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Feasibility of an online rehabilitation program

Submission date
15/01/2018

Recruitment status
No longer recruiting

Registration date
23/01/2018

Overall study status
Completed

Last Edited
03/08/2018

Condition category
Ear, Nose and Throat

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Hearing aids are the most common intervention for hearing loss. However, the majority of people who get them do not use them. This is an issue because hearing loss can lead to communication difficulties, resulting in reduced quality of life. Rehabilitation programs can help people to use their hearing aids and interact in social settings more effectively. Programs delivered via the internet may also help people with hearing loss access them. This study is looking at an online rehabilitation program for people with hearing loss. The program covers different topics, including information about hearing aids, ways to improve communication, and relaxation techniques. The program aims to help people use their hearing aids and interact in social settings more effectively. The program is made up of 5 modules that cover different topics such as hearing aids, communication strategies, and relaxation techniques. The study aims to see whether a study assessing the program can be done in people with hearing loss in the publically-funded UK National Health Service (NHS). This study will make sure that the program is clear and that it covers the right topics. This will help the research team to prepare for a study that will test how effective the program is in larger group of people.

Who can participate?
Adults aged 18 and older who get hearing aids for the first time and people who have worn hearing aids for at least one year or more.

What does the study involve?
Participants are asked to attend two study visits. On the first visit (up to 1 and half hours in total) participants are asked a number of questionnaires about their hearing and how it affects their day-to-day life. They are also shown how to use the online program. After this session, they are asked to complete up to five modules of the program. Each module takes up to one hour to complete, and each participant will have up to one-week to complete a module. After completing the modules, participants are asked a number of questionnaires about their hearing and their experiences with hearing aids. Some participants may also be invited to take part in a small group discussion that takes place on a separate day. The group discussion lasts no more than 1.5 hours. With the researcher and other participants, they are able to share their views on the program, such as what they liked or disliked.

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. NIHR Nottingham Hearing Biomedical Research Unit (UK)
2. Nottingham Audiology Adult Services (UK)
3. Adult Audiology Department (UK)

When is the study starting and how long is it expected to run for?
November 2016 to June 2019

Who is funding the study?
Oticon A/S (Denmark)

Who is the main contact?
Dr Melanie Ferguson
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
32078

Study information

Scientific Title
Assessing the feasibility of a clinical trial of an online audiological rehabilitation program

Study objectives
Hypothesis:
The study will determine the feasibility of conducting a full-scale clinical trial assessing the

effectiveness of an online audiological rehabilitation program in an NHS clinical sample of adult hearing aid users.

The study will estimate the following feasibility parameters:
Recruitment
1. Willingness of clinicians to recruit participants
2. Willingness of participants to consent
3. Number of eligible patients

Feasibility/acceptability of approach (Quantitative outcomes)
1. Characteristics of the outcome measures
2. Standard deviation of outcome measures to estimate sample size
3. Follow-up rates, response rates to questionnaires, adherence/compliance rates
4. Time needed to collect and analyse data

Users' perspective/opinions of the intervention (Qualitative outcomes)
1. Participant's views regarding delivery of the program through different devices
2. How the program is used and how often (i.e. usability)
3. Participants views concerning what they like and dislike about the program (i.e. acceptability)
4. How much of the program is completed (adherence)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire & The Humber- Leeds East Research Ethics Committee, 23/09/2016, ref: 16/YH/04220

Primary study design
Interventional

Study design
; Both; Design type: Process of Care, Psychological & Behavioural, Rehabilitation, Qualitative

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/ Other disorders of ear

Interventions
An online audiological rehabilitation program, the Eriksholm Guide to Better Hearing, is issued to an NHS clinical sample of i) first-time, and ii) existing adult hearing aid users. The internet-based intervention consists of up to five-weekly, one-hour modules that each include self-studies, training, and professional video coaching in hearing loss, hearing aids, and communication strategies.

Study participants participate in the study for up to 8 hours. This includes 1.5 hours for baseline measures, up to one-hour to complete each weekly module of the Eriksholm Guide to Better Hearing, and up to 1.5 hours post-intervention measures.

A sub-sample of 16 participants are invited to take part in focus groups lasting 1.5 hours, increasing the participation time in the sub-sample to 9.5 hours.

Intervention Type
Other

Primary outcome(s)
Hearing-specific quality of life is measured using the Hearing Handicap Inventory for the Elderly (HHIE) at baseline and immediately post-intervention.

Key secondary outcome(s)
1. Hearing aid benefit is measured using the Glasgow Hearing Aid Benefit Profile (GHABP) and International Outcome Inventory for Hearing Aids (IOI-HA) at baseline and immediately post-intervention
2. Hearing aid self-efficacy is measured using the Measure of Audiologic Rehabilitation Self-efficacy for Hearing Aids (MARS-HA) at baseline and immediately post-intervention
3. Social behaviours and perceptions are measured using the Social Participation Restrictions Questionnaire (SPaRQ) at baseline and immediately post-intervention
4. Hearing aid skills are measured suing the Practical Hearing Aid Skills Test (PHAST) at baseline and immediately post-intervention
5. Hearing aid knowledge is measured using the Hearing Aid and Communication Knowledge (HACK) questionnaire at baseline and immediately post-intervention
6. Change in hearing difficulty is measured using the Clinical Global Impression scale immediately post-intervention
7. Participants' views of the intervention will be measured using a purpose-designed feedback questionnaire and, in a sub-group of participants (N=16), focus groups immediately post-intervention

Completion date
30/08/2018

Eligibility

Key inclusion criteria
1. Ability to give informed consent
2. English as first spoken language or good understanding of English
3. Adults aged ≥18 years (no upper age limit)
4. Mild-to-moderate hearing loss (average hearing threshold across octave frequencies 0.25-4kHz ≥20 and ≤70dB HL[1])
5. Have either:
5.1. Used hearing aids for at least one year (existing hearing aid users), or
5.2. Have not used hearing aids or alternative form of amplification (e.g. personal sound amplification product) within the past two years (first-time hearing aid users)
6. Access the Internet and compatible device (e.g. computer or tablet device)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Report having severe tinnitus
2. Diagnosis of Ménière's disease
3. Patients who are unable to complete the questionnaires with assistance due to age-related problems such as cognitive decline and dementia

Date of first enrolment
21/11/2016

Date of final enrolment
21/03/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
NIHR Nottingham Hearing Biomedical Research Unit
Ropewalk House
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Study participating centre
Nottingham Audiology Adult Services
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Study participating centre
Adult Audiology Department
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Sponsor information

Organisation
University of Nottingham

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Research organisation

Funder Name
Oticon Fonden

Alternative Name(s)
Oticon Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Denmark

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
Participant information sheet		23/01/2018	23/01/2018	No	Yes