

# Feasibility of an online rehabilitation program

<b>Submission date</b> 15/01/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/01/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 03/08/2018	<b>Condition category</b> Ear, Nose and Throat	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

melanie.ferguson@nottingham.ac.uk

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Melanie Ferguson

**ORCID ID**

<http://orcid.org/0000-0002-8096-869X>

**Contact details**

NIHR Nottingham Hearing Biomedical Research Unit

113 The Ropewalk

Ropewalk House

Nottingham

United Kingdom

NG1 5DU

+44 (0)115 823 2600

melanie.ferguson@nottingham.ac.uk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

## Study design

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

## Primary study design

Interventional

## Secondary study design

Non randomised study

## 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**

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 measure**

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

## **Secondary outcome measures**

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 using 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

## **Overall study start date**

01/11/2016

## **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  $\geq 18$  years (no upper age limit)
4. Mild-to-moderate hearing loss (average hearing threshold across octave frequencies 0.25-4kHz  $\geq 20$  and  $\leq 70$ dB 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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 60; UK Sample Size: 60

**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**

England

United Kingdom

**Study participating centre**

NIHR Nottingham Hearing Biomedical Research Unit

Ropewalk House

113 The Ropewalk

Nottingham  
United Kingdom  
NG1 5DU

**Study participating centre**

**Nottingham Audiology Adult Services**

Nottingham University Hospitals NHS Trust  
Ropewalk House  
113 The Ropewalk  
Nottingham  
United Kingdom  
NG1 5DU

**Study participating centre**

**Adult Audiology Department**

Chesterfield Royal Hospital NHS Foundation Trust  
Calow  
Chesterfield  
United Kingdom  
S44 5BL

## **Sponsor information**

**Organisation**

University of Nottingham

**Sponsor details**

Research Governance  
Research and Graduate Services  
King's Meadow Campus  
Lenton Lane  
Nottingham  
England  
United Kingdom  
NG7 2RD

**Sponsor type**

Hospital/treatment centre

**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

## Publication and dissemination plan

Dissemination of the study findings will cover the following avenues:

1. Talks and poster presentations at national and international conferences, primarily Audiology (e.g. British Academy of Audiology Annual Conference). Estimated between June 2018 and January 2019.
2. Planned publication in peer-reviewed national or international journal (e.g. International Journal of Audiology). Estimated between June 2018 and January 2019.
3. Publish article in professional newsletter (e.g. ENT and Audiology News). Estimated between June 2018 and January 2019.
4. Newsletter to all participants who took part in the research, including results. Estimated between June 2018 and January 2019.

## Intention to publish date

31/01/2019

## 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?
<a href="#">Participant information sheet</a>		23/01/2018	23/01/2018	No	Yes

