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Feasibility and effectiveness of Ida Telecare tools for audiology patients

Submission date
30/10/2017

Recruitment status
No longer recruiting

Registration date
17/01/2018

Overall study status
Completed

Last Edited
05/10/2022

Condition category
Ear, Nose and Throat

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 identifing 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

Previous plain English summary:
Background and study aims
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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

Study website
http://www.hearing.nihr.ac.uk/research/Mild-to-moderate-hearing-loss

Contact information

Type(s)
Scientific

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Dr Helen Henshaw

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

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NG1 5DU

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 ≥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?
Participant information sheet	version V3.0	13/11/2017	17/01/2018	No	Yes
Results article	Sub-study 2 qualitative study results	23/02/2022	22/04/2022	Yes	No
Results article	Sub-study 2 randomised clinical trial results	18/04/2022	22/04/2022	Yes	No
Protocol file	version 3.0	13/11/2017	05/10/2022	No	No