaker and Ryan Boyd) collaborated to formulate the open-ended question by incorporating relevant information to encourage users to provide comprehensive responses regarding the primary factors influencing hearing aid uptake and recommendations to others with hearing difficulties. However, for the current study, only the descriptions related to cost were analyzed, considering that numerous participants in the original study mentioned cost-related factors in their responses. The open-ended question was phrased as follows:

For many people, getting and wearing a hearing aid is a major life decision. They often say that getting a hearing aid is embarrassing and makes them feel or look old. Others worry about the cost or what others will say. How did you deal with these issues when you decided to buy a hearing aid? What motivated you to get hearing aids? Was there a single reason or event that convinced you or were there many reasons? Please provide as much detail as possible about the reason(s) why you decided to get hearing aids. What would you recommend to others who are starting to have hearing problems?

5.3.2 Participants and Data Collection

The participants in the original study were adults (18 years and older) with hearing difficulties who had been or were current hearing aid users. The sample was recruited from the Hearing Tracker website (www.hearingtracker.com) and the Lexie Hearing (www.lexiehearing.com) US database. The Hearing Tracker website is an online platform for consumers to freely share their opinions and experiences regarding hearing aids (Swanepoel et al., 2023). Participants from the Hearing Tracker community had received conventional face-to-face hearing care services from hearing healthcare professionals, which were obtained either from private clinics, public health centers, or discount warehouses. On the other hand, individuals from the Lexie Hearing US database had purchased self-fitting, behind-the-ear (BTE), OTC Lexie Lumen hearing aids online, along with the accompanying application (Swanepoel et al., 2023). In October and November 2021, an email invitation containing a link to an online informed consent form and questionnaire was sent to the Hearing Tracker and Lexie Hearing US databases. Informed consent was required before the participants could complete the online questionnaire.

5.3.3 Data Analysis

The original dataset included 642 users, consisting of 415 prescription users and 227 OTC users. The dataset was screened in Microsoft Excel to identify responses to the open-ended question related to hearing aid cost. The researcher carefully reviewed each response manually without relying on specific keyword searches. A total of 241 responses (179/241 responses from prescription hearing aid users and 62/241 responses from OTC hearing aid users) were identified as related to cost and included in the present study. Qualitative content analysis was used systematically to examine and interpret the data to identify patterns, themes, and relationships. Knudsen et al. (2011) described coding and categorization as critical components of qualitative data analysis. Coding involves assigning labels or tags to specific segments of the data, while categorization involves grouping these codes into broader categories. The authors emphasized that the coding and categorization process should be iterative and involve ongoing reflection and revision to ensure that the emerging categories accurately capture the data.

The primary researcher (MK) read the data multiple times to develop an understanding of its content and to identify meaningful units of text. Using an inductive approach (i.e., bottom-up), the researcher assigned specific codes to the meaning units and organized them into broader categories and domains. This approach is particularly valuable for exploring new or under-researched topics, providing new insights and understandings based on the collected data. The qualitative content analysis involved an iterative process where the researcher constantly revisited and refined the coding and categorization. As the analysis progressed, MK revised codes or created new categories based on emerging patterns in the data. This iterative approach facilitated a nuanced and comprehensive understanding of the data, ensuring the identification of all relevant patterns. To assess the inter-coder reliability, 25% of the coding was randomly cross-checked by other research team members (IO and EB). Any discrepancies were resolved through discussions with the rest of the research team to ensure responses were categorised appropriately by consensus. The result of the inter-coder reliability check showed a high level of agreement among the team members, with a 97% agreement rate. This demonstrates that the coding process was consistent and reliable, and the codes were applied consistently across different team members. We have provided a codebook as supplementary material to ensure transparency in our methodology (see Supplementary Material 1 - Appendix N).

5.4 Results

The demographic characteristics of participants are shown in Table 5.1. A total of 241 hearing aid users were included in the study, with 179 being prescription users and 62 being OTC users. The mean age of prescription users was 66.7 years (SD = 13.2), while OTC users had a lower mean age of 63.0 years (SD = 13.4). In terms of gender distribution, the majority of prescription users were male (62.0%), while the majority of OTC users were female (51.6%). Only one participant in the study identified as non-binary. When asked about self-reported hearing difficulty (i.e., hear everything, sometimes don't hear, regularly don't hear, and almost never hear), most users reported that they regularly don't hear, with 48.0% of prescription users and 56.5% of OTC users falling into this category. The mean duration of hearing difficulties was shorter for OTC users (14.0 years; SD 13.5) compared to prescription users (22.4 years; SD 16.6). However, the mean duration before purchasing a hearing aid was relatively similar for both groups, with prescription users waiting 8.1 years SD 12.1 and OTC users waiting 7.9 years SD 9.8 before purchasing hearing aids. Most prescription users (56.4%) purchased their hearing aids from hearing aid clinics or universities.

Table 5.1 Demographic characteristics of hearing aid users

Characteristic	Prescription users (n = 179)	OTC users (n = 62)	Total users (n = 241)
Age (mean; SD)	66.7 (13.2)	63.0 (13.4)	65.8 (13.3)
Gender (n; %)			
Male	111.0 (62.0%)	30.0 (48.4%)	141.0 (58.5%)
Female	67.0 (37.4%)	32.0 (51.6%)	99.0 (41.1%)
Non-binary	1.0 (0.6%)	-	1.0 (0.4%)
Self-reported hearing difficulty (n; %)			
Hear everything	-	1.0 (1.6%)	1.0 (0.4%)
Sometimes don't hear	47.0 (26.3%)	19.0 (30.6%)	66.0 (27.4%)
Regularly don't hear	86.0 (48%)	35.0 (56.5%)	121.0 (50.2%)
Almost never hear	46.0 (25.7%)	7.0 (11.3%)	53.0 (22.0%)
Duration of hearing difficulties in years (mean; SD)	22.4 (16.6)	14.0 (13.5)	20.2 (16.3)
Duration before hearing aid purchase in years (mean; SD)	8.1 (12.1)	7.9 (9.8)	8.0 (11.6)
Hearing aid purchase (n; %)			
Hearing aid clinic or university	101 (56.4%)	-	101 (41.9%)
Discount warehouse (e.g., Costco, Sam's Club)	36 (20.1%)	-	36 (14.9%)
Internet or online	11 (6.1%)	62 (100%)	73 (30.3%)
Pharmacy hearing center	2 (1.1%)	-	2 (0.8%)
Other	29 (16.2%)	-	29 (12.0%)

Note. OTC = over the counter, A dash ("-") indicates none or 0. Percentages may not add up to exactly 100% due to rounding.

The qualitative content analysis of hearing aid user perspectives on the relationship between hearing aid cost and hearing aid uptake are shown in Tables 5.2 and 5.3. Table 5.2 provides the domains and categories identified for prescription hearing aid users, and Table 5.3 provides the domains and categories identified for OTC hearing aid users. Notably, some individuals who used OTC devices had previously used prescription devices and vice versa. Nevertheless, our analysis aimed to differentiate between responses pertaining to prescription and OTC devices when this was clearly apparent from the textual responses. In both groups, three overarching domains were apparent that were related to cost: perceived enablers, perceived barriers, and recommendations, with 14 categories recognized for prescription users and 12 for OTC users.

Table 5.2 Prescription hearing aid user perspectives on the relationship between cost and uptake of hearing aids

Domain	Category	n	Meaning unit examples
Perceived enablers	External support	46	*The VA paid for my hearing aids (P172, 80 yrs., male)*
	Affordable options	42	*Shopped for the best value (P32, 70 yrs., male)*
	Availability of finances	40	*I had enough discretionary income so price wasn't an issue (P116, 71 yrs., female)*
	Cost-benefit	29	*Yes hearing aids expensive and hard get used to it but the quality of life gets better when you can hear (P228, 49 yrs., male)*
Perceived barriers	High cost of HAs in general (i.e., OTC or prescription HAs)	91	*Cost was a major reason why I delayed getting hearing aids (P138, 65 yrs., female)*
	Not covered by insurance	14	*The cost of hearing aids is a MAJOR financial burden and medical insurance does not assist (P300, 47 yrs., female)*
	Cost-benefit concern	8	*Doesn't matter, have paid thousands over the years and I still can't hear (P207, 65 yrs., female)*
	Long-term and ongoing costs	5	*Could not afford to replace even one (P386, 73 yrs., female)*
Recommendations	Seek professional support	13	*Go to a professional audiologist and get tested and get an audiogram to determine your level of hearing loss before you buy (P70, 57 yrs., female)*
	Do research before you buy	9	*Do a lot of research before you buy (P217, 80 yrs., male)*
	Purchase new technology	8	*Purchase the most current technology you can afford (P312, 63 yrs., female)*
	Avoid OTC or cheaper hearing aids	4	*Don't try to diagnose yourself and buy hearing aids online or over the counter – you will most likely waste money (P275, 81 yrs., male)*
	Seek financial support	4	*My recommendation for others who are starting to have hearing problems are to seek out professional assistance with financing if needed (P300, 47 yrs., female)*
	Do a hearing aid trial before you buy	3	*Be sure to try first (P92, 76 yrs., male)*

Note. This table includes direct quotes from participants; therefore, there might be grammatical errors. HAs = hearing aids; OTC = over the counter, VA = Veteran's Affairs

5.4.1 Prescription Hearing Aid User Perspectives

Domain 1: Perceived Enablers Related to Cost

Perceived enablers included four categories, presented in Table 5.2 and Figure 5.1. Several participants reported having the financial ability to afford hearing aids. Therefore, the cost was not a hindrance for them. Some participants described the cost-benefit of hearing aids, as they felt that the benefits of purchasing and using hearing aids outweigh the costs associated with it, e.g., improved hearing, improved quality of life, and increased participation in activities of daily living. Affordable options were mentioned by some participants who either shopped around for the best prices or discovered that hearing aids were more affordable at specific places, e.g., discount warehouses. Many participants reported receiving external support to pay for their hearing aids, e.g., financial assistance from organizations like the Veteran's Affairs or Vocational Rehab, health insurance, or financial support from a family member(s).

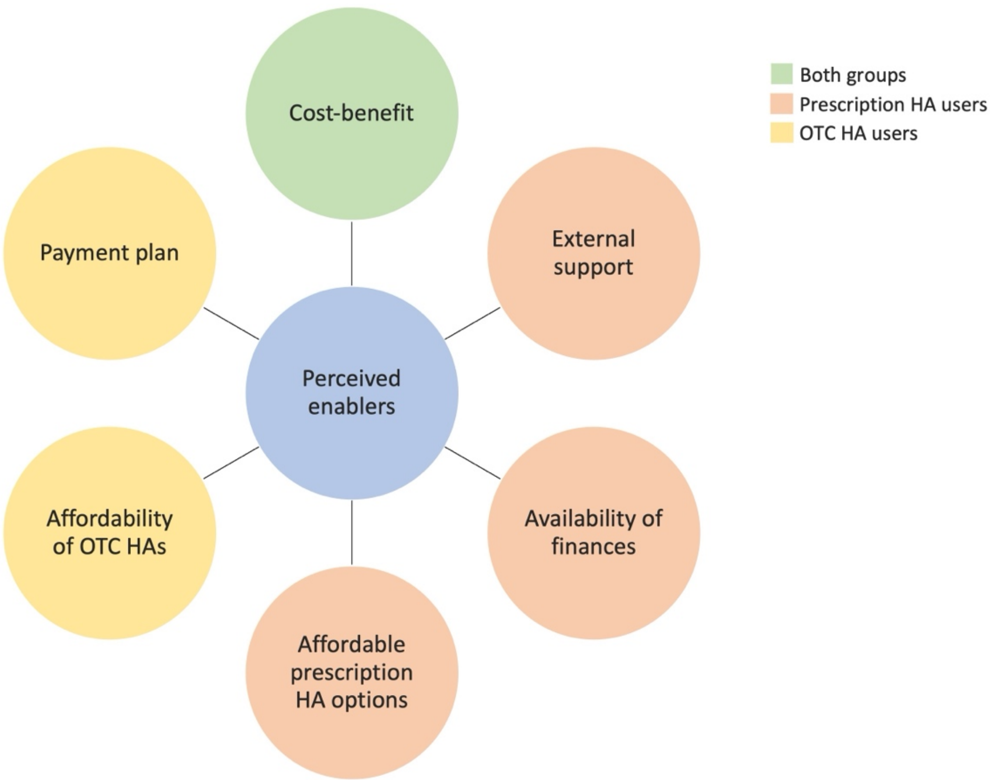

Figure 5.1 Categories related to cost identified for perceived enablers of hearing aid uptake

Domain 2: Perceived Barriers Related to Cost

Perceived barriers included four categories (see Table 5.2 and Figure 5.2). Most participants viewed the high cost of hearing aids as a significant impediment to their uptake, leading to postponed acquisition for some participants. Some participants mentioned the lack of insurance coverage for hearing aids as a financial burden. In the cost-benefit concern category, some participants felt that the cost of hearing aids did not justify their perceived benefits. Despite paying a significant amount to purchase hearing aids, these participants still experienced difficulty hearing, e.g., some still reported difficulty understanding speech in background noise or listening to music. Long-term and ongoing costs, such as repair and replacement costs, were also mentioned by some participants.

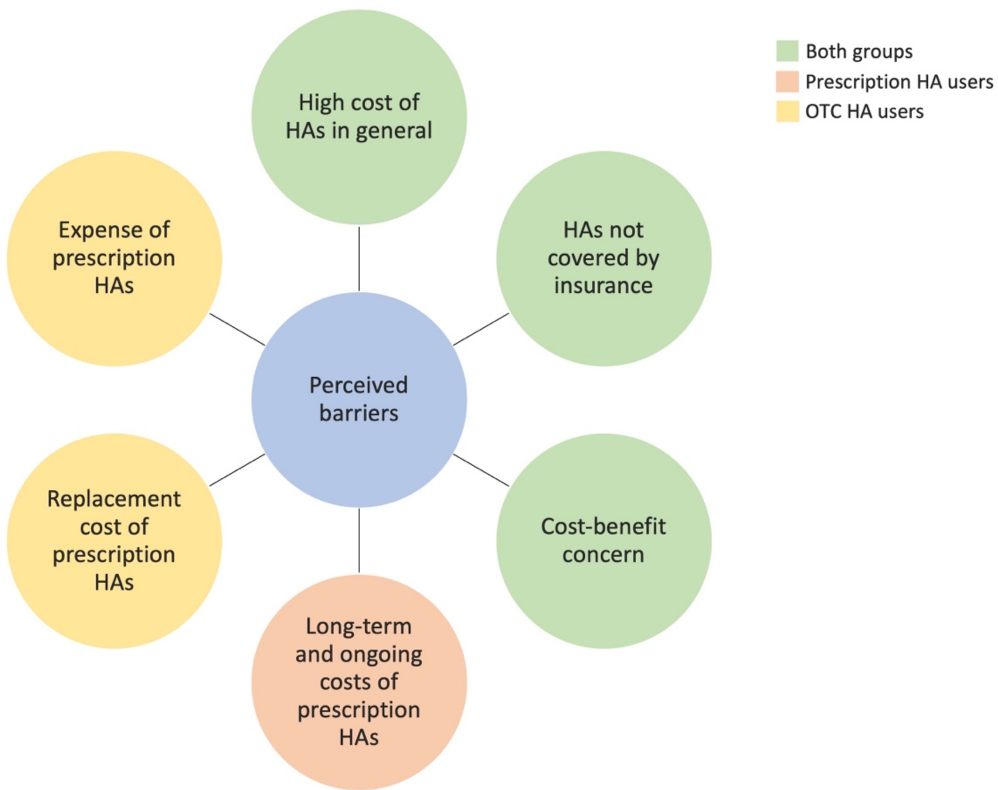

Figure 5.2 Categories related to cost identified for perceived barriers to hearing aid uptake

Domain 3: Recommendations Related to Cost

Recommendations included six categories (see Table 5.2 and Figure 5.3). Participants recommended the importance of seeking professional support before purchasing hearing aids, e.g., consulting an audiologist and getting a hearing test before purchasing or seeking medical advice from an Ear-Nose-Throat (ENT) specialist. Some participants also suggested doing research before buying hearing aids, including looking for information online and on hearing aid manufacturer websites.

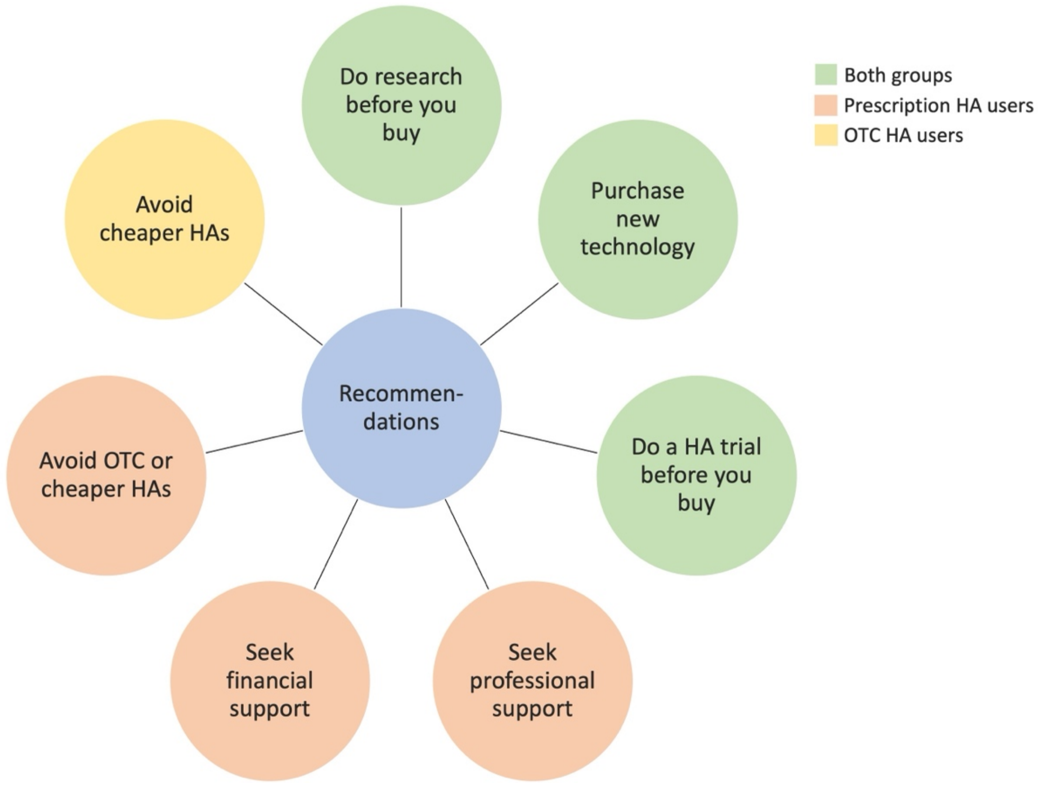

Figure 5.3 Categories related to cost identified for recommendations to others with hearing difficulties

Another key category was purchasing new technology. Participants suggested that individuals purchase the most current technology they can afford or upgrade their hearing aids when their budget permits. Furthermore, some participants cautioned against purchasing OTC or less expensive hearing aids. A smaller representation also identified seeking financial support as important, suggesting exploring finance or grant funding options. Finally, a number of participants recommended doing a hearing aid trial before making a purchase.

5.4.2 OTC Hearing Aid User Perspectives

Domain 1: Perceived Enablers Related to Cost

Perceived enablers included three categories, presented in Table 5.3 and Figure 5.1. In this domain, most participants reported the affordability of OTC devices as a key factor in their decision to purchase hearing aids. A few mentioned the payment plan offered by Lexie Hearing as an enabler. In the cost-benefit category, participants expressed that they generally perceived their hearing aids as providing good value for the money spent, citing perceived benefits from their use.

Domain 2: Perceived Barriers Related to Cost

Perceived barriers included 5 categories, presented in Table 5.3 and Figure 5.2. The high cost of hearing aids, in general, was reported as a significant barrier for many participants. In this category, OTC users may have referred to the high cost of OTC or prescription devices. A number of participants specifically mentioned the expense of prescription hearing aids as a barrier, with some indicating that they could not afford to replace their prescription hearing aids when they were lost or damaged and, therefore, they purchased OTC hearing aids. The lack of insurance coverage was also a barrier for some OTC hearing aid users. Lastly, cost-benefit concerns were raised by some participants who felt that the hearing aids did not improve their hearing even though they were very expensive.

Domain 3: Recommendations Related to Cost

Four categories of recommendations (Table 5.3 and Figure 5.3) were identified. Some OTC hearing aid users recommended researching before purchasing hearing aids to find the right fit for their hearing and budget. One participant advised upgrading hearing aids with new technology, while another participant cautioned against cheaper hearing aids due to poor sound quality. Lastly, another participant recommended trying out hearing aids through a free trial to assess their effectiveness.

Table 5.3 Over-the-counter hearing aid user perspectives on the relationship between cost and uptake of hearing aids

Domain	Category	n	Meaning unit examples
Perceived enablers	Affordability of OTC HAs	27	*I was very happy with the product and it was more affordable than the co-pay my insurance required. (P651, 73 yrs., male)*
	Payment plan	4	*Having small monthly payments sold me on the deal with Lexie! (P500, 29 yrs., female)*
	Cost-benefit	2	*They're too expensive but at least with them I can hear (P521, 55 yrs., female)*
Perceived barriers	High cost of HAs in general (i.e., OTC or prescription HAs)	25	*Could not really afford them (P523, 72 yrs., male)*
	Expense of prescription HAs	12	*Bought a $3000.00 set of hearing aids from an audiologist that lasted about two years and quit working. Too expensive to replace (P682, 64 yrs., male)*
	Replacement cost of prescription HAs	5	*But when I lost one..... the cost to replace it had gone up so much I still couldn't afford to do it (P630, 74 yrs., female)*
	Not covered by insurance	3	*Getting the hearing aids was not a big issue except for the cost as my insurance does not cover them (P668, 57 yrs., female)*
	Cost-benefit concern	3	*I was also concerned that I would spend a large amount of money and they would not help me (P487, 41 yrs., female)*
Recommendations	Do research before you buy	4	*Search for right hearing aids for you, your hearing and your budget (P482, 66 yrs., female)*
	Purchase new technology	1	*I upgraded them because the technology advanced a lot in a year (P672, 51 yrs., male)*
	Avoid cheaper hearing aids	1	*First one was cheap crap with poor sound quality (P678, 72 yrs., male)*
	Do a hearing aid trial before you buy	1	*Execute a free trial and see if aids help (P724, 83 yrs., male)*

OTC = Over-the-counter; HA = hearing aid

Note: This table includes direct quotes from participants, therefore there might be grammatical errors.

5.5 Discussion

The relationship between hearing aid cost and uptake, as well as cost-related recommendations for others with hearing difficulties, were explored in a sample of 179 prescription and 62 OTC hearing aid users. The results of qualitative content analysis of open-ended responses and practice implications, framed within the context of the Health Belief Model (HBM) proposed by Rosenstock (1966), are discussed below. The HBM provides a valuable perspective for understanding various health behaviors, including the poor uptake of hearing aids (Rosenstock, 1966). The HBM psychological framework proposes that an individual's decision to engage in health-related actions, such as hearing aid uptake, is influenced by perceived factors such as susceptibility, severity, benefits, barriers, self-efficacy, and cues to action (Saunders et al., 2016).

5.5.1 Perceived Enablers Related to Cost

This study identified several perceived enablers related to cost that influence hearing aid uptake. This is in line with the HBM, as these factors facilitate the adoption of hearing aids by addressing barriers, enhancing the perceived benefits, and increasing individuals' confidence in their ability to manage costs and make informed decisions. Most prescription hearing aid users reported that external support, such as financial assistance from organizations, health insurance coverage, or support from family members, played a significant role in facilitating hearing aid uptake. These findings align with previous research indicating that access to financial support positively affects hearing aid uptake (Jilla et al., 2020; Knoetze et al., 2023b). Therefore, it is essential for stakeholders to focus on making financial assistance programs more widely available and easily accessible to those who require it. However, it is important to recognize that financial assistance or insurance coverage does not guarantee universal adoption. For example, in countries like Norway and the United Kingdom, where hearing aids are fully subsidized by the government, a significant proportion of individuals still do not obtain hearing aids (Kirkwood, 2015).

Partly contributing to this trend is the concept of an inelastic demand function within the hearing aid industry (Amlani, 2023). In other words, as the retail price of hearing aids increases or decreases, there is no significant change in the number of hearing aids sold (Amlani, 2023). For instance, Amlani and De Silva (2005) reported a demand function of |0.49|, indicating that even when hearing aids are provided at no cost to the consumer, only 49 out of 100 individuals would adopt hearing aids, while the remaining 51 individuals would choose not to adopt them, despite the absence of financial cost. Hearing aid cost is, therefore, not the only consideration when individuals decide whether to take up hearing aids. In line with the multi-dimensional perspective of the HBM, other factors, such as readiness to change and stigma, should also be taken into account by hearing healthcare professionals when addressing barriers to hearing aid uptake (Knoetze et al., 2023a; Knoetze et al., 2023b).

Many prescription hearing aid users reported having the financial means to afford hearing aids, eliminating cost as a barrier. Some prescription hearing aid users mentioned affordable options as an enabler. This emphasizes the importance of considering individual financial circumstances and the ability to afford hearing aids. Hearing healthcare professionals should use a shared decision-making approach when discussing the cost options of hearing aids since it has been identified as a difficult-to-discuss topic (Ekberg et al., 2017). To facilitate shared informed decision-making, patients must be provided with clear and comprehensive information on all the available options to allow them to play an active part in the decision-making process (Pryce et al., 2016). Furthermore, offering a range of hearing aids at different price options allows the patient to choose the most suitable option for them and may lead to a smoother interaction between the hearing healthcare professional and the patient (Ekberg et al., 2017). This aligns with the HBM's emphasis on cues to action, where well-informed individuals are more likely to take action when they perceive the benefits outweigh the barriers.

Some participants from both groups emphasized the benefits of hearing aids, such as improved hearing, quality of life, and participation in daily activities, which outweighed the costs associated with purchasing hearing aids. This is in agreement with McMahon et al. (2021), who also found that cost-benefit evaluations influence hearing help-seeking or hearing aid uptake decisions. In another study, Brent (2019) carried out a cost-benefit analysis of hearing aids by converting the Quality Adjusted Life Year (QALY) to a benefit estimate, including the direct benefits as well as indirect benefits related to reducing dementia symptoms, and found that the benefits of hearing aids were very large relative to the costs. Therefore, hearing healthcare professionals should raise awareness regarding the direct and indirect benefits of hearing aids. They can do this by providing educational materials and online resources or incorporating discussions in the initial consultation for prescription users. This could motivate individuals to take up hearing aids, regardless of the associated cost (Knoetze et al., 2023a).

In the case of OTC hearing aid users, the affordability of OTC devices was identified as an important factor enabling them to purchase hearing aids. This suggests that the lower cost of OTC hearing aids relative to prescription hearing aids may contribute to increased uptake of hearing aids for some potential users for whom the cost of hearing aids is a potential barrier to uptake. Some OTC hearing aid users mentioned the availability of payment plans as an enabler for individuals who cannot afford the full cost upfront or lack insurance coverage or external support. Other OTC manufacturers should also consider offering payment plans to make their products more affordable and accessible.

5.5.2 Perceived Barriers Related to Cost

The study's findings regarding perceived barriers related to cost link directly with the HBM's construct of perceived barriers, which can hinder health-related behaviors, such as hearing aid uptake. The high cost of hearing aids was consistently reported by both groups as a significant barrier to uptake, in line with previous research (Jilla et al., 2020; Lin, 2018). OTC hearing aid users reported the high cost of hearing aids in general (which may also refer to the cost of OTC hearing aids), as well as the expense of prescription hearing aids specifically, as barriers to uptake. Lack of insurance coverage exacerbated the financial burden for some prescription hearing aid users, as also reported by McKee et al. (2019) and Jilla et al. (2020). Hearing healthcare professionals can play a role in advocating for improved insurance coverage for hearing aids. Collaborating with insurance providers and policymakers to expand coverage options can help reduce the financial burden on patients. Hearing aid users in both groups expressed concerns about the cost of hearing aids not justifying their perceived benefits, as some still experienced hearing difficulties even after purchasing and using expensive hearing aids. The long-term costs associated with repairs and replacements were mentioned by prescription hearing aid users. Healthcare professionals and OTC vendors should discuss the long-term costs of hearing aids, such as maintenance, repairs, and replacements. Patients must have a clear understanding of the financial commitment beyond the initial purchase to plan accordingly. Providing maintenance packages or extended warranties as a part of hearing aid sales can also help alleviate long-term cost concerns. A few OTC hearing aid users mentioned affordability issues when it came to replacing or repairing lost or damaged prescription hearing aids, leading them to opt for OTC alternatives. As OTC hearing aids become more prevalent, it is important for hearing healthcare professionals to educate patients about the potential advantages and limitations of OTC devices. This guidance can help individuals make informed decisions regarding their hearing needs and budget constraints. The findings from both prescription and OTC hearing aid users' perspectives underscore the need for interventions that effectively address the cost-related barriers associated with hearing aid uptake, such as exploring options for insurance coverage and promoting affordable hearing aid options.

5.5.3 Recommendations Related to Cost

In addition to Knoetze et al. (2023a), this study's preliminary findings contribute to the limited body of research on hearing aid users' recommendations within the context of cost-related statements. User recommendations provide important information regarding the preferences, needs and experiences of hearing aid users. Both prescription and OTC hearing aid users provided many similar recommendations in this study. Prescription hearing aid users stressed the importance of consulting audiologists or ENT specialists before purchasing hearing aids, highlighting the value of hearing assessment and professional guidance in decision-making. Researching hearing aids was seen as important in making informed choices by both groups. Participants from both groups recommended considering purchasing the most current technology or upgrading hearing aids when the budget permits, indicating a desire for optimal technology and performance. Recent consumer surveys have shown that hearing aid users tend to purchase the highest level of technology which is more expensive, although many of these users report cost as an issue for hearing aid uptake (Bannon et al., 2022; Manchaiah et al., 2021). Moreover, seeking financial support through various options, such as financial plans or grant funding, was suggested by a few prescription hearing aid users as a means to overcome cost barriers. By emphasizing the importance of consulting professionals, researching options, and seeking financial support, the study underscores the role of the HBM's cues to action and self-efficacy in guiding individuals toward adopting hearing aids. This information may be useful for hearing healthcare professionals, researchers, and policymakers in developing interventions and policies that are more effective, acceptable, and aligned with the expectations of hearing aid users.

5.5.4 Study Limitations

This exploratory study has several limitations, and the results must be viewed in light of these. First, the study's results included a secondary analysis of an open-ended question about why people purchase hearing aids (Knoetze et al., 2023a). It is important to note that the data was not originally intended for this specific research question. Consequently, the depth and specificity of information related to hearing aid costs may be limited and should be viewed as preliminary. Second, the study population consisted of individuals who already obtained hearing devices, potentially introducing selection and response biases. As participants were self-selected through outreach efforts, their perspectives may not fully represent the broader population with hearing loss. Additionally, there is a risk of self-selection in our study population, recruited from online platforms like Hearing Tracker, as participants likely represent a subset of individuals more engaged in discussing hearing aids. For this reason, caution should be exercised when generalizing the findings. Nevertheless, the study provides valuable insights into the views of those pursuing hearing aids regarding the relationship between cost and uptake. Third, the survey did not include any questions to determine whether participants paid for their hearing aids or received them at no cost. Therefore, a stratified analysis was not possible, and we could not discuss differences in perspectives between those who paid for their hearing aids and those who received them at no cost, including those covered by health insurance. Future research should incorporate questions about the cost participants paid for their hearing aids and their income background to understand the financial aspects of hearing aid uptake for a comprehensive analysis of users' perspectives. Fourth, demographic data, e.g., race, ethnicity and income level, was not collected or available for analysis. This limited our ability to explore how these factors interact with participants' experiences and perspectives on the relationship between hearing aid cost and uptake. Additionally, the demographics of this sample may not reflect the diversity of the population. Finally, only one brand of OTC hearing aid users was included in the study, which is not representative of all OTC hearing aid users. Therefore, further research specifically focused on the relationship between hearing aid cost and uptake, especially among OTC users using different OTC hearing aids, is warranted to advance understanding in this field.

5.6 Conclusion

This exploratory study makes a notable contribution to the existing literature by providing valuable insights into the perspectives of both prescription and OTC hearing aid users regarding the relationship between cost and uptake. The inclusion of user recommendations related to cost, often overlooked in previous works, further enriches the understanding of factors influencing hearing aid adoption. The high cost of hearing aids was identified as a significant barrier to uptake by both groups. While external support, such as financial assistance and health insurance coverage, have the potential to facilitate hearing aid uptake in certain individuals, it is important to note that they do not guarantee universal adoption. The lower cost of OTC hearing aids compared to prescription aids was identified as an enabler for uptake. Both groups provided similar recommendations to others with hearing difficulties. However, prescription users recommended seeking professional support, whereas OTC users recommended researching hearing aids before purchasing them. By considering the perspectives and recommendations of hearing aid users, interventions can be developed to address the perceived barriers and enhance the perceived benefits of using hearing aids. This can improve access to hearing aids, aligning with the principles of the HBM to promote health-related behaviors.

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CHAPTER 6

USABILITY AND PERFORMANCE OF SELF-FITTING OVER-THE-COUNTER HEARING AIDS

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6.1 Abstract

Purpose: Over-the-counter (OTC) hearing aids can potentially improve access to hearing healthcare and enable individuals with mild-to-moderate hearing loss to self-manage their condition. This study compares usability and performance across a range of self-fitting over-the-counter (OTC-SF) hearing aids.

Research Design: A cross-sectional study evaluated six OTC-SF hearing aids.

Study Sample: 43 adults with self-perceived mild-to-moderate hearing difficulties participated.

Data Collection and Analysis: Participants were randomly assigned to self-fit two of six OTC-SF hearing aids using manufacturer-provided instructions and smartphone applications. These included the HP Hearing PRO, Jabra Enhance Plus, Lexie B2 Powered by Bose, Lexie Lumen, Soundwave Sontro, and Sony CRE-C10. Usability was assessed based on fitting time, Hearing

Aid Skills and Knowledge (HASK), self-reported ease of the self-fitting process, and the Post-Study System Usability Questionnaire (PSSUQ). Performance was evaluated with the Judgement of Sound Quality (JSQ) test and speech-in-noise benefit using the Digits-In-Noise (DIN) and QuickSIN tests.

Results: Fitting time ranged between 14.4 and 27.1 minutes, with Lexie Lumen requiring the longest (27.1; SD 5.9) and HP Hearing PRO the shortest (14.4; SD 1.9). HASK scores varied, with Soundwave Sontro scoring highest (8.9/10) and HP Hearing PRO lowest (6.8/10). Self-reported ease of self-fitting and PSSUQ scores did not differ significantly between the OTC-SF hearing aids. Overall sound quality and clarity ratings significantly differed, with Lexie B2 receiving the highest ratings (8.1/10 and 7.5/10) and HP Hearing PRO the lowest (6.3/10 and 5.1/10). Speech-in-noise benefit did not differ significantly between devices. Thematic analysis identified seven themes regarding the participant's self-fitting experience and six themes related to the researcher's field notes. Participants generally found OTC-SF hearing aids user-friendly, although issues with Bluetooth connectivity, handling and insertion, and sound quality were noted as common challenges by the researcher.

Conclusions: Usability and performance of OTC-SF hearing aids were similar across devices in terms of post-usability and speech-in-noise benefit. However, devices showed variations in fitting time, HASK, and sound quality, including overall impression and clarity. These findings can support consumers and healthcare professionals in decision-making and recommendations. Further research is needed on long-term usability and selection processes for OTC-SF hearing aids.

Key Words: Over-the-counter hearing aids, Direct-to-consumer hearing devices, Hearing aids, Usability, Performance

Abbreviations

DIN = Digits-In-Noise

FDA = Food and Drug Administration

HASK = Hearing Aid Skills and Knowledge

INFOQUAL = Information quality

INTERQUAL = Interface quality

JSQ = Judgement of Sound Quality

OTC = Over-the-Counter

OTC-SF = Self-fitting Over-the-Counter

OTC-PS = Pre-set Over-the-Counter

PSSUQ = Post-Study System Usability Questionnaire

QuickSIN = Quick Speech-in-Noise

REM = Real-ear measurement

SYSUSE = System usefulness

6.2 Introduction

Hearing loss is a prevalent sensory impairment that affects 430 million people worldwide (World Health Organization[1]). While hearing aids have long been the primary intervention for addressing hearing difficulties (World Health Organization[1]) barriers such as cost, limited access, and stigma have hindered their widespread adoption (Knoetze et al[2]; Knudsen et al[3]). Globally, less than 11% of individuals with disabling hearing loss use hearing aids (Bisgaard et al[4]). There have been significant developments in hearing technology over the last decade, including advanced prescription hearing aids and direct-to-consumer (DTC) devices, such as personal sound amplification products, hearables, and consumer audio devices (Manchaiah et al[5,6]; Tran & Manchaiah[7]). These innovations have paved the way for new service-delivery models, like the emergence of Over-the-Counter (OTC) hearing aids. OTC hearing aids have emerged as a promising alternative, potentially improving access to hearing healthcare and enabling people with mild-to-moderate hearing loss to self-manage their condition (Food and Drug Administration[8]).

On October 17, 2022, the Food and Drug Administration (FDA) established a rule for a new OTC hearing aid category. The final rule allows consumers with perceived mild-to-moderate hearing loss to purchase hearing aids directly from stores or online retailers without requiring a medical exam, prescription, or a fitting by an audiologist (Food and Drug Administration[8]). The FDA defined two sub-categories for OTC hearing aids, namely 1) OTC hearing aids with standardized output profiles (i.e., pre-set programs; OTC-PS) and 2) self-fitting OTC (OTC-SF) hearing aids, which allow users to program their hearing aids with a self-fitting strategy and customize their hearing aid settings according to their needs and preferences (Food and Drug Administration[8]).

The concept of self-fitting hearing aids were introduced over a decade ago (Convery et al[9]). Convery et al[10] evaluated the self-fitting process of a commercially available hearing aid and found that most participants could complete the process without error. However, the authors noted that the success rate could be improved by support from trained personnel and through improvements to the design and instructions. Keidser & Convery[11] further emphasized that with the appropriate design and support, self-fitting hearing aids can become a more affordable and accessible option.

Recent studies on OTC-SF hearing aids related to the newly established FDA category have demonstrated comparable benefit and satisfaction outcomes to audiologist-fit hearing aids for individuals with self-perceived mild-to-moderate hearing loss (Sabin et al[12]; De Sousa et al[13]). Sabin et al[12] validated an OTC-SF method using a Bose prototype hearing aid, enabling users to select their signal processing parameters using a mobile application consisting of two dials simultaneously controlling the gain and compression of all frequency bands. Their study found the self-fit group reported better sound quality, and there were no differences in clinical measures of speech-in-noise benefit or satisfaction (Sabin et al[12]). More recently, De Sousa et al[13] conducted a randomized controlled trial to compare the effectiveness of an OTC-SF hearing aid using in-situ audiometry and an audiologist-fitted hearing aid using best practices. The self-fitting parameters were determined by a proprietary algorithm using in-situ threshold measurements (at 0.5, 1.0, 2.0, 3.0, 4.0, and 6.0 kHz) conducted through the hearing aids by using the accompanying smartphone application. Their study found that the short-term benefit and satisfaction outcomes of the OTC-SF hearing aids were comparable to the audiologist-fit hearing aids using best practices. In another large-scale cross-sectional observational study, no difference in benefit and satisfaction hearing aid outcomes was observed between a group of individuals who had prescription hearing aids fit by hearing healthcare professionals (n=406) and a group of individuals who had OTC-SF hearing aids (n=250) that demonstrated that it is possible to obtain positive benefit and satisfaction outcomes from OTC-SF hearing aids in individuals with mild-to-moderate hearing loss

(Swanepoel et al[14]). However, we are not aware of any studies examining the benefit and satisfaction outcomes of commercially available OTC-SF hearing aids.

Despite promising outcomes reported in some of these early studies, concerns regarding the safety, handling, self-adjustment, service delivery models, counseling, audiological care, and potential for optimal benefits and adverse events of OTC hearing aids persist among hearing healthcare professionals[15]. A study by Manchaiah et al[15] in 2023 revealed that over 50% of hearing healthcare professionals expressed opposition to OTC hearing aids due to these concerns. Additionally, consumer attitudes towards OTC hearing aids highlight apprehensions regarding the direct-to-consumer model, with 84% expressing discomfort and a preference for in-person consultation with hearing healthcare professionals[16]. Notably, older adults and individuals with less interest in hearing aids were less inclined towards OTC options, while those with prior experience with direct-to-consumer models and those lacking insurance coverage were more likely to pursue OTC hearing aids. Therefore, it is crucial to evaluate the usability and performance of OTC hearing aids to ensure both their safety and efficacy.

The market has seen a proliferation of OTC hearing aids with unique self-fitting strategies. However, there is limited research on OTC hearing aids currently on the market (Manchaiah et al[17]). No study has yet compared the self-fitting process between OTC-SF hearing aids in terms of usability and performance, leaving a significant gap in current research. Understanding the usability and performance of different OTC-SF hearing aids is essential for several reasons. Firstly, it empowers consumers to make informed choices, offering them more accessible and affordable hearing solutions and potentially enhancing their quality of life. Secondly, it can guide healthcare professionals in recommending suitable OTC options. Thirdly, it can contribute to establishing regulations and standards in the industry, ensuring the safety and efficacy of OTC-SF hearing aids. Therefore, this study compared the usability and performance of several FDA-approved OTC-SF hearing aids available to consumers. The specific objectives included examining the following aspects: 1. Usability: a) Device fitting time, b) Hearing aid skills and knowledge, c) Ease of self-fitting process, and d) Usability of the device. 2. Performance: e) Device sound quality, and f) Speech-in-noise benefit.

6.3 Materials and Method

6.3.1 Study Design

This study used a cross-sectional design to compare the usability and performance of the HP Hearing PRO, Jabra Enhance Plus, Lexie B2 Powered by Bose, Lexie Lumen, Soundwave Sontro, and Sony CRE-C10 hearing aids. We selected these specific OTC hearing aids since they were the only available OTC-SF hearing aids under $1000 between December 2022 and February 2023 (see Table 6.1). Ethical clearance was obtained from the University of Pretoria Humanities Research Ethics Committee (HUM021/1122).

Table 6.1 Characteristics of self-fitting OTC hearing aids (n = 6)

Hearing aid	Style	Price per pair	Rechargeable battery	Bluetooth streaming	Ingress Protection rating	App name	Fitting strategy
HP Hearing Pro	Earbud-style	$499	Yes	Yes	IP54	HP Hearing	In-situ hearing test
Jabra Enhance Plus	Earbud-style	$799	Yes	Yes – iPhone only	IP52	Jabra Enhance	In-situ hearing test
Lexie B2	Receiver-in-the-canal	$999	Yes	Yes - iPhone only	IP67	Lexie	Self-adjustment
Lexie Lumen	Behind-the-ear	$799	No	No	IP67	Lexie	In-situ hearing test
Soundwave Sontro	Receiver-in-the-canal	$849	No	No	N/A	otoTune	In-situ hearing test
Sony CRE-C10	Completely-in-the-canal	$999	No	No	IPX4	Sony Hearing Control	In-situ hearing test

6.3.2 Participants

Purposive sampling was used to recruit a total of 43 participants. We used various social media platforms to promote study participation and invited interested individuals to complete a Google Form in order to check their eligibility. On the form, participants were asked to describe their hearing ability (without a hearing aid) by selecting one of the following options: 1) my hearing is good, 2) I have little difficulty, 3) I have a lot of difficulty, or 4) I cannot hear at all. In addition, participants were required to rate their hearing difficulties as slight, mild, moderate, or severe. To be considered for the study, participants needed to report their hearing ability as having little or a lot of difficulty and rate their hearing difficulties as mild or moderate. Eligible participants included adults (>18 years) who self-reported mild-to-moderate hearing difficulties and no active outer- and middle-ear pathologies. Additionally, participants were required to have a high level of English proficiency, as determined by an online English proficiency test.

To minimize potential order effects, we used a Latin square method to assign 29 participants to two of the following self-fitting devices: the Jabra Enhance Plus, Lexie B2 Powered by Bose, Lexie Lumen, Soundwave Sontro, or Sony CRE-C10 hearing aids. An additional 14 participants were recruited and assigned to self-fit the HP Hearing PRO and Lexie Lumen or Sony CRE-C10 devices. This led to each of the six OTC-SF hearing aids being tested for usability and performance by 13 to 15 users. Five out of 43 participants reported previous hearing aid use.

6.3.3 Data Collection

The self-reported and clinical measures were aimed at examining the usability, including (a) device fitting time as observed and recorded by the researcher; (b) hearing aid skills and knowledge using the validated Hearing Aid Skills and Knowledge (HASK) test (Saunders et al[18]); (c) ease of self-fitting process measured using a single item structured question and qualitative data including an open-ended question regarding the overall self-fitting experience and researcher field notes; (d) usability of the device measured using the validated Post-Study System Usability Questionnaire (PSSUQ; Lewis[19]) as well as hearing aid performance, including (e) device sound quality and clarity measured using the validated Judgement of Sound Quality (JSQ; Gabrielsson et al[20]) self-reported rating scale, and (f) speech-in-noise benefit using the validated Digits-In-Noise (DIN) and Quick Speech-in-Noise (QuickSIN) tests. Real-ear measurement (REM) data were obtained but will be presented in a separate article.

6.3.3.1 Baseline Assessments and Fitting

Before self-fitting the OTC-SF hearing aids, a baseline hearing assessment was conducted by a qualified audiologist. This assessment included otoscopic examination, tympanometry, pure-tone audiometry, and unaided speech-in-noise tests, such as the DIN and QuickSIN in a sound-proof booth. In addition, participants were required to complete an online English proficiency test to ensure a high level of proficiency (https://www.efset.org). Participants self-fit their assigned OTC-SF hearing aids using an iPhone X and the manufacturer-provided instructions on the accompanying smartphone application. If participants were unable to self-fit, they could request assistance from the researcher or accompanying family member.

6.3.3.2 Device Fitting Time

During the self-fit process, the researcher observed and recorded the time taken for each fitting. Time was measured using a stopwatch to ensure consistency and accuracy. The timer was started when the participant opened the smartphone application, and the measurement was continuous throughout the fitting process, including periods of participant inquiry and researcher assistance. This approach aimed to capture the entirety of the fitting experience, from initial setup to final adjustments, offering a comprehensive understanding of the self-fit process.

6.3.3.3 Hearing Aid Skills and Knowledge

The researcher assessed the participants' hearing aid skills and knowledge using selected items from the HASK test (Saunders et al[18]) immediately after self-fitting. It is important to note that participants were not expected to have prior knowledge of hearing aids upon entering the study. Instead, the HASK test aimed to assess participants' ability to perform essential tasks related to OTC-SF hearing aids, which would have been explained through the self-fitting app's instructions. These items included distinguishing left from right, inserting the right hearing aid, inserting the left hearing aid, changing the volume, and switching the hearing aids on and off. The items related to the batteries (as some of the OTC-SF hearing aids were rechargeable), cleaning (as the devices were clean when taken out of the box), telephone use, program use, troubleshooting, and storage were excluded as they were not relevant for all the OTC-SF hearing aids. Each item was given a score out of two points. Participants who did not know the information or could not complete the task received zero points. Those who were aware of the information but required assistance from the researcher received one point. Participants who demonstrated knowledge and performed the task correctly received two points. The total score was out of 10 points, with possible scores ranging from 0 to 10.

6.3.3.4 Ease of Self-fitting Process

After each self-fitting, participants were asked to rate the ease of the self-fitting process using a 5-point Likert scale, with one being very easy and five being very difficult. The question was: "How easy was the self-fit process?" Additionally, they were asked to complete an open-ended question that was phrased as follows: "Tell us about your overall experience." The researcher also took field notes during each fitting.

6.3.3.5 Post-use Usability of the Device

Participants completed version 3 of the PSSUQ to measure their post-use usability of the OTC-SF hearing aids (Lewis[19]). The PSSUQ comprised 16 standardized questions, following a 7-point Likert scale and a not-applicable option. The overall result is determined by averaging the scores across the 7-point scale. The possible scores range from 1 to 7, with lower scores indicating higher post-use usability. The PSSUQ consists of three sub-scales, namely system usefulness (SYSUSE; possible scores range between 1 to 7, information quality (INFOQUAL; possible scores range between 1 to 7, and interface quality (INTERQUAL; possible scores range between 1 to 7).

6.3.3.6 Device Sound Quality

To assess the sound quality of the OTC-SF hearing aids, we used specific items from the Judgement of Sound Quality (JSQ) rating scale (Gabrielsson et al[20]). Given the potential challenges in evaluating certain items, such as fullness and spaciousness, especially immediately after fitting the OTC-SF hearing aids, we focused on easily understandable and reliable items for rating. These items included the overall impression (i.e., very bad to very good) and clarity of sound (i.e., very unclear to very clear). Participants rated sound quality on a scale of zero to ten (11-point Likert scale), with higher scores indicating better sound quality.

6.3.3.7 Speech-in-Noise Benefit

Aided speech-in-noise tests (DIN and QuickSIN) were conducted after each fitting in a sound-proof booth at 70 dB HL. Speech-in-noise benefit was assessed by subtracting the aided scores from the unaided scores.

6.3.4 Data Analysis

We used IBM SPSS version 28.0.1.0 to analyze the data. Preliminary analysis showed that the data violated the assumption of normality ($p < .05$) for all variables according to Shapiro-Wilk's test. We conducted descriptive statistics to provide a comprehensive overview of the data, which included calculating measures such as mean, median, standard deviation, and range. To evaluate possible differences among the various OTC-SF hearing aids in terms of usability and performance measures, we employed the Kruskal-Wallis test. Afterward, we conducted pairwise comparisons using Dunn's (1964) procedure, as it corrects for multiple comparisons. Additionally, we examined the qualitative feedback on the open-ended questions and researcher field notes to gain insights into the participants' experiences and opinions. Recognizing the need for a deeper understanding beyond quantitative measures, we employed inductive thematic analysis. This method allowed us to derive themes and patterns directly from the data without applying pre-existing theoretical frameworks or assumptions (Braun & Clarke[21]). The primary researcher coded the data into meaningful units of information, which were then grouped into similar themes (Braun & Clarke[21]). To include additional perspectives, co-authors, both experienced in thematic analysis, cross-checked the coding, and any inconsistencies were resolved through discussion until an agreement was reached.

6.4 Results

Participants were 55.8% male and 44.2% female (Table 6.2). The mean age was 59.7 years (SD 14.3). Regarding self-perceived hearing difficulty, 44.2% reported having a little trouble, while 55.8% reported having a lot of trouble. Self-perceived degree of hearing loss was reported to be mild in 23.3% of cases and moderate in 76.7% of participants. The mean Pure-Tone Average

(PTA) for frequencies 0.5, 1, 2, and 4 kHz was 36.5 (SD 16.5) for the left ear and 32.8 (SD 16.7) for the right ear (Supplementary Material 1; Appendix P).

Table 6.2 Demographic characteristics of participants

	All participants (n = 43)	HP Hearing PRO (n = 14)	Jabra Enhance Plus (n = 15)	Lexie B2 (n = 15)	Lexie Lumen (n = 14)	Sontro (n = 14)	Sony CRE-C10 (n = 13)
Sex (n; %)							
Male	24 (55.8%)	6 (42.9%)	9 (60%)	8 (53.3%)	7 (50%)	11 (78.6%)	6 (46.2%)
Female	19 (44.2%)	8 (57.1%)	6 (40%)	7 (46.7%)	7 (50%)	3 (21.4%)	7 (53.8%)
Age							
Mean years (SD)	59.7 (14.3)	60.5 (12.1)	62.6 (13.1)	60.9 (16.3)	55.9 (15.2)	60.4 (14.1)	56.5 (16.1)
Self-perceived hearing difficulty (n; %)							
I have a little trouble	19 (44.2%)	4 (28.6%)	7 (46.7%)	7 (46.7%)	4 (28.6%)	8 (57.1%)	7 (53.8%)
I have a lot of trouble	24 (55.8%)	10 (71.4%)	8 (53.3%)	8 (53.3%)	10 (71.4%)	6 (42.9%)	6 (46.2%)
Self-perceived degree of hearing loss (n; %)							
Mild	10 (23.3%)	4 (28.6%)	2 (13.3%)	3 (20%)	2 (14.3%)	4 (28.6%)	4 (30.8%)
Moderate	33 (76.7%)	10 (71.4%)	13 (86.7%)	12 (80%)	12 (85.7%)	10 (71.4%)	9 (69.2%)
Mean PTA for 0.5, 1, 2, 4 kHz (SD)							
Left	36.5 (16.5)	35.1 (18.2)	35.0 (17.7)	39.4 (15.9)	35.6 (15.7)	37.5 (15.8)	33.7 (15.9)
Right	32.8 (16.7)	34.2 (19.1)	35.7 (14.0)	36.1 (16.7)	31.4 (19.4)	28.6 (13.9)	28.1 (15.6)

SD = Standard deviation, PTA = Pure tone average

A summary of usability and performance measures of OTC-SF hearing aids is presented in Table 6.3. The device fitting time, hearing aid skills and knowledge, and device sound quality (clarity and overall ratings) differed significantly between OTC-SF hearing aids. See Supplementary Material 2 (Appendix Q) for pairwise comparisons. The self-reported ease of self-fitting, PSSUQ scores, and speech-in-noise benefit were not significantly different between OTC-SF hearing aids. These results are discussed in detail in the following section.

Table 6.3 Summary of usability and performance measures of six OTC hearing aids

	Usability									Performance	
Hearing aid (no. participants, n)	Device fitting time in minutes* Mean (SD)	Self-reported ease of self-fitting Mean (SD)	PSSUQ overall Mean (SD)	PSSUQ SYSUSE Mean (SD)	PSSUQ INFOQUAL Mean (SD)	PSSUQ INTERQUAL Mean (SD)	HASK total score* Mean (SD)	JSQ clarity score* Mean (SD)	JSQ overall impression* Mean (SD)	QuickSIN benefit Mean (SD)	DIN benefit Mean (SD)
HP Hearing PRO (n = 14)	14.4 (1.9)	2.1 (0.7)	2.0 (1.3)	2.1 (1.3)	1.8 (1.1)	2.2 (1.8)	6.8 (1.3)	5.1 (2.1)	6.3 (1.7)	1.2 (2.4)	-0.2 (1.7)
Jabra Enhance Plus (n = 15)	19.7 (6.1)	1.7 (0.6)	1.8 (0.7)	1.6 (0.7)	1.7 (0.7)	2.1 (1.3)	7.3 (1.8)	6.9 (2.1)	6.8 (1.9)	1.0 (2.5)	0.4 (1.8)
Lexie B2 (n = 15)	21.9 (11.4)	2.1 (1.0)	1.8 (0.7)	1.8 (0.9)	1.8 (0.7)	1.7 (0.8)	8.8 (1.5)	7.5 (1.8)	8.1 (1.2)	1.1 (3.6)	2.4 (4.7)
Lexie Lumen (n = 14)	27.1 (5.9)	1.7 (0.7)	1.5 (0.7)	1.6 (1.0)	1.5 (0.5)	1.4 (0.7)	7.2 (2.0)	6.8 (1.7)	7.6 (1.8)	-0.8 (3.2)	-0.0 (1.8)
Soundwave Sontro (n = 14)	15. 7 (5.2)	1.8 (0.4)	1.9 (0.9)	1.8 (0.8)	2.0 (1.1)	1.8 (0.9)	8.9 (1.4)	6.4 (1.8)	6.5 (1.8)	0.00 (2.2)	-0.2 (2.2)
Sony CRE-C10 (n = 13)	24.2 (6.6)	2.4 (1.0)	1.8 (1.0)	1.7 (0.8)	1.9 (1.2)	1.8 (1.0)	8.1 (1.9)	6.2 (1.7)	7.0 (1.5)	-0.5 (1.4)	0.3 (1.2)
All devices (n = 85)	20.5 (8.0)	2.0 (0.8)	1.8 (0.9)	1.8 (0.9)	1.8 (0.9)	1.8 (1.1)	7.8 (1.8)	6.5 (2.0)	7.1 (1.7)	0.4 (2.7)	0.5 (2.7)

*Significant difference between hearing aids according to Kruskal-Wallis test (p < .05)
SD = Standard deviation, PSSUQ = Post-Study System Usability Questionnaire (scores ranging between 1 to 7 with lower scores indicating better usability), HASK = Hearing Aid Skills and Knowledge (scores ranging between 0 to 10 with higher scores indicating better skills and knowledge), JSQ = Judgement of Sound Quality (scores ranging between 0 to 10 with higher scores indicating better sound quality), QuickSIN = Quick Speech-in-Noise, DIN = Digits-In-Noise

6.4.1 Usability

6.4.1.1 Device Fitting Time

The average device fitting time ranged between 14.4 to 27.1 minutes across all devices, with mean and median times as 20.5 and 17.0 minutes, respectively. Lexie Lumen had the longest average fitting time (27.1; SD 5.9), followed by Sony CRE-C10 (24.2; SD 6.6). HP Hearing PRO had the shortest (14.4; SD 1.9), followed by Soundwave Sontro (15. 7; SD 5.2). Device fitting times differed significantly (Kruskal-Wallis; $\chi 2(5) = 33.755$, $p < .001$) between OTC-SF hearing aids. Post hoc analysis revealed that Lexie Lumen exhibited significantly longer fitting times compared to all other OTC-SF hearing aids except for Sony CRE-C10 (Figure 6.1). Furthermore, there were significant differences in device fitting times between HP Hearing PRO and all the other OTC-SF hearing aids except Soundwave Sontro, with HP Hearing PRO showing significantly shorter fitting times (Figure 6.1).

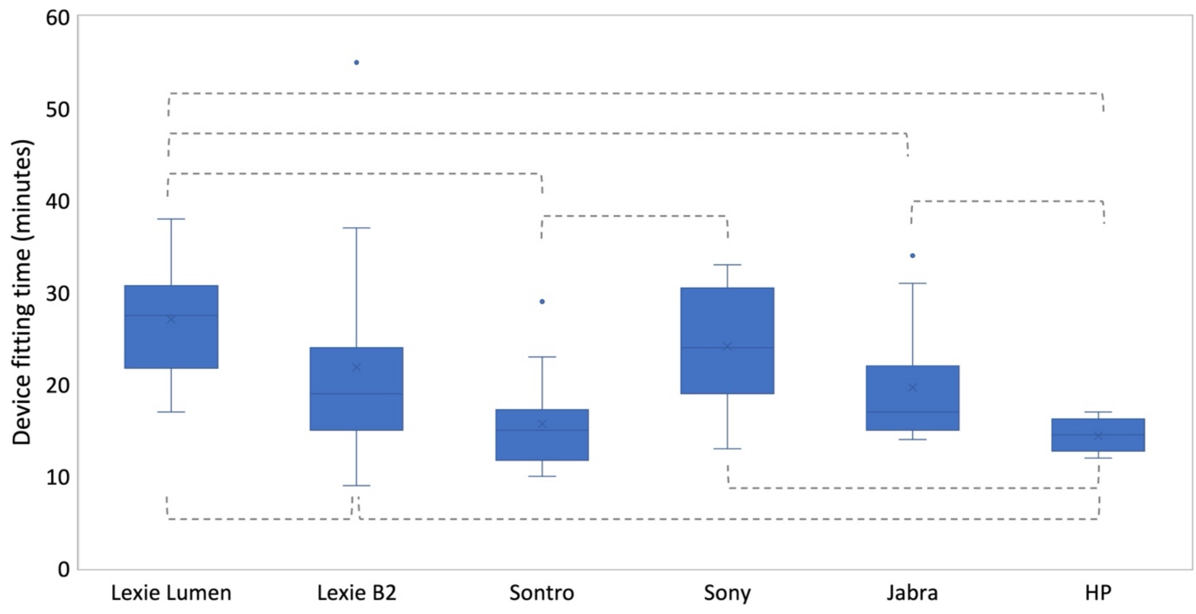

Figure 6.1 Device self-fitting duration.

Boxplots include outliers, min, Q1, median, Q3, and max. Dashed lines represent pairwise comparisons that were significantly different (p < .05).

6.4.1.2 Hearing Aid Skills and Knowledge

The average hearing aid skills and knowledge scores ranged between 6.8 and 8.9, with mean and median scores of 7.8 and 8.0 out of 10, respectively. Soundwave Sontro (8.9; SD 1.4) and Lexie B2 (8.8; SD 1.5) had the highest average scores, whereas HP Hearing PRO (6.8; SD 1.3) had the lowest average score (Figure 6.2). Hearing aid skills and knowledge scores (Kruskal-Wallis; $\chi2(5) = 17.700$, $p = .003$) were significantly different between hearing aids. Soundwave Sontro and Lexie B2 scored significantly better than HP Hearing PRO, Lexie Lumen, and Jabra Enhance Plus (Figure 6.2). The five previous hearing aid users had an average HASK score (8.2; SD 2.2), which was similar (7.8; SD 1.8) to the 38 new hearing aid users.

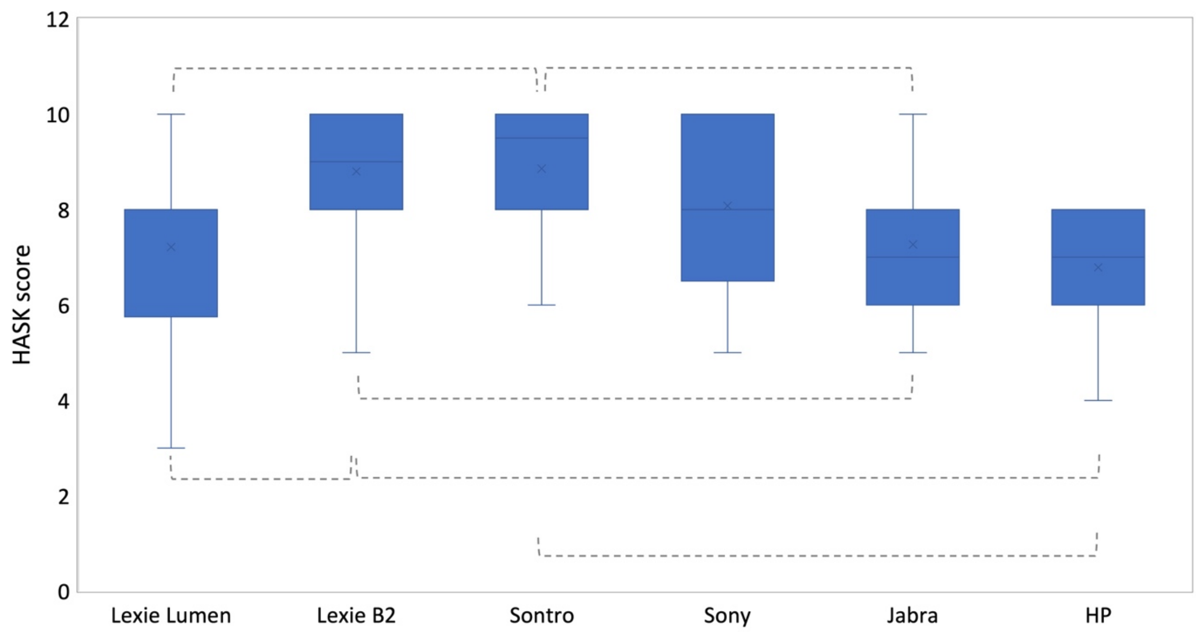

Figure 6.2 Hearing Aid Skills and Knowledge (HASK) scores.

Boxplots include outliers, min, Q1, median, Q3, and max. Dashed lines represent pairwise comparisons that were significantly different (p < .05).

6.4.1.3 Ease of Self-fitting Rating

The average self-reported ease of self-fitting scores ranged between 1.7 and 2.4 out of 5, with mean and median ratings of 2.0 and 2.0, respectively. Lexie Lumen had the best average self-reported ease of self-fitting score (1.7; SD 0.7). There was no significant difference between self-reported ease of self-fitting across devices. Additionally, the five previous hearing aid users had an average self-reported ease of self-fitting score (2.1; SD 0.9), which was similar (2.0; SD 0.8) to the 38 new hearing aid users.

6.4.1.4 Thematic Analysis of the Overall Self-fitting Experience

For the open-ended question, seven themes were identified in the thematic analysis, including (a) ease of use and fit, (b) physical comfort and feel, (c) app functionality, (d) instruction clarity, (e) improved hearing, (f) sound quality and noise-related problems, and (g) user satisfaction (Table 6.4). Participants generally reported ease in self-fitting for most OTC-SF hearing aids, except for Sony CRE-C10. However, mixed responses were recorded regarding the physical comfort and feel of the OTC-SF hearing aids. For example, Lexie B2 users found them comfortable to wear, whereas some HP Hearing PRO users found them bulky and uncomfortable, and some Sony CRE-C10 users had trouble inserting them. Participants generally provided favorable feedback regarding the accompanying smartphone applications, although a few mentioned the need for improvement or review. Clear instructions were appreciated by most users, contributing to their overall satisfaction with the self-fitting process. Users generally expressed satisfaction with the self-fitting process, especially the Lexie Lumen and Sontro Soundwave users. Many users reported improved hearing and enhanced clarity as a positive outcome while using the OTC-SF hearing aids. However, some concerns were raised about the sound quality, particularly with completely-in-canal (CIC) or earbud-style designs such as Sony CRE-C10, Jabra Enhance Plus, and HP Hearing PRO. Users also reported issues with their own voices, echoing sounds, and feedback.

Table 6.4 Thematic analysis of participant responses to the open-ended question regarding overall experience of the self-fitting process (n = 43)

Theme	Example responses
Ease of use and fit	*It is very easy. You will just have to get used to insert the hearing aids - it will take practice - ITE user* *It was very easy and quick to learn - BTE user*
Physical comfort and feel	*I find them bulky and uncomfortable - ITE user* *Light on ear - BTE user*
App functionality	*App is easy to understand - ITE user* *App needs review - BTE user*
Instruction clarity	*Easy to follow instructions - ITE user* *Very clear instructions - BTE user*
Improved hearing	*I can hear better - ITE user* *I could immediately hear better - BTE user*
Sound quality and noise-related problems	*Sound is hollow - ITE user* *Sounds clear and crisp - BTE user*
User satisfaction	*Wow fantastic fit and sound - ITE user* *World changing experience - BTE user*

Note: ITE refers to earbud-style or completely-in-the-canal hearing aids and BTE refers to behind-the-ear or receiver-in-the-canal hearing aids

6.4.1.5 Thematic Analysis of the Researcher's Field Notes

Six themes emerged, including (a) assistance with device handling and insertion, (b) difficulties with smartphone usage, (c) connectivity issues, (d) technical errors and retesting, (e) family involvement, and (f) user experience and feedback (Table 6.5). During the self-fitting process, many of the participants (n = 14) struggled with inserting and handling the devices, in particular, the Lexie Lumen and HP Hearing PRO hearing aids. Some participants required assistance with inserting the HP Hearing PRO earbuds, changing the Lexie Lumen slim tubes, or inserting the Sony CRE-C10 batteries. Difficulties with smartphone usage were noted, ranging from participants being uncomfortable with smartphones to specific issues with using certain devices. Connectivity problems with Bluetooth were also evident, with many participants (n = 18) struggling to pair or connect their OTC-SF hearing aids, often requiring assistance. Technical errors, such as offline servers or app malfunctions, were documented, leading to the need for retesting or encountering obstacles during the testing phase.

Furthermore, family members played an active role in assisting some participants throughout the self-fitting process. Participants provided diverse feedback on their experiences, with some expressing concerns about sound quality or app functionality. For instance, some participants reported hearing their voices while wearing the Jabra Enhance Plus hearing aids, and a few were unsure when the Lexie B2 hearing aids were switched on because they had not yet placed them in their ears to hear the activation tune when connecting the devices to the smartphone. In one case, a participant was unable to complete the Sony CRE-C10 fitting because the application indicated that their hearing loss was too severe for the hearing aids, according to the in-situ hearing test performed.

Table 6.5 Thematic analysis of field notes taken by the researcher during the self-fitting process

Theme	Example notes
Assistance with device handling and insertion	*Required assistance with insertion as earbuds kept falling out - ITE user* *Required assistance with inserting batteries - BTE user*
Difficulties with smartphone usage	*Participant owns Nokia and struggled using iPhone - BTE user* *Participant is not so comfortable with technology - ITE user*
Bluetooth connectivity issues	*Required assistance with pairing and clicked "my earbuds are not flashing blue" - ITE user* *Required assistance with connectivity and prompt to click on circles - BTE user*
Technical errors and retesting	*Cloud server offline - ITE user* *App only recorded in-situ test results for one ear or no results were recorded - BTE user*
Family involvement	*Daughter assisted a lot - ITE user* *Husband assisted - BTE user*
User experience and feedback	*Participant mentioned that his own voice echoes - ITE user* *Participant mentioned that the app's text could be bigger - not the first to mention - BTE user*

Note: ITE refers to earbud-style or completely-in-the-canal hearing aids and BTE refers to behind-the-ear or receiver-in-the-canal hearing aids

6.4.1.6 Post-use Usability

On the PSSUQ, a lower score equals higher post-use usability. The average PSSUQ overall scores ranged between 1.5 and 2.0, with mean and median scores of 1.8 and 1.5, respectively. Lexie Lumen had the best average score for the overall PSSUQ and all the sub-scales (see Table 6.3). HP Hearing PRO had the worst average score for the overall PSSUQ (2.0; SD 1.3), PSSUQ SYSUSE (2.1; SD 1.3), and PSSUQ INTERQUAL (2.2; SD 1.8). However, there was no significant difference between OTC-SF hearing aids across these measures.

6.4.2 Performance

6.4.2.1 Device Sound Quality

Average overall impression ratings ranged between 6.5 and 8.1 out of 10, with mean and median scores of 7.1 and 7.0, respectively. Lexie B2 (8.1; SD 1.2) and Lexie Lumen had the highest average overall impression ratings (7.6; SD 1.8), whereas HP Hearing PRO (6.3; SD 1.7) and Soundwave Sontro (6.5; SD 1.8) had the lowest average overall impression ratings (Figure 6.3). Overall impression ratings (Kruskal-Wallis; $\chi2(5)$ =11.168, p = .048) were significantly different between OTC-SF hearing aids, with HP Hearing PRO significantly lower than Lexie Lumen and Lexie B2. Soundwave Sontro was also significantly lower than Lexie B2 (Figure 6.3).

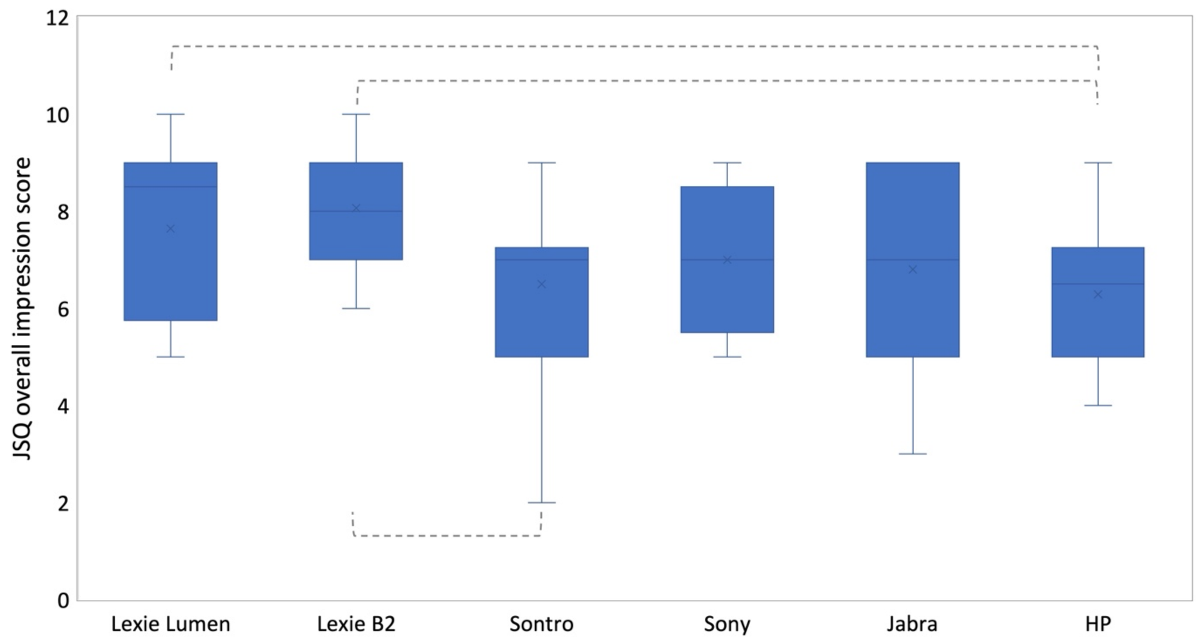

Figure 6.3 Judgment of Sound Quality (JSQ) overall impression scores.

Boxplots include outliers, min, Q1, median, Q3, and max. Dashed lines represent pairwise comparisons that were significantly different ($p < .05$).

The average clarity ratings ranged between 5.1 and 7.5, with mean and median ratings of 6.5 and 7.0, respectively. Lexie B2 had the highest average clarity rating out of 10 (7.5; SD 1.8), whereas HP Hearing PRO had the lowest clarity rating out of 10 (5.1; SD 2.1). Clarity ratings (Kruskal-Wallis; $\chi2(5) = 12.988$, $p = .023$) significantly differed between OTC-SF hearing aids, with HP Hearing PRO being significantly lower than Lexie B2, Lexie Lumen, and Jabra Enhance Plus. Lexie B2 was also significantly higher than Sony CRE-C10 (see Figure 6.4).

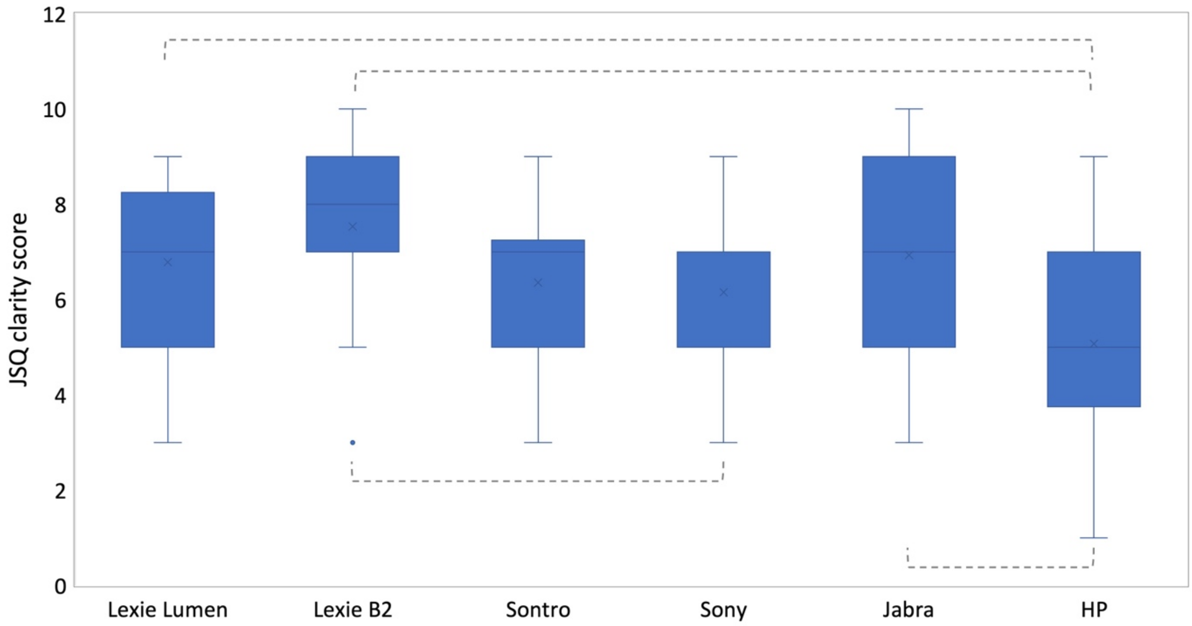

Figure 6.4 Judgment of Sound Quality (JSQ) clarity scores.

Boxplots include outliers, min, Q1, median, Q3, and max. Dashed lines represent pairwise comparisons that were significantly different ($p < .05$).

6.4.2.2 Speech-in-Noise Benefit

Average speech-in-noise benefit on the QuickSIN ranged between -0.8 and 1.1, with a mean and median of 0.4 and 0, respectively. The average speech-in-noise benefit for the DIN ranged between -0.2 and 2.4, with a mean and median of 0.5 and 0.2, respectively. Speech-in-noise benefit was not significantly different between OTC-SF hearing aids.

6.5 Discussion

The usability and performance across the six FDA-approved OTC-SF hearing aids demonstrated similar general trends, including aspects like post-use usability (i.e., PSSUQ) and speech-in-noise benefit (i.e., QuickSIN). However, differences were evident for certain measures, like fitting time, hearing aid skills and knowledge, and sound quality, including overall impression and clarity.

Overall, the post-use usability scores on the PSSUQ were similar across devices and better than the means determined by Sauro & Lewis[22] from 21 different studies. This suggests that OTC-SF hearing aids were generally found to be user-friendly. Lexie Lumen consistently demonstrated higher scores on the overall PSSUQ and all the sub-scales, potentially due to clear app-based instructions and demonstrational videos that support usability, similar to findings by Convery et al[23]. Device fitting time, however, varied among different OTC-SF hearing aids, and Lexie Lumen required the longest initial setup time. This may be partly due to some users who struggled to measure and select the right size slim tubes before learning to insert them. These differences in fitting time may have implications for user satisfaction and convenience, although not observed in the current study. Users who prioritize a comprehensive introduction to OTC-SF hearing aids and precise adjustments may prefer devices like Lexie Lumen. At the same time, those who value a faster fitting process may opt for other OTC-SF hearing aids with shorter duration fittings. Ultimately, the user's preference should be considered alongside other usability and performance measures.

The study also highlighted differences in hearing aid skills and knowledge across different devices, potentially linked to the effectiveness of user instructions provided within the associated apps of these OTC-SF hearing aids. Most users appreciated the clear instructions the accompanying smartphone applications provided, as evident from the thematic analysis.

Incorporating strategies, such as using larger fonts, pictogram illustrations or videos, and using everyday language, may aid users in self-fitting and managing their hearing aids (Convery, Keidser, Hartley, et al[24]). The app design and access to clear and comprehensive user instructions can significantly impact users' ability to self-fit and manage their hearing aids, which is important for successful benefit and satisfaction outcomes (Saunders et al[25]). Better hearing aid handling can increase hearing aid use and improve user satisfaction (Mothemela et al[26]). Overall, it is noteworthy that the quality and suitability of hearing health information are important to improve the adoption, use, benefit, and satisfaction of hearing devices (Manchaiah et al[27]).

In the open-ended responses, participants generally reported ease in self-fitting for most OTC-SF hearing aids, except for Sony CRE-C10. The researcher documented several challenges faced by the participants when self-fitting the Sony CRE-C10 hearing aids. Firstly, some participants had trouble inserting the batteries and distinguishing between the left and right markers since they were very small. Secondly, many participants attempted to close both battery doors simultaneously before connecting the hearing aids, which caused connection failures as the devices could only connect one at a time. Thirdly, one participant could not complete the fitting process for the Sony CRE-C10 hearing aids as the Sony Hearing Control app indicated that their hearing loss was too severe for the hearing aids to be effective based on the in-situ hearing test. Lastly, as with the other In-The-Ear (ITE) devices (i.e., Sony CRE-C10, Jabra Enhance Plus, HP Hearing PRO), participants raised concerns about hearing one's voice, echoing sounds and feedback. This information underscores the importance of form factors, device design, and user interface, which can significantly impact the overall user experience. Individuals who are looking for more situational use may prefer this form factor, whereas those who like to use their devices all day long may prefer BTE styles, although this needs to be investigated in further studies.

Similar to Convery et al[23], not all participants were able to perform the self-fitting independently, as some required assistance from the researcher or family members during the self-fit process. The need for assistance with Bluetooth connectivity for most OTC-SF hearing aids suggests that improvements may be necessary in terms of user-friendly Bluetooth pairing and connectivity. These findings highlight that despite the generally user-friendly nature of OTC-SF hearing aids, some individuals might still require assistance during the self-fitting process. OTC users need to recognize the potential need for assistance, perhaps involving their significant others in the self-fitting process. Audiological rehabilitation models recommend the involvement of significant others in the rehabilitation process, as it can significantly improve benefit and satisfaction outcomes (Hickson et al[28]; Manchaiah et al[29]). Moreover, hearing healthcare professionals can also offer valuable support services to some individuals utilizing OTC-SF hearing aids who still require additional support, ensuring a smoother self-fitting process and usage experience.

In terms of performance, behavioral outcomes such as speech-in-noise benefit were similar across devices. Device sound quality ratings, however, varied significantly among different OTC-SF hearing aids, suggesting that some OTC-SF hearing aids may provide a more satisfactory listening experience regarding overall sound quality and clarity. For users, this may influence their perception of the effectiveness of the OTC-SF hearing aids and their overall satisfaction (Mothemela et al[26]). In line with Manchaiah et al[6], our study showed that higher-priced devices, like Lexie B2 or Sony CRE-C10, might provide better sound quality compared to lower-priced devices, like HP Hearing PRO (Table 6.1). However, such benefits were not replicated in behavioral measures of speech-in-noise. Users may consider sound quality as an important factor when selecting OTC-SF hearing aids while hearing healthcare providers can use this information to guide users toward options aligning with their expectations and preferences. These results suggest the need for consumer-centric metrics of audio performance that can aid consumers in decision-making while evaluating OTC hearing aids for purchase.

6.5.1 Study Limitations and Future Directions

This is the first study to examine the usability and performance of OTC-SF devices that are currently in the market using a structured way of providing timely knowledge. However, the study has a few limitations. The study was limited to six OTC-SF hearing aids. This selection might not encompass the entire spectrum of available OTC-SF devices rapidly entering the market. Moreover, very little is known about the OTC-PS devices, which potentially limits broader generalizability. We recruited 43 participants with self-perceived mild-to-moderate hearing difficulties and good English proficiency. This specific demographic might not represent the entire population that could benefit from OTC-SF hearing aids. Conducting the study in a controlled environment where users were observed might have influenced their behavior and responses. Participants might have been more attentive or felt pressured to perform better than they would in their typical day-to-day settings. This controlled environment might not fully replicate real-world conditions where various distractions and environmental factors could impact the usability and performance of OTC-SF hearing aids differently. Speech-in-noise tests were not counterbalanced between aided and unaided conditions. The selective inclusion of HASK items offers a focused evaluation aligned with the study objectives but may compromise construct validity and potentially introduce bias, which should be considered in interpreting the scale results. The comparisons were, however, within subjects and between devices, which mitigates potential bias effects.

In future research, longitudinal studies to evaluate the performance and usability of OTC-SF hearing aids over extended periods would provide valuable insights into long-term effectiveness and user satisfaction. Furthermore, investigating individuals' decision-making process when selecting OTC-SF devices would offer useful information about user preferences and factors influencing their choices. It would also be beneficial to investigate whether previous hearing aid use affects the usability and performance of OTC devices, which could provide essential insights into potential differences in user experience.

Investigating the level of assistance needed during self-fitting and its potential impact on user experience could provide valuable insights for family members or healthcare professionals, helping them better support OTC-SF users in optimizing their hearing aid experience. Incorporating assessments of vision and dexterity could enhance our understanding of how these factors influence the usability and performance of OTC devices, thereby contributing to more comprehensive user-centric evaluations. Moreover, exploring the usability, performance, benefit, and satisfaction outcomes of OTC-PS hearing aids can help improve our understanding of the benefits and limitations of pre-set OTC hearing aids. Finally, researchers could compare the benefit and satisfaction outcomes of different OTC-SF hearing aids to determine their effectiveness.

6.6 Conclusion

This study demonstrated similar usability and performance across multiple OTC-SF hearing aids, except for a few dimensions, including device fitting time, hearing aid skills and knowledge, and sound quality regarding overall impression and clarity. These areas of differences may be important for users, providing valuable insights into the trade-offs associated with different devices. Qualitative feedback from participants using the ITE designs emphasizes the need for further refinement in acoustics and fitting techniques to mitigate challenges related to self-perception of sound. Furthermore, improvements may be necessary regarding user-friendly Bluetooth pairing and connectivity. The design and user interface of OTC-SF hearing aids play an important role in the user experience, and further improvements in these areas, such as clear and comprehensive instructions, may enhance overall usability and satisfaction. These findings can support consumers and hearing healthcare professionals in making informed decisions and recommendations regarding OTC-SF hearing aids. Further research is needed to explore the device selection process, long-term usability, and satisfaction with OTC hearing aids, including the OTC-PS hearing aids.

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CHAPTER 7

COMPARING SELF-FITTING STRATEGIES FOR OVER-THE-COUNTER HEARING AIDS: A CROSSOVER TRIAL

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7.1 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 over the counter (OTC-SF) hearing aids?

Findings

This crossover trial found that both strategies produced equivalent overall Abbreviated Profile of Hearing Aid Benefit (APHAB), overall International Outcome Inventory for Hearing Aids (IOI-HA) satisfaction, speech-in-noise performance and real-ear measurements. However, self-adjustment resulted in meaningfully higher satisfaction and daily use on 2 IOI-HA subscales, underscoring the benefits of user participation.

Meaning

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

7.2 Abstract

Importance

Fewer 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 Food and Drug Administration (FDA)-approved OTCs compared with prescription-based approaches. However, to our knowledge, 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-participant pseudo-randomized clinical trial was conducted between July and November 2023. Twenty-eight participants were pseudo-randomly assigned to 1 of the 2 self-fitting strategies, and they experienced both interventions for 4 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 used Lexie B2 Plus hearing aids (Lexie Hearing by hearX Group), with an automated fitting based on in-situ tests conducted through the app.

Main Outcomes and Measures

The primary outcome was Abbreviated Profile of Hearing Aid Benefit (APHAB). Secondary outcomes were 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 4-week field trial using each strategy.

Results

Twenty-eight participants (mean age [SD] 60.2 [12.0] years) 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 to 0.6]) and overall IOI-HA satisfaction (Rosenthal's *r* = 0.0 [95% CI, -0.3 to 0.2]). Self-adjustment users reported higher satisfaction (Rosenthal's *r* = -0.4 [95% CI, -0.6 to -0.1]) and longer daily use (Rosenthal's *r* = -0.3 [95% CI,-0.5 to 0.0]) compared with those using 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.

7.3 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 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 examinations, 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 2 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 more than 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. [5] used 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. An observational study demonstrated positive outcomes for OTC-SF compared with prescription hearing aids.[13] Moreover, De Sousa et al. [14] used an in-situ audiometry fitting strategy and found 6-week outcomes of OTC-SF hearing aids to be comparable to fitting by an audiologist-fit.

Existing studies have validated OTC-SF hearing aids using 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 aimed to bridge this gap by directly comparing 2 self-fitting strategies in OTC-SF hearing aids - self-adjustment and in-situ audiometry - among adults with self-perceived mild-to-moderate hearing difficulties.

7.4 Method

7.4.1 Study design

A cross-over, within-participant pseudo-randomized clinical 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 (Supplementary Material 1, 2 and 3 - Appendix R, S and T). The trial was registered at ClinicalTrials.gov (NCT05782153), and institutional review board approval was obtained from the University of Pretoria Humanities Research Ethics Committee. Twenty-eight participants were randomly assigned to 1 of the 2 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 4 weeks before transitioning to the other, ensuring a comprehensive comparative analysis for both self-fitting strategies.

7.4.2 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. In addition, participants were required to have a high level of English proficiency, determined through an online test[16] 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 1 of the 2 self-fitting strategies (self-adjustment or in-situ audiometry). Randomization was determined using an AI generator (ChatGPT, version 3.5, Open AI) and was not concealed because 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 actual self-fitting scenarios.

Throughout the trial, 2 participants withdrew, resulting in 28 adults (14 men and 14 women with a mean (SD) age of 60.2 (12.0) years, 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 because she struggled to adapt to wearing different aids for an extended period.

7.4.3 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 (Supplementary Material 4 - Appendix U), 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.[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 used 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 (Supplementary Material 5 - Appendix V).

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.

7.4.4 Data Analysis

Data were analyzed using SPSS Statistics software (version 29.0; IBM). We used paired sample *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 participants. We identified significant differences with clinical relevance by examining effect size and 95% CIs. Cohen's *d* was utilized for *t*-test findings with interpretation categorized as small ($d \leq 0.2$), small to medium (*d*, 0.2 to < 0.5.), medium ($d = 0.5$), medium to large (*d*, > 0.5 to < 0.8.), and large ($d \geq 0.8$)[17]. For the Wilcoxon signed rank test, Rosenthal *r* was calculated as z/√N, and its interpretation included small ($r \leq 0.1$), small to medium (r, > 0.1 to < 0.30), medium ($r = 0.3$), medium to large (*r*, > 0.3 to < 0.5), and large ($r \geq 0.5$)[17]. The effect sizes would be considered clinically meaningful if they were medium or larger.

7.5 Results

7.5.1 Baseline Assessments

The study included 28 participants (Table 7.1) with equal sex distribution and a mean (SD) age of 60.2 (SD 12.0) years. Overall, 14 of the participants (50%) self-reported having a little hearing trouble, while the other half (n = 14; 50%) reported having a lot of trouble. Seven participants (25%) reported mild hearing difficulties, while 21 (75%) reported moderate hearing difficulties. The mean (SD) four-frequency pure-tone average (PTA) was 32.4 (14.9) and 36.8 (16.3) dB HL for the left and right ears, respectively (Supplementary Material 6 - Appendix W). Participants had a mean (SD) unaided DIN score of -8.2 (1.8) and a QuickSIN score of 7.0 (4.8).

Table 7.1 Participant Characteristics in 28 Participants

Characteristic	No. (%)
Sex (n; %)	
Female	14 (50)
Male	14 (50)
Age, mean (SD), y	60.2 (12.0)
Self-perceived hearing difficulty	
I have a little trouble	14 (50)
I have a lot of trouble	14 (50)
Self-perceived degree of hearing loss	
Mild	7 (25)
Moderate	21 (75)
PTA for 0.5, 1, 2, 4 kHz, mean (SD)	
Left	32.4 (14.9)
Right	36.8 (16.3)

Unaided DIN score	-8.2 (1.8)
Unaided QuickSIN	7.0 (4.8)

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

7.5.2 Abbreviated Profile of Hearing Aid Benefit

No clinically meaningful differences were found between self-adjustment and in-situ self-fitting strategies within participants for any APHAB subscales (ease of communication [EC]: Rosenthal *r* = -0.1; 95% CI, -0.4 to 0.1)(background noise [BN]: Cohen *d* = -0.1; 95% CI, -0.5 to 0.2)(reverberation [RV]: Cohen *d* = -0.3; 95% CI, -0.6 to 0.1)(aversion [AV]: Rosenthal *r* = -0.2; 95% CI, -0.5 to 0.0) or global scores (Cohen *d* = -0.2, 95% CI, -0.6 to 0.2) after the 4-week field trial. Overall APHAB benefit from baseline did not differ meaningfully between the 2 self-fitting methods (EC: Rosenthal *r* = -0.1, 95% CI, -0.4 to 0.1)(BN: Cohen *d* = 0.1, 95% CI, -0.2 to 0.5)(RV: Cohen *d* = 0.3, 95% CI, -0.1 to 0.6)(AV: Rosenthal's *r* = -0.2, 95% CI, -0.5 to 0.0)(Global: Cohen *d* = 0.2, 95% CI, -0.2 to 0.6)(Table 7.2 and Figure 7.1).

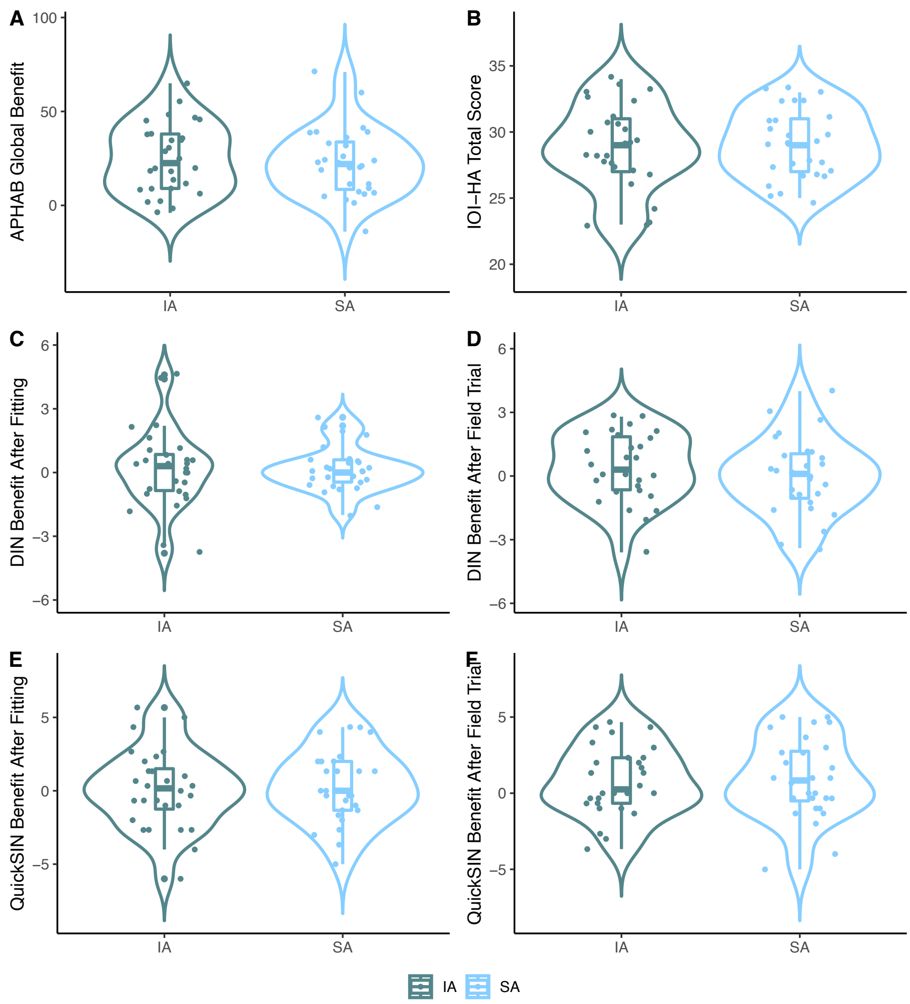

Figure 7.1 Outcome measures across the trial for the in-situ audiometry (IA) self-fitting and self-adjustment (SA) self-fitting.

(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.

Table 7.2 APHAB Scores for the Unaided Baseline, After 4-week Trial and Benefit for the Self-Adjustment and In-Situ Audiometry Self-fitting Strategies Among 28 Participants

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

Abbreviations: 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 $r = z/\sqrt{N}$ 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.

7.5.3 International Outcome Inventory for Hearing Aids

There was no clinically meaningful difference between the 2 self-fitting strategies (Rosenthal *r* = 0.0; 95% CI,−0.3 to 0.2) for IOI-HA total scores. However, the self-adjustment self-fitting method demonstrated meaningfully longer daily use (Rosenthal *r* = −0.3; 95% CI, −0.5 to 0.0) and higher satisfaction (Rosenthal *r* = −0.4; 95% CI, −0.6 to −0.1) compared with the in situ audiometry self-fitting strategy. No meaningful differences were found for the other subscales (Supplementary Material 7 - Appendix X). See Table 7.3 and Figure 7.1.

Table 7.3 IOI-HA Scores After Self-Adjustment and In-Situ Audiometry Self-Fitting Among 28 Participants

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

[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; $r \geq 0.3$

7.5.4 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 to 0.4) or QuickSIN (Cohen *d* = −0.1; 95% CI, −0.4 to 0.3) immediately after fitting. Benefit scores after 4 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 to 0.6) or QuickSIN scores (Rosenthal r = −0.1; 95% CI, −0.3 to 0.2). See Figure 7.1 and Supplementary Material 8 (Appendix Y).

7.5.5 Real-ear Measurements

For both self-fitting strategies, the average difference in output between 125 and 8000 Hz was within 5 dB of the National Acoustic Laboratories–Non-Linear 2 (NAL-NL2)[18] targets for average (65 dB sound pressure level [SPL]) and loud speech (75 dB SPL) immediately after fitting and following 4 weeks of using the hearing aids. The mean (SD) differences for soft speech (55 dB SPL) between 125 and 8000 Hz slightly exceeded 5 dB (after fitting: in situ audiometry 5.9 (4.4) dB, self-adjustment 6.6 (5.8) dB; after trial: in situ audiometry 6.8 (5.7) dB, self-adjustment 6.8 (6.0) dB. No clinically meaningful differences were observed between average speech (65 dB SPL) immediately after fitting (Cohen d = −0.2; 95%CI, −0.6 to 0.2) or after the field trial (Cohen d = −0.1; 95% CI, −0.4 to 0.3) as illustrated in Figure 7.2. Similar findings were observed for soft speech (55 dB SPL) immediately after fitting (Cohen d = −0.2; 95% CI, −0.5 to 0.1]) and after the field trial (Cohen d = −0.0; 95%CI, −0.3 to 0.3) as well as for loud speech (75 dB SPL) immediately after fitting (Cohen d = −0.1; 95%CI,−0.4 to 0.1) and after the field trial (Cohen d = −0.1; 95% CI, −0.3 to 0.2). See Supplementary Material 9 and 10 - Appendix Z and AA.

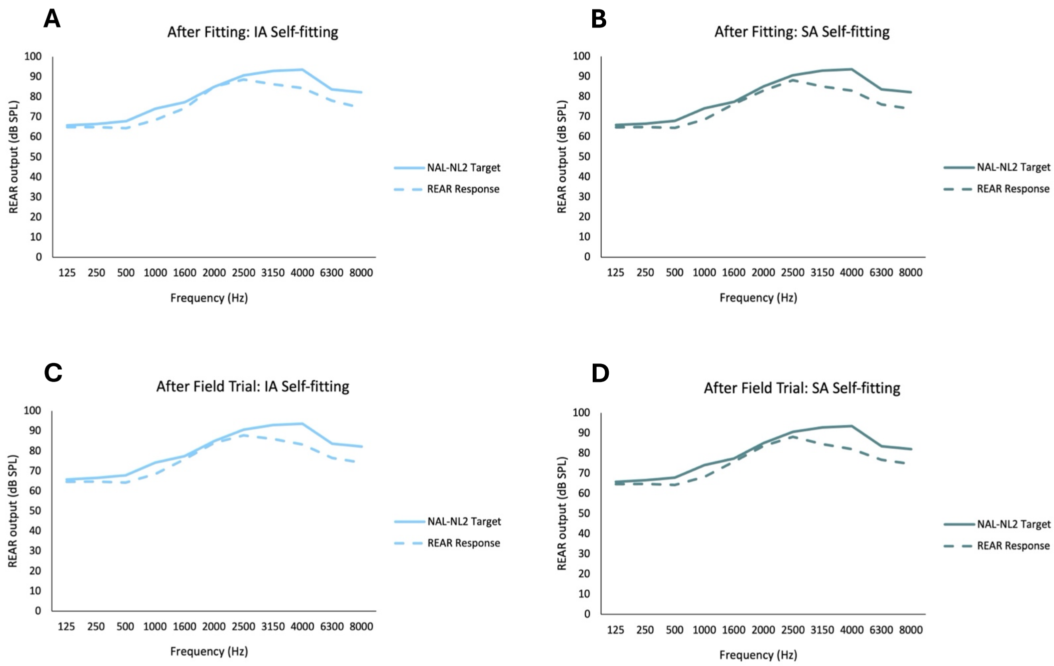

Figure 7.2 (A) Comparison of NAL-NL2 target and real ear output in dB SPL for the in-situ audiometry self-fitting strategy immediately after fitting, (B) Comparison of NAL-NL2 target and real ear output in dB SPL for the self-adjustment self-fitting strategy immediately after fitting, (C) Comparison 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.

7.5.6 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. Of the 28 participants, 8 (28.6%) maintained their original world volume settings (ie, overall gain across the frequencies), while 10 (35.7%) opted to increase the world volume with a mean (SD) increase of 11.1 (9.7) increments. However, 10 participants (35.7%) decreased the world volume by a mean (SD) of 8.2 (3.0) increments. Moreover, 10 participants (35.7%) did not alter the spectral tilt settings. Among participants who made adjustments to the spectral tilt settings, 6 participants (21.4%) opted for enhancing the treble, with a mean (SD) adjustment of 11.7 (9.8) increments. Conversely, 12 participants (42.9%) preferred a shift toward lower bass, with a mean (SD) change of 9.8 (8.0) increments.

7.6 Discussion

This crossover trial directly compared 2 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 2 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 lower bound of the CIs 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.[5,19]

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, because specific self-fitting strategies may be more suitable for certain individuals.[7,19] 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, this study showed that self-fit users prefer a comfort fit, which may result in higher frequency amplification levels slightly below the NAL-NL2 targets.[5,14,19] User preferences may lead to self-reported benefits but may not always result in optimal clinical performance. When evaluating hearing aid fitting strategies, it is important to distinguish between subjective user preferences and objective behavioral measures. Although user satisfaction is valuable, it should be balanced with the need to ensure hearing aid settings are optimal for clinical 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.[5,14] Speech-in-noise test performance in a lab setting may not accurately reflect 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 everyday 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.

7.7 Limitations

The findings of this clinical trial support the effectiveness of self-fitting strategies for OTC-SF hearing aids, aligning with previous studies.[5,13,14] However, this 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 clinical trial. We did not include a washout period, which could have further strengthened the internal validity of the study. Our sample size also limited our ability to conduct robust statistical analyses investigating correlations between outcomes and demographic variables. In addition, the study's design limited our ability to assess the long-term outcomes of the different self-fitting strategies.

7.8 Conclusion

To our knowledge, this clinical trial is the first to show that for OTC-SF hearing aids, self-adjustment and in-situ audiometry fitting strategies were both associated with 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 2 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.

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CHAPTER 8

DISCUSSION AND CONCLUSION

This chapter aims to provide a comprehensive context for the findings obtained in Studies I to V, discuss the clinical implications, and critically evaluate the barriers and enablers of hearing help-seeking, hearing aid uptake, and outcomes of OTC hearing aids.

8.1 Overview of research findings

The main aim of this thesis was to investigate the factors influencing help-seeking behavior for hearing difficulties and the uptake of hearing aids, as well as to evaluate the effectiveness and usability of OTC-SF hearing aids. This aim was addressed across five separate studies. The key research findings from each study are presented below.

Study I - Review of Factors Influencing Help-seeking and Hearing Aid Uptake

The systematic review showed that several factors influencing hearing help-seeking and hearing aid uptake have been studied, with some reported only once (10/70 for help-seeking and 62/159 for uptake). Research has primarily focused on hearing aid uptake (70%) rather than help-seeking (30%), highlighting the need to understand help-seeking as a crucial first step in acquiring hearing aids, as noted by Meyer and Hickson (2012). Understanding help-seeking is increasingly important due to changes in service delivery models, including OTC hearing aids (Food and Drug Administration, 2022). This review identified new predictors, such as cognitive anxiety for both help-seeking and hearing aid uptake (Kelly et al., 2011; Kelly-Campbell & Parry, 2014) and urban residency for uptake (Chan et al., 2017; He et al., 2018). Age and sex were generally not predictive consistent with previous reviews (Knudsen et al., 2010; Meyer & Hickson, 2012), although older individuals and males were more likely to seek help or uptake hearing aids in some reports. Social pressure influences help-seeking (Meister et al., 2014; Pronk et al., 2017), while perceived benefit and positive attitudes towards hearing aids predict uptake (Cobelli et al., 2014; Meyer et al., 2014). Financial support strongly predicts hearing aid uptake but not help-seeking (Cho et al., 2022; Laplante-Lévesque et al., 2012; Meyer et al., 2014; Simpson et al., 2019; Tahden et al., 2018). The severity of hearing loss and greater self-reported hearing disability are key predictors of hearing aid uptake, as reported in previous reviews (Knudsen et al., 2010; Meyer & Hickson, 2012). Understanding the factors influencing hearing help-seeking and hearing aid uptake can support public health and clinical initiatives to encourage these behaviors.

Study II – Qualitative Analysis of Reasons for Hearing Aid Uptake in the US

The reasons for hearing aid uptake were categorized into three domains: personal impact, social difficulties, and auditory difficulties, encompassing 11 main categories and 48 sub-categories. User recommendations to others with hearing difficulties comprised eight main categories. Most identified categories align with previous studies (Jenstad & Moon, 2011; Knoetze, Manchaiah, et al., 2023; Knudsen et al., 2010; Meyer & Hickson, 2012; Ng & Loke, 2015). However, this study offered more detailed reasons, such as specific speech perception issues motivating uptake (Humes & Dubno, 2021). It highlighted the effectiveness of promoting positive motivators over barriers, unlike other studies focused on why people avoid interventions (Muhorakeye & Biracyaza, 2021; Radez et al., 2021). Participants adopted hearing aids not only for hearing improvement but also for overall well-being, covering socio-emotional, cognitive, and physical aspects (Vercammen et al., 2020). This supports framing hearing health within broader healthy living contexts (Saunders et al., 2021). Financial access and reduced self-consciousness were major motivators, and addressing these barriers could enhance uptake (Fischer et al., 2011; Wallhagen, 2009).

Uptake was driven by intrinsic readiness or extrinsic social support, with awareness of benefits supporting intrinsic motivation. Social difficulties, such as communication issues, were significant motivators, highlighting the need to involve communication partners in consultations (Kamil & Lin, 2015; Manchaiah et al., 2012). In the auditory domain, self-reported hearing difficulties were a strong predictor of uptake, as reported by Gallagher and Woodside, 2018. Participants also cited entertainment purposes, such as TV watching, as reasons for uptake. Highlighting situational benefits of hearing aids in counseling could be beneficial (Laplante-Lévesque et al., 2011). This study uniquely documented users' recommendations to others, suggesting that accepting clinical recommendations increases the likelihood of adoption. Our findings may inform strategies to promote behavior change and enhance hearing aid uptake in those open to hearing aids.

Study III - Perspectives on Hearing Aid Cost and Uptake: Prescription vs. OTC Users

The analysis revealed three primary domains: enablers to hearing aid uptake related to cost, barriers to hearing aid uptake related to cost, and cost-related recommendations for others with hearing difficulties. Fourteen categories were identified for prescription users and twelve for OTC users. For prescription hearing aid users, financial support from organizations, insurance, or family significantly facilitated uptake, aligning with previous research (Jilla et al., 2020; Knoetze, Manchaiah, et al., 2023). Many prescription users reported having the means to afford hearing aids, thus eliminating cost as a barrier. OTC users highlighted affordability as a key enabler, suggesting that lower costs facilitate uptake for those with financial constraints. Payment plans were also beneficial, making hearing aids more accessible.

Both groups identified high cost as a significant barrier, consistent with previous studies (Jilla et al., 2020; Lin, 2018). Prescription users cited a lack of insurance coverage and concerns about long-term costs. OTC users noted high costs and affordability issues when replacing or repairing prescription aids, leading them to choose OTC alternatives. Participants recommended consulting professionals, researching options, and seeking financial support. Prescription users valued professional guidance, while both groups recommended purchasing the most current technology when possible. Understanding and addressing cost-related enablers and barriers for both prescription and OTC users can help develop effective interventions to improve hearing aid uptake.

Study IV - Usability and Performance of Self-Fitting OTC Hearing Aids

While the usability and performance of OTC-SF hearing aids were generally comparable, variations in fitting time, HASK scores, and sound quality existed. Post-use usability scores (PSSUQ) were generally high across devices, surpassing the averages reported by Sauro and Lewis, 2016. Lexie Lumen had the highest usability scores, possibly due to its app-based instructions and demonstration videos, as supported by Convery et al. (2019). However, Lexie Lumen required the longest fitting time, as users struggled with selecting and inserting the right size slim tubes. Users who prefer thorough initial setups might favor Lexie Lumen, while those seeking faster fittings might choose other devices. User skills and knowledge varied across devices, linked to the effectiveness of instructions in the accompanying apps. Effective app design and comprehensive instructions significantly impact user satisfaction and hearing aid use (Mothemela et al., 2023; Saunders et al., 2017).

Most participants self-reported ease of self-fitting, except for Sony CRE-C10, which posed several challenges. Issues included battery insertion, small markers, connection failures, and fitting difficulties for severe hearing loss. Participants also reported problems with hearing their voices and feedback on in-the-ear (ITE) devices. These findings highlight the importance of user-friendly design and interface, with preferences varying between situational and all-day use. Similar to Convery et al. (2019), some participants needed help with self-fitting, especially with Bluetooth connectivity. This indicates that while OTC-SF hearing aids are generally user-friendly, some users may still require support. Involving significant others in the process can enhance outcomes (Hickson et al., 2014; Mothemela et al., 2023). Speech-in-noise benefits were similar across devices, but sound quality ratings varied, affecting user satisfaction. Higher-priced devices like Lexie B2 and Sony CRE-C10 offered better sound quality than lower-priced options like HP Hearing PRO, although this did not translate to better speech-in-noise performance. Users should consider sound quality when selecting OTC-SF hearing aids, and healthcare providers can guide them based on these preferences. These findings underscore the need for consumer-centric metrics to aid decision-making in evaluating OTC hearing aids.

Study V - A Crossover Trial Comparing Self-Fitting Strategies for OTC Hearing Aids

Self-adjustment and in-situ audiometry self-fitting methods showed no clinically meaningful differences in APHAB benefit, overall IOI-HA satisfaction, speech-in-noise performance, and REMs. However, self-adjustment participants reported higher satisfaction and longer daily use on two IOI-HA subsections, possibly due to greater control and customization, allowing users to tailor settings to their preferences. This aligns with previous research showing a preference for self-selected settings (Convery, Keidser, & Hartley, 2011; Sabin et al., 2020). Despite these findings, the lower bound of the confidence intervals suggests that these effects might not be as meaningful or might not exist in a broader population. Participants' adjustments during the in-situ self-fitting field trial emphasize the need for flexibility to customize settings based on individual needs (Convery, Keidser, & Hartley, 2011; Convery, Keidser, Dillon, et al., 2011). Self-adjustment may be preferred by tech-savvy users who want complete control, while those less familiar with technology might benefit more from the structured approach of in-situ audiometry. A combined approach could offer a comprehensive solution catering to diverse preferences.

Consistent with prior research, self-fit users preferred a "comfort fit," resulting in gain being slightly below NAL-NL2 targets (De Sousa et al., 2023; Sabin et al., 2020). This preference may lead to self-reported benefits but not always optimal real-world performance. Evaluating fitting strategies requires balancing user satisfaction with ensuring optimal real-world performance through objective assessments. No significant differences in speech-in-noise scores between self-fitting strategies for DIN and QuickSIN tests suggest comparable speech perception in noise regardless of the method. However, adaptive speech-in-noise testing shows minimal benefits (De Sousa et al., 2023; Sabin et al., 2020). Future studies should use fixed speech-in-noise testing to better reflect real-world scenarios. Our findings support the effectiveness of self-fitting strategies for OTC-SF hearing aids, aligning with previous studies (De Sousa et al., 2023; Sabin et al., 2020; Swanepoel et al., 2023). Self-adjustment can significantly enhance satisfaction and daily use of hearing aids, highlighting the importance of user involvement in self-fitting.

8.2 Clinical implications

8.2.1 Implications for clinicians to increase help-seeking and hearing aid uptake

In addressing the complex landscape of hearing help-seeking and hearing aid uptake behaviors, the application of the COM-B model offers a structured approach that integrates Capability (i.e., physical and psychological capacity), Opportunity (i.e., external factors including social and physical opportunities), and Motivation (i.e., incentives and attitudes) as essential components to change Behavior (Michie et al., 2011). This section therefore explores clinical recommendations from this research project guided by the COM-B model and focusing on strategies to enhance individuals' hearing help-seeking and increase the adoption of hearing aids. Each subsection delves into specific areas, including addressing stigma and raising public awareness, holistic and targeted assessment, effective communication, counselling and support for hearing aids, integrating hearing health into overall well-being, using a family-centered approach and addressing financial barriers. Figure 8.1 provides an evidence-based framework to support hearing help-seeking and hearing aid uptake.

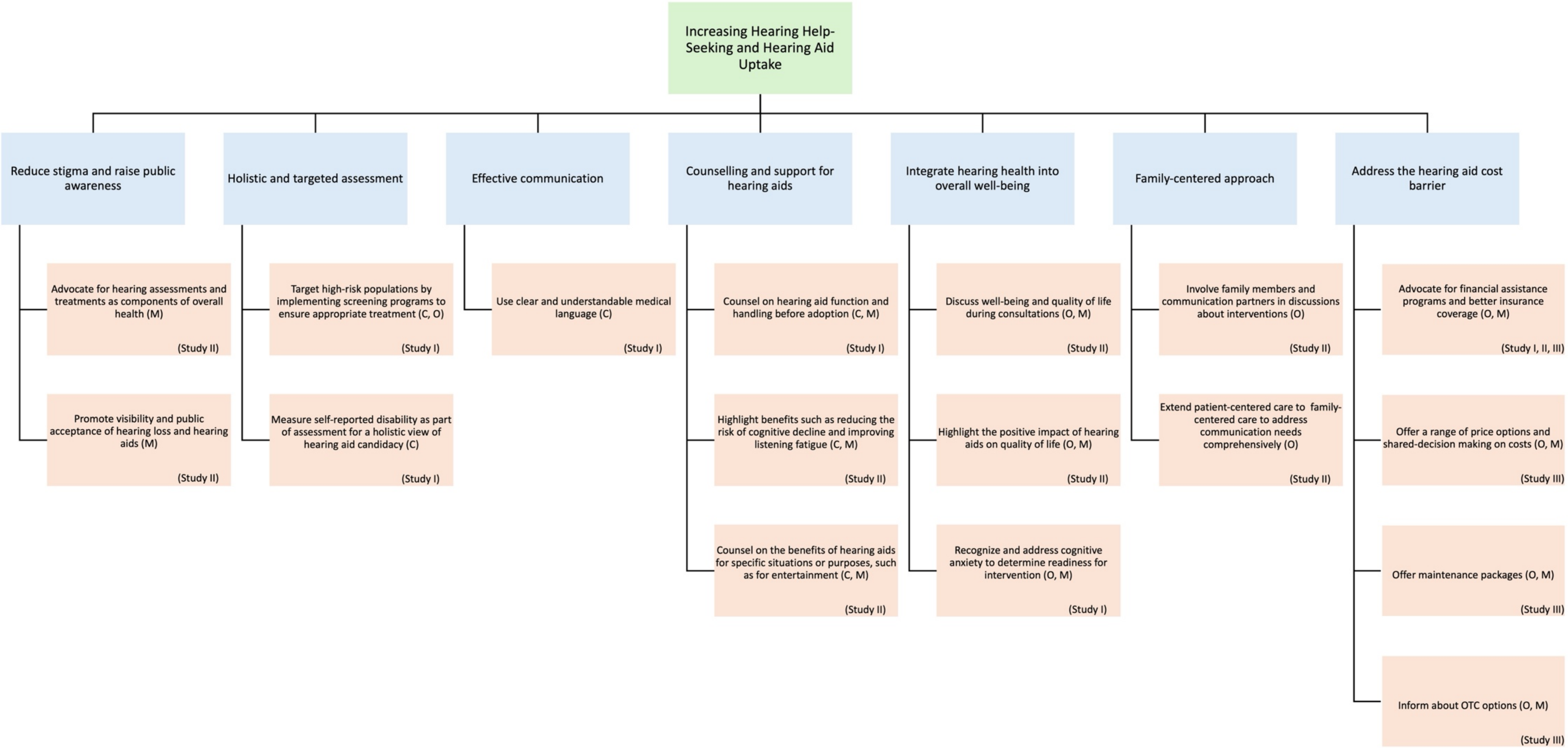

Figure 8.1 An evidence-based framework to support hearing help-seeking and hearing aid uptake.

Note: COM-B model: C = Capability, O = Opportunity, M = Motivation, B = Behavior. Study I = Factors Influencing Hearing Help-Seeking and Hearing Aid Uptake in Adults: A Systematic Review of the Past Decade, Study II = Reasons for hearing aid uptake in the United States: A qualitative analysis of open-text responses from a large-scale survey of user-perspectives, Study III = Perspectives on hearing aid cost and uptake for prescription and over-the-counter hearing aid users.

8.2.1.1 Addressing stigma and raising public awareness

In Study II, some participants chose to take up hearing aids because they felt less self-conscious about the discreet design, while others were not concerned about their appearance (Knoetze, Beukes, et al., 2023). It is important for hearing healthcare professionals to raise awareness and acceptance of hearing loss and hearing aids to reduce stigma and encourage more people to use them. Treating hearing loss as a part of overall health and promoting regular hearing assessments can help reduce the stigma associated with hearing loss (Wallhagen, 2009). Reducing stigma and increasing public acceptance can significantly increase patients' personal and social motivation to adopt hearing aids.

8.2.1.2 Holistic and targeted assessment

In study I, six studies showed a positive correlation between higher levels of self-reported disability, as measured by standardized tools, and the uptake of hearing aids (Knoetze, Manchaiah, et al., 2023). In line with the recommendations of Humes and Dubno (2021), including self-reported hearing disability assessments and pure tone audiometry during initial evaluations can provide valuable insights into hearing aid candidacy. Assessing self-reported hearing disability can enhance an individual's psychological capability by offering a more comprehensive understanding of their hearing difficulties, potentially increasing their willingness to adopt hearing aids.

Comorbidities such as diabetes, hypertension, and a history of stroke were found to have a negative impact on hearing aid uptake in Study I (Kuo et al., 2016; Nawaz et al., 2021; Samocha-Bonet et al., 2021). These chronic conditions may limit individuals' ability to manage their hearing loss due to constraints related to time, financial resources, and other competing health issues. As a result, hearing healthcare professionals should prioritize high-risk populations by implementing routine hearing screenings, preferably in mainstream healthcare settings (Knoetze, Manchaiah, et al., 2023). By ensuring that individuals with comorbidities are regularly screened, healthcare professionals can enhance these patients' psychological capability by increasing their knowledge of their hearing status. This, in turn, can empower them to take necessary actions to manage their hearing health. Early identification and intervention provide the necessary opportunities for these individuals to receive and benefit from appropriate hearing treatments.

8.2.1.3 Effective communication

Study I identified new factors influencing hearing aid uptake, including the language used by health professionals (Knoetze, Manchaiah, et al., 2023). Adorni et al. (2021) found that medical language was more effective in persuading people to obtain hearing aids than everyday language, which might seem inappropriate and unprofessional, leading to mistrust. Conversely, Sciacca et al. (2017) found that patients were less likely to obtain hearing aids if audiologists used language at a reading grade level, as reduced understanding can limit patient involvement in decision-making. The language used by health professionals directly impacts patients' psychological capability. Appropriate medical language can build trust and convey expertise, enhancing patients' understanding and ability to make informed decisions. Conversely, overly complex or unprofessional language can diminish understanding and trust, reducing patients' involvement and willingness to adopt hearing aids. Therefore, hearing healthcare professionals should balance their language - using medical terms to establish professionalism while ensuring clarity and understandability. This approach enhances patients' psychological capability, facilitating better comprehension and higher rates of hearing aid adoption.

8.2.1.4 Counselling and support for hearing aids

Additionally, Study I identified two studies that found that understanding hearing aid function positively influenced hearing aid uptake (Knoetze, Manchaiah, et al., 2023). This emphasizes the importance of counseling on hearing aid function and handling before patients decide to use them. Enhancing understanding of hearing aid function improves psychological capability, enabling patients to feel more confident in their ability to use the devices. Raising awareness about the benefits of hearing aids, such as improving psychosocial functioning (Oosthuizen et al., 2022), reducing listening fatigue (Holman et al., 2021), and mitigating cognitive decline risks (Livingston et al., 2020), can increase intrinsic motivation as reported in Study II (Knoetze, Beukes, et al., 2023). Knowing these benefits supports the decision to adopt hearing aids. Moreover, Study II found that some individuals use hearing aids mainly for entertainment, such as watching TV (Knoetze, Beukes, et al., 2023). Incorporating such specific benefits in counseling can enhance capability and motivation as patients recognize the practical advantages of hearing aids in their daily lives.

8.2.1.5 Integrating hearing health into overall well-being

In Study II, the reasons for hearing aid uptake span all three core well-being dimensions: socio-emotional well-being, cognitive well-being, and physical well-being (Vercammen et al., 2020). Participants reported adopting hearing aids to improve their quality of life (socio-emotional well-being), prevent auditory deprivation (cognitive well-being), and ensure personal safety (physical well-being). Hearing healthcare professionals should broaden their perspective on hearing health by incorporating discussions on well-being and quality of life into their consultations, emphasizing the positive impact of hearing aids across various dimensions of well-being (Knoetze, Beukes, et al., 2023). Discussing the wide-ranging benefits of hearing aids enhances patients' social and physical opportunities by creating an environment where the comprehensive advantages of hearing aids are clearly communicated, making adoption more appealing. Highlighting how hearing aids can improve socio-emotional, cognitive, and physical well-being increases the intrinsic motivation to adopt them.

Furthermore, cognitive anxiety has been identified as a predictor for seeking hearing help and adopting hearing aids in Study I (Knoetze, Manchaiah, et al., 2023). People with hearing loss may experience increased cognitive anxiety due to the unpredictability of communication breakdowns (Kelly et al., 2011; Kelly-Campbell & Parry, 2014). Seeking treatment can help mitigate this anxiety. Being aware of cognitive anxiety signs allows healthcare professionals to assess patients' readiness for intervention, addressing both the motivational and opportunity aspects of the COM-B model by providing psychological support and a clear pathway to managing their hearing health.

8.2.1.6 Family-centered approach

It is widely recognized that hearing loss can result in social challenges, including isolation, which may contribute to additional mental health issues (Shukla et al., 2020). Therefore, it was anticipated that factors like communication problems, difficulties in social interactions, and social withdrawal would be reported as motivators for adopting hearing aids in Study II (Knoetze, Beukes, et al., 2023). Communication partners also face challenges, such as communication difficulties, social restrictions, and reduced relationship satisfaction due to their partner's hearing loss (Kamil & Lin, 2015; Manchaiah et al., 2012). Involving communication partners, such as family members, in discussions about hearing interventions can enhance social opportunities for patients. This approach aligns with the shift from patient-centered care to family-centered care, addressing the patient's and their family's communication needs (Nerina et al., 2013). By including family members, healthcare professionals can create a supportive environment that encourages hearing aid adoption and consistent use, as family members can provide encouragement and reinforce positive communication habits.

8.2.1.7 Addressing financial barriers

In Study II, participants often mentioned that they decided to get hearing aids because they had the financial means or support to do so (Knoetze, Beukes, et al., 2023). Studies I and III have shown that access to financial support, such as third-party funding, positively impacts the adoption of hearing aids (Knoetze, Manchaiah, et al., 2023; Knoetze et al., 2024). Financial support and affordability play a key role in allowing more people to get hearing aids, making them accessible to a wider range of individuals. When financial barriers are reduced, people are more motivated to opt for hearing aids since they can afford the treatment. Hearing healthcare professionals can also advocate for improved insurance coverage for hearing aids, as suggested in Study III (Knoetze et al., 2024). By advocating for better insurance coverage, there is an increase in the accessibility of hearing aids as they become more affordable, and it also increases motivation by addressing patients' financial concerns and encouraging them to opt for hearing aids.

In Study II, affordable options were noted to encourage more people to take up hearing aids (Knoetze, Beukes, et al., 2023). This emphasizes the importance of considering each person's financial situation. Healthcare professionals should involve patients in the decision-making process by discussing cost options using a shared decision-making approach and providing clear information about the available choices. Providing a variety of hearing aids at different prices can make hearing aids more accessible to more people and can motivate patients by involving them in the decision-making process.

Hearing aid users in Study III have expressed concerns about the long-term costs associated with repairs and replacements (Knoetze et al., 2024). Addressing these concerns by providing information and offering financial solutions, such as maintenance packages, can increase the opportunity for sustained use. It also motivates patients by alleviating anxiety over unforeseen expenses.

Affordability was a significant factor for OTC hearing aid users in Study II when considering the uptake of hearing aids (Knoetze, Beukes, et al., 2023). OTC hearing aids are more affordable than most prescription aids, which can make them more accessible to those who are deterred by the cost. Offering payment plans also helped increase the uptake of hearing aids, suggesting that other OTC manufacturers should consider providing similar options. By lowering the cost of OTC hearing aids and offering payment plans, hearing healthcare professionals can create more opportunities and motivation for individuals to adopt hearing aids by reducing the immediate financial burden.

8.2.2 Enhancing user experience in OTC hearing aids

Figure 8.2 outlines the key elements for enhancing user experience in OTC hearing aids, based on Studies IV and V findings.

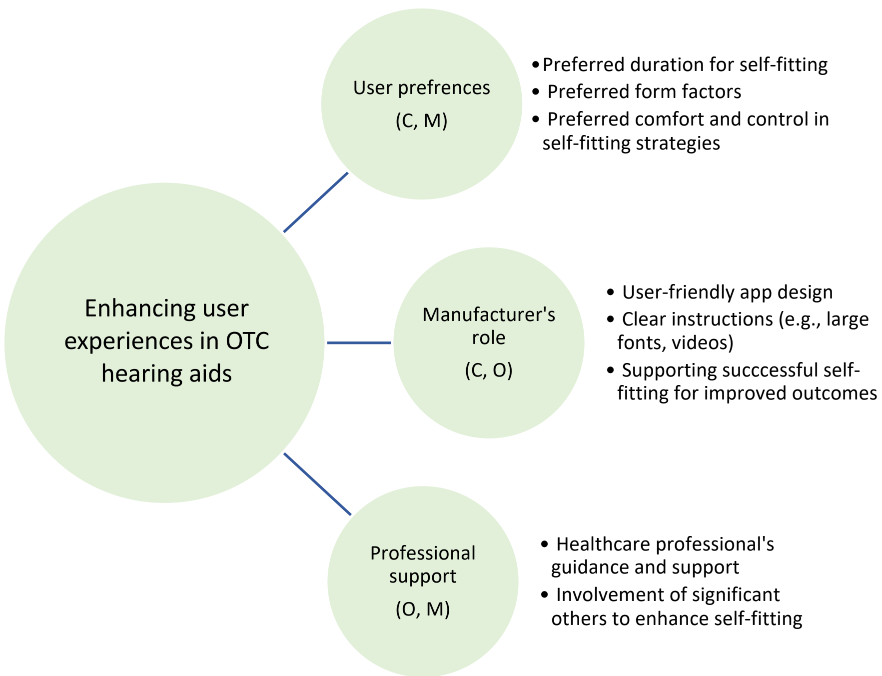

Figure 8.2 Enhancing user experience in OTC-SF hearing aids (Study IV and V)

The findings from Study IV indicate that current OTC-SF hearing aids are generally user-friendly, with various models catering to different user preferences. This suggests that users have the physical capability to handle and operate these devices. Users who prioritize a comprehensive introduction to the device and precise adjustments may prefer options like Lexie Lumen. In contrast, those who value a quicker fitting process might opt for other models. Ultimately, the user's preference should be considered alongside usability and performance measures. Form factors, device design, and user interface are crucial elements that impact the overall user experience. While some users may prefer OTC-SF hearing aids for situational use, others might opt for Behind-The-Ear (BTE) styles for all-day use, although further studies are needed to confirm these preferences. Furthermore, Study V demonstrated that it is important to consider the diverse needs of consumer groups is critical, as certain self-fitting strategies may be more appropriate for different individuals. For example, tech-savvy users who prefer full control over the fitting may favor self-adjustment strategies. Conversely, those less familiar with technology or needing guidance may benefit from structured in-situ audiometry fitting, which aids in setting initial parameters. Understanding these preferences can motivate users to select the most suitable device and fitting strategy.

Manufacturers should focus on user-friendly design and clear app instructions to enhance the usability of OTC-SF hearing aids. This improves users' psychological capability by making it easier to understand and follow instructions. Incorporating larger fonts, pictogram illustrations, videos, and everyday language in user manuals can improve self-fitting. The availability of comprehensive user instructions and well-designed apps provides users with the physical opportunity to effectively self-fit and manage their hearing aids. Additionally, the app design and access to comprehensive user instructions are critical for users to self-fit and manage their hearing aids effectively, leading to higher satisfaction and benefit outcomes (Convery et al., 2019; Saunders et al., 2017).

Despite the user-friendly nature of OTC-SF hearing aids, some users may still require assistance. Healthcare professionals can play a crucial role by educating users on proper use and maintenance. They can provide hands-on demonstrations and training sessions to ensure users effectively self-fit their hearing aids. Regular check-ins and virtual consultations further support ongoing monitoring and guidance. Healthcare professionals can also help create an environment that encourages user engagement and social interaction, enhancing social opportunities. In line with previous research, involving significant others in the self-fitting process can significantly improve the user's experience and benefit and satisfaction outcomes (Hickson et al., 2014; Manchaiah et al., 2020). Significant others as part of this process can provide emotional and practical support, which is important during the initial adjustment period. Higher benefit and satisfaction outcomes from effective self-fitting can motivate users to engage in the process and persist with using their hearing aids.

8.3 Study strengths and limitations

8.3.1 Study strengths

Study I - Review of Factors Influencing Help-seeking and Hearing Aid Uptake

This study covered an extensive period from January 2011 to February 2022, providing a broad and up-to-date overview of the literature. The systematic approach ensured thorough and unbiased identification, evaluation, and synthesis of relevant studies, representing the highest level of evidence. It investigated a large number of audiological and non-audiological factors for hearing help-seeking and hearing aid uptake.

Study II - Reasons for Hearing Aid Uptake in the US: Qualitative Analysis of Survey Responses

This study drew from a notably larger sample compared to many qualitative studies in the field, enhancing the robustness and generalizability of the findings. Focusing on hearing aid user perspectives, this study offers valuable insights into their motivations and experiences, enriching our understanding of their decision-making processes. Including prescription and OTC hearing aid users, this study provides a comprehensive perspective encompassing different pathways to accessing hearing aids. This study is the first to investigate hearing aid users' recommendations to others with hearing difficulties.

Study III - Perspectives on Hearing Aid Cost and Uptake: Prescription vs. OTC Users

This study integrated the Health Belief Model into its analysis, providing a theoretical foundation for understanding the factors influencing hearing aid uptake. By framing the discussion within the HBM, the study enhances the findings' interpretative framework and theoretical rigor. Similar to Study II, this study included a sample of 179 prescription and 62 OTC hearing aid users, providing a relatively large and diverse participant pool. This enhances the generalizability of the findings and allows for the exploration of differences and similarities between the two groups. By incorporating user perspectives, the study offers practical recommendations for addressing cost-related barriers and enhancing uptake, thus increasing the relevance and applicability of the findings.

Study IV - Usability and Performance of Self-Fitting OTC Hearing Aids

This study included a wide range of FDA-approved OTC-SF hearing aids, broadly comparing different products available on the market. Using standardized tools like the Post-Study System Usability Questionnaire (PSSUQ) to evaluate post-use usability ensured a consistent and reliable measure of user experience. This study combined quantitative data (usability scores, fitting times) with qualitative feedback (open-ended responses), providing a well-rounded view of user experiences.

Study V - A Crossover Trial Comparing Self-Fitting Strategies for OTC Hearing Aids

The cross-over design allowed each participant to experience both self-fitting strategies (self-adjustment and in-situ audiometry), reducing variability and enhancing the reliability of comparisons. Using a within-subjects design minimized the impact of individual differences (e.g., degree of hearing loss, age, experience with technology) on the outcomes, leading to more precise comparisons between self-fitting strategies. While not truly randomized, this study's pseudo-randomized design still aimed to distribute participants across conditions in a way that reduced potential biases. This study evaluated a broad range of outcomes, including APHAB benefit, IOI-HA satisfaction, speech-in-noise performance, and real-ear measurements, offering a holistic view of the effectiveness of self-fitting strategies.

8.3.2 Study limitations

Study I - Review of Factors Influencing Help-seeking and Hearing Aid Uptake

The synthesis methods used in this study (i.e., direction of effect and vote-counting) did not provide information on the magnitude of the effects. This lack of detail in quantifying effect size limits our ability to evaluate the strength and practical significance of the findings, thereby constraining both the depth of analysis and the potential applicability of the results in real-world settings.

Study II - Reasons for Hearing Aid Uptake in the US: Qualitative Analysis of Survey Responses

This study may potentially have some sampling bias due to participant recruitment and self-selection methods. Lexie participants were verified hearing aid users because they had purchased Lexie hearing aids, whereas we could not independently verify the hearing aid usage of Hearing Tracker participants, as it was based on their self-reported data in the larger study. The complexity of the open-ended question, which included multiple sub-questions, might have resulted in selective responses. Furthermore, Lexie participants were not required to meet a minimum word count, leading to some brief responses that lacked detailed context. The sample comprised individuals who had already adopted hearing aids, which may not reflect all potential users, especially those who are strongly opposed to using hearing aids or face significant barriers to access.

Study III - Perspectives on Hearing Aid Cost and Uptake: Prescription vs. OTC Users

This study included a secondary analysis of an open-ended question about why people purchase hearing aids. It is important to note that the data were not originally collected for this specific research question, which may limit the depth and specificity of information related to hearing aid costs. Therefore, these findings should be considered preliminary. The study population consisted of individuals who already own hearing devices, which may introduce selection and response biases. As participants were self-selected through outreach efforts, their views may not represent the broader population with hearing loss. Additionally, the study population was recruited from online platforms like Hearing Tracker, likely representing a more engaged subset of individuals discussing hearing aids. Consequently, caution is advised when generalizing the findings. Nevertheless, the study offers valuable insights into the perspectives of those pursuing hearing aids regarding the relationship between cost and uptake. The survey did not include questions about whether participants paid for their hearing aids or received them at no cost, preventing a stratified analysis. We could not explore differences in perspectives between those who paid for their hearing aids and those who received them at no cost, including those covered by health insurance. Demographic data such as race, ethnicity, and income level were not collected or available for analysis. This limited our ability to examine how these factors interact with participants' experiences and perspectives on the relationship between hearing aid cost and uptake. Additionally, the demographics of the sample may not reflect the diversity of the population.

The study also included only one brand of OTC hearing aid users, which does not represent all OTC hearing aid users.

Study IV - Usability and Performance of Self-Fitting OTC Hearing Aids

This study focused on six OTC-SF hearing aids, which may not represent the full range of OTC-SF devices emerging in the market. Additionally, the lack of information on OTC-PS devices could limit the study's generalizability. The sample consisted of 43 participants who perceived themselves to have mild-to-moderate hearing loss and had good English proficiency, which may not reflect the broader population that could benefit from OTC-SF hearing aids. Conducting the study in a controlled environment where participants were observed might have influenced their behavior and responses, possibly making them more attentive or pressured to perform better than they would in everyday situations. This setting may not accurately replicate real-world conditions, where distractions and environmental factors could affect the usability and performance of OTC-SF hearing aids differently. Speech-in-noise tests were not counterbalanced between aided and unaided conditions. While including specific HASK items provided a focused evaluation aligned with the study's objectives, it might compromise construct validity and introduce potential bias, which should be considered when interpreting the results. The comparisons were, however, within subjects and between devices, which mitigates potential bias effects.

Study V - A Crossover Trial Comparing Self-Fitting Strategies for OTC Hearing Aids

In this study the randomization process was compromised because participants had to be replaced due to a technical issue with the research app, resulting in a pseudo-randomized controlled trial. Additionally, the absence of a washout period may have affected the study's internal validity. The sample size was too small to allow for strong statistical analyses of the correlations between outcomes and demographic variables. Furthermore, the study design restricted our ability to evaluate the long-term outcomes of the different self-fitting strategies.

8.4 Recommendations for future research

Figure 8.3 illustrates the suggested areas for future research on hearing help-seeking, hearing aid adoption, and over-the-counter hearing aids, as detailed in Studies I-V.

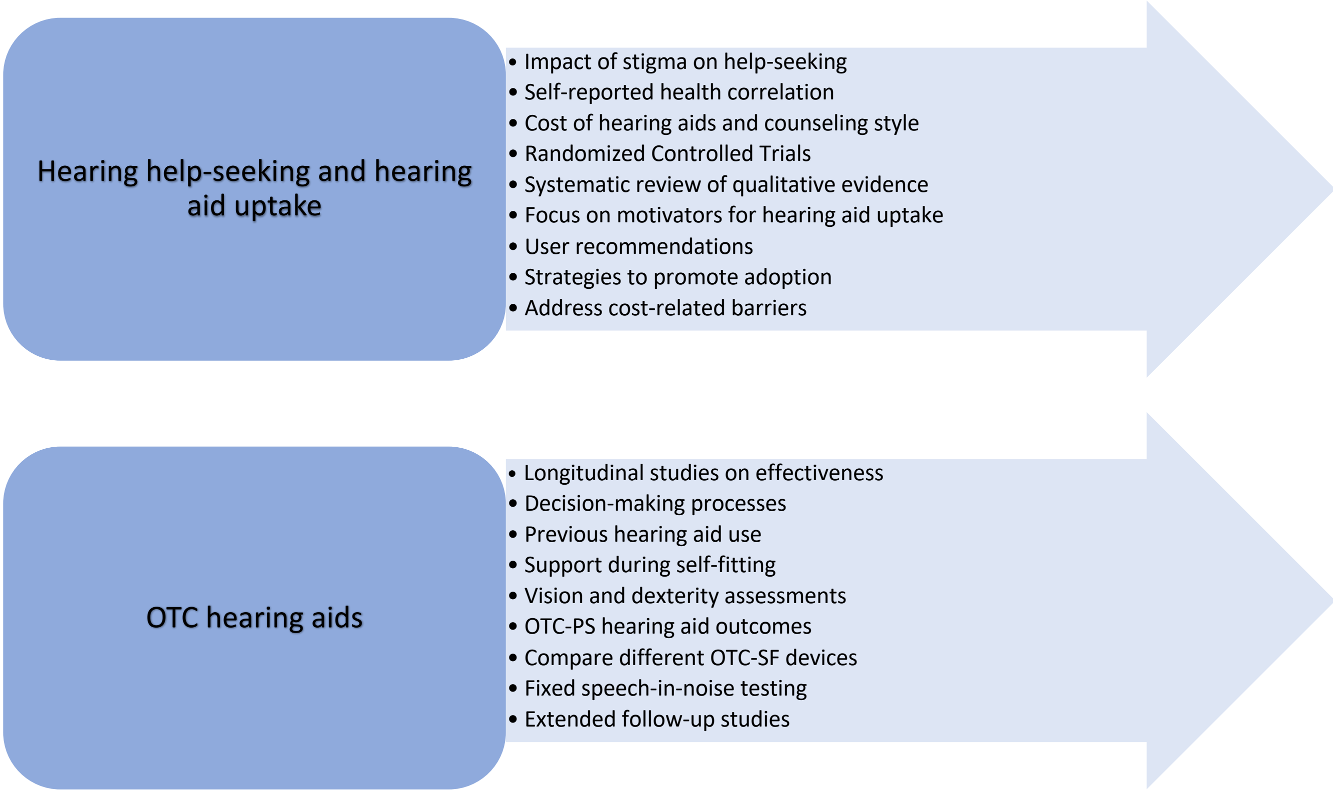

Figure 8.3 Recommendations for future research on hearing help-seeking, hearing aid uptake and OTC hearing aids

8.4.1 Hearing help-seeking and hearing aid uptake

Additional research is needed in areas with limited evidence, such as the impact of stigma on seeking hearing help. Further studies should address topics with mixed findings, like the connection between self-reported health and both hearing help-seeking and hearing aid adoption. Other factors that warrant investigation include the cost of hearing aids and the counseling style, as these have been noted to influence hearing aid adoption in clinical settings, though the evidence is sparse. More rigorous studies with stronger evidence, such as randomized controlled trials, are needed in both hearing help-seeking and hearing aid adoption. Conducting a systematic review and synthesis of qualitative research could provide additional insights into the factors influencing these behaviors. Future studies should focus on the factors that motivate a person to take up hearing aids, as reported by the hearing aid users in Study II, rather than on the barriers, as it may be more effective in promoting hearing aid uptake.

More research is also necessary on hearing aid users' recommendations for others with hearing difficulties. This information can help hearing healthcare professionals and service-delivery models better understand what hearing aid users value and what could enhance the uptake of hearing aids. Further research is needed to develop strategies for promoting change and encouraging the adoption of hearing aids among those who are hesitant to use them. The perspectives of both prescription and OTC hearing aid users highlight the importance of addressing cost-related barriers associated with hearing aid adoption. This includes exploring insurance coverage options and promoting affordable hearing aid choices.

8.4.2 OTC hearing aids

Conducting longitudinal studies to assess the effectiveness and user satisfaction of OTC-SF hearing aids over extended periods would yield valuable insights. Exploring individuals' decision-making processes when choosing OTC-SF devices would provide useful information on user preferences and influencing factors. Additionally, investigating the impact of previous hearing aid use on the usability and performance of OTC devices could reveal important differences in user experience. Research should also examine the level of support required during self-fitting and its potential influence on user experience could offer valuable insights for family members or healthcare professionals aiming to enhance support for OTC-SF users. Assessing vision and dexterity could deepen our understanding of how these factors affect the usability and performance of OTC devices, contributing to more comprehensive user-centered evaluations. Evaluating the usability, performance, benefits, and satisfaction outcomes of OTC-PS hearing aids would improve our understanding of the strengths and limitations of pre-set OTC devices. Comparing the benefit and satisfaction outcomes across different OTC-SF hearing aids would help determine their overall effectiveness. Future studies should consider using fixed speech-in-noise testing rather than only adaptive speech-in-noise testing to ensure standardized and comparable assessments of speech perception benefits. Extended follow-up and larger sample sizes are necessary to evaluate the long-term effectiveness of self-fitting approaches in OTC-SF hearing aids including assessments of individual and combined efficacy, and exploring relationships between outcomes, degree of hearing loss, age, and other relevant variables.

8.5 Conclusion

This research project, encompassing five studies, focused on barriers and facilitators to seeking hearing help and adopting hearing aids in adults. Key contributions include identifying significant predictors, such as hearing sensitivity for hearing aid uptake, and non-predictive factors, such as education level for help-seeking. The study also addresses the mixed findings, such as links with self-reported health. A critical finding is the impact of financial barriers and insurance coverage on access to hearing aids, affecting prescription and OTC users. The usability and performance of OTC-SF hearing aids were similar in post-usability and speech-in-noise benefits but varied in fitting time, HASK, and sound quality. Self-adjustment and in-situ audiometry strategies for OTC hearing aids provided comparable outcomes, with self-adjustment potentially enhancing user satisfaction and engagement. These insights emphasize the need for targeted interventions to overcome financial barriers and improve accessibility while accommodating diverse and personal motivations for obtaining hearing aids. Additionally, these findings can inform consumers, manufacturers, and healthcare professionals in making decisions and recommendations regarding OTC-SF hearing aids.

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APPENDICES

Appendix A: Ethical Clearance (HUM008/0822)

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Fakulteit Geesteswetenskappe
Lefapha la Bomotho

Humanities 100.
Since 1919

1 September 2022

Dear Miss MC Knoetze

Project Title:	Factors influencing hearing help-seeking and hearing device uptake in adults
Researcher:	Miss MC Knoetze
Supervisor(s):	Prof DCDW Swanepoel
Department:	Speech Language Pathology and Audiology
Reference number:	16005725 (HUM008/0822)
Degree:	Doctoral

Thank you for the application that was submitted for ethical consideration.

The Research Ethics Committee notes that this is a literature-based study and no human subjects are involved.

The application has been approved on 1 September 2022 with the assumption that the document(s) are in the public domain. Data collection may therefore commence, along these guidelines.

Please note that this approval is based on the assumption that the research will be carried out along the lines laid out in the proposal. However, should the actual research depart significantly from the proposed research, a new research proposal and application for ethical clearance will have to be submitted for approval.

We wish you success with the project.

Sincerely,

Prof Karen Harris
Chair: Research Ethics Committee
Faculty of Humanities
UNIVERSITY OF PRETORIA
e-mail: tracey.andrew@up.ac.za

Room 7-27, Humanities Building, University of Pretoria, Private Bag X20, Hatfield 0028, South Africa
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Appendix B: Ethical Clearance (HUM021/1122)

Faculty of Humanities
Fakulteit Geesteswetenskappe
Lefapha la Bomotho

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Humanities 100.
Since 1919

8 June 2023

Dear Prof DCDW Swanepoel,

Project Title:	Comparing self-fitting strategies in over-the-counter hearing aids
Researcher:	Prof DCDW Swanepoel
Supervisor(s):	
Department:	Speech Language Pathology and Audiology
Reference number:	02606623 (HUM021/1122 Line 3) (Amendment)
Degree:	Staff Research / Non Degree

Thank you for the application to amend the existing protocol that was previously approved by the Committee.

The revised / additional documents were reviewed and **approved** on 08 June 2023 along these guidelines, further data collection may therefore commence (where necessary).

Please note that this approval is based on the assumption that the research will be carried out along the lines laid out in the amended proposal. Should your actual research depart significantly from the proposed research, it will be necessary to apply for a new research approval and ethical clearance.

We wish you success with the project.

Sincerely,

Prof Karen Harris
Chair: Research Ethics Committee
Faculty of Humanities
UNIVERSITY OF PRETORIA
e-mail: tracey.andrew@up.ac.za

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Appendix C: Ethical Clearance Notification Letter (HUM021/1122)

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Department of Speech-Language Pathology and Audiology

WHO Collaborating Centre for Prevention of Deafness and Hearing Loss

15 July 2024

TO: Humanities Research Ethics Committee

RE: HUM021/1122

I am writing to inform you about a minor update related to the approved research project *Comparing self-fitting strategies in over-the-counter hearing aids* (HUM021/1122).

I would like to notify the committee that a PhD student (Miss Megan Knoetze; student number: 16005725) who served as the research assistant on this project, will be using some of this data (collected during Phases 1 and 2 of the study) towards a portion of her doctoral studies. Specifically, this data will contribute to two of the five articles comprising her PhD project. This utilization aligns with the original aims and scope of our study, and no additional data collection will be conducted.

During the initial consent process, all participants were informed that their anonymized data could be used for further academic research, including publications. The data was handled with strict confidentiality, ensuring that individual participants could not be identified in any publications in line with the initial application.

Thank you for your attention to this matter. Should you require any further information or documentation, please do not hesitate to contact me.

Sincerely,

Prof De Wet Swanepoel

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Appendix D: Informed consent for study IV

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Department of Speech-Language Pathology and Audiology

WHO Collaborating Centre for Prevention of Deafness and Hearing Loss

Dear Sir/Madam,

INVITATION TO PARTICIPATE IN RESEARCH STUDY

You are kindly invited to participate in a research study held at the Department of Speech-Language Pathology and Audiology, University of Pretoria. The purpose of the study is to compare self-fitting strategies in Over-the-Counter (OTC) hearing aids.

Purpose of the study
This study will compare different self-fitting strategies between OTC hearing aids that are currently available on the market. The study will compare the self-fit process, usability and performance of different OTC hearing aids, including Lexie, Sontro, HP, Sony, and Jabra devices.

Am I a candidate to participate?
In order to be eligible to participate in the study, you will need to be:

- 18 years or older
- Suspect that you have mild to moderate hearing loss or have previously been diagnosed with mild to moderate hearing loss
- Should not have a history of recurrent ear infections or other middle ear pathologies
- Have a high level of proficiency in English
- Own an Android or iOS smartphone with access to mobile data

What will I need to do if I choose to participate?
Participants will be asked to attend two sessions at the University of Pretoria at no cost. Each session will take approximately two hours, scheduled at a time convenient to the participant.

Session 1

- **English proficiency test**

For this test, participants will be asked to conduct the online 15 min EF SET English proficiency test. The test is done by selecting one of a number of responses to English phrases. The instruction is to select the response that is most appropriate to the sentence.

- **Otoscopy**

For this examination, the participant will be seated upright while the audiologist visually inspects the ear canal by placing an otoscope (ear light) in the ear.

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- **Pure tone audiometry**

For this test, the participant will be seated in a soundproof booth. Headphones will be placed on the ears. The participant will be asked to respond to a series of soft sounds (at different pitches) by pressing a button. This will be done to measure the participant's hearing sensitivity.

- **Unaided speech perception testing**

The QuickSIN, Digits-in-Noise (DIN) and word recognition testing will be performed in the sound field using the speakers in the soundproof booth. For the QuikSIN, a list of sentences will be presented in noise. Participants will be requested to say the sentences that were heard. For the DIN, participants will be asked to listen to the digits presented and say the digits in the order that it was heard. If they were uncertain, they would be instructed to guess. For the word recognition testing, words will be presented in quiet and participants will be asked to repeat the words.

Session 2

- **Hearing aid fitting**

After participants have been assigned to different conditions, they will complete the self-fitting of each of the five devices (Lexie, Sontro, HP, Sony, and Jabra devices) using the instructions provided by the manufacturers. The self-fit process will be timed.

- **Questionnaires**

Participants will complete a self-reported questionnaire, Post Study System Usability Questionnaire (PSSUQ) and Judgement of Sound Quality (JSQ) after each fitting.

- **Real ear measurements**

Real ear measurements will be performed after each fitting. For this standard clinical test, a small thin tube (probe microphone) will be inserted in the ear canal along with the hearing aid. This test measures the exact sound levels that are presented by the hearing aid. For this test, the participant will only be requested to stay seated while speech sounds are presented via the equipment's speaker.

- **Aided speech perception testing**

After each fitting, participants will complete speech perception testing (QuickSIN, DIN and word recognition testing) while wearing the hearing aids.

Are there any risks or benefits for me if I participate in this study?

Participants will not be exposed to any risk or experience any discomfort during this study. This study involves no direct benefits.

What are your rights as a participant?

Your participation in this study is entirely voluntary. You may decline to participate or stop at any time during the study.

Confidentiality

All your information will be kept confidential. Once the datasheet has been completed, a number will be allocated to your datasheet. Your name will not appear on any document. Research articles in scientific journals will not include any information that could identify you. All of the data collection sheets from this study will be stored for a period of 15 years in both hard copies and scanned electronic versions.

Before you agree to take part, you should fully understand what is involved. If you have any questions that this letter does not fully explain, please do not hesitate to contact Prof De Wet Swanepoel at dewet.swanepoel@up.ac.za.

CONSENT TO PARTICIPATION IN A RESEARCH STUDY

I, ____, hereby consent to participate in the research study. I have read and understood the consent letter and have been given the opportunity to ask questions, and I am satisfied that they have been answered satisfactorily. I understand that I will not be reimbursed for participating in this research study. I am aware that I may withdraw from the research study at any point, should I wish to do so. I understand that every effort will be made to ensure that I am not harmed in this research study. I consent that my results from this study may be used anonymously in research publications and for future research.

Signature: ____

Date: ____

Appendix E: Informed consent for study V

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Department of Speech-Language Pathology and Audiology

WHO Collaborating Centre for Prevention of Deafness and Hearing Loss

Dear Sir/Madam,

INVITATION TO PARTICIPATE IN RESEARCH STUDY
You are kindly invited to participate in a research study held at the Department of Speech-Language Pathology and Audiology, University of Pretoria. The purpose of the study is to compare self-fitting strategies in Over-the-Counter (OTC) hearing aids.

Purpose of the study
This study will compare the existing self-fitting strategy of the Lexie B2 Powered by Bose hearing aids (i.e., direct adjustment) to a newly developed in-situ audiometry fitting strategy.

Am I a candidate to participate?
In order to be eligible to participate in the study, you will need to be:

- 18 years or older
- Suspect that you have mild to moderate hearing loss or have previously been diagnosed with mild to moderate hearing loss
- Should not have a history of recurrent ear infections or other middle ear pathologies
- Have a high level of proficiency in English
- Own an Android or iOS smartphone with access to mobile data

What will I need to do if I choose to participate?
Participants will be asked to attend three sessions at the University of Pretoria at no cost. Each session will take approximately two hours, scheduled at a time convenient to the participant.

Session 1

- **English proficiency test**

For this test, participants will be asked to conduct the online 15 min EF SET English proficiency test. The test is done by selecting one of a number of responses to English phrases. The instruction is to select the response that is most appropriate to the sentence.

- **Otoscopy**

For this examination, the participant will be seated upright while the audiologist visually inspects the ear canal by placing an otoscope (ear light) in the ear.

- **Pure tone audiometry**

For this test, the participant will be seated in a soundproof booth. Headphones will be placed on the ears. The participant will be asked to respond to a series of soft sounds (at different pitches) by pressing a button. This will be done to measure the participant's hearing sensitivity.

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- **Unaided speech perception testing**

The QuickSIN, Digits-in-Noise (DIN) and word recognition testing will be performed in the sound field using the speakers in the soundproof booth. For the QuikSIN, a list of sentences will be presented in noise. Participants will be requested to say the sentences that were heard. For the DIN, participants will be asked to listen to the digits presented and say the digits in the order that it was heard. If they were uncertain, they would be instructed to guess. For the word recognition testing, words will be presented in quiet and participants will be asked to repeat the words.

- **Hearing aid experience questionnaire**

The participant will be asked to answer a series of Likert-style questions or statements related to their hearing with and without a hearing aid using a validated questionnaire called the Abbreviated Profile of Hearing Aid Benefit (APHAB**)**. The questionnaires will be uploaded electronically and participants will complete them in the session using a tablet provided by the researchers.

- **Hearing aid fitting**

Participants will be fitted with the Lexie B2 Powered by Bose hearing aids either using the self-fit strategy or the in-situ audiometry fitting strategy (depending on which group they are in). The self-fit process will be timed and participants will be asked to rate how easy it was using a Likert scale.

- **Real ear measurements**

For this standard clinical test, a small thin tube (probe microphone) will be inserted in the ear canal along with the hearing aid. This test measures the exact sound levels that are presented by the hearing aid. For this test, the participant will only be requested to stay seated while speech sounds are presented via the equipment's speaker.

- **Aided speech-in-noise testing**

Participants will complete speech perception testing (QuickSIN, DIN and word recognition testing) while wearing the hearing aids.

Participants will be asked to wear the hearing aids for 28 days for approximately 6 hours per day.

Session 2

After 4 weeks, participants will be asked to return for session 2.

- **Hearing aid experience questionnaires**

Participants will be asked to complete the APHAB and International Outcome Inventory for Hearing Aids (IOI-HA) questionnaires to determine hearing aid benefit and satisfaction.

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- **Hearing aid fitting**

Participants will be fitted with the same hearing aids using the alternative fitting strategy (i.e., those who were fitted using the self-fit strategy will now be fitted using the in-situ audiometry and vice versa). The self-fit process will be timed and participants will be asked to rate how easy it was using a Likert scale.

- **Real ear measurements and aided speech perception testing**

Real ear measurements and aided speech-in-noise testing will be performed again.

Thereafter, participants will be asked to wear the hearing aids for another 28 days for approximately 6 hours per day.

Session 3

After 4 weeks, participants will be asked to return for session 3.

- **Hearing aid experience questionnaires**

Participants will complete the APHAB as well as the IOI-HA to determine hearing aid benefit and satisfaction after hearing aid fitting.

Participants will then be able to keep the Lexie B2 Powered by Bose hearing aids and smartphone application to use for free.

Are there any risks or benefits for me if I participate in this study?

Participants will not be exposed to any risk or experience any discomfort during this test. Once the study has been completed, participants will get the Lexie B2 Powered by Bose hearing aids and smartphone application to use for free.

What are your rights as a participant?

Your participation in this study is entirely voluntary. You may decline to participate or stop at any time during the study.

Confidentiality

All your information will be kept confidential. Once the datasheet has been completed, a number will be allocated to your datasheet. Your name will not appear on any document. Research articles in scientific journals will not include any information that could identify you. All of the data collection sheets from this study will be stored for a period of 15 years in both hard copies and scanned electronic versions.

Before you agree to take part, you should fully understand what is involved. If you have any questions that this letter does not fully explain, please do not hesitate to Prof De Wet Swanepoel at dewet.swanepoel@up.ac.za.

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Department of Speech-Language Pathology and Audiology

WHO Collaborating Centre for Prevention of Deafness and Hearing Loss

CONSENT TO PARTICIPATION IN A RESEARCH STUDY

I, ____, hereby consent to participate in the research study. I have read and understood the consent letter and have been given the opportunity to ask questions, and I am satisfied that they have been answered satisfactorily. I understand that I will not be reimbursed for participating in this research study. I am aware that I may withdraw from the research study at any point, should I wish to do so. I understand that every effort will be made to ensure that I am not harmed in this research study. I consent that my results from this study may be used anonymously in research publications and for future research.

Signature: ____

Date: ____

Room 3-5, Communication Pathology
Building
University of Pretoria, Private Bag X20
Hatfield 0028, South Africa
Tel +27 (0)12 420 4280
Fax +27 (0)12 420 3517
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Faculty of Humanities
Department of Speech-Language Pathology and Audiology
Fakulteit Geesteswetenskappe
Departement Spraak-Taalpatologie en Oudiologie
Lefapha la Bomotho
Kgoro ya Phatholotši ya Polelo-Maleme le Go kwa

Appendix F: Permission to analyze data for studies II and III

Gmail Megan Knoetze <meggieknoetze@gmail.com>

Permission to access and analyze data

2 messages

Megan Knoetze <meggieknoetze@gmail.com> Fri, Jul 29, 2022 at 12:36 PM
To: "Manchaiah, Vinaya" <VINAYA.MANCHAIAH@cuanschutz.edu>
Cc: De Wet Swanepoel <dewet.swanepoel@up.ac.za>

Dear Prof Manchaiah,

I hope this email finds you well.

Yesterday we received feedback from our departmental research committee after they reviewed my PhD proposal.

Will Prof please provide me with written permission to access and analyze the dataset from your cross-sectional survey study regarding hearing aid experiences for my PhD study 2 and study 3?

Kind regards,
Megan Knoetze

Manchaiah, Vinaya <VINAYA.MANCHAIAH@cuanschutz.edu> Fri, Jul 29, 2022 at 7:54 PM
To: Megan Knoetze <meggieknoetze@gmail.com>
Cc: De Wet Swanepoel <dewet.swanepoel@up.ac.za>, "Manchaiah, Vinaya" <VINAYA.MANCHAIAH@cuanschutz.edu>

Dear Megan

I am writing to confirm that you have permission to access and analyze the data that was collected by me at Lamar University. I have also attached the IRB approval for this project.

Sincerely,
Vinay

Vinaya Manchaiah, AuD, MBA, PhD
Professor @ University of Colorado School of Medicine
Director of Audiology @ University of Colorado Hospital (UCHealth)
Personal website: www.vinayamanchaiah.com
Lab website: www.virtualhearinglab.org

From: Megan Knoetze <meggieknoetze@gmail.com>
Sent: Friday, July 29, 2022 4:36 AM
To: Manchaiah, Vinaya <VINAYA.MANCHAIAH@CUANSCHUTZ.EDU>
Cc: De Wet Swanepoel <dewet.swanepoel@up.ac.za>
Subject: Permission to access and analyze data

[External Email - Use Caution]

[Quoted text hidden]

Appendix G: IRB approval for cross-sectional study (Studies II and III)

[EXTERNAL] IRB-FY21-248 - Initial: Initial - Exempt - Approved

do-not-reply@cayuse.com <do-not-reply@cayuse.com>
Fri 7/23/2021 3:40 PM
To: Vinaya Manchaiah <vmanchaiah@lamar.edu>

RESEARCH & SPONSORED PROGRAMS ADMINISTRATION
LAMAR UNIVERSITY

Jul 23, 2021 3:40:40 PM CDT

Vinaya Channapatna Manchaiah

Re: Exempt - Initial - IRB-FY21-248 Hearing aid experiances

Dear Dr. Vinaya Channapatna Manchaiah

Lamar University's Institutional Review Board (IRB) for Human Research Participants Protection has completed its review of your submission and has deemed your study to be exempt from further IRB review.

Category 2.(i). Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording).
The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.

As a research investigator, please be aware of the following:

- You will immediately report to the IRB via LU Cayuse any injuries or other unanticipated problems involving risks.
- You acknowledge and accept your responsibility for protecting the rights and welfare of human research participants and for complying with all parts of 45 CFR Part 46, the LU IRB Policy and Procedures.
- You will ensure that legally effective informed consent is obtained and documented if necessary. If written consent is required, the consent form must be signed by the participant or the participant's legally authorized representative. A copy is to be given to the person signing the form and a copy is to be kept for your file.
- Any proposed changes, including changes to your survey, hard copy or in Qualtrics, from previously approved IRB applications must be submitted to the Office of Research and Sponsored Programs via LU Cayuse. The proposed changes cannot be initiated without IRB review and approval.

Once your study is complete, please login to Cayuse and close your study.

Cross-sectional survey about hearing aid experiences

Section 1: Demographic and hearing aid related information (10 questions)

How old are you? ______ years

Please indicate your gender:
Male
Female
Non-binary (or gender neutral)

Do you have any difficulty with your hearing (without hearing aids)?
No, I always hear everything
Yes, sometimes I do not hear what is being said
Yes, I regularly do not hear what is being said
Yes, I almost never hear what is being said

How long have you had hearing loss? ____ in years

Do you own a hearing aid for your:
Right ear
Left ear
Both ears

How many years have you worn hearing aids, in total? ____ in years

From the time you first learned you had a hearing problem how long did you wait before purchasing your first hearing aids? ____ in years

What type of hearing aid do you use?
In-the-ear (ITE) hearing aids (Hearing aid sits completely/entirely in the ear)

Behind-the-ear (BTE) hearing aids (Hearing aid has 2 parts:
One part, the mould, sits in the ear and the other part, the hearing aid, sits behind the ear)

Which brand hearing aid do you currently use?
Kirkland
Oticon
Phonak
ReSound
Signia/Siemens
Starkey
Unitron
Widex
Other (please specify): _____

How did you purchase your current hearing aids?
From a hearing clinic (private or university)
Discount Warehouse (Costco, Sams, etc)
Internet / Online
Pharmacy Hearing Center (CVS)
A hearing professional came to my residence
Other, please specify: _____

Section 2: Open-ended questions (4 questions) Set minimum word count to 20 in each question. Also make sure there is a larger response box for user to type and see their response.

For many people, getting and wearing a hearing aid is a major life decision. They often say that getting a hearing aid is embarrassing and makes them feel or look old. Others worry about the cost or what others will say. How did you deal with these issues when you decided to buy a hearing aid? What motivated you to get hearing aids? Was there a single reason or event that convinced you or were there many reasons? Please provide as much detail as possible about the reason(s) why you decided to get hearing aids. What would you recommend to others who are starting to have hearing problems?
Have hearing aids changed your life in a meaningful way? Why or why not? We would really like to know your experience with your hearing aids and how you think and feel about your hearing aids.

We are trying to understand when people do and do not wear their hearing aids. Are there times when you choose not to wear your hearing aid(s)? Please tell us about these times and why? Why do you think people often avoid wearing hearing aids in situations that they really should?

We talk to audiologists and hearing aid companies. Tell us how you would like hearing aids to change to be more useful for you and the people around you. Please be honest. We really would like your thoughts and feelings about this. Your comments will help us when we talk to people in the industry.

Section 3: Hearing aid benefit/satisfaction (7 items)
International Outcome Inventory for Hearing Aids (IOI-HA; Cox & Alexander, 2002)

Think about how much you used your present hearing aid(s) over the past two weeks. On an average day, how many hours did you use the hearing aid(s)?
None
Less than 1 hour a day
1 to 4 hours a day
4 to 8 hours a day
More than 8 hours a day

Think about the situation where you most wanted to hear better, before you got your present hearing aid(s). Over the past two weeks, how much has the hearing aid helped in that situation?
Helped not at all
Helped slightly
Helped moderately
Helped quite a lot
Helped very much

Think again about the situation where you most wanted to hear better. When you use your present hearing aid(s), how much difficulty do you STILL have in that situation?
Very much difficulty
Quite a lot of difficulty
Moderate difficulty
Slight difficulty
No difficulty

Considering everything, do you think your present hearing aid(s) is worth the trouble?
Not at all worth it
Slightly worth it
Moderately worth it
Quite a lot worth it
Very much worth it

Over the past two weeks, with your present hearing aid(s), how much have your hearing difficulties affected the things you can do?
Affected very much
Affected quite a lot
Affected moderately
Affected slightly
Affected not at all

Over the past two weeks, with your present hearing aid(s), how much do you think other people were bothered by your hearing difficulties?
Bothered very much
Bothered quite a lot
Bothered moderately
Bothered slightly
Bothered not at all

Considering everything, how much has your present hearing aid(s) changed your enjoyment of life?
Worse
No change
Slightly better
Quite a lot better
Very much better

Section 4: General health and well-being and social network (9 questions)

In general, would you say your health is:
Excellent
Very good
Good
Fair
Poor

In general, would you say your mental health is:
Excellent
Very good
Good
Fair
Poor

How would you rate your quality of life?
Very poor
Poor
Neither poor nor good
Good
Very good

In a typical week, how much time do you spend in total on moderate and vigorous physical activities where your heartbeat increases and you breathe faster (e.g., brisk walking, cycling, heavy gardening, running, recreational sport):
Less than ½ an hour (30 minutes)
½ an hour to 1½ hour (30-90 minutes)
1½ - 2½ hours (90-150 minutes)
2½ - 5 hours (150-300 minutes)
More than 5 hours (more than 300 minutes)

How many people live in your household? _______

How many children/grandchildren do you have? Children ____ / Grandchildren ____

How many people do you know that you would call a close friend? _______

How many people do you know that have hearing loss but who do not have hearing aids? _______

How many people do you know that have hearing loss and have/wear hearing aids? _____

Section 5: Additional demographic information (7 questions)

Which of the following options best describe your work situation?
Employed or homemaker
Out of work or looking for work
Student
Unable to work
Retired

What is the highest level of schooling (education) you have completed?
Less than high school
High School
Some college but not degree
A university degree

Please select one of the following options that describes your living arrangement/ situation:
I live with my family
I live with my spouse/partner
I live with a friend
I live on my own

What is your ethnicity?
Hispanic or Latino
Not-Hispanic or Latino

What is your race?
American Indian
Alaska Native, Asian
Black or African American
Native Hawaiian
Other Pacific Islander
White
More than One Race

What is your pretax household income, approximately?
Under $25,000
$25,000 to $49,999
$50,000 to $99,999
$100,000 to $149,000
$150,000 or more

**We are inviting a few people who completed the questionnaire to participate in a virtual interview (Zoom). Are you interested in participating in this interview study?*
Yes, please share your email address: _________
No

Appendix I: Informed consent for cross-sectional study (Studies II and III)

Participant informed consent form

Hearing aid experiences

Online Info (Starting Page)

Hearing aid experiences

Dear Sir/Madam

Hearing aid benefit and satisfaction as reported by its users are generally measured using standardized questionnaires. However, not all the items within these questionnaires are applicable and/or considered important by all hearing aid users. For this reason, using open-ended questions may have some value in gathering deeper insights into real-world and everyday life of hearing aid users. In this study we aim to examine perspectives of hearing aid users from their own words. We hope that the knowledge generated from this study will help facilitate hearing aid journey as well as in designing the future generation hearing aids.

The study has been approved by the Lamar University's Institutional Review Board (IRB-FY21-248). All the information recorded will be kept confidential and stored in an encrypted manner. Participation in this study is voluntary. Estimated time of survey is 15 minutes. The attached document has some additional information. However, we are happy to answer any questions you may have before the start of this study.

I give my consent to participate in this study

- Yes
- No

Appendix J: Chapter 3 Supplementary Material 1 (Study I)

Supplementary Table 1. Audiological factors influencing hearing help-seeking

Category and factors	No. of studies	Result	References
Hearing Sensitivity			
Worst ear PTA (1, 2, 4 kHz)	1	+ (in females)	Pronk et al. (2017)
Better ear PTA (0.5, 1, 2 kHz)	1	0	Kelly et al. (2011)
Better ear PTA (0.5, 1, 2, 4 kHz)	2	0, +	Mukari & Hashim (2018), Meyer et al. (2014)
Hearing screening			
Hearing screening at 1 and 3 kHz	1	+	Sawyer et al. (2020)
Reason for hearing screening	1	0	Meyer et al. (2011)
Self-reported Hearing Difficulties and Beliefs			
Perceived hearing loss	1	0	Meyer et al. (2011)
Self-reported hearing disability	1	+	Pronk et al. (2017)
Tinnitus	1	0	Mukari & Hashim (2018)
Otorrhea	1	0	Mukari & Hashim (2018)
Hearing Beliefs Questionnaire (HBQ)			
Susceptibility (higher)	1	+	Saunders et al. (2013)
Severity	1	0	Saunders et al. (2013)
Benefits	1	0	Saunders et al. (2013)
Barriers (lower)	1	-	Saunders et al. (2013)
Self-efficacy	1	0	Saunders et al. (2013)
Cues to action (higher)	1	+	Saunders et al. (2013)
Communication Difficulties			
Self-assessment of communication	1	+	Meyer et al. (2014)
Communication Profile for the Hearing Impaired:			
Performance - social (higher)	1	-	Humes & Dubno (2021)
Performance - work (higher)	1	-	Humes & Dubno (2021)
Performance - home(higher)	1	-	Humes & Dubno (2021)
Performance - problem awareness (lower)	1	-	Humes & Dubno (2021)
Environment - communication need	1	0	Humes & Dubno (2021)
Environment - physical characteristics	1	0	Humes & Dubno (2021)
Environment - attitudes of others	1	0	Humes & Dubno (2021)
Environment - behaviors of others	1	0	Humes & Dubno (2021)
Strategies - maladaptive behaviors	1	0	Humes & Dubno (2021)
Strategies - verbal strategies	1	0	Humes & Dubno (2021)
Strategies - nonverbal strategies	1	0	Humes & Dubno (2021)
Personal adjustment - self-acceptance	1	0	Humes & Dubno (2021)
Personal adjustment - acceptance of loss	1	0	Humes & Dubno (2021)
Personal adjustment - anger	1	0	Humes & Dubno (2021)
Personal adjustment - displacement of responsibility	1	0	Humes & Dubno (2021)
Personal adjustment - exaggeration of responsibility	1	0	Humes & Dubno (2021)
Personal adjustment - discouragement	1	0	Humes & Dubno (2021)
Personal adjustment - stress	1	0	Humes & Dubno (2021)
Personal adjustment - withdrawal	1	0	Humes & Dubno (2021)

Personal adjustment - denial (higher)	1	-	Humes & Dubno (2021)
Expectations and Perceived Benefits from Hearing aids			
Attitude towards hearing aids: Benefits scale	2	+, +	Meyer et al. (2014), Pronk et al. (2017)
Attitude to hearing aids	1	0	Meyer et al. (2014)
Attitude towards hearing aids: Negative support scale	1	0	Meyer et al. (2014)
Basic handling scale	1	0	Meyer et al. (2014)
Considered hearing aids before*	1	+	Meyer et al. (2011)
Other			
Noise exposure	1	0	Mukari & Hashim (2018)

Note: PTA = Pure Tone Average. "+" indicates a positive association between the factor and the outcome, "–" a negative association, "0" no association. *Significant factors that have not been reported in previous reviews relevant to the specific outcome.

Supplementary Table 2. Non-audiological factors influencing hearing help-seeking

Category and factors	No. of studies	Result	References
Demographics			
Age (older)	5	0, +, +, 0, 0	Mukari & Hashim (2018), Sawyer et al. (2020), Saunders et al. (2013), Meyer et al. (2011), Kelly et al. (2011)
Age participant felt	1	0	Sawyer et al. (2020)
Sex (male)	6	+, 0, +, +, 0, 0	Sawyer et al. (2020), Mukari & Hashim (2018), Saunders et al. (2013), Öberg et al. (2012), Meyer et al. (2011), Kelly et al. (2011)
Ethnicity	2	0, 0	Sawyer et al. (2020), Mukari & Hashim (2018)
Marital status	1	0	Mukari & Hashim (2018)
Education	3	0, 0, 0	Sawyer et al. (2020), Mukari & Hashim (2018), Öberg et al. (2012)
Area of residence	2	0, 0	Mukari & Hashim (2018), Meyer et al. (2011)
Living situation	1	0	Sawyer et al. (2020)
Retired	1	0	Meyer et al. (2014)
Socioeconomic Status			
Socioeconomic position	1	0	Benova et al. (2015)
Wealth	1	0	Sawyer et al. (2020)
Perceived income	1	0	Mukari & Hashim (2018)
Pension	1	0	Meyer et al. (2014)
Health, Cognition and Mental Health			
Self-reported health* (better)	3	-, +, 0	Sawyer et al. (2020), Meyer et al. (2014), Öberg et al. (2012)
Number of diseases	1	0	Öberg et al. (2012)
Cognitive performance*	2	+, 0	Sawyer et al. (2020), Öberg et al. (2012)
Cognitive anxiety*	1	+	Kelly et al. (2011)
Mental health	2	0, 0	Mukari & Hashim (2018), Öberg et al. (2012)
Social pressure, Stigma and Social Activities			
Social pressure	2	+, +	Pronk et al. (2017) , Meister et al. (2014)
Stigma	1	+ (in females)	Pronk et al. (2017)

Number of social activities*	1	-	Sawyer et al. (2020)
Number of leisure activities	1	0	Sawyer et al. (2020)
Attitudes and Behavioral Control			
Attitude to ageing	1	0	Sawyer et al. (2020)
Attitude towards behavior*	1	+	Meister et al. (2014)
Behavioral control*	1	+	Meister et al. (2014)
Other			
Source of recruitment	1	0	Pronk et al. (2017)
Technology	1	0	Ham et al. (2014)
Recall hearing screening result*	1	+	Meyer et al. (2011)

Note: "+" indicates a positive association between the factor and the outcome, "–" a negative association, "0" no association. *Significant factors that have not been reported in previous reviews relevant to the specific outcome.

Supplementary Table 3. Audiological factors influencing hearing aid uptake

Category and factors	No. of studies	Result	References
Hearing Sensitivity			
Hearing screening (1 and 3 kHz)	1	+	Sawyer et al. (2020)
Worst ear PTA (1, 2, 4 kHz)	1	+	Pronk et al. (2019)
Better ear PTA (0.5, 1, 2, 4 kHz)	11	+, +, +, +, +, +, +, 0, 0, +, +	Maidment & Wege (2021), Nixon et al. (2021), Humes (2021), He et al. (2018), Ridgway et al. (2016), Saunders et al. (2016), Fischer et al. (2011), Laplante-Lévesque et al. (2012), Chang et al. (2016), Meyer et al. (2014), Ridgway et al. (2015)
Better ear PTA (0.5, 1, 2 kHz)	1	0	Kelly et al. (2011)
PTA (0.5, 1, 2, 4 kHz above 25 dB HL)	2	+, +	Tran et al. (2021), Gopinath et al. (2011)
Mean binaural PTA (0.5, 1, 2 kHz)	1	+	Singh & Launer (2018)
Mean binaural PTA (0.5, 1, 2, 4 kHz)	1	+	Singh & Launer (2016)
High-frequency PTA (3, 4, 6, 8 kHz and 2, 3, 4, 6, 8 kHz)	2	+, +	Weycker et al. (2021), Simpson et al. (2019)
Low-frequency PTA (0.25, 0.5, 1 kHz)	1	0	Simpson et al. (2019)
Degree of hearing loss (e.g., severe to profound)	1	+	Chua Wei De (2021)
Erber's area (includes hearing thresholds poorer than 35 dB in the frequency range below 1000 Hz)*	1	+	Robertson et al. (2012)
Bilateral hearing loss*	1	+	Angara et al. (2021)
Duration of Hearing Loss and Age of Diagnosis			
Age of hearing loss onset	2	+, + (>58 group)	Chan et al. (2017), Moschis et al. (2015)

Hearing loss duration	5	+, 0, +, + (<58 group), 0	Cho et al. (2022), Humes (2021), Saunders et al. (2016), Moschis et al. (2015), Laplante-Lévesque et al. (2012)
Self-reported Hearing Difficulties and Beliefs			
Self-reported hearing difficulties	9	+, +, 0, +, +, +, +, 0, +	Maidment & Wege (2021), Angara et al. (2021), He et al. (2018), Ridgway et al. (2016), Ridgway et al. (2015), Fischer et al. (2011), Gopinath et al. (2011), Otavio et al. (2016), Tahden et al. (2018)
Self-reported hearing disability (e.g., HHI)	11	0, +, +, +, 0, +, +, 0, +, 0, 0	Cho et al. (2022), Weycker et al. (2021), Simpson et al. (2019), Saunders et al. (2016), Kelly-Campbell & Parry (2014), Fischer et al. (2011), Gopinath et al. (2011), Chang et al. (2016), Van Leeuwen et al. (2021), Pronk et al. (2019), Laplante-Lévesque et al. (2012)
Difficulty when someone whispers*	1	+	Gopinath et al. (2011)
Hearing disability perceived by others	1	0	Laplante-Lévesque et al. (2012)
Hearing difficulties perceived by others*	1	+	Weycker et al. (2021)
Disturbance to daily life	1	0	Chang et al. (2016)
Uses closed captions*	1	+	Weycker et al. (2021)
Tinnitus	3	0, 0, 0	Cho et al. (2022), Angara et al. (2021), Chang et al. (2016)
Vertigo	1	0	Chang et al. (2016)
Hearing beliefs questionnaire:			
Susceptibility (lower)	2	0, +	Saunders et al. (2016), Saunders et al. (2013)
Severity (higher)	2	+, 0	Saunders et al. (2016), Saunders et al. (2013)
Benefits (higher)	2	+, +	Saunders et al. (2016), Saunders et al. (2013)
Barriers (higher)	2	0, -	Saunders et al. (2016), Saunders et al. (2013)
Self-efficacy (lower)	2	+, 0	Saunders et al. (2016), Saunders et al. (2013)
Cues to action (higher)	2	+, +	Saunders et al. (2016), Saunders et al. (2013)
Speech Perception			
Signal-to-noise ratio loss*	2	+, +	Kelly-Campbell & Parry (2014), Robertson et al. (2012)
Speech recognition threshold*	2	0, +	Van Leeuwen et al. (2021), Robertson et al. (2012)
Word recognition score	1	0	Robertson et al. (2012)
Word recognition in quiet	1	0	Simpson et al. (2019)
Low-context sentences recognition in babble*	1	-	Simpson et al. (2019)
High-context sentences in babble*	1	0	Simpson et al. (2019)
Connected Speech Test	1	0	Humes (2021)
Acceptable Noise Level	1	0	Humes (2021)
Audiology Appointment, Hearing Assessment and Consultation			
Self-referred for hearing test*	1	+	Saunders et al. (2016)
First hearing aid consultation institution*	1	+	Cho et al. (2022)
Hearing aid recommendation	1	0	Cho et al. (2022)
Recent hearing test*	2	+, +	Angara et al. (2021), He et al. (2018)
Participant’s recommendation of dispenser services	1	0	Pronk et al. (2019)
Consulted audiologist*	1	+	Moschis et al. (2015)
Consulted ear, nose and throat doctor	1	0	Moschis et al. (2015)
Consulted hearing aid dispenser*	1	+	Moschis et al. (2015)

Referral source	1	0	Ridgway et al. (2016)
Later time of the day (vs. earlier)*	1	-	Singh & Launer (2018)
Day of the week	1	0	Singh & Launer (2018)
Attending appointment with other	1	+	Singh & Launer (2016)
Language	1	0	Tran et al. (2021)
Health literacy	1	0	Tran et al. (2021)
Medical language*	1	+	Adorni et al. (2021)
Flesch–Kincaid reading grade level of audiologist talk* (higher)	1	-	Sciacca et al. (2017)
Audiologists' number of sentences	1	0	Sciacca et al. (2017)
Communication Difficulties			
Communication partner assignment	1	0	Pronk et al. (2019)
Perceived communication program effectiveness	1	0	Laplante-Lévesque et al. (2012)
Perceived suitability of the individual communication program*	1	-	Laplante-Lévesque et al. (2012)
Communication self-efficacy*	1	-	Laplante-Lévesque et al. (2012)
Perceived likely adherence	1	0	Laplante-Lévesque et al. (2012)
Perceived suitability of group communication program	1	0	Laplante-Lévesque et al. (2012)
Other people's recommendation of the communication programs	1	0	Laplante-Lévesque et al. (2012)
Communication Profile for the Hearing Impaired:			
Performance - social (lower scores)	2	-, -	Humes & Dubno (2021), Humes (2021)
Performance - work (lower scores)	2	-, -	Humes & Dubno (2021), Humes (2021)
Performance - home (lower scores)	2	-, -	Humes & Dubno (2021), Humes (2021)
Performance - problem awareness (higher scores)	2	+, +	Humes & Dubno (2021), Humes (2021)
Environment - communication need	2	0, 0	Humes & Dubno (2021), Humes (2021)
Environment - physical characteristics	2	0, 0	Humes & Dubno (2021), Humes (2021)
Environment - attitudes of others	2	0, 0	Humes & Dubno (2021), Humes (2021)
Environment - behaviors of others	2	0, 0	Humes & Dubno (2021), Humes (2021)
Strategies - maladaptive behaviors	3	0, 0, 0	Humes & Dubno (2021), Humes (2021), Pronk et al. (2019)
Strategies - verbal strategies (higher scores)	3	0, +, 0	Humes & Dubno (2021), Humes (2021), Pronk et al. (2019)
Strategies - nonverbal strategies (higher scores)	3	+, +, 0	Humes & Dubno (2021), Humes (2021), Pronk et al. (2019)
Personal adjustment - self-acceptance (lower)	3	0, +, 0	Humes & Dubno (2021), Humes (2021), Pronk et al. (2019)
Personal adjustment - acceptance of loss (higher)	3	+, 0, 0	Humes & Dubno (2021), Humes (2021), Pronk et al. (2019)
Personal adjustment - anger	2	0, 0	Humes & Dubno (2021), Humes (2021)
Personal adjustment - displacement of responsibility (higher)	2	+, 0	Humes & Dubno (2021), Humes (2021)

Personal adjustment - exaggeration of responsibility (lower)	2	0, +	Humes & Dubno (2021), Humes (2021)
Personal adjustment - discouragement	2	0, 0	Humes & Dubno (2021), Humes (2021)
Personal adjustment - stress	3	0, 0, 0	Humes & Dubno (2021), Humes (2021), Pronk et al. (2019)
Personal adjustment - withdrawal (lower)	3	0, -, 0	Humes & Dubno (2021), Humes (2021), Pronk et al. (2019)
Personal adjustment - denial (lower)	2	0, -	Humes & Dubno (2021), Humes (2021)
Belief, Expectation and Understanding of Hearing aids			
HearSupport received*	1	+	Pronk et al. (2019)
Understanding HA function*	1	+	He et al. (2018)
Hearing aid handling*	2	+, 0	Meyer et al. (2014), Pronk et al. (2019)
Desire for hearing aids	2	0, 0	Ridgway et al. (2016), Ridgway et al. (2015)
Concerns about hearing aid cost and practices	1	0	Laplante-Lévesque et al. (2012)
Attitude towards hearing aids: Benefits scale	1	+	Meyer et al. (2014)
Attitude towards hearing aids	2	+, +	Meyer et al. (2014), Cobelli et al. (2014)
Attitude towards hearing aids: Negative support scale	1	-	Meyer et al. (2014)
Expected Consequences of Hearing Aid Ownership (ECHO)			
Positive effects	1	+	Humes (2021)
Negative effects	1	0	Humes (2021)
Service and cost	1	+	Humes (2021)
Personal image	1	+	Humes (2021)

Note: PTA = Pure Tone Average, HHI = Hearing Handicap Inventory. "+" indicates a positive association between the factor and the outcome, "–" a negative association, "0" no association. *Significant factors that have not been reported in previous reviews relevant to the specific outcome.

Supplementary Table 4. Non-audiological factors influencing hearing aid uptake

Category and factors	No. of studies	Result	References
Demographics			
Age (older)	25	0, 0, 0, 0, +, 0, 0, 0, +, +, 0, 0, 0, +, 0, +, 0, +, +, 0, 0, +, 0, 0, -	Cho et al. (2022), Weycker et al. (2021) , Van Leeuwen et al. (2021), Tran et al. (2021), Maidment & Wege (2021), Nixon et al. (2021), Humes (2021) , Chua Wei De (2021), Angara et al. (2021), Sawyer et al. (2020), Pronk et al. (2019), Simpson et al. (2019), He et al. (2018), Singh & Launer (2018), Sciacca et al. (2017), Singh & Launer (2016) , Ridgway et al. (2016), Saunders et al. (2016) , Saunders et al. (2013) , Robertson et al. (2012) , Fischer et al. (2011) , Gopinath et al. (2011) , Kelly et al. (2011) , Laplante-Lévesque et al. (2012) , Chang et al. (2016)
Duration in old-age roles	1	0	Moschis et al. (2015)
Number of transitions experienced	1	0	Moschis et al. (2015)
Sex (male)	20	0, 0, 0, 0, 0, 0, 0, +, -, 0, 0, 0, 0, +, 0, 0, 0, 0, 0, +	Cho et al. (2022), Weycker et al. (2021), Van Leeuwen et al. (2021), Tran et al. (2021), Maidment & Wege (2021), Humes (2021), Chua Wei De (2021), Angara et al. (2021), Simpson et al. (2019), He et al. (2018), Singh & Launer (2016), Ridgway et al. (2016), Ridgway et al. (2015), Öberg et al. (2012), Robertson et al. (2012), Fischer et al.

			(2011), Gopinath et al. (2011), Kelly et al. (2011), Laplante-Lévesque et al. (2012), Chang et al. (2016)
Race (white)	4	0, +, +, 0	Tran et al. (2021), Angara et al. (2021), Simpson et al. (2019), He et al. (2018)
Education	12	+, +, 0, 0, 0, +, 0, 0, 0, 0, +, 0	Cho et al. (2022), Weycker et al. (2021), Van Leeuwen et al. (2021), Tran et al. (2021), Humes (2021), Angara et al. (2021), Pronk et al. (2019), Simpson et al. (2019), He et al. (2018), Öberg et al. (2012), Fischer et al. (2011), Laplante-Lévesque et al. (2012)
Country of birth	1	0	Pronk et al. (2019)
Area of residence* (urban)	2	+, +	He et al. (2018), Chan et al. (2017)
Living situation	3	0, 0, 0	Van Leeuwen et al. (2021), Pronk et al. (2019), Laplante-Lévesque et al. (2012)
Marital status	5	+, 0, 0, 0, 0	Van Leeuwen et al. (2021), Tran et al. (2021), Angara et al. (2021), Simpson et al. (2019), He et al. (2018)
Household size	1	0	Angara et al. (2021)
Job	2	0, 0	Tran et al. (2021), Cho et al. (2022)
Job control	1	0	Van Leeuwen et al. (2021)
Psychological job demand*	1	+ (in males)	Van Leeuwen et al. (2021)
Need for recovery after work	1	0	Van Leeuwen et al. (2021)
Retired	1	0	Simpson et al. (2019)
Socioeconomic Status			
Socioeconomic status (higher)	5	0, 0, +, +, +	Maidment & Wege (2021), Nixon et al. (2021), Simpson et al. (2019), Laplante-Lévesque et al. (2012), Tahden et al. (2018)
Household income*	2	+, 0	Cho et al. (2022), He et al. (2018)
Income	2	0, 0	Humes (2021), Pronk et al. (2019)
Poverty income ratio	1	0	Angara et al. (2021)
Pension*	1	+	Meyer et al. (2014)
Hearing Healthcare Funding and Health Insurance			
Eligibility for subsidized hearing services	1	0	Laplante-Lévesque et al. (2012)
Applied for subsidized hearing services*	1	+	Laplante-Lévesque et al. (2012)
Government assistance*	1	+	Cho et al. (2022)
Senior Mobility Fund*	1	+	Chua Wei De (2021)
Health insurance*	2	+, 0	Tran et al. (2021), Angara et al. (2021)
Health			
Self-reported health (better)	4	-, -, +, +	Nixon et al. (2021), Sawyer et al. (2020), Öberg et al. (2012), Tahden et al. (2018)
Chronic health conditions	1	0	Simpson et al. (2019)
Self-reported diabetes*	1	-	Maidment & Wege (2021)
Self-reported hypertension*	1	-	Maidment & Wege (2021)
Self-reported dementia	1	0	Maidment & Wege (2021)

Self-reported history of stroke*	1	-	Gopinath et al. (2011)
Number of diseases	1	0	Öberg et al. (2012)
Cognition and Mental Health			
Cognition	3	0, 0, 0	Humes (2021), Öberg et al. (2012), Tahden et al. (2018)
Cognitive reasoning: similarities*	1	+	Meyer et al. (2014)
Cognitive anxiety*	2	+, +	Kelly-Campbell & Parry (2014), Kelly et al. (2011)
Mental health	2	0, 0	Nixon et al. (2021), Öberg et al. (2012)
Distress	1	0	Van Leeuwen et al. (2021)
Attention	1	0	Nixon et al. (2021)
Psychomotor function	1	0	Nixon et al. (2021)
Executive function	1	0	Nixon et al. (2021)
Visual learning	1	0	Nixon et al. (2021)
Working memory	1	0	Nixon et al. (2021)
Loneliness scale	1	0	Nixon et al. (2021)
Social network	1	0	Nixon et al. (2021)
Anxiety	1	0	Nixon et al. (2021)
Depression	1	0	Nixon et al. (2021)
Memory	1	0	Nixon et al. (2021)
Affect and personality	1	0	Humes (2021)
Emotional response	1	0	Pronk et al. (2019)
Motivation, Support, Subjective Norms and Trust			
Autonomous motivation*	2	+, +	Ridgway et al. (2016), Ridgway et al. (2015)
Autonomous support	1	0	Ridgway et al. (2016)
Controlled motivation	1	0	Ridgway et al. (2016)
Subjective norm	2	+, +	Cobelli et al. (2014), Meister et al. (2014)
Trust	1	0	Cobelli et al. (2014)
Attitude X trust	1	0	Cobelli et al. (2014)
Subjective norm X trust*	1	+	Cobelli et al. (2014)
Attitudes towards Behavior and Control			
Behavioral control*	1	+	Meister et al. (2014)
Attitude towards behavior*	1	+	Meister et al. (2014)
Locus of control	1	0	Laplante-Lévesque et al. (2012)
Readiness for change			
Precontemplation (lower)	3	0, +, 0	Pronk et al. (2019), Saunders et al. (2016), Laplante-Lévesque et al. (2012)
Contemplation (higher)	3	0, +, +	Pronk et al. (2019), Saunders et al. (2016), Laplante-Lévesque et al. (2012)
Action (higher)	3	0, +, 0	Pronk et al. (2019), Saunders et al. (2016), Laplante-Lévesque et al. (2012)
Committed action	1	0	Pronk et al. (2019)

Other			
Self-efficacy	1	0	Van Leeuwen et al. (2021)
Technology	2	+, 0	Tahden et al. (2018), Ham et al. (2014)

Note: "+" indicates a positive association between the factor and the outcome, "–" a negative association, "0" no association. *Significant factors that have not been reported in previous reviews relevant to the specific outcome.

Checklist for Reporting Results of Internet E-Surveys (CHERRIES)

Checklist Item	***Explanation***	***Page Number***
Describe survey design	Describe target population, sample frame. Is the sample a convenience sample? (In "open" surveys this is most likely.)	10
IRB approval	Mention whether the study has been approved by an IRB.	8
Informed consent	Describe the informed consent process. Where were the participants told the length of time of the survey, which data were stored and where and for how long, who the investigator was, and the purpose of the study?	11
Data protection	If any personal information was collected or stored, describe what mechanisms were used to protect unauthorized access.	12
Development and testing	State how the survey was developed, including whether the usability and technical functionality of the electronic questionnaire had been tested before fielding the questionnaire.	8-10
Open survey versus closed survey	An "open survey" is a survey open for each visitor of a site, while a closed survey is only open to a sample which the investigator knows (password-protected survey).	11
Contact mode	Indicate whether or not the initial contact with the potential participants was made on the Internet. (Investigators may also send out questionnaires by mail and allow for Web-based data entry.)	11
Advertising the survey	How/where was the survey announced or advertised? Some examples are offline media (newspapers), or online (mailing lists – If yes, which ones?) or banner ads (Where were these banner ads posted and what did they look like?). It is important to know the wording of the announcement as it will heavily influence who chooses to participate. Ideally the survey announcement should be published as an appendix.	11
Web/E-mail	State the type of e-survey (eg, one posted on a Web site, or one sent out through e-mail). If it is an e-mail survey, were the responses entered manually into a database, or was there an automatic method for capturing responses?	11
Context	Describe the Web site (for mailing list/newsgroup) in which the survey was posted. What is the Web site about, who is visiting it, what are visitors normally looking for? Discuss to what degree	11

	the content of the Web site could pre-select the sample or influence the results. For example, a survey about vaccination on a anti-immunization Web site will have different results from a Web survey conducted on a government Web site	
Mandatory/voluntary	Was it a mandatory survey to be filled in by every visitor who wanted to enter the Web site, or was it a voluntary survey?	11
Incentives	Were any incentives offered (eg, monetary, prizes, or non-monetary incentives such as an offer to provide the survey results)?	11
Time/Date	In what timeframe were the data collected?	11
Randomization of items or questionnaires	To prevent biases items can be randomized or alternated.	9
Adaptive questioning	Use adaptive questioning (certain items, or only conditionally displayed based on responses to other items) to reduce number and complexity of the questions.	N/A
Number of Items	What was the number of questionnaire items per page? The number of items is an important factor for the completion rate.	9
Number of screens (pages)	Over how many pages was the questionnaire distributed? The number of items is an important factor for the completion rate.	9
Completeness check	It is technically possible to do consistency or completeness checks before the questionnaire is submitted. Was this done, and if "yes", how (usually JAVAScript)? An alternative is to check for completeness after the questionnaire has been submitted (and highlight mandatory items). If this has been done, it should be reported. All items should provide a non-response option such as "not applicable" or "rather not say", and selection of one response option should be enforced.	N/A
Review step	State whether respondents were able to review and change their answers (eg, through a Back button or a Review step which displays a summary of the responses and asks the respondents if they are correct).	9
Unique site visitor	If you provide view rates or participation rates, you need to define how you determined a unique visitor. There are different techniques available, based on IP addresses or cookies or both.	N/A
View rate (Ratio of unique survey	Requires counting unique visitors to the first page of the survey, divided by the number of unique site visitors (not page views!). It is not unusual to have view rates of less than 0.1 % if the survey is voluntary.	N/A

visitors/unique site visitors)		
Participation rate (Ratio of unique visitors who agreed to participate/unique first survey page visitors)	Count the unique number of people who filled in the first survey page (or agreed to participate, for example by checking a checkbox), divided by visitors who visit the first page of the survey (or the informed consents page, if present). This can also be called “recruitment” rate.	N/A
Completion rate (Ratio of users who finished the survey/users who agreed to participate)	The number of people submitting the last questionnaire page, divided by the number of people who agreed to participate (or submitted the first survey page). This is only relevant if there is a separate “informed consent” page or if the survey goes over several pages. This is a measure for attrition. Note that “completion” can involve leaving questionnaire items blank. This is not a measure for how completely questionnaires were filled in. (If you need a measure for this, use the word “completeness rate”.)	11
Cookies used	Indicate whether cookies were used to assign a unique user identifier to each client computer. If so, mention the page on which the cookie was set and read, and how long the cookie was valid. Were duplicate entries avoided by preventing users access to the survey twice; or were duplicate database entries having the same user ID eliminated before analysis? In the latter case, which entries were kept for analysis (eg, the first entry or the most recent)?	N/A
IP check	Indicate whether the IP address of the client computer was used to identify potential duplicate entries from the same user. If so, mention the period of time for which no two entries from the same IP address were allowed (eg, 24 hours). Were duplicate entries avoided by preventing users with the same IP address access to the survey twice; or were duplicate database entries having the same IP address within a given period of time eliminated before analysis? If the latter, which entries were kept for analysis (eg, the first entry or the most recent)?	N/A
Log file analysis	Indicate whether other techniques to analyze the log file for identification of multiple entries were used. If so, please describe.	N/A
Registration	In “closed” (non-open) surveys, users need to login first and it is easier to prevent duplicate entries from the same user. Describe how this was done. For example, was the survey never displayed a second time once the user had filled it in, or was the username stored together with	N/A

	the survey results and later eliminated? If the latter, which entries were kept for analysis (eg, the first entry or the most recent)?	
Handling of incomplete questionnaires	Were only completed questionnaires analyzed? Were questionnaires which terminated early (where, for example, users did not go through all questionnaire pages) also analyzed?	11
Questionnaires submitted with an atypical timestamp	Some investigators may measure the time people needed to fill in a questionnaire and exclude questionnaires that were submitted too soon. Specify the timeframe that was used as a cut-off point and describe how this point was determined.	N/A
Statistical correction	Indicate whether any methods such as weighting of items or propensity scores have been used to adjust for the non-representative sample; if so, please describe the methods.	N/A

This checklist has been modified from Eysenbach G. Improving the quality of Web surveys: the Checklist for Reporting Results of Internet E-Surveys (CHERRIES). J Med Internet Res. 2004 Sep 29;6(3):e34 [erratum in J Med Internet Res. 2012; 14(1): e8.]. Article available at https://www.jmir.org/2004/3/e34/; erratum available https://www.jmir.org/2012/1/e8/. Copyright ©Gunther Eysenbach. Originally published in the Journal of Medical Internet Research, 29.9.2004 and 04.01.2012.

Consolidated criteria for reporting qualitative studies (COREQ): Domain 3

Developed from:
Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

No. Item	Guide questions/description	Reported on Page #
Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	Page 13
25. Description of the coding tree	Did authors provide a description of the coding tree?	Page 13
26. Derivation of themes	Were themes identified in advance or derived from the data?	Page 13
27. Software	What software, if applicable, was used to manage the data?	Page 12
28. Participant checking	Did participants provide feedback on the findings?	Page 13
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	Tables 1-4
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Page 13-18
31. Clarity of major themes	Were major themes clearly presented in the findings?	Page 13-18
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Page 18-26

Appendix M: Chapter 5 Proof of Article Acceptance (Study III)

AJA-23-00116R4
Perspectives on hearing aid cost and uptake for prescription and over-the-counter hearing aid users
American Journal of Audiology

Dear Dr. De Swanepoel,

I am pleased to accept your manuscript for publication in American Journal of Audiology.

As the author of an accepted article, you have the option to choose open access publishing, which can increase readership, online attention, and citation levels. ASHA assesses an article processing charge (APC) of $2,000 for the open access option. You can find out more about Open Access by visiting https://academy.pubs.asha.org/asha-journals-author-resource-center/manuscript-submission/open-access/

Thank you for the opportunity to review and publish your work.

Best Regards,

Nicholas S. Reed, AuD
Editor
American Journal of Audiology

Attention NIH-funded authors

ASHA now deposits to PubMed Central, on behalf of authors, any articles that have received NIH funding. These articles are made publicly available via PMC—in their final, published form—6 months after publication. All NIH-funded articles published in ASHA's journals from the first issues of 2015 forward have been deposited to PMC.

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Codebook

Prescription Hearing Aid Users

Code	**Description**	**Example**
External support	Participants reported receiving external financial support to get hearing aids. This could refer to financial assistance from organizations like Veterans Affairs and Vocational Rehab or medical insurance or financial support from family or friends.	*The VA paid for my hearing aids (P172, 80 yrs., male)*
Affordable options	Participants reported shopping around for the best prices or that they discovered that hearing aids were more affordable at specific places, such as discount warehouses.	*Shopped for the best value (P32, 70 yrs., male)*
Availability of finances	Participants reported having the financial ability to afford hearing aids, i.e., cost was not a barrier for them.	*I had enough discretionary income so price wasn't an issue (P116, 71 yrs., female)*
Cost-benefit	Participants described the cost-benefit of hearing aids, as they felt that the benefits of purchasing and using hearing aids outweigh the costs associated with it, e.g., improved hearing, improved quality of life, and increased participation in activities of daily living.	*Yes hearing aids expensive and hard get used to it but the quality of life gets better when you can hear (P228, 49 yrs., male)*
High cost of HAs in general (i.e., OTC or prescription HAs)	Participants reported the high cost of hearing aids in general as a barrier to uptake. This could refer to prescription or OTC devices. Participants	*Cost was a major reason why I delayed getting hearing aids (P138, 65 yrs., female)*

	also described the high cost being the reason for delayed uptake.	
Not covered by insurance	Participants reported the lack of medical insurance coverage as a barrier to hearing aid uptake.	*The cost of hearing aids is a MAJOR financial burden and medical insurance does not assist (P300, 47 yrs., female)*
Cost-benefit concern	Participants reported being concerned that the cost of hearing aids will not justify their perceived benefits, e.g., despite paying a significant amount to purchase hearing aids still experiencing difficulty hearing.	*Doesn't matter, have paid thousands over the years and I still can't hear (P207, 65 yrs., female)*
Long-term and ongoing costs	Participants reported the long-term and ongoing costs, i.e., repair and replacement costs as a financial burden.	*Could not afford to replace even one (P386, 73 yrs., female)*
Seek professional support	Participants recommended seeking professional support before purchasing hearing aids, e.g., consulting with an audiologist or Ear-Nose-Throat specialist.	*Go to a professional audiologist and get tested and get an audiogram to determine your level of hearing loss before you buy (P70, 57 yrs., female)*
Do research before you buy	Participants recommended doing research before purchasing hearing aids, including looking for information online and on hearing aid manufacturer websites.	*Do a lot of research before you buy (P217, 80 yrs., male)*
Purchase new technology	Participants recommended purchasing the most current technology or upgrading hearing aids.	*Purchase the most current technology you can afford (P312, 63 yrs., female)*
Avoid OTC or cheaper hearing aids	Participants advised against purchasing OTC or cheaper hearing aids.	*Don't try to diagnose yourself and buy hearing aids online or over the counter – you will most likely waste money (P275, 81 yrs., male)*
Seek financial support	Participants recommended seeking financial support, such as finance or grant funding options.	*My recommendation for others who are starting to have hearing problems are to seek out professional assistance with financing if needed (P300, 47 yrs., female)*
Do a hearing aid trial before you buy	Participants recommended doing a hearing aid trial before purchasing hearing aids. This may	*Be sure to try first (P92, 76 yrs., male)*

	have included asking for a demonstration or trying different brands to find the right fit.	

OTC = Over-The-Counter, HA = Hearing Aid

OTC Hearing Aid Users

Code	Description	Example
Affordability of OTC HAs	Participants reported the affordability of OTC hearing aids as an enabler for hearing aid uptake.	*I was very happy with the product and it was more affordable than the co-pay my insurance required. (P651, 73 yrs., male)*
Payment plan	Participants reported the payment plan offered by Lexie as an enabler for hearing aid uptake.	*Having small monthly payments sold me on the deal with Lexie! (P500, 29 yrs., female)*
Cost-benefit	Participants described the cost-benefit of hearing aids, as they felt that the benefits of purchasing and using hearing aids outweigh the costs associated with it, e.g., improved hearing, improved quality of life, and increased participation in activities of daily living.	*They're too expensive but at least with them I can hear (P521, 55 yrs., female)*
High cost of HAs in general (i.e., OTC or prescription HAs)	Participants reported the high cost of hearing aids in general as a barrier to uptake. This could refer to prescription or OTC devices. Participants also described the high cost being the reason for delayed uptake.	*Could not really afford them (P523, 72 yrs., male)*
Expense of prescription HAs	Participants specifically mentioned the expense of prescription hearing aids as a barrier.	*Bought a $3000.00 set of hearing aids from an audiologist that lasted about two years and quit working. Too expensive to replace (P682, 64 yrs., male)*
Replacement cost of prescription HAs	Participants specifically mentioned the replacement cost of prescription hearing aids as a barrier.	*But when I lost one..... the cost to replace it had gone up so much I still couldn't afford to do it (P630, 74 yrs., female)*

Not covered by insurance	Participants reported the lack of medical insurance coverage as a barrier to hearing aid uptake.	*Getting the hearing aids was not a big issue except for the cost as my insurance does not cover them (P668, 57 yrs., female)*
Cost-benefit concern	Participants reported being concerned that the cost of hearing aids will not justify their perceived benefits, e.g., despite paying a significant amount to purchase hearing aids still experiencing difficulty hearing.	*I was also concerned that I would spend a large amount of money and they would not help me (P487, 41 yrs., female)*
Do research before you buy	Participants recommended doing research before purchasing hearing aids.	*Search for right hearing aids for you, your hearing and your budget (P482, 66 yrs., female)*
Purchase new technology	Participants recommended purchasing the most current technology or upgrading hearing aids.	*I upgraded them because the technology advanced a lot in a year (P672, 51 yrs., male)*
Avoid cheaper hearing aids	Participants advised against purchasing cheaper hearing aids.	*First one was cheap crap with poor sound quality (P678, 72 yrs., male)*
Do a hearing aid trial before you buy	Participants recommended doing a hearing aid trial before purchasing hearing aids.	*Execute a free trial and see if aids help (P724, 83 yrs., male)*

OTC = Over-The-Counter, HA = Hearing Aid

Journal of the American Academy of Audiology
Journal of the American Academy of Audiology
To: Megan Knoetze, Cc: Editor, pikereg@jmu.edu

Yesterday at 17:17
Details

12-Aug-2024

JAAA-24-Mar-0037.R1 - Usability and Performance of Self-Fitting Over-the-Counter Hearing Aids

Dear Ms. Knoetze:

The American Academy of Audiology is pleased to inform you that your manuscript referenced above has been accepted for publication in the *Journal of the American Academy of Audiology*.

The Academy is now taking on the publishing process for the journal after a five-year contract with an external publisher. New publication vendors will be handling the journal-publishing duties beginning in August and September of 2024.

Your manuscript will head into production as soon as the new vendors are on the job. Your first indication that your manuscript has entered the new publishing queue will be an email coming to you from the ScholarOne submission system that informs you of the acceptance of your manuscript. After that, your manuscript will go through copyediting and typesetting, you will receive a proof for review and you will receive an Academy copyright form to be signed by all authors.

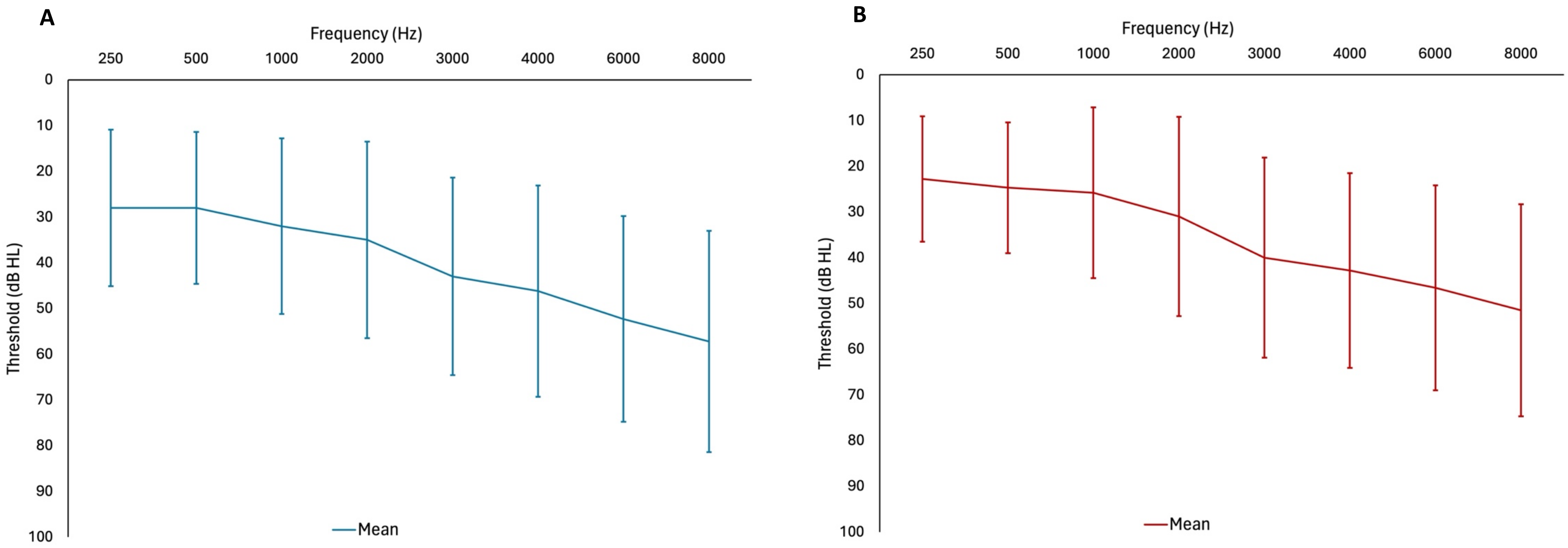
We will provide an estimated online publication date for your article after the new publishing systems are up and running.

Thank you very much for your support of JAAA. The Academy looks forward to this opportunity to work with you.

Best wishes,

Erin G. Piker
Editor-In-Chief
Journal of the American Academy of Audiology

Appendix P: Chapter 6 Supplementary Material 1 (Study IV)



Supplementary Material 1. (A) Distribution of conventional pure tone audiometric frequencies for the left ear, (B) Distribution of conventional pure tone audiometric frequencies for the right ear, n = 43. Standard deviations are shown as error bars.

Supplementary Material 2. Pairwise comparisons with significant differences using Dunn's (1964) procedure

Outcome measure and pairwise comparison	Significance level
Device fitting time	
HP – Jabra	*p* = .020
HP – Lexie B2	*p* = .014
HP – Sony	*p* = <.001
HP – Lexie Lumen	*p* = <.001
Sontro- Sony	*p* = .001
Sontro – Lexie Lumen	*p* = <.001
Jabra – Lexie Lumen	*p* = .010
Lexie B2 – Lexie Lumen	*p* = .015
Heaing Aid Skills and Knowledge	
HP – Lexie B2	*p* = .002
HP – Sontro	*p* = .002
Jabra – Lexie B2	*p* = .014
Jabra – Sontro	*p* = .014
Lexie Lumen – Lexie B2	*p* = .023
Lexie Lumen – Sontro	*p* = .022
Judgement of Sound Quality Overall	
HP – Lexie Lumen	*p* = .033
HP – Lexie B2	*p* = .005
Sontro – Lexie B2	*p* = .019
Judgement of Sound Quality Clarity	
HP – Lexie Lumen	*p* = .034
HP – Jabra	*p* = .014
HP – Lexie B2	*p* = <.001
Sony – Lexie B2	*p* = .037

Supplementary Material 1. CONSORT checklist of information to include when reporting randomised crossover trials

Section/topic	Item No	Description	Page No*
Title†	1a	Identification as a randomised crossover trial in the title	This study was not a true randomized controlled trial therefore it was only identified it as a crossover trial. See page 1.
Abstract†	1b	Specify a crossover design and report all information outlined in table 2	Page 2-4
Introduction:			
Background‡	2a	Scientific background and explanation of rationale	Page 5-6
Objectives‡	2b	Specific objectives or hypotheses	Page 5-6
Methods:			
Trial design†	3a	Rationale for a crossover design. Description of the design features including allocation ratio, especially the number and duration of periods, duration of washout period, and consideration of carry over effect	Page 7
Change from protocol‡	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Page 8-9
Participants‡	4a	Eligibility criteria for participants	Page 7-8
Settings and location‡	4b	Settings and locations where the data were collected	Page 7-11
Interventions†	5	The interventions with sufficient details to allow replication, including how and when they were actually administered	Page 9-11

Section/topic	Item No	Description	Page No*
Outcomes‡	6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	Page 11
Changes to outcomes‡	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size†	7a	How sample size was determined, accounting for within participant variability	Page 8
Interim analyses and stopping guidelines‡	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation‡	8a	Method used to generate the random allocation sequence	Page 8
Sequence generation‡	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Page 8
Allocation concealment mechanism‡	9	Mechanism used to implement the random allocation sequence§ (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Page 8
Implementation†	10	Who generated the random allocation sequence,§ who enrolled participants, and who assigned participants to the sequence of interventions	Page 8
Blinding‡	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
Similarity of interventions‡	11b	If relevant, description of the similarity of interventions	Page 9-11
Statistical methods†	12a	Statistical methods used to compare groups for primary and secondary outcomes which are appropriate for crossover design (that is, based on within participant comparison)	Page 11

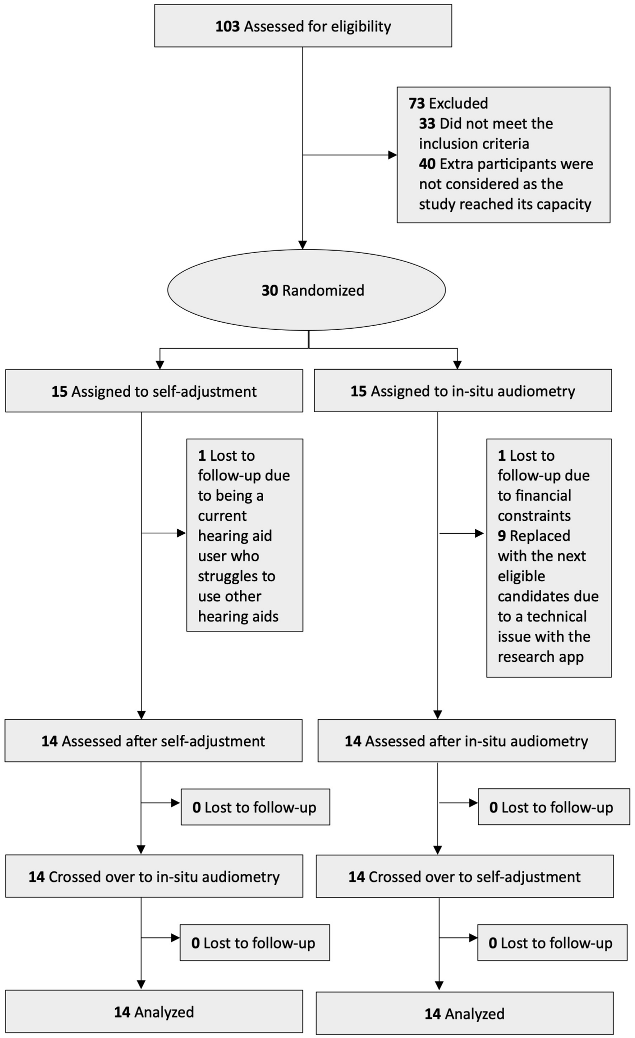
Section/topic	Item No	Description	Page No*
Additional analyses‡	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Page 11
Results			
Participant flow (a diagram is strongly recommended)†	13a	The numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome, separately for each sequence and period	CONSORT flow diagram - Figure 1
Losses and exclusions†	13b	No of participants excluded at each stage, with reasons, separately for each sequence and period	Page 8-9
Recruitment‡	14a	Dates defining the periods of recruitment and follow-up	Page 7-8
Trial end‡	14b	Why the trial ended or was stopped	Page 7
Baseline data†	15	A table showing baseline demographic and clinical characteristics by sequence and period	Table 1
Numbers analysed†	16	Number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Tables 1-3 (n specified in titles).
Outcomes and estimation†	17a	For each primary and secondary outcome, results including estimated effect size and its precision (such as 95% confidence interval) should be based on within participant comparisons.¶ In addition, results for each intervention in each period are recommended	Page 11-14
Binary outcomes‡	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Page 11-14
Ancillary analyses‡	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory	Page 11-14
Harms†	19	Describe all important harms or untended effects in a way that accounts for the design (for specific guidance, see CONSORT for harms32)	N/A

Section/topic	Item No	Description	Page No*
Discussion:			
Limitations†	20	Trial limitations, addressing sources of potential bias, imprecision, and if relevant, multiplicity of analyses. Consider potential carry over effects	Page 16
Generalisability‡	21	Generalisability (external validity, applicability) of the trial findings	Page 14-17
Interpretation‡	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Page 14-17
Other information:			
Registration‡	23	Registration number and name of trial registry	Page 7
Protocol‡	24	Where the full trial protocol can be accessed, if available	Page 7
Funding‡	25	Sources of funding and other support (such as supply of drugs), role of funders	Page 18

CONSORT=Consolidated Standards of Reporting Trials.

- * Note: page numbers are optional depending on journal requirements.
- † Modified original CONSORT item.
- ‡ Unmodified CONSORT item.
- § Random sequence here refers to a list of random orders, typically generated through a computer program. This should not be confused with the sequence of interventions in a randomised crossover trial, for example receiving intervention A before B for an individual trial participant.
- ¶ A within participant comparison takes into account the correlation between measurements for each participant because they act as their own control, therefore measurements are not independent.

Appendix S: Chapter 7 Supplementary Material 2 (Study V)



Supplementary Material 2. Consolidated Standards of Reporting Trials (CONSORT) flow diagram

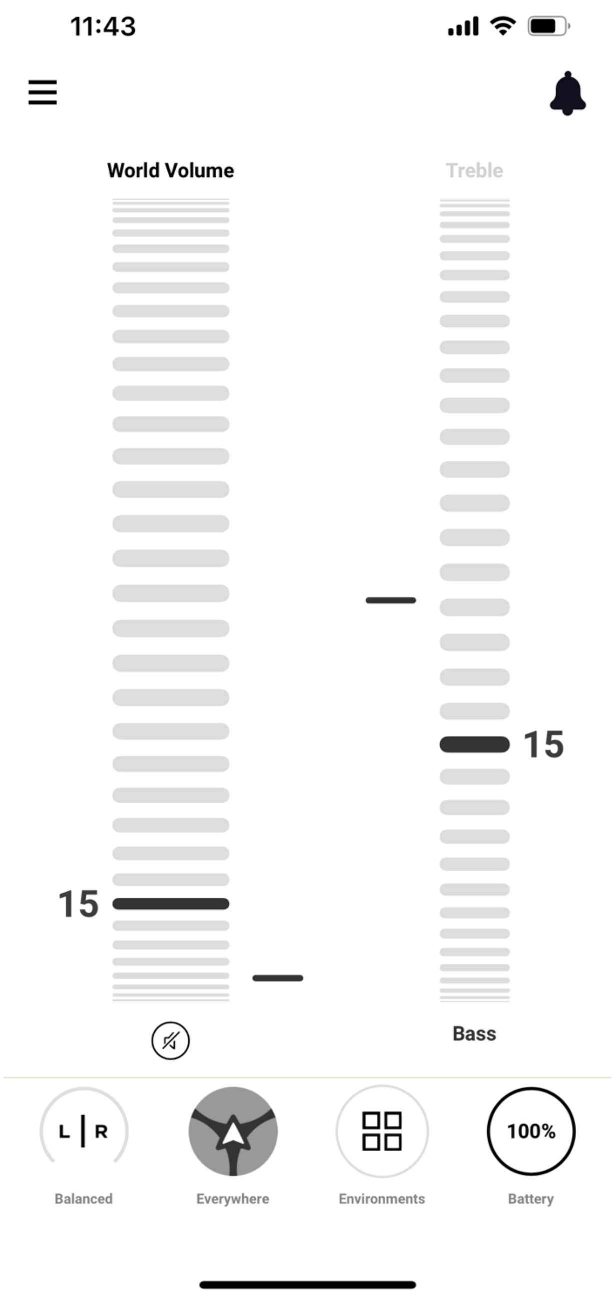
Supplementary Material 3. Information to include in abstract of report of randomised crossover trial: extension of CONSORT for abstracts checklist

Item	Description	
Title*	Identification of study as a randomised crossover trial	This study was not a true randomized controlled trial therefore it was only identified it as a pseudo-randomized-crossover trial.
Trial design*	Description of the trial design (crossover trial and number of periods)	Design settings and participants
Methods:		
Participants†	Eligibility criteria for participants and the settings where the data were collected	Eligible participants specified under objectives Setting specified under design settings and participants
Interventions*	Interventions intended for all participants	Interventions
Objective†	Specific objective or hypothesis	Objectives
Outcome†	Clearly defined primary outcome for this report	Main outcomes and measures
Randomisation*	How participants were allocated to sequences	Design settings and participants
Blinding (masking)*	Whether or not participants, care givers, and those assessing the outcomes were blinded to intervention	N/A
Results:		
Numbers randomised*	Number of participants randomised to each sequence	Design settings and participants
Recruitment†	Trial status‡	Trial registration
Numbers analysed*	Number of participants analysed	Design settings and participants

Item	Description	
Outcome*	For the primary outcome, the estimated effect size and its precision based on within participant comparisons	Results
Harms†	Important adverse events or side effects	N/A
Conclusions†	General interpretation of the results	Conclusions and relevance
Trial registration†	Registration number and name of trial register	Trial registration
Funding†	Source of funding	Not specified in abstract as it is not within the journal's guidelines but specified in funding support section (Page 18).

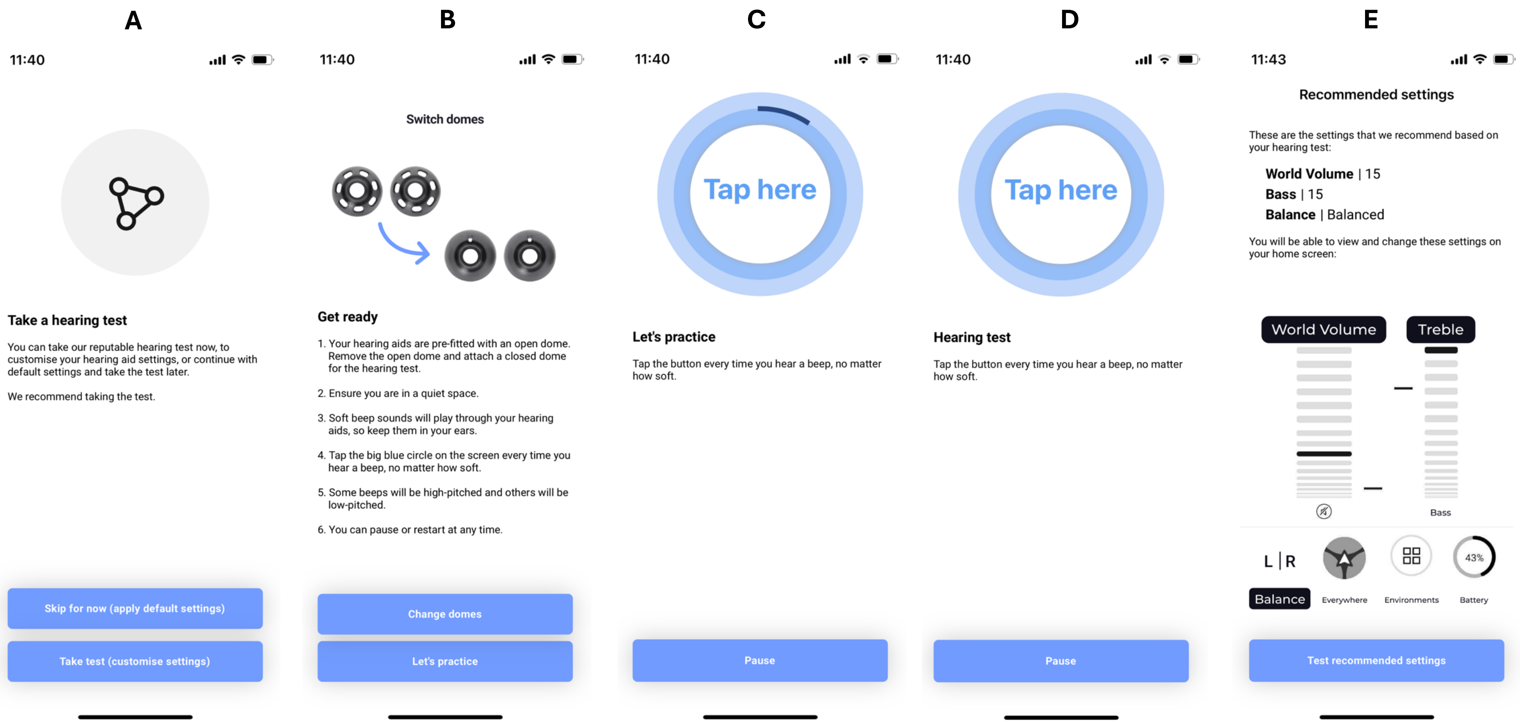
CONSORT=Consolidated Standards of Reporting Trials.

- * Modified original CONSORT item.
- † Unmodified CONSORT item.
- ‡ This is applicable to conference abstracts.

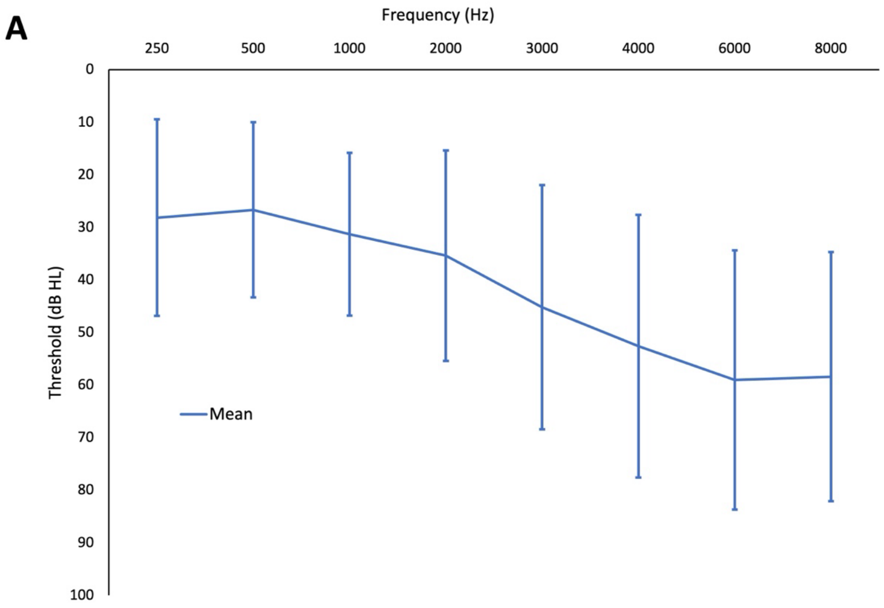


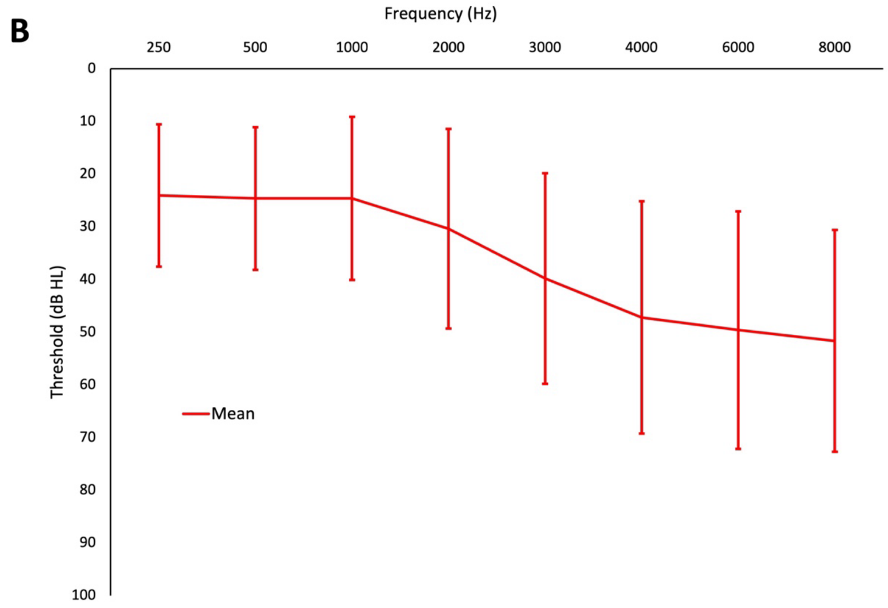
Supplementary Material 4. The Lexie app interface for the self-adjustment self-fitting process. The app interface provided a set of intuitive controls conceptualized as 'wheels,' which allowed users to modify key acoustic parameters. These parameters included world volume, i.e., overall gain (or amplification level) and spectral tilt (the balance of bass and treble frequencies).

Appendix V: Chapter 7 Supplementary Material 5 (Study V)

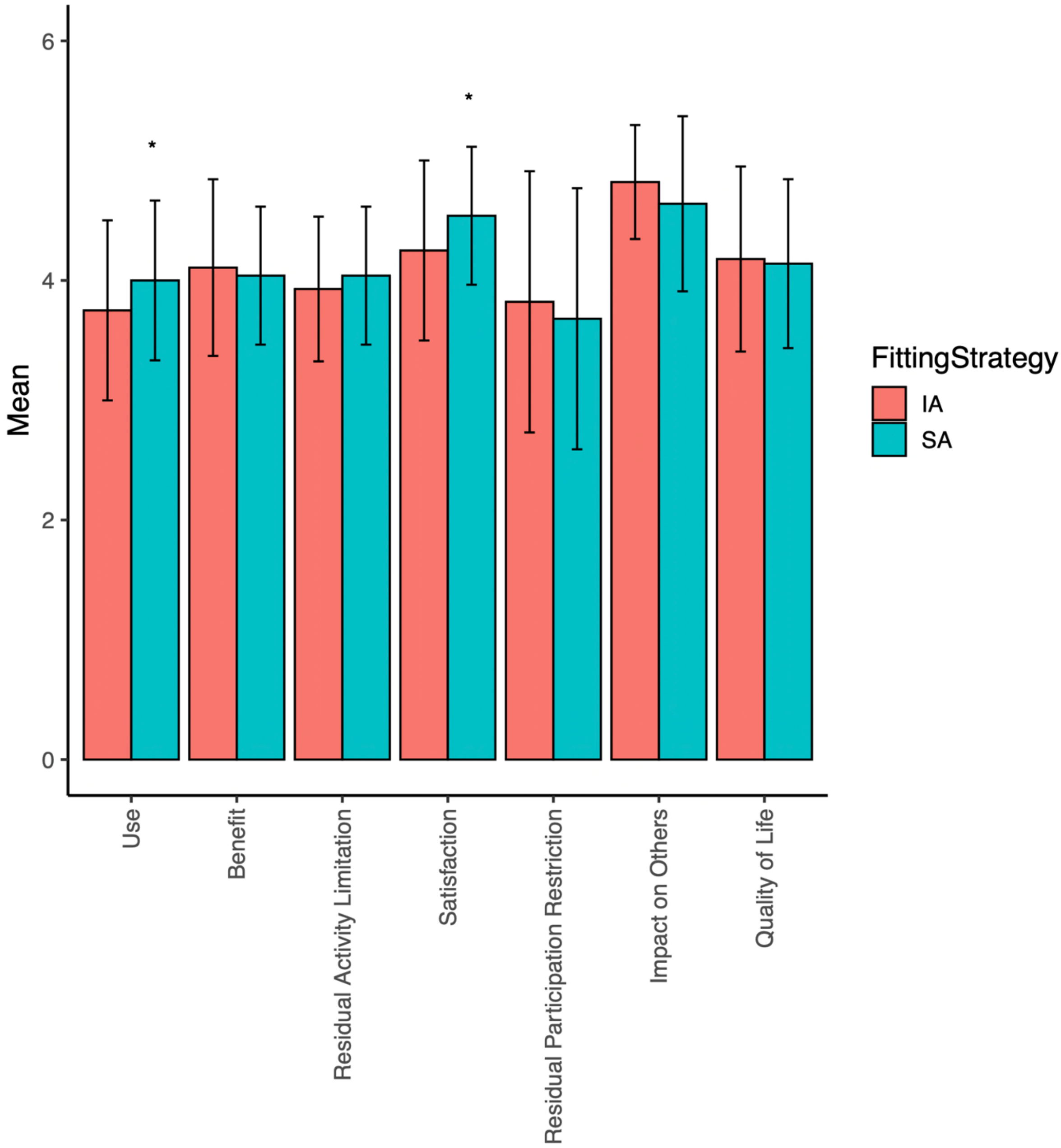


Supplementary Material 5. The Lexie app interface for the in-situ audiometry self-fitting process. (A) The app prompted the participants to take a hearing test, (B) The app provided instructions to the participants for the in-situ hearing test using their hearing aids, (C) The app facilitated a practice round to ensure that the participants comprehend the instructions, (D) The app initiated the in-situ hearing test, (E) Based on the hearing test results, the app recommended personalized settings.





Supplementary Material 6. (A) Distribution of conventional pure tone audiometric frequencies for the left ear, (B) Distribution of conventional pure tone audiometric frequencies for the right ear, n = 28. Standard deviations are shown as error bars.



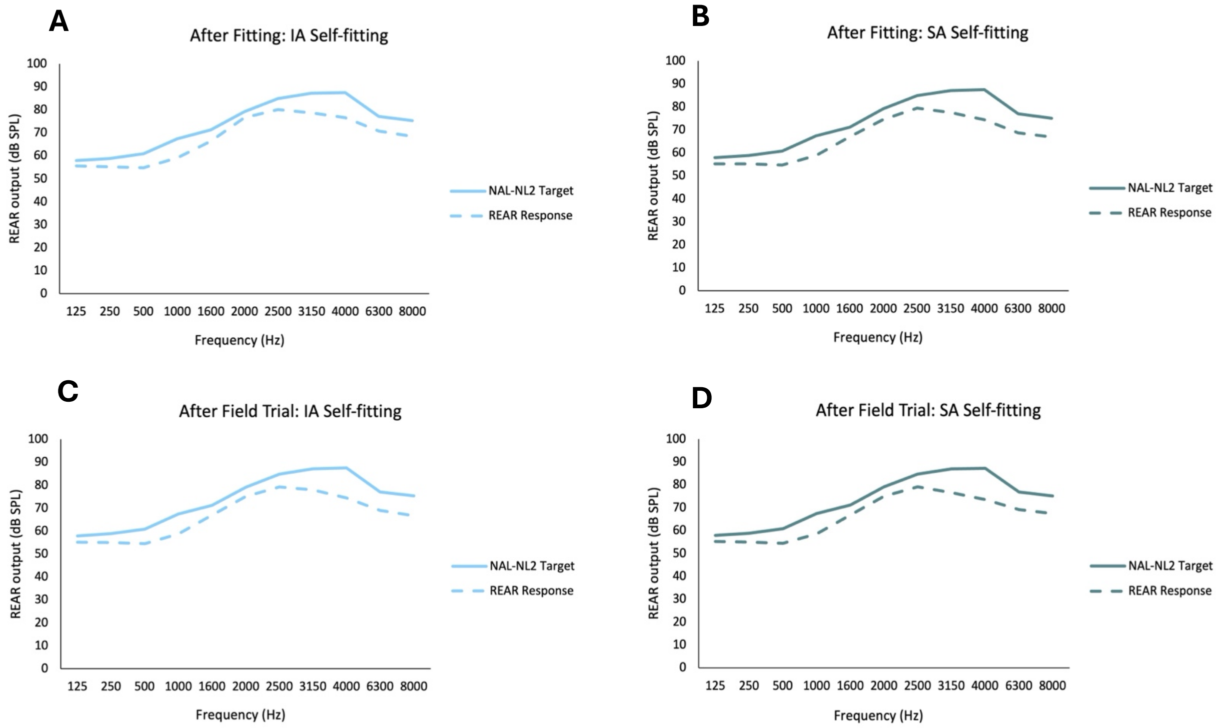
Supplementary Material 7. International Outcomes Inventory for Hearing Aids (IOI-HA) items for the in-situ audiometry (IA) self-fitting and self-adjustment (SA) self-fitting measured after approximately four weeks of hearing aid use. *Clinically meaningful advantage ($r \geq 0.3$).

Supplementary Material 8. DIN and QuickSIN Benefit Scores for the Self-Adjustment and In-situ Audiometry Self-fitting Strategies After Fitting and After Field Trial (n = 28)

	After Fitting: SA Self-fitting **Median (Min – Max)**	**After Fitting: IA Self-fitting** **Median (Min – Max)**	**Effect size** **(95% CI)**	**After Trial: SA Self-fitting** **Median (Min – Max)**	**After Trial: IA Self-fitting** **Median (Min – Max)**	**Effect size** **(95% CI)**
DIN	0.0 (-2.0 to 2.6)	0.3 (-3.8 to 4.6)	Cohen *d* = 0.0 (-0.4 to 0.4)	0.1 (-3.4 to 4.0)	0.3 (-3.6 to 2.8)	Cohen *d* = 0.2 (-0.1 – 0.6)
QuickSIN	0.0 (-5.0 to 4.3)	0.2 (-6.0 to 5.7)	Cohen *d* = -0.1 (-0.4 to 0.3)	0.8 (-5.0 to 5.0)	0.3 (-3.7 to 4.7)	Rosenthal *r* = -0.1 (-0.3 – 0.2)

Abbreviations: DIN, Digits-in-Noise; QuickSIN, Quick Speech-in-Noise; SA, Self-adjustment; IA, In-situ Audiometry

Appendix Z: Chapter 7 Supplementary Material 9 (Study V)



Supplementary Material 9. (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 55 dB SPL International Speech Test Signal.

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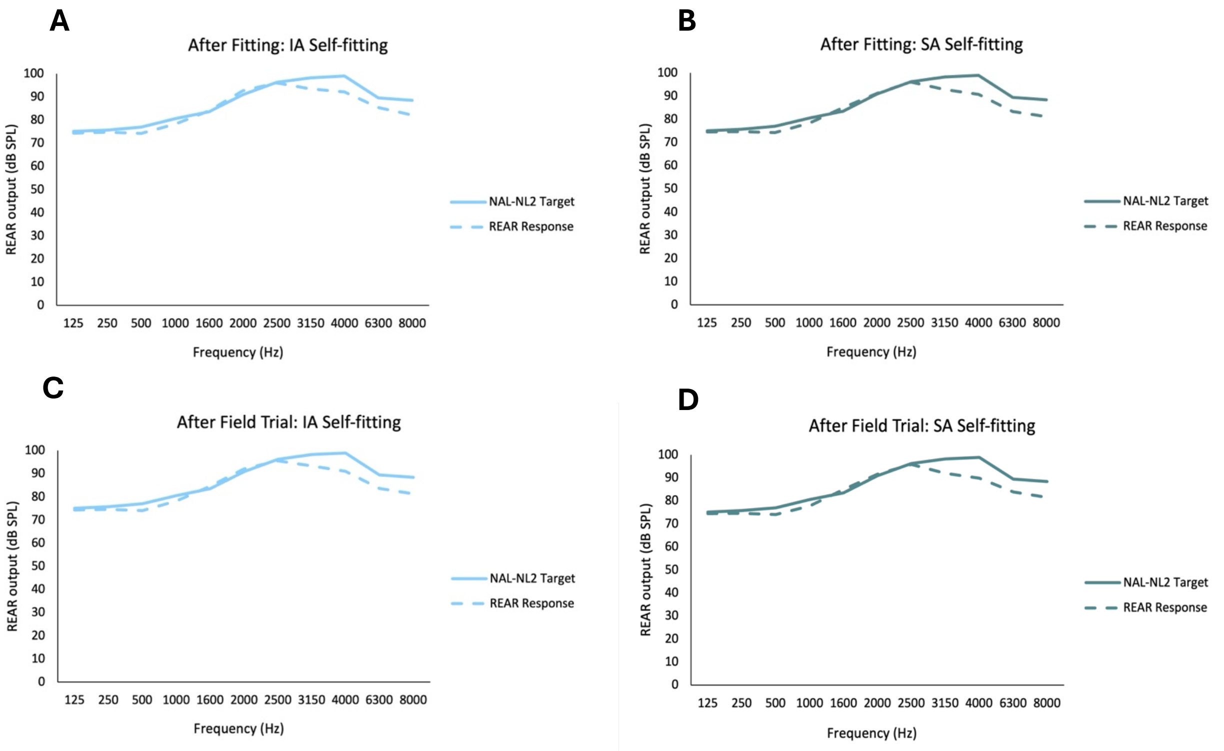
Appendix AA: Chapter 7 Supplementary Material 10 (Study V)



Supplementary Material 10. (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 75 dB SPL International Speech Test Signal.*