ISRCTN14882247 https://doi.org/10.1186/ISRCTN14882247

Getting ready for cochlear implant assessment using online tools at home

Submission date
13/10/2017

Recruitment status
Stopped

Registration date
20/02/2018

Overall study status
Stopped

Last Edited
01/04/2019

Condition category
Ear, Nose and Throat

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

Plain English summary of protocol

Background and study aims
The assessment process for a cochlear implant (CI) is often long. A lot of information is gathered about the patient including what they hope to gain from receiving a CI and what their expectations are. This is done as a face to face appointment with when the patient first attends the CI centre. It has been suggested that using online tools and apps before this type of appointment can improve the patient's preparation for the appointment. The tools and apps have also been suggested to help the patient take a more active part in the appointment. We suggest that a fact to face appointment may not be the best way to enable adults to fully consider their hearing and communication needs. We think that if a person started thinking about their needs before their first appointment, with help from their family and friends, the first appointment would be more focussed on their needs rather than being use to gather as much information as possible. The aim of the study is to trial the Ida Institute online tools 'Living Well Online' and 'My Turn to Talk' with adults that are going through the assessment process. The study will include a treatment group and a non-treatment group; people will be sorted randomly into one of the two groups. One group will use the tools before their first appointment and the other group will not use the tools.

Who can participate?
Adults aged 18 and older who have been referred for a cochlear implant assessment.

What does the study involve?
Participants are randomly allocated to one of two groups. into either the treatment group or the control group. The treatment group will be given access to the online tools before their first appointment and be asked to use the tools at home at some point before they attend the CI centre for their first appointment. They will be advised that they can use the online tools as often as they wish and wherever they wish to use them. They will be asked to email the results from the online tools to the clinician. Each participant will have their own study ID. The control group will not be given access to the online tools. Both groups will continue on the usual assessment pathway. Both groups will have the first appointment recorded and analysed.

What are the possible benefits and risks of participating?
The treatment group may get benefit from the online tools, as they are designed to help patient' s going through the assessment process. No risks associated with participation in this study

Where is the study run from?
University of Southampton Auditory Implant Service (UK)

When is the study starting and how long is it expected to run for?
September 2017 to December 2018

Who is funding the study?
Ida Institute (UK)

Who is the main contact?
Dr. Helen Cullington (Scientific)
h.cullington@southampton.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Helen Cullington

ORCID ID
https://orcid.org/0000-0002-5093-2020

Contact details
University of Southampton Audiotry Implant Service
University of Southampton
University Road
Southampton
United Kingdom
SO17 1BJ

Type(s)
Scientific

Contact name
Dr Padraig Kitterick

Contact details
The NIHR Nottingham Hearing Biomedical Research Unit
Ropewalk House
113 The Ropewalk
Nottingham
United Kingdom
NG1 5DU
+44 115 823 2626
Padraig.Kitterick@Nottingham.ac.uk

Additional identifiers

Protocol serial number
University of Southampton ERGO 28011

Study information

Scientific Title
Online tools to improve empowerment and readiness for assessment for cochlear implantation

Study objectives
Primary hypothesis:
The interactions and discussions during the communication assessment appointment in the telecare tools group will be more patient-centered and allow individual needs to be explored, rather than be primarily an information gathering exercise

Secondary hypotheses:
1. Service users (patients) will feel positive about telecare tools, measured qualitatively using online feedback questionnaire.
2. The telecare tools group will show a greater satisfaction with their clinic appointment than the control group
3. The telecare tools group will demonstrate a positive change in their own empowerment compared to the control group

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Southampton University Ethics Board: ERGO, ref: 28011;

Primary study design
Interventional

Study design
Two-arm randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
People with hearing impairment undergoing assessment for cochlear implantation

Interventions
Online empowerment tools provided to patients in the 'Intervention group', before they attend the cochlear implant centre for their assessment appointments.

Control group: standard clinical care pathway
Participants in the control group will continue with their usual care pathway; they will not have access to the Ida Institute telemedicine tools. Their communications appointment at USAIS will

be video recorded and analysed. We will collect the following information from participants when they attend the centre; this information is not entered into the app or online tool:
• Age
• Gender
• Highest level of qualification (see Appendix 1)
• Duration of deafness
The clinician doing the communications appointment will be assigned a code (e.g. clinician1); their specialty will be noted (e.g. speech and language therapy).

Intervention group: Ida Institute tools
Those randomised into the treatment group (telemedicine group) will receive access to the Ida Institute tools: Living Well Online and My Turn to Talk. They will be asked to work with the tools at home at some point prior to their communications appointment at the centre.
Participants may access the tools as often as they wish and can use them wherever they wish (at home, at a friend's house, at the library etc.). They will be encouraged to give as much detail as possible. They will then be asked to email the results to the clinician. In the process of emailing, the website asks them to enter an 'ID provided by audiologist' – this will be their study enrolment ID e.g. IDA002.
Their communications appointment at USAIS will be video recorded and analysed.
We will collect the following information from participants when they attend the centre; this information is not entered into the app or online tool:
• Age
• Gender
• Highest level of qualification (see Appendix 1)
• Duration of deafness
The clinician doing the communications appointment will be assigned a code (e.g. clinician1); their specialty will be noted (e.g. speech and language therapy).

Randomisation
Consenting participants are allocated to the telecare tools pathway or the standard care pathway using minimization software, balancing for age, gender, duration of deafness, and highest qualification level. It will not be possible to blind participants to which group they are in. Clinicians will not be blinded as to which group their patient belongs to, as they will receive the summaries from the telemedicine group ahead of the appointment. The approach will use biased coin minimisation with a base probability of 0.7. Imbalance between the groups will be quantified using the marginal balance method (Han et al. 2009).

Intervention Type
Behavioural

Primary outcome(s)
Difference in content of communications during the clinical assessment appointment between treatment group and control group is measured using qualitative analysis of the video recordings.

Key secondary outcome(s)
1. Patient preference for and experience of telecare tools is measured using feedback from online questionnaire
2. Patient satisfaction with communications appointment is measured using qualitative analysis
3. Patient empowerment measured using a modified version of an empowerment tool previously developed for CI users (CI-EMP) at baseline and after appointment

Completion date
31/12/2018

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Adult (aged 18 years or more) referred for cochlear implant assessment
2. Able to give informed consent
3. Sufficient English to understand study documentation and telecare tools
4. Access to a computer or device with internet access

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Those that do not fulfil the inclusion criteria plus any medical condition or known disability that would limit their capacity to use the telecare tools
2. Those who do not attend the routine assessment appointments scheduled as part of their usual care

Date of first enrolment
01/03/2018

Date of final enrolment
31/08/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Southampton Auditory Implant Service
University of Southampton Auditory Implant Service
Building 19
Highfield
Southampton
United Kingdom
SO17 1BJ

Sponsor information

Organisation
The University of Southampton Auditory Implant Service

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
University/education

Funder Name
Ida Institute

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Primary Investigator: Dr. Helen Cullington, h.cullington@soton.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V2	01/02/2018	01/04/2019	No	Yes