Feasibility and effectiveness of Ida Telecare tools for NHS Audiology patients

Ida Telecare

IRAS ID: 232078

PROTOCOL VERSION 3.0 date 13th November 2017

- **This protocol has been designed to ensure regard for the HRA guidance**

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IRAS Number:	232078
SPONSORS Number:	17IH006
FUNDERS Number:	N/A
SPONSOR	Nottingham University Hospitals NHS Trust

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):

Dr Helen Henshaw

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Funder(s)	Ida Institute
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Committees	**Project Management Group** Dr Helen Henshaw, details as above Dr David Maidment, details as above Dr Eithne Heffernan, details as above Dr Melanie Ferguson, details as above Ms. Melanie Gregory, details as above Ms Claire Benton, details as above

STUDY SUMMARY

Study Title	Feasibility and effectiveness of Ida Telecare tools for NHS Audiology patients
Internal ref. no. (or short title)	Ida Telecare
Study Design	Feasibility study and RCT
Study Participants	Patients attending Nottingham Audiology Service
Planned Size of Sample (if applicable)	**Feasibility study:** N/A **RCT:** n=56 (28 per arm)
Follow up duration (if applicable)	N/A
Planned Study Period	16th October 2017- 31st August 2018
Research Question/Aim(s)	**Sub-study 1: Feasibility** Aim: To assess uptake, feasibility and mechanisms of benefit of the Ida Telecare tools in patients attending Nottingham Audiology Service for the first-time. Specific objectives: 1. To examine uptake of the Ida Telecare tools by patients. 2. To identify how and at what point the tools are used by patients in the NHS audiology pathway. 3. To examine goal-setting and short-term goal attainment in a sub-set of patients. 4. To identify and code the 'active ingredients' of the Ida Telecare tools for promoting health behaviour change using the Behaviour Change Technique (BCT) Taxonomy. 5. To examine patients' and audiologists' views of the Ida Telecare tools in terms of acceptability, use, and relevance. **1. Sub-study 2: Effectiveness** Aim: To evaluate the effectiveness of the Ida *'Why Improve My Hearing?'* Telecare tool in first-time NHS audiology patients, compared to standard care.

	<u>Specific objectives:</u> 1. To evaluate the impact of using *the 'Why Improve My Hearing?*' tool on patient self-efficacy, readiness to manage their hearing loss, hearing aid uptake and hearing aid use (quantitative). 2. To use the COM-B system to investigate the views and experiences of patients and audiologists regarding use of the tool in the audiological rehabilitation process (qualitative).

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
Ida Institute	Feasibility: £7,841.53 ($9,976) RCT: £7,862.00 ($10,000) **Total: £15,703.53** ($19,976) *Exchange rate used: £1 = $1.27, correct as of 26.06.17*
East Midlands Clinical Research Network	CRN-funded Research Audiologist in place to support recruitment at NUH.

ROLE OF STUDY SPONSOR AND FUNDER

Nottingham University Hospitals NHS Trust will act as the Sponsor for this research project, assuming overall responsibility for the initiation and management of the study. The sponsor will work closely with the Chief Investigator to report study progress to the funder (Ida Institute) as necessary.

Certain research activities surrounding study conduct and data analysis and reporting are delegated to the Chief Investigator and these are outlined in an agreement separate to this protocol. Regular meetings will be held between the Sponsor and the chief investigator and study coordinator as grant holders, to discuss the management of the study finances.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITTEES/GROUPS & INDIVIDUALS

Project Management Group

Dr Helen Henshaw (Chief Investigator and Senior Research Fellow, NIHR Nottingham BRC): Lead and manage research project. Responsibility to ensure that all research standards are met, including good clinical practice and coordination of mandatory approvals. In collaboration with the Study Co-ordinator, to manage the project on a day-to-day basis, collect quantitative and qualitative data from participants and analyse participant data.

Dr David Maidment (Study Co-ordinator and Research Fellow, NIHR Nottingham BRC): In collaboration with the Chief Investigator, to co-ordinate the project on a day-to-day basis, collect quantitative and qualitative data from participants and analyse participant data.

Dr Eithne Heffernan (Research Fellow, NIHR Nottingham BRC): Responsibility for the qualitative aspects of study Arm 2: Effectiveness, including data collection, analysis and write-up.

Dr Melanie Ferguson (Consultant Clinical Scientist (Audiology), Nottingham University Hospitals NHS Trust, Hon. Associate Professor, University of Nottingham and MMHL Research Area Lead, NIHR Nottingham BRC): Line manager of Chief Investigator and Study Co-ordinator, with overall responsibility for research in the MMHL research area.

Ms. Melanie Gregory (Director, Ear Foundation): Key advisor on the initial design and development of Ida Telecare tools and their intended mechanisms of benefit (Arm 1: Feasibility).

Ms Claire Benton (Head of Audiology, Nottingham Audiology Services, Nottingham University Hospitals NHS Trust): Responsibility for co-ordinating clinical audiology input, specifically in terms of access to patient recruitment correspondence for the inclusion of study information packs for new NHS audiology patients.

The Project Management Group will meet 3 times during the 12 month study to monitor progress against the project plan, resolve issues around research activity and plan future research progress.

Protocol contributors

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KEY WORDS:

Telecare
Self-management
Hearing loss
Audiology
Hearing aid
COM-B

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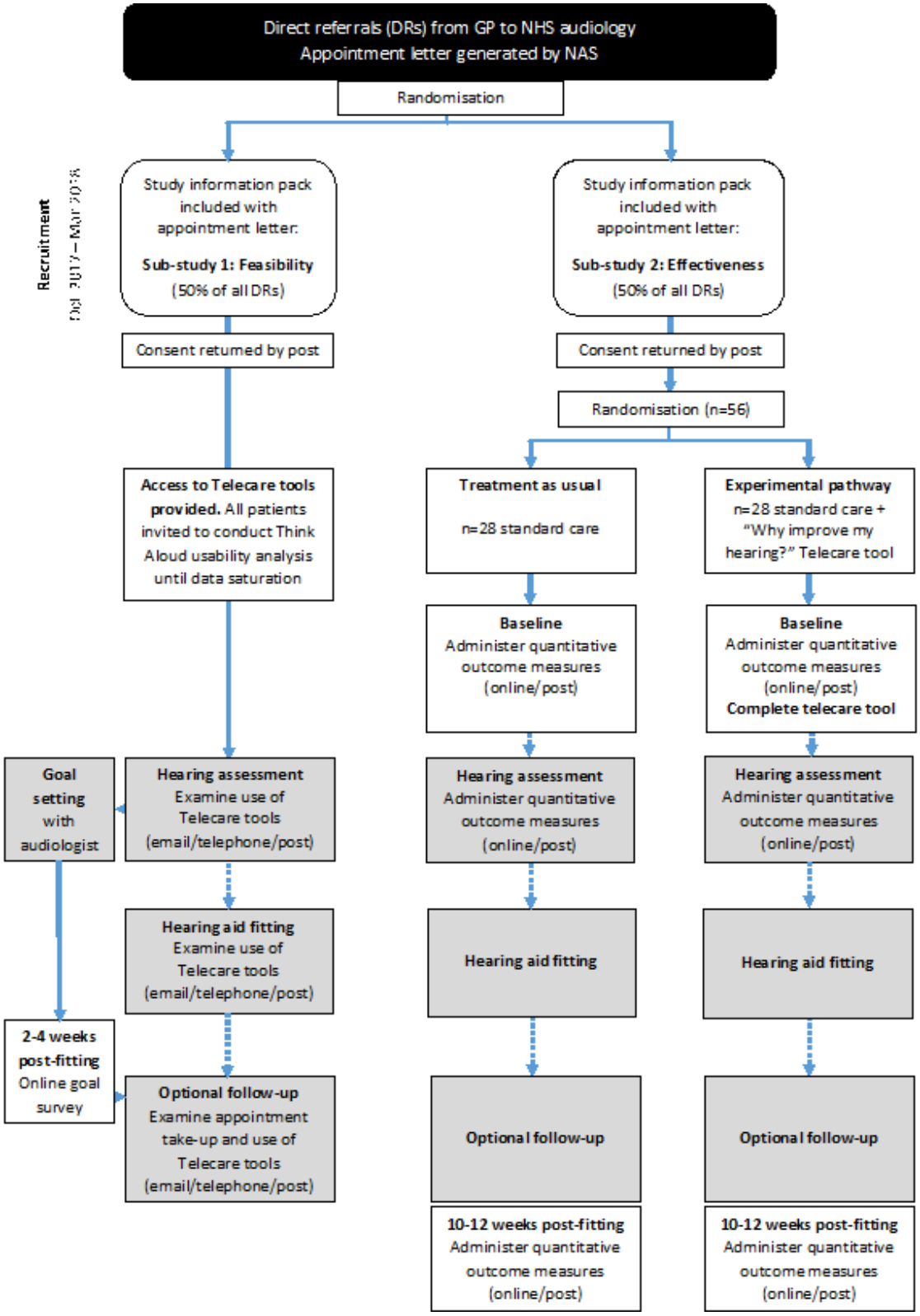
STUDY FLOW CHART



STUDY PROTOCOL

Feasibility and effectiveness of Ida Telecare tools for NHS Audiology patients.

1. BACKGROUND

Acoustic amplification provided by hearing aids is currently the primary clinical management strategy for adults with hearing loss. In the UK, around 2 million people have hearing aids (Action on Hearing Loss 2015), however, up to 40% of adults do not use them (Barker et al. 2014). Failing to manage hearing loss can result in continued communication difficulties, social withdrawal and reduced quality of life for both the individual (Heffernan et al. 2016) and their communication partner (Kamil and Lin 2015). From a publicly funded health services perspective, hearing aid non-use represents a significant wastage of limited healthcare resources, and has been used to justify the withdrawal (or 'rationing') of hearing services in parts of the UK National Health Service (NHS). As hearing aid fitting alone is not an optimum intervention for everyone, there is a need to identify additional strategies to help patients successfully manage their hearing loss.

Evidence suggests that people with hearing loss who are aware of their communication needs and concerns prior to their hearing appointments are more motivated to take action (Beck et al. 2007; Poost-Foroosh et al. 2011), better equipped to make decisions (Laplante-Lévesque et al. 2010; Laplante-Lévesque et al. 2010) and guide the support they need from audiologists to help them on their journey (English 2005; Grenness et al. 2014). Consequently, patient satisfaction with care is improved (Laplante-Lévesque et al. 2012; Weinstein 2015). In 2011 The King's Fund published their seminal report on 'Making shared decision-making a reality, No decision about me, without me'. This report was commissioned to help understand how the health system in England could be improved. The key message was that shared decision-making was not currently the 'norm' and the report provided a number of evidence-based recommendations for how this could be embedded within practice. Recommendations included greater national provision of decision aids, common and consistent approaches to shared decision-making (e.g. conduct, quality monitoring, provision and support), and the inclusion of shared decision-making in commissioning standards and contracts. Health commissioners are expected to ensure that health care is distributed 'appropriately, equitably and efficiently, while remaining responsive to the wishes and concerns of individual patients' (The King's Fund 2011). Yet, to reach standardisation in NHS care, three things need to be in place. First, the intervention/approach should be evidence-based. Second, there should be a consistent method or approach that is easy to implement (e.g. a standard protocol or tool). Third, there should be a clear understanding of how this is delivered, used and evaluated in clinical practice.

The Ida Telecare Platform

Ida telecare (http://idainstitute.com/toolbox/telecare/) offers an online platform of easy-to use tools and resources to help people with hearing loss prepare for appointments and successful manage daily communication and decisions related to their hearing. There are 6 unique telecare tools:

1. **Living well Online**
   The individual identifies when communication (with/without hearing aids) is most easy and difficult and which steps they can take to improve communication.

2. **My Turn to Talk for Adults**
   The individual identifies their most important communication partners and questions they wish to discuss.

3. **Tinnitus Thermometer**
   The individual explains how they are experiencing their tinnitus at the time of the appointment and what expectations they have.

4. **Why Improve My Hearing?** (Appendix 4.)
   The individual reflects on how improved hearing and communication would change their everyday life.

5. **Top Tips for Managing Conversation**
   The individual learns effective tips and tricks for successful communication and hears from other people with hearing loss how they apply the methods.

6. **Dilemma Game**
   The individual reviews common difficulties in communication situations and reviews possible solutions while being encouraged to think up their own.

The tools have been designed to cover three main areas; i) prepare for your first appointment (tools 1-4), ii) prepare for follow up (tools 1-3), and iii) everyday life with hearing loss (tools 5-6). The aim of the tools is to foster person-centred care and enhance long-term relationships between patients and clinicians.

Previous research: Ida Motivation Tools

Understanding patient's motivations as to why it is important for them to seek help for their hearing loss may be one approach that can improve hearing aid adoption and use (Ridgeway et al. 2015). Motivational Engagement has been put forward as a means of addressing patients' motivations (Rubak et al. 2005), and has been successfully applied to people with hearing loss (Beck and Harvey 2009; Aazh 2015). The Ida Institute previously developed Motivation Tools (Line, Box, and Circle) to facilitate collaborative interactions between the audiologist and the patient. The Motivation Tools are specifically designed to guide the audiologist to identify where the patient lies within the rehabilitation process so that they can better support, engage and coach patients during appointments. The Tools are, therefore, intended to open a dialogue to facilitate shared decision-making, identify individual needs, set joint goals, and support self-management. These have been highlighted as the four guiding principles to help audiologists engage with patients in all key aspects of the rehabilitation process, enhancing motivation (British Society of Audiology 2016). In collaboration with the Ida Institute, MF led the first published study to evaluate the Ida Institute's Motivation Tools (Ferguson et al. 2016). The study showed that the Motivation Tools could be successfully incorporated into the UK audiology clinic structure, and that audiologists who used them were positive about their use. When the Motivation Tools were used, patients reported a number of benefits at the hearing assessment and hearing aid fitting appointments compared to a 'standard' care control group. These included greater self-efficacy and readiness to follow the recommendations' of their audiologist, reduced anxiety levels, and higher levels of shared decision-making (Ferguson et al. 2016; Ferguson et al. 2016). Furthermore, across this and another study, self-efficacy, readiness and positive expectations predicted satisfaction with hearing aids when measured 6-10 weeks post-hearing aid fitting (Ferguson et al. 2016). However, the Tools were used with patients who had already opted to receive hearing aids. The next stage of research is to assess the feasibility of using the Tools as part of the patient's decision-making process at *the initial hearing assessment* to guide future care decisions (e.g. adoption, or not, of hearing aids).

The Line Motivation Tool has also been incorporated into the '*Why Improve My Hearing?*' Telecare Tool. The Tool is intended to be used online by the patient prior to their assessment and/or hearing aid fitting appointment, and asks '*How important is it for you to improve your hearing?'*. This question taps

into readiness to take action. The Tool encourages the patient to think about how and why improving their hearing in different situations could affect their daily life. Encouraging patients to use the Tool and reflect on their individual needs *before* they come to clinic could not only save time during the appointment, but could also result in the patient being better prepared ahead of time to work with the audiologist on matters that are important and relevant to them. The provision of internet-delivered audiological rehabilitation is becoming increasingly recognised as a means of extending services beyond the confines of the clinic to improve patient outcomes. For example, online rehabilitation programs have been shown to improve outcomes in both first-time (Ferguson et al. 2016) and existing hearing aid users (Thorén et al. 2014). Whether the early delivery of internet-based hearing healthcare confers benefits to people with hearing loss who have not yet attended their first clinic appointment remains to be established.

2. RATIONALE

Evidence suggests that people with hearing loss who are aware of their communication needs and concerns prior to their hearing appointments are more motivated to take action (Beck et al. 2007; Poost-Foroosh et al. 2011), better equipped to make decisions (Laplante-Lévesque et al. 2010; Laplante-Lévesque et al. 2010) and guide the support they need from audiologists to help them on their journey (English 2005; Grenness et al. 2014). Consequently, patient satisfaction with care is improved (Laplante-Lévesque et al. 2012; Weinstein 2015). Furthermore, understanding patient's motivations as to why it is important for them to seek help for their hearing loss may be one approach that can improve hearing aid adoption and use (Ridgeway et al. 2015). The provision of internet-delivered audiological rehabilitation is becoming increasingly recognised as a means of extending services beyond the confines of the clinic to improve patient outcomes. For example, online rehabilitation programs have been shown to improve outcomes in both first-time (Ferguson et al. 2016) and existing hearing aid users (Thorén et al. 2014). Whether the early delivery of internet-based hearing healthcare confers benefits to people with hearing loss who have not yet attended their first clinic appointment remains to be established.

The present investigation will offer an initial assessment of the **feasibility** of providing Ida Telecare tools (tool uptake, use, and intended mechanisms of benefit) within an NHS audiology service. It will use the Medical Research Council (MRC) Process evaluation of complex interventions (Moore et al. 2015) as a framework to formally evaluate the implementation, mechanisms of action and influencing factors on the use of the tools. These are factors specifically recommended to accompany evaluations of efficacy for all complex interventions. The research will go further to examine what the "active ingredients" of each of the telecare tools are to elicit health behaviour change, which will help guide appropriate and sensitive outcome selection for future tool efficacy analyses. Finally, it will provide key parameter estimates for implementation of the Ida telecare tools in NHS audiology.

A second concurrent research arm will provide an initial assessment of the **effectiveness** of one of the Ida Telecare tools, '*Why Improve My Hearing?*' to improve patient self-efficacy and readiness to manage their own hearing health. The Tool will be used by one group of patients before their first assessment appointment and compared to a group receiving standard clinical care. This builds upon a published assessment of the effectiveness of Ida Institute's 'the line' (incorporated within the *'Why Improve My Hearing?'* telecare tool), extending this research by examining whether patient-led motivational engagement might influence self-efficacy, readiness and shared decision-making for hearing aid uptake.

3. THEORETICAL FRAMEWORK

The Behaviour Change Wheel (BCW) was specifically developed to examine Health-related Behaviour Change arising from an intervention (Michie et al. 2011). It represents a collection of mini-frameworks to link intervention function and policy categories to behaviour (See **Fig 1**, Appendix 5.). The COM-B system forms the 'hub' of the BCW (See **Fig 2**, Appendix 5.) and identifies three core components predicting an individual's health behaviour change arising from interventions:

- **Capability**: The individual's psychological and physical capacity to engage in the activity. This includes having the necessary knowledge and skills.
- **Opportunity**: Factors that lie outside of the individual that make the behaviour possible or prompt it.
- **Motivation**: Brain processes that energise and direct behaviour. This includes habitual processes and emotional responses as well as analytical decision making.

The COM-B system is gaining substantial interest across numerous health conditions and has been specifically identified as a desired approach to the conceptualisation of Health Behaviour Change in audiology research (Coulson et al. 2016).

The Theoretical Domains Framework (TDF) is a validated integrative framework of theories of behaviour change, developed by psychological theorists, in collaboration with health service researchers and health psychologists (Cane et al. 2012). The TDF enables theoretical constructs relating to behaviour change (grouped into domains) to be mapped directly to the COM-B system components of Capability, Opportunity and Motivation (See **Fig 3**, Appendix 5.). In this research, the TDF will be used as a framework by which to thematically organise data. This will enable data to be mapped to the COM-B system to identify the determinants of health behaviour change arising from the Ida Telecare tools.

The Behaviour Change Technique (BCT) Taxonomy v1 (Michie et al. 2013) is an extensive, consensually agreed hierarchically structured taxonomy of techniques used in behaviour change interventions (See **Fig 4**, Appendix 5.). A Behaviour Change Technique is an observable, replicable and irreducible component of an intervention designed to alter or redirect causal processes that regulate behaviour (an "active ingredient", Michie et al. 2013, pp.82).

Taken together, these four approaches represent the latest developments in the science of Health-related Behaviour Change. In this research we will use these resources in the following ways:

Feasibility: The BCT Taxonomy will be used to identify the smallest aspects of health behaviour change comprising each of the Ida Telecare tools, thus identifying the "active ingredients" of behaviour change arising from the Ida telecare platform. This will then be mapped to the COM-B system in terms of how they relate influence health-related behaviour change

Effectiveness: The use and impact of the *'Why Improve My Hearing?'* telecare tool in the audiological rehabilitation process will be examined qualitatively using semi-structured interviews with patients and audiologists. Data will be subjected to inductive thematic analysis (Braun and Clarke 2006), guided by the research question. Generated codes and themes will then be organised using the TDF and mapped to the COM-B system to examine if, and if so how, the intervention initiated health behaviour change according to individuals' Capability, Opportunity and Motivation.

4. RESEARCH QUESTION / AIM(S)

Sub-study 1: Feasibility

Research Question: How, when and why do NHS audiology patients use the Ida Telecare tools to prepare for their hearing appointments.

Aim: To assess the feasibility of providing Ida telecare tools to NHS audiology patients using a process evaluation.

Sub-study 2: Effectiveness

Research Question: How might the *'Why Improve my Hearing?'* telecare tool help patients manage their own hearing health?

Aim: To examine the effectiveness of the Ida '*Why Improve My Hearing?*' Telecare tool, to improve patient self-efficacy and readiness to manage their own hearing health.

4.1. Objectives

Sub-study 1: Feasibility

Specific objectives:

1. Implementation (feasibility) of the tools: ***How and when are the Ida telecare tools used by patients?***
    a. Establish study recruitment rates.
    b. Examine usability of the tools using Think Aloud techniques.
    c. Quantify uptake, usability and completeness of the tools by patients.
    d. Identify whether the tools used by patients in-between appointments/in place of appointments (e.g. in place of the optional follow-up).

2. Mechanisms of impact: ***What mechanisms of benefit do the tools target?***
    a. What are the key mechanisms targeted by the tools (e.g. knowledge or skill, motivation) and are these obvious to patients and audiologists?
    b. How might we expect the targeted mechanisms to improve patient experiences and outcomes (e.g. improved self-efficacy, readiness to take action) and what might the best measures be to capture success?

3. Contextual factors: ***What influences patients' use of the tools?***
    a. Explore at what stage in the pathway the tools might be most useful to patients
    b. Identify key barriers to use and how might these be overcome.
    c. Establish whether there any informational/support gaps or additional tool requirements.

Sub-study 2: Effectiveness

Specific objectives:

1. To evaluate the impact of using the Tool on hearing aid uptake, use, self-efficacy and patient's readiness to manage their hearing loss (Quantitative).

2. To use the COM-B model to investigate the views and experiences of patients and audiologists in terms of how the Tool was used in the audiological rehabilitation process (Qualitative).

4.2. Outcome

To provide important information to inform the implementation of Ida Telecare platform into a routine NHS adult audiology service and preliminary evidence for the effectiveness of the *'Why Improve My Hearing?'* Ida Telecare tool.

5. STUDY DESIGN AND METHODS OF DATA COLLECTION AND DATA ANALYSIS

Study design: Two single-centre sub-studies assessing 1. Feasibility of implementing the Ida Telecare platform within an NHS adult audiology service, and 2. Effectiveness of the Ida Telecare tool *'Why Improve My Hearing?',* in a cohort of first-time NHS audiology patients. Both sub-studies will use mixed-methods (integrating quantitative and qualitative methodologies), which is considered advantageous in the evaluation of patient-centred care, providing an in-depth understanding of the patient experience (Agency for Healthcare Research and Quality 2013).

All patients invited to direct referral hearing assessment appointments at Nottingham Audiology Service between September 2017 and February 2018 will receive a study information pack alongside their appointment confirmation letter. The pack will contain a study invitation letter, the participant information sheet and a reply slip with a pre-paid addressed envelope for return. Upon receipt of completed reply slips, eligible patients will be randomised to one of the two intervention sub-studies (feasibility or effectiveness) using minimised allocation based on gender (male/female) and age: younger (<70 years old)/older (70 years old or greater). The minimised allocation will be generated and maintained by a researcher not directly involved in patient recruitment or testing (e.g. EH, MAF), using OxMaR software (O'Callaghan 2014). Patients will be contacted by a researcher (by telephone) to answer any questions they may have about the study. The researcher will then send an informed consent form for the patient to complete and return by email or post.

Recruitment will take place for a fixed duration of 6 months. If the recruitment target of n=56 patients for sub-study 2 has been reached before the end of the 6-month recruitment period, all subsequent patients returning reply slips will be automatically allocated to the feasibility study (sub-study 1).

Sub-study 1: Feasibility

1. Implementation: Feasibility data and Think Aloud

Patients enrolled on this sub-study arm will be sent links to each of the Ida telecare tools by the Research Assistant (RA) by email wherever possible (alternatively via post) and invited to use as many of the online tools as they wish at home, prior to each of their hearing appointments (assessment, fitting, optional follow-up). Patients will be asked to provide the researcher with a copy of

the .PDFs (by email or printed and sent via post) for all completed tools at each stage of the patient pathway. To examine recruitment rates we will quantitatively assess:

a. the number of information packs sent to patients
b. the number of reply slips received (response rate)
c. the number of participants returning reply slips who are willing to take part in the study.

We will also record whether there are any patients who return reply slips wishing to take part, but are unable to for any personal (e.g. lack of technical knowledge required to use online tools) or technical reasons (e.g. no computer/internet). Continuous data will be summarised using means and standard deviations and categorical data will be summarised using percentages.

A subset of study participants (n=15) who are deemed eligible for hearing aid fitting will generate, in collaboration with the audiologist, short, medium and long-term personal goals relating to their aural rehabilitation. Goal setting will take place during the hearing assessment appointment. Goals will be recorded on a purpose-designed form that the patient will use to monitor their own progress towards achieving the goals. How successful the patient has been at achieving their short-term goal only will be assessed 2-4 weeks after they are fitted with hearing aids via a short online questionnaire provided by the audiologist.

A different subset of study participants will attend the research unit at Ropewalk House, where they will complete whichever tools they choose whilst performing 'Think Aloud'. Think Aloud is a method whereby participants speak aloud any words in their mind as they complete a task (Lewis 1982). It offers real-time assessments of individual's thought processes and problem-solving techniques, providing in-depth data about the usability of materials that is not typically externalized (Boren and Ramey 2000). The Think Aloud activities will be video recorded and analysed by the research team using inductive thematic coding alongside data collection. Data collection will end when new codes cease to be generated (estimated at 6-8 participants).

Within the NHS, patients typically attend a hearing assessment appointment followed by a hearing aid fitting appointment. Often, there is also an optional 10-week follow up appointment. The researcher will contact patients by telephone or email (according to patient preference) no more than 5 working days after each hearing appointment to:

i) ensure data held about patients' use of the Telecare tools is accurate and complete and to obtain any outstanding .PDF files for completed tools,
ii) establish whether or not the tools were discussed with the audiologist during the appointment,
iii) establish the outcome of the appointment (i.e. for hearing assessment appointments: no treatment, onward referral to ENT, or prescribed hearing aids), and
iv) establish whether or not patients have attended or booked further appointments e.g. 'repair' appointments (additional audiological care and hearing aid maintenance), or an optional follow-up.

For those participants choosing not to opt-in to a follow-up appointment with an audiologist, we will identify whether any of the Ida telecare tools were used in place of that formal appointment.

2. Mechanisms of impact: BCT Taxonomy coding

Each of the Ida telecare tools will be examined in terms of their intended mechanisms of action for bringing about health behaviour change by the research team. First, the CI will speak directly with the Ida institute to gather details about the development of the tools and the underpinning theory guiding

them. The research team will then use BCT Taxonomy (Michie et al., 2013) to code the "active ingredients" of each telecare tool. The BCT Taxonomy enables users to specify the smallest components of behaviour change interventions that can bring about change. By identifying and defining the targeted behaviour change components of the Ida telecare tools, relevant and appropriate outcome measures can be proposed for efficacy studies that will be sensitive to those mechanisms of benefit.

3. Contextual Factors: Semi-structured interviews

Semi-structured interviews with patients and audiologists will be conducted by a member of the research team to gather in-depth information about:

- why patients decided to use the telecare tools
- what benefit(s) both patients and audiologists attributed to use of the tools
- at what stage in the pathway the tools might be most relevant and/or useful to patients
- any additional information or support that might have been useful to include within the tools, or any extra tools or activities that might be considered
- whether patients experienced any barriers to use of the tools and how these might be addressed.

Interview schedules have been created by the research team and will be reviewed by patient representatives to ensure questions are clear and relevant to patients. Data collection will cease once data saturation has been reached. A sample size of n≤15 has been found to be generally sufficient to achieve data saturation for semi-structured interviews(Guest et al. 2006).

Interviews will be audio recorded and anonymously transcribed verbatim. Transcripts will be analysed by the research team using inductive thematic analysis. Generated codes and themes relating to benefit(s) of the interventions and additional suggested content will be organised using the TDF and mapped to the COM-B system to examine how the telecare tools might influence health behaviours according to individuals' Capability, Opportunity and Motivation.

Sub-study 2: Effectiveness

1. Impact of the 'Why Improve My Hearing?' Ida telecare tool

Enrolled patients to this sub-study will be minimised to one of two arms: (i) treatment-as-usual, patients receiving standard care only, and (ii) experimental pathway, patients receive standard care plus access to the Ida Telecare *'Why Improve My Hearing?'* tool online prior to their first assessment. Minimised allocation will be based on gender (male/female) and age: younger (<70 years old)/older (70 years old or greater). The minimisation will be generated and maintained by a researcher not directly involved in patient recruitment or testing (EH, MAF), using OxMaR software (O'Callaghan 2014).

The following validated outcome measures will be completed online or via post in accordance with the patients' preference:

Baseline – before completion of the '*Why Improve My Hearing?*' Ida telecare tool and immediately post hearing assessment appointment:

- *Measure of Audiologic Rehabilitation Self-efficacy for Hearing Aids* (MARS-HA) (West and Smith 2007). Includes four subscales: basic handling, advanced handling, adjustment to hearing aids, and aided listening skills. Respondents indicate how confident they are that they

could do the things described on an 11-point scale (0%=cannot do this, to 100%=certain I can do this).

- *Short-form Patient Activation Measure* (PAM) (Hibbard et al. 2005). A 13-item measure that assesses patient knowledge, skill, and confidence for self-management of their health. Each item is scored on a four-point ordinal scale (0 = disagree strongly to 3 = agree strongly).
- *Expected Consequences of Hearing aid Ownership* (ECHO) (Cox and Alexander 2000). A 15-item self-assessment instrument for evaluating expectations about hearing aids from which four composite scores are derived (positive effect, service and cost, negative features and personal image). Each item is scored using a seven-point Likert scale (A = not at all to G = tremendously).
- *Social Participation in adults with mild-to-moderate hearing loss* (SPaRQ) *(Heffernan et al. 2015; Heffernan et al. 2016).* A 25-item questionnaire designed to assess the effects of hearing loss on the emotional (n = 13), and social/situational adjustment (n = 12) of older people, scored using a three-point scale (4 = yes; 2 = sometimes; 0 = no).
- *Hearing Handicap Inventory for the Elderly* (HHIE) (Ventry and Weinstein 1982). A 25-item questionnaire designed to assess the effects of hearing loss on the emotional (n = 13), and social/situational adjustment (n = 12) of older people, scored using a three-point scale (4 = yes; 2 = sometimes; 0 = no).
- *Glasgow Hearing Aid Benefit Profile* (GHABP), Part I (Gatehouse 1999). Assesses hearing disability (or activity limitations) and handicap (or participation restrictions; Part I), and hearing aid use, benefit, residual disability and satisfaction (Part II). Each domain is measured on a five-point scale.
- *Stage of readiness questionnaire* (Babeu et al., 2004) is a 5-item measure that indicates readiness to obtain and use hearing aids.
- [immediately post hearing assessment only] *Audiology outpatient survey* (Ferguson et al., 2016), a 10-item measure of patient satisfaction with the service.

Patients' pure-tone audiometric hearing thresholds will be obtained following the initial hearing assessment from NAS records.

10-12 weeks post hearing aid fitting

- *Percentage of patients that take-up hearing aids* using the NAS patient management system
- *Hearing aid use* (data logging internal to the hearing aid)
- *MARS-HA*
- *SPaRQ*
- *HHIE*
- *GHABP, Part II*
- *Satisfaction with Amplification in Daily Life* (SADL) (Cox and Alexander 1999). A 15-item companion instrument to the ECHO questionnaire, from which four composite scores are derived (positive effect, service and cost, negative features and personal image). Each item is scored using a seven-point Likert scale (A = not at all to G = tremendously).
- *PAM*

Continuous data (e.g. age) will be summarised using means and standard deviations, whereas categorical data (e.g. gender) will be summarised using percentages. Medians and quartiles will be reported for non-parametric data, and means, standard deviations and 95% confidence intervals for normally-distributed parametric data. Normality of continuous data will be assessed using histogram plots and the Shapiro Wilk Test. For each measure, the difference between arms will be examined

using parametric (e.g. T-test) or non-parametric (e.g. Wilcoxon Rank Sum Test) statistics where appropriate. For categorical data, Chi-square test will be used, and Fishers exact test if any of the cells are less than 5. Statistical significance will be set at p=.05 and corrected (e.g. Bonferroni) for multiple comparisons. As outcome data will be collected after the intervention period, no interim analyses will be performed.

2. ***Patient and Audiologist views and experiences***

For the alternative pathway only:

A sub-set (6/28) of hearing assessment appointments will be video recorded to enable a detailed assessment of how the tools were jointly used by the patient and audiologist. The videos will also be shared with the research funders to identify how the tools might be improved or amended to better suit patients' needs in future.

A sample of patients and audiologists will be recruited from the alternative pathway using maximum variation sampling (Patton 1990), to take part in semi-structured interviews with a member of the research team. Interviews will examine patients and audiologists perceptions and experiences of using the 'Why Improve My Hearing?' telecare tool, specifically:

- what influenced patients use of the tool
- how, when and where the tool was used by patients in preparation for their hearing assessment appointment
- how the tool was used jointly by audiologists and patients within the clinical appointment
- what benefit(s) patients and audiologists attributed to use of the tool

The interview schedules will be designed to provide an in-depth understanding, and will be reviewed by patient representatives to ensure clarity of concepts and relevance to patients. Data collection will cease once data saturation has been reached.

Interviews with patients and audiologists will be audio recorded and anonymously transcribed verbatim. Transcripts will be subjected to inductive thematic analysis by the Study Co-ordinator, guided by the research questions. Generated codes and themes will be categorised according to the TDF and mapped to the COM-B system to examine if, and if so how, the intervention prompted changes in health behaviours relative to individuals' Capability, Opportunity and Motivation.

Study timeline

	2017					2018							
	study	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug
Study set-up and recruitment													
Seek approvals (Ethics/sponsor)													
Study setup													
NAS Audiologist briefing													
Recruitment of NAS direct referral patients													
Feasibility													
Quantitative data collection (initial assessment)													
Quantitative data collection (fitting)													
Qualitative Think Aloud & concurrent analyses													
Quantitative data collection (follow-up)													
BCT Taxonomy coding													
Qualitative semi-structured interviews													
Qualitative interview transcription & analysis													
Quantitative data analysis													
Write-up and dissemination													
Effectiveness													
Quantiativce data collection (initial assessment)													
Qualitative semi-structured interviews													
Qualitative analysis using COM-B													
Quantiative data collection (6-weeks post-fit)													
Quantitative data analysis													
Write-up and dissemination													

Data Storage and Access

All data will be stored in password protected databases (e.g. SPSS) or files on a secure part of the NIHR Nottingham BRC network that is accessed only by members of the research team. All paper files will be stored in locked cupboards within the NIHR Nottingham BRC. Audio and video recordings will be securely stored electronically for a period of no more than 18 months. Arrangements will be made for the confidential destruction of these recordings within 6 months of the planned study end-date of 31st August 2018.

Anonymised data arising from this research may be shared with other genuine researchers.

6. STUDY SETTING

Adult patients will be recruited from Nottingham Audiology Service (NAS), Nottingham University Hospitals NHS Trust. Quantitative outcomes will be obtained by telephone, email or post. Qualitative assessments will take place at the NIHR Nottingham BRC.

7. SAMPLE AND RECRUITMENT

7.1. Eligibility Criteria

Over 200 new patients attend initial hearing assessment appointments at NAS each month. Typical response rates for similar recruitment strategies at NAS has been at least 10 consenting patients per month (Ferguson et al. 2016).

All patients invited to direct referral hearing assessment appointments at NAS between September 2017 and February 2018 will be invited to take part in the study.

7.1.1. Inclusion criteria

- Adults aged ≥18 years (no upper age limit)
- Ability to offer informed consent
- Fluent in the English language (written and spoken, does not have to be their first language)
- Access to the Internet.

7.1.2. Exclusion criteria

- Previously prescribed hearing aids

7.2. Sampling

7.2.1. Size of sample

Sub-study 1: Feasibility

- Quantitative: Not applicable

One of the main aims of this Arm is to identify recruitment rates/intervention take-up in this population.

- Qualitative:
  - Think Aloud n=6-8 patients

Data collection will cease once data saturation has been reached. A sample size of 6-8 has been found to be generally sufficient to achieve data saturation for Think Aloud techniques (Henshaw et al. 2017).

  - Semi-structured interviews with patients and audiologists: n≤15

Data collection will cease once data saturation has been reached (Guest et al. 2006).

Sub-study 2: Effectiveness

- Quantitative: n=56 participants (n=28 per arm)

In order to detect a 10% change in MARS-HA (smallest possible change) at a power of 80% and type II error rate of 5%, a total of 50 participants are required, 25 in each arm. This was calculated using a standard deviation for global MARS-HA scores derived from (Ferguson et al. 2016). As outcome measures will be taken immediately post-assessment, it is expected that fewer than usual participants will fail to complete outcome measures. Hence, a conservative attrition rate of 15% has been used, thus accounting for attrition, a total of 56 participants (28 per arm) will be recruited.

- Qualitative: Semi-structured interviews with patients and audiologists

Data collection will cease once data saturation has been reached.

7.2.2. Sampling technique

Total population sampling will be used (all patients invited to direct referral hearing assessment appointments at NAS) over a 6 month period (September 2017-February 2018).

7.3. Recruitment

7.3.1. Sample identification

All patients invited to direct referral hearing assessment appointments at NAS between beginning-September 2017 and end-February 2018 will be sent a study information pack alongside their appointment confirmation letter, by post (sent via NAS, with administrative assistance from a NIHR Nottingham BRC researcher). The pack will contain a study invitation letter, a participant information sheet, and a reply slip with a pre-paid addressed envelope for return. Half of the information packs will recruit patients to the Feasibility sub-study, and half to the Effectiveness sub-study. Only participants who return the reply slip stating that they are happy to take part in the study will be contacted by the research team. The research team will not access information stored in NHS patient records in this research, with the exception of hearing assessment results (Pure Tone Audiometric (PTA) thresholds) and hearing aid take-up rates, which are data required to fully describe the study sample.

For visits to the research unit, travel expenses will be reimbursed and participants will be offered a token payment of £5 per hour to, in part, recompense for their time.

Audiologists involved in seeing patients that have taken part in this research will be identified by the Nottingham Audiology Service administration team. All audiologists involved will all be invited by email to take part in semi-structured interviews. The email will provide the audiologist information sheet as an attachment. Those audiologists agreeing to take part in the interviews will be invited to attend the NIHR Nottingham Biomedical Research Unit where informed consent will be obtained.

7.3.2. Consent

Patient and audiologist information sheets and consent forms will have been approved by the Sponsor, REC and Health Research Authority (HRA) and satisfies all legal requirements. These documents will have been provided to participants prior to their visit to NAS or the NIHR Nottingham BRC.

Informed consent will be obtained by the NIHR Nottingham BRC researcher at the NIHR Nottingham BRC. This will be obtained prior to the participant undergoing any activities that are specifically for the purposes of the study.

There will be an opportunity for potential participants to ask questions, whereby the potential participant and a NIHR Nottingham BRC researcher will discuss the nature and objectives of the study and possible risks associated with their participation.

The researcher will assess the capacity of the participant to consent to take part in the research. For consent to be ethical and valid in law, participants must be capable of giving consent for themselves and they will satisfy all the following requirements:

- 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)

8. ETHICAL AND REGULATORY CONSIDERATIONS

Prior to the commencement of the research, including the recruitment of potential participants, the protocol and all supporting documentation (Patient Information Sheet, Consent Form, etc.) will be reviewed and approved by the Sponsor, an NHS Research Ethics Committee (REC) and the Health Research Authority (HRA). Review is in line with the principles outlined in the NHS Research Governance Framework for Health and Social Care (2nd Edition) and with consideration to Good Clinical Practice Guidelines. No amendments to the protocol are to be made without permission of the Sponsor

To ensure data confidentiality, no one from the research team will have access to patient data without explicit consent – this includes the screening of medical notes to identify potential participants. Only participants expressing an interest in taking part in the study (those returning a reply slip) will be approached by a researcher at the NIHR Nottingham Biomedical Research Unit to assess eligibility.

There are no direct benefits to participants taking part in the feasibility arm of this research. However, participation in the effectiveness arm may result in improved self-efficacy and readiness for patients to manage their hearing loss.

It is not expected that this study will pose any significant risks to participants. There is minimal risk that adults with hearing loss may experience minimal distress when completing the questionnaires. All questionnaires are validated, frequently used in research, and are not known to be associated with any adverse events or reactions. Steps will also be taken to minimise burden placed on participants when completing the questionnaires. They will have ample time to complete each questionnaire at home, and advised to take breaks whenever needed.

8.1. Assessment and management of risk

If participants express a concern about their hearing loss or any other aspect of their health, they will be advised to contact NAS or their GP respectively.

All participants will be provided contact details of the Chief Investigator via the Participant Information Sheet should participants require further clarification or additional information on the research procedure, or have any other queries or concerns about the research or the way in which it is being conducted. The Participant Information Sheet will also inform the participants that they can contact the Patient Advice and Liaison Service (PALS), Nottingham University Hospitals NHS Trust.

8.2. Research Ethics Committee (REC) review & reports

Prior to commencing any study activities, the research will be reviewed and approved by an NHS Research Ethics Committee (REC) and the Health Research Authority (HRA).

The NUH Research & Innovation department, acting on behalf of Nottingham University Hospitals NHS Trust as the Sponsor will review and confirm that the site has capacity and capability to deliver all aspects of the study defined by the relevant section of the protocol.

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.

8.3. Peer review

This research protocol has been reviewed both internally by the NIHR Nottingham BRC leadership team and externally by the Ida Institute research committee who awarded funding for this research to be conducted. Confirmation received on 04/05/2017.

8.4. Patient & Public Involvement

Patients and the public will be actively involved in this research through advising and reviewing patient documents (patient information sheet and semi-structured interview schedules). The BRC has a dedicated Patient and Public Involvement (PPI) advisory group and employs a PPI manager who can offer training and support to PPI representatives as required.

8.5. Regulatory Compliance

Before any patients are enrolled into the study, the Principal Investigator will apply for HRA approval for the study and will make contact with the R&I department and the local Clinical Research Network (as this study is suitable for portfolio adoption).

Prior to commencing recruitment, capacity and capability to conduct the study will be confirmed, as per the HRA approval letter.

Any amendment to the protocol should be considered that it may potentially affect capacity to continue in the study, the Principal Investigator will inform the Sponsor of the proposed amendment. The amendment will be submitted as per Section 8.7.

8.6. Protocol compliance

Researchers are expected to conduct the study in accordance with the protocol. Non-compliances will be reported as per the Sponsor procedure *SOP-RES- 017 Non Compliance and Serious Breach Reporting*. All protocol non-compliances are expected to be reported to the sponsor, who will assess the non-compliance and report to REC is deemed appropriate.

Accidental protocol deviations can happen at any time. They must be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.

Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

8.7. Amendments

If the Principal Investigator wishes to make any amendments to the study, they will be expected to follow the process outline in Sponsor procedure *SOP-RES-024 Amendments to Active Research Studies*.

It is the Sponsor's responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC.

In order to make a substantial amendment to the REC application or the supporting documents, a valid notice of amendment should be submitted to the REC for consideration. Site R&D departments will also need to be provided with the information on the amendment in order to assess their continued capacity and capability for the study.

Non-substantial amendments also need to be notified to the HRA as well as the relevant R&D departments of participating sites to assess whether the amendment affects the continued capacity for that site.

Amendment history will be tracked in Appendix 3, and logged in the Trial Master File.

8.8. Adverse Event

Definitions

Adverse Event (AE): any untoward medical occurrence in a patient or clinical study subject.

Serious Adverse Event (SAE): any untoward and unexpected medical occurrence or effect that:

Results in death

- Is life-threatening – refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe
- Requires hospitalisation, or prolongation of existing inpatients' hospitalisation
- Results in persistent or significant disability or incapacity
- Is a congenital anomaly or birth defect

Medical judgement should be exercised in deciding whether an AE is serious in other situations. Important AEs that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above, should also be considered serious.

Hospitalisations for elective treatment of a pre-existing condition do not need reporting as SAEs.

Reporting Procedures

Depending on the nature of the event the reporting procedures below should be followed. Any questions concerning adverse event reporting should be directed to the Chief Investigator in the first instance.

Non serious AEs: All such events, whether expected or not, should be recorded.

Serious AEs: An SAE form (TAFR01910) should be completed should be completed without unjustified delay and sent to the Chief Investigator, who will then report to the Sponsor.

All SAEs should be reported to the REC where in the opinion of the Chief Investigator, the event was:

- **'related'**, i.e. resulted from the administration of any of the research procedures; and
- **'unexpected'**, i.e. an event that is not listed in the protocol as an expected occurrence

Sponsor contact details for SAEs:

ii. Email (RDSAE@nuh.nhs.uk)

iii. Hand delivered, not mailed (R&I, NHSP, C Floor, South Block, QMC)

iv. Telephone (0115 9709049) if written report not immediately possible

Any queries, please contact a member of staff in the Research & Innovations department:

Telephone 0115 9709049 or 0115 9249924 ext 70659 or 70660.

8.9. Data protection and patient confidentiality

Case Report Forms (CRFs)
Each participant will be assigned a study identity code number, allocated at randomisation if appropriate, for use on CRFs, other study documents and the electronic database. The documents and database will also use their initials (of first and last names separated by a hyphen or a middle name initial when available) and date of entry into the study (dd/mm/yy).

CRFs will be treated as confidential documents and held securely in accordance with regulations. The investigator will make a separate confidential record of the participant's name, date of birth, local hospital number or NHS number, and Participant Study Number (the Study Recruitment Log), to permit identification of all participants enrolled in the study, in accordance with regulatory requirements and for follow-up as required.

CRFs shall be restricted to those personnel approved by the local Principal Investigator and recorded on the 'Study Delegation Log.'

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 Investigator is the data custodian and shall sign a declaration ensuring accuracy of data recorded in the CRF.

Source Documents
Source documents shall be filed at the investigator's site and may include but are not limited to, consent forms, current medical records, laboratory results and records. A CRF may also completely serve as its own source data. Only study staff as listed on the Delegation Log shall have access to study documentation other than the regulatory requirements listed below.

Direct access to source data/documents
The CRF and all source documents shall made be available at all times for review by the Principal Investigator, Sponsor's designee and inspection by relevant regulatory authorities (e.g. DH, Human Tissue Authority).

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, 1998. The CRF will only collect the minimum required information for the purposes of the study. CRFs 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 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. Electronic data will be backed up every 24 hours to both local and remote media in encrypted format.

Record Retention and Archiving
In compliance with the ICH/GCP guidelines, the Principal Investigator will maintain all records and documents regarding the conduct of the study. These will be retained for at least 15 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.

The Study Master File and study documents held by the Principal Investigator on behalf of the Sponsor shall be finally archived at secure archive facilities at NBRC. This archive shall include all study databases and associated meta-data encryption codes.

8.10. Indemnity

As Nottingham University Hospitals NHS Trust is acting as sponsor for this study, NHS indemnity applies. NHS bodies are legally liable for the negligent acts and omissions of their employees. Non-negligent harm is not covered by the NHS indemnity scheme. The Nottingham University Hospitals NHS Trust, therefore, cannot agree in advance to pay compensation in these circumstances. In exceptional circumstances an ex-gratia payment may be offered

Access to the final study dataset
The research team, SSG and Sponsor will have access to the final study dataset.

8.11. Indemnity

As Nottingham University Hospitals NHS Trust is acting as sponsor for this study, NHS indemnity applies. NHS bodies are legally liable for the negligent acts and omissions of their employees. Non-negligent harm is not covered by the NHS indemnity scheme. The Nottingham University Hospitals NHS Trust, therefore, cannot agree in advance to pay compensation in these circumstances. In exceptional circumstances an ex-gratia payment may be offered.

8.12. Access to the final study dataset

The research team, SSG and Sponsor will have access to the final study dataset.

Informed consent will be obtained from all study participants for anonymised data to be used in any future secondary analysis.

9. DISSEMINATION POLICY

9.1.Dissemination policy

Ownership of the data arising from this study resides with the Sponsor. On completion of the study, the study data will be analysed and tabulated, and a Final Study Report will be prepared in accordance with ICH guidelines, and submitted to the Sponsor and REC.

Following review and approval by the Sponsor, study data may be presented at conferences and department meetings, and published in a peer-reviewed journal by study investigators. Funding from NIHR, R&I NUH, and any other supporting bodies (e.g. University of Nottingham) will be acknowledged.

The sponsor owns the data arising from the study.

On completion of the study, the data will be analysed and tabulated and a Final Study Report prepared.

Participants will be notified of the outcome of the study, via a specifically designed newsletter.

We will communicate the results of this study effectively. Dissemination of the research findings will be far-reaching and aim to cover as many potential avenues as possible to ensure maximal coverage of results to Audiology and relevant professionals, government and policymakers, researchers, educational institutes, people with hearing loss and HA users.

- Talks and poster presentations at national and international conferences and meetings, primarily Audiology and ENT (e.g. British Academy of Audiology, British Society of Audiology, American Academy of Audiology), and INVOLVE conference.
- Publish articles in peer-reviewed national and international journals in accordance with TIDieR guidance. It is anticipated that most publications will be in hearing and auditory science journals.
- Publish articles in professional newsletters (e.g. BAA, BSA, ENT and Audiology News, Audiology Today (USA)).
- Publish articles in newsletters of relevant national (e.g. Action on Hearing Loss, Hearing Link, The Ear Foundation) and local charities (e.g. Nottingham Deaf Society), in addition to utilising their social media and communication channels, which we have agreed in advance.
- Disseminate articles and media clips through web-based activities (e.g. youtube videos, podcasts, blogs, NIHRTV).
- Collaborate with professional audiology and policy making organisations (eg. BSA Practice Guidance, BAA, GP-led clinical commissioning groups), and NHS England (e.g. Chief Scientific Office) to include research findings in documentation and guidelines.

- Examples of learning resources made available to relevant newsletters and at public events (e.g. Deaf Awareness Week) and other organisations (e.g. Nottingham Deaf Society).
- Press releases and interviews with local and national media (e.g. radio, television, newspapers).
- Findings to research participants via newsletter and talks and open days

9.2. Authorship eligibility guidelines and any intended use of professional writers

Data arising from this study will be presented in the Final Study Report. The SSG will be responsible for ensuring that anyone who meets all four criteria for authorship, as set out by the International Committee of Medical Journal Editors (ICMJE), will be offered an authorship on this report and that all those designated authors on this Report meet the four criteria for authorship. Individuals who do not meet all four criteria but who contributed substantially to the study will be acknowledged. Criteria for authorship as set out by the ICMJE include:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work
2. Drafting the work or revising it critically for important intellectual content
3. Final approval of the version to be published
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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11. APPENDICIES

11.1. Appendix 1- Required documentation

- CVs of the research team
- GCP certificates of the research team
- PIS on headed paper
- Consent form on headed paper
- Study outcome questionnaire on headed paper
- Copy of the delegation log, signed by the PI

11.2. Appendix 2 – Schedule of Procedures (Example)

Procedures [a]Feasibility arm [b]Effectivenss arm	**Visit**			
	Pre-initial assessment	**Initial assessment**	**Fitting**	**Follow-up**
Informed consent (post)[a,b]	x			

Demographics and History questionnaire (post)[a,b]	x			
Observation of treatment (phone/email/post)[a]	x	x	x	x
Observation of treatment (phone/email/post)[b]	x			
Think Aloud[a]	x			
MARS-HA[b]		x		
PAM[b]		x		
ECHO[b]		x		
HHIE[b]		x		
Hearing aid data logging[b]				x
GHABP[b]				x
IOI-HA[b]				x
SADL[b]				x
Semi-structured interviews[a,b]				x

11.3. Appendix 3 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made

List details of all protocol amendments here whenever a new version of the protocol is produced.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC committee.

11.4. Appendix 4 – Ida telecare tool, Why Improve My Hearing?

Situation 1

Identify a situation

Choose a photo that shows a situation where you've had difficulty hearing.

Choose or upload an image 

Describe your situation

Mark the number that best describes how important it is for you to improve your hearing.

1

1 10

Why did you place the marker where you did?

Write a sentence or two

What will happen if you continue as you are today?

Write a sentence or two

What would happen if you get a hearing aid and improve your hearing right now?

Write a sentence or two

Add a situation or go to the summary

11.5. Appendix 5 – Health Behaviour Change materials

Fig 1. The Behaviour Change Wheel (BCW)

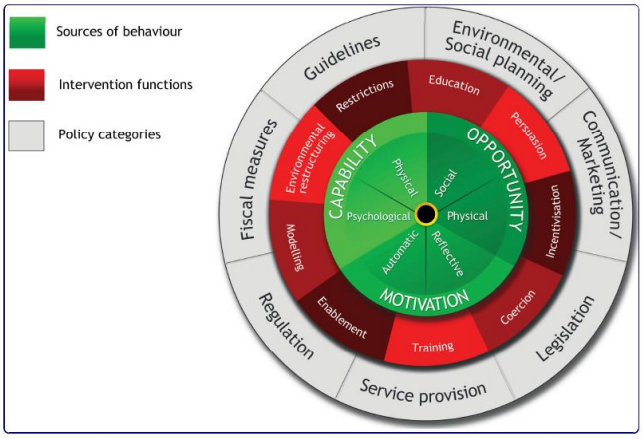

Fig 2. The COM-B System

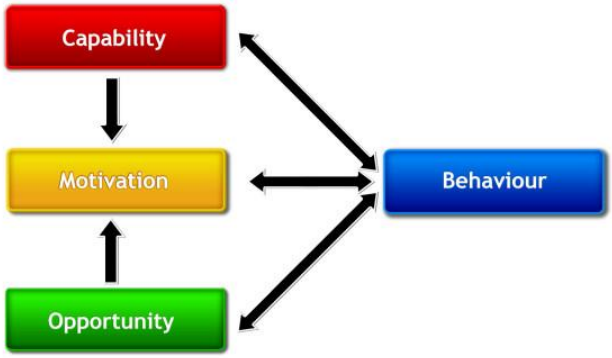

Fig 3. The Theoretical Domains Framework (TDF)

COM	COM subdivision	Theoretical Domains Framework
Capability	Psychological	Cognitive and interpersonal skills Memory, attention and decisions process Behavioural regulation Knowledge
	Physical	Physical Skills
Opportunity	Social	Social influences
	Physical	Environmental context and resources
Motivation	Reflective	Social/professional role and identity Beliefs and capabilities Optimism Goals, intentions and motivation Beliefs about consequences
	Automatic	Reinforcement Emotion

Fig 4. The Behaviour Change Techniques (BCT) Taxonomy: 93 hierarchically-clustered techniques

Page	Grouping and BCTs
1	**1. Goals and planning**
	1.1. Goal setting (behavior) 1.2. Problem solving 1.3. Goal setting (outcome) 1.4. Action planning 1.5. Review behavior goal(s) 1.6. Discrepancy between current behavior and goal 1.7. Review outcome goal(s) 1.8. Behavioral contract 1.9. Commitment
3	**2. Feedback and monitoring**
	2.1. Monitoring of behavior by others without feedback 2.2. Feedback on behaviour 2.3. Self-monitoring of behaviour 2.4. Self-monitoring of outcome(s) of behaviour 2.5. Monitoring of outcome(s) of behavior without feedback 2.6. Biofeedback 2.7. Feedback on outcome(s) of behavior
5	**3. Social support**
	3.1. Social support (unspecified) 3.2. Social support (practical) 3.3. Social support (emotional)
6	**4. Shaping knowledge**
	4.1. Instruction on how to perform the behavior 4.2. Information about Antecedents 4.3. Re-attribution 4.4. Behavioral experiments
7	**5. Natural consequences**
	5.1. Information about health consequences 5.2. Salience of consequences 5.3. Information about social and environmental consequences 5.4. Monitoring of emotional consequences 5.5. Anticipated regret 5.6. Information about emotional consequences
8	**6. Comparison of behaviour**
	6.1. Demonstration of the behavior 6.2. Social comparison 6.3. Information about others' approval
9	**7. Associations**
	7.1. Prompts/cues 7.2. Cue signalling reward 7.3. Reduce prompts/cues 7.4. Remove access to the reward 7.5. Remove aversive stimulus 7.6. Satiation 7.7. Exposure 7.8. Associative learning
10	**8. Repetition and substitution**
	8.1. Behavioral practice/rehearsal 8.2. Behavior substitution 8.3. Habit formation 8.4. Habit reversal 8.5. Overcorrection 8.6. Generalisation of target behavior 8.7. Graded tasks
11	**9. Comparison of outcomes**
	9.1. Credible source 9.2. Pros and cons 9.3. Comparative imagining of future outcomes
12	**10. Reward and threat**
	10.1. Material incentive (behavior) 10.2. Material reward (behavior) 10.3. Non-specific reward 10.4. Social reward 10.5. Social incentive 10.6. Non-specific incentive 10.7. Self-incentive 10.8. Incentive (outcome) 10.9. Self-reward 10.10. Reward (outcome) 10.11. Future punishment
15	**11. Regulation**
	11.1. Pharmacological support 11.2. Reduce negative emotions 11.3. Conserving mental resources 11.4. Paradoxical instructions
16	**12. Antecedents**
	12.1. Restructuring the physical environment 12.2. Restructuring the social environment 12.3. Avoidance/reducing exposure to cues for the behavior 12.4. Distraction 12.5. Adding objects to the environment 12.6. Body changes
17	**13. Identity**
	13.1. Identification of self as role model 13.2. Framing/reframing 13.3. Incompatible beliefs 13.4. Valued self-identify 13.5. Identity associated with changed behavior
18	**14. Scheduled consequences**
	14.1. Behavior cost 14.2. Punishment 14.3. Remove reward 14.4. Reward approximation 14.5. Rewarding completion 14.6. Situation-specific reward 14.7. Reward incompatible behavior 14.8. Reward alternative behavior 14.9. Reduce reward frequency 14.10. Remove punishment
19	**15. Self-belief**
	15.1. Verbal persuasion about capability 15.2. Mental rehearsal of successful performance 15.3. Focus on past success 15.4. Self-talk
19	**16. Covert learning**
	16.1. Imaginary punishment 16.2. Imaginary reward 16.3. Vicarious consequences