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Cochlear implant home care

Submission date
11/04/2018

Recruitment status
No longer recruiting

Registration date
22/06/2018

Overall study status
Completed

Last Edited
14/04/2022

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
Cochlear implants provide hearing to people with severe to profound deafness. Around 1,200 people receive a cochlear implant in the UK each year, and numbers are likely to rise, as only 5% of people that could get an implant in the UK have one. In the UK, 18 centres provide adult cochlear implant care. Care provision involves assessment, surgery, a resource-intensive period of adjusting and fine tuning the device after surgery, and long-term rehabilitation with the implant. As there are so few centres, they may be several hours away from the patient's home, meaning patients must travel long distances, take time off work, and can result in family-life disruption. Currently in the UK, implant centres review patients on a clinic-led basis, which can mean patients attending appointments that are not necessarily beneficial to them. During a routine appointment it can be brought to light that the patient has experienced some hearing deterioration without realising. This is helped by changing or replacing equipment, which the patient could do themselves at home, without travelling into the centre. The aim of this study is to make the care pathway for people with cochlear implants more patient-centred, leading to a more efficient and effective service. An earlier clinical trial at the University of Southampton, led by Helen Cullington investigated how successful a remote care pathway would be for 60 people with cochlear implants. Thirty of the 60 patients did not use any remote care tools and carried on visiting the clinic as set out by the clinic schedule. The other 30 patients used the remote care tools which consisted of home hearing tests, the ability to do some fine tuning on their hearing device, a personalised online tool with rehabilitation, help, advice and troubleshooting tips, as well as some equipment being sent to their homes for upgrading what they already had. The results showed that people on the remote care pathway were more empowered, had better hearing and were engaged with the remote care tools and wanted to carry on using them. It is hoped that the roll out of the remote care pathway that has been designed and tested by the research team will result in more empowered and confident patients, more accessible and equal care for all patients, stable hearing, more efficient and patient-centred services, and more satisfied and engaged patients and clinicians.

Who can participate?
Patients aged 18 or over who use a cochlear implant

What does the study involve?
Participants are given information about the home care pathway after they receive the cochlear implant. Once they have used it for a few months they are given the options open to them, i.e.

standard care pathway at the cochlear implant centre or remote care pathway with home care tools. The decision to enrol on the remote care pathway is made only once all information has been given and when the patient and people involved with their life and care have discussed the options. If the patient decides to enrol on the home care pathway they are given access to home care tools including a home hearing test, a personalised web app, and the ability to do some fine tuning of their implant and equipment upgrades at home. The patient's clinician at the cochlear implant centre has access to their results and activity. This includes alerting clinicians when results or use of the tools is outside expected ranges. Cochlear implant centre appointments are given as and when the patients need them, whether they are requested by the patient or offered to the patient due to results from the home care tools. Otherwise, participants carry on with home care. Participants can access the tools as often as they wish and wherever they wish to use them, e.g. at home, at work, at a friend's house, library etc. If a patient decides that they do not want to carry on using the home care tools, they can switch back to the standard clinical pathway at the cochlear implant centre.

What are the possible benefits and risks of participating?
Patients using the home care tools may be more empowered and confident about managing their own care. Patients using the home care tools may experience more stable hearing and be more engaged and satisfied with their hearing care. The introduction of a remote care pathway might result in more accessible and equal care for all cochlear implant users. Cochlear implant clinicians may be more engaged and satisfied. The possible risks are that patients will be falsely reassured their hearing is good despite there being a problem. However, the test that will be used has been tested extensively and has good reliability. The home care tools will also allow patients to feedback how they are feeling about the hearing. Another possible risk is that the patient does not use the remote care tools and does not attend the clinic either. However, the web app will notify clinicians of abnormal results including the patient not using the tools, and this can be followed up with the patient quickly. The remote care pathway does not have the ability to measure specifics about the implant, which means there might be a device issue that is missed. Patients' hearing performance will be monitored and they will also be encouraged to answer questions about their hearing performance. Small changes in device parameters that do not affect hearing performance may not require intervention and may introduce unnecessary worry. A missed medical issue is a potential risk; however, the web app will have information about infections, questions about comfort of the implant, and the ability for the patient to upload photos of their implants for the clinicians to see and act upon if necessary. Participating cochlear implant centres may experience an initial increase in patients on the remote care pathway attending clinic due to the unfamiliarity of the remote care pathway. The study will monitor this.

Where is the study run from?
The lead centre is the University of Southampton Auditory Implant Service. Cochlear implant centres that will participate in the project will be in the UK.

When is the study starting and how long is it expected to run for?
November 2017 to January 2021

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

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

Contact information

Type(s)
Public

Contact name
Dr Helen Cullington

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

Contact details
Building 19
University of Southampton Auditory Implant Service
Highfield Campus
University Road
Southampton
United Kingdom
SO17 1BJ
+44 (0)2380597606
H.Cullington@southampton.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
242575

Protocol serial number
IRAS 242575, ERGO 40383

Study information

Scientific Title
Telemedicine for adults with cochlear implants in the UK: empowering patients to manage their own hearing healthcare

Acronym
CHOICE

Study objectives
This project will scale up and evaluate a person-centred long-term follow-up pathway for people using cochlear implants incorporating a home hearing test, personalised webapp, self-adjustment of device, and home sound processor upgrades.

Expected improvements:
1. More empowered and confident patients
2. More accessible and equitable care

3. Stable hearing
4. More efficient, person-centred and scalable service
5. More satisfied and engaged patients and clinicians

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval as of 21/11/2019:
1. Approved 19/10/2018, University of Southampton Ethics and Research Governance (Research & Innovation Services, University of Southampton, Highfield Campus, Southampton SO17 1BJ; +44 (0)2380 595058; rgoinfo@soton.ac.uk), ref: 40383
2. Approved 28/11/2018, South Central - Hampshire A Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT; +44 (0)2071 048241; nrescommittee.southcentral-hampshirea@nhs.net), ref: 18/SC/0658

Previous ethics approval:
University of Southampton Ethics and Research Governance and National Research Ethics Committee - submission pending

Study design
Quality Improvement (QI) project to roll out a new person-centred clinical care pathway

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
This project introduces a new care pathway choice to adults using cochlear implants: cochlear implant home care. The patients choosing this pathway will be given access to:
1. Home hearing test
2. Personalised web app

Clinicians at each participating cochlear implant centre will be encouraged and supported to provide:
1. Self-mapping (if appropriate)
2. Upgraded sound processor at home

Participants are given information about the home care pathway after they receive the cochlear implant. Once they have used it for a few months they are given the options open to them, i.e. standard care pathway at the cochlear implant centre or remote care pathway with home care tools. The decision to enrol on the remote care pathway is made only once all information has been given and when the patient and people involved with their life and care have discussed the options. If the patient decides to enrol on the home care pathway they are given access to home care tools including a home hearing test, a personalised web app, and the ability to do some fine tuning of their implant and equipment upgrades at home. The patient’s clinician at the cochlear

implant centre has access to their results and activity. This includes alerting clinicians when results or use of the tools is outside expected ranges, or when the patient has not interacted with the tools at all for 3 months. Cochlear implant centre appointments are given as and when the patients need them, whether they are requested by the patient or offered to the patient due to results from the home care tools. Otherwise, participants carry on with home care. Participants can access the tools as often as they wish and wherever they wish to use them, e.g. at home, at work, at a friend's house, library etc. If a patient decides that they do not want to carry on using the home care tools, they can switch back to the standard clinical pathway at the cochlear implant centre.

The trialists hope to roll out the new remote care pathway in late summer 2018. Some baseline centre data will be collected before then. The evaluation will continue until the end of 2019. After this time it is hoped that the remote care pathway will continue as a routine service delivery choice.

Intervention Type
Mixed

Primary outcome(s)
Primary outcome number 1: What is the impact of the roll out of the new care pathway on users of the programme (staff and people with cochlear implants)?
The impact of the roll out of the new care pathway on users of the programme will be evaluated by capturing the view of patients, staff and stakeholders by qualitatively investigating how the new pathway works in terms of feasibility and acceptability at each participating centre using:
1. Focus groups, comprising of a focus group for staff members and a focus group for patients each with up to 20 people
2. Patient interviews on a one to one basis
3. Case studies carried out by staff on selected patients, which will be anonymised to the research and evaluation team. These will be analysed for themes
These will take place after introduction of the remote care tools and will be led and scheduled by the independent evaluators Wessex Academic Health Science Network (Wessex AHSN).

Primary outcome number 2: Does the new care pathway increase empowerment for people with cochlear implants while having no detrimental effect on their hearing and quality of life?
The effects of the new care pathway on the users' state of empowerment related to their healthcare, quality of life and hearing will be measured by collecting data over the course of the roll out of the new pathway using:
1. Locally collected data
2. Quantitative information in the form of staff and patient reports of their experience of the new pathway using R-outcomes
3. Quantitative data in the form of dashboards will be used to inform progress
4. Service level activity captured in appointment schedules, staff contact logs and data provided through the CHOICE app and clinician portal. This will be used to investigate:
4.1. Change in use of outpatient appointments as a consequence of using the remote care pathway, including numbers and types of clinic attendances and other contacts, and numbers of self-initiated versus service-initiated (scheduled) appointments, and reasons for clinic attendance /type of appointment
4.2. Staff uptake and confidence in the system will be measured using numbers of patients registered on the new care pathway
4.3. Number or staff registered on clinician portal
4.4. Patient uptake will be measured using the numbers of patients using the new care pathway

4.5. Whether distance from the clinic influences uptake of the new care pathway and equity of access to care will be measured using mapping of activity by postcode
4.6. Cost incurred by the patients and any accompanying persons whilst on the conventional pathway will be measured using travel time, travel cost, hours off work, childcare costs
4.7. Stability of hearing of people on the remote care pathway will be measured using the home hearing test results
4.8. Number of errors in online resources, adverse events, missed issues

Key secondary outcome(s))

Current secondary outcome measures as of 10/10/2019:
Secondary outcomes: evaluation of the roll out in the context of the below:

The use of remote care programme from patients and staff will be collected using R-outcomes survey tool (Benson et al., 2010), which will gather data as follows:
1. The Health Confidence Score (HCS) measures people's capability to look after their own health, with dimensions for confidence about knowledge, self-management, ability to get help and shared decision-making (Benson, Potts, & Bowman, 2016). This will be done continually throughout the roll out the remote care pathway
2. The health status score (HowRu) is a short generic health status (health-related quality of life) measure, with four dimensions for pain and discomfort, mental distress, disability and dependence, each rated on four levels. HowRu has been validated against SF-12 and EQ-5D-5L and at the individual patient level (Benson, Potts, Whatling, & Patterson, 2013; Benson et al., 2010; Hendriks et al., 2015). This will be done continually throughout the roll out the remote care pathway
3. The Personal Wellbeing Score (PWS) covers satisfaction, worthwhileness, happiness and anxiety, based on the ONS-4 Personal Wellbeing standard, used in the Annual Population Survey for Great Britain (Office for National Statistics, 2015). This will be done continually throughout the roll out the remote care pathway

In order to be able to compare the results from previous projects the following measures will also be carried out:
1. Patient activation will be measured using the Patient Activation Measures (PAM) at the point of entry to the remote care pathway and at the end of the project or after 6 months
2. The CI-EMP questionnaire will be used to measure how empowered people are to manage their own cochlear implant care at the point of entry to the remote care pathway and at the end of the project or after 6 months
3. The EQ-5D-5L will be used to measure mobility, self-care, usual activities, pain/discomfort and anxiety/depression in patients using the remote care pathway at the point of entry to the remote care pathway and at the end of the project or after 6 months
4. The HUI mark 3 will be used in order to device health states for the people on the remote care pathway at the point of entry to the remote care pathway and at the end of the project or after 6 months
5. Global rating of change scales will be used to capture whether patients perceive that there has been a change in their hearing, empowerment and quality of life, this will be done at the end of the project or after 6 months

In order to evaluate the impact of the new remote care pathway on staff the:
1. Work Wellbeing Score (WWS) measures happiness at work; this will be measured at training sessions planned for July 2018
2. Job Confidence Score (JCS) measures staff confidence that they have the knowledge, self-

efficacy, support and involvement needed to do their job as well as possible; this will be measured at training sessions planned for July 2018 and then will be repeated at focus groups and follow up by email

In order to understand what factors facilitate or inhibit the roll out of the remote care pathway the NoMAD questionnaire measures the behaviours of staff in response to the new care pathway; this will be used with staff during the beginning of the roll out period and at the end of the data collection period.

To assess whether the anticipated changes to clinic activity happen as a result of the remote care pathway and whether this has any implications for the clinic workforce, the clinic activity and type of activity associated with patients on the remote care pathway will be monitored throughout the data collection period until the end of the data collection period.

The economic impact of the introduction of a remote care pathway will be evaluated by monitoring clinic activity. Predictive modelling will also be applied to estimate the impact of scaling up the remote care pathway beyond the target cohort of several thousand patients. The costs associated with the delivery of follow-up activity will be sourced from each site to understand the impact of uptake of remote care. Patient participants will also be invited to complete a short survey about the cost implications of switching to remote care (e.g. impact on travel costs, need for childcare etc)

Previous secondary outcome measures:
Secondary outcomes: evaluation of the roll out in the context of the below:

The use of remote care programme from patients and staff will be collected using R-outcomes survey tool (Benson et al., 2010), which will gather data as follows:
1. The Health Confidence Score (HCS) measures people's capability to look after their own health, with dimensions for confidence about knowledge, self-management, ability to get help and shared decision-making (Benson, Potts, & Bowman, 2016). This will be done continually throughout the roll out the remote care pathway
2. The health status score (HowRu) is a short generic health status (health-related quality of life) measure, with four dimensions for pain and discomfort, mental distress, disability and dependence, each rated on four levels. HowRu has been validated against SF-12 and EQ-5D-5L and at the individual patient level (Benson, Potts, Whatling, & Patterson, 2013; Benson et al., 2010; Hendriks et al., 2015). This will be done continually throughout the roll out the remote care pathway
3. The Personal Wellbeing Score (PWS) covers satisfaction, worthwhileness, happiness and anxiety, based on the ONS-4 Personal Wellbeing standard, used in the Annual Population Survey for Great Britain (Office for National Statistics, 2015). This will be done continually throughout the roll out the remote care pathway

In order to be able to compare the results from previous projects the following measures will also be carried out:
1. Patient activation will be measured using the Patient Activation Measures (PAM) at the point of entry to the remote care pathway and at the end of the project July 2020
2. The CI-EMP questionnaire will be used to measure how empowered people are to manager their own cochlear implant care at the point of entry to the remote care pathway and at the end of the project July 2020
3. The EQ-5D-5L will be used to measure mobility, self-care, usual activities, pain/discomfort and anxiety/depression in patients using the remote care pathway at the point of entry to the remote care pathway and at the end of the project July 2020

4. The HUI mark 3 will be used in order to device health states for the people on the remote care pathway at the point of entry to the remote care pathway and at the end of the project July 2020
5. Global rating of change scales will be used to capture whether patients perceive that there has been a change in their hearing, empowerment and quality of life, this will be done at the end of the project July 2020

In order to evaluate the impact of the new remote care pathway on staff the:
1. Work Wellbeing Score (WWS) measures happiness at work; this will be measured at training sessions planned for July 2018
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To assess whether the anticipated changes to clinic activity happen as a result of the remote care pathway and whether this has any implications for the clinic workforce, the clinic activity and type of activity associated with patients on the remote care pathway will be monitored throughout the data collection period until the end of the data collection period July 2020.

The economic impact of the introduction of a remote care pathway will be evaluated by monitoring clinic activity. Predictive modelling will also be applied to estimate the impact of scaling up the remote care pathway beyond the target cohort of several thousand patients. The costs associated with the delivery of follow-up activity will be sourced from each site to understand the impact of uptake of remote care. Patient participants will also be invited to complete a short survey about the cost implications of switching to remote care (e.g. impact on travel costs, need for childcare etc)

Completion date
31/01/2021

Eligibility

Key inclusion criteria
Patient inclusion criteria:
1. Person using cochlear implant (any device, unilateral or bilateral)
2. Living in the UK
3. Aged 18 years or more
4. Able to give informed consent to data sharing
5. Access to a computer or device with internet access
6. Willing and able to comply with a cochlear implant home care pathway

Health professional inclusion criteria:
Staff at participating cochlear implant centre

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Patient 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 telemedicine tools
2. Patients using other cochlear implant online/app telemedicine tools

Date of first enrolment
11/06/2019

Date of final enrolment
31/01/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Southampton Auditory Implant Service
University of Southampton Auditory Implant Service (USAIS)
Building 19
Highfield
Southampton
United Kingdom
SO17 1NX

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road

Manchester
United Kingdom
M13 9WL

Study participating centre
South Tees Hospitals NHS Foundation Trust
The James Cook University Hospital
Cheriton House
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
University College London Hospital
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
United Kingdom
NW1 2PG

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Nottingham University Hospitals NHS Trust
Queens Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
St Thomas' Hospital
Westminster Bridge Road

London
United Kingdom
SE1 7EH

Sponsor information

Organisation
University of Southampton Auditory Implant Service

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Charity

Funder Name
The Health Foundation

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		13/04/2022	14/04/2022	Yes	No
Funder report results	Impact evaluation report	01/07/2021	17/01/2022	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1.9	17/12/2020	17/01/2022	No	No