Investigating the impact of hearing aids on social participation in first-time adult hearing aid users: A 13-month longitudinal study

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Short title: New hearing aid users and their social participation

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SYNOPSIS

Title	Investigating the impact of hearing aids on social participation in first-time adult hearing aid users: A 13-month longitudinal study
Short title	New hearing aid users and their social participation
Chief Investigator	Dr Jack A Holman
Objectives	Does first-ever hearing aid fitting change social participation?
Study Configuration	Single centre
Setting	Hearing Sciences – Scottish Section, Glasgow Royal Infirmary
Number of participants	32
Eligibility criteria	• Aged 50 – 90 years of age • Awaiting first-ever use of hearing aids • Ability to understand spoken and written English and given informed consent
Description of interventions	A longitudinal study over 13 months Four face-to-face visits: **Pre-hearing aid fitting** • Informed Consent • Ear examination and hearing test • Demographic and hearing health questionnaire • x3 questionnaires (SPaRQ, RHHI, HEARLI-Q) • Semi-structured interview including SNA • EMA survey **3 weeks, 6months and 12 months post fitting** • x3 questionnaires (SPaRQ, RHHI, IOI-HA) • Semi-structured interview including SNA • EMA survey Two remote/online contact points: **3 months and 9 months post fitting**: • x2 questionnaires (HEARLI-Q and open text box responses)
Duration of study	Overall duration: 2 years Per participant – involvement is over 13 months.
Methods of analysis	Numerical data Repeated measures design – assessing changes in scores longitudinally in each participant and conducting linear mixed effects models to analyse changes from before to after hearing aid fitting within and between participants. Qualitative research

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	Reflexive thematic analysis (familiarisation with the data, creating initial codes, collating codes and grouping into themes)

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ABBREVIATIONS

CI Chief Investigator overall

EMA Ecological Momentary Assessment

GCP Good Clinical Practice

GCRF Glasgow Clinical Research Facility

HEARLI-Q Hearing-Related Lifestyle Questionnaire

IOI-HA International Outcome of Inventory for Hearing Aids

NHS National Health Service

PI Principal Investigator at a local centre

PIS Participant Information Sheet

REC Research Ethics Committee

RHHI Revised Hearing Handicap Inventory

R&D Research and Development department

SNA Social Network Analysis

SPaRQ Social Participation Restriction Questionnaire

UoN University of Nottingham

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STUDY BACKGROUND INFORMATION AND RATIONALE

Social participation is strongly associated with quality of life, psychological wellbeing and healthy ageing (Fu et al., 2021). Healthy ageing allows people to continue to participate and play a central role in families and communities which in turn can strengthen society. If the later stages of life are overshadowed by poor health or social isolation, the implications for older people and for society are much more negative (World Health Organization (WHO), 2020).

Hearing loss can affect people in various ways depending on when the hearing loss develops in a person's lifetime, the cause of the hearing loss, the progression and severity of the hearing loss over time, and the extent to which assistive technology (e.g. hearing aids and implants) can improve hearing ability. Hearing loss can place differing demands on an individual's communication and social interactions - varying greatly depending on the roles and status of the people involved and the social context, whether the situation be a formal meeting versus a casual chat, in a 1-1 conversation, group settings, or larger public gatherings (Motala et al., 2024; Shukla et al., 2021). Hearing loss is prevalent in the elderly population, with potentially negative outcomes for aging (Silveira et al., 2024). It can also lead to behavioural changes (Bott & Saunders, 2021) and impact social participation, personal relationships and emotional wellbeing (Bennett et al., 2022). A person with hearing loss may not engage in social situations in the same way as they used to, or as a normally hearing person can, and they may experience strained relationships or reduced social participation as a result (Motala et al., 2024).

Choi (2023) reported that midlife and older adults with self-reported hearing impairment were more likely to experience social participation restrictions, with a stronger association in the midlife adult group. Social participation restriction was investigated using two questions asking about the difficulty (on a scale of 1 (no difficulty) to 4 (unable to do)) a respondent had, without using any special equipment, in (1) going out to things like shopping, movies, or sporting events, and (2) participating in social activities such as visiting friends, attending clubs/meetings, or going to parties. On the other hand, Yamada et al. (2012) found no association between self-reported hearing loss and social participation in a large cohort of people aged ≥ 65 years who were reviewed annually in a longitudinal study over three years. In Yamada's study social participation was measured in terms of reported engagement in visiting friends, giving advice to family or friends, visiting friends or family in the hospital, and initiating conversations with young people; any reduction from baseline scoring was deemed as a decline.

Hearing interventions, such as hearing-aid provision, have the potential to mitigate negative health impacts of hearing loss by ensuring adequate audibility to facilitate social interaction and thus encourage people with hearing loss to connect socially (Bott & Saunders, 2021). Holman et al. (2021) showed an increase in social activity level and reduced social participation restriction over a 6-month period after first hearing aid fitting. A large population-based cohort study noted that individuals with hearing loss who reported using hearing aids were more likely to participate in leisure activities than participants with hearing loss who did not use hearing aids (Fisher et al., 2015). By contrast, other studies have shown that social participation was not significantly associated with hearing aid use in adults (Fuentes-Lopez et al., 2017; Sawyer et al., 2019).

These contradictory findings are likely related to differences in methodologies and measures used to capture differing aspects of social participation. For example, assessing levels of activity by asking about relatively formal settings only versus questions specific to informal leisure activities. The lack of a clear definition may have contributed to the array of measures used, and the apparently inconsistent results.

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This study will explore the effect of hearing aid fitting on an individual's social participation - in a mixed-methods longitudinal designed study.

The study seeks to capture an in-depth picture of the social participation of individuals and will examine how first-ever hearing aids effect social participation in the first 12-13 months. This will give us a greater understanding of the ways we can comprehensively measure the social participation of individuals, look at interpersonal differences and understand the extent to which hearing loss and hearing aid fitting influence social participation. Having a better understanding may help how we support people who face challenges or dissatisfaction with their social participation and in assessing how interventions (such as hearing aids) may improve a person's social participation.

STUDY OBJECTIVES AND PURPOSE

PURPOSE

Does first-ever hearing aid fitting change social participation?

Using a mixed methods approach made up of audiological assessments (hearing test and examination of the ear canal and eardrum), questionnaires, semi-structured interview and surveys, the study aims to gain a comprehensive and in-depth understanding of the experiences (in the first 12-13 months) of initial hearing aid users in relation to their social participation.

PRIMARY OBJECTIVE

The primary outcome measures will be to compare scores on the ecological momentary assessment (EMA) ratings of social engagement and experience for social participation situations over the course of a participant's 13-month involvement in the study.

Differences in an individual's social networks analysis (SNA) will be examined in this longitudinal study to see if there are changes in social structure over time. This will involve looking at the network size, number of connections related to activities someone does, how they feel about the social connections and the support they get from their social network.

SECONDARY OBJECTIVES

Assessing longitudinal changes in:

- International Outcome Inventory for Hearing Aids (IOI-HA) questionnaire - effectiveness of hearing aid(s).
- Revised Hearing Handicap Inventory (RHHI) - emotional and social impacts of hearing loss.
- Social Participation Restrictions Questionnaire (SPaRQ) - how hearing limits social life
- The Hearing-Related Lifestyle Questionnaire (HEARLI-Q) - the influence of hearing ability in everyday listening situations.

Qualitative outcome measures - investigating the semi-structured interview and open text box response answers over the longitudinal study to explore personal perspectives, motivations and responses to questions related to social participation difficulties and avoidance, using reflexive thematic analysis.

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STUDY DESIGN

STUDY CONFIGURATION

A single-centre, longitudinal designed study over 13-months in first-ever adult hearing aid users, using a mixed methods approach with audiological assessments (hearing test and examination of the ear canal and eardrum), questionnaires, semi-structured interviews and smart-phone surveys.

STUDY MANAGEMENT

The study will be managed from the Hearing Sciences – Scottish Section. Project management will be responsibility of Lindsey Steele (co-investigator and PhD Student). Lindsey will be responsible for data collection (participant visits – performing hearing tests, distributing questionnaires, conducting interviews), data analysis and interpretation, and reporting and dissemination.

The Chief Investigator has overall responsibility for the study and shall oversee all study management.

The data custodian will be the Chief Investigator.

DURATION OF THE STUDY AND PARTICIPANT INVOLVEMENT

Study Duration: Study enrolment will run for 6 months with end date on last visit last participant (on their 12-month post hearing aid fitting face-to-face visit to the department). The total duration of the entire study will be 18 months.

Participant Duration: Each participant will be involved for 13 months approximately with visits to the department prior to hearing aid fitting, 3 weeks, 6 months and 12 months post hearing aid fitting. In addition, remote/online contact with participants will be made at 3 and 9 months post hearing aid fitting.

End of the Study

The end of the study will be the last visit of the last participant.

SELECTION AND WITHDRAWAL OF PARTICIPANTS

Recruitment

The study visits will take place within the University of Nottingham research department, based in Glasgow (Hearing Sciences – Scottish Section, New Lister Building level 3, Glasgow Royal Infirmary).

Participants will be recruited from NHS Greater Glasgow and Clyde audiology departments. The initial identification will be made by a member of the patient's usual care team (NHS audiology staff). Firstly, the audiology care team will ask the patient to provide consent for their contact details to be shared with the NHS Glasgow Clinical Research Facility (GCRF) so that a letter of invitation can be sent to prospective participants. The audiology care team will share the potential participants contact details via secure email transfer with GCRF and GCRF will then dispose of the electronic records containing the patient contact details (using approved data deletion methods) once they have carried out the administrative task of sending post to potential participants. The administrative task of packaging and posting the letter of invitation and PIS will be undertaken by the GCRF, who are an established research unit specifically designed to facilitate and support research within the NHS. This arrangement has been discussed with the NHS audiology manager as the least burdensome

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approach for audiology staff (when they are dealing with the demands of their day-to-day roles). Information about the study will also be on display (poster and flyer format) in the relevant clinical areas and hospital atrium/waiting areas for potential participants to contact the Hearing Sciences- Scottish Section directly.

If a potential participant consents to their contact information being shared with the GCRF, then receives the letter of invitation and PIS and would be interested in taking part in the study, they can contact the Hearing Sciences- Scottish Section for further information (vie email, phone or post). At this point the investigator team at Hearing Sciences – Scottish Section will inform the participant of all aspects pertaining to participation in the study.

All the information is only available in English and participants need to have sufficient command of English to be eligible for the study. People who are not fluent in English or who need an interpreter or translator service will not be selected to be part of the study as all questionnaires are in English. In addition, there is a need to maintain high quality understanding of the study topic, and this may not be guaranteed via interpreter-mediated interviews, in addition to the questionnaires only being validated in English language.

It will be explained to the potential participant that entry into the study is entirely voluntary and that their treatment and care will not be affected by their decision. It will also be explained that they can withdraw at any time but attempts will be made to avoid this occurrence. In the event of their withdrawal it will be explained that their data collected so far cannot be erased and we will seek consent to use the data in the final analyses where appropriate.

Eligibility criteria

Inclusion criteria

- Adults aged 50 - 90 years (inclusive).
- Ability to give informed consent.
- Presence of a hearing loss (with a 4-frequency average (0.5-4kHz) of hearing thresholds greater than 25 dB HL in their better hearing ear).
- Awaiting first ever fitting of hearing aid(s).
- Available for the study visits over 13 months (e.g. not expected to be moving out of the local area).
- Sufficient command of English to read, understand and complete questionnaires

Exclusion criteria

- Ear pathologies - acute or chronic middle ear diseases.
- Troublesome tinnitus.
- Fluctuating hearing loss.

Expected duration of participant participation

Study participants will be participating in the study over 13 months (involving four 1.5-2 hour face-to-face visits and two 10-minute remote/online contact points).

Participant Withdrawal

Participants may be withdrawn from the study either at their own request or at the discretion of the Investigator. The participants will be made aware that this will not affect their future care.

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Participants will be made aware (via the information sheet and consent form) that should they withdraw the data collected to date cannot be erased and may still be used in the final analysis.

Informed consent

All participants will provide written informed consent. The Informed Consent Form will be signed and dated by the participant before they enter the study. The Investigator will explain the details of the trial and provide a Participant Information Sheet, ensuring that the participant has sufficient time to consider participating or not. The Investigator will answer any questions that the participant has concerning study participation.

Informed consent will be collected from each participant before they undergo any interventions (including ear examination, hearing test and history taking) related to the study. One copy of this will be kept by the participant and one will be kept by the Investigator. The University of Nottingham research team will not have any access to participants' medical records and therefore no copy of the consent form will be placed in the patient's hospital records.

Should there be any subsequent amendment to the final protocol, which might affect a participant's participation in the trial, continuing consent will be obtained using an amended Consent form which will be signed by the participant.

Completion and subsequent return of questionnaires will be taken as informed consent and separate written informed consent will not be sought.

STUDY REGIMEN

Once a potential participant has contacted Hearing Sciences – Scottish Section and wishes to proceed with involvement in the study they will come for an initial visit at the pre-hearing aid fitting stage.

Participants will have x4 face to face visits over 13 months - prior to first hearing aid fitting, 3 weeks post fitting, 6 months post fitting and at 12 months post fitting of first hearing aid(s). All visits will take place at the Hearing Sciences - Scottish Section department (New Lister Building, within Glasgow Royal Infirmary).

Four face-to-face visits:

Pre-hearing aid fitting – 2 hours

- Informed Consent – opportunity to ask questions and go through the PIS.
- Ear examination and hearing test - using otoscopy and basic pure tone audiometry to measure the quietest sounds someone can hear. Audiological assessment equipment is owned by the University of Nottingham. Equipment is CE marked, used within its licenced indication, annually serviced and calibrated in line with the British Society of Audiology Guidance Documents.

  NOTE: NHS Greater Glasgow and Clyde are a participant identification centre only. The University of Nottingham research staff will not have any access to any medical records or historic audiological test results. Consequently, a hearing test (basic pure tone audiometry) and ear examination (otoscopy) will be completed as part of the study protocol. If any concerning or abnormal findings are identified during the testing, we will ask the participant to contact their local audiology care provider for further review and investigation. Participants will already have had a hearing test as part of their routine NHS audiology care pathway (in the process of being selected as

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potential participant for this study), hence it is unlikely that abnormal findings would be identified at this stage.

- Demographic and hearing health questionnaire – to get some background/basic health information about participants.
- x3 questionnaires (SPaRQ, RHHI, HEARLI-Q).
- Semi-structured interview including SNA.
- EMA survey – smartphone-based surveys sent daily over 7 days asking about an individual's social participation experiences and level of engagement.

3 weeks, 6months and 12 months post fitting – 1 hour 30 mins

- x3 questionnaires (SPaRQ, RHHI, IOI-HA)
- Semi-structured interview including SNA.
- EMA survey.

Two remote/online contact points (each lasting 10 minutes)
3 months and 9 months post fitting:

- x2 questionnaires (HEARLI-Q and open text box responses)

The following questionnaires will be used in the study:

- Revised Hearing Handicap Inventory (RHHI) - emotional and social impacts of hearing loss.
- Social Participation Restrictions Questionnaire (SpaRQ) - how hearing limits social life
- The Hearing-Related Lifestyle Questionnaire (HEARLI-Q) - the influence of hearing ability in everyday listening situations.
- International Outcome Inventory for Hearing Aids (IOI-HA) questionnaire - effectiveness of hearing aid(s).

All semi-structured interviews will last no longer than 20 minutes. They will be audiotaped (using a USB yeti microphone and the software Audacity, which is fully compliant with GDPR) and transcribed verbatim using Whisper AI (which is run entirely on the local University of Nottingham private server). Personal identifiers will be removed. In line with ICH/GCP guidelines, regulations and in accordance with the University of Nottingham Code of
Research Conduct and Research Ethics, the Chief Investigator will maintain the recordings (. The interview will include social network analysis (SNA) - a structured method to map relationships by asking participants about their connections and interactions. In addition, participants will be set up with a series of smartphone-based surveys for seven days, called ecological momentary assessment (EMA). The EMA surveys will be presented, either on the participants phone or on a loaned smartphone (provided by the department), via a free app which will be downloaded to the phone. A loaned phone can be provided, if required, which will have features disabled (no call or data allowance) apart from the EMA app. Instructions relating to phone usage will be provided (e.g. on/off, silence function). A phone charger and safety timer plug will also be provided for the duration of the study. At the end of the study, the research team will arrange for the collection and return of the loaned phone and charging equipment. This will be at the convenience of the participant (in person or arrange for postage).

Information about the smartphone application:

- How are the apps accessed? Are they commercially available?

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The smartphone application ‘RealLife Exp’ is manufactured by LifeData. It is a free commercially available app and can be downloaded to a smartphone. A set of survey questions specific to the research project are downloaded, which is created by the research team at Hearing Sciences – Scottish Section, University of Nottingham.

- Do participants have to use the app?

Yes – participants will be asked to respond to questions relating to their opinion and experience of social participation. Questions will be sent three times a day over the course of one week (at four different time points over 13 months) - using rating/scaling questions (e.g. very negative to very positive), multiple choice and open text (for you to type their own thoughts, feelings and explanation). Each set of questions will not take more than 5 minutes to complete, and you are only to respond to the surveys if it is safe to do so (e.g. not when driving).

- What data is collected and what personal data is being used?

The responses to study survey questions are collected. A participant will enter a unique study identification number. No personal identifiable data will pass through the app.

- How is the app data kept secure and is data stored on secure UK servers?

The data (prompts and responses) is owned by the Hearing Sciences – Scottish Section, University of Nottingham. LifeData keeps the content private and acts as a temporary steward of the data. The company (LifeData) is based in the USA but is GDPR compliant and complies with the UK Extension to the EU-US Data Privacy Framework. The researchers will have access to the raw data via a password protected account. Data is stored on servers located in the United States. The participant response data is downloaded from LifeData, via a password protected account, and saved onto secure local University of Nottingham servers.

- What happens to the data at the end of the study?

All data on LifeData is deleted and LifeData have no residual access to this data. In compliance with ICH/GCP guidelines, regulations and in accordance with the University of Nottingham Code of Research Conduct and Research Ethics, the Chief Investigator will maintain all records and documents regarding the conduct of the study. These will be retained for 7 years.

There will be a short start-up survey to complete (explaining what the participant is to expect with the EMA surveys). Over the next seven days the participant will be asked to respond to 3 short surveys per day. Each survey should take no longer than 5 minutes to answer. Surveys will ask participants to reflect on the day they are having in relation to their social participation situations and experiences with the hearing aids in these environments. At the end of the seven days participants will receive an end of study notification on the phone.

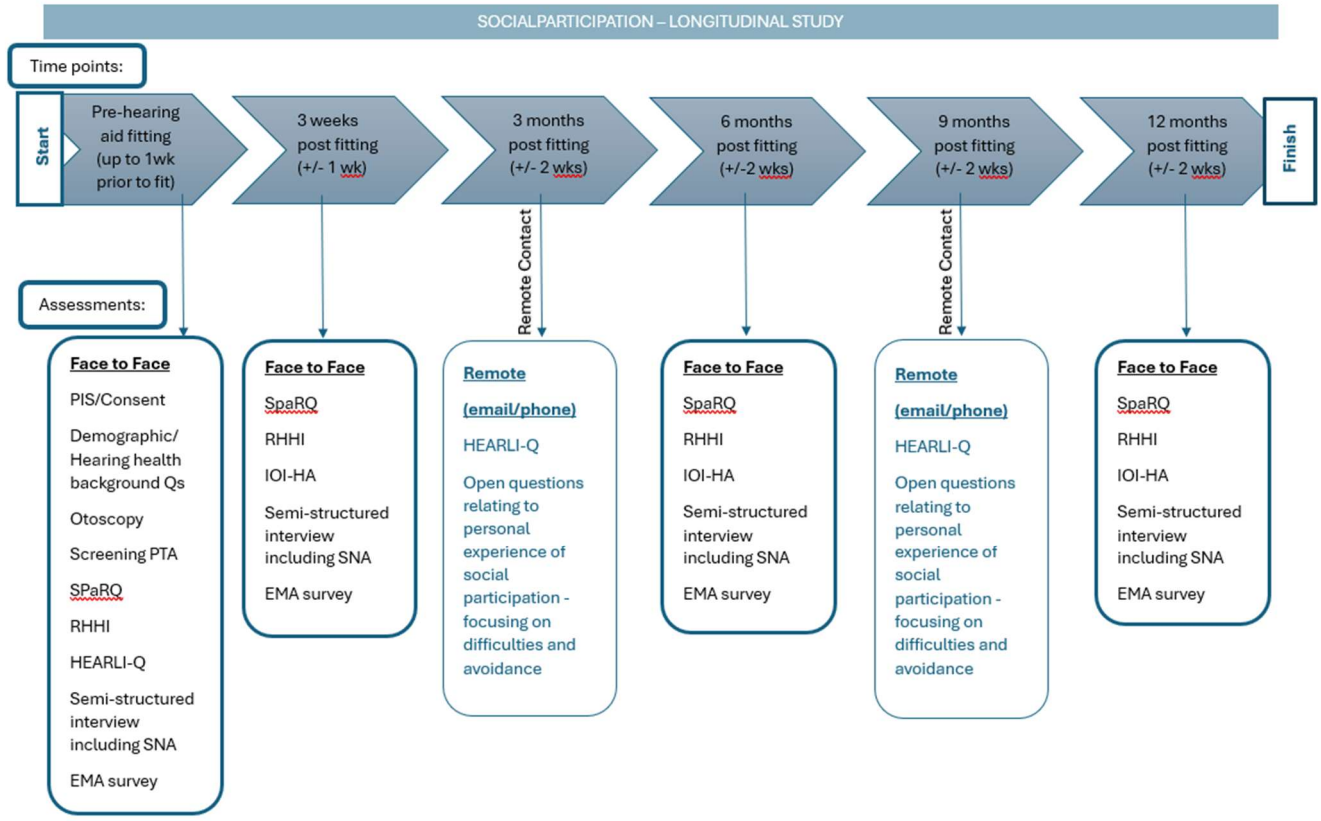
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Participants will be contacted by phone or email (according to personal preference) by the PhD student after the initial hearing aid fitting to arrange future visits - at 3 weeks, 6 months and 12 months. These follow up visits will take less time, compared to the initial visit.

There will be x2 additional non face-to-face contact points at 3 and 9 months post fitting. These will be completed via email or phone (depending on personal preference) and comprise 1 questionnaire - the hearing-related lifestyle questionnaire, and a few short open text box response questions related to personal experience of social participation (focusing on any difficulties or avoidance). These 'visits' will last up to 10 minutes and are necessary to touch base with participants and encourage participant retainment in the study for the duration of the 12 months post hearing aid fitting.

If a participant, over the course of the longitudinal study, stops using their hearing aid(s), we would still want them to continue with the scheduled visits/time points.

Schematic Timeline:



Compliance

Participant retention for a longitudinal study may potentially be an issue however this will be addressed by arranging study times that are convenient for individuals and study visits will be limited in duration (approximately 2 hours for first visit and 1h 30 mins at the x3 follow up visit) to reduce burden. Shorter 'touch base' contact will also be made with participants at 3 and 9 months to help encourage participant retention.

If one of the face-to-face visits is missed at 3 weeks, 6 months or 12 months post hearing aid fitting then all data collected (outside the missed visit) will be used for analysis purposes. The remote/online contact points at 3 and 9 months will be helpful to ensure retention but again if missed – all data acquired bar the missed visits will be included in analysis. The smartphone surveys (EMA) will be reviewed for quality of data/submissions and if a participant has not

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completed or missed excessive surveys we will discuss with the participant in the first instance and consider sending a repeat, if they are happy to proceed with study participation.

Criteria for terminating the study

If there are issues with study conduct (e.g. poor recruitment, attrition of participants), then this could lead to termination of the study. Any data collected will be utilised for analyse and archived accordingly, with retention for 7 years.

ANALYSES

Methods

The quantitative data generated by the study will be analysed by the investigators within the Hearing Science - Scottish Section on a University of Nottingham computer using Microsoft Excel and appropriate statistical software (R). This will involve - assessing the changes in scores longitudinally in each participant via descriptive statistics (looking at the distribution of scoring in the questionnaire scores at different time points) and conducting linear mixed effects models to analyse changes from before to after hearing aid fitting within and between participants.

Qualitative data (transcriptions of the audio recordings from the interviews) will be analysed using the software Nvivo. Reflexive thematic analysis will be used. This involves familiarisation with data, creating initial codes, collating codes (adjusting/revising) and grouping codes into themes. This is an iterative process of evaluation and revision, involving all investigators.

Analysis will take place on password protected university computers (backed up to the University of Nottingham servers). The server is physically hosted in the Hearing Sciences department.

Sample size and justification

There is no existing data from mixed-method longitudinal studies of people with hearing loss using EMA or SNA that would directly inform our sample size calculation. However, we are able to conduct a sample size calculation using questionnaires common to the proposed study and previous studies. A published 6-month longitudinal study of people with hearing loss before and after first-ever hearing aid fitting (Holman, Drummond and Naylor et al. 2021) utilised the Social Participation Restrictions Questionnaire (SPaRQ) and Hearing Handicap Inventory for the Elderly (from which the RHHI is composed). The effect sizes of the variables were 0.9 for the hearing handicap inventory and 0.7 and 0.6 for the two subscales of the SPaRQ. Using the smallest effect size (0.6), a power of 80% and alpha error of 0.05 for paired samples t-test results in a sample of 26 participants.

Allowing for potential drop out, particularly given the demands of a longitudinal study, we have set planned recruitment to 32 participants.

ADVERSE EVENTS

The occurrence of an adverse event as a result of participation within this study is not expected and no adverse event data will be collected.

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ETHICAL AND REGULATORY ASPECTS

None of the study activities are known to be associated with adverse events or adverse reactions.

The study is a longitudinal design so there is the concern for the potential attrition and loss of participants over the duration of the study. This will be managed by offering flexible and convenient times to visit the department. The brief contact at the 3-month and 9-month stages will be less burdensome (not face-to-face) and will help to maintain participant engagement and foster a positive relationship with participants

There is the possibility that participants assume the proposed study is related to their ongoing NHS medical treatment as it ties in with the timing of their hearing aid fitting. This is combated by clearly stating in the invitation and information sheet that the study is not related to, and will not affect, their ongoing medical treatment. This will be reiterated during regular study communications.

ETHICS COMMITTEE AND REGULATORY APPROVALS

The study will not be initiated before the protocol, consent forms and participant information sheets have received approval / favourable opinion from the Research Ethics Committee (REC), the respective National Health Service (NHS) or other healthcare provider's Research & Development (R&D) department, and the Health Research Authority (HRA) if required. Should a protocol amendment be made that requires REC approval, the changes in the protocol will not be instituted until the amendment and revised informed consent forms and participant information sheets (if appropriate) have been reviewed and received approval / favourable opinion from the REC and R&D departments. A protocol amendment intended to eliminate an apparent immediate hazard to participants may be implemented immediately providing that the REC are notified as soon as possible and an approval is requested. Minor protocol amendments only for logistical or administrative changes may be implemented immediately; and the REC will be informed.

The study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice and the UK Department of Health Policy Framework for Health and Social Care, 2017.

INFORMED CONSENT AND PARTICIPANT INFORMATION

The process for obtaining participant informed consent will be in accordance with the REC guidance, and Good Clinical Practice (GCP) and any other regulatory requirements that might be introduced. The investigator and the participant shall both sign and date the Consent Form before the person can participate in the study.

The participant will receive a copy of the signed and dated forms and the original will be retained in the Study records.

The decision regarding participation in the study is entirely voluntary. The investigator or their nominee shall emphasize to them that consent regarding study participation may be withdrawn at any time without penalty or affecting the quality or quantity of their future medical care, or loss of benefits to which the participant is otherwise entitled. No study-specific interventions will be done before informed consent has been obtained.

The investigator will inform the participant of any relevant information that becomes available during the course of the study, and will discuss with them, whether they wish to continue with the study. If applicable they will be asked to sign revised consent forms.

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If the Consent Form is amended during the study, the investigator shall follow all applicable regulatory requirements pertaining to approval of the amended Consent Form by the REC and use of the amended form (including for ongoing participants).

Completion and subsequent return of questionnaires will be taken as informed consent and separate written informed consent will not be sought

RECORDS

Study Forms

Each participant will be assigned a unique study identity code number, for use on study forms, other study documents and in the electronic database. The electronic database will also contain identifiers - a participant's name, contact details and date of birth (dd/mm/yy).

Study forms will be treated as confidential documents and held securely in accordance with regulations. The investigator will have a separate confidential record (on the electronic database) of the participant's name, date of birth and Participant Study Number, to permit identification of all participants enrolled in the study, in case additional follow-up is required.
Study forms shall be restricted to those personnel approved by the Chief or local Investigator and recorded as such in the study records.

All paper forms shall be filled in using black ballpoint pen. Errors shall be lined out but not obliterated by using correction fluid and the correction inserted, initialled and dated.
The Chief or local Investigator shall sign a declaration ensuring accuracy of data recorded in the study forms.

Source documents

Source documents shall be filed at the investigator's site and may include but are not limited to, consent forms, study records, field notes, interview transcriptions and audio records. A study form may also completely serve as its own source data. Only study staff shall have access to study documentation other than the regulatory requirements listed below.

Direct access to source data / documents

The study forms and all source documents shall made be available at all times for review by the Chief Investigator, Sponsor's designee and inspection by relevant regulatory authorities.

DATA PROTECTION

All study staff and investigators will endeavour to protect the rights of the study's participants to privacy and informed consent, and will adhere to the Data Protection Act, 2018. The study forms will only collect the minimum required information for the purposes of the study. Study forms will be held securely, in a locked room, or locked cupboard or cabinet. Access to the information will be limited to the study staff and investigators and any relevant regulatory authorities (see above). Computer held data including the study database will be held securely and password protected. All data will be stored on a secure dedicated web server. Access will be restricted by user identifiers and passwords (encrypted using a one-way encryption method).

Information about the study in the participant's medical records / hospital notes will be treated confidentially in the same way as all other confidential medical information.

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Electronic data will be backed up every 24 hours to both local and remote media in encrypted format.

QUALITY ASSURANCE & AUDIT

INSURANCE AND INDEMNITY

Insurance and indemnity for clinical study participants and study staff is covered within the NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of HSG (96)48. There are no special compensation arrangements, but study participants may have recourse through the NHS complaints procedures.

The University of Nottingham as research Sponsor indemnifies its staff with both public liability insurance and clinical trials insurance in respect of claims made by research subjects.

STUDY CONDUCT

Study conduct may be subject to systems audit for inclusion of essential documents; permissions to conduct the study; CVs of study staff and training received; local document control procedures; consent procedures and recruitment logs; adherence to procedures defined in the protocol (e.g. inclusion / exclusion criteria, timeliness of visits); accountability of study materials and equipment calibration logs. The Study Coordinator/Academic Supervisor, or where required, a nominated designee of the Sponsor, shall carry out a site systems audit at least yearly and an audit report shall be made.

STUDY DATA

Monitoring of study data shall include confirmation of informed consent; source data verification; data storage and data transfer procedures; local quality control checks and procedures, back-up and disaster recovery of any local databases and validation of data manipulation. The Study Coordinator/Academic Supervisor, or where required, a nominated designee of the Sponsor, shall carry out monitoring of study data as an ongoing activity.

Entries on study forms will be verified by inspection against the source data. A sample of study forms (10% or as per the study risk assessment) will be checked on a regular basis for verification of all entries made. In addition, the subsequent capture of the data on the study database will be checked. Where corrections are required these will carry a full audit trail and justification.

Study data and evidence of monitoring and systems audits will be made available for inspection by the REC as required.

RECORD RETENTION AND ARCHIVING

In compliance with the ICH/GCP guidelines, regulations and in accordance with the University of Nottingham Code of Research Conduct and Research Ethics, the Chief or local Principal Investigator will maintain all records and documents regarding the conduct of the study. These will be retained for at least 7 years or for longer if required. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility.

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The study documents held by the Chief Investigator on behalf of the Sponsor shall be finally archived at secure archive facilities at the University of Nottingham. This archive shall include all anonymised audio recordings, study databases and associated meta-data encryption codes.

DISCONTINUATION OF THE STUDY BY THE SPONSOR

The Sponsor reserves the right to discontinue this study at any time for failure to meet expected enrolment goals, for safety or any other administrative reasons. The Sponsor shall take advice as appropriate in making this decision.

STATEMENT OF CONFIDENTIALITY

Individual participant medical or personal information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted above.

Participant confidentiality will be further ensured by utilising identification code numbers to correspond to treatment data in the computer files.

Such medical information may be given to the participant's medical team and all appropriate medical personnel responsible for the participant's welfare.

If information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly.

Data generated as a result of this study will be available for inspection on request by the participating physicians, the University of Nottingham representatives, the REC, local R&D Departments and the regulatory authorities.

PUBLICATION AND DISSEMINATION POLICY

Following data collection and analysis the results of the study will be reported as part of a PhD thesis. Dissemination will be done within 12 months of study completion - in peer reviewed scientific journals, conference presentations, public engagement events, newsletters and social media. Participants will not be identified in any publications.

USER AND PUBLIC INVOLVEMENT

A patient and public involvement panel were presented with the plans for elements of the methodology (EMA – smart phone surveys) and gave their feedback. The feedback was taken into consideration and the schedule of questions adapted accordingly to create a workable and satisfactory format. The PIS, recruitment poster/flyer and letter of invitation have been sent to individuals in the patient and public involvement group for their feedback (in email communication).

STUDY FINANCES

Funding source

This study is funded by WS Audiology (as part of a 4-year PhD studentship).

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Participant stipends and payments

Participants will be paid an inconvenience allowance of £100. This is made up of £20 for every face-to-face visit to the department (x4 occasions) and £10 for the remote (online) contact points (x2 occasions). This money will be provided in cash or via a shopping gift voucher (depending on participant preference). Travel expenses will be offered for visits to the department (capped at £5 per visit).

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SIGNATURE PAGES

Signatories to Protocol:

Chief Investigator: Dr Jack Holman

Date: 15/Jul/2026

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