

Innovating for Improvement

Personalised long-term follow-up of
people with cochlear implants using
remote care

University of Southampton



About the project

Project title:

Personalised long-term follow-up of people with cochlear implants using remote care

Lead organisation:

University of Southampton Auditory Implant Service

Partner organisation:

in partnership with University of Southampton colleagues from Southampton Management School and Electronics and Computer Science, along with the University of Nottingham, Cochlear UK and service users.

Project lead/s:

Helen Cullington

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Part 1: Abstract

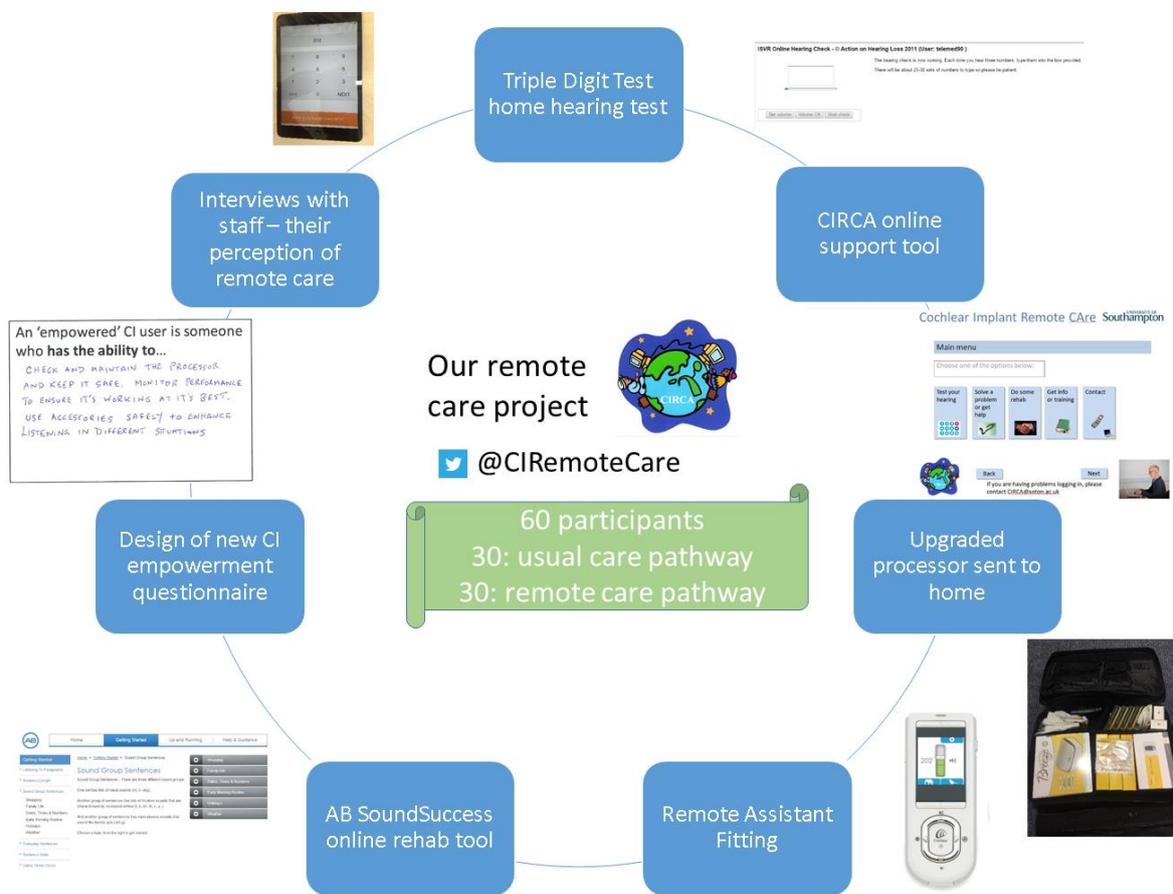
Around 1,400 people receive a cochlear implant in the UK each year. These patients require lifetime follow-up in order for their implant to be checked and adjusted, and for rehabilitation. Cochlear implant care is provided at one of 19 specialist tertiary centres in the UK, which may be several hours away from the patient's home, necessitating travelling expense, time off work and family disruption. At the University of Southampton Auditory Implant Service, we completed an innovative project to make this care pathway patient-centred and provide a more efficient service to allow for more timely identification of issues. We designed, implemented and evaluated a long-term follow-up pathway for people with cochlear implants, offering them remote self-monitoring, self-adjustment of devices, and a personalised online intervention package for testing their own hearing at home. The package of care included information, self-rehabilitation, advice, equipment training and troubleshooting. The customised remote control technology allowed people with a certain implant model to adjust their own hearing levels.

We ran a 6 month clinical trial with 60 people randomised to either the remote care pathway or a control group who followed their usual appointment schedule. The main outcome evaluated was patient empowerment; this has been shown to be strongly linked to better outcomes in people with long-term conditions. We were concerned that the medical focus of the generic Patient Activation Measure® would not be sensitive enough to assess empowerment in people with cochlear implants, who are using a long-term technological solution to their deafness. We therefore designed a new measure of empowerment for people with cochlear implants. We found that only the remote care group had a significant increase in their cochlear implant empowerment after using the remote care tools, although the PAM® score in both groups was unchanged. Quality of life remained unchanged in the two groups. The hearing test result in clinic had improved in the remote care group, although they had not noticed a change. The control group, however, felt their hearing had become slightly worse. This may suggest that the remote care group were more able to take action to keep their hearing stable during the trial.

How we tested our intervention

We enrolled 60 people using cochlear implants and randomised them to either the remote care group or a control group. The control group followed their usual care pathway. The remote care group were given some tools to care for their implant and hearing at home:

- Home hearing test on iPad or computer (Triple Digit Test)
- CIRCA online support tool for troubleshooting, rehab, info etc.
- Upgraded processor sent to home instead of clinic visit (if upgrade due)
- Remote assistant fitting for people with newer Cochlear device – ability to fine tune hearing with implant at home
- Access to additional rehabilitation tool (AB SoundSuccess)



What has gone well

Service user involvement	✓
Recruitment	✓
Clinical care team motivated and interested and looking to future	✓
Home hearing test	✓
CIRCA online support tool	✓
Liaison with Cochlear (commercial partner)	✓

We began the project with a call for Patient and Public Involvement (see leaflet in Appendix 1.1). Although our previous work had suggested that people with cochlear implants were interested to take more control of their hearing care, we wanted to do this in a more formal way. Many cochlear implant wearers from around the country

got in touch to say they were interested to help out. A few service users also replied to say they were not interested in remote care at this time. Of course we were aware that remote care would not be for everyone. The strong national interest in the project meant that recruiting 60 participants was easy.

"I would love to be involved in developing remote care, in any way that will help your project"

"I do not understand the



"Sorry, am not sure whether I would feel confident using technology myself at home"

We obtained great user feedback from two focus groups in October 2015: one to discuss what patients would like to do themselves at home, and the other to talk about what it means to be an empowered user of a cochlear implant.

1..more opportunity in control of my cochlear implant at home. it would benefit more as sound booth isn't real world. so would love to try remote mapping at home.

Opportunity to direct map to suit a particular environment "on the move" would be a bonus.
 - " -
 aware - provide an option. - everyone is different
 - provide interactive on-line support.

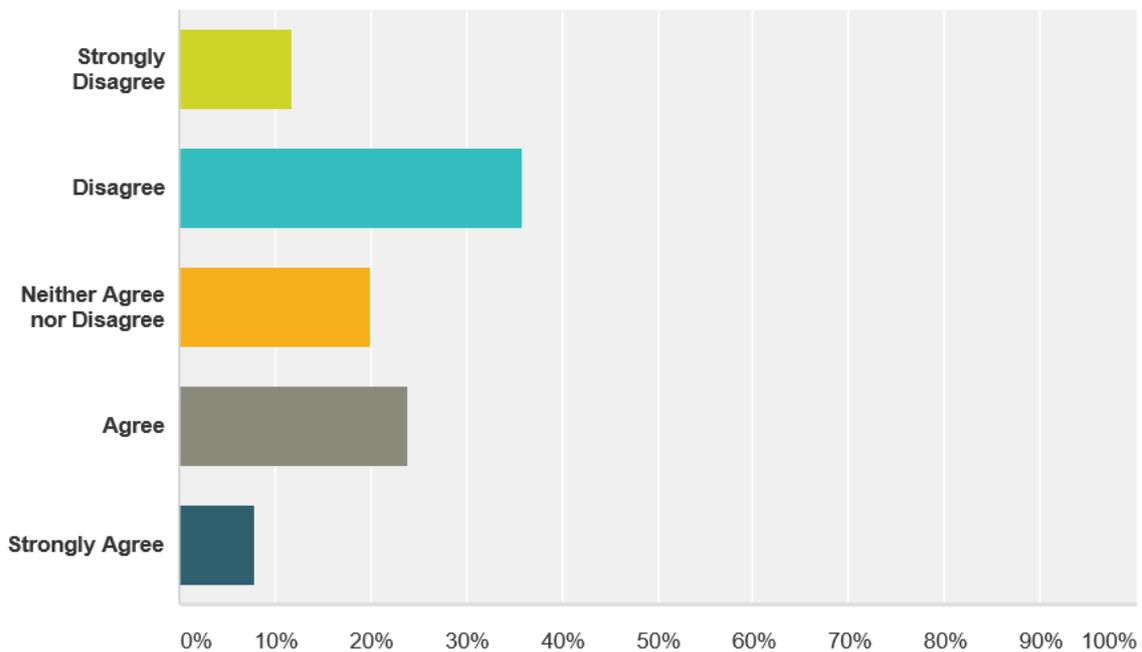
"When we roll this out to teenagers?"
 "When can we start using this with teenagers too?"

The project has embedded well within our clinical service in Southampton. Clinicians are interested and motivated and assuming that remote care will be offered clinically in the future. The

administrative and support team are supportive and committed to the project. We have worked hard to communicate the aims of the project to the clinical team; this has paid off. Nationally there has been much interest in the project, with presentations at several national and international meetings even before there were any results to share. Liaison with the company Cochlear has gone well; they shared tools and information freely. The online support tool – CIRCA - worked well and was well-used, although there were initial log on problems.

I found it difficult to log on to CIRCA.

Answered: 25 Skipped: 2



Our challenges

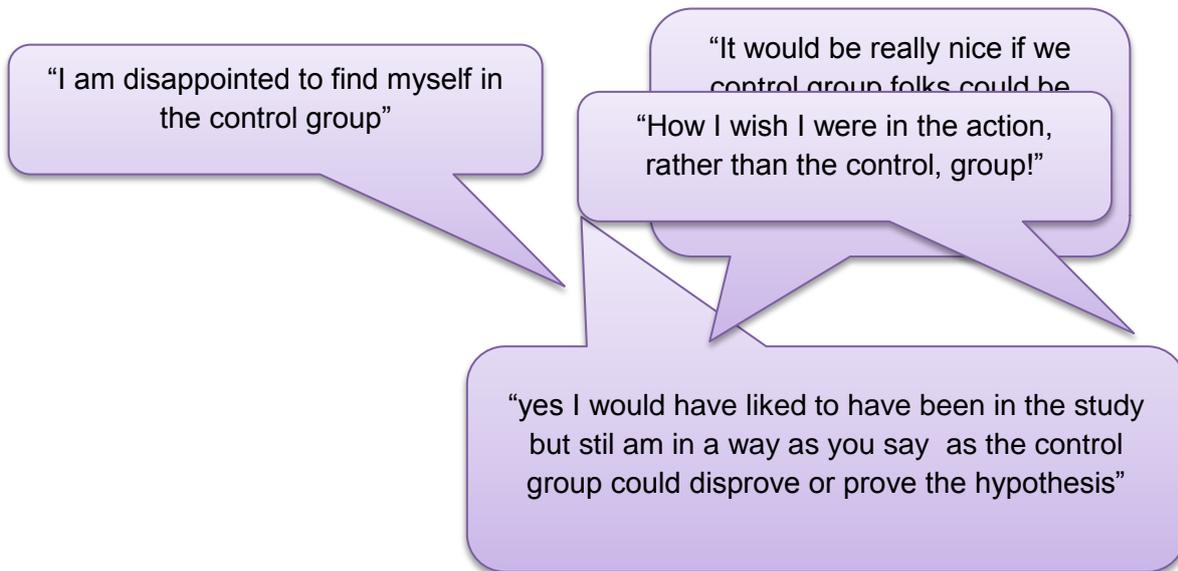
When we rolled out the online support tool, we had not fully anticipated the difficulties some people would have connecting to the resource at home; within a few days we built an FAQ document (Appendix 1.2) – I wish we had given this to people earlier. The log on process was and difficult for some users to navigate.

"I think I can now access everything but I have to say it has not been particularly user friendly for me, or intuitive"

cumbersome

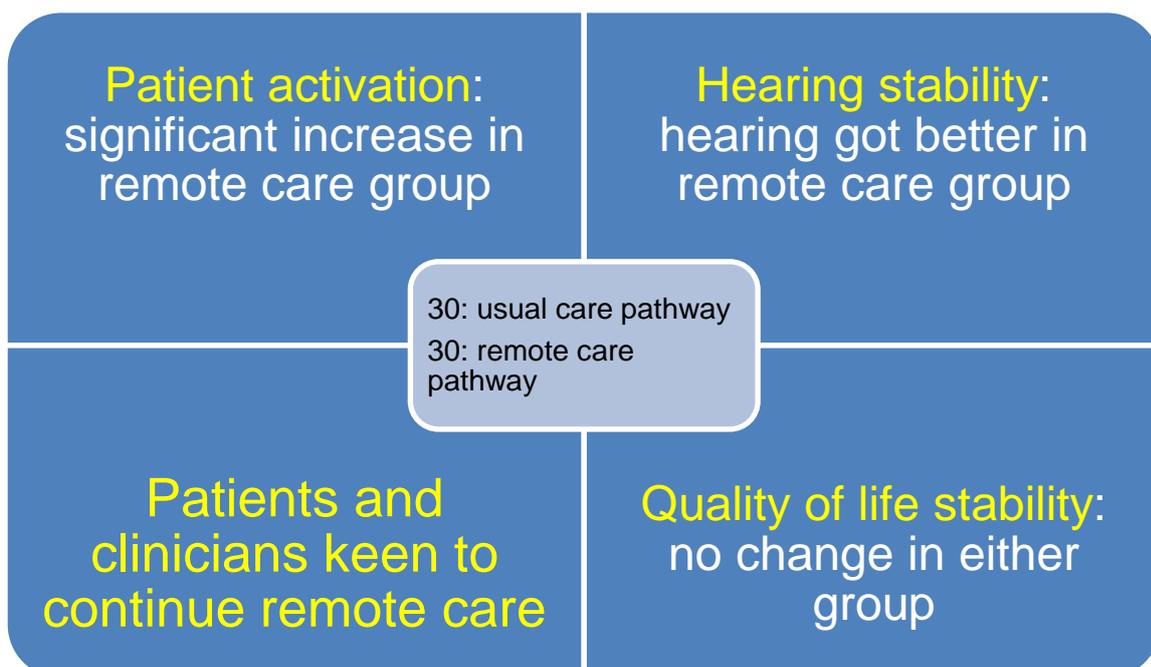
When we did the randomisation at the start of the project, some people were disappointed to be in the control group. We carefully counselled that their role was equally important and provided written material to remind them of this. We were worried that people in the control group would drop out of the project. However, we

were delighted that every single person in the control group stayed in the project and attended for exit measures.



Our outcomes

Our main outcome evaluated was patient empowerment; this has been shown to be strongly linked to better outcomes in people with long-term conditions. We also wanted to be sure that the hearing and quality of life of those in the remote care group would not deteriorate due to their non-attendance at clinic. We measured these outcomes at the beginning and end of the project and compared results in the two groups (usual care and remote care). We found the following results:



What we have learned

Don't start clinical trial too soon – change will be more sustainable if more time invested in engaging stakeholders
Budget for a research assistant – so much research admin
Don't try and do everything yourself – delegate tasks to other team members
Don't underestimate how much help people may need when logging into a website
Do not ask people their highest qualification and allow a free text response – give choices
Don't overestimate the skills and time available for the PI (Cullington) to learn how to build an online support tool from scratch
Consider any effects on the validity of the data beforehand, and compensate for them if possible

Part 2: Progress and outcomes

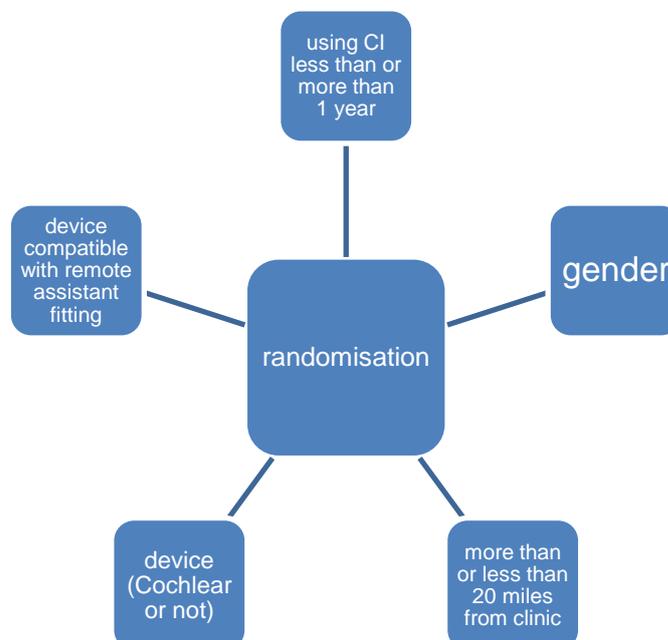
We measured these **primary**, **secondary** and **feasibility** outcomes:

- Patient Activation Measure® (PAM®)
- Cochlear implant empowerment measure (CI-EMP)
- speech recognition testing (BKB sentences in quiet and noise and Triple Digit Test, TDT).
- the Speech, Spatial and Qualities of Hearing questionnaire (SSQ)
- quality of life questionnaire: Health Utilities Index (HUI) mark 3
- recruitment (number of eligible and willing participants)
- attrition (drop-out) and bias
- adherence to protocol
- acceptability of randomisation to service users
- willingness and ability to use remote care tools

The primary outcome measure (activation) was analysed by Kitterick while he was blinded to which group was the remote care group.

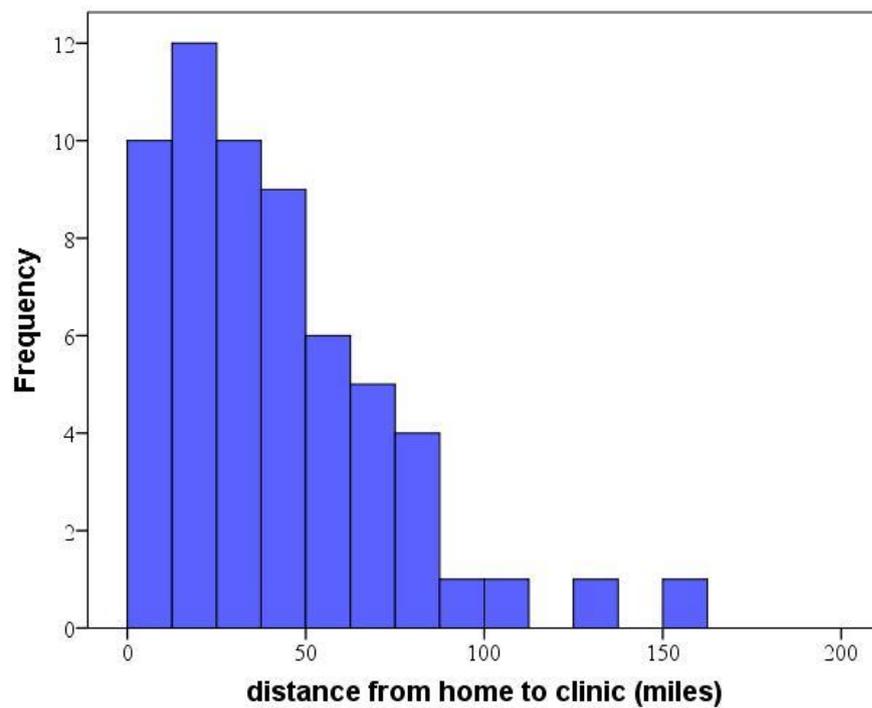
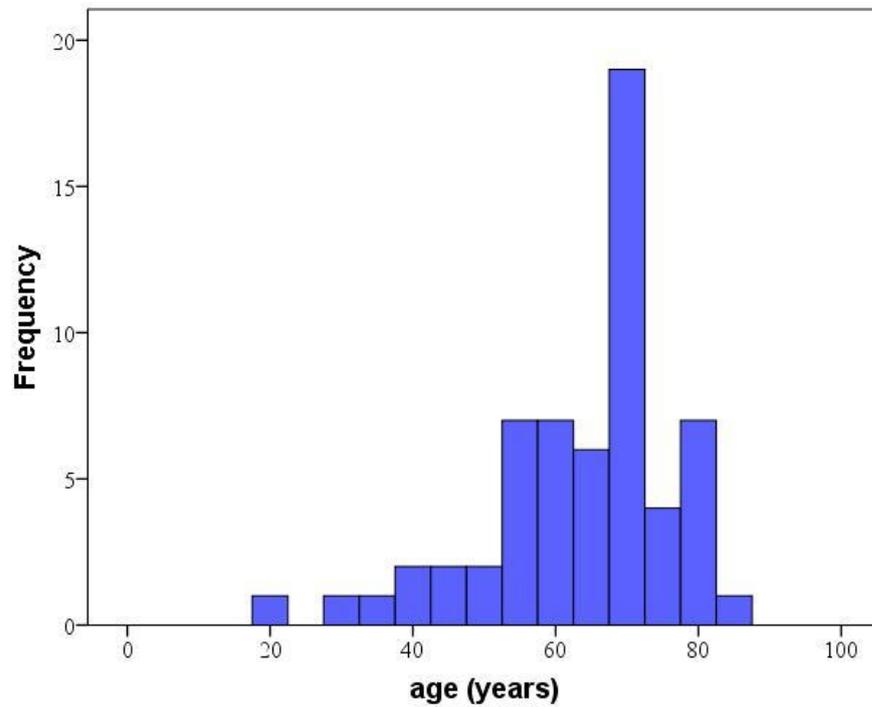
Participants

Sixty adults using cochlear implants took part and were randomised to either a control group who followed their usual care pathway or a remote care group. The randomisation balanced the two groups for the following factors:



The 36 female and 24 male participants were aged from 20 to 83 years, with an average of 63 years in the control group and 64 years in the remote care group.

They lived between 5 and 156 miles from their cochlear implant centre, with an average of 42 miles.

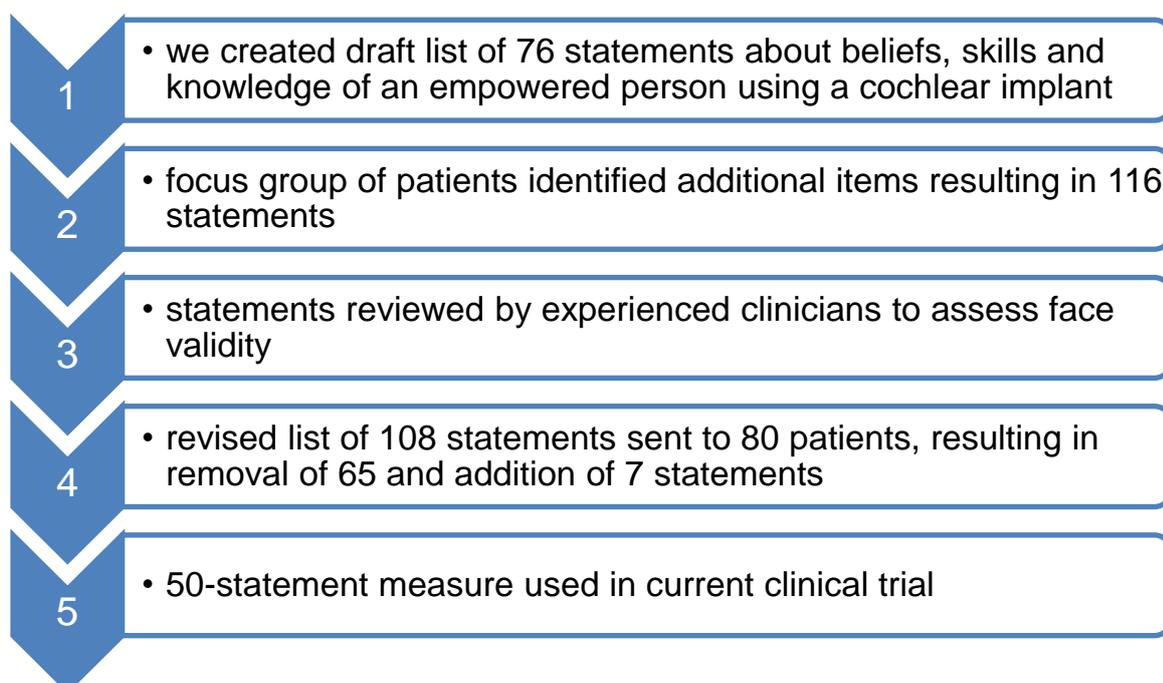


Patient activation (PAM® and CI-EMP)

Measuring empowerment in people with cochlear implants

We expected that providing cochlear implant care remotely would increase how empowered patients were to look after their own hearing and maintain their devices. So the primary outcome measure was the Patient Activation Measure® (PAM®): a widely-used and well-validated measure of the extent to which a patient believes they are the best person to look after their health, knows about their health condition and the treatment they are receiving, and has the skills to manage their condition and deal with episodes of ill-health. However, at face value the items in the PAM® questionnaire may not be wholly appropriate for people using cochlear implants. For example, it contains references to medicines and treatments and therefore would be more appropriate to those patients who are receiving pharmacological rather than technological interventions. One aim of the current study was therefore to explore the feasibility of creating a measure of empowerment that focuses on issues that are more relevant to people using implants.

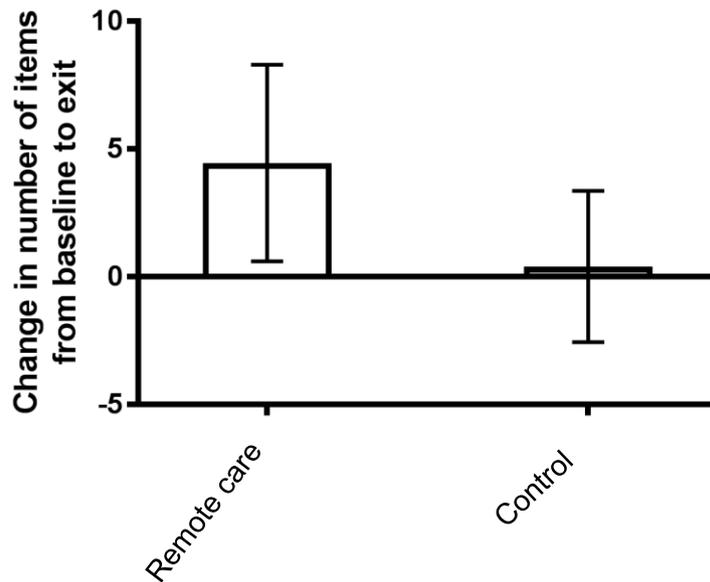
The new measure was developed in five stages:



Patients in the trial were provided with the list of statements and asked to express how well they felt each statement described their own beliefs, knowledge, and skills. Their responses were captured using a 5-point Likert scale ranging from 'Very true' to 'Very untrue'. The questionnaire was done at baseline and at the study exit (Appendix 1.3).

Participants' responses were analysed in terms of the number of statements that they felt strongly reflected their own beliefs, knowledge, or skills. On average, people in the remote care group were found to strongly agree with an additional 5 statements at the exit interview compared to at baseline. Participants in the control

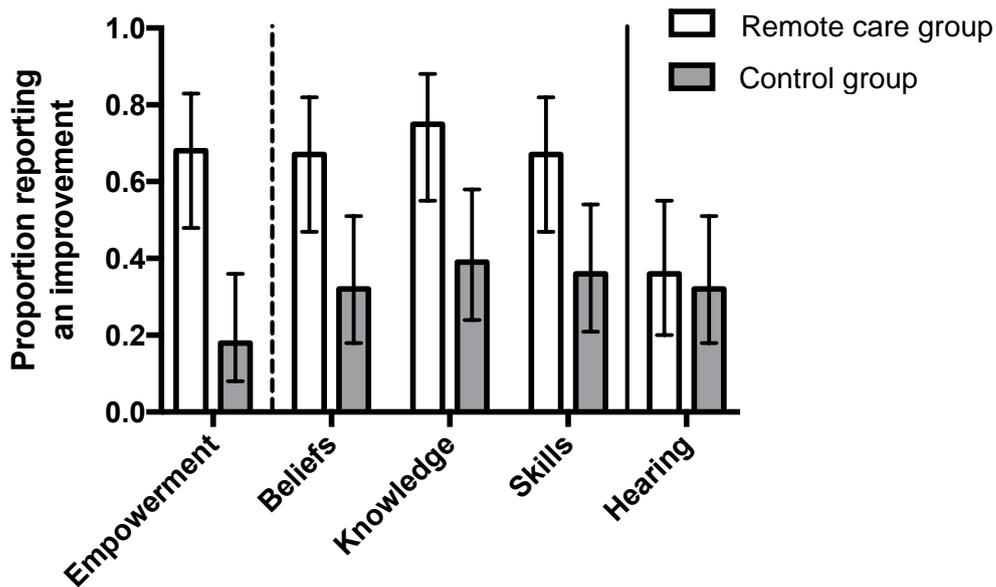
group showed no change in the number of statements they strongly agreed with over time (see graph below). This indicated that **the remote care group had an increase in empowerment**, whereas no such change was found in the control group.



An 'empowered' CI user is someone who knows... How it works
 How to clean CI
 " " Disassemble CI
 To recognise faults
 change from Rechargeable to
 Disposable Batteries

Participants were also asked to complete global ratings of change questions at the exit. These ratings were obtained by asking participants whether aspects of their empowerment had *changed* since the baseline visit in the study, by choosing one of 7 options that varied from 'Much improved' to 'Much worse'. The proportion of patients in each group that reported an

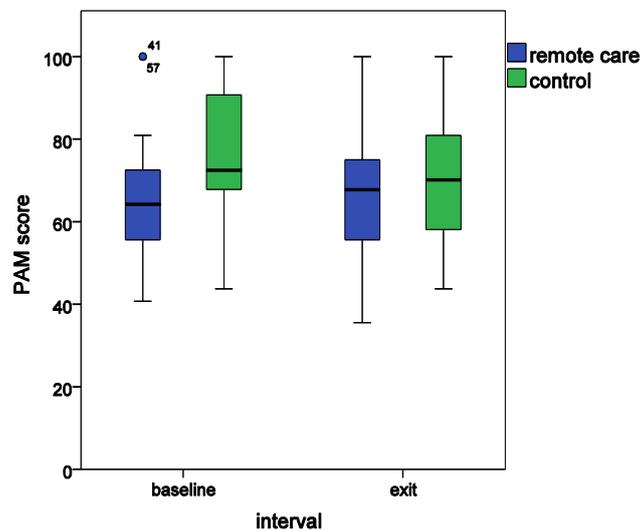
improvement from baseline to the exit interviews are shown in the figure below. A significantly larger proportion of participants in the remote care group reported a change since the baseline visit compared to the control group. This change was evident both for their overall level of empowerment but also their beliefs about taking control of their own care, their knowledge about how to take control, and their skills in being able to take control. The fact that participants in the remote care group identified with a greater number of statements about being empowered (previous figure) and were also more likely to report a change in their level of empowerment strongly suggests that they were more empowered at the end of the study than at the start. As anticipated, the proportion of participants reporting a change in their hearing abilities was small and similar in the two groups.



Error bars show 95% confidence intervals for the proportions.

Patient Activation Measure®

We compared the change in PAM® score in each group from baseline to exit. Neither group showed a significant change in PAM® score during the study. At baseline however, the control group was significantly more activated than the remote care group, although the two groups were not significantly different at exit.



Hearing stability

We compared the hearing of people in the control group with those in the remote care group; we were interested in hearing in quiet and hearing in noise (these are the main benefits of a cochlear implant).

Speech recognition testing (BKB sentences in quiet and noise and Triple Digit

Test, TDT)

Traditional clinic test measures (sentences in quiet and noise) showed no difference in the change during the project between control and remote care. However only the remote care group showed a significant improvement on the Triple Digit Test. This may have been because they had got better at doing the test as many of them did it a lot at home, or this test may be more sensitive to small changes in hearing performance than the traditional clinic tests.

Self-assessment of hearing ability (Speech, Spatial and Qualities of Hearing questionnaire, SSQ)

The Speech, Spatial, and Qualities of hearing questionnaire allows people to rate their own hearing in three domains:

1. Hearing speech e.g.

You are talking with one other person in a quiet, carpeted lounge-room. Can you follow what the other person says?

Not at all 0 1 2 3 4 5 6 7 8 9 10 *Perfectly*

This question does not apply to me.

2. Spatial hearing i.e. where sounds come from e.g.

You are sitting around a table or at a meeting with several people. You can't see everyone. Can you tell where any person is as soon as they start speaking?

Not at all 0 1 2 3 4 5 6 7 8 9 10 *Perfectly*

This question does not apply to me.

3. hearing quality e.g.

Do you find it easy to recognise different people you know by the sound of each one's voice?

Not at all 0 1 2 3 4 5 6 7 8 9 10 *Perfectly*

This question does not apply to me.

We were interested to see if there was any change in hearing ability in the two groups after the trial. The self-perceived hearing ability in the remote care group did not change, however it did become slightly worse in the control group for the overall hearing assessment and the domain of hearing speech. This may suggest that the remote care group were able to take action to keep their hearing stable during the trial.

Quality of life stability (Health Utilities Index (HUI) mark 3)

Quality of life was assessed using the Health Utilities Index Mark 3. This is a questionnaire that measures health-related quality of life on eight dimensions including hearing and speech. Neither group (remote care or control group) showed a significant change in quality of life during the study period.

6 Which **one** of the following best describes how you have been feeling during the past **4 weeks**?

Happy and interested in life.

Somewhat happy.

Somewhat unhappy.

Very unhappy.

So unhappy that life was not worthwhile.

Dropout rate

One person in the remote care group chose to drop out of the study after 2 months.

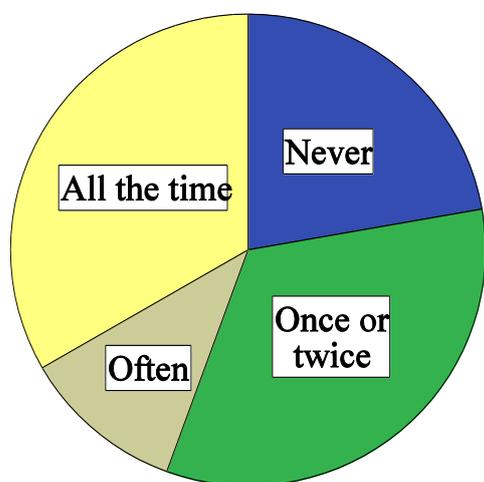
“Sorry but I am unable to continue with my own testing, I have lots of problems with checking in on the compute so have decided not to carry on with it, I would much prefer to meet some one and be face to face.”

Dropout
rate = 2%

The remaining 59 people stayed in the study. Two people were too unwell to attend for exit measures, although they kindly completed questionnaires from home.

Use of remote assistant fitting

Ten people were shown how to change their sound processor programs using remote assistant fitting. Remote assistant fitting can only be used with one specific device; all eligible people were given it. Nine people answered a question about how much they had used remote assistant fitting. As expected for such a new tool, the feedback was variable.



What did the patients think?

This was the first time that people using cochlear implants have been given remote care tools. What they told us about the tools is very important to shape how we are going to proceed now. Here are some quotes and videos of patients talking about what they liked about remote care:

“First a whopping big thank you for the SoundSuccess. It fits so much with many of the thoughts I’ve been having.”

“There are a lot of very interesting features, eg rehab and information that I will definitely use in the future”

“This is great I hope I do not lose this facility after the trial finishes”

“the CIRCA software. I chose Using the Telephone as my first goal ... Finally I must say how thrilled I was just to be able to pick up the telephone receiver without outright panic. I haven’t lifted a receiver for some 40 years or so”



http://bit.do/remote_care

The home hearing test

Many people using the remote care tools reported that the home hearing test was their favourite tool. They found it valuable to monitor their hearing and take action if required. Several people reported doing the test at least every day, and experimenting with different processor settings to find the optimum result. One participant was even interested to see if his hearing changed after going to the pub!

Hearing Test

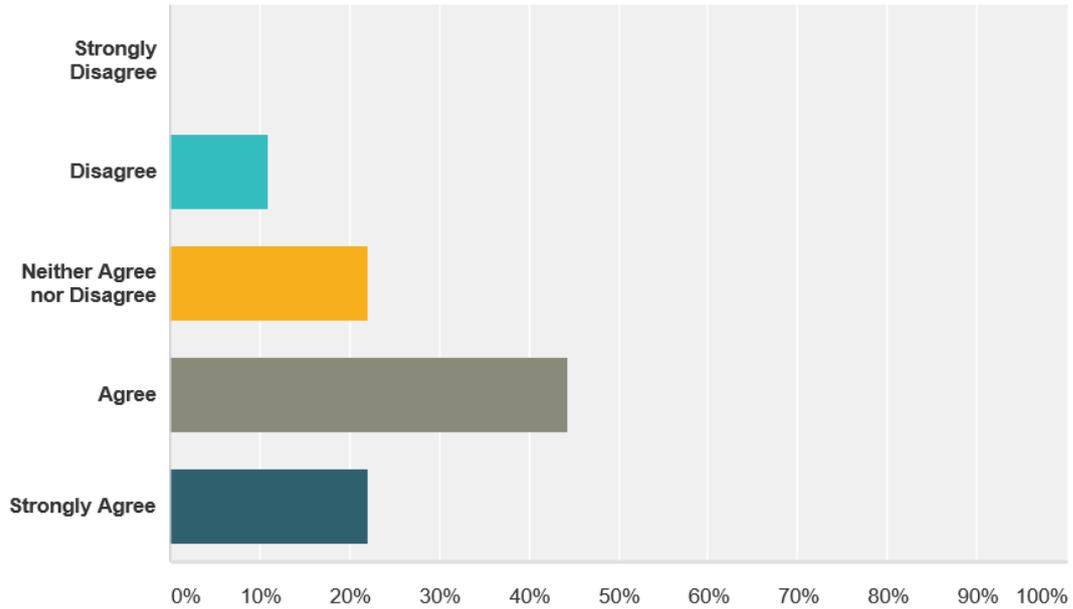
Speakers set to $\frac{1}{4}$	} Hearing aid in left ear taken out Implant on mic with default volume. Other noise eliminated.
Screen volume set to $\frac{1}{2}$	
Program set to 0.60	

The online support tool

We asked all remote care participants to answer some questions about CIRCA, the online support tool; responses were received from 27. Those that did not respond were the one person who dropped out, and the two people too ill to attend. Sixty-seven percent of people found the CIRCA website useful, and 64% of people would recommend it to other people with cochlear implants. However, we received a lot of constructive feedback about what people would want in the next version.

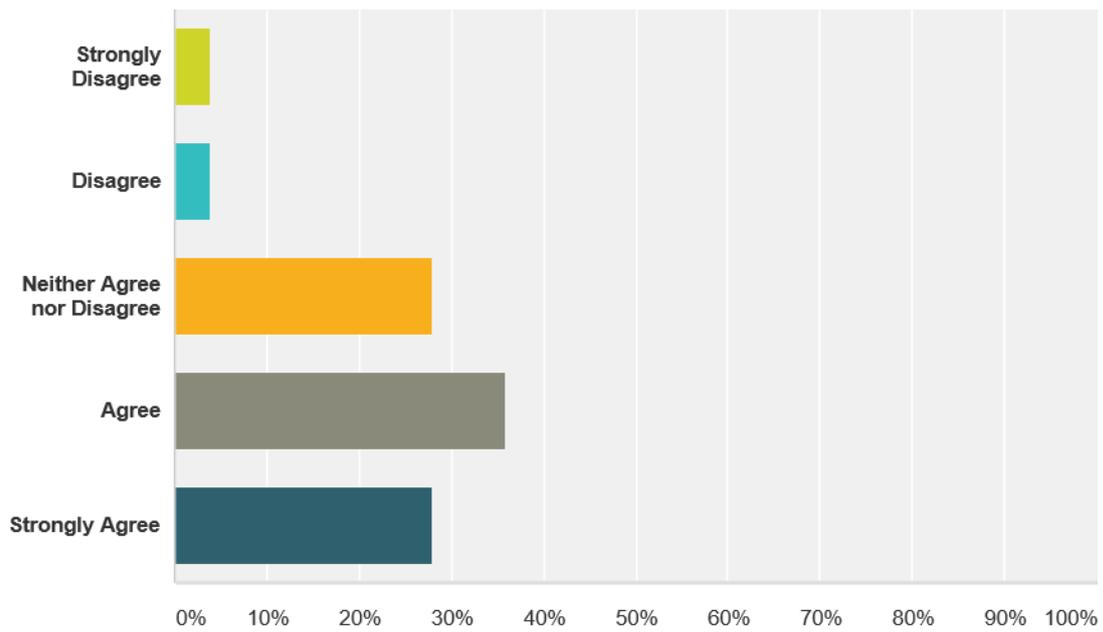
The content of the CIRCA website was useful for me.

Answered: 27 Skipped: 0



I would recommend the CIRCA website to other people with implants.

Answered: 25 Skipped: 2

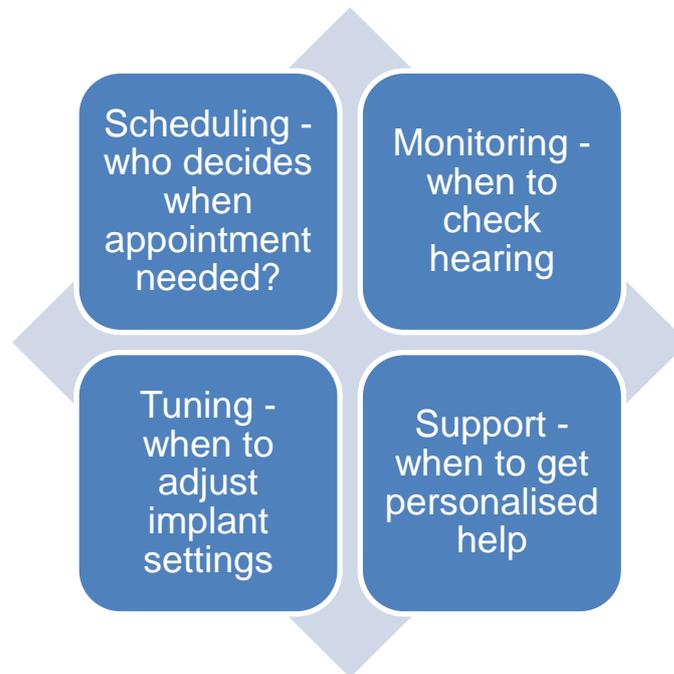


Preference for care pathways delivered using remote care tools

We wanted to measure the preferences of patients for remote care over usual care. As the current model of remote care included multiple different elements (e.g. self-monitoring, self-tuning, etc.), we used a Decision Choice Experiment (DCE) to:

- confirm that patients really do prefer at least some forms of remote care over a centralised care provision model
- explore whether their preferences differ based on which elements of remote care are provided.

The DCE provided patients with a range of possible care pathways that included one or more elements of remote care. The different elements that were used to construct these theoretical pathways were based on focus groups with patients and also chosen to reflect, as far as possible, the elements that were trialled in the current trial. Four elements were chosen:



We created a simple one-line statement to describe the current usual care, and then wrote one or more statements to describe alternative models of care delivered using available remote care tools.

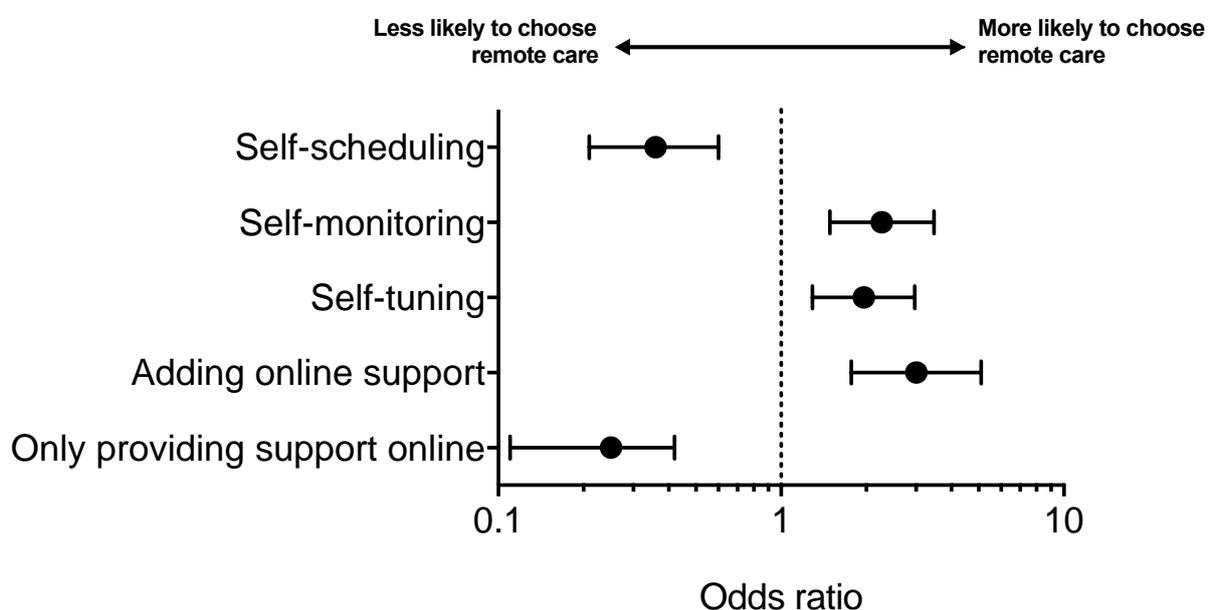
Element	Usual care	Remote care
Scheduling Who decides when the next clinic appointment will be?	The implant clinic (but the patient can request appointments when required)	The patient
Monitoring When are a patient's speech understanding abilities monitored?	During implant clinic appointments only by an audiologist	Between appointments by the patient themselves at home and also during clinic appointments by an audiologist
Tuning Who can fine-tune the cochlear implant settings?	The audiologist only during implant clinic appointments	The patient at any time using a remote control and the audiologist during clinic appointments
Support Where can a patient get rehabilitation and troubleshooting information that is personalised to their needs?	From the implant clinic only	<ul style="list-style-type: none"> • Through a personalised website and from implant clinic OR • Through a personalised website only

The factorial combinations created by varying these four elements resulted in 23 theoretical alternative care pathways that included some form of remote care. Patients were presented with each of these 23 pathways and were asked to indicate whether they would choose the alternative care pathway or usual care. The two pathways were simply labelled 'A' and 'B' and patients indicated their choice by ticking a box:

	Implant Service A	Implant Service B
Who decides when the next clinic appointment will be?	The implant clinic (but the patient can request appointments when required)	The patient
When is the ability to understand speech monitored?	During implant clinic appointments only by an audiologist	During implant clinic appointments only by an audiologist
Who can fine-tune the cochlear implant?	The audiologist only during implant clinic appointments	The audiologist only during implant clinic appointments
Where can patients get rehabilitation and troubleshooting information that is personalised to their needs?	From the implant clinic only	Through a personalised website only
	Implant Service A	Implant Service B
I would choose: <i>(tick one box only)</i>	<input type="checkbox"/>	<input type="checkbox"/>

Patients were asked to express these preferences at baseline and at the end of the trial.

The graph below summarises the results of the analysis. Patients were found to be more likely to choose remote care over usual care if they could monitor their own ability to understand speech ('self-monitoring') or fine-tune the settings on their own implant ('self-tuning'). The strength of their preferences for remote care did not increase further if both self-monitoring and self-tuning were provided, probably because either of these changes already meant that they were almost certain to choose remote care. They also preferred a remote care pathway if it included personalised online support resources in addition to support from the implant centre. Participants were less likely to choose remote care if it meant that they had sole responsibility for scheduling appointments ('self-scheduling') or if support was only provided online, even if it was personalised.



The overall impact of each element of remote care on patients' preferences for the alternative care pathways. The symbols represent the 'odds ratio' and the horizontal bars its confidence interval. Odds ratios less than 1 indicate the patient was less likely to choose the remote care pathway if that element was included, whereas odds greater than one indicated an increased likelihood of choosing remote care.

The analysis also found that the effect of imposing self-scheduling on a care pathway differed depending on what other elements of remote care were included. The provision of tools to allow either self-monitoring or self-tuning significantly reduced the negative effect on self-scheduling. In other words, self-scheduling was far less likely to deter participants from choosing remote care as long as they could also self-monitor their own hearing or self-tune their device. Therefore, it would be appropriate to ensure that self-scheduling was not offered without additional tools and resources to support the ability and confidence of patients to know when an appointment might be needed.

We had no strong expectation as to whether the preferences of those patients who

received remote care during the trial would change as a result of having direct experience of these kinds of changes to their care pathway. The analysis indicated that there was no change in participants' preferences over the six-month period. It is possible that the preferences of those participants who received remote care increased over the course of the study but that this choice experiment was not sensitive enough to detect it: this sample of participants was already highly likely to choose remote care at baseline. However, the results appear to suggest that experience of using remote care tools did not reduce participants' preferences for remote care, which is compatible with the positive feedback we received.

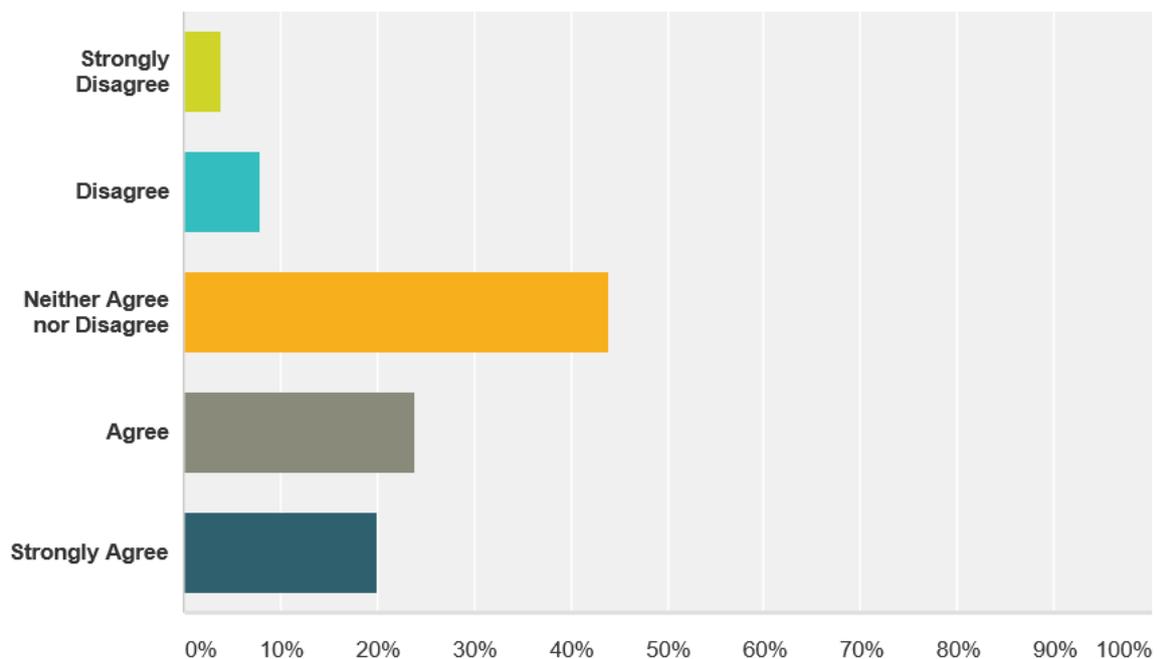
Part 3: Cost impact

Cochlear implant services are provided at specialist tertiary centres; there are 19 in the UK. Each centre has a contract with NHS England (D09/S/A Specialised Ear Surgery – Cochlear Implants). Cochlear implants will be funded if the patient fulfils candidacy criteria under NICE TAG 166 (2009). The cost of service provision at the centre varies according to how long patients are after surgery, whether they are adult or child, and whether they receive one or two cochlear implants (adults usually have one). This project assumes that person-centred care will begin in adults and later be modified and extended to children, so the financial cost of the current service provision for adults with one implant after the first year was used.

The tables below show the annual cost of financial provision of the current service and estimates of the remote care pathway (please keep confidential). Feedback from participants suggested that some people on the remote care pathway would be happy to continue managing their own care remotely and only coming to the clinic when there was a problem. Forty-four percent of people felt that using CIRCA would reduce their number of visits to the clinic (44% of people were unsure).

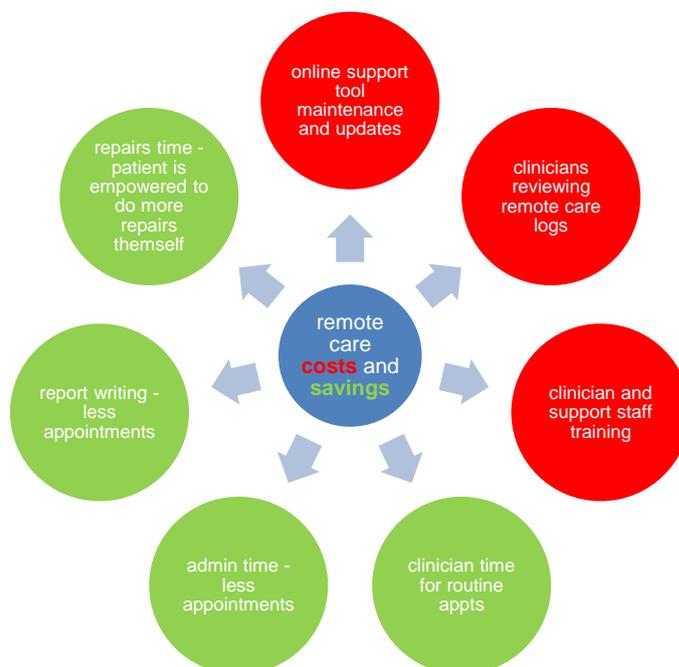
I think that using the CIRCA website could reduce my number of visits to the clinic.

Answered: 25 Skipped: 2



This clinical trial ran for only 6 months so it is difficult to estimate the long-term costings for remote care.

If remote care is introduced routinely, we estimate savings in the following:



The remote pathway represents a cost saving of around £326 per patient. Currently our centre cares for 1100 patients, with around 100 new patients receiving implants each year. We are not anticipating short term cost savings; our ultimate aim is to improve service quality and provision to deaf people. The clinician and administrative hours that are saved each year on a straightforward patient would be used to treat a new or complex patient.

Current

	clinician hours	admin hours	salary cost	other cost	total cost
Medical				80	80
Rehab workshops	2		164		164
Audiology	2		164		164
Rehab review	1		82		82
Admin: letters, parking, records, data, ordering equip, seeking funds		1	51		51
Repairs staff time	0.5	3	194		194
Repairs, batteries, upgrade			0	1700	1700
Replacement of equipment & calibration			0	30	30
Report writing	0.75		62		62
Compliance, statistical & reporting	1	1	133		133

Database maintenance	0	29	29
Training of local professionals	0	15	15
Publications	0	10	10
		TOTAL	2714

Remote pathway

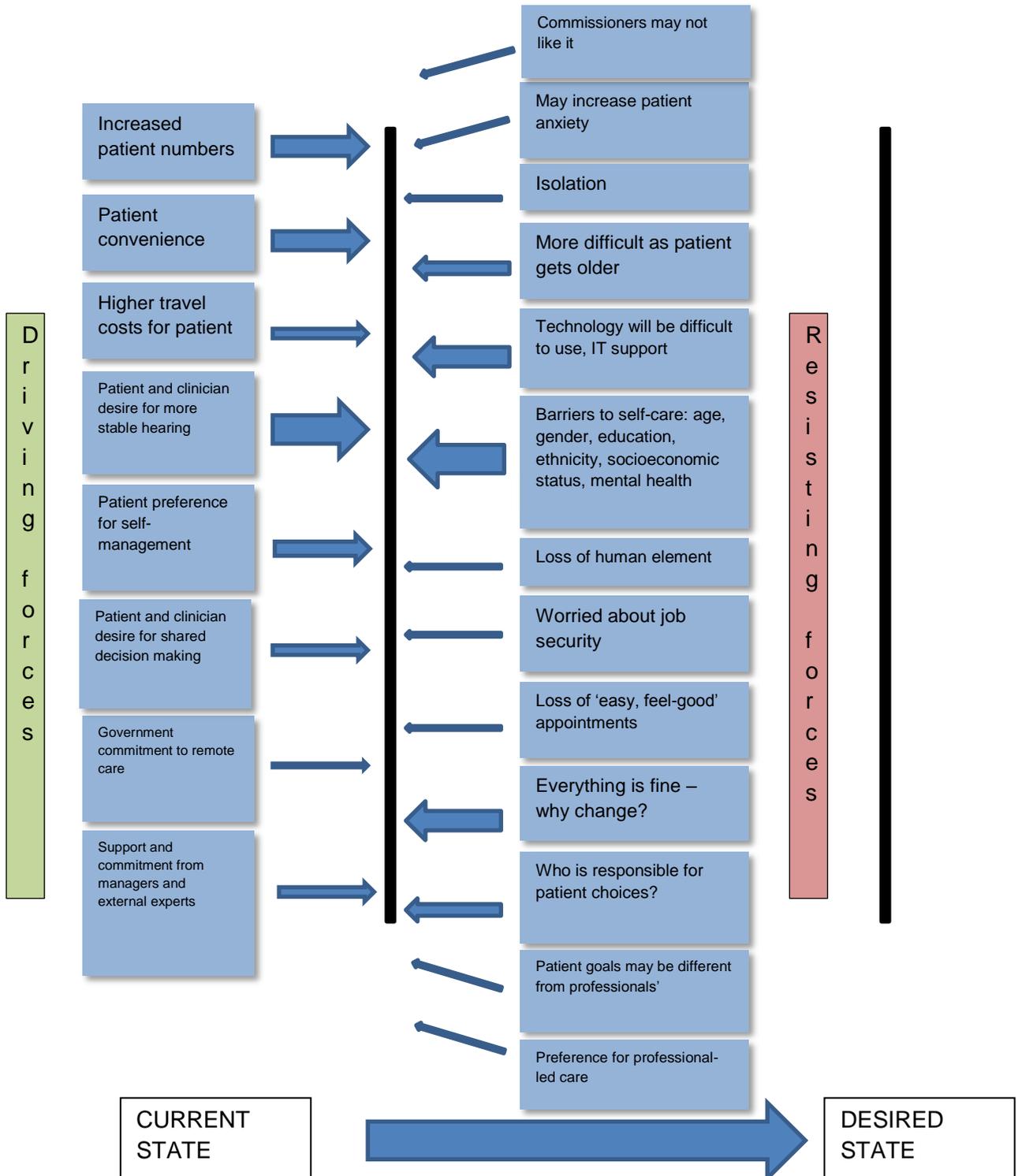
	clinician hours	admin hours	salary cost	other cost	total cost
Medical				80	80
Rehab workshops	0		0		0
Audiology - reviewing remote logs	1		82		82
Rehab review	0		0		0
Admin: letters, parking, records, data, ordering equip, seeking funds		0.5	26		26
Repairs staff time	0.5	1	93		93
Repairs, batteries, upgrade			0	1700	1700
Replacement of equipment & calibration			0	30	30
Report writing	0.5		41		41
Compliance, statistical & reporting	1	1	133		133
Database maintenance			0	29	29
Online support tool maintenance	1		82		82
Clinician and support staff training	0.5	0.5			67
Training of local professionals			0	15	15
Publications			0	10	10
				TOTAL	2388

There is more work to be done before remote care can be offered routinely to people with cochlear implants – we want to incorporate all the excellent feedback we have had from patients and clinicians into the next rollout.

Part 4: Learning from your project

Did we achieve all that we hoped for?

We are very pleased that our project did achieve all that we hoped for. A trial of remote care in people with cochlear implants had not been done before, and there were challenges to be overcome. Before beginning the project, we thought hard about the barriers we could face and how to overcome them. We considered the driving and resisting forces to be as follows in order to move from the current service delivery model to a remote care model:



This project has only incorporated a 6 month clinical trial with only a fraction of our patients using the remote care tools, but we have tried to build for a larger rollout in future.

Reducing clinician restraining forces

From the start, we always referred to the project to other clinicians as '**our remote care project**', not 'my remote care project'. We think that this helped engender a sense of ownership of the project. The project lead (Cullington) had the full support of her manager (the Director of the Auditory Implant Service). He views remote care as our main research and clinical service provision innovation. This commitment from leadership has made a big difference.

Reducing patient restraining forces

We were very concerned that patients would hear about remote care and feel that the centre was closing, or downsizing, or that we would not be available to help them in future. Reducing patient concerns involved communication. The lead (Cullington) wrote about the project for patient newsletters and the centre's website. We were also able to find out and address patient concerns in focus groups.

Reducing other restraining forces

Although we intended to have a face to face meeting with commissioners about the project, this has not happened yet. This is because we feel that it would be better to wait until we are planning the larger scale rollout, with direct implications for the commissioners. We did communicate via email though.

Things that didn't work out quite how we planned

We have learned a lot about change and how to implement it during this project. Here are our main learning points:

1. *Don't start clinical trial too soon – change will be more sustainable if more time invested in engaging stakeholders*

Initially we thought we would launch straight into a 1 year clinical trial. However, we soon came to realise that any change we implemented would be more likely to be sustainable if far more planning and service user engagement was done first.

2. *Budget for a research assistant – so much research admin*

We found that we were spending a lot of time on research admin, especially in the early days of contacting service users and recruitment. Perhaps some of our time could have been better spent if we had help with the admin.

3. Don't try and do everything yourself – delegate tasks to other team members

The project PI (Cullington) took ownership of the project and probably struggled to delegate areas to other team members. While it is positive that the project had strong leadership, delegation is part of good leadership and having more ambassadors for the project would have been helpful.

4. Don't underestimate how much help people may need when logging into a website

Many people in the project had little experience of computers, and we had probably underestimated how much support would be needed when they first registered on the online support tool. Having a research assistant responsible for support during this time would make things easier, and we will plan for this when we roll out the next version.

5. Do not ask people their highest qualification and allow a free text response – give choices

Although probably obvious to most more experienced researchers, it was not a good idea to ask participants to tell me their highest qualification. This resulted in them telling me about qualifications that I had not heard of, and making it very difficult to categorise. We therefore asked the question again at exit measures, and provided a choice (Appendix 1.4). Any demographic information we needed should be asked in a closed set format.

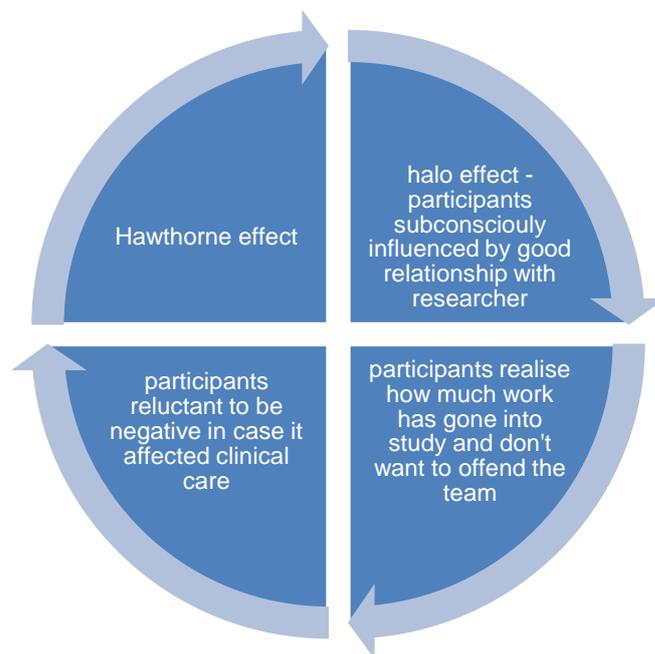
6. Don't overestimate the skills and time available for the PI (Cullington) to learn how to build an online support tool from Scratch

Initially we had planned that the PI (Cullington) would learn how to program in LifeGuide and build the online support tool. However, this very quickly seemed untenable, especially with all the other project tasks ongoing, and we ended up paying a very experienced PhD student to build the intervention. This was a very smart move as she had used LifeGuide interventions a lot, so also had good tips for what works in terms of content and flow.

7. Consider any effects on the validity of the data beforehand, and compensate for them if possible

In a clinical trial like this, it is difficult to ameliorate bias effects in the data, mostly because blinding participants is not possible and the participants were all motivated and nice people who wanted to help the research. The results of any clinical trial need to be viewed with ample consideration of the Hawthorne effect – this is the possible impact of research participation on behaviour i.e. do you behave differently if you know you are being studied? It is possible that those people using remote care tools were more engaged with the process simply

because they knew they were being studied. In addition, there may have been other confounding factors, as shown below:



During the project exit measures, we held focus groups with those participants who had used remote care. Full analysis of this has not yet been completed due to the necessity of the exit measures being at the end of July. We are committed to spending a lot of time analysing this valuable resource in order to move forward.

We were fortunate to receive much constructive feedback about CIRCA, the online support tool via a Survey Monkey questionnaire. This will directly inform our next build and would benefit from fuller analysis. Some responses are shown below:

What extra features would you like to see in future versions of CIRCA?

I found it difficult getting onto cochlear website could, this be included
I can't think any of the extra features on CIRCA website.
I would prefer to be able to actually test the status of my implant directly rather than relying on my hearing to do so - i.e. plugging the implant in to test it.
More useful app to try different things at home
Results of hearing tests available to view.
lipreading tests with sounds
I would like to see a clearer 'how to order' section and an improvement to online support tool as I am not always sure how to do an adjustment of my programme when using my fine tuner.
none
A tick list of supply requests. For example I request something which was misunderstood for something else because I couldn't remember what it was called
don't know.
More about wireless technology, how to fit and what is available

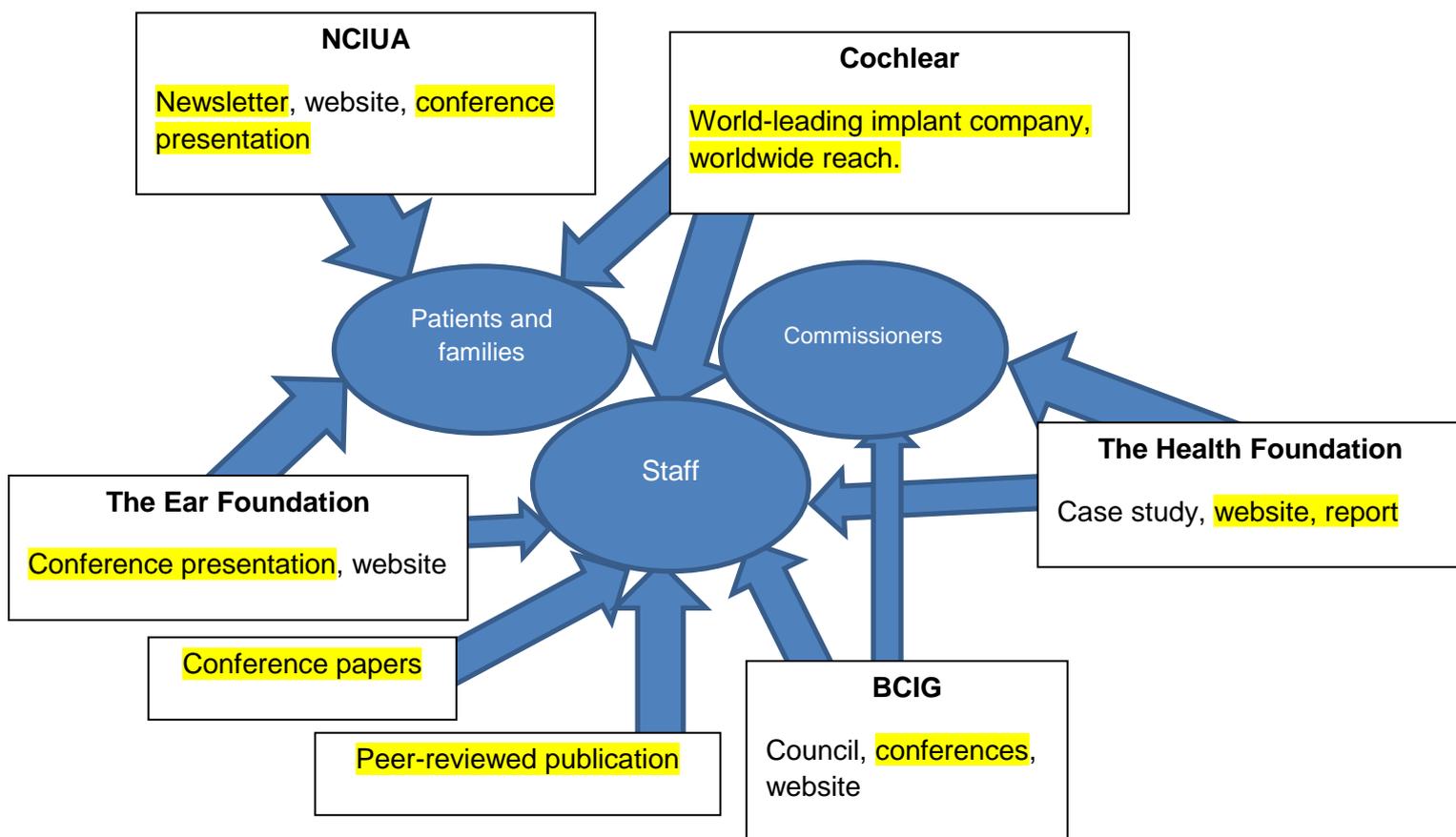
Nothing
I apologise for not being determined to make it work.
It just needs a complete revamp. I think the information is there, it's just difficult to find and very boring. Need a lot more human interest eg stories of patients with CIs
More instructions. So complicated. Badly designed.
to be kept upto date with Neurelec
Actual auditory training exercises.
I would need some attraction to make me want to use it sufficiently to become much more familiar with it.
More sophisticated hearing test - perhaps some physical box to connect or bluetooth to computer and small ability to do some adjustments
Unable to answer
Case studies of what people do when they encounter a problem.
As described above think there could be more tests on a graded basis checking hearing apart from numerical perhaps deciphering words etc. Generally the tests are fun to do but some variation would be more enjoyable and helpful to gaining more benefit from the CI. I also believe that CIRCA would be more useful after say one year of CI before ways are set in its use.
nothing comes to mind
A chat room perhaps. More advice /knowledge about when to raise lower treble bass and how best to mix that in different hearing environments
More self testing and results

Part 5: Sustainability and spread

Dissemination

We set up a Twitter account for the project @CIRemoteCare and have found it a useful way to give short updates on progress. There has been much media interest (see Appendix 1.5).

Our original plan for dissemination involved engaging our key stakeholders: patients and their families, staff and commissioners. Below is our original plan with areas we have achieved highlighted.



Presentations about the project:

1. 12th European Symposium Paediatric Cochlear Implant, Toulouse, 2015 (e-poster)
2. British Cochlear Implant Group Annual Meeting, 2015
3. National Cochlear Implant Users Association annual conference, 2015
4. National Biomedical Research Unit in Hearing, 2015
5. 2nd International Meeting on Internet and Audiology, Denmark, 2015



Appendix 1: Resources and appendices

1.1 We had this leaflet printed and sent it to our adults with cochlear implants, left it in the waiting room, linked to it on our website and twitter. It resulted in over 100 patients wanting to help out: some were happy to come to focus groups, others have spent time at home reviewing resources online for us

Auditory Implant
Service



**The
Health
Foundation**

UNIVERSITY OF
Southampton

GET INVOLVED IN PLANNING RESEARCH ON REMOTE CARE



We would like to involve people using cochlear implants or waiting to receive a cochlear implant in the planning and monitoring of our research. This will involve focus groups and meetings where you will give your perspective as a person using a cochlear implant. You would work as an equal partner with the research team.

Our research project is funded by The Health Foundation and aims to look into offering some remote care to adults using cochlear implants. This may involve being able to test your hearing at home using a mobile app or computer, doing a little of your own tuning and having access to a website to manage all other aspects of your cochlear implant care. We need involvement from people who use our services as your perspective will be different from ours, and you are the experts in what cochlear implant users need.

This position is voluntary but your travel expenses would be paid. You don't need any previous experience, just a willingness to give your perspective. If you would like to be involved but cannot travel, we would love your input by phone, email or post and would share our plans with you in this way.

Please get in touch with any questions or if you are interested to find out more.

Helen Cullington
H.Cullington@Southampton.ac.uk 023 80 597606
University of Southampton Auditory Implant Service
SO17 1BJ

1.2 FAQ document sent to remote care participants

CIRCA – Frequently Asked Questions

Thank you for being in the remote care project.

As you know, this is the first time we have tried doing remote care, so some things are not running completely smoothly! If you find anything that doesn't work well (or works really well!), let me know. I can't change anything in this version (or I will lose all the data), but I can definitely make it better next time.

Here are some questions/issues people have had:

It doesn't work when I click on the link <https://circa.lifeguidewebsites.org>

What can I do?

You could also try the link <https://circa.lifeguidewebsites.org/player/play/circa>

If this doesn't work either, type the address into the address bar. In the picture below, delete www.google.co.uk/ and instead type in circa.lifeguidewebsites.org and press Enter/Return.



Google Search

I'm Feeling Lucky

The hearing test gave me a result with two numbers after the decimal point (eg 2.25), but I can only enter one number after the decimal point in CIRCA.

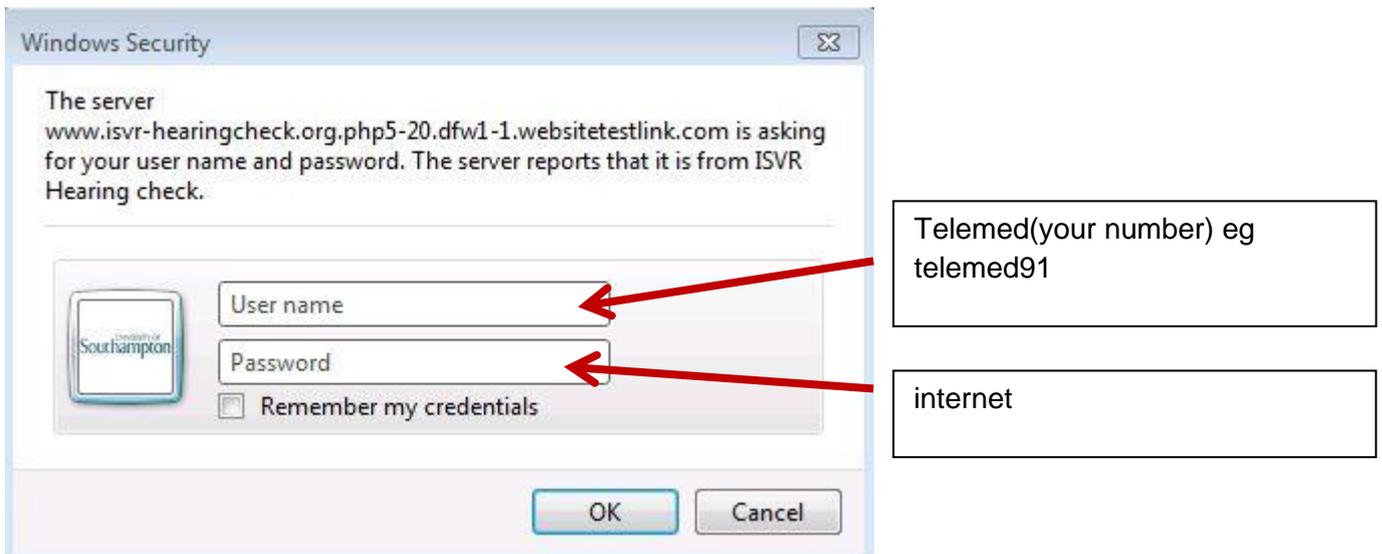
You will need to round the number up or down. If the final number is 5 or more (eg 2.25), round up to 2.3. If the final number is less than 5 (eg 2.24) round down to 2.2.

Which program on the speech processor should I use for the hearing test? Should I use my hearing aid as well?

Use your normal listening program. It is best not to use your hearing aid as well, just test the implant. In future versions, I hope that you will be able to enter notes so you can note down how you did the hearing test eg P4, right ear.

I am so confused with the passwords!

Sorry, it is confusing! The hearing test only uses the password internet; it will never change.



Once you have registered with CIRCA with the password internet, it will ask you to change the password and from then onwards you use whatever password you have changed it to.

I have forgotten my CIRCA password

It is easy to reset.

- 1) Go to login page (click login not register), enter your study ID (eg telemed91)
- 2) Click reset password at bottom of screen

- 3) Enter the e-mail you registered with
- 4) Check your email: you should have a new password
- 5) Click next on CIRCA website, this will take you to the login page,
- 6) Enter your user ID (eg telemed91) and enter the password you received in the e-mail, make sure that there is no space at the end (especially when you use copy, paste)
- 7) When you are logged in, you can click on the change the password link
- 8) Enter the password received in the e-mail as a current one, then enter the new one and re-type the new one

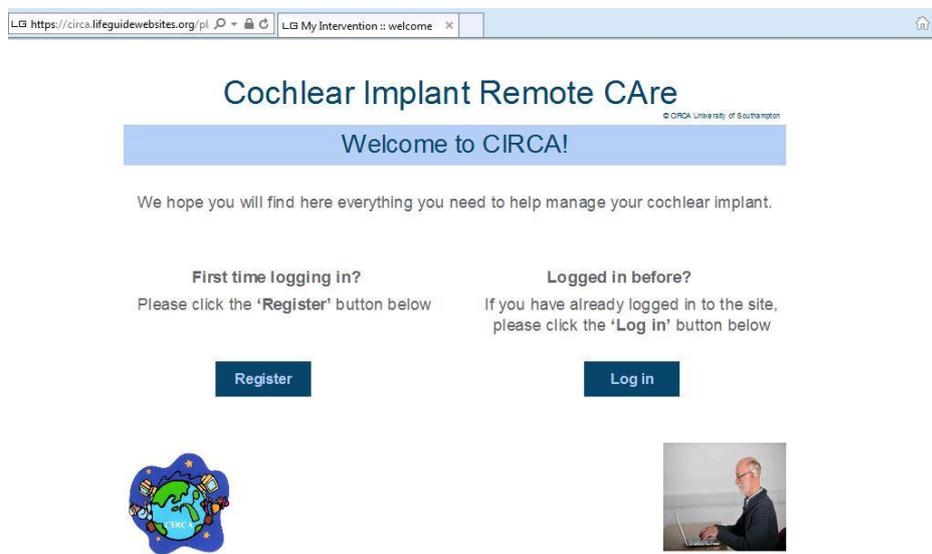
I can't seem to get registered on CIRCA

It can be tricky the first time.

Click on or copy this link into the browser address bar:

<https://circa.lifeguidewebsites.org>

It should get you to this screen:



If you get to a different screen, or the link doesn't work, please email me (circa@soton.ac.uk) and let me know exactly what happened and what browser you were using please (Internet Explorer, Firefox, Google Chrome etc).

I forgot to enter a negative number for my hearing test result

I'm sorry, the text is so small. Please email me and I will try to correct it.

I thought I had registered with CIRCA, but now it is asking me to go through the whole process again

The first time you register, you will need to go through the whole process including the hearing test and questionnaire. Let me know if this happens even though you did that.

Can I use CIRCA on an iPad?

CIRCA is not designed to work on a tablet, but some parts of it may. It is best to register on a computer though. The hearing test link will NOT work on an iPad.

I am confused about my baseline testing. Both BKB sentences in adaptive noise and the Triple Digit Test seem to be a test of listening in noise, and both gave a result in dB, but my Triple Digit Test was much better. Which test is right?

Although both results are the signal to noise ratio where you can understand the speech, the tests are different because BKB uses sentences and TDT just uses numbers. The numbers test is easier because there are a closed set of responses (numbers from 1 to 9), whereas the sentences could be anything. So people always score better on the numbers than the sentences. It doesn't make either a better test, although you could argue that the numbers test is better as it's not relying on brain power and language knowledge so much; it is more a test of just hearing.

1.3 We were concerned that the generic Patient Activation Measure®, PAM®, may not be sensitive enough to show changes in people who use cochlear implant devices. We therefore designed CI-EMP – a disease-specific empowerment scale. This is the long version that the 60 trial participants completed.

Cochlear Implant Empowerment Scale (CI-EMP)

This questionnaire contains lists of statements. The statements are organised into three sections: what you believe about your implant, what you know about your implant, and what you can do with your implant. Please read each statement carefully and tell us how much you think the statement describes your beliefs, knowledge, or abilities.

How to fill in this questionnaire

You will be asked to indicate how much each statement describes your own experience of using your cochlear implant. You will be given five options to choose from. Please tick **one** of the possible options for each statement. If you don't think a particular statement applies to you, please select the 'N/A' option.

Please remember that there are no correct or incorrect answers to these statements. It is important that you tell us how much each statement really reflects what you believe, know, and can do with your cochlear implant.

If you have any questions about how to fill in this questionnaire, please don't hesitate to ask the member of staff who gave it to you.

Participant ID: _____

Date (DD/MMM/YYYY, e.g. 01/JAN/2016): ____ / ____ / ____

Please indicate your age bracket

- 18-29
- 30-39
- 40-49
- 50-59
- 60-69
- 70-79
- 80 or over

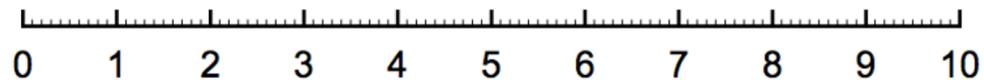
Please indicate what year you received your first or only implant (e.g. 2001)

(If you have had reimplantation surgery, please indicate the year of the original implantation surgery)

Please put a mark on the scale below to tell us how engaged and empowered you feel you are in looking after your own hearing

*Not at all
engaged*

*As engaged
as I can be*



What you believe: Please indicate how well each statement describes your own beliefs.

	Very untrue	Somewhat untrue	Neutral	Somewhat true	Very true	N/A
<i>When it comes to what my implant can do for me, I know best</i>	<input type="checkbox"/>					
<i>How well I hear with my implant is under my control</i>	<input type="checkbox"/>					
<i>Taking an active role in my own cochlear implant care is important for my hearing</i>	<input type="checkbox"/>					
<i>No one else can look after my implant better than I can</i>	<input type="checkbox"/>					
<i>I am the expert about the best care for my hearing</i>	<input type="checkbox"/>					
<i>I believe there are things I can do to help me hear better in noise or when conversations get difficult</i>	<input type="checkbox"/>					
<i>I am in control of my hearing</i>	<input type="checkbox"/>					
<i>I believe that taking care of my implant myself will ensure the best results</i>	<input type="checkbox"/>					
<i>It is important to make decisions about my hearing together with my cochlear implant centre</i>	<input type="checkbox"/>					
<i>I am the best person to check if my implant is working as it should</i>	<input type="checkbox"/>					
<i>It is better if I am able to look after myself if there is a problem with my implant</i>	<input type="checkbox"/>					
<i>I am in charge of using my implant to its full potential</i>	<input type="checkbox"/>					

What you know: Please indicate how well each statement below describes what you know.

	Very untrue	Somewhat untrue	Neutral	Somewhat true	Very true	N/A
<i>I know where to get spare speech processor batteries from</i>	<input type="checkbox"/>					
<i>I know how to order extra items that my cochlear implant centre doesn't supply</i>	<input type="checkbox"/>					
<i>I know about assistive technologies; e.g. Roger Pen, Smart-Link, etc.</i>	<input type="checkbox"/>					
<i>I know the specific model of implant that I have</i>	<input type="checkbox"/>					
<i>I know that there is advice and equipment available to help me hear on the telephone, hear the TV, hear at meetings or in the work place</i>	<input type="checkbox"/>					
<i>I know there are rehabilitation tools, computer programs, and smartphone apps that may help me hear music or deal with difficult listening situations</i>	<input type="checkbox"/>					
<i>I know about schemes to help hearing-impaired people in the work place</i>	<input type="checkbox"/>					
<i>I know why I should keep my head away from metal (e.g. an umbrella handle)</i>	<input type="checkbox"/>					
<i>I know what to do when flying or going through security scanners</i>	<input type="checkbox"/>					
<i>I understand why my cochlear implant magnet should not be too tight</i>	<input type="checkbox"/>					
<i>I know why I need to change my microphone cover and how often to do it</i>	<input type="checkbox"/>					
<i>I know the safety guidelines for my cochlear implant</i>	<input type="checkbox"/>					
<i>I know if there are wireless options available for my speech processor</i>	<input type="checkbox"/>					

What you can do: Please indicate how well each statement below describes what you can do.

	Very untrue	Somewhat untrue	Neutral	Somewhat true	Very true	N/A
<i>I can take the pieces of my speech processor apart and put them back together again</i>	<input type="checkbox"/>					
<i>I can change the volume on my implant</i>	<input type="checkbox"/>					
<i>I know how to change my cable/wire</i>	<input type="checkbox"/>					
<i>I can change parts of my implant when they need replacing</i>	<input type="checkbox"/>					
<i>I am able to resolve any problems with my implant</i>	<input type="checkbox"/>					
<i>I can change the program on my implant</i>	<input type="checkbox"/>					
<i>I can change the settings on my implant</i>	<input type="checkbox"/>					
<i>I am willing and able to ask people to change their positioning to help me hear</i>	<input type="checkbox"/>					
<i>I can use assistive technology (loops, Roger Pen, etc.) with my speech processor</i>	<input type="checkbox"/>					
<i>I am able to pair my remote control if I get a new speech processor or remote</i>	<input type="checkbox"/>					
<i>I know how to use the loop/telecoil system on my speech processor</i>	<input type="checkbox"/>					
<i>I can solve certain problems with my implant on my own</i>	<input type="checkbox"/>					
<i>I can carry out tasks at home to care for my cochlear implant</i>	<input type="checkbox"/>					

What you can do: Please indicate how well each statement below describes what you can do.

	Very untrue	Somewhat untrue	Neutral	Somewhat true	Very true	N/A
<i>I am able to tell others how much I can hear with my implant</i>	<input type="checkbox"/>					
<i>I am comfortable telling people I have a hearing loss</i>	<input type="checkbox"/>					
<i>I am willing to ask people to speak more clearly</i>	<input type="checkbox"/>					
<i>I know where to go and who I should contact to resolve a problem with my implant if I am unable to solve it myself</i>	<input type="checkbox"/>					
<i>I feel confident that I could talk to an audiologist about my implant</i>	<input type="checkbox"/>					
<i>I understand roughly what the audiologist is trying to do when I have tuning at the centre</i>	<input type="checkbox"/>					
<i>I am able to tell when my hearing is worse than it usually is</i>	<input type="checkbox"/>					
<i>I know what to do if things don't sound right</i>	<input type="checkbox"/>					
<i>I know what to do if my batteries don't seem to be lasting long enough</i>	<input type="checkbox"/>					
<i>I carry spare batteries and parts</i>	<input type="checkbox"/>					
<i>I can adjust my implant to try to resolve a problem on my own</i>	<input type="checkbox"/>					
<i>I can contact a cochlear implant user group for additional help and support such as the National Cochlear Implant Users Association</i>	<input type="checkbox"/>					

1.4 Qualifications choices for collecting participant demographic information

Highest Level of Qualification



Subject ID

Date

Please read the following descriptions and tick **one** of the boxes that best describes the **highest** level of qualification you hold.

Level of Qualification	Description	Tick
No qualifications	No academic or professional qualifications	
Level 1 qualifications	1-4 O Levels/CSE/GCSEs (any grades), Entry Level Foundation Diploma, NVQ Level 1, Foundation GNVQ, Basic/Essential Skills	
Level 2 qualifications	5+ O Level (Passes)/CSEs (Grade 1)/GCSEs (Grades A*- C), School Certificate, 1 A Level/2-3 AS levels/VCEs, Intermediate/Higher Diploma, Welsh Baccalaureate Intermediate Diploma, NVQ Level 2, Intermediate GNVQ, City and Guilds Craft, BTEC First/General Diploma, RSA Diploma	
Apprenticeship		
Level 3 qualifications	2+ A Levels/VCEs, 4+ AS Levels, Higher School Certificate, Progression/Advanced Diploma, Welsh Baccalaureate Advanced Diploma, NVQ Level 3; Advanced GNVQ, City and Guilds Advanced Craft, ONC, OND, BTEC National, RSA Advanced Diploma	
Level 4+ qualifications	Degree (for example BA, BSc), Higher Degree (for example MA, PhD, PGCE), NVQ Level 4-5, HNC, HND, RSA Higher Diploma, BTEC Higher level, Foundation degree (NI)	
Professional qualifications	For example teaching, nursing, accountancy	
Other qualifications	Vocational/Work-related Qualifications, Foreign Qualifications (Not stated/level unknown)	

1.5 Media. We have worked closely with University of Southampton media office to promote the project. Typing 'cochlear implant remote care' into Google results in the first 7 results being about our project. Here are some examples:

<http://www.southampton.ac.uk/news/2016/01/cochlear-implant-remote-care-study.page>

🏠 > News and events > Latest news

Remote care for cochlear implant users

Published: 22 January 2016



Dr Helen Cullington

Audiologists from the University of Southampton are investigating how a new patient-centred approach can help cochlear implant users manage their own care programme.

A cochlear implant is a surgically implanted electronic device that can improve a person's ability to hear and understand speech if they can't benefit from a hearing aid. There are more than 13,000 people using cochlear implants in the UK.

Currently, cochlear implant users have to visit their implant clinic annually for the rest of their lives to monitor hearing and check their implant device. However, some patients are looking to manage their own care needs or they may not be able to attend clinic sessions due to work, family commitments or travel considerations.

This month, a new study from the University of Southampton [Auditory Implant Service](#) will see 60 patients take part in a clinical trial using an online care package to determine whether the routine annual check can be replaced with a personalised online version, better suited to the user's needs. The study is being funded by the Health Foundation.

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Science News

from research organizations

Remote care for cochlear implant users

Date: January 22, 2016
Source: University of Southampton
Summary: Audiologists are investigating how a new patient-centered approach can help cochlear implant users manage their own care program. A cochlear implant is a surgically implanted electronic device that can improve a person's ability to hear and understand speech if they can't benefit from a hearing aid.

Share: Total shares: 64

Get 10% off

FULL STORY

Audiologists from the University of Southampton are investigating how a new patient-centered approach can help cochlear implant users manage their own care program.

A cochlear implant is a surgically implanted electronic device that can improve a person's ability to hear and understand speech if they can't benefit from a hearing aid. There are more than 13,000 people using cochlear implants in the UK.

Currently, cochlear implant users have to visit their implant

Audiology Worldnews

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New study: remote care for people with cochlear implants

Published on Monday, 01 February 2016 08:23

ASSISTANCE

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A team of audiologists from the University of Southampton (UK) are examining how cochlear implant users could manage their own care program through a remote system.

News Medical for Life Sciences and Medicine reports on the 6-month randomized study that will include two groups: one following a standard clinical program and

<https://www.youtube.com/watch?v=kWJU-nROF3I>



New Cochlear Implant Clinical Trial At University Of Southampton

that's solent

That's Solent TV

Subscribe 212

75 views

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1 0

Published on 3 Feb 2016

A new clinical trial is taking place at the University of Southampton to help people with deafness or severe hearing loss. It focusses on patients who have received cochlear implants - small devices that can give deaf people back their hearing. The aim is to help people with the devices

1.6 Peer-reviewed publications

Our protocol paper was published (open access) in *BMJ Open*

<http://bmjopen.bmj.com/content/6/5/e011342.full>

Downloaded from <http://bmjopen.bmj.com/> on August 8, 2016 - Published by group.bmj.com

Open Access

Protocol

BMJ Open Personalised long-term follow-up of cochlear implant patients using remote care, compared with those on the standard care pathway: study protocol for a feasibility randomised controlled trial

Helen Cullington,¹ Padraig Kitterick,² Lisa DeBold,³ Mark Weal,⁴ Nicholas Clarke,⁵ Eva Newberry,⁶ Lisa Aubert³

To cite: Cullington H, Kitterick P, DeBold L, *et al*. Personalised long-term follow-up of cochlear implant patients using remote care, compared with those on the standard care pathway: study protocol for a feasibility randomised controlled trial. *BMJ Open* 2016;6:e011342. doi:10.1136/bmjopen-2016-011342

► Prepublication history for this paper is available online. To view these files please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2016-011342>).

Received 29 January 2016

ABSTRACT

Introduction: Many resources are required to provide postoperative care to patients who receive a cochlear implant. The implant service commits to lifetime follow-up. The patient commits to regular adjustment and rehabilitation appointments in the first year and annual follow-up appointments thereafter. Offering remote follow-up may result in more stable hearing, reduced patient travel expense, time and disruption, more empowered patients, greater equality in service delivery and more freedom to optimise the allocation of clinic resources.

Methods and analysis: This will be a two-arm feasibility randomised controlled trial (RCT) involving 60 adults using cochlear implants with at least 6 months device experience in a 6-month clinical trial of remote care. This project will design, implement and evaluate a person-centred long-term follow-up pathway for people using cochlear implants offering a triple approach of remote and self-monitoring, self-adjustment of device and a personalised online support tool for home access.

Strengths and limitations of this study

- This will be the first randomised controlled trial (RCT) of a triple approach to remote care for people using cochlear implants.
- No formal power calculations were performed as this is the first study of its kind and acts as a feasibility RCT.
- The generic Patient Activation Measure (PAM) may not be sensitive enough to show change in people with cochlear implants: a condition-specific empowerment measure may be required.
- People using cochlear implants who volunteer to take part may not be representative of the population of people with implants.

INTRODUCTION

Cochlear implants are the most successful of

The protocol has been accepted for publication in the American Journal of Audiology

Cullington, Helen, Kitterick, Padraig, DeBold, Lisa, Weal, Mark, Clarke, Nicholas, Newberry, Eva and Aubert, Lisa (2016) Have cochlear implant; won't have to travel. Introducing telemedicine to people using cochlear implants. *American Journal of Audiology*.

ISRCTNregistry

We registered this project as a clinical trial with the ISRCTN registry

<http://www.isrctn.com/ISRCTN14644286>