Hearing Loss and Patient Reported Experience (HELP): Using patient experience to improve audiology services

SPONSOR - University Hospitals Bristol and Weston NHS Foundation Trust

Research reference numbers

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This protocol has regard for the HRA guidance and order of content

Signature page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.
I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor
I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: Date:
..../...../.....

Name (please print):
.....

Position:
.....

Chief Investigator:

Signature: Date:
..../...../.....

Name: (please print):

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Funder(s)	NIHR HSDR funding stream REF NIHR131597

Key Protocol Contributors				
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Ms Melanie Ward (Co-Applicant)	Head of Service	Leading clinical site through all phases of the research	Hearing Therapy and Audiology department	Virgin Care and Health
Dr Rosemary Greenwood (Co-Applicant)	Medical Statistician	Provide steering on statistical methods	Research Design Service	University Hospitals Bristol and Weston NHS FoundationTrust
Dr Sian Noble (Co-Applicant)	Senior Lecturer in Health Economics	Provide steering in health economic methods	Bristol Medical School	University of Bristol
Dr Rachel Shaw (Co-Applicant)	Reader in Health Psychology	oversight qualitativemethods	Psychology	Aston University
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STUDY SUMMARY

Aims: We aim to improve knowledge of patient experience of hearing loss. People with hearing loss have to adapt communication and navigate hearing services (audiology). We have designed a way to show whether the services are working well for their patients.

Background: In hearing services, most people with hearing loss are given hearing aids, but 40% of these are not used. People stop using hearing aids because they find practical management and adapting to new sound hard. For some, managing the aids is more difficult than managing hearing loss without hearing aids. Hearing loss affects every aspect of communication and daily life but nearly half are getting no useful help. There are other services (e.g. Hearing Therapy) that could be offered to these people, but some parts of the country do not pay for those services.

Patient Reported Experience Measures (PREMs) are simple questionnaires about specific conditions and could be used to show whether audiology helps or not. We need this because the UK has different ways to provide services for hearing loss, from hospitals though to SpecSavers. We need to use the PREM to ensure that everyone gets the services they need which may prevent the fitting of aids that are not going to be used.

Design: To create the PREM, first we will talk to people with hearing loss who do and do not seek help from hearing services. We will recruit them from clinical sites and voluntary groups across the country. We will explore common issues and problems of coping with hearing loss and efforts to manage hearing aids, helped by our patient advisors. This information will lead us to produce a questionnaire. We will ask people who work in hearing services and patient groups to help with how the questionnaire reads and looks by telling us what they understand by each question. We will then ask a larger number of people to fill it in, compare it with other questionnaires and see if it is different for people who have had different types of NHS support with their hearing loss. Finally, we will see how the PREM works in a hearing clinic. By talking to audiology staff, we can find out whether this could be used in day-to-day practice. It can tell us about useful changes to the way services are delivered e.g. services at care homes, rather than clinics.

We will refer to groups of patient advisors for this project. These groups cover different age groups as

they have quite different issues with wearing hearing aids. Additionally, we will use four further groups to advise from the perspective of overlooked communities e.g. South Asian groups, Learning disability groups and residents in care homes. These groups will support our research by advising on recruitment, interview questions, understanding of our findings and how best to manage the project.

Dissemination: We will produce newsletters and publish them in Action on Hearing loss magazines as well as reporting on social media to engage with the community. We will also report findings at local and regional meetings and conferences and feed our findings into undergraduate and postgraduate audiology training. We will make the tool available for services to access and use in routine care and provide any necessary training and support. In the long term we hope to use this to show the services are better at identifying and providing the right help to different types of people.

Study Title	**Hearing Loss and Patient Reported Experience (HELP):** **Using patient experience to improve audiology**
Internal ref. no. (or short title)	**HELP DT/2021/7154**
Study Design	We propose three linked studies. Firstly, to develop a clear conceptual framework to describe the trade-offs and efforts required coping with hearing loss with and without hearing services support. Secondly, to develop a Patient Reported Experience Measure (PREM) to complement existing outcome measures in practice. Finally, to assess whether a measure would be taken up and used by services and whether it would help services decipher how they could adjust to meet patient needs.
Study Participants	Participants will include any people who have hearing loss, whether corrected by hearing aids or receiving support from hearing services or not.
Planned Size of Sample (if applicable)	WP1: n= 32 patients and 12 carer/family members WP2: n= 300 participants for validity testing; 10 for think aloud analysis WP3: n= 10-15 staff; 10 patients
Follow up duration (if applicable)	n/a
Planned Study Period	We propose three-years to complete all studies. This includes milestones of developing a theoretical model of the work involved in managing hearing loss and audiological interventions by month 16; developing the PREM tool (development completed by month 28); planning the implementation by month

	27 and evaluating the PREM in clinical practice for the last 10 months.
Research Question/Aim(s)	We aim to understand the features of the work of living with hearing loss ('illness work') and the work of accessing & living with hearing aids ('treatment work'). This knowledge will enable us to develop a tool to capture patient work. In doing so we can inform services about what is particularly challenging about using their services & treatments. This will lead to changes in how services are delivered, which means they support their patients' needs better.

SUMMARY OF RESEARCH

Aims and Objectives:

We aim to improve understanding of the patient work required in managing both hearing loss and uptake of audiology services. We will:

a) Establish a clear conceptual understanding of patient experience in audiology and coping with hearing loss (identified as a requirement for a PREM).

b) Provide a measure to base comparisons within and across services, supporting commissioner and service-providers. In doing so we provide the means to improve equality in service provision by offering services in a way that meet varied needs.

Our objectives are: To conduct three linked studies:

Work package 1: To develop a conceptual model to explain how work of coping with hearing loss (including hearing aids) is experienced. We plan a systematic review using narrative synthesis and a qualitative interview study.

Work package 2: To develop a PREM tool based on themes arising in work package 1, followed by reliability and validity testing. This includes evaluation of contrasting clinical help-seeking and non-help-seeking participants with hearing loss.

Work package 3: To implement the PREM in contrasting clinical locations and examine potential for the PREM to lead to service changes.

These work packages (WP) will run at parallel time points over the 3 years e.g. WP 3 implementation interviews will begin in year 1 alongside WP 1 and continue into year 2.

SPONSOR
University Hospitals Bristol and Weston NHS Foundation Trust
Research and Innovation, Level 3, UH Bristol Education and Research Centre, Upper Maudlin Street, Bristol BS2 8AE.

FUNDER
This study is supported by an NIHR HSDR grant. (Funding stream REF NIHR131597).

SUPPORTING INSTITUTIONS
Aston University: Aston University Applied Audiology research group specialize in examining interaction between patients and audiology service providers. As part of the College of Health and Life Sciences we form a multidisciplinary research group with a strong track record in improving health care and outcomes.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

STUDY STEERING GROUP
The Study Steering Committee (TSC/SSC) will have a supervisory and advisory role. It will have overall oversight of the trial or research study and provide advice to the study/trial management group, funder and sponsor of the research.
Our study steering group make up is to be confirmed by NIHR. We have invited potential members who bring independent insight into the provision of services in audiology nationally and internationally; individuals who commission health services; commissioners with a focus on patient centred care and individuals with insight into PREM development and adaptation to complex communication needs.
Our steering group will be comprised of 8 independent members, 2 advisory members who are not independent with 1 PPI lead and the CI. Sponsor representatives and other research or clinical group members may be invited to observe but not participate in the steering group. The study steering group will meet approximately six times throughout the study and will include a methodologist, patient partner, sponsor representative, colleagues in commissioning and clinical academic.

RESEARCH MANAGEMENT GROUP
Day to day management
The Research will be managed on a day to day basis by the Chief Investigator, who will supervise the research team at Aston University, and liaise with the co-investigators as needed.

Study Management Group
The study management group (comprising co-applicants representing the UHBW, University of Bristol, Aston University, HCRG Care Group (formerly Virgin Care and Health), NHS Tayside, and other

members of the research team) will be held monthly (by teleconference) throughout the Research to discuss the progress of the Research and the clinical study that forms part of the Research

These regular research meetings (monthly & online) will discuss key moments in day to day running of the project including decisions about data gathering and analysis.

PPI APPROACH, MANAGEMENT AND SUPPORT

Our PPI strategy reflects the diverse and heterogeneous nature of the population affected by hearing loss in the UK. Certain groups are more likely to be affected by hearing loss including people from South Asia (Indian, Pakistani and Bangladeshi communities); older adults in residential care and adults with learning disabilities. By directly targeting groups of these people, we will expand the reach of our PPI inclusion.

1. We have interest and agreement from South Asian community groups and have been directed to specific local Imams who would be able to enhance access to a broader range of people. We will meet face to face.
2. We have identified residential care homes with which we have existing relationships. We will meet individuals face to face.
3. We have agreement from Sheffield Voices community group (a group who facilitate involvement in research for adults with learning disabilities). We will meet using online platforms.
4. Aston PPI group comprises people from the local community who have experience of hearing loss, this group includes student members and is younger in age (18-40). They meet virtually and will advise via phone/email/online routes.
5. Bath PPI group are a well-established group of older adults who support and advise on service delivery and research. They meet face to face or via email.

Our management and coordination of PPI activities will be the responsibility of Nisha Dhanda (researcher with PPI responsibility) and Jean Straus (Public member), working closely with Helen Pryce and the rest of the research team. With monthly meetings throughout and regular contact we will seek advice, guidance and steering from our PPI contributors at every stage of the research process. Our PPI leads will speak to marginalised individuals in settings that suit them e.g. residential home and will not require travel. Likewise, our younger PPI group have requested online contact only without face-to-face meetings. Therefore, online meetings and email contact will also be used at each stage. Where PPI members travel to meetings, we will reimburse their costs and provide refreshments. We loan specialist headsets to enable people with hearing loss to hear better on the phone and via online platforms. By using a researcher who has connections to the British Pakistani community in Birmingham we will use

informal word of mouth and snowball sampling to access individuals who could contribute steering and research participation. Our early PPI work confirmed that it is important to have someone who personally knows the community. Our PPI leads are both experienced in communicating with people who have complex communication needs and will support communication with both those who find it easy to contribute in one-to-one meetings but also those who struggle to communicate and need additional time and prompting to state preferences.

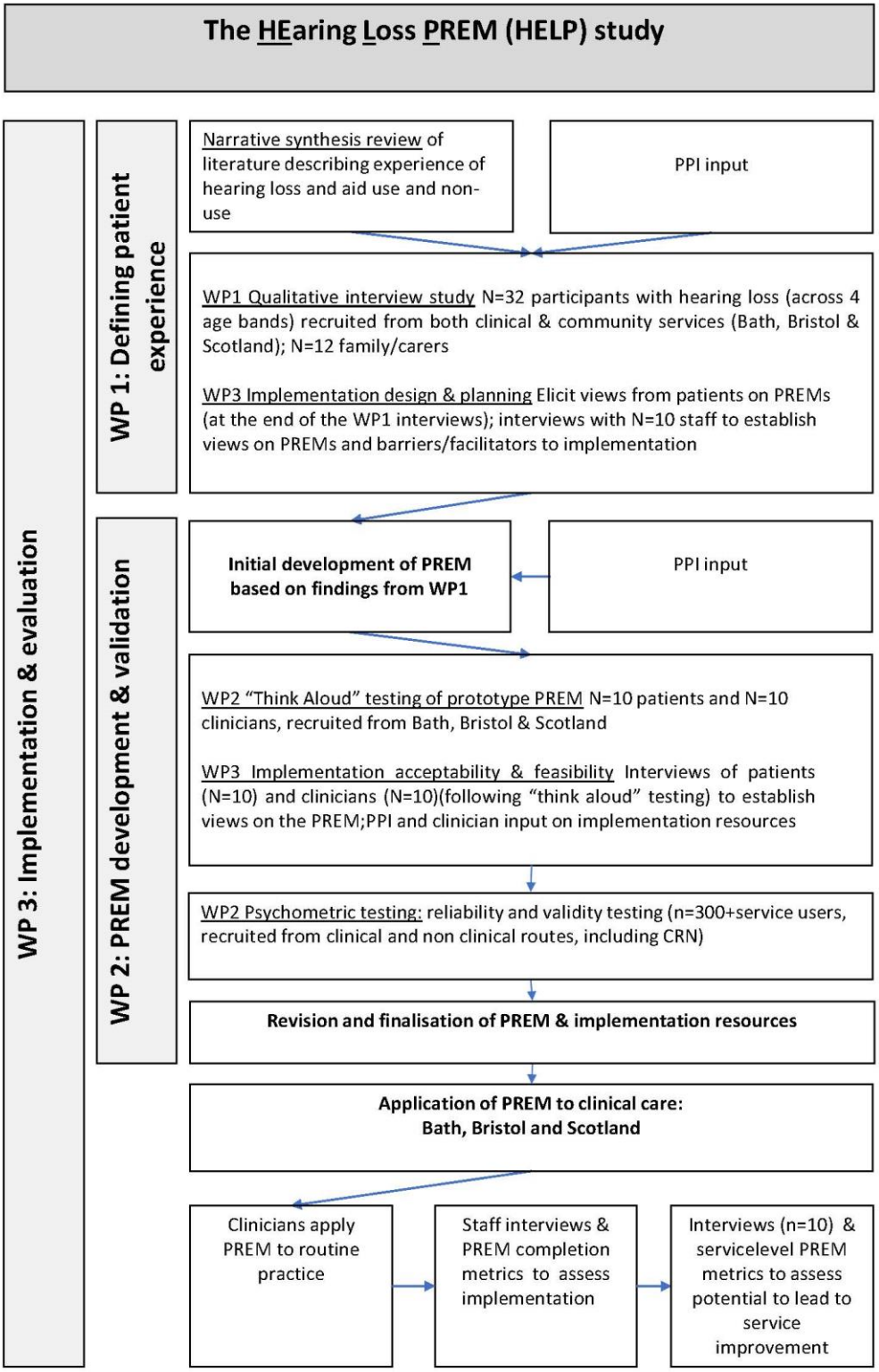
PPI activities will include:

- Reviewing Patient Information Sheets and Consent forms
- Advising on recruitment and sampling
- Planning interview strategy
- Checking coding and analysis procedures
- Addressing any uncertainties in interpretation of research literature and data
- Advising on PREM format
- Advising on PREM administration – particularly to marginalised groups, use of languages,interpreters etc.
- Advising on implementation and evaluation in work package 3
- Advising on implementation to services including staff training
- Advising on dissemination
- Participation in dissemination with groups & individuals

Jean Straus, Helen Pryce and Nisha Dhanda will keep fieldnote diaries of the PPI input, activities, engagement and outcomes. This will facilitate publications to include detail of the role PPI members played in shaping the research, the impact of their views on the PREM tool under development and of the theoretical modelling of the work of hearing loss and their contribution to guiding clinical services on uptake of the PREM tool.

KEY WORDS: Hearing loss; PREM; patient centered care

STUDY FLOW CHART



STUDY PROTOCOL

1.0 BACKGROUND AND RATIONALE

We know little about the patient experience of using hearing aids so there is a risk we give them to people who cannot and do not want to use them. One in two of us will have a significant hearing loss in older life and 0.2% of live births are born with a hearing loss. Hearing loss affects our communication and social function (1), resulting in loneliness (2), social isolation (2) and depression (1). It perpetuates socioeconomic inequality with greatest prevalence associated with lower socioeconomic status (3). There is no cure, but people with hearing loss are offered a hearing aid. Hearing aids provide amplification, enabling their users to hear some sounds more clearly. As technology develops hearing aids have improved significantly in functionality and practicality, but the workload of managing hearing aids has increased (e.g. learning to use Bluetooth to pair devices, sequencing turning on and off different devices, managing complex settings etc.). All this treatment work is devolved to the patient.

2.0 Rationale: Why research is needed now

Our PPI groups point out that the first few months of using a new hearing aid can be particularly tiring and frustrating. Our younger PPI groups confirm research findings that this work alongside stigma of hearing aids often means that people do not want hearing aids (4) and frequently hearing aids are abandoned at this point (5). The result is up to 40% of hearing aids issued may not be used (6). Audiology service provision is not tailored to individual need: Audiology services are commissioned differently in different parts of the country, with the introduction of 'Any Qualified Provider' (AQP) services meaning that large corporations and optical chains have been awarded NHS contracts to provide audiology services in England. PPI work suggests this has resulted in choice of location, but little variation in types of service on offer. AQP service providers in England are funded only to provide hearing aids so there is a real risk of waste (e.g. prescribing hearing aids the patient has no intention of wearing). It overlooks patient values and preferences for their care (7). NICE guidance proposes that patients be fitted with hearing aids and then given motivational interviewing to increase their motivation to use them (8). This overlooks the possibility that other interventions may have lower overall efficacy at correcting hearing loss but might be more suitable and in line with patient preferences. For example, using a TV aid to hear TV better or using an amplified phone to improve the quality sound the patient really cares about hearing may be more suitable than a hearing aid, which is physically difficult to fit. Some patients may simply benefit from counselling to come to terms with the change in their hearing and prepare to take action,

rather than commit immediately to using a hearing aid.

3.0 Theoretical underpinning:

We aim to improve understanding of the patient work required in managing both hearing loss and uptake of audiology services. We will:

a) Establish a clear conceptual understanding of patient experience in audiology and coping with hearing loss (identified as a requirement for a PREM).

b) Provide a measure to base comparisons within and across services, supporting commissioner and service providers. In doing so we provide the means to improve equality in service provision by offering services in a way that meets varied needs.

4.0: Our objectives are: To conduct three linked studies:

Work package 1: To develop a conceptual model to explain how work of coping with hearing loss (including hearing aids) is experienced. We plan a systematic review using narrative synthesis and a qualitative interview study.

Work package 2: To develop a PREM tool based on themes arising in work package 1, followed by reliability and validity testing. This includes evaluation of contrasting clinical help-seeking and non help-seeking participants with hearing loss.

Work package 3: To implement the PREM in contrasting clinical locations and examine potential for the PREM to lead to service changes.

These work packages (WP) will run at parallel time points over the 3 years e.g. WP 3 implementation interviews will begin in year 1 alongside WP 1 and continue into year 2.

2.0 METHODS

WP 1 –To define patient experience and capture the work of coping with hearing loss by participants who seek clinical help and those who do not.

This will explain the trade-offs that patients make between using hearing aids and managing without. It will describe and model the reasons why hearing aid non-use occurs. Building a conceptual framework, we will conduct a systematic literature review using narrative synthesis to identify early themes and use these themes as the basis for interview questions examining qualitative accounts of people living with hearing loss and adapting to hearing aids. Our key questions are:

'What is the reported patient experience of managing hearing loss?' and 'what is the reported patient experience of hearing service use?' We take patient experience to mean data gathered from patients with experience of hearing loss and/or hearing aids, that explicitly describes that experience.

CI (HP) and Post-Doctoral Research Associate (PDRA) will lead the review of the existing literature to develop initial themes. In order to make sense of the themes that are included within both quantitative evidence (surveys, epidemiological findings and observational descriptive accounts) and qualitative detailed descriptions we will use a narrative synthesis design following the JBI manual for narrative synthesis (27). We will formulate search terms based on PPI suggestions and clinical experience and use Web of Science, Medline, Scopus and PsychInfo databases to identify relevant articles. We will search the 'grey' literature via the 'open grey' site.

Our inclusion criteria will be:

- Articles that include data on patient experience of hearing loss
- Articles that include data on patient experience of hearing aids
- Articles that refer to adult (over 18 years) experiences

Exclusion criteria:

- Articles that refer to paediatric experiences only
- Articles that refer to simple use and take up of devices without including detail on patient experience
- Opinion piece articles and review articles that do not directly include data from patients but posit viewpoints from researchers or clinicians.

Procedure for synthesis: Helen Pryce & PDRA will search and appraise articles. Abstracts of all identified articles will read by both HP & PDRA, in relation to the inclusion/exclusion criteria, and any disagreements will be taken to the wider team. All abstracts meeting the inclusion criteria will then be read in full. The wider research team and PPI groups will advise and check on criteria and inclusion/exclusion decisions. Studies will be appraised using methodologically relevant criteria (e.g. JBI checklists or Critical Appraisal Skills Programme tools) (27,28). The synthesis will treat evidence sensitively, depending on its quality rating; the highest quality will confer high levels of trustworthiness; findings from poorer studies will not be relied upon without congruence from better quality studies. The narrative synthesis will produce an interpretative and critical account of the evidence and will identify the important conceptual features of the experience of living with hearing loss to be explored further in the interviews.

We will then produce a narrative review of the evidence of patterns in experience and identify important conceptual features to further explore in the interviews. PPI work proposes that there are differences in how people live with hearing loss across the life course and that the process of living with hearing loss may change in important ways as we age. The patterns from the literature that form early concepts or themes that matter to use and non-use of hearing aids at different life stages will form the basis for the interview topics.

Qualitative interview study

We will conduct an interview study, informed by grounded theory, with the aim of developing a theoretical understanding of how the work of hearing loss is negotiated alongside personal and social changes.

Grounded theory methodologies are particularly well suited to developing an understanding of patterns across contrasting cases and processes that influence those patterns. In comparison to other qualitative methodologies, grounded theories offer explanatory potential as well as description (29). In this case we want to find out not only what the work of hearing loss and hearing aid use is and how it is experienced but what factors inform variation in this experience, e.g. how do factors contribute to the experience. Grounded theory emphasises that meanings are created not within individuals nor texts but amongst individuals and texts, i.e., they share important features and these shared features are particularly relevant to questions about shared experience (in this case of hearing loss, use and non-use of hearing aids). There is some debate amongst researchers about the use of grounded theory and the emphasis placed within different approaches. In our case we subscribe to a view that grounded theory methods are principles and strategies, not constraining procedures. As such we will refer to our approach as 'informed by grounded theory' and that grounded theoryoffers the principles and guidance. For example, being guided by the notion of sampling as purposeful and designed to provide maximum variation of cases leads us to target cases from under-represented communities in

health research.

To support the implementation work, the qualitative research team will also establish patients' views on PREMs and implementation. They will also conduct up to 10 interviews with staff at participating clinical sites. Full details are given in WP3 below.

Sampling and recruitment:

Recruitment

Our clinical sites will advertise the study to potential participants on our behalf. Melanie Ward, Amanda Hall and Laura Turton will advertise the study to their new and existing patients and to staff. Amanda Hall and Laura Turton are linked to paediatric and adult services and staff and will advertise to both. Melanie Ward will advertise to adult service users and staff.
Volunteer participants will make direct contact with the researchers who will sample and recruit individuals into the study.
Our advertisements will also be distributed via leads of tinnitus groups, teachers of lip-reading classes, staff in residential care settings, and clinical audiology departments in Bath, Bristol and Tayside. In addition, our PPI work in South Asian community groups and care homes will prompt snowball sampling in which word of mouth advertisement will lead potential participants to make contact with the research group.
The volunteers who make contact to the researchers will be sent information sheets and invited to discuss the study further with the researcher.

Sample identification

Those who volunteer will discuss participation with the researchers. The researchers will confirm that the individual has some experience of hearing loss directly or as a carer/ partner or parent. Staff will be identified through their professional role. The researchers will note the broad demographic characteristics of each individual and compare this with the sample already recruited. Where we have a particular group heavily represented in our sample we will involve the participant in the questionnaire development and testing but not include in interview. No personal identifiable information will be recorded unless the individual is recruited.

Consent

<u>Participants consenting for interviews and questionnaire testing</u>

We will obtain written informed consent from all interview participants at the start of an arranged interview time. Participants will have had at least a week to consider the participant information sheet and ask questions in advance. Participants who volunteer for online meetings will post their consent form back in a pre-paid envelope. The researcher will record the consent process verbally at the start of the interview as well.

<u>Participants consenting for questionnaire testing only</u>

The participants in the reliability and validity testing for the PREM tool will consent in writing ahead of completion of measures. They will examine a participant information sheet, confirm they have read it and consent ahead of completion of the questionnaire tools. These sections form part of the online questionnaire tool on Qualtrics and consent will be completed

at the start of the questionnaire completion.

Consent for participants with fluctuating capacity

We welcome participation from adults with additional cognitive and communication difficulties but will require capacity to consent for participation. Researchers in care home settings with a large number of potential participants who also experience dementia will check likely capacity with care staff and consent those who are able to independently provide consent to interview and questionnaire completion. The researcher will check that participants can:

- understand the purpose and nature of the research
- understand what the research involves, its benefits (or lack of benefits), risks and burdens
- understand the alternatives to taking part
- be able to retain the information long enough to make an effective decision.
- be able to make a free choice
- be capable of making this particular decision at the time it needs to be made (though their capacity may fluctuate, and they may be capable of making some decisions but not others depending on their complexity)

Purposeful sampling is a core part of grounded theory in which participants are sought to provide contrast in important features of their experience. To provide a wealth of data from different perspectives we have a recruitment strategy that targets specific marginalised groups. Grounded theory recruitment frequently includes targeting of contrasting features in cases. Thus as our findings build we may target cases that could provide contrast to our previous data. We plan to recruit participants through NHS and private sector clinical and non-clinical routes. Firstly, we will recruit current hearing service users and those referred for hearing aidprovision from Audiology departments in England and Scotland. Our site at University Hospitals Bristol and Weston NHS Foundation Trust (UHBW) incorporates Bristol, Somerset and South Gloucestershire. Our Bath site includes Wiltshire and North Somerset. Our Scottish sites include Perth, Dundee and Angus. This geographical spread will enable us to examine help-seekers from rural, urban and semi-urban settings in contrasting postcode locations. This will enable us to find cases across the age range with contrasting demographic features in terms of sex, income, housing and clinical needs. We will also achieve contrast in clinical context with NHS Scotland commissioning a broader range of services than in England.

In addition, we will actively seek to recruit from non-clinical sites including care homes, supported living centres and community groups. Our Aston PPI group have advised on our recruitment and locations to reach additional participants who are not help-seekers. This PPI group is comprised of younger people who are predominantly from minority ethnic backgrounds who know the local area of Birmingham well. We have been encouraged to recruit from Green Lane mosque and some of the women's groups in the area (exercise groups for older Asian women and mindfulness group for Asian women). Our PPI suggests that approach by a researcher from the same religious background as the targeted group and that snowball sampling is likely to be most suitable. We will take advice from PPI groups on translation of participant information sheets and consent forms and will use translation services to provide these in relevant

languages. We have been advised that it is likely that participants would have access to and prefer to use informal interpreters (family members) rather than formal interpreter services but that this should be an available back up option. We will recruit participants via word of mouth from our PPI and will interview and advise on interpretation of data. We have been advised that social stigma around hearing loss is likely to impact recruitment and so we need to adapt to discuss views of sensory changes in ageing in general rather than individuals' specific problems in hearing. Our Bath PPI group have advised us of the importance of interviewing people in their own homes and reducing travel burdens. Amanda Hall and Helen Pryce will lead recruitment in collaboration with clinical service leads. We will advertise the study via the clinical services to potential participants who will make direct contact with Helen Pryce if they are willing to participate. We are stratifying our sample to ensure that we learn about the experience of having hearing loss and either using or not using hearing aids across the life course.

Inclusion criteria

1. **Young adults (aged 16-29 years):** Transitioning from paediatric to adult services & negotiating independence (we will recruit 4-6 young people, including those with additional disabilities such as learning disabilities, via Bristol Children's Hearing Centre transition to adult services team plus up to 4 parents)

2. **Adults aged 30-49 years:** Managing hearing loss while pursuing career/work and family life (we will recruit 4-6 people with diagnosed hearing loss either using or not using hearing aids from snow ball sampling from PPI groups, Scotland, Bath, Bristol services plus 2-4 partners)

3. **Adults aged 50-79 years:** Noticing symptoms of hearing loss for the first time (we will recruit 4-6 hearing aid users and 5-8 non-users from Birmingham community groups, Scotland, Bath & Bristol services and PPI links)

4. **Adults aged 80 years to end of life:** Most likely to have hearing loss. Other health conditions likely and changes in living situation possible (we will recruit 4-6 hearing aid users, 4-6 non-users and 2-4 carers from residential care settings in Birmingham)

Exclusion criteria

Volunteers without close connection to or experience of hearing loss.

In each case we will target groups with invitations to participate and those who volunteer to participate will make direct contact with the research group (led by Helen Pryce). This is a recruitment strategy which we have used in several previous studies.

Discontinuation/withdrawal of participants

Each participant has the right to withdraw at any time and information relating to all withdrawals will be recorded. If a participant wishes to discontinue, data collected up until that point will be kept and included in the analysis.

Data gathering: We will conduct individual interviews in locations preferred by participants and including their homes,

university, clinical premises or online /phone. Interviews will be guided by a schedule of key themes derived from our narrative literature review and will centre on the experience of hearing loss and the trade-offs people make in coping with hearing loss. We will explore all aspects of 'illness work' and 'treatment work' in this regard including emotional work, practical efforts to reduce impact of hearing loss and decisions about hearing aid uptake and use. Interviews will be conducted by PDRA1, PDRA2, Helen Pryce and Saira Hussain. Interviews will be audio recorded and fieldnotes from each interview including thoughts and memoswill be recorded by the researcher involved.

Data analysis: In accordance with grounded theory methods, data analysis and interviewing will be synchronous. Field notes and audio recordings of interviews will form the basis of the data set. Interview recordings will be transcribed by a transcription service and anonymised by the researcher (PDRA1).
Meaning statements will be examined and every line of transcript will be coded to summarise key content. Codes will be compared across and between transcripts and will be collated to broader categories with properties and dimensions that capture the range of meanings. Finally, codes will be grouped into a paradigm to explain the variation in experience. This way we will:

1. Describe the range of 'illness work' associated with hearing loss
2. Describe the 'treatment work' of using hearing aids and audiology services
3. Capture the variations that exist and the important influences that contrast different social groups and different age groups

At key decision making points we will consult our PPI groups to check that our process and early findings have not missed some aspect of experience, e.g. during the development of interview schedules, labelling codes and categories, formulating the framework and discussing how the framework operates.

We will ensure credibility to the research process through transparent decision making, including PPI views. The CI (Pryce) and co-investigator (Rachel Shaw -qualitative methods expert) will supervise the analysis closely and ensure consistency. They will blind code a subset of transcripts and compare coding. The qualitative research group (Pryce, Shaw, Hussain, Post-doctoral research associates) will examine and compare codes and generate a model of work with hearing loss that is relevant to all age bands, as well as sub-group analysis of the four age bands to highlight the variations in need at each life stage. We will examine the fit of this model to previous models and existing theories and we will encourage reflection from all researchers through discussion and debriefing. We will keep field notes of reflections and thoughts following interviews to support this.

Outputs from WP 1:

1. A framework or model to describe variation across a diverse sample of the components and operating features of the work of hearing loss and use of hearing aids.
2. The features that determine how the model operates that would form the basis of the PREM tool.
3. A systematic review of the experience of living with hearing loss.

WP 2 - PREM Development and validation

To ensure that our PREM is informed by current best evidence on the use of PREM tools we will review the PREM literature over the course of the project and ensure that we are following current recommendations during the development phase. This will include monthly literature searches and synthesis of findings by our RA. This work will inform the planning and design stages of our Person Based Approach to implementation.

Prototype PREM development: The data from interviews in WP1 will be used to base items for the PREM, which will be developed based on classical test theory (30). This work will be led by Rebecca Knibb. Careful consideration will be given to the different age groups interviewed as part of WP1 and whether one PREM would be suitable for all age groups. If the model developed as part of WP1 suggests different items are relevant for different ages, PREMS will be developed in accordance with this.

Consideration will also be given to items that may be particularly relevant for different ethnicities. Items drawn from the data will form one (or more) prototype scale(s) of statements with which participants rate alevel of agreement on a Likert scale (e.g. 1=not at all, to 5=all the time) (32). We anticipate that included statements will capture the trade-offs between access (including costs) and participation in audiological care (including use of hearing aids as directed) versus the workload burden involved.

The prototype scale(s) will consist of a larger number of items, which will be discussed by the project team and the PPI groups. Each item will be assessed for clarity, readability, necessity and for overlap with other items in the scale. Items will remain in the prototype scale based on agreement with the team and PPI groups. Any disagreement on the inclusion of an item will be discussed further in relation to the data generated from WP1 until agreement is reached on its inclusion or exclusion. The prototype PREM will then be assessed for readability using reading age software (readable.io) and language will beadjusted to meet requirements for a reading age of 7 (below UK average reading age). The PREM will also be worded so that it can be used as carer-proxy scales for any patient who is not able to complete the PREM themselves. This will assist in widening access and usability of the PREM for people who may have difficulty completing it themselves due to a learning disability or having a condition such as dementia. It may also be possible to create Easy Read versions of the PREM and translated versions.

Cognitive testing: We will recruit, and invite for interview, 10 participants and 5-8 clinicians from Bath, Bristol & Tayside Audiology departments and non-clinical groups (lip-reading classes, social care settings etc.) to pilot the prototype scale(s)using a ‘think aloud’ (31) approach where participants explain what they think each item means and how they would score it. This will allow us to ascertain the clarity of both concepts and language, and adjust any items that are not understood as intended. We will ask patient and clinician participants how the PREM was to complete and what their views on it are. We will include a thematic analysis of the experiences of completion of the PREM which will contribute to our implementation of the work package.

Reliability and validity testing: Following required revisions, the PREM will be distributed to people with hearing loss who have consented to take part in the study (recruited from Bath, Bristol & Tayside Audiology departments,

clinical research network audiology leads social care settings, lip-reading classes, national charity links and social media adverts). We will be guided by services about their preferred method for administering the PREM but anticipate adding the PREM to 'Auditbase' patient management systems (PROMs currently part of the system). In addition, we will provide paper copies for services administering the PREM away from clinic sites. The researchers will upload paper administered results to the Qualtrics system. Guidelines suggest a minimum of 300 participants are optimal in scale development (32) and we therefore aim to recruit to this number or recruit a minimum of 10 individuals for each item in the prototype scale, whichever is the largest sample size. The PREM will be administered via a secure online server (Qualtrics), alongside already validated scales for content validity analysis. To reach social care settings, further completion of the questionnaires will be conducted in person with researchers visiting residential care settings. As research suggests isolation and depression are associated with hearing loss, construct validity will be assessed by examining correlations between our hearing loss PREM, the Hospital Anxiety and Depression Scale (33) and the UCLA Loneliness scale (34). We will use a generic quality of life scale (the EQ-5D 5L)(35) and a measure of health literacy such as the HLQ (36) but use our patient partners to support the choice of which tools to use. Participants will also be asked to complete the PREM two weeks after initial completion to assess re-test reliability. Item reduction will include identifying items with poor levels of completion and those withoutdiscriminant properties (where virtually all participants have recorded the same response category. Internal consistency of these domains will be assessed using Cronbach's alpha. Internal structural validity of the scale(s) will be assessed using exploratory factor analysis non-orthogonalrotations to investigate or confirm the number of domains using factor selection with Eigen values above 1.

To improve the consistency and reliability of this step several split samples will be extracted using different random splits and the process repeated at least 10 times. Rasch analysis will be employed with these subscales to identify whether subgroups based on the age, gender or ethnicity of the responders found different items more important than others. It will also be used to further investigate whether there is the opportunity to reduce the number of items based on relative importance of the item from qualitative data, lack of fit to the Rasch model, redundancy detected earlier and evidence of a response bias that would adversely impact its use in a diverse population. A further Rasch analysis will be attempted to investigate whether the dimensionality of the tool can be ignored in favor of a much shorter form that might have better uptake when used within a clinical setting.

Pearson's bivariate correlations will be conducted between scale scores to assess construct validity. The sample size will allow investigation of correlations as low as 0.2 to be statistically significant at the 5% level. Intraclass correlations will be conducted to assess temporal stability of the scale. Between-subjectst-tests and Pearson's correlations will assess the discriminative validity of the scale by comparing across demographic and hearing loss characteristics, and health resource use. Rebecca Knibb and Rosemary

Greenwood will oversee statistical methods; Sian Noble will oversee health economic methods.

Output of WP 2: Valid and reliable PREM/s to capture quantitative variations in patient experience

WP 3 - To implement the PREM in contrasting clinical locations and explore the potential for the

PREM to lead to service improvements

This work package will identify the key issues around implementation of the PREM into Audiology clinicalservices from both the patient and clinician perspective, develop a set of implementation resources and training package, and evaluate the process of implementing the PREM into contrasting NHS Audiology clinical sites (contrasts with demographics & health systems).

It will use implementation strategies to guide implementation of the PREM and will evaluate the success of these strategies across a range of implementation outcomes. It will then explore the potential for the PREMto lead to service improvements. Our key questions are:

1. Can the PREM be successfully implemented into routine Audiology service practice?
2. Does the PREM have potential to lead to improvements in Audiology services?

Design: We will conduct a mixed methods evaluation focusing on the process and outcomes of implementation of the PREM, and the potential for the PREM to improve service delivery and outcomes.
We will use the Person-Based Approach (PBA) to develop resources to support the implementationof the PREM developed in WP 2. The PBA will run throughout the research project drawing on data from each WP and also collecting data to support implementation. The process places patients and staff at the heart of the co-design process around implementation. This will be further supported by PPI input to ensure our approach is diverse and inclusive. Using these co-participatory methods will ensure that the
PREM that has been developed and can be deployed in such a way that it is acceptable and meaningful forpatients and staff.
Amanda Hall (AH) will lead this WP of the project in partnership with JB, working with HP, the researchersand the head of department at each site. Each department will be responsible for implementing the PREMat their own site and collecting their own service level data. The research team will be responsible for evaluating the implementation outcomes. The department and the research team will work together to analyse the PREM service level data.

Clinical sites: The PREM will be implemented at Audiology departments in Bristol, Bath and Tayside. Two ofthe co-applicants are heads of service at Bath (MW) and Tayside (LT); AH is employed by the Bristol Audiology department. The sites serve populations varying in a range of key demographic factors (Appendix 1). In addition, the Bristol and Tayside sites cover both paediatric and adult hearing services, and the Bristol and Tayside departments provide hearing services for people with learning disability. All sites provide services for people in care homes. All Audiology services use a standard electronic Audiology patient

management system to record patient appointments, demographics, and interventions. These systems canbe modified to store additional variables. Service level data can be extracted for analysis using reporting software integrated within the system.

The processes of implementation and evaluation

1. *Implementation planning and design*

In year 1, the qualitative research team will conduct up to 10 interviews with staff at participating clinical sites to support implementation planning and design. These interviews will focus on the potential barriers and facilitators to implementation of a PREM tool. We will explore clinician views, values around hearing service provision and the logistical needs of introducing such a tool. Participating patients in WP1 will be asked at the end of their interview about their views on PREMs and the process of completion. This will tellus about the preferences held for completion of the tool and the patient perspective of the value and purpose of the tool. The staff and patient data will be used alongside the literature review to design and develop resources (paper and/or digital) that will support the adoption and use of the PREMs by staff and patients. These processes align with the *planning* and *design* stages 1 and 2 of PBA. Particular attention will be paid to how the PREM can be incorporated into clinical workflow and how barriers to use can be overcome. We will draw on theoretical behaviour change theory such as the behaviour change wheel and the taxonomy of behaviour change strategies . Interview data will be analysed thematically using reflexive thematic analysis and data interpretation will be supported by PPI guidance.

2. *Acceptability and feasibility*

The phase 2 cognitive interviews include 'think aloud' evaluation of the PREM and will extend to discussing views on the PREM and the draft implementation resources that have been developed with both clinicians andpatients. PPI guidance will also be included. This approach represents PBA stage 3, development and evaluation of acceptability and feasibility. We will use these data to refine implementation resources and training materials.

3. *Implementation and evaluation*

We will support implementation of the PREM in our clinical sites using the resources developed above (e.g. support video/ screen based support/paper leaflets etc. plus in person training). We will use quantitative andqualitative data at the end of the 3 month implementation period to assess how the PREM is perceived and used by staff in practice along with an evaluation of the implementation process. Key metrics will include: acceptability, appropriateness, feasibility, adoption, reach, cost and sustainability (42). This corresponds to PBA stage 4, *implementation and trialing*.

Qualitative study: The researchers will run individual interviews with staff at each site at the end of the 3 month implementation period. The topic guide will be informed by the metrics above, covering topics such ashow the PREM fits with their normal work patterns, perception of the PREM, perception of training, changes madeto incorporate the PREM into clinics etc. It will also cover views on the implementation resources. At each site, we anticipate recruiting around 10 staff (covering a range of experience and grade) including

managers. All interviews will be recorded, transcribed verbatim and analysed using thematic analysis (41). The researchers will analyse the data overseen by JB. These themes will lead to revision of implementationresources if necessary. These findings will be guided by PPI interpretations.

Quantitative measures: AH and the researchers will work with the head of department at each site to evaluate service implementation. This will include analysis in each site of service level data covering the 3 month implementation period (to allow for assessment and review of new patients) including: percentage of PREMs completed, completion of the PREM across the range of patient demographics seen over the 3 months, completion rate by clinician, extent of missing data within the PREM.

Outputs: Three site-specific evaluations, incorporating the quantitative and qualitative data, analysing the process of implementation according to the key metrics of success, with an assessment of key barriers andenablers.

Evaluation of service outcomes: We will evaluate the potential for the PREM to be used for service improvement, both at the service level and the individual clinician/patient level. At the end of the implementation period, AH and the researchers will work with each service to summarise their three-month PREM data. This will provide a quantitative descriptive summary of the key constructs of the PREM, which weanticipate may cover areas such as the experiences of help-seeking, difficulties and costs of accessing services, and the workload of managing any treatment received. We will provide a summary of PREM data forthe whole service and also broken down across key patient demographics e.g.age bands, sex, ethnicity, care home resident etc.

We will work with each service to identify areas for service improvement based on their PREM findings, andpropose different models for reconfiguring service provision based on areas identified as requiring improvement). Any service reconfiguration will aim to improve patient experience for potentially the same orlower costs.

Qualitative study: The researchers will interview staff including managers at each site at the end of the implementation period. The topic guide will cover perceived benefits of the PREM both for the service andfor individual patients; also views on the service improvement plans informed by the PREM and the proposed service reconfiguration. The data gathering, analysis and interpretation are as described above.

Outputs: An analysis of PREM data for each site with a service improvement plan. Identification of keythemes relating to the potential for the PREM to be used for service improvement.

Table 1: The process of implementation

Implementation and evaluation of the PREM		
Project year 1 - 2	**Year 2-3**	**Year 3**
PBA Stage 1 & 2	**PBA Stage 3**	**PBA Stage 4**
Planning and design of implementation	**Acceptability and feasibility of implementation**	**Implementation & evaluation**
Staff views on PREM and implementation	Patient views on prototype PREM & implementation resources	Service level implementation metrics of PREM: Acceptability Appropriateness Feasibility Adoption Reach Cost Sustainability
Patient views on PREM and implementation	Clinician views on prototype PREM & implementation resources	Staff views on implementation of PREM
Literature review on PREMs	Optimise implementation resources	Service level PREM data: Descriptive summary of key constructs of PREM
Service mapping		Staff views on usefulness of PREM service level data for service improvement
Design and develop implementation resources		

Outputs of WP 3

1. Detailed case studies of the process and outcomes of implementation of the PREM for each service.
2. Summary PREM data for each service, identifying key areas for service improvement with costed plans forservice improvement.
3. Implementation resources pack for dissemination and roll-out of the PREMs into wider Audiologypractices

ETHICAL AND REGULATORY CONSIDERATIONS

The research methods proposed uphold core ethical principles. Participants are invited on a voluntary basis to consent to take part. Participants are fully informed about what will happen to their data. Data are kept confidential and are pseudonymised (interviews) and anonymised

(questionnaire completion). Participation requires written informed consent. Our work will comply with principles of Good Clinical Practice.

Assessment and management of risk

Risks to participants in this study are minimal. There is the possibility that discussing some topics will create some distress and this will be managed by checking whether the participant would prefer the recording be stopped and provide time to discuss the distressing issue. If need be the researcher will signpost to other services including the patient liaison services with NHS providers. Our researchers will minimise their risks interviewing by conducting interviews online where possible. If in-person interviews are needed (depending on degree of hearing loss or access, for instance) participants may be interviewed in their homes or at another location where they can speak confidentially (e.g. quieter cafes for example). Where there are free spaces in clinical settings these will be offered. In the case of home interviews, researchers will follow our sponsor UHBW NHS Trust lone working policies including plans to check in with another member of the research team before and after interviews.

https://www.nhsemployers.org/sites/default/files/media/Improving-safety-for-lone-workers_0.pdf

Safety Reporting

Although not expected, any adverse events will be recorded and reported in accordance with University Hospitals Bristol's Research Safety Reporting SOP if necessary.

Authorisations

The study will be performed subject to favourable opinion/ authorisation/permission or equivalent from all necessary regulatory and other bodies. This includes but is not limited to REC, HRA, NHS Trusts.

Research Ethics Committee (REC) and other Regulatory review & reports

- Before the start of the study, a favourable opinion will be sought from a REC (researchers should check if they are required to gain a favourable opinion from the UK Health Departments Research Ethics Service NHS REC) or other REC approval) for the study protocol, informed consent forms and other relevant documents e.g. advertisements.

For NHS REC reviewed research

- Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.
- All correspondence with the REC will be retained.
- It is the Chief Investigator's responsibility to produce the annual reports as required.
- The Chief Investigator will notify the REC of the end of the study.
- An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.
- If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.
- Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

Regulatory Review & Compliance

- Before any site can enrol patients into the study, the Chief Investigator/Principal Investigator or designee will ensure that appropriate approvals from participating organisations are in place. Specific arrangements on how to gain approval from participating organisations are in place and comply with the relevant guidance. Different arrangements for NHS and non NHS sites are described as relevant.

Amendments

- For any amendment to the study, the Chief Investigator or designee, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

The process for making amendments is:

1 Researcher or clinical partner identify the amendment required.

2. The research management group will be consulted about implications of amendment.

3. If amendment proceeds, research steering group will be advised of the amendment and asked to provide a response to the research management group decision.

4. The CI will advise the REC who approved the study and the sponsor of the amendment and will follow guidance on http://www.hra.nhs.uk/resources/after-you-apply/amendments/

Peer review

This protocol and the detailed plan for our study was reviewed by Aston University research governance team, NIHR funding committee and the Bristol Research Design Service committee. Any edits suggested by each committee have been incorporated into the final version.

These reviews were:

a) **Independent**: At least two individual experts should have reviewed the study. The definition of independent used here is that the reviewers must be external to the investigators' host institution and not involved in the study in any way. Reviewers do not need to be anonymous.

b) **Expert**: Reviewers should have knowledge of the relevant discipline to consider the clinical and/or service-based aspects of the protocol, and/or have the expertise to assess the methodological qualitative aspects of the study.

c) **Proportionate**: Peer review should be commensurate with the size and complexity of the study. Large multicentre studies should have higher level (more reviewers with broader expertise and often independent review committee or board), and potentially international peer review.

Data protection and patient confidentiality

All study data will be stored on a secure University of Aston password protected server. The database will be designed so as to protect patient/participant information in line with the General Data Protection Regulation. Study staff will ensure that the participants' anonymity is maintained through protective and secure handling and storage of patient/participant information at the study centres (as relevant) in line with the Ethics approval. All documents will be stored securely and only accessible by study staff and authorised personnel. Data will be collected and retained in accordance with the General Data Protection Regulation. The Chief Investigator, Dr Helen Pryce-Cazalet will act as Data Custodian.

- Limited personal information (address email address, contact phone number and name) is recorded to facilitate contact and arrange interview or to share questionnaires. These

details will be retained in a secure file on clinical sites (where the participant is recruited via clinical sites). These files will be locked in a secure location in each clinical site.

- Characteristics such as acorn category of postcode will be recorded in fieldnotes and a table of participants but will not record postcodes or other personal data.
- This will be held on a password protected secure computer supplied by Aston University.
- At the point of data gathering a recording of the interview will be made on an encrypted Dictaphone. The audio file will be sent for transcription via secure data transfer to an Aston University approved transcription service immediately following the interview and once transcribed and checked, the audio recording will be deleted.
- Transcripts will be pseudonymised participant name. Details of locations, hospitals, participant identifiers etc. will be removed. Transcripts will be held only on secure university computers and accessed by the researchers.
- Secure maintenance of the data and the linking code in separate locations using encrypted digital files within password protected folders and storage media.
- No personal data will be shared with the sponsor or anyone outside of immediate appropriately delegated qualitative researchers

Data Management

Where applicable, a random sample of at least 10% of Case Report Forms will be checked, by the study Research Team, against entries within the database and with the source data for quality purposes. The percentage checked will be increased if a significant error rate is found. In addition, the first set of recruitment data collected from a new site will be scrutinized.

Storage of records

Study documents (paper and electronic) will be retained in a secure location during and after the study has finished. All essential documents, including patient records and other source documents will be retained for a period of 5 years following the end of the study. Where study related information is documented in the hard copy medical records – those records will be identified by a 'Do not destroy before dd/mm/yyyy' label where date is 5 years after the last patient last visit. Where electronic records are in use, trust policy will be followed

Indemnity

This is an NHS-sponsored research study. If there is negligent harm during the clinical trial when the NHS body owes a duty of care to the person harmed, NHS Indemnity covers NHS staff, medical academic staff with honorary contracts, and those conducting the trial. NHS Indemnity does not offer no-fault compensation and is unable to agree in advance to pay compensation for non-negligent harm. Ex-gratia payments may be considered in the case of a claim.

Research Governance Statement

This study will be conducted in accordance with:

- The principles of Good Clinical Practice, as set out in the International Conference for Harmonisation of Good Clinical Practice (ICH GCP) guidelines
- The UK Policy Framework for Health and Social Care Research

Monitoring and Audit

The study will be monitored in accordance with UHBW's Monitoring SOP. All study related documents will be made available on request for monitoring and audit by UHBW, the relevant Research Ethics Committee and for any other regulatory authorities.

Access to the final study dataset

- Researchers directly involved in a data gathering and analysis will be the only individuals to have access to the full dataset. This means the qualitative data will be seen by Helen Pryce and Aston post doctoral research associate. Anonymised data will shared with methodologist.
- The quantitative data will be seen by Research leads and Research Associate only.

  Anonymised data will be available to the wider steering group for scrutiny.

DISSEMINATION

Our research will lead to the following outputs:

A new understanding of the work of hearing loss and hearing aid use with a description of the nature ofthe trade–offs that individuals make in determining how and whether to use hearing aids. This output will inform clinical providers through conference presentations at the UK professional body for Audiology and Hearing Therapy (British Academy of Audiology (BAA) and the learned society for Audiology and Hearing Therapy (British Society for Audiology). We will publish articles from our work in both peer reviewed journals(e.g. International Journal of Audiology) and professional magazines (BAA magazine, Audacity etc.).

A PREM tool to quantify and capture changes in the work resulting from audiology services care. This will be a free-to-use validated and reliable tool for UK hearing services. The tool will be supported by targeted implementation resources for clinicians e.g. instructional videos, leaflets and software compatible with existing patient management systems. Our project website will include downloadable pdf versions. We will disseminate this to colleagues via conferences (BSA, BAA and international e.g. Hearing Across the Lifecourse conference). We will approach BSA special interest groups who produce professional guidance on practice (and link to project site). In particular the Adult Rehabilitation group to

include the PREM in assessments of service outcomes. Helen Pryce is a former trustee of the BSA and has ongoing contact with members and makes contributions to guidance.

Identified service level changes that improve the equality of care across different patients. The specific changes will vary between sites and services but are likely to share some features in adapting delivery of services. Local commissioners of study sites will be informed of proposed changes. Our objectives for dissemination are:

d) To raise awareness amongst audiology providers and commissioners and to increase broad uptake and use of the newly developed PREM. Our commissioner collaborator stresses the need for clinical buy-in to influence commissioning decisions so our principle goal is to invite clinical colleagues to think creatively about how service provision could be altered to be more in line with patient experience.
e) To increase public awareness of both our model explaining work of hearing loss and hearing aids, our understanding of the trade-offs people make and the potential for the PREM to improve clinical understanding of the needs of their patients.

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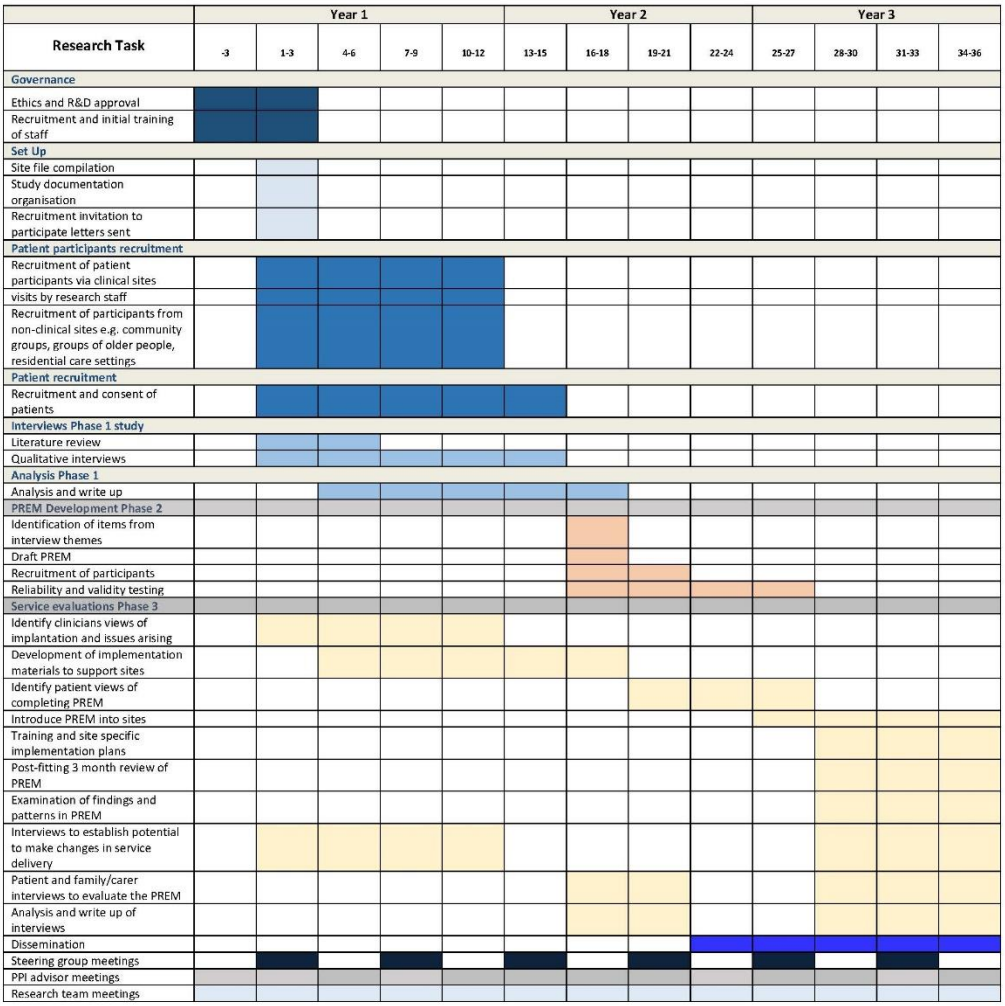
Appendix 1: Gantt chart summarising project activity

Hearing Loss & Patient Reported Experiences (HELP): Using patient experience to improve Audiology services



Any queries please contact Helen Pryce h.pryce-cazalet@aston.ac.uk

Protocol appendix 2

Procedure if capacity to provide consent is in unclear

1. The researcher will follow guidance on the mental capacity act and assume consent unless there are indications that the individual participant may not be able to provide consent at the time of the interview or questionnaire completion.
2. If capacity is unclear the researcher will assess it by asking questions in line with the Newcastle 85+ study procedures.
3. This will be done prior to signing the consent form.
4. Check that the person must is able to hear the statements and questions.
5. Check that the person has read the information leaflet.
6. Identify that they can ask questions at any time.

'I know that you have read the information leaflet, but one of the things we need to check is that people understand the study and what it will involve for them if they choose to take part. So if I can read you a small section of the information leaflet and then check your understanding of it. Is that all right?

Question 1:

"We are asking you to take part in a research study to investigate the experiences of hearing loss people have. If you take part I would ask you questions about your life – is that ok?"

Question 2:

'So, in a few words, can you tell me what the study is about?'

Question 3:

'From what I said earlier, can you tell me what would happen to you if you agreed to take part in this study?'

7. **Complete this checklist:**

CONSENT CHECKLIST FOR INVESTIGATORS

1. Has the consent protocol been adhered to? Yes – No

2. Has the participant/relative/carer/consultee read the 'Participant Information Booklet' (Circle all who apply).

Part: Yes – No – N/A

Rel: Yes – No – N/A

Car: Yes – No – N/A

Cons: Yes – No – N/A

3. Have you given an oral explanation to the participant/representative, including:

· this is a research study? Yes – No

· participation is voluntary? Yes – No

· the aims of the study? Yes – No

· the likely duration of the participant's involvement? Yes – No

· the expected benefits to the participant and/or others? Yes – No

· what risks, inconvenience, discomfort or distress may reasonably be anticipated for this participant?

Yes – No

· that a refusal to participate or withdrawal from the whole or part of the study may be given without reasons and will not affect the usual care?

Yes – No

· that personal information will be treated as strictly confidential only available to the research team?

Yes – No

· whom to contact and how? Yes – No

4. If you have answered NO or not answered any of the above Questions record

why:……
…….

5. Have you allowed the participant/representative sufficient time to consider the matter, discuss with others if wished, and ask you any questions?

Yes – No

6. In your opinion, has the participant/consultee understood and given informed consent/ approval to this study?
Yes – No

7. Has the participant/consultee signed and dated the consent/
approval form? Yes – No

8. Has the participant/consultee received a photocopy of this form? Yes – No

Investigator name:…… Designation:…….

Signature:…… Date:…….