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Evaluation of interactive videos for hearing aid users

Submission date	Recruitment status	[_] Prospectively registered
03/09/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/09/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/11/2015	Ear, Nose and Throat	

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

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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 sand communication, based on the concept of reusable learning objects.

Intervention Type
Other

Primary outcome(s)
Subjective hearing aid use measured by the Glasgow Hearing Aid Benefit Profile, 6-weeks post hearing aid fitting.

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
United Kingdom

England

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

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

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