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m-health technologies for hearing aid users

Submission date 15/01/2018	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 23/01/2018	**Overall study status** Completed	
Last Edited 20/06/2022	**Condition category** Ear, Nose and Throat	

Plain English summary of protocol

Background and study aims
People with hearing loss struggle to hold conversations with others. This can be socially isolating and lowers quality of life. Hearing aids help overcome hearing loss. However, many people know little about them. Hearing aids can be difficult to use and do not give perfect hearing. Many hearing aids are therefore abandoned or underused. In the past, we have worked with hearing aid users to produce multimedia, interactive educational videos about how best to use hearing aids and to communicate well. We have shown that these videos improve patient's knowledge of hearing aids and communication. They have also increased hearing aid use and improved patient' s confidence. Educational videos can be improved by tailoring them to the needs of each person. They can also be more easily accessed by running them on the internet. Mobile devices, such as smartphones and tablet computers, provide an ideal means to achieve this. This research aims to work with hearing aid users to adapt our existing educational videos for use with people's own mobile devices. Informed by the views of first-time hearing aid users, we plan to develop a larger study. This is to see whether our new educational videos, delivered through mobile devices, really make a difference to the lives of those affected by hearing loss. If they do, we plan to find out how and why. The overall study goal is to improve hearing aid use by helping hearing aid users to self-manage their condition.

Who can participate?
Adults aged 18 and older who are first-time hearing aid users.

What does the study involve?
Participants are asked to try out educational videos on their own devices. After 10-12 weeks participants are asked questions about how they got on with them, what worked and what made a difference to them.

What are the possible benefits and risks of participating?
There are no direct benefits or risks with participating.

Where is the study run from?
1. Nottingham Biomedical Research Centre (BRC) (UK)
2. Nottingham Audiology Adult Services (UK)

When is the study starting and how long is it expected to run for?
February 2018 to September 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT03136718

Protocol serial number
33776

Study information

Scientific Title
The development and feasibility of m-health technologies to improve hearing aid use and benefit in first-time hearing aid users

Study objectives
The aim of this study will establish the feasibility of a theoretically-driven, personalised educational intervention delivered through mobile technologies in first-time hearing aid users.

Ethics approval required

Old ethics approval format

Ethics approval(s)
East of England – Cambridgeshire and Hertfordshire Research Ethics Committee, 28/03/2017, ref: 17/EE/0117

Study design
; Both; Design type: Prevention, Psychological & Behavioural, Rehabilitation, Qualitative

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Ear, nose and throat, Primary sub-specialty: Ear, nose and throat; UKCRC code/ Disease: Ear/ Diseases of middle ear and mastoid

Interventions
A theoretically-driven, personalised educational intervention delivered through mobile technologies based on the C2Hear (https://www.youtube.com/C2HearOnline) multimedia videos, or Reusable Learning Objects (RLOs). The intervention will include shorter 'bite-sized' RLOs suitable for mobile technologies (or mRLOs), which will also enable individualised learning.

Participants are asked to try out the videos on the their own devices. After 10-12 weeks participants speak to each user individually. Participants are asked questions about how they got on with them, what worked and what made a difference to them.

Intervention Type
Other

Primary outcome(s)
Hearing aid use is measured using datalogging (i.e. use in hours per day internal to the hearing aid) following 10-12 weeks of independent use of the mRLO intervention.

Key secondary outcome(s))
1. Self-reported hearing-related handicap and disability is measured using the Glasgow Hearing Aid Benefit Profile (GHABP) Part I at baseline
2. Self-reported hearing aid use, benefit, satisfaction and residual disability is measured using the GHABP Part II following 10-12 weeks of independent use of the mRLO intervention
3. Hearing-specific quality of life is measured using the Hearing Handicap Inventory for the Elderly (HHIE) at baseline and immediately post-intervention
4. Hearing aid self-efficacy is measured using the Measure of Audiologic Rehabilitation Self-efficacy for Hearing Aids (MARS-HA) at baseline and following 10-12 weeks of independent use of the mRLO intervention
5. Social behaviours and perceptions are measured using the Social Participation Restrictions Questionnaire (SPaRQ) at baseline and following 10-12 weeks of independent use of the mRLO intervention
6. Hearing aid knowledge is measured using the Hearing Aid and Communication Knowledge (HACK) questionnaire at baseline and following 10-12 weeks of independent use of the mRLO

intervention
7. Working memory is measured using the Wechsler Adult Intelligence Scale Digit Span task at baseline and following 10-12 weeks of independent use of the mRLO intervention
8. Change in hearing difficulty is measured using the Clinical Global Impression scale following 10-12 weeks of independent use of the mRLO intervention
9. Participants will be asked if they experienced any adverse effects arising from the intervention 10-12 weeks of independent use of the mRLO intervention

Completion date
30/09/2018

Eligibility

Key inclusion criteria
1. Adults aged ≥18 years (no upper age limit)
2. First-time hearing aid users (or if previous users, but not having worn hearing aids for more than 3 years)
3. English as first spoken language or good understanding of English. It is important that participants can understand the content of the resources and work with the interactive elements, as well as be able to answer outcome questionnaires, to ensure valid data are collected.
4. Familiar with mobile technologies (e.g. owns a smartphone or tablet device, or uses one regularly)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Unable to complete the questionnaires without assistance due to age-related problems (e.g. cognitive decline or dementia), to ensure valid data are collected.

Date of first enrolment
05/02/2018

Date of final enrolment
30/06/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
National Institute for Health Research (NIHR)
Nottingham Biomedical Research Centre (BRC)
Ropewalk House
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Study participating centre
Nottingham Audiology Adult Services
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Sponsor information

Organisation
Nottingham University Hospitals NHS Trust

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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?
HRA research summary			28/06/2023	No	No
Interim results article	qualitative results	05/08/2020	20/06/2022	Yes	No
Participant information sheet	version V3	22/03/2017	23/01/2018	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes