

# Feasibility and effectiveness of Ida Telecare tools for audiology patients

<b>Submission date</b> 30/10/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 17/01/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/10/2022	<b>Condition category</b> Ear, Nose and Throat	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Plain English summary as of 24/09/2018:

### Background and study aims

The Ida Institute has developed a range of easy-to-use online tools designed to help people with hearing loss prepare for audiology appointments, make important decisions related to their hearing healthcare, and successfully manage everyday communication. Thinking about these things ahead of time can help patients feel better prepared when deciding with the clinician how best to manage their hearing loss. Patients who make choices that are right for them (such as obtaining a hearing aid, or not), are more likely to live well with their hearing loss. This study will assess how adults attending an NHS audiology clinic use the Ida telecare tools and when (feasibility) and how effective the 'Why Improve My Hearing?' tool is at improving their outcomes (effectiveness). The feasibility part of the study will look at how often the tools are used by patients by also identifying what the 'active ingredients' of the tools are to change health behaviour, and anything that helps or hinders patients' use of the tools. The effectiveness part of the study is interested to see if patients who complete the 'Why Improve My Hearing?' Tool before they visit the audiology clinic have better outcomes compared to people who do not. We will also have in-depth discussions with patients and audiologists about what they think of the Tool.

### Who can participate?

Adults aged 18 and older who have hearing loss.

### What does the study involve?

The Ida Telecare Platform use unique telecare tools that help improve communication, improving hearing, effective tips and tricks for successful communications and common difficulties and solutions. Participants are randomly allocated to one of the two sub-studies (feasibility or effectiveness). Those in the feasibility study select whether or not they wish to use any (or all) of the Ida telephone tolls prior to the hearing assessment, hearing air fitting and follow-up appointments. Those in the effectiveness complete the 'Why Improve My Hearing' telecare tool prior to their hearing assessment appointment. This is discussed with the audiologist. The feasibility study assesses if the tools are usable and the participants and audiologists perceptions and experiences of using the telecare tools. The effectiveness of the study is assessed by looking at the benefits of the hearing aids, quality of life, social

participation, patient activation, readiness to take up hearing aids and the consequences of hearing aids.

What are the possible benefits and risks of participating?

Participants may benefit from improvements in their communication. It is not expected that this research will pose any risk to participants. None of the tools, quantitative outcome measures or qualitative data collection methods are likely to cause any harm, distress or adverse reaction to adults with hearing loss. There are no likely ethical, legal or management issues arising from this research. Study participants will have ample time to complete tools and outcomes, including breaks where required.

Where is the study run from?

NIHR Nottingham Biomedical Research Unit

When is the study starting and how long is it expected to run for?

September 2017 to August 2018

Who is funding the study?

Ida Institute (UK)

Who is the main contact?

Dr Helen Henshaw (Scientific)

[helen.henshaw@nottingham.ac.uk](mailto:helen.henshaw@nottingham.ac.uk)

Previous plain English summary:

Background and study aims

The Ida Institute has developed a range of easy-to-use online tools designed to help people with hearing loss prepare for audiology appointments, make important decisions related to their hearing healthcare, and successfully manage everyday communication. Thinking about these things ahead of time can help patients feel better prepared when deciding with the clinician how best to manage their hearing loss. Patients who make choices that are right for them (such as obtaining a hearing aid, or not), are more likely to live well with their hearing loss. This study will assess how adults attending an NHS audiology clinic use the Ida telecare tools and when (feasibility) and how effective the 'Why Improve My Hearing?' tool is at improving their outcomes (effectiveness). The feasibility part of the study will look at how often the tools are used by patients by also identifying what the 'active ingredients' of the tools are to change health behaviour, and anything that helps or hinders patients' use of the tools. The effectiveness part of the study is interested to see if patients who complete the 'Why Improve My Hearing?' Tool before they visit the audiology clinic have better outcomes compared to people who do not. We will also have in-depth discussions with patients and audiologists about what they think of the Tool.

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Where is the study run from?

Queens Medical Centre (UK)

When is the study starting and how long is it expected to run for?

June 2017 to August 2018

Who is funding the study?

Ida Institute (UK)

Who is the main contact?

Dr Helen Henshaw (Scientific)

[helen.henshaw@nottingham.ac.uk](mailto:helen.henshaw@nottingham.ac.uk)

### **Study website**

<http://www.hearing.nihr.ac.uk/research/Mild-to-moderate-hearing-loss>

## **Contact information**

### **Type(s)**

Scientific

### **Contact name**

Dr Helen Henshaw

### **ORCID ID**

<http://orcid.org/0000-0002-0547-4403>

### **Contact details**

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# Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

35810

## Study information

### Scientific Title

Feasibility and effectiveness of Ida Telecare tools for NHS Audiology patients

### Study objectives

Sub-study 1 aim:

The aim of this study is to assess uptake, feasibility and mechanisms of benefit of the Ida Telecare tools in patients attending Nottingham Audiology Service for the first-time.

Sub-study 2 Aim:

The aim of this study is to evaluate the effectiveness of the Ida 'Why Improve My Hearing?' Telecare tool in first-time NHS audiology patients, compared to standard care.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

South Central – Oxford C Research Ethics Committee, 10/10/2017, ref: 17IH006

### Study design

Randomised; Both; Design type: Treatment, Education or Self-Management, Validation of investigation /therapeutic procedures

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

See additional files

## **Health condition(s) or problem(s) studied**

Specialty: Ear, nose and throat, Primary sub-specialty: Ear, nose and throat; UKCRC code/  
Disease: Ear/ Other disorders of ear

## **Interventions**

This study consists of two single-centre sub-studies assessing:

1. Feasibility of implementing the Ida Telecare platform within an NHS adult audiology service
2. Effectiveness of the Ida Telecare tool 'Why Improve My Hearing?', in a cohort of first-time NHS audiology patients

Both sub-studies use mixed-methods (integrating quantitative and qualitative methodologies), which is considered advantageous in the evaluation of patient-centered care, providing an in-depth understanding of the patient experience (Agency for Healthcare Research and Quality 2013).

All participants invited to direct referral hearing assessment appointments at Nottingham Audiology Service between September 2017 and February 2018 receive a study information pack alongside their appointment confirmation letter. The pack contains 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 are 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 is generated and maintained by a researcher not directly involved in patient recruitment or testing using OxMaR software. Participants are contacted by a researcher (by telephone) to answer any questions they may have about the study. The researcher then sends an informed consent form for the patient to complete and return by email or post.

Recruitment takes 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 are automatically allocated to the feasibility study (sub-study 1).

### **The Ida Telecare Platform**

Ida telecare (<http://idainstitute.com/toolbox/telecare/>). 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?**

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.

Sub-study 1, Feasibility: Patients select whether or not they wish to use any (or all) of the Ida telecare tools (total n=6) prior to their hearing assessment, hearing aid fitting and follow-up appointments.

Sub-study 2, Effectiveness: Patients complete the 'Why Improve My Hearing' telecare tool prior to their hearing assessment appointment. A copy is made available within the appointment and is discussed with the audiologist.

## Intervention Type

Other

## Primary outcome measure

Sub-study 1: Feasibility

1. Usability of the tools are measured using the Think Aloud Techniques in a subset of participants at pre-hearing assessment
2. Patients and audiologists perceptions and experiences of using the telecare tools are examined in a subset of participants using semi-structures interviews at 12 weeks post follow-up assessment

Sub-study 2, Effectiveness:

Self-efficacy is measured using the Measure of Audiological Rehabilitation Self-efficacy for Hearing Aids (MARS-HA) at baseline, post-hearing assessment and 10-12 weeks post-hearing aid fitting.

## Secondary outcome measures

Sub-study 2, Effectiveness:

1. Hearing-specific quality of life is measured using the Hearing Handicap Inventory for the Elderly (HHIE) at baseline, post-hearing assessment and 10-12 weeks post-hearing aid fitting
2. Hearing aid benefit is measured using the Glasgow Hearing Aid Benefit Profile (GHABP) at baseline, post-hearing assessment and 10-12 weeks post-hearing aid fitting
3. Social participation is measured using the Social Participation in adults with mild to moderate hearing loss questionnaire (SPARQ) at baseline, post-hearing assessment and 10-12 weeks post-hearing aid fitting
4. Patient activation is measured using the Short-form Patient Activation Measure (PAM) at baseline, post-hearing assessment and 10-12 weeks post-hearing aid fitting
5. Readiness to take-up hearing aids is measured using the Stages of Readiness Questionnaire at baseline and post-hearing assessment
6. Consequences of hearing aid ownership are measured using the Expected Consequences of Hearing aid Ownership (ECHO) at baseline and post-hearing assessment
7. Satisfaction with hearing aids is measured using the Satisfaction with Amplification in Daily Life (SADL) at 10-12 weeks post-hearing aid fitting
8. Hearing aid use is measured using hearing aid datalogging at 10-12 weeks post-hearing aid fitting

9. Satisfaction with the service is measured using the Audiology Outpatient Survey at 10-12 weeks post-hearing aid fitting
10. Patients and audiologists perceptions and experiences of using the telecare tool will be examined in a subset of participants (< n=15) using semi-structured interviews 12 weeks post-hearing aid fitting

**Overall study start date**

01/09/2017

**Completion date**

31/08/2018

## **Eligibility**

**Key inclusion criteria**

1. Adults aged  $\geq 18$  years (no upper age limit)
2. Ability to offer informed consent
3. Fluent in the English language (written and spoken)
4. Access to the Internet

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 56; UK Sample Size: 56

**Total final enrolment**

57

**Key exclusion criteria**

Previously prescribed hearing aids

**Date of first enrolment**

02/10/2017

**Date of final enrolment**

29/06/2018

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Queens Medical Centre**

Nottingham University Hospitals NHS Trust  
Derby Road  
Nottinghamshire  
Nottingham  
United Kingdom  
NG7 2UH

## Sponsor information

**Organisation**

Nottingham University Hospitals NHS Trust, Research & Innovation

**Sponsor details**

Queens Medical Centre  
Derby Road  
Nottingham  
England  
United Kingdom  
NG7 2UH

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/05y3qh794>

## Funder(s)

**Funder type**

Charity

**Funder Name**

Ida Institute

## Results and Publications



## Publication and dissemination plan

1. Talks and poster presentations at national and international conferences and meetings.
2. Planned published 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 (e.g. International Journal of Audiology, Ear & Hearing, Trends in Hearing). Estimated n=2 articles between December 2018 and June 2019.
3. Planned published articles in professional newsletters (e.g. BAA, BSA, ENT and Audiology News; UK, Audiology Today; USA), estimated n=2 between June 2018 and January 2019.

## Intention to publish date

01/06/2019

## Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

## IPD sharing plan summary

Other

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	version V3.0	13/11/2017	17/01/2018	No	Yes
<a href="#">Results article</a>	Sub-study 2 qualitative study results	23/02/2022	22/04/2022	Yes	No
<a href="#">Results article</a>	Sub-study 2 randomised clinical trial results	18/04/2022	22/04/2022	Yes	No
<a href="#">Protocol file</a>	version 3.0	13/11/2017	05/10/2022	No	No