

Evaluation of interactive videos for hearing aid users

Submission date 03/09/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/09/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/11/2015	Condition category Ear, Nose and Throat	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Hearing loss, or deafness, is a very common condition which develops as people get older. There are two main types of hearing loss: conductive hearing loss, where the problem is in the middle ear (i.e. in the ear drum) and sensorineural hearing loss (SNHL), where the problem lies in the inner ear (cochlea), or the nerve that carries information from the ear to the brain for interpretation. People suffering from SNHL often use hearing aids, as this type of hearing loss cannot be corrected surgically and so is usually permanent. People can find it quite trying to have to use hearing aids, and so new ways are being developed to improve their experiences. The aim of this study is to find out whether providing patients with interactive videos (multimedia reusable learning objects) can help people who are beginning to use hearing aids in their day-to-day life.

Who can participate?

Adults using a hearing aid for the first time, with mild to moderate sensorineural hearing loss in their better ear.

What does the study involve?

In the first stage of the study, reusable learning objects (RLO's) are created, in the form of online videos and DVD's, to provide advice and information to help people to cope with having to use hearing aids. In the second stage of the study, participants are randomly allocated into two groups. Participants in the first group are provided with RLO's to add to the information given by audiologists at their hearing aid fittings. Participants in the second group are not provided with RLO's.

What are the possible benefits and risks of participating?

Not provided at time of registration.

Where is the study run from?

Nottingham Hearing Biomedical Research Unit (UK)

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

January 2011 to May 2013

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

Who is the main contact?
Dr Melanie Ferguson

Contact information

Type(s)
Scientific

Contact name
Dr Melanie Ferguson

Contact details
Nottingham Hearing Biomedical Research Unit
Nottingham University Hospitals NHS Trust
Ropewalk House
113 The Ropewalk
Nottingham
United Kingdom
NG1 5DU

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10200

Study information

Scientific Title
Evaluation of interactive videos for enhancing benefit for new hearing aid users

Acronym
HEAR-IT

Study objectives
The overall aim is to assess whether interactive, multimedia reusable learning objects (RLOs) to supplement information provided by audiologists at the HA fitting resulted in enhanced benefit and use for first-time HA users.

Objectives are to:
1. Develop a series of short RLO's to provide a broad range of auditory rehabilitation advice and information, accessible via DVD or the internet.

2. Establish uptake and compliance of the RLO's.
3. Assess knowledge and understanding of general principles of HAs, listening and communication tactics.
4. Assess the benefits and cost-effectiveness of the RLO's

Ethics approval required

Old ethics approval format

Ethics approval(s)

10/H0403/97

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Topic: Ear, nose and throat; Subtopic: Ear (all Subtopics); Disease: Ear, nose & throat

Interventions

HEAR-IT: Educational programme on practical and psycho-social aspects of hearing loss, hearing aid and communication, based on the concept of reusable learning objects.

Intervention Type

Other

Primary outcome measure

Subjective hearing aid use measured by the Glasgow Hearing Aid Benefit Profile, 6-weeks post hearing aid fitting.

Secondary outcome measures

1. EQ-5D measured at hearing aid fitting and 6 weeks post hearing aid fitting
2. Hearing Aid and Communication Knowledge questionnaire (HACK) measured 6 weeks post hearing aid fitting
3. Hearing aid use (datalogging); measured 6 weeks post hearing aid fitting
- Hearing Handicap Inventory for the Elderly (HHIE) measured 6 weeks post hearing aid fitting
4. Hospital Anxiety and Depression Scale (HADS) measured at hearing aid fitting and 6 weeks

post hearing aid fitting

5. International Outcome Inventory for Hearing Aids (IOI-HA) measured 6 weeks post hearing aid fitting

6. Practical Hearing Aid Skills Test (PHAST) measured 6 weeks post hearing aid fitting

7. Satisfaction with Amplification with Daily Life (SADL) measured 6 weeks post hearing aid fitting

8. Short Form Patient Activation Measure (PAM) measured at hearing aid fitting and 6 weeks post hearing aid fitting

Overall study start date

03/01/2011

Completion date

31/05/2013

Eligibility

Key inclusion criteria

1. Aged 18 years or over
2. First time hearing aid users
3. Sensorineural hearing loss in the better hearing ear (puretone average >20 dB over 0.25, 0.5, 1, 2 and 4 kHz).
4. English as a first spoken language or a good understanding of English

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 200

Key exclusion criteria

1. Inability to use the interactive videos and do not have family members or friends to assist them
2. Inability to complete the questionnaires with assistance due to age-related problems (e.g. cognitive decline and dementia)
3. No access to DVD player and television, or computer
4. Patients who require an additional followup appointment after hearing aid fitting as part of their individual management plan

Date of first enrolment

03/01/2011

Date of final enrolment

31/05/2013

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Nottingham University Hospitals NHS Trust

Nottingham Hearing Biomedical Research Unit

Ropewalk House

113 The Ropewalk

Nottingham

United Kingdom

NG1 5DU

Sponsor information

Organisation

Nottingham University Hospitals NHS Trust

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

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2015		Yes	No