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Remote care of cochlear implant users

Submission date
16/10/2015

Recruitment status
No longer recruiting

Registration date
20/10/2015

Overall study status
Completed

Last Edited
08/05/2018

Condition category
Ear, Nose and Throat

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] 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. The cochlea is a complex part of the inner each which is responsible for converting sound waves into electrical messages which the brain can interpret. When the cochlea becomes damaged, standard hearing aids (which work by making sounds louder) do not work and so a cochlear implant is often recommended. A cochlear implant (CI) is an electronic medical device which is designed to do the work of the damaged cochlea. It consists of an external sound processor and internal parts which work to convert sounds into electrical signals. Once a patient has had the surgery to install a CI, they commit to regular adjustment and rehabilitation appointments in the first year and then yearly follow-up appointments, in order to ensure that the implant is working properly. These appointments can be very inconvenient for the patient as they often have to travel a long way to specialist implant centres. It is thought that for many patients, these appointments are not necessary and that patients would benefit from having more control over their care plans. A possible solution for this could be using remote care, in which the patient is able to access support and information online and can keep medical staff up to date with their condition from their own homes. The aim of this study is to find out whether a remote care plan would work well for patients with cochlear implants.

Who can participate?
Adults who have been using a cochlear implant for at least 6 months.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group (remove care group) receive all of their cochlear implant care remotely for six months. This involves tools to test how well the device is working, online support, and help with their speech. Those in the second group (control group) continue to use their current cochlear implant and receive usual care. Patients in both groups attend a clinic after six months, in which they are interviewed in order to find out how well their care plan has been working for them.

What are the possible benefits and risks of participating?
There are no real benefits of participating, although adults in the remote care group may find the remote care tools useful. There are no risks of participating in the 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?
May 2015 to July 2017

Who is funding the study?
The Health Foundation (UK)

Who is the main contact?
Dr Helen Cullington
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Contact information

Type(s)
Public

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Study information

Scientific Title
Randomised control trial of personalised long-term follow-up of Cochlear Implant patients using Remote CAre, compared to those on the standard care pathway

Acronym
CIRCA

Study objectives

Primary Hypothesis:
The remote care group will show a greater increase in patient engagement over the 6 month remote care trial period than the control group, measured using the Patient Activation Measure (PAM®) and the custom-designed cochlear implant patient empowerment measure.

Secondary Hypotheses:
1. There will be no more deterioration in hearing in the remote care group compared to the control group measured using speech recognition (BKB sentences, Triple Digit Test), the Spatial Speech Qualities questionnaire and self-report of hearing ability on the long-term follow-up questionnaire
2. There will be no more deterioration in quality of life in the remote care group compared to the control group measured using the Health Utilities Index mark 3
3. Service users (patients) will feel positive about remote care measured qualitatively from feedback in online support tool and in focus groups
4. Clinicians will feel positive about remote care measured qualitatively from three interviews with up to 10 members of clinical staff

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University of Southampton, 16/10/2015, ref: ERGO 15329
2. South Research Ethics Committee, 28/10/2015, ref: 15/NW/0860

Primary study design
Interventional

Study design
Single-centre randomised controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Deafness

Interventions
Participants are randomly allocated to the control arm or the treatment arm.

Treatment arm: Those randomised into the treatment group (remote care group) will receive all their cochlear implant care remotely for 6 months. This will involve:
1. Online speech perception test
2. Checking internal device impedances and settings (those using Cochlear devices only)
3. Long-term follow-up questionnaire as prompt for solving hearing difficulties
4. Use of an online support tool for rehabilitation, troubleshooting, information etc
5. Upgraded speech processor delivered to home instead of clinic visit (if due within study period)
Participants may access the tools as often as they wish (minimum twice required for project) and can use them wherever they wish (home, when out and about etc)

Control arm: Those in the control group will continue their usual long-term follow-up including clinic visits where appropriate. They will not have access to remote care.

Intervention Type
Other

Primary outcome(s)
Change (from day of entry into study to 6 months after remote care introduced) in patient activation measured using the Patient Activation Measure (PAM®) and the custom-designed cochlear implant patient empowerment measure in both the control and treatment arms.

Key secondary outcome(s)
1. Stability of hearing measured by change (from day of entry into study to 6 months after remote care introduced) in speech recognition measured using BKB sentences, the Triple Digit Test, the Spatial Speech Qualities questionnaire and self-report of hearing ability on the long-term follow-up questionnaire in both the control and treatment arms.
2. Stability of quality of life measured by change (from day of entry into study to 6 months after remote care introduced) in quality of life in measured using the Health Utilities Index mark 3 in both the control and treatment arms.
3. Patient preference in treatment arm reported qualitatively from feedback in online support tool and in focus groups
4. Clinician preference measured qualitatively from three interviews with up to 10 members of clinical staff

Completion date
31/07/2016

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Living in the United Kingdom
3. Cochlear implant user (any device, unilateral or bilateral) for at least 6 months
4. Able to give informed consent
5. Sufficient English to understand study documentation and participate in testing
6. 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. Not been using a cochlear implant user for at least 6 months
2. Living outside the United Kingdom
3. Aged less than 18 years
4. Unable to give informed consent
5. Insufficient English to understand study documentation and participate in testing
6. No access to a computer or device with internet access
7. Possessing any medical condition or known disability that would limit their capacity to use the online support tool

Date of first enrolment
01/11/2015

Date of final enrolment
14/11/2015

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
University of Southampton

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Charity

Funder Name
The Health Foundation

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	01/04/2018		Yes	No
Protocol article	protocol	13/05/2016		Yes	No
HRA research summary			28/06/2023	No	No