R33 PHASE STUDY: PROTOCOL

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A WhatsApp-Delivered AI-Enabled Support Programme versus Paper-Based Support for First-Time Hearing Aid Users in Low-Resource Communities: A Randomized Controlled Trial

ClinicalTrials.gov Brief Title (under 300 characters, plain language):

WhatsApp AI Support vs Paper Support for First-Time Hearing Aid Users

Document Approval

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3. Acronyms and abbreviations

ADE	Adverse Device Event
AE	Adverse Event
AI	Artificial-intelligence
ANOVA	Analysis of Variance
CAPA	Corrective and Preventive Action
CHWs	Community Healthcare Workers
CIOMS	Council for International Organizations of Medical Sciences
CIP	Clinical Investigation Protocol
dB HL	Decibel Hearing Level
dB SPL	Decibel Sound Pressure Level
DD	Device Deficiency
EC	Ethics Committee

GCP	Good Clinical Practice
HA	Hearing Aids
Hz	Hertz
IC	Informed Consent
IOI-HA	International Outcome Inventory for Hearing Aids
LMICs	Low- and middle-income countries
mHealth	Mobile Health
POPIA	Protection of Personal Information Act
RCT	Randomized Controlled Trial
SAE	Serious Adverse Event
SNI	Social Network Index
SOP	Standard Operating Procedure
TMF	Trial Master File

4. Purpose

The purpose of this study is to advance hearing care in low- and middle-income countries (LMICs) through the rigorous evaluation and optimization of innovative interventions and technologies. This study encompasses the following key aim:

This study aims to evaluate the effectiveness of a WhatsApp-delivered AI-enabled support and acclimatization programme for adults receiving preset hearing aids in low-resource community settings. The AI-enabled programme combines two complementary components delivered through the same WhatsApp channel: (i) a structured push programme of 16 voice notes and images delivered over four weeks, and (ii) an on-demand artificial-intelligence (AI) conversational support agent available throughout the four-week intervention period. The primary objective is to determine whether this WhatsApp-delivered AI-enabled programme results in superior hearing aid self-efficacy compared to receiving the equivalent core information in a paper-based pamphlet at the time of fitting. By comparing hearing aid self-efficacy, hearing aid outcomes, and user engagement between the intervention (WhatsApp AI-enabled) and control (paper-based) groups, this study seeks to establish whether AI-enabled digital delivery provides superior support and leads to better self-efficacy for first-time hearing aid users compared to traditional paper-based methods.

5. Responsibilities

Table 1 describes the roles and responsibilities assigned to clinical research team members.

Table 1. Study personnel

Role	Name	Responsibility
Co-Principal Investigator	De Wet Swanepoel	Study planning, oversight, data analyses, and reporting
Co-Principal Investigator	David R Moore	Study planning, oversight, data analyses, and reporting
Co-Principal Investigator	Naveen Negaraj	Study planning, oversight, data analyses, and reporting
Co-investigator	Herman Myburgh	Study planning, technical oversight, data analyses, and reporting
Co-investigator & Statistician	Marien A Graham	Study planning, technical oversight, data analyses, and reporting
Site Coordinator	Tersia de Kock	Study planning, technical oversight, data collection, analysis, and reporting. Site coordinator for Khayelitsha district
Research Coordinator	Karina De Sousa	Study planning, technical oversight, data collection, data analysis, and reporting
Research Coordinator & Site Coordinator	Caitlin Frisby	Study planning, technical oversight, data analyses, and reporting. Site coordination for Atteridgeville district

6. Statement of compliance

The clinical investigation has obtained the required approval from the Ethics Committee (EC) of the Faculty of Humanities at the University of Pretoria. Participants will be informed that their participation in the investigation is voluntary. Prior to any data collection, participants will sign a statement of Informed Consent (IC) that meets the requirements of local regulations and the Protection of Personal Information Act (POPIA).

7. General

7.1. Introduction

Hearing loss is a significant global health issue, particularly in low- and middle-income countries (LMICs) (World Health Organization, 2021). In 2020, over half a billion people globally had a disabling hearing loss, with 1.5 billion experiencing mild-to-complete hearing loss in at least one ear (World Health Organization, 2021). The impact of hearing loss is especially severe in LMICs, where 90% of those with moderate to profound hearing loss reside, yet access to hearing health care is sparse to non-existent (Mulwafu et al., 2017; World Health Organization, 2021). In sub-Saharan Africa, hearing aid penetration is less than 3%

among those who could benefit, starkly contrasting with the high prevalence and impact of hearing loss (Bisgaard et al., 2021). Globally, hearing loss ranks as the third leading cause of years lived with disability, underscoring the urgent need to address its impact on communication, cognition, education, employment, and social participation (World Health Organization, 2021).

The World Health Organization (WHO) has outlined several strategies to improve global hearing health, including the use of innovative digital technologies and task-shifting by training community health workers (CHWs) (World Health Organization, 2021). The use of over-the-counter hearing aids, such as preset devices, has also been recommended for LMICs (World Health Organization, 2021, 2024). We previously conducted an RCT exploring the feasibility of CHW-facilitated hearing aid fittings using preset devices in community settings. However, there remains limited evidence on effective strategies to support first-time users in the acclimatization period following fitting.

Provision of clear, accessible information on hearing aid use, maintenance, and communication strategies is critical for successful outcomes. Traditionally, this information is delivered in a paper-based format at the time of fitting; however, retention and engagement with written material can be limited, particularly in populations with lower literacy levels. Mobile health (mHealth) solutions, such as WhatsApp-based support programmes, offer an opportunity to deliver information gradually and interactively, potentially improving user engagement, confidence, and long-term device use.

This study builds on the WHO's recommendations for integrating digital technologies into hearing care and expands on an initial evaluation, which demonstrated the feasibility of an mHealth-based support and acclimatization programme delivered via WhatsApp (Frisby et al., 2023). The present study further evaluates this programme among adults receiving preset hearing aids in community-based settings in South Africa. The intervention consists of structured voice notes and images covering key aspects of hearing aid use, maintenance, and communication tips over a four-week period. By comparing outcomes between participants receiving solely the WhatsApp-delivered AI-enabled support programme and those receiving only the equivalent information in a paper-based format at the time of fitting, this study aims to determine whether digital delivery enhances self-efficacy, hearing aid use, acclimatization, and self-reported benefits for first-time hearing aid users.

Study Aims

This study aims to evaluate the effectiveness of a WhatsApp-delivered AI-enabled support and acclimatization programme, compared to traditional paper-based support, for adults receiving preset hearing aids in community-based settings in South Africa. The AI-enabled programme combines two complementary components delivered through the same WhatsApp channel: (i) a structured push component consisting of 16 voice notes and images sent over four weeks, covering hearing aid use, maintenance, troubleshooting, and communication strategies; and (ii) an on-demand AI conversational support agent available throughout the four-week intervention period, enabling participants to ask free-text questions and receive individualized, educationally-bounded responses. The two components are conceived as complementary: structured content delivers a planned curriculum at the right pace for acclimatization, while the AI agent answers ad-hoc questions and addresses individual concerns as they arise. We hypothesize that this WhatsApp-delivered AI-enabled intervention will result in superior hearing aid self-efficacy at five weeks post-fitting compared to receiving the equivalent core information in a paper-based pamphlet at the time of fitting.

To test this hypothesis, we will conduct a two-arm randomized controlled trial with blinded outcome assessment, in which all participants receive preset hearing aids fitted by trained community healthcare workers (CHWs). Participants will be randomly assigned to one of two groups:

- **Experimental group (WhatsApp-delivered AI-enabled support):** receives the AI-enabled support and acclimatization programme delivered exclusively via WhatsApp, comprising (i) 16 structured voice notes and images delivered over four weeks and (ii) on-demand access to the AI conversational support agent throughout the four-week intervention period.
- **Control group (paper-based support):** receives the equivalent core support information delivered exclusively in a printed pamphlet at the time of fitting.

This design compares two delivery models for hearing aid support information, a WhatsApp-delivered AI-enabled programme versus traditional paper-based provision, for first-time hearing aid users in low-resource community settings. Follow-up occurs one week after completion of the 4-week intervention. Therefore, follow-up visits to complete outcome measures will be conducted at five weeks post-fitting to ensure all experimental group participants have completed the intervention.

The primary outcome will be hearing aid self-efficacy, assessed using the Measure of Audiologic Rehabilitation Self-Efficacy for Hearing Aids (MARS-HA) global score at five weeks post-fitting. Secondary outcomes will include self-reported average daily use assessed using an open-ended question, self-reported hearing aid benefit, use, and satisfaction as measured by the International Outcome Inventory for Hearing Aids (IOI-HA), perceived hearing handicap assessed using the Revised Hearing Handicap Inventory – Screening (RHHI-S), hearing aid skills and knowledge assessed using the Hearing Aid Skills and Knowledge Inventory (HASKI), and social connectedness assessed using the Berkman-Syme Social Network Index (SNI). Device retention and any device-related issues will also be recorded as additional secondary outcomes. All participants will be provided with a contact number for CHWs should they require additional assistance.

Rationale

Given the limited access to hearing care in LMICs due to prohibitive costs and scarcity of trained professionals, this study leverages mHealth solutions and task-shifting to CHWs as a sustainable and scalable approach. Preliminary studies have demonstrated the feasibility of CHW-facilitated hearing aid fittings and the potential of digital support programmes to improve user outcomes. However, there is a lack of evidence from randomized controlled trials comparing digital versus traditional paper-based support in LMICs. By evaluating differences in hearing aid self-efficacy, hearing aid benefit, use, satisfaction, perceived handicap, and practical device skills, this study will provide evidence on whether mHealth-delivered support offers superior support compared to standard paper-based information.

If mHealth support demonstrates superior outcomes, it would justify scaling up digital acclimatization programmes as part of community-based hearing care models, leveraging widely available platforms such as WhatsApp to improve hearing aid success in underserved populations.

7.2. Sponsor details and investigational site(s)

Sponsor Name: National Institute of Deafness and Communication Disorders of the National Institutes of Health (NIH)

Address: NIDCD Information Clearinghouse, 1 Communication Avenue
Bethesda, MD 20892-3456, United States of America

Funding source: Award Number 5R33DC020134 awarded to De Wet Swanepoel and David R. Moore; Research Funding

7.3 Investigational site(s)

The clinical study will take place at two sites across two Provinces in South Africa.
Community centres or homes (if participants do not have access to the community centre) across:

1. Atteridgeville District, Gauteng, South Africa
2. Khayelitsha District, Western Cape, South Africa

7.4 Description of the interventions used in experimental design

Hearing Aid

All participants will receive a pair of Go Ultra hearing aids (GoHearing), which are rechargeable, behind-the-ear (BTE) preset hearing aids designed for adults with mild-to-moderate hearing loss. These devices feature digital sound processing, noise reduction, wind noise suppression, and Bluetooth streaming capabilities. The Go Ultra hearing aids include four preset listening programmes that the user can manually select to suit different listening environments. The devices also incorporate programme and volume memory functions, allowing users to maintain their preferred settings. As an affordable over-the-counter (OTC) option, the Go Ultra has been recommended for use in LMICs due to its low cost (under $130 USD per pair) and ease of fitting without specialised audiological equipment (World Health Organization, 2021, 2024).

The Go Ultra device labelling indicates a target population of adults with mild-to-moderate hearing loss. The present trial enrols participants across a broader hearing loss range (mild to severe; PTA 20 to <80 dB), consistent with the R21 feasibility study within this R33 portfolio (Frisby et al., 2023) and reflecting the population most likely to benefit from low-cost OTC amplification in LMIC community settings, where access to alternative devices is severely limited. Participants with severe loss (PTA 60 to <80 dB) may receive less measurable gain than those with mild-to-moderate loss; any such effect on outcome measures is expected to be non-differential between the two trial arms and will be examined in a planned subgroup analysis by hearing loss severity (mild, moderate, moderately-severe to severe).

WhatsApp-Delivered AI-Enabled Support and Acclimatization Programme (Experimental Arm)

Participants randomized to the experimental arm will receive a WhatsApp-delivered AI-enabled support and acclimatization programme. These participants will receive only the WhatsApp-delivered programme and will not receive the paper-based support. The

programme integrates two complementary components, both delivered through the same WhatsApp channel.

Component 1: Structured push content

A pre-defined sequence of 16 voice notes and images, designed to provide clear and accessible information on the key aspects of hearing aid use, maintenance, troubleshooting, and communication strategies. Messages are delivered on a fixed schedule, sent every second day from the time of fitting over a 30-day period, to promote engagement and to support participants during the early acclimatization period. The voice notes and images are produced in English, isiXhosa, and Sepedi; participants receive content in the language they select at onboarding. All push content is savable and remains permanently accessible to the experimental arm participant within the WhatsApp conversation thread. WhatsApp was selected as the delivery platform because of its high penetration in South Africa, its suitability for voice- and image-based communication for participants with varying literacy levels, and its low data overhead.

Component 2: AI conversational support agent

Throughout the four-week intervention period, participants in the experimental arm will have on-demand access to an AI-assisted conversational support agent integrated into the same WhatsApp channel. The agent enables participants to ask free-text questions about hearing aid use, maintenance, troubleshooting, and communication strategies, and to receive individualized, educationally grounded responses. The agent is guided by a curated knowledge base of educational materials, including the hearing aid user manual, study-specific frequently asked questions, and evidence-based content on hearing aid use, care, and communication; this knowledge base is combined with a large language model (LLM) conversational layer. Responses are individualized and may vary between users and interactions.

The AI agent operates strictly within an educational and supportive scope and does not provide diagnostic, medical, or treatment advice. Participants who report symptoms requiring clinical attention, including but not limited to sudden hearing loss, ear pain, ear discharge, bleeding, dizziness, or fever with ear involvement, are routed by rule-based safety triggers to the study CHWs or the supervising audiology team. Predefined prompting constraints, hard-coded safety routing rules, and a continuously audited transcript review process are described in Section 16.5 (AI-Related Adverse Events).

Onboarding and data provision

On the day of the hearing aid fitting, the CHWs will provide structured assistance to onboard participants to the WhatsApp-based programme. Onboarding includes saving the programme contact number, opting in to receive the structured push content, and a brief orientation to the AI conversational agent, including its scope and limitations. To ensure equitable access to the intervention and to minimize financial barriers in this low-income population, participants allocated to the experimental arm will be provided with a one-month unlimited WhatsApp-specific data bundle at the time of onboarding. The data bundle is intended solely to enable receipt of the intervention content and engagement with the AI agent, and is not expected to influence outcomes beyond enabling delivery.

Paper-Based Support Programme (Control Arm)

Participants randomized to the control arm will receive equivalent core support information delivered exclusively via a printed pamphlet provided at the time of fitting. The pamphlet covers the same content domains as Component 1 of the experimental intervention: hearing aid use, maintenance, troubleshooting, and communication tips, presented in clear and concise language with supporting illustrations. The pamphlet includes information in English, isiXhosa, and Sepedi; participants can read the version in their preferred language. This approach reflects current community-based fitting practice, in which information is typically provided once during the fitting session, with no structured follow-up support. Participants retain the pamphlet and may refer to it at any time. Control arm participants will not receive any support via WhatsApp during the study period. This group will not have access to the AI conversational agent.

Comparison logic

This design contrasts two delivery models for the same core hearing aid support content: a WhatsApp-delivered AI-enabled programme (structured push content combined with on-demand AI conversational support) versus traditional one-off paper provision. The trial, therefore, evaluates the AI-enabled programme as an integrated package; positive or negative effects cannot be attributed to either Component 1 or Component 2 in isolation, and the trial is not designed to dismantle the relative contribution of the two components. A planned future trial within the R33 portfolio will address dismantling of the components if the AI-enabled programme demonstrates effectiveness in the present study.

7.5 Summary of the Clinical Investigation

Title: A WhatsApp-Delivered AI-Enabled Support Programme versus Paper-Based Support for First-Time Hearing Aid Users in Low-Resource Communities: A Randomized Controlled Trial

Purpose: To determine whether a structured, phased WhatsApp-delivered AI-enabled support programme delivered exclusively via WhatsApp provides superior hearing aid self-efficacy, benefit, use, satisfaction, and practical device skills compared to receiving equivalent information exclusively in a paper-based format at the time of fitting.

Population: 66 evaluable adult participants (80 will be recruited as an attrition buffer) (aged ≥18 years, no upper age limit) with mild-to-severe hearing loss (pure-tone average 20–<80 dB HL in both ears) living in low-resource community settings.

Design: Two-arm randomised controlled trial with blinded outcome assessment.

Initiation date: March 2026

Completion date: March 2027

8. Clinical investigation objectives

The main aim of this project is to determine the effectiveness of a structured, phased WhatsApp-delivered AI-enabled support programme delivered via WhatsApp in terms of hearing aid self-efficacy, benefit, use, satisfaction, and practical device skills compared to receiving equivalent information in a paper-based format at the time of fitting. Users will be fitted with preset devices in this two-arm randomised controlled trial with blinded outcome assessment.

Primary endpoint hypothesis

Primary Endpoint

The primary endpoint of this study is self-reported hearing aid self-efficacy, measured using the MARS-HA global score at five weeks post-fitting. The endpoint assesses the difference in mean MARS-HA global score between the experimental (WhatsApp-delivered AI-enabled support) and control (paper-based support) arms.

Superiority

Null Hypothesis (H_0): There is no difference in mean MARS-HA global score at five weeks post-fitting between participants randomised to the WhatsApp-delivered AI-enabled support programme and those randomised to paper-based support.

Alternative Hypothesis (H_1): Participants randomised to the WhatsApp-delivered AI-enabled support programme will demonstrate a higher mean MARS-HA global score at five weeks post-fitting than participants randomised to paper-based support.

Powered detectable difference and interpretation

No minimum clinically important difference (MCID) for the MARS-HA has been established in the context of mHealth or AI-enabled interventions for first-time hearing aid users in low-resource settings. In the absence of an anchor-based MCID, the study is powered to detect a moderate standardised effect size of Cohen's d = 0.5, which is widely accepted as a meaningful effect in audiologic rehabilitation research. A review of published literature indicates that the standard deviation for the MARS-HA global score in adult hearing aid users consistently ranges from 12.8 to 15.9 points (Chen et al., 2025; Ferguson et al., 2016; Fuentes-López et al., 2019; Johnson et al., 2018; Jorbonyan et al., 2025; Kelly-Campbell & McMillan, 2015; Meyer et al., 2014; Smith & Lea West, 2006; West & Smith, 2007). Using a conservative standard deviation estimate of 15 points, an effect size of d = 0.5 corresponds to a between-group difference of 7.5 points on the MARS-HA global score.

The 7.5-point margin, therefore, represents the minimum between-group difference the study is statistically powered to detect at α = 0.05 with 80% power, rather than a pre-defined clinical threshold of meaningful change. Effect estimates will be reported with 95% confidence intervals and interpreted in context against the published distribution of MARS-HA scores in comparable populations. Should the observed effect fall below 7.5 points but with a confidence interval excluding zero, this will be reported as a statistically detectable but smaller-than-anticipated effect, with implications discussed in light of contemporary critique of binary statistical significance thresholds (Wasserstein et al., 2019).

9. Clinical investigation design

An open-label, two-arm, randomized controlled trial with 66 evaluable participants (80 will be recruited as an attrition buffer) will be used. The estimated timeline for trial completion is approximately five weeks post-hearing aid fitting. The clinical trial will be conducted across two sites (Various communities in the Western Cape Province of South Africa and Atteridgeville District in the Gauteng Province of South Africa). See Figure 1 below for a visual depiction of the trial design.

Randomization (full details provided below) allocation sequence will be generated before recruitment, but assignment will occur strictly after eligibility is confirmed and baseline

assessments completed. This will ensure that each participant is assigned to one of the two study arms (Control or Experimental Group) (full randomization details below).

Before enrolment, community members will be screened to determine if they have access to their own personal WhatsApp on their own personal phone. Once access to WhatsApp has been determined, participants will be enrolled and proceed to baseline assessments. After baseline assessments to determine candidacy (T0), participants will be allocated to their previously randomized intervention group (T1). There will be one control group receiving a paper-based support programme only and one experimental group receiving a WhatsApp-delivered AI-enabled support programme only. Following fitting (T1), there will be a 4-week field trial, with a follow-up visit scheduled at five weeks (T2).

Participants randomized to the experimental group will receive CHW-assisted onboarding to the WhatsApp-delivered AI-enabled support programme at the fitting visit, along with provision of a one-month WhatsApp data bundle to support uninterrupted receipt of intervention content during the four-week intervention period.

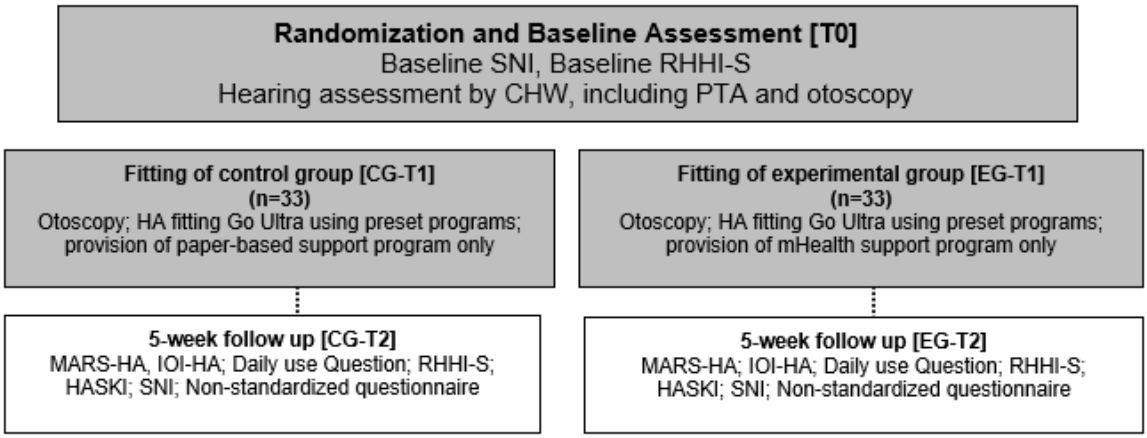


Figure 1. Proposed clinical trial design.

The primary endpoint will be the five-week follow-up. The primary outcome measure will be the MARS-HA.

As no established minimal clinically important difference (MCID) has been defined for this measure in the context of an mHealth intervention, the study was powered to detect a moderate standardized effect size of Cohen's d = 0.5, which is widely considered a meaningful effect. A review of published literature indicates that the standard deviation for the MARS-HA

global score in adult hearing aid users consistently ranges from 12.8 to 15.9 points (Chen et al., 2025; Ferguson et al., 2016; Fuentes-López et al., 2019; Johnson et al., 2018; Jorbonyan et al., 2025; Kelly-Campbell & McMillan, 2015; Meyer et al., 2014; Smith & Lea West, 2006; West & Smith, 2007).

Using a conservative standard deviation estimate of 15 points, a moderate effect size corresponds to an absolute difference of 7.5 points between the intervention and control groups.

- Target Difference = 0.5 (effect size) × 15 points (SD) = 7.5 points

The secondary measures will include an open-ended question on self-reported average daily hearing aid wear time, International Outcome Inventory for Hearing Aids (IOI-HA), the Revised Hearing Handicap Inventory – Screening (RHHI-S), the HASKI (Hearing Aid Skills and Knowledge Inventory), and the Berkman-Syme Social Network Index (SNI). Baseline RHHI-S and SNI scores will be compared with scores obtained at the five-week follow-up visit.

Additionally, a questionnaire with Likert scale questions and open-ended questions targeting participant perceptions on the support programme content and delivery will be completed.

10. Randomization:

The allocation sequence is generated before recruitment, but assignment occurs strictly after eligibility is confirmed and baseline assessments are completed to minimize allocation bias and maintain balance across the two study arms. A total of 66 evaluable participants (33 per arm) will be recruited across two data collection sites: The Western Cape Province and the Atteridgeville District in the Gauteng Province of South Africa. However, 80 participants will be recruited as an attrition buffer. Randomization will be implemented using a pre-generated sequence and managed via a centralized, password-protected Google Sheet to streamline and secure the process.

Permuted block randomization with a block size of 4, 6, and 8 will be used. This method ensures that each of the two study arms, Control (paper-based support programme) and Experimental (mHealth support programme), receives an equal number of participants throughout the enrollment process while preventing predictability in participant assignments. Within each block, participants will be randomly allocated to one of the two arms, maintaining allocation concealment until assignment.

Participants will be randomised to either the Control or Experimental arm using permuted block randomisation with variable block sizes of 4, 6, and 8. Within each block, participants will be allocated in equal numbers to each arm (i.e., 2:2, 3:3, or 4:4 per block), with the order of assignments randomly determined. Block sizes will vary randomly to reduce the risk of predictability while maintaining balance between study arms throughout recruitment. The randomization list will be generated using a secure software tool or random number generator such as the online tool Sealed Envelope (https://www.sealedenvelope.com/simple-randomiser/v1/lists), with the final sequence stored securely. The final allocation sequence will be prepared before the start of recruitment. Once a participant has completed baseline assessments (T0) and is confirmed eligible by the community healthcare worker (CHW), the site administrator will enter their details into the predetermined Google Sheet to reveal the assigned study arm (T1).

11. Ethical considerations

The proposed clinical trial has obtained ethical approval from the University of Pretoria Humanities Research Ethics Committee. The protocol will also be registered on Clinicaltrials.gov.

11.1 Informed consent

Informed consent ensures adherence to the ethical principle of autonomy, ensuring that the individual makes their decisions freely and independently to partake in the study (DoH, 2020). Study personnel will receive training on the Informed Consent Form (ICF) (Appendix I) and the ICF Standard Operating Procedure (ICF-SOP) prior to study initiation (Appendix II). All training will be logged and recorded within the Site Master File (SMF), and if there are any changes to the ICF process, all study personnel will be retrained.

A CHW will discuss and inform the individual about the study to determine their willingness to participate and obtain written informed consent from the participant. The ICF and consent process will be offered to the individuals in English, isiXhosa, or Sepedi. All individuals willing to participate in the clinical study will be informed to the fullest extent possible about the study in terms that they are able to understand. All individuals willing to participate in the clinical investigation will have an opportunity to ask questions about the study to ensure that they have a complete understanding of what their participation would entail.

All individuals will be informed that their participation is voluntary and they can withdraw from the study at any time without penalty. They will be required to personally sign the ICF, which will include a statement that meets the requirements of local regulations and the Protection of Personal Information Act (POPIA). The ICF will also be signed and dated by the person responsible for obtaining informed consent from the individual. A copy of the ICFs will be provided to the participant, and a signed copy will also be filed with the participant's source documentation. Should the individual be illiterate, an impartial witness will be asked to sign and date the ICF on behalf of the individual after verbal consent has been obtained.
The Ethics Committee of the Faculty of Humanities at the University of Pretoria has reviewed and granted approval. (Appendix III).

Topics covered in the ICF include:

- A description of the clinical investigation
- Information regarding their voluntary participation
- Potential risks and discomforts
- Benefits to participation
- Alternative procedures or treatments
- Confidentiality
- Data collection and sharing of results
- Conditions of termination of participation
- Reimbursement
- Compensation in the event of a trial-related injury
- Contact details

If any updates or revisions are made to the currently approved version of the ICF, the revised version will be re-approved by the EC, and re-consent will take place to ensure the participant is aware of the changes made and agrees to continue to participate in the study. The ICF-SOP (doc number xxx) provides an in-depth overview of the procedure discussed above.

11.2 Reimbursement

Participants allocated to the mHealth intervention group will receive a one-month WhatsApp-specific data bundle to enable access to the study intervention. This provision is considered a reasonable accommodation to facilitate participation rather than a form of reimbursement or inducement. No financial compensation will be provided to participants in either study arm. All participants will have their hearing assessed free of charge by trained CHWs. All participants

who are eligible to receive hearing aids will be able to keep their hearing aids free of charge upon completion of the study.

11.3 Confidentiality

All participant records and results will be coded alpha-numerically to ensure adherence to the ethical principle of confidentiality. No identifying information or results will be made known in the data analysis or reporting process to allow others to become aware of a specific participant's identity. Information regarding confidentiality will also be contained in the ICF (Appendix I). The research team members and CHWs will know the identity of the participants. However, a participant code will be assigned to each participant so that the data captured, recorded, stored, and reported remains anonymous.

The data will be kept in hard copy in the Trial Master File (TMF) for a period of 10 years and will also be stored electronically in a password-protected Excel spreadsheet that only the research team will have access to. This electronic version will also be stored for a period of 10 years as per the University of Pretoria's data management policy. The results obtained from the research study will be recorded anonymously and reported honestly and as accurately as possible.

11.4 Validity and reliability

Validity determines if the measurements are accurate and whether they are measuring what they intend to measure (Portney, 2020). To ensure validity, all baseline measurements will be conducted in the same manner by trained CHWs. The CHWs all have the same training on the equipment. A refresher training session that covers equipment use and study procedures will be done prior to data collection commencement. Training for all participating CHWs will be recorded on the trial training log (Appendix IV). Testing will be done using the same standard of equipment at each site, which will be calibrated according to the necessary regulations before any testing is conducted.

Reliability describes the consistency of measurement or correlation between repeated observations or measurements (Irwin et al., 2018). To ensure reliability, the study protocol will remain the same for each participant, where possible. During the baseline and follow-up visits, standardized questionnaires will be used to assess participants' subjective experiences with the hearing aids. Using standardized, validated questionnaires ensures consistency in the measurement of subjective experiences across all participants and visits. Consistency in the

questions and response options helps in obtaining reliable and consistent data over time, improving the reliability of the study.

Single-timepoint use of the MARS-HA — conceptual and psychometric rationale.
The MARS-HA assesses an individual's confidence in performing a defined set of hearing-aid-related tasks (e.g., changing a battery, cleaning the device, using the device in noise). For first-time hearing aid users, who by definition have not used a hearing aid prior to enrolment, baseline self-efficacy for these tasks is conceptually undefined: participants cannot reliably rate confidence in tasks they have never performed. Baseline administration would therefore not provide a meaningful within-person comparator, and the design instead uses the MARS-HA as a between-arms comparison at a single post-fitting timepoint (five weeks). This is consistent with conventional use of the instrument in studies of new hearing aid users (Ferguson et al., 2016; Smith & West, 2006).

Recent COSMIN-based evaluations have acknowledged gaps in responsiveness, measurement error, and minimal clinically important change (MIC) data for the MARS-HA, which limit its use for longitudinal change scoring. Because the present trial uses a single post-test endpoint and does not rely on within-person change or pre–post responsiveness, these COSMIN limitations do not apply. The MARS-HA's structural validity and internal consistency are well-established (West & Smith, 2007) and are the relevant psychometric properties for the present between-arms comparison.

11.5 Follow-up

Follow-up occurs one week after completion of the 4-week intervention. The following follow-ups will be needed, where participants will complete self-reported outcome measures:

- Five weeks

11.6 Dissemination plan

Dissemination of findings. Trial results will be disseminated through three channels. (1) Peer-reviewed publication of the main results in an open-access international audiology journal, with submission planned within 12 months of database lock. (2) Community-level feedback to participants and host community organisations at Atteridgeville and Khayelitsha, comprising a plain-language summary in the three trial languages (English, isiXhosa, Sepedi) delivered through the community health workers within three months of the main results being accepted for publication. (3) Stakeholder briefings to the Western Cape and Gauteng Departments of Health, the hearX Foundation, and Hold My Hand SA. The protocol and de-identified individual

participant data will be deposited in an accessible repository in line with NIH data-sharing policy and ClinicalTrials.gov results-reporting requirements. The trial will be registered on ClinicalTrials.gov before the first participant enrolment.

12. Participant population

12.1 Recruitment

Participants will be recruited using a self-report or community referral mode of hearing loss detection and snowball sampling within communities (Leedy & Omrod, 2015). Community healthcare workers from the hearX Foundation (also residing in the communities) will contact leaders of various community networks, such as community NGOs, elderly groups, and religious groups, to explain and create awareness of the study. Interested individuals will be provided with the CHW's contact details, and they will then have the opportunity to contact the CHWs for more information. CHWs will also conduct awareness talks at various community networks, such as community NGOs, elderly groups, and religious groups, to inform community members of the study. Participants will be selected from individuals who indicate their availability to be part of this study, grant permission to be included as participants, and have access to their own personal WhatsApp (data costs for the mHealth intervention will be supported for participants allocated to the experimental group). The participants' contact details will be kept strictly confidential, and only the CHWs will have access to these details.

Power:

The primary outcome measure for this trial is the global score on the Measure of Audiologic Rehabilitation Self-Efficacy for Hearing Aids (MARS-HA). As no established minimal clinically important difference (MCID) has been defined for this measure in the context of an mHealth intervention, the study was powered to detect a moderate standardized effect size of Cohen’s d = 0.5, which is widely considered a meaningful effect.

A review of published literature indicates that the standard deviation for the MARS-HA global score (on the 0–100 scale) in adult hearing aid users consistently ranges from 12.8 to 15.9 points (Chen et al., 2025; Ferguson et al., 2016; Fuentes-López et al., 2019; Johnson et al., 2018; Jorbonyan et al., 2025; Kelly-Campbell & McMillan, 2015; Meyer et al., 2014; Smith & Lea West, 2006; West & Smith, 2007).

Using a conservative standard deviation estimate of 15 points, a moderate effect size corresponds to an absolute difference of 7.5 points between the intervention and control groups. Using G*Power software (Faul et al., 2007), the minimum required sample size to

detect a between-group difference of 7.5 points on the MARS-HA global score (corresponding to Cohen's d = 0.5 with a conservative SD estimate of 15) at α = 0.05 with 80% power is 33 evaluable participants per arm (total 66 evaluable). To allow for an anticipated attrition rate of approximately 17.5% over the 5-week intervention and follow-up period — consistent with attrition observed in community-based mHealth and hearing aid trials in LMIC settings (Frisby et al., 2023) — a total of 80 participants (40 per arm) will be recruited. If attrition exceeds 20% by the midpoint of recruitment (40 enrolled), recruitment will be extended pro rata to ensure 66 evaluable participants reach the primary endpoint at five weeks post-fitting. An attrition-monitoring review will be conducted by the research coordinator at the midpoint, with the outcome and any consequent recruitment-target adjustment documented in the TMF.

12.2 Inclusion criteria

Consenting adults fulfilling the following criteria will be recruited for the clinical trial:

- 18 years and older
- Confirmed mild to severe (20 to < 80 dB PTA in both ears) hearing loss (determined during baseline assessments)
- Willing/available to commit to 5-week follow-up
- Must have access to their own personal WhatsApp
- Functional proficiency in English, isiXhosa, or Sepedi sufficient to provide informed consent and to self-complete the study outcome measures in one of these three languages, as judged by the recruiting CHW during the screening conversation.

The inclusion and exclusion criteria form will be completed to keep a record of all the individuals who have met the criteria and are included in the clinical investigation. Records will also be kept in the TMF.

12.3 Exclusion criteria

- Younger than 18 years
- Hearing loss too severe (≥80 dB HL PTA)
- Normal hearing (<20 dB HL PTA)
- Middle ear pathology, such as otitis media, active drainage from the ears.
- Unwilling/unavailable to commit to a 5-week follow-up.
- Unilateral hearing loss
- No access to WhatsApp/only has access via another individual's WhatsApp
- Home language other than English, isiXhosa, or Sepedi, where the individual does not have functional proficiency in any of these three languages.

The inclusion and exclusion criteria form will be completed to keep a record of all individuals who meet the criteria and those who were excluded from the study. The investigational devices are designed for a set criteria of individuals, hence the specific exclusion criteria that have been set out to ensure that the results/ feedback from the clinical investigation are able to be generalized to the appropriate population and relevant claims made to be appropriate.

12.4 Procedure for withdrawal

Individuals have the right to withdraw from the study at any point in time without any negative or adverse consequences. All participants who are enrolled in the clinical trial will be recorded on the screening and enrollment log form after ensuring that they meet all the inclusion criteria. Participants will be withdrawn from the study when/if it is deemed that there are any risks associated with the use of the devices. These events/risks will be documented on the Adverse Events (AE) or Serious Adverse Events (SAE) form, and actions taken will be logged so that there is a record of the duration of participation in the clinical trial.

All individuals enrolled in the clinical trial will be recorded in the enrollment log. Should there be participants who are lost to follow-up, the researchers will try to contact them. Should they be unreachable, the details will be documented with their case report forms, including the duration of their participation in the study, the reason for exclusion/lost-to-follow-up, and methods used by the researchers to follow up with them.

The clinical study aims to enroll 66 participants. A total of 80 will be recruited as an attrition buffer.

12.5 Relationship between investigation population and target population

The population that most often requires access to community-based hearing aid fitting services is individuals 18 years of age or older with self-perceived or confirmed mild to severe hearing loss. Therefore, as mentioned above, the selected adults who meet the outlined inclusion and exclusion criteria are representative. Language-based exclusion and generalisability. Outcome measures and the ICF are validated in this study in English, isiXhosa, and Sepedi only. Participants whose home language is none of these three and who lack functional proficiency in any of them will be excluded; this is expected to apply primarily to a minority of community members at the Atteridgeville site whose home language is Setswana, Sesotho, isiZulu, Xitsonga, or Tshivenda. Findings are therefore generalisable to the broader population of community-dwelling adults with mild-to-severe hearing loss who are

proficient in at least one of the three trial languages; future trials within the R33 portfolio will extend language coverage to support broader generalisability.

12.6 Expected number of participants

This study aims to enroll 66 participants (33 in each arm) using an open-label, two-arm, randomized controlled design. The participants will be divided into two groups and randomized into either the control (only paper-based support programme) or experimental (only mHealth support programme) group. However, 80 participants will be recruited as an attrition buffer.

13. Testing schedule and equipment

Table 2 below details the equipment that will be used during the clinical trial.

Table 2. Clinical trial equipment

Equipment	Description
hearScope™ (hearX Group, Pretoria, South Africa)	The trained CHWs will perform otoscopy to inspect the outer ear to identify any possible ear disease (e.g., wax impaction, perforation, or ear infection) and to evaluate the patency of the ear canal to accommodate a hearing aid. These images are also uploaded onto a secure mHealth cloud-based data management platform where a professional team (audiologists and ENT) can remotely review the images and assist the CHWs in determining participant eligibility.
BeBird® Video Otoscope (Bebird Technology Co., Ltd., Shenzhen, China)	The trained CHWs will perform otoscopy to inspect the outer ear and ear canal for signs of possible ear disease (e.g., wax impaction, tympanic membrane perforation, or ear infection) and to evaluate the patency of the ear canal for hearing aid fitting. High-resolution images and videos captured during the examination can be viewed in real time through the accompanying smartphone application. The images and videos may be uploaded to a secure mHealth cloud-based data management platform, where a professional team (audiologists and ENT) can remotely review the images and assist the CHWs in determining participant eligibility.
Remmie® Health Smart Otoscope (Remmie Health, Inc., Denver, CO, USA)	The trained CHWs will perform otoscopy to inspect the outer ear and ear canal for signs of possible ear disease (e.g., wax impaction, tympanic membrane perforation, or ear infection) and to evaluate the patency of the ear canal for hearing aid fitting. Images and videos obtained during the examination can be viewed through the smartphone-connected application and securely shared for remote review. These images and videos may be uploaded to a secure mHealth cloud-based data management platform, where a professional team (audiologists and ENT) can remotely review the images and assist the CHWs in determining participant eligibility.

hearTest™ (hearX Group, Pretoria, South Africa)	CHWs will facilitate hearing assessments using the hearTest. Pure tone air conduction thresholds at 500, 1000, 2000, and 4000 Hz will be determined. Participants will be asked to respond (i.e., raising their hand) every time they hear a tone, even when the tones become softer. (Sennheiser HD280 Pro headphones calibrated according to International Organization for Standardization 389-1 [ISO] 2013 and International Organization for Standardization 389-9 [ISO] 2014 standards). These results are also uploaded onto a secure mHealth cloud-based data management platform where a professional team (audiologists and ENT) can remotely review and assist the CHWs in determining participant eligibility.
Go Ultra Hearing aids (Go Hearing)	Go Ultra hearing aids (Left and right pair) in non-identifying packaging, including user manual, domes (small, medium, large - open and closed), slim tubes (various sizes), slim tube measuring tool, cleaning kit, and charger.
International Outcome Inventory for Hearing Aids (IOI-HA)	The IOI-HA is a validated seven-item questionnaire to measure the effectiveness of the hearing aid intervention (Cox and Alexander, 2002). It targets seven domains, including (i) daily use, (ii) benefit, (iii) residual activity limitations, (iv) satisfaction, (v) residual participation restrictions, (vi) impact on others, and (vii) quality of life. Each item has five response choices, from worst to best outcome (Appendix V). The IOI-HA has been translated into the languages most commonly used in these communities, namely isiXhosa and Sepedi. All translated instruments underwent forward-backward translation and pilot testing for cultural equivalence (Hall et al., 2018). The participants will have the option to complete the IOI-HA in either of these languages or in English. The IOI-HA total score (range 7–35; higher scores indicate better hearing-aid outcomes, including use, benefit, satisfaction, and quality of life) will be measured at 5 weeks post-fitting.
Revised Hearing Handicap Inventory and Screening Tool (RHHI-S)	The RHHI-S is a validated 10-item questionnaire that is a strong, unidimensional, clinically informative measure of self-perceived hearing handicap that can be used by adults of all ages (Cassarly, Matthews, Simpson, & Dubno, 2020). Each question has three possible responses: yes, sometimes, or no. The RHHI-S has been translated into the languages most commonly used in these communities, namely isiXhosa and Sepedi. All translated instruments underwent forward-backward translation and pilot testing for cultural equivalence (Hall et al., 2018). The participants will have the option to complete the RHHI-S in either of these languages or in English. RHHI-S total score (range 0–40; higher scores indicate greater perceived hearing handicap) will be measured at baseline and 5 weeks post-fitting (Appendix VI)
Berkman-Syme Social Network Index (SNI)	The Berkman-Syme Social Network Index (SNI) is a well-established tool used to assess the extent of an individual's social connections. The SNI examines the relationship between social networks and health outcomes. The SNI evaluates social integration by assessing four key domains: Marital status – Whether the individual is married or in a committed partnership.

	Contacts with close friends and relatives – Frequency of social interactions with family and friends. Religious group membership – Whether the individual is part of a church or religious group and attends regularly. Participation in voluntary or community organizations – Involvement in social or civic groups outside of family and work. The SNI assigns points based on the individual's responses to the above components. Scores range from 0 to 4, with higher scores indicating greater social integration. The SNI will be measured at baseline and 5 weeks post-fitting. The SNI has been translated into the languages most commonly used in these communities, namely isiXhosa and Sepedi. All translated instruments underwent forward-backward translation and pilot testing for cultural equivalence (Hall et al., 2018). The participants will have the option to complete the SNI in either of these languages or in English (Appendix VII)
Non-standardized Questionnaire	A non-standardized questionnaire will be included to obtain information from the participants on their perceptions of the support programme, as well as self-reported daily use in hours. This includes Likert scale and open-ended questions, which will be measured at 5 weeks post-fitting (Appendix VIII)
HASKI-clin	The HASKI (Hearing Aid Skills and Knowledge Inventory) is a clinician-administered questionnaire designed to evaluate the practical skills and knowledge of hearing aid users. It covers key areas such as basic handling (insertion, removal, cleaning, and battery management), operational knowledge (using settings, adjusting controls, and troubleshooting), communication strategies (effective use in different environments), self-management (accessing resources and scheduling appointments), and care and maintenance (routine care and recognizing when professional servicing is needed). This tool helps audiologists identify areas where users may need additional training or support, ultimately improving hearing aid outcomes and user satisfaction. Scoring of the HASKI-clin is calculated by summing the total number of items identified as competent (not problematic), dividing this by the number of items for which a response was given (i.e., excluding the “Not Applicable responses), and multiplying by 100 to give a percentage of competency. Items are equally weighted. A higher overall score indicates greater competency (i.e., a score of 100% represents full competency). This will be measured at 5 weeks post-fitting (Appendix IX)
MARS-HA	The Measure of Audiologic Rehabilitation Self-Efficacy for Hearing Aids (West & Smith, 2007) is a 24-item self-report instrument measuring four factors: (1) Basic Handling, (2) Advanced Handling, (3) Adjustment, and (4) Aided Listening. Each item is rated on a 0–100% confidence scale in 10% increments (0% = no confidence at all, 100% = full confidence). The global score is the arithmetic mean of the 24 item responses and ranges from 0 to 100, with higher scores indicating greater hearing aid self-efficacy. Subscale scores are calculated as the mean of the items contributing to each factor. A global score of 80% or higher is conventionally

	interpreted as high self-efficacy; scores below 80% indicate low to moderate self-efficacy. The MARS-HA has been translated into isiXhosa and Sepedi for use in this study; both translations underwent forward-backward translation and pilot testing for cultural equivalence (Hall et al., 2018). Participants may complete the MARS-HA in English, isiXhosa, or Sepedi. The MARS-HA will be administered at five weeks post-fitting (Appendix X).

Procedure – All assessment and fitting procedures will be facilitated by the CHWs

Pre-enrolment:

CHWs screen community members to determine if they have access to their own personal WhatsApp. Only if the community member has access to their own WhatsApp can they be enrolled for Baseline assessments. The randomization allocation sequence is generated before recruitment, but assignment occurs strictly after eligibility is confirmed and baseline assessments are completed.

T0: Baseline assessment

- Assess participants for candidacy
- Obtain Informed Consent from the participants
- Record demographic information
- Complete the baseline SNI and RHHI-S
- Conduct otoscopy
- Conduct an audiometric evaluation to ensure that participants meet the pure tone air-conduction thresholds to be included.
- The clinical research audiologists will then establish candidacy by reviewing the otoscopy and PTA results. The eligible participants will be randomly allocated to either the Control or Experimental group. The allocation sequence is generated before recruitment, but assignment occurs strictly after eligibility is confirmed and baseline assessments are completed. A random number generator will allocate participant numbers to the respective arms. As soon as a participant is enrolled, they will automatically be assigned to one of the two arms based on the predefined randomization process. This approach ensures unbiased group allocation from the outset of the study. This randomization will be done by an additional independent party.

T1: Hearing-aid fitting and SP provision

Once randomized into one of the two groups, participants will be booked for Visit 2 for hearing aid fitting. All participants will undergo otoscopy before the hearing aid fitting.

Control Group

- Participants in the control group will be fitted with Go Ultra hearing aids on one of the four preset programs. Participants will select the program they feel most comfortable with.
- This will be conducted by the CHW.
- Participants will receive a paper-based version of the support program only.

Experimental Group

- The CHW will fit each participant with Go Ultra hearing aids on one of the four preset programs. Participants will select the program they feel most comfortable with.
- Participants will begin to receive the mHealth version of the support program and will continue to receive only this over a period of 4 weeks.
- CHW will assist participants with onboarding to the WhatsApp-delivered AI-enabled support programme and confirm successful receipt of the initial message before the participant leaves the site. Provision of the one-month WhatsApp data bundle will occur at this visit.

T2: Follow-up #1

- Follow-up occurs one week after completion of the 4-week intervention, as five-weeks post hearing aid use.
- The Measure of Audiologic Rehabilitation Self-Efficacy for Hearing Aids (MARS-HA), International Outcome Inventory for Hearing Aids (IOI-HA), an open-ended question on self-reported daily hour use, the Revised Hearing Handicap Inventory – Screening (RHHI-S), SNI, the HASKI (Hearing Aid Skills and Knowledge Inventory), and a non-standardized questionnaire will be completed by the participants.
- An administrative assistant will collect outcome measures to avoid CHW bias. The administrative assistant collecting outcome measures is blinded to group allocation.
- The HASKI will be administered by a professional audiologist with the assistance of the administrative assistant.

Table 3 illustrates the timing of each outcome measure administered.

Table 3: Outcome measurement timing

Tool	Timepoint
MARS-HA	Five-week Follow-up
HASKI-clin	Five-week Follow-up
International Outcome Inventory for Hearing Aids(IOI-HA)	Five-week Follow-up
Revised Hearing Handicap Inventory and Screening Tool (RHHI-S)	Baseline; five-week Follow-up
Berkman-Syme Social Network Index (SNI)	Baseline; five-week Follow-up
Non-standardized Questionnaire	Five-week Follow-up

Table 4 presents the SPIRIT 2013 schedule of enrolment, interventions, and assessments for the study, including participant screening, randomization, hearing aid fitting procedures, support programme delivery, and outcome measurement timepoints across the trial period.

Table 4. SPIRIT Figure: Schedule of enrolment, interventions, and assessments

Study period	**Pre-enrolment**	**Baseline (T0)**	**Hearing Aid Fitting & Support Provision (T1)**	**Five-week Follow-up (T2)**
Timepoint	**Prior to enrolment**	**Week 0**	**Following randomization**	**Week 5 post-fitting**
ENROLMENT				
WhatsApp access screening	**X**			
Eligibility screening		**X**		
Informed consent		**X**		
Randomization		**X**		
INTERVENTIONS				
Go Ultra hearing aid fitting.			**X**	
Paper-based support programme (Control)			**X**	
AI-enabled WhatsApp support programme (Experimental)			**X**	

Study period	Pre-enrolment	Baseline (T0)	Hearing Aid Fitting & Support Provision (T1)	Five-week Follow-up (T2)
WhatsApp onboarding and data bundle provision			X	
ASSESSMENTS				
Demographic information		X		
Otoscopy		X	X	
Pure-tone audiometry		X		
SNI		X		X
RHHI-S		X		X
MARS-HA				X
IOI-HA				X
HASKI-clin				X
Open-ended daily hearing aid use question				X
Non-standardized questionnaire				X
Adverse events/troubleshooting			X	X

Abbreviations: AI = Artificial Intelligence; CHW = Community Health Worker; HASKI-clin = Hearing Aid Skills and Knowledge Inventory; IOI-HA = International Outcome Inventory for Hearing Aids; MARS-HA = Measure of Audiologic Rehabilitation Self-Efficacy for Hearing Aids; RHHI-S = Revised Hearing Handicap Inventory – Screening; SNI = Berkman-Syme Social Network Index.

14. Statistical design and analysis

Data analysis will be conducted using IBM Statistical Packages of the Social Sciences (SPSS v30.0, Chicago, Illinois). Figures will be completed in R (v 4.3.2; *R* Core Team, 2023).

Design: This is an open-label, two-arm, randomized controlled design. The participants will be divided into two groups and randomized into either the control (only paper-based support programme) or experimental (only mHealth support programme) group. The challenges are limitations in the sensitivity of the outcome measures and the inability to blind the experimental group.

Analysis populations

Primary analysis. The primary analysis of the MARS-HA global score at five weeks post-fitting will follow the intention-to-treat (ITT) principle. All randomised participants will be analysed in the arm to which they were allocated, regardless of intervention received or completion status. Missing primary outcome data will be handled by multiple imputation under the missing-at-random (MAR) assumption, with sensitivity analyses using a complete-case approach and a tipping-point analysis to assess robustness to plausible departures from MAR.

Per-protocol sensitivity analysis. A pre-specified per-protocol analysis will be conducted as a sensitivity analysis to assess the effect of the intervention as delivered. Participants will be included in the per-protocol population if they meet the following exposure thresholds:

- Experimental arm: received at least 12 of 16 structured push messages (Component 1; receipt defined by WhatsApp message-delivery confirmation logs) AND had at least one logged interaction with the AI conversational agent (Component 2) during the intervention period.
- Control arm: confirmed receipt of the printed pamphlet at the fitting visit (recorded on the fitting case report form).

Concordance between ITT and per-protocol effect estimates will be reported. Any meaningful discrepancy in direction or magnitude between the two analyses will be discussed transparently in the results paper. Adherence to the per-protocol exposure thresholds will also be reported descriptively as an engagement outcome.

Multiple comparisons. The primary analysis uses a single primary outcome at a single time point; no adjustment for multiple comparisons is required for the primary analysis. Secondary outcomes will be considered exploratory and interpreted with reference to point estimates and 95% confidence intervals rather than formal multiplicity-corrected null-hypothesis testing.

Statistical tests:

Firstly, data cleaning will be conducted. This process involves identifying and correcting or removing inaccurate entries (which could be due to data capture errors) and addressing incorrectly formatted data. Following data cleaning, a missing value analysis will be undertaken. Missing data will be categorized as missing completely at random (MCAR), missing at random (MAR), missing not at random (MNAR), or structurally missing data, as the classification determines the appropriate handling method.

Following the missing values analysis, descriptive statistics such as measures of location (mean and median), measures of spread (standard deviation and interquartile range), and counts (frequencies and percentages) will be extracted. For continuous variables, normality will be assessed using the Shapiro–Wilk test. The Shapiro–Wilk test will be used rather than the Kolmogorov–Smirnov test, as it has greater power in detecting departures from normality (Field, 2024).

For correlational analysis, the parametric Pearson correlation (if normal) or the nonparametric Spearman correlation (if non-normal) will be used. To test for differences in biographical data between two independent groups (e.g., male vs. female), the parametric independent samples t-test (if normal) or the nonparametric Mann–Whitney U test (if non-normal) will be applied. For comparisons involving three or more independent groups, the parametric ANOVA test (if normal) or the nonparametric Kruskal–Wallis test (if non-normal) will be used. For all statistical tests, a 5% level of significance will be applied.

For the primary (MARS-HA) and secondary (HASKI-Clin) outcome measures, data will be treated as continuous variables. Descriptive statistics, including measures of location (mean and median) and measures of spread (standard deviation and interquartile range), will be reported. Normality of the data distribution will be assessed using the Shapiro–Wilk test. Between-group comparisons (mHealth vs. paper-based) will be conducted using parametric independent samples t-tests if data are normally distributed, or nonparametric Mann–Whitney U tests if data deviate significantly from normality. If relationships between the MARS-HA and HASKI-Clin scores, or between these and other continuous outcome measures, are explored, correlational analyses will be performed using the parametric Pearson correlation (for normally distributed data) or the nonparametric Spearman correlation (for non-normal data). Where appropriate, multiple linear regression models may be constructed with the MARS-HA and HASKI-Clin scores as dependent variables to identify predictors of hearing aid self-efficacy and practical skills. Potential predictors may include age, gender, degree of hearing loss, intervention type (mHealth vs. paper-based), and site. Model assumptions (normality, linearity, and homoscedasticity) will be checked prior to interpretation.

In accordance with COSMIN guidance, the MARS-HA is used for between-group comparison at a single endpoint, rather than repeated-measures change scoring, which mitigates concerns related to responsiveness or minimal important change.

For the remaining secondary outcome measures, the respondents will be asked to respond by marking the response that most accurately represents their situation as they perceive it. Descriptive statistics will be computed, and measures of location (mean if normal, median if non-normal) and measures of variability (standard deviation if normal, interquartile range if non-normal) will be reported. Pearson correlations (if normal) or Spearman correlations (if non-normal) will be used to calculate correlations. For example, the number of problems respondents experience with their hearing aids will be correlated with satisfaction and benefit. Comparisons between groups will be made, for example, for differences in satisfaction and benefit between males and females, the independent samples t-test (if normal) or the Mann-Whitney test (if non-normal) will be used. The independent samples t-test and Mann-Whitney tests are used to test for differences between two unrelated/independent groups. For three or more groups, the one-way ANOVA test (if parametric) and the Kruskal-Wallis test (if non-normal) will be used.

The IOI-HA has seven items concerned with the use of hearing aids, covering the benefits perceived, remaining activity limitation, satisfaction, residual participation restriction, effect on significant others, and change in quality of life. The response data will be checked for normality using the Shapiro-Wilk test. If the response data is normally distributed, then parametric tests will be used; on the other hand, if the response data differs significantly from normality, nonparametric tests will be used. Descriptive statistics will be computed, and measures of location (mean if normal, median if non-normal) and measures of variability (standard deviation if normal, interquartile range if non-normal) will be reported. Kendall's tau, which is a nonparametric measure of relationships between ranked data, will be used to compute the intercorrelation of the seven questions (Stephens, 2002). The results from the intercorrelations will be supported by a principal component analysis, which will be used to identify factors. This is in line with several studies that have applied factor analysis on the IOI-HA, showing that the responses can be described by two main factors (Arlinger et al., 2017). Factor 1 represents use, benefit, satisfaction, and quality of life (i.e., Items 1, 2, 4, and 7), whereas Factor 2 represents residual activity limitations, residual participation restrictions, and impact on others (i.e., Items 3, 5, and 6) (Arlinger et al., 2017). Factor 1 (typically referred to as "me and my hearing aids"), Factor 2 (typically referred to as "me and the rest of the world"), and the mean IOI-HA total scores will be related to the demographic questions (age, gender, degree of hearing loss) using correlations and tests for differences. For the latter, these comparisons between, say, males and females, will be done using the independent samples t-test (if normal) or the Mann-Whitney test (if non-normal). The independent samples t-test and Mann-Whitney tests are used to test for differences between two unrelated/independent groups. For

three or more groups, the one-way ANOVA test (if parametric) or the Kruskal-Wallis test (if non-normal) will be used. The mean IOI-HA total score, the mean IOI-HA total score for Factor 1, and the mean IOI-HA total score for Factor 2 will be represented as a function of average hearing thresholds (PTA; 0.5, 1, 2, and 4 kHz), respectively (Arlinger et al., 2017). Scatterplots with mean IOI-HA total scores (vertical axis) as a function of PTA (horizontal axis) will be created, and second-order polynomial regression lines will be fit to these figures, which will assist with interpreting relationships. Say, for example, the curve has a slightly concave downward shape, then clients with very mild hearing loss reported very high mean scores. Logistic regression models will also be built. For example, the first question of the IOI-HA instrument asks about, on an average day, how many hours a respondent used their hearing aid(s). The options are 'none', 'less than 1 hour a day', '1 to 4 hours a day', '4 to 8 hours a day', and 'more than 8 hours a day'. Logistic regression can be utilized to assess predictors (age, gender, degree of hearing loss) associated with the non-regular use of hearing aids (Aazh et al., 2015).

For the RHHI-S, ten questions are scored 0 = “No”, 2 = “Sometimes”, 4 = “Yes”, that assess how an individual perceives the social and emotional effects of hearing loss with questions such as “Does a hearing problem cause you to feel embarrassed when meeting new people?”, and “Do you have difficulty hearing when someone speaks in a whisper?”. The score can range from a minimum of 0 (if a respondent answers “no” to all ten questions) to a maximum of 40 (if a respondent answers “yes” to all ten questions). The values are interpreted as follows: 0-8 (suggest no hearing handicap), 10-24 (suggest mild-moderate hearing handicap), 26-40 (suggest significant hearing handicap) (Mccabe, 2019). The scores will be related to the demographic questions (age, gender, degree of hearing loss) using correlations and tests for differences. As explained above, the tests for differences between two unrelated/independent groups will be conducted using the independent samples t-test (if normal) or the Mann-Whitney test (if non-normal). For three or more groups, the one-way ANOVA test (if parametric) or the Kruskal-Wallis test (if non-normal) will be used. Scatterplots with RHHI-S scores (vertical axis) as a function of PTA (horizontal axis) will be created, and second-order polynomial regression lines will be fit to these figures, which will assist with interpreting relationships. Say, for example, the curve has a slightly concave downward shape, then clients with very mild hearing loss reported very high mean scores. Logistic regression models will also be built. For example, the first question of the RHHI-S instrument asks, “Does a hearing problem cause you to feel embarrassed when meeting new people?” Take the first question of the RHHI-S, for example. Logistic regression can be utilized to assess predictors (age,

gender, degree of hearing loss) associated with feeling embarrassed about one's hearing aid when meeting new people.

The Berman-Syme Social Network Index (SNI) evaluates participants' social connectedness based on four domains: (1) marital status, (2) frequency and quantity of contact with friends and relatives, (3) participation in religious meetings, and (4) involvement in community or organizational groups. Following the approach outlined by Loucks et al. (2006), responses on the Berkman-Syme SNI are converted into binary scores and then summed to create a composite index ranging from 0 to 4. Participants receive a score of 1 if they are married and 0 if they are not. For close social contacts, a score of 0 is assigned if an individual reports having 0–2 close friends and 0–2 close relatives; otherwise, a score of 1 is given. Regarding participation in community organizations, individuals who do not participate receive a score of 0, while those who do are assigned a score of 1. For religious attendance, a score of 0 is given to those attending services less than or equal to every few months, and a score of 1 is assigned to those attending once or twice a month or more frequently. The total score reflects the degree of social integration, with higher scores indicating greater social connectedness. The scores will be related to the demographic questions (age, gender, degree of hearing loss) using correlations and tests for differences. As explained above, the tests for differences between two unrelated/independent groups will be conducted using the independent samples t-test (if normal) or the Mann-Whitney test (if non-normal). For three or more groups, the one-way ANOVA test (if parametric) or the Kruskal-Wallis test (if non-normal) will be used. Predictors of higher or lower social connectedness scores will be explored using generalized linear models, with age, gender, and degree of hearing loss included as covariates.

Secondary analyses will be considered exploratory and interpreted cautiously without formal correction for multiplicity. Subgroup analysis by hearing loss severity. A pre-specified subgroup analysis will compare MARS-HA global scores between the two arms within strata defined by baseline pure-tone average: (i) mild (PTA 20 to <35 dB), (ii) moderate (PTA 35 to <50 dB), and (iii) moderately-severe to severe (PTA 50 to <80 dB). This will allow examination of whether intervention effects differ across hearing loss severity, given that severe-loss participants may experience compressed gain with the preset Go Ultra device.

15. Data management

15.1 Data entry and collection

Data collection will primarily take place in a paper format, which includes the ICF, patient file data, and the Case Report Form (CRF). Data from the CRF will be electronically transcribed for further data analysis.

After obtaining necessary study approvals, the study will employ a comprehensive Subject Eligibility Checklist (Appendix XI) encompassing all inclusion and exclusion criteria. This checklist will ascertain an individual's eligibility for study enrollment. Each interested individual will undergo this assessment, and the completed form will be securely filed within their respective study file.

Each individual who undergoes the screening evaluation, whether eventually enrolled or not, will be meticulously documented on the Subject Eligibility Checklist (Appendix XI) specific to the site. These records will be maintained within the Site Master File (SMF). It is essential to emphasize that no procedures to evaluate eligibility will commence without obtaining informed consent. Likewise, these records will be securely stored within each individual’s study file.

Personal and demographic data collected for the study will be meticulously recorded on the Baseline Data Collection form (Appendix XII) and kept within the respective participant study file. Data from study activities will be accurately documented on the results form (Appendix XII). All study forms will be securely stored in the participant study files.

Each participant will have a dedicated CRF that comprehensively captures and reflects all their data. This information will subsequently be transferred to an electronic data system for further analysis and management.

15.2 Data quality control and validation

The PI or responsible research team member will maintain all study documents and source documentation in their original format in compliance with South African Good Clinical Practice (GCP) guidelines.

To ensure data quality, all clinical research audiologists will be trained on the study procedure and measures for data collection, prior to participants being assessed. A training log will be kept as proof of training and retraining activities. There will be clear data normalization

protocols, i.e., methods of recording data will be consistently captured on the set data collection sheets, and there will be clearly defined protocols for each clinical measure conducted throughout the clinical trial. Clinical evaluations will conform to consistent formats to ensure consistency in the data. Source data will be captured on fillable forms and captured electronically afterward for statistical analysis.

Internal monitoring activities will take place to ensure data integrity and completeness. A weekly scheduled data validation check will be conducted by the research personnel, where data will be reviewed for completeness and accuracy prior to eCRF capturing. Electronically transcribed data will also be reviewed for completeness and correctness in relation to the source documentation. In addition, the data will be audited for accuracy at each site monitoring visit by an independent monitor.

15.3 Data privacy and retention policy

Following the ICF completion, where identifying information will be visible, an alphanumeric code will be assigned to each participant. All data to be collected post-ICF will have the specific alphanumeric code to ensure participant anonymity. Only the research personnel working directly with the participant will have access to the identifiable information. Data from the CRF will be transferred/transcribed to a cloud-based electronic data platform (Google Suite) with 2-factor authentication access in place. Participant study data will be kept for a minimum of 10 years, as set out by the Health Sciences Research Ethics Committee of Pretoria.

Data residency and cross-border transfer. Electronic study data will be stored within the University of Pretoria's Google Workspace Enterprise tenancy, governed by a Data Processing Addendum (DPA) with Google that provides POPIA-equivalent data protection standards, including AES-256 encryption at rest and TLS 1.3 in transit, role-based access control, comprehensive audit logging, and contractual restrictions limiting Google's processing of the data to that necessary for service provision. Because Google Workspace infrastructure operates partly outside the Republic of South Africa, cross-border transfer of personal information is conducted in accordance with POPIA Section 72 via two complementary mechanisms: (a) the binding contractual safeguards in Google's DPA, which provide an adequate level of protection comparable to POPIA, and (b) explicit participant consent for cross-border processing of de-identified data as part of the informed consent process. The ICF will disclose the use of Google Workspace and the cross-border transfer in plain language and will give participants the option to consent to this aspect of data processing.

15.4 Data ownership and data sharing

Data ownership primarily resides with the University of Pretoria and the hearX Foundation who oversees the study and retains ultimate ownership of the collected data. However, all parties involved, including investigators, institutions, and participants, hold a vested interest and responsibility in ensuring data accuracy and integrity. Access to study data, both identifiable and unidentifiable, will be strictly limited to authorized personnel. Any sharing or utilization of the data (unidentifiable) will necessitate prior approval from the University of Pretoria and the hearX Foundation. Publication will follow NIH and institutional policies, with hearX acknowledged as an industry partner. De-identified participant-level data will be shared upon reasonable request in accordance with NIH data-sharing policies.

15.5 Audit trail

The study will maintain a comprehensive audit trail to document all entries, changes, additions, or deletions made to the study data throughout its lifecycle, whether in paper format or electronically transcribed. This audit trail will include, but not be limited to, a record of all data entry, modifications, and access logs. Any modifications made to the data will undergo rigorous scrutiny. Each alteration will be methodically recorded, and a clear linkage to the responsible party for each change will be established. This meticulous audit trail will serve as a safeguard against unauthorized data handling and provide transparency in data management processes. The maintenance of an audit trail aligns with regulatory requirements, ensuring data integrity, traceability, and compliance with GCP guidelines.

Documents need to be retained for at least 15 years after the discontinuation of the clinical investigation. Documents may be retained for longer periods of time upon agreement with the sponsor or in accordance with regulatory requirements. Records are not allowed to be destroyed without written permission from the Sponsor.

16. Adverse events and device defects/deficiencies

16.1 Adverse events

Adverse events (AEs) are any untoward medical occurrences, unintended injuries, or diseases in participants related to the investigational device.

For the current clinical investigation, possible AEs could include:

- Risk of an ear infection due to contamination or cross-contamination of disease between participants through equipment and/or surface contaminants.

- Possible allergic reaction from use of the hearing aids, due to device material (e.g., itchy ears or otitis externa).
- Possible increase in wax build-up due to occlusion of ear canals, which may cause itchiness and irritation.
- Possible headaches from prolonged device use, especially during the first few days of use.

16.2 Serious Adverse Events (SAE)

Any AE that leads to a death or to a serious deterioration in the health of the participant or that results in a life-threatening injury, permanent impairment of a body structure/function, hospitalization, or medical intervention is considered an SAE. For the current clinical investigation, no SAEs are anticipated.

16.3 Adverse Device Effect (ADE)

AE related to the use of a medical device. For the current clinical investigation, possible ADEs could include:

- Device material causing an allergic reaction in a participant's ear
- A device deficiency of unintended loud sound output that may result in a temporary threshold shift.

16.4 Device Deficiencies (DD)

Any device defect related to the identity, quality, durability, reliability, safety, or performance of the devices. Device deficiencies include malfunctions, use errors, and inadequacies in the information supplied by the manufacturer, including labeling. For the current clinical investigation, a possible DD could include:

- Any device defect related to the performance or safety of the devices, e.g., audio output, faulty components that would deviate from the standard performance set out by the manufacturer.

16.5 AI-Related Adverse Events

The experimental arm of this trial includes access to an AI conversational support agent as Component 2 of the WhatsApp-delivered AI-enabled support programme (described in Section 8.4). The AI agent introduces a class of potential adverse events distinct from the physical device-related events covered in Sections 16.1 to 16.4. An AI-related adverse event (AI-AE) is defined for the purposes of this study as any response generated by the conversational agent that has the potential to cause harm to a participant, either directly

through inappropriate guidance or indirectly through failure to escalate a condition requiring clinical attention.

Categories of AI-AE

- Missed safety escalation: failure of the agent to recognize and route a participant message containing a red-flag symptom (sudden hearing loss, severe ear pain, ear discharge, bleeding from the ear, sudden dizziness, fever with ear involvement, sudden unilateral tinnitus, pressure sore or non-healing skin in the ear canal, or expression of self-harm) to the study CHW or audiology team.
- Out-of-scope clinical advice: provision by the agent of diagnostic, medical, treatment, or medication advice that falls outside the agent's defined educational scope.
- Inaccurate device guidance: provision of incorrect instructions regarding hearing aid handling, cleaning, charging, or use that could plausibly cause physical harm, device damage, or impede the participant's safe use of the device.
- Inappropriate response to psychological distress: failure to respond supportively, or response in a manner likely to exacerbate distress, when a participant discloses emotional difficulty, frustration, or thoughts of self-harm.
- Breach of language or cultural appropriateness: response in a language other than that nominated by the participant, or use of culturally inappropriate framing that risks alienation or disengagement.

Risk mitigation

Three layers of mitigation operate in combination:

- Deterministic pre-retrieval safety triggers. The full list of red-flag phrases (Category 1 above) is implemented as rule-based pattern matching applied to every incoming participant message before the large language model is invoked. Any match triggers an immediate scripted safety response and a notification to the study CHW. This rule layer cannot be bypassed by the language model.
- Constrained system prompt and knowledge base. The agent's system prompt enforces the educational-only scope, the validate-before-fixing response posture, and a fallback behavior when the user query is out of scope. The knowledge base contains only curated, study-approved content; the agent retrieves from it and does not generate device-specific instructions from general-language model knowledge.
- Continuous transcript audit. A random sample of 20 participant conversations per week, stratified by site, will be reviewed by a study audiologist within 72 hours of

conversation occurrence. Reviews use a structured rubric covering each AI-AE category.

Reporting

All AI-AEs identified through transcript audit, participant report, CHW report, or automated trigger logs will be recorded on the AE/SAE form with the AI-AE category indicated. Reporting timelines follow Section 16.6 (Adverse event reporting) with the following additions:

- Any confirmed missed safety escalation (Category 1) is automatically classified as at minimum a moderate-severity AE and is reported to the EC within 72 hours, regardless of whether participant harm occurred.
- Any AI-AE resulting in actual or reasonably foreseeable participant harm — including physical harm, delayed medical care, psychological harm, or distress requiring intervention — is classified as a Serious Adverse Event (SAE) and reported to the EC within 24 hours and to the sponsor within 48 hours, in line with the SAE process in Section 16.2.
- AI-AEs not meeting harm thresholds (e.g., minor breaches of scope, minor language-matching failures) are logged for quality improvement and summarised in the final study report.

Corrective action

Where an AI-AE indicates a systemic weakness in the agent's behaviour (for example, a recurring failure to recognise a specific red-flag phrase), the study team will implement a corrective and preventive action (CAPA) involving (i) updates to the deterministic safety triggers and/or system prompt, (ii) re-testing against a held-out evaluation set, and (iii) EC notification of the change. Substantive changes to the agent that materially alter its behaviour will be classified as protocol amendments and managed under Section 17.

Participant safeguards

All experimental arm participants will be informed during the informed consent process that the WhatsApp-delivered programme includes an AI conversational agent, that the agent does not provide medical advice, and that any symptoms or concerns requiring clinical attention should be reported to the study CHW directly using the contact number provided at fitting. The contact number for the study CHW will be sent to every experimental arm participant by the AI agent at the start of the intervention period and will be reinforced within the structured push content.

16.6 Adverse event reporting

All AEs will be recorded on the AE/SAE form and will be added to the participant's file.

The research team will review any AE within 48–72 hours and decide whether any external parties, such as the device developers or Ethics Committee, need to be notified. All SAEs will be reported to EC within 24 hours, and sponsor notification will be made within 48 hours. All AEs will be characterized by the following criteria as set out in Table 5.

Table 5. Adverse Event criteria

Criteria	Grading
Severity	Mild
	Moderate
	Marked
	Severe
Relationship	Not related
	Definitely related
Action taken	None
	Study intervention modified
	Study intervention discontinued
	Subject withdrawal from study
	Hospitalization
	Other
Outcome	Resolved
	Ongoing
	Worsening
	Death
	Unknown

Expected	Yes
	No

16.7 Data and Safety Monitoring Board

Given the short duration of the intervention (five weeks), the use of a SAHPRA-registered clinically available hearing aid with a well-characterized safety profile, the low anticipated rate of serious adverse events, and the non-medication, non-invasive nature of the intervention, a formal Data and Safety Monitoring Board (DSMB) is not required for this trial. It is also used in the US as an OTC device. Safety oversight will be provided by the study's Co-Principal Investigators in consultation with the study audiology team, with adverse events reviewed by the research coordinator within 48–72 hours of report and SAEs notified to the EC within 24 hours and to the sponsor within 48 hours, in line with Section 16.6. Should the trial be expanded, the duration extended, or the device changed in a way that materially alters the risk profile, the need for a DSMB will be reconsidered as a protocol amendment.

17. Amendments and deviations to the protocol

A protocol deviation is described as an event where the investigator, research team member, or the site personnel did not conduct the study in accordance with the investigational protocol or agreement.

The clinical trial will be conducted in compliance with the SA GCP guidelines along with the applicable regulatory requirements. The sponsor should notify the regulatory authority and EC of any changes in the study protocol/documentation. If the sponsor intends to make changes after approval has been obtained, a re-application should be submitted to the relevant authority and EC, indicating the contents and grounds for change. Essential changes are such changes that can have an effect on the safety of the participants, influence the interpretation of results, or influence requirements assessed by the ECs.

Investigators, research team members, or site personnel need to obtain approval from the clinical study management team before deviating from the investigational protocol, except in an instance where it is necessary to protect the life or physical well-being of a participant in an emergency. All approvals need to be documented in writing and maintained in the study files. Prior approval is not expected in situations where there are unforeseen circumstances that are beyond the control of the investigator, research team, or site personnel.

17.1 Protocol deviations & study violations

Protocol Deviation: An accidental or unintentional change to, or non-compliance with, the research protocol that does not increase risk or decrease benefit or does not have a significant effect on the participants' safety or well-being; and/or the reliability of the study data.

Examples of possible protocol deviations may include:

- Inadequate record keeping: Incorrect and missing data captured during study assessments/evaluations.
- Incorrect participant enrollment: Enrolling a participant who did not meet the stipulated inclusion/exclusion criteria.

Study Violation: A change, divergence from the study design or procedures defined in the protocol that might significantly affect participants' safety, well-being, and/or the reliability of the study data.

Examples of possible study violations may include:

- Incorrect or missing study procedures: Conducting/ performing new procedures/ assessments/ evaluations not in line with the original approved clinical investigational protocol.
- Unreported AE/SAEs: Not reporting or documenting AE/SAEs that occur during the clinical investigational study, which can affect the safety of the study participants.

Reporting Requirements:

PIs/site coordinators and their teams must report (Appendix XIII) to the study sponsor any protocol deviations. This should, in turn, be documented and submitted to the EC for review. Study violations should be reported within 24 hours of the event.

Documentation and Storage:

All deviation reports and related documents will be kept in the SMF, and digital copies of it will be stored electronically on a cloud-based Google server with 2-factor authentication and strict access control.

Reporting:

Protocol deviations will also be documented in the final study report upon study conclusion.

Personnel Training:

Study personnel will receive pre-study communication training regarding deviation definitions and reporting timeframes to ensure accurate reporting. Training records will be kept for all personnel.

References:

Aazh, H., Deepak, P., Kiran, N., & and Moore, B. C. J. (2015). Hearing-aid use and its determinants in the UK National Health Service: A cross-sectional study at the Royal Surrey County Hospital. *International Journal of Audiology*, *54*(3), 152-161. https://doi.org/10.3109/14992027.2014.967367

Arlinger, S., Nordqvist, P., & Öberg, M. (2017). International Outcome Inventory for Hearing Aids: Data From a Large Swedish Quality Register Database. *Am J Audiol*, *26*(3s), 443-450. https://doi.org/10.1044/2017_aja-16-0123

Bisgaard, N., Zimmer, S., Laureyns, M., & Groth, J. (2021). A model for estimating hearing aid coverage world-wide using historical data on hearing aid sales. *International Journal of Audiology*, 1-9. https://doi.org/10.1080/14992027.2021.1962551

Chen, J., Shen, Y., Lin, Q., Feng, Y., & Li, H. (2025). Translation of Chinese version of the measure of audiologic rehabilitation self-efficacy for hearing aids and the self-efficacy among hearing aid users in China: Application of the questionnaire. *Plos One*, *20*(8), e0330163. https://doi.org/10.1371/journal.pone.0330163

Ferguson, M. A., Woolley, A., & Munro, K. J. (2016). The impact of self-efficacy, expectations, and readiness on hearing aid outcomes. *Int J Audiol*, *55 Suppl 3*, S34-41. https://doi.org/10.1080/14992027.2016.1177214

Frisby, C., Eikelboom, R. H., Mahomed-Asmail, F., Kuper, H., Moore, D. R., de Kock, T., Manchaiah, V., & Swanepoel, D. W. (2023). Mobile Health Hearing Aid Acclimatization and Support Program in Low-Income Communities: Feasibility Study. *JMIR Formative Research*, *7*(1), e46043. https://doi.org/10.2196/46043

Fuentes-López, E., Fuente, A., Valdivia, G., & Luna-Monsalve, M. (2019). Does educational level predict hearing aid self-efficacy in experienced older adult hearing aid users from Latin America? Validation process of the Spanish version of the MARS-HA questionnaire. *Plos One*, *14*(12), e0226085. https://doi.org/10.1371/journal.pone.0226085

Hall, D. A., Zaragoza Domingo, S., Hamdache, L. Z., Manchaiah, V., Thammaiah, S., Evans, C., Wong, L. L., Audiology, I. C. o. R., & NETwork, T. R. (2018). A good practice guide for translating and adapting hearing-related questionnaires for different languages and cultures. *International Journal of Audiology*, *57*(3), 161-175.

Johnson, C. E., Jilla, A. M., Danhauer, J. L., Sullivan, J. C., & Sanchez, K. R. (2018). Benefits from, Satisfaction with, and Self-Efficacy for Advanced Digital Hearing Aids in Users with Mild Sensorineural Hearing Loss. *Semin Hear*, *39*(2), 158-171. https://doi.org/10.1055/s-0038-1641742

Jorbonyan, A., Abolfathi Momtaz, Y., Foroughan, M., & Mehrkian, S. (2025). Translation, Cross-Cultural Adaptation, and Psychometric Properties of the Persian Version of the Measure of Audiologic Rehabilitation Self-Efficacy for Hearing Aids (P-MARS-HA). *Audiology Research*, *15*(2), 31. https://www.mdpi.com/2039-4349/15/2/31

Kelly-Campbell, R. J., & McMillan, A. (2015). The Relationship Between Hearing Aid Self-Efficacy and Hearing Aid Satisfaction. *Am J Audiol*, *24*(4), 529-535. https://doi.org/10.1044/2015_aja-15-0028

Mccabe, D. (2019). Hearing Screening in Older Adults. *Best Practices in Nursing Care to Older Adults*(12). https://hign.org/sites/default/files/2020-06/Try_This_General_Assessment_12.pdf

Meyer, C., Hickson, L., & Fletcher, A. (2014). Identifying the barriers and facilitators to optimal hearing aid self-efficacy. *Int J Audiol*, *53 Suppl 1*, S28-37. https://doi.org/10.3109/14992027.2013.832420

Mulwafu, W., Ensink, R., Kuper, H., & Fagan, J. (2017). Survey of ENT services in Sub Saharan Africa: Little Progress Between 2009 and 2015. *Global Health Action*, *10(1)*, 1289736–1289736. . https://doi.org/10.1080/16549716.2017.1289736

Smith, S. L., & Lea West, R. (2006). Hearing Aid Self-Efficacy of New and Experienced Hearing Aid Users. *Seminars in Hearing*, *27*(4), 325-329. https://doi.org/10.1055/s-2006-954860

Stephens, D. (2002). The International Outcome Inventory for Hearing Aids (IOI-HA) and its relationship to the Client-oriented Scale of Improvement (COSI). *Int J Audiol*, *41*(1), 42-47. https://doi.org/10.3109/14992020209101311

West, R. L., & Smith, S. L. (2007). Development of a hearing aid self-efficacy questionnaire. *Int J Audiol*, *46*(12), 759-771. https://doi.org/10.1080/14992020701545898

World Health Organization. (2021). *World Report on Hearing*. Available from: https://www.who.int/publications/i/item/world-report-on-hearing

World Health Organization. (2024). *Hearing aid service delivery approaches for low-and middle-income settings*. World Health Organization.

Cohen, J. (1988). Statistical power analysis for the behavioral sciences (2nd ed.). Lawrence Erlbaum Associates.

Faul, F., Erdfelder, E., Lang, A.-G., & Buchner, A. (2007). G*Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. Behavior Research Methods, 39, 175–191. https://doi.org/10.3758/BF03193146

Miola, A. C., & Miot, H. A. (2021). P-value and effect-size in clinical and experimental studies. Jornal Vascular Brasileiro, 20, Article e20210038. https://doi.org/10.1590/1677-5449.210038

Téllez, A., García, C. H., & Corral-Verdugo, V. (2015). Effect size, confidence intervals , and statistical power in psychological research. Psychology in Russia: State of the Art, 8(3), 27-46. https://doi.org/10.11621/pir.2015.0303

Wasserstein, R. L. (2019). Moving to a world beyond “p< 0.05”. The American Statistician, 73(Sup1), 1-19.