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# Personalised long-term follow-up of cochlear implant patients using remote care, compared to those on the standard care pathway: study protocol for a feasibility randomised control trial.

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## ABSTRACT

### Introduction

Many resources are required to provide post-operative 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 Control Trial (RCT) involving 60 adult cochlear implant users 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 cochlear implant users offering a triple approach of remote and self-monitoring, self-adjustment of device and a personalised online support tool for home speech recognition testing, information, self-rehabilitation, advice, equipment training and troubleshooting.

The main outcome measure is patient activation. Secondary outcomes are stability and quality of hearing, stability of quality of life, clinic resources, patient and clinician experience, and any adverse events associated with remote care. We will examine the acceptability of remote care to service users and clinicians, the willingness of participants to be randomised, and attrition rates. We will estimate numbers required to plan a fully powered RCT.

### Ethics and dissemination

Ethical approval was received from North West – Greater Manchester South Research Ethics Committee (15/NW/0860) and University of Southampton Research Governance Office (ERGO 15329).
Results will be disseminated in the clinical and scientific communities and also to the patient population via peer-reviewed research publications both online and in print, conference and meeting presentations, posters, newsletter articles, website reports, and social media.
Trial registration number ISRCTN 14644286

**Strengths and limitations of this study**

- This will be the first RCT of a triple approach to remote care for cochlear implant users
- No formal power calculations were done as this is the first study of its kind and acts as a feasibility RCT
- The generic Patient Activation Measure® may not be sensitive enough to show change in cochlear implant users: a disease-specific empowerment measure may be required
- Cochlear implant users who volunteer to take part may not be representative of the population of users of cochlear implants

## INTRODUCTION

Cochlear implants are the most successful of all neural prostheses [1]; they can provide hearing to people with severe to profound deafness. Approximately 1,200 people receive a cochlear implant in the United Kingdom (UK) each year [2]. The total number of implant users is around 13,000 in the UK [2] and 500,000 worldwide [estimated from 3]. Numbers are likely to increase rapidly: fewer than 5% of eligible people in the UK have received an implant [estimated from 4 5], and the number of pensioners is projected to increase by 28% by 2035 [6]. Cochlear implant care in the UK is provided at one of 19 tertiary centres involving assessment, surgery, and a resource-intensive acute phase of device adjustment and rehabilitation. These centres may be several hours away from the patient's home necessitating travel expense, time off work and family disruption. Currently UK implant centres review patients on a clinic-led schedule; this means that review appointments can occur that provide little benefit to the patient. Conversely when some patients attend a routine appointment, there is hearing deterioration which the patient had not noticed. This is often remedied by replacing equipment that the patient could have done at home. Making this care pathway patient-centred instead may provide a more efficient and effective service and allow more timely identification of issues.

When a patient attends a long-term follow-up appointment, the following tasks may be done: speech recognition testing, device adjustment, rehabilitation, equipment check and troubleshooting, and provision of replacement or upgraded equipment. We propose that at least some of these tasks could be done by the patient themselves at home, and that cochlear implant users should only attend clinic when there is clinical need (no more routine appointments). Potential benefits for the patient are:

- more stable hearing (problems identified and resolved quicker)
- better hearing (ability to fine tune when away from clinic)
- convenience of not travelling to routine appointments
- reduction of travel cost and time, time off work and disruption to family life
- increased confidence to manage own hearing
- greater equality in service delivery (same level of service regardless of distance from clinic)

It may also mean that the clinic has greater resources (time, money, space) to see complex cases and the expanding population of new patients. Cochlear implant users and their families would generally like to take a more active role in their care and welcome telemedicine [7 8]. The NHS has a strong commitment to supporting self-care for people with long-term conditions [9] with 'the vision of a citizen-centred, digitally-enabled, health and social care system'[10]. Evidence shows a significant improvement in

outcomes when patients use self-management tools [11] and those who are activated and involved in their care tend to have better health outcomes [12 13].

**Speech recognition testing**

The speech reognition measure used in UK clinics is Bamford-Kowal-Bench (BKB) sentences [14]; these are usually performed in a sound-treated room in the clinic by experienced clinicians, although there are some reports of testing remotely using an assistant at a remote location and video conferencing facilities [15 16]. Speech perception in noise testing using digits has been developed [17]; digits are highly familiar stimuli and are usually known by people with even basic language skills. Digit testing requires a closed set response and thus is suitable for self-testing over the telephone or internet [18 19] and has a minimal learning effect [20]. The test correlates well with speech recognition in noise with sentences in cochlear implant users [21-24]. A digit test in English is freely available online at the Action on Hearing Loss website [25] and also as an application for mobile devices (Action on Hearing Loss Hearing Check).

**Device adjustment**

In order to provide benefit to a hearing-impaired person, the levels of electrical stimulation need to be individually adjusted for both soft and loud sounds on up to 22 electrode contacts in the cochlea. The levels can change as the cochlear implant user becomes more used to listening, more experienced at doing the task and as physiological changes occur. Most cochlear implant centres offer frequent appointments in the first few months following implantation and annual adjustment appointments thereafter [26]. Device adjustment usually occurs in the clinic in a sound-treated room, led by an experienced clinician. Several centres are now offering remote device programming [16 27-34]. However these reports continue to use a clinician-centred model involving the patient attending a centre closer to their home where an assistant is present, and the cochlear implant centre clinician leading the session using video conferencing and remote desktop connection.

Cochlear implant users have commented that they would like to be able to adjust their device parameters in their own home or work environment, rather than just in the sound-treated clinic room [7]. The company Cochlear® have introduced a self-fitting paradigm (Remote Assistant Fitting) using the speech processor remote control that patients already have. This allows adjustment of programming to be done by the patient at any time and anywhere with equivalent hearing outcomes to audiologist-led sessions [35].

**Rehabilitation**

Many clinical resources are devoted to rehabilitation after people receive a cochlear implant; the new sound can be difficult to get used to. Rehabilitation appointments are frequent in the first year and may be offered annually thereafter.

**Equipment troubleshooting/repairs/spares provision/upgrades**

Cochlear implant speech processors are complex; some parts need regular replacement in order to keep the device in optimum condition. No reminder is given on the device. Many NHS cochlear implant centres offer an upgraded speech processor around every 5 years, requiring a clinic visit.

This paper describes the protocol for a feasibility project to design, introduce and evaluate a patient-centred remote care approach for long-term adult cochlear implant users. This is necessary preparatory work for a fully powered RCT that will be extended across the UK. It is a prospective randomised control trial whereby 60 patients are randomised to either a control group (usual clinical care) or a remote care group where they are given access to new remote care tools. The patients in the remote care group will monitor their hearing at home, and some can fine-tune their hearing to suit their own real-world environment. Their other needs will be met through a personalised online support tool. Empowering the patient to self-care at home could enable better and more stable hearing and a more convenient and accessible service.

## METHODS AND ANALYSIS

### Trial design

This will be a two-arm feasibility RCT involving 60 adult cochlear implant users with at least 6 months device experience in a 6 month clinical trial of remote care (see Figure 1 flow chart). This feasibility trial will inform a later fully powered RCT.

### Setting and participants

The trial will be conducted at the University of Southampton Auditory Implant Service (USAIS): a tertiary treatment centre mostly funded by NHS referrals. The study sponsor is the University of Southampton. The funder (The Health Foundation) and sponsor have not contributed towards the study protocol. Some anonymised data will be analysed at University of Nottingham. Cochlear implant users will not necessarily be USAIS patients.

### Proposed sample size

No formal power calculations were done as this is a feasibility trial to plan a later RCT. The literature suggests sample sizes around 30 to 50 for a feasibility trial [36 37]. Sixty participants was selected (30 in each group) in order to gather a range of different service users' experiences of the remote care tools and to estimate the effect size on the primary outcome measure.

### Recruitment

Potential participants will be sent a covering letter and the Participant Information Sheet several weeks before consenting. The clinical trial will begin in January 2016. There has been much interest in the project among UK cochlear implant users, so adequate enrollment to reach target size is not of concern.

The Principal Investigator (PI) (Cullington) will access the USAIS clinical database and contact patients who fulfil the inclusion criteria, excepting those who have indicated that they do not wish to receive research invitations. Information will also be placed in the USAIS waiting room.

An advertisement will be placed on the USAIS website (www.AIS.southampton.ac.uk) from the date of ethical approval to the end of recruitment. A link will be tweeted from @UoS_AIS and @CIRemoteCare once a week from study ethical approval to end of recruitment. Details of the study will be placed on the National Cochlear Implant Users' Association website.

Patients from other centres may respond to the advertisement; we will obtain participants' permission to notify individual teams if their patients are involved.

**Inclusion criteria**

- Cochlear implant user (any device, unilateral or bilateral) for at least 6 months
- Living in the UK
- Aged 18 years or more
- Able to give informed consent
- Sufficient English to understand study documentation and participate in testing
- Access to a computer or device with internet access

**Exclusion criteria**

- Those that do not fulfil the inclusion criteria plus any medical condition or known disability that would limit their capacity to use the online support tool

**Randomisation**

Participants who consent to the study will enter the randomisation, which will be done by the PI using a computer program at the baseline visit. A minimisation approach to randomisation will attempt to balance the groups on the following factors:

- CI user less than a year or more than a year
- Gender
- Distance from clinic (local or non-local i.e. within 20 miles or more than 20 miles away)
- Device (Cochlear or not)
- Ability to use Cochlear Remote Assistant Fitting (or not)

**Blinding**

It will not be possible to blind participants to which group they are in. Baseline measures will be completed before allocation. Efforts will be made to blind clinicians to which group the participant belongs to when they perform exit measures. Where possible, blinded measures will be passed to University of Nottingham for analysis.

**Interventions**

*Control group: standard clinical care pathway*

Participants in the control group will continue with their usual care pathway; they will not have access to remote care. They will be asked to attend twice for this project: baseline and exit measures.

*Intervention group: remote care*

Those randomised into the treatment group (remote care group) will receive cochlear implant care remotely for 6 months. Clinic appointments will be given if required, and participants must still adhere to any medical check-ups with the cochlear implant surgeon. Participants may access the tools as often as they wish (minimum twice required for project) and can use them wherever they wish (at home, at a friend's house, at the library etc.). Remote care will comprise:

1 Remote and self-monitoring

Remote care trial participants will access a password-protected online speech recognition test based on the Triple Digit Test (TDT). The site is provided and maintained by Action on Hearing Loss. Participants will listen to sets of three digits in background noise and type in the numbers they hear. Participants will be required to do self testing at least in months 1 and 6, but can do it at any time.

2 Self-adjustment of device (Remote Assistant Fitting)

Only those cochlear implant users with newer Cochlear devices (CI500 series, CI422 or CI24RE devices using CP800 or CP900 series processors) will be able to participate in the self-adjustment of device; the other manufacturers do not have these tools yet. Participants will use Remote Assistant Fitting to adjust their device programming at any time anywhere. Patients will be required to do self-adjustment at least in months 1 and 6, but can do it at any time.

Those patients in the trial who are eligible for a processor upgrade will receive the upgrade at home rather than coming into the clinic. This will apply to users of all devices.

3 Online support tool

The research team will design a new online support tool for adult cochlear implant users using LifeGuide [38]. LifeGuide is an open source software platform that allows the development and trialling of interactive web-based interventions. This will be an iterative process incorporating feedback from service users at all stages, including focus groups of adult cochlear implant users. The online support tool

(Cochlear Implant Remote Care, CIRCA) will incorporate personalised equipment help and information, troubleshooting, rehabilitation, goal-setting, help with music and telephone use and a method of ordering replacement equipment in an easy format to people who may not be used to the Internet. It will also store the TDT speech recognition test result and provide a comparison with the baseline test and appropriate feedback. Participants will be given a unique log in to this support tool; they can access it at any time. They will have the option to include a mobile phone number if they wish to receive reminder text messages.

The participant will enter the following:

- name they would like to be called
- email address
- main speech processor
- month and year of implant surgery
- date microphone cover and rechargeable batteries were changed (if appropriate)
- year of birth (optional)
- first part of postcode (optional)
- born deaf or lost hearing (optional)
- mobile phone number (optional)

**Outcome measures**

*Baseline measures*

All participants will undergo the following baseline measures after signing the consent form:

- speech recognition testing (BKB sentences in quiet and noise and Triple Digit Test, TDT).
- Patient Activation Measure® (PAM®) [39 40]
- the Speech, Spatial and Qualities of Hearing questionnaire (SSQ) [41]
- quality of life questionnaire: Health Utilities Index (HUI) mark 3 [42]

Those in the remote care arm of the project will also receive training for the remote care tools, and will have their remote control self-mapping features activated (if eligible).

The following information will be collected on both the control group and remote care group during the clinical trial:

- Number of nature of clinic contacts and visits (including non-attendance)
- Repair logs
- Age
- Gender
- Postcode (to calculate distance to clinic) – Postcode data will be used once only in order to calculate the distance to clinic and will then be destroyed
- Cochlear implant device and speech processor
- Highest formal educational qualifications
- Which cochlear implant centre takes care of the participant

All staff will be reminded to document all contact with patients as usual. Additionally in the remote care group, logs of their interaction with the remote care tools will be stored to assess adherence and utility.

*Exit measures (summer 2016)*

All participants will undergo the following exit measures:

- speech recognition testing (BKB sentences in quiet and noise and TDT)
- PAM®)
- SSQ questionnaire
- HUI3

Travel expenses will be paid for both baseline and exit measure visits. The day of the exit measures will be considered to be the day the participants exit from the trial.

Participants in the remote care group will be asked to attend a focus group on the day of their exit measures. Focus groups will be audio recorded and transcribed. A small number of participants in the remote care group will be asked if they would be willing to be videoed talking about remote care. These videos will be stored securely on a University of Southampton password-protected network using just the participant's ID. They will be used in presentations to report and promote the research.

*Primary outcome measure*

- Change (from day of entry into study to 6 months after remote care introduced) in patient activation measured using the PAM®

*Secondary outcome measures*

- 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 TDT, the SSQ questionnaire in both the control and treatment arms
- 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 measured using the HUI3 in both the control and treatment arms
- Patient preference in treatment arm reported qualitatively from feedback in online support tool and focus groups
- Clinician preference measured qualitatively from three interviews with up to 10 members of clinical staff

*Feasibility outcomes*

- Recruitment
- Attrition and bias
- Adherence
- Acceptability of randomization to service users

**Hypotheses**

*Primary*

- 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 PAM®.

*Secondary*

- There will be no more deterioration in hearing in the remote care group compared to the control group, measured using speech recognition (BKB, TDT) and the SSQ questionnaire.
- There will be no more deterioration in quality of life in the remote care group compared to the control group, measured using the HUI3.
- Service users (patients) will feel positive about remote care, measured qualitatively from feedback in online support tool and in focus groups.

- Clinicians will feel positive about remote care, measured qualitatively from three interviews with up to 10 members of clinical staff.

**Staff change management assessment**

Moving to remote care represents a significant change to cochlear implant centre staff; feedback will be obtained throughout from clinicians using a SharePoint feedback site, discussions at centre meetings, the project steering group, and informal discussions. A formal change evaluation will also occur. Interviews will be conducted with 10 members of the multidisciplinary team at 3 month intervals over a period of six months, (i.e. 0,3,6 months). This will enable us to better capture the on-going and iterative relationships between perceptions and learning and how these change in response to leadership, social context and decision-making processes over time [43]. Interviews will be carried out in the work place or over the phone in accordance with the guidelines and codes of conduct recommended by both the British and American Psychological Societies [44 45]. Repeated interviews with the same individuals will provide insights into how the nature and content of challenges of telehealth implementation and acceptance are changing and evolving as part of a dynamic process. Examining and understanding staff responses to the change will optimise the chance of the change being sustainable.

The following information will be collected from staff:

- Age (in 10 year age bands)
- Gender
- Role in team
- Number of years working in cochlear implant centre

*Staff recruitment*

Ten staff members who work with adult cochlear implant users at USAIS will be recruited. An email will be sent to all eligible staff enclosing the Staff Participant Information Sheet. This information will also be placed on the staff SharePoint site. Any staff member working at USAIS in a clinical role with adult cochlear implant users will be eligible to take part, including staff who support patient equipment needs.

**Data handling**

Data will be managed according to the University of Southampton Research Data Management Policy (RDMP). An individual study Data Management Plan is stored on the University network. Stored data

will be coded and anonymised, will not include name or address information and will be stored securely: all electronic data will be password protected. Hard copy data will be stored in a locked filing cabinet in a secure office. The University provides secure storage for all active research data (http://library.soton.ac.uk/researchdata/unistorage) The data are regularly backed up and a copy of the back up is regularly off-sited to a secure location for disaster recovery purposes. Research data will be kept for at least 10 years in line with University of Southampton policy.

Metadata records for the data (and published outputs) will also be maintained on the the University of Southampton Institutional Research Repository (ePrints). Each deposit can be assigned a unique Digital Object Identifier (DOI) via the DataCite scheme, allowing it to be cited in publications. No personal data or identifiable data will be included in the data stored in the repository. This will be in accordance with the university's data security policy (http://www.calendar.soton.ac.uk/sectionIV/dppolicy.pdf) and the requirements of the Data Protection Act (1998).

The terms of the PAM® license specify that up to 250 participants can be tested until August 2016. Non-personally identifiable individual data must be shared with Insignia. The data shared shall include individual level data records containing answers to each of the PAM ®questions, and if captured i) demographic variables, health status and condition variables ii) specific outcome variables including health behaviours, self-management behaviours and whether patients using PAM® improved the self-management aspects of their health care and iii) the PAM® materials' effect on or relationship to patient health care utilisation and costs. Such data shall be reported to Insignia in an electronic format around September 2016.

A data monitoring committee is not required due to the short period of follow-up and minimal project risks.

**Trial organisation and monitoring**

The trial is led by the PI (Cullington). Monthly research team meetings will be held. We have formed a Steering Group, with the remit of reflecting on the process and governance of the project including adverse events monitoring. The Steering Group comprises three USAIS clinicians, the USAIS Director, the PI, a consultant on change management (NC) and two service users (patients). It will meet at least three times.

**Data analysis plan**

To comply with recommendations, analysis will be mainly descriptive [46]. Scores on the patient activation measures (primary outcome), quality of life and hearing results will be compared between the two groups (control and remote care group), although statistical analysis of any differences will be interpreted with caution as no formal power calculation was in place, and will primarily be used to estimate effect sizes. Analysis will focus on whether the generic PAM® is sensitive enough to show change, or whether a disease-specific empowerment measure needs to be developed. Clinician and participant feedback, use of clinic resources (number and type of appointments) and feasibility outcomes will be reported and analysed qualitatively. IBM SPSS Statistics 21 will be used.

**Public and patient involvement**

The research team has a strong commitment to PPI; a member of the research team is a service user. Two additional service users are on the project Steering Group. Local and national publicity (website, twitter, presentation to National Cochlear Implant Users' Association, newsletter articles, letters, emails, Yahoo group) have already invited help in designing the research.

## ETHICS AND DISSEMINATION

Ethical approval was received from North West – Greater Manchester South Research Ethics Committee (15/NW/0860) and University of Southampton Research Governance Office (ERGO 15329).

### Ethics

Participation is entirely voluntary and it has been stressed to patients that if they do not participate, this will not affect their usual clinical care in any way. Written informed consent will be taken from all participants by the PI who has regular GCP (Good Clinical Practice) training. Participants are free to withdraw at any point without giving a reason. A risk analysis has been approved by University of Southampton.

The PI will inform paticipants during the trial if any new information comes to light which may affect their willingness to participate.

### Confidentiality

Linked anonymity will be used. Participants will be assigned a unique identifier on enrollment. All results will be stored using only this ID. The lookup table will be stored on a password-protected University of Southampton network in a password-protected file separate from the study results, and will be accessible only to the research team.

Adults with cochlear implants are still rare in the general population (approximately 0.01% of the UK population). BMJ reporting guidelines will be followed: we will not report three or more indirect identifiers (for example place of treatment, sex, rare disease or treatment, age) for any individuals[47].

### Dissemination

Research results will be presented locally, nationally and internationally. Dissemination will include but not be limited to peer-reviewed research publications both online and in print, conference and meeting presentations, posters, newsletter articles, website reports, and social media. In order to inform cochlear implant users of the results, information will be sent to the National Cochlear Implant Users' Association and other patient groups, and the USAIS patient newsletter. Participants will be offered the opportunity to receive a summary of the findings.

## CONCLUSION

This will be the first RCT of a triple approach to remote care for cochlear implant users. The study results will inform further work on a larger scale roll out of cochlear implant remote care in the UK.

## TRIAL STATUS

At the time of writing (January 2016), 58 participants have been enrolled.

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## REFERENCES


1. Wilson BS, Dorman MF. Cochlear implants: current designs and future possibilities. J Rehabil Res Dev 2008;**45**(5):695-730
2. BCIG. Annual update 2014-2015. Secondary Annual update 2014-2015 2015.
3. NIDCD. http://www.nidcd.nih.gov/health/hearing/pages/coch.aspx. Secondary http://www.nidcd.nih.gov/health/hearing/pages/coch.aspx 2014.
4. Action on Hearing Loss. Facts and figures on hearing loss and tinnitus. In: Action on Hearing Loss, ed., 2011.
5. Ear Foundation. Cochlear implants. In: Ear Foundation information leaflet, ed., 2015.
6. Office for National Statistics. National population projections, 2010-based statistical bulletin, 2011.
7. Cullington HE. What do our service users really want? [poster]. British Cochlear Implant Group Annual Conference. Ayrshire, 2013.
8. Tsay IA. Using a patient-driven software tool for programming multiple cochlear implant patients simultaneously in a telemedicine setting. ProQuest Information & Learning, 2013.
9. NHS. Five year forward view. In: NHS, ed., 2014.
10. National Information Board. Personalised Health and Care 2020

WORK STREAM 1.1 ROADMAP Enable me to make the right health and care choices Providing patients and the public with digital access to health and care information and transactions, 2015.

11. Panagioti M, Richardson G, Small N, et al. Self-management support interventions to reduce health care utilisation without compromising outcomes: a systematic review and meta-analysis. BMC health services research 2014;**14**:356 doi: 10.1186/1472-6963-14-356[published Online First: Epub Date]|.
12. Hibbard JH, Greene J, Shi Y, et al. Taking the long view: how well do patient activation scores predict outcomes four years later? Medical care research and review : MCRR 2015;**72**(3):324-37 doi: 10.1177/1077558715573871[published Online First: Epub Date]|.
13. Mosen DM, Schmittdiel J, Hibbard J, et al. Is patient activation associated with outcomes of care for adults with chronic conditions? The Journal of ambulatory care management 2007;**30**(1):21-9
14. Bench J, Kowal A, Bamford J. The BKB (Bamford-Kowal-Bench) sentence lists for partially-hearing children. Br J Audiol 1979;**13**(3):108-12
15. Goehring JL, Hughes ML, Baudhuin JL, et al. The effect of technology and testing environment on speech perception using telehealth with cochlear implant recipients. J Speech Lang Hear Res 2012;**55**(5):1373-86 doi: 10.1044/1092-4388(2012/11-0358)[published Online First: Epub Date]|.
16. Hughes ML, Goehring JL, Baudhuin JL, et al. Use of telehealth for research and clinical measures in cochlear implant recipients: a validation study. J Speech Lang Hear Res 2012;**55**(4):1112-27 doi: 10.1044/1092-4388(2011/11-0237)[published Online First: Epub Date]|.
17. Smits C, Kapteyn TS, Houtgast T. Development and validation of an automatic speech-in-noise screening test by telephone. International Journal of Audiology 2004;**43**:15-28
18. Smits C, Houtgast T. Results from the Dutch speech-in-noise screening test by telephone. Ear Hear 2005;**26**(1):89-95
19. Smits C, Merkus P, Houtgast T. How we do it: The Dutch functional hearing-screening tests by telephone and internet. Clinical otolaryngology : official journal of ENT-UK ; official journal of Netherlands Society for Oto-Rhino-Laryngology & Cervico-Facial Surgery 2006;**31**(5):436-40 doi: 10.1111/j.1749-4486.2006.01195.x[published Online First: Epub Date]|.
20. Smits C, Theo Goverts S, Festen JM. The digits-in-noise test: assessing auditory speech recognition abilities in noise. J Acoust Soc Am 2013;**133**(3):1693-706 doi: 10.1121/1.4789933[published Online First: Epub Date]|.
21. Mahafzah M. The Triple Digit Test: a self-test of speech perception in cochlear implant users. University of Southampton, 2013.
22. Aidi T. The Triple Digit Test: A validity and feasibility study. University of Southampton, 2015.
23. Kaandorp MW, Smits C, Merkus P, et al. Assessing speech recognition abilities with digits in noise in cochlear implant and hearing aid users. Int J Audiol 2015;**54**(1):48-57 doi: 10.3109/14992027.2014.945623[published Online First: Epub Date]|.
24. Agyemang-Prempeh A. Telemedicine in cochlear implants: a new way of conducting long term patient follow-up. University of Southampton, 2012.

25. Action on Hearing Loss. Check your hearing. Secondary Check your hearing 2015. http://www.actiononhearingloss.org.uk/your-hearing/look-after-your-hearing/check-your-hearing/take-the-check.aspx.
26. Vaerenberg B, Smits C, De Ceulaer G, et al. Cochlear Implant Programming: A Global Survey on the State of the Art. The Scientific World Journal 2014;**2014**:1-12
27. Eikelboom RH, Jayakody DM, Swanepoel DW, et al. Validation of remote mapping of cochlear implants. Journal of telemedicine and telecare 2014;**20**(4):171-77 doi: 10.1177/1357633x14529234[published Online First: Epub Date]|.
28. Kuzovkov V, Yanov Y, Levin S, et al. Remote programming of MED-EL cochlear implants: users' and professionals' evaluation of the remote programming experience. Acta Otolaryngol 2014;**134**(7):709-16 doi: 10.3109/00016489.2014.892212[published Online First: Epub Date]|.
29. McElveen JT, Jr., Blackburn EL, Green JD, Jr., et al. Remote Programming of Cochlear Implants: A Telecommunications Model. Otol Neurotol 2010;**31**(7):1035-40 doi: 10.1097/MAO.0b013e3181d35d87 [doi][published Online First: Epub Date]|.
30. Ramos A, Rodriguez C, Martinez-Beneyto P, et al. Use of telemedicine in the remote programming of cochlear implants. Acta Otolaryngol 2009;**129**(5):533-40 doi: 795233871 [pii]
10.1080/00016480802294369 [doi][published Online First: Epub Date]|.
31. Rodriguez C, Ramos A, Falcon JC, et al. Use of telemedicine in the remote programming of cochlear implants. Cochlear Implants Int 2010;**11 Suppl 1**:461-4 doi: 10.1179/146701010x12671177204624[published Online First: Epub Date]|.
32. Wesarg T, Wasowski A, Skarzynski H, et al. Remote fitting in Nucleus cochlear implant recipients. Acta Otolaryngol 2010;**130**(12):1379-88 doi: 10.3109/00016489.2010.492480[published Online First: Epub Date]|.
33. Wasowski A, Skarzynski PH, Lorens A, et al. Remote fitting of cochlear implant system. Cochlear Implants Int 2010;**11 Suppl 1**:489-92 doi: 10.1179/146701010x12671177318105[published Online First: Epub Date]|.
34. Samuel PA, Goffi-Gomez MV, Bittencourt AG, et al. Remote programming of cochlear implants. CoDAS 2014;**26**(6):481-6 doi: 10.1590/2317-1782/20142014007[published Online First: Epub Date]|.
35. Botros A, Banna R, Maruthurkkara S. The next generation of Nucleus((R)) fitting: a multiplatform approach towards universal cochlear implant management. Int J Audiol 2013;**52**(7):485-94 doi: 10.3109/14992027.2013.781277[published Online First: Epub Date]|.
36. Sim J, Lewis M. The size of a pilot study for a clinical trial should be calculated in relation to considerations of precision and efficiency. Journal of clinical epidemiology 2012;**65**(3):301-8 doi: 10.1016/j.jclinepi.2011.07.011[published Online First: Epub Date]|.
37. Browne RH. On the use of a pilot sample for sample size determination. Statistics in medicine 1995;**14**(17):1933-40
38. Introduction to the LifeGuide: software facilitating the development of interactive behaviour change internet interventions. The Society for the Study of Artificial Intelligence and Simulation of Behaviour; 2009; Edinburgh.
39. Hibbard JH, Mahoney ER, Stockard J, et al. Development and testing of a short form of the patient activation measure. Health services research 2005;**40**(6 Pt 1):1918-30 doi: 10.1111/j.1475-6773.2005.00438.x[published Online First: Epub Date]|.
40. Hibbard JH, Stockard J, Mahoney ER, et al. Development of the Patient Activation Measure (PAM): conceptualizing and measuring activation in patients and consumers. Health services research 2004;**39**(4 Pt 1):1005-26 doi: 10.1111/j.1475-6773.2004.00269.x[published Online First: Epub Date]|.
41. Gatehouse S, Noble W. The Speech, Spatial and Qualities of Hearing Scale (SSQ). Int J Audiol 2004;**43**(2):85-99
42. Feeny D, Furlong W, Boyle M, et al. Multi-attribute health status classification systems. Health Utilities Index. PharmacoEconomics 1995;**7**(6):490-502
43. Pettigrew AM. Context and action in the transformation of the firm. J Manage Stud 1987; **24**(6):649-70
44. American Pyschological Association. Ethical principles of Psychologists and code of conduct. , 2002.
45. British Psychological Society. Code of Ethics and Governance. 2009
46. Lancaster GA, Dodd S, Williamson PR. Design and analysis of pilot studies: recommendations for good practice. Journal of evaluation in clinical practice 2004;**10**(2):307-12 doi: 10.1111/j.2002.384.doc.x[published Online First: Epub Date]|.

47. Hrynaszkiewicz I, Norton ML, Vickers AJ, et al. Preparing raw clinical data for publication: guidance for journal editors, authors, and peer reviewers. Bmj 2010;**340**:c181 doi: 10.1136/bmj.c181[published Online First: Epub Date]|.

## AUTHOR CONTRIBUTIONS

Cullington, Kitterick, DeBold, Weal, Clarke, Newberry and Aubert made substantial contributions to the conception and design of the work, revised it critically for intellectual content and approved the final manuscript. They agree to be accountable for their work. Cullington leads the work and takes overall responsibility for the manuscript. Kitterick was involved in all aspects. DeBold and Aubert were responsible for the incorporation of the parts of the protocol specific to Cochlear devices; Weal worked especially on the LifeGuide parts; Newberry gave particular input to PPI; Clarke was responsible for the staff assessment components.

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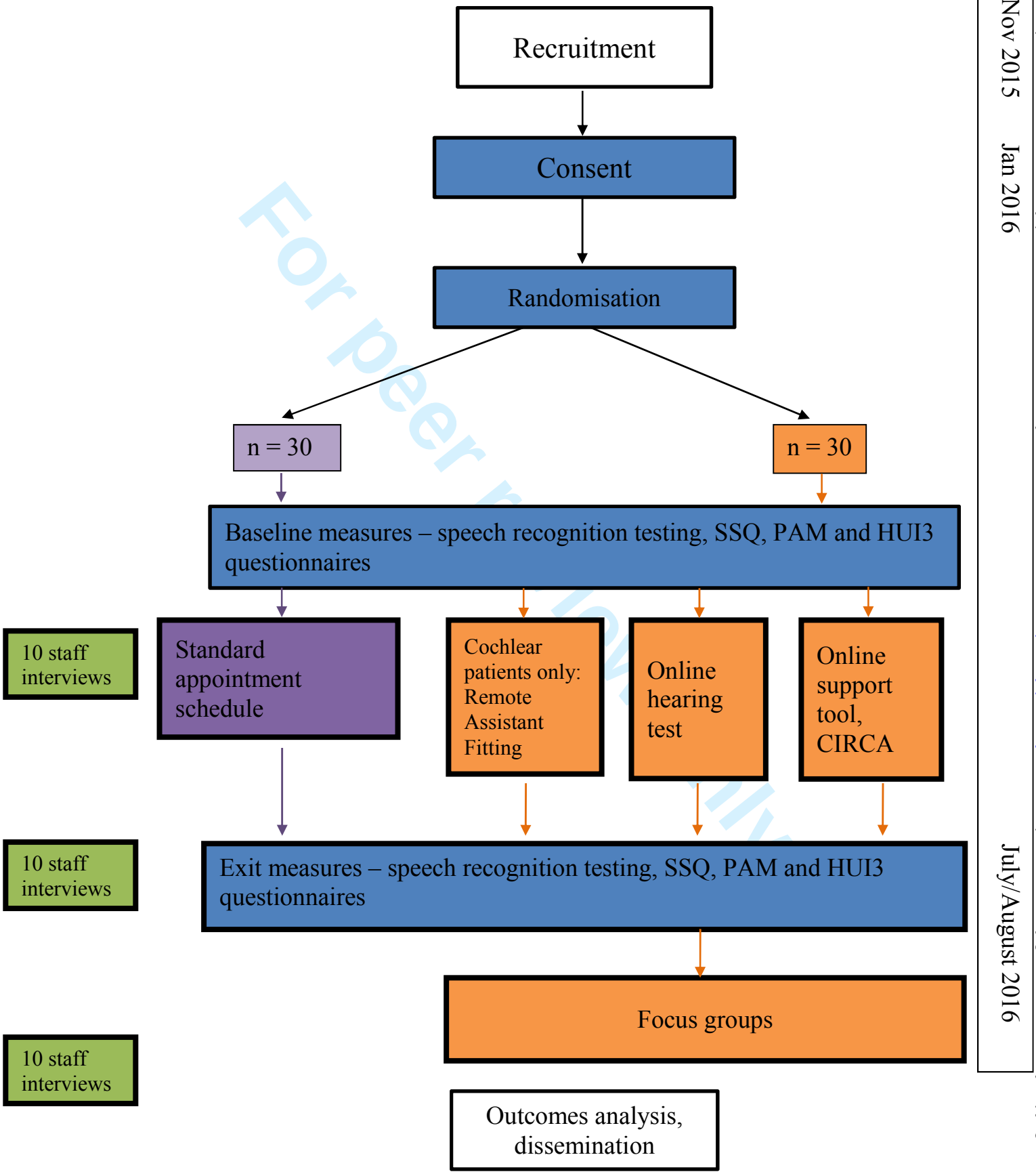
COMPETING INTERESTS STATEMENT

The PI, Cullington, performs occasional private consultancy work for the cochlear implant company Cochlear Europe.










Nov 2015 Jan 2016 July/August 2016


SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

| Section/item | Item No | Description | Addressed on page number |
|---|---|---|---|
| **Administrative information** | | | |
| Title | 1 | Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym | _____1_____ |
| Trial registration | 2a | Trial identifier and registry name. If not yet registered, name of intended registry | _____3_____ |
| | 2b | All items from the World Health Organization Trial Registration Data Set | _in registry entry_ |
| Protocol version | 3 | Date and version identifier | N/A for article_ |
| Funding | 4 | Sources and types of financial, material, and other support | _____8,23_____ _ |
| Roles and responsibilities | 5a | Names, affiliations, and roles of protocol contributors | _____1-2____ |
| | 5b | Name and contact information for the trial sponsor | _____8____ |
| | 5c | Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities | _____8_____ |
| | 5d | Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) | _____8, 14_____ |

| | | | |
|---|---|---|---|
| **Introduction** | | | |
| Background and rationale | 6a | Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention | 5-7 |
| | 6b | Explanation for choice of comparators | |
| Objectives | 7 | Specific objectives or hypotheses | 13-14 |
| Trial design | 8 | Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) | 8 |
| **Methods: Participants, interventions, and outcomes** | | | |
| Study setting | 9 | Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained | 8 |
| Eligibility criteria | 10 | Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) | 9 |
| Interventions | 11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | 10-11 |
| | 11b | Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) | N/A |
| | 11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) | 12 |
| | 11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | 10 |
| Outcomes | 12 | Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended | 12-13 |
| Participant timeline | 13 | Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) | Figure 1 |

| | | | |
|---|---|---|---|
| Sample size | 14 | Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations | 8 |
| Recruitment | 15 | Strategies for achieving adequate participant enrolment to reach target sample size | 8 |
| **Methods: Assignment of interventions (for controlled trials)** | | | |
| Allocation: | | | |
| Sequence generation | 16a | Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions | 9 |
| Allocation concealment mechanism | 16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned | 9 |
| Implementation | 16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | 9 |
| Blinding (masking) | 17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | 9 |
| | 17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial | |
| **Methods: Data collection, management, and analysis** | | | |
| Data collection methods | 18a | Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol | 11-14 |
| | 18b | Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols | |

| | | | |
|---|---|---|---|
| Data management | 19 | Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol | _____15_____ |
| Statistical methods | 20a | Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol | _____16_____ |
| | 20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | _____ |
| | 20c | Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) | _____ |
| **Methods: Monitoring** | | | |
| Data monitoring | 21a | Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed | ____15_____ |
| | 21b | Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial | _____ |
| Harms | 22 | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct | _____16-17____ |
| Auditing | 23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor | _____ |
| **Ethics and dissemination** | | | |
| Research ethics approval | 24 | Plans for seeking research ethics committee/institutional review board (REC/IRB) approval | _____17_____ |
| Protocol amendments | 25 | Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) | _____ |

| | | | |
|---|---|---|---|
| Consent or assent | 26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | ____17_____ |
| | 26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | ___N/A_____ |
| Confidentiality | 27 | How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial | _____17___ |
| Declaration of interests | 28 | Financial and other competing interests for principal investigators for the overall trial and each study site | _____24_____ |
| Access to data | 29 | Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators | ____15____ |
| Ancillary and post-trial care | 30 | Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation | _____ |
| Dissemination policy | 31a | Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions | _____17_____ |
| | 31b | Authorship eligibility guidelines and any intended use of professional writers | _____ |
| | 31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | _____ |
| **Appendices** | | | |
| Informed consent materials | 32 | Model consent form and other related documentation given to participants and authorised surrogates | _____ |
| Biological specimens | 33 | Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable | ____N/A_____ _ |

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

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



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

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## ABSTRACT

### Introduction

Many resources are required to provide post-operative 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 speech recognition testing, information, self-rehabilitation, advice, equipment training and troubleshooting.

The main outcome measure is patient activation. Secondary outcomes are stability and quality of hearing, stability of quality of life, clinic resources, patient and clinician experience, and any adverse events associated with remote care. We will examine the acceptability of remote care to service users and clinicians, the willingness of participants to be randomised, and attrition rates. We will estimate numbers required to plan a fully powered RCT.

### Ethics and dissemination

Ethical approval was received from North West – Greater Manchester South Research Ethics Committee (15/NW/0860) and the University of Southampton Research Governance Office (ERGO 15329).
Results will be disseminated in the clinical and scientific communities and also to the patient population via peer-reviewed research publications both online and in print, conference and meeting presentations, posters, newsletter articles, website reports, and social media.
Trial registration number ISRCTN 14644286

**Strengths and limitations of this study**

- This will be the first RCT of a triple approach to remote care for people using cochlear implants
- No formal power calculations were done as this is the first study of its kind and acts as a feasibility RCT
- The generic Patient Activation Measure® 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 all neural prostheses;[1] they can provide hearing to people with severe to profound deafness. Approximately 1,200 people receive a cochlear implant in the United Kingdom (UK) each year.[2] The total number of people with implants is approximately 14,000 in the UK and 600,000 worldwide.[3] Numbers are likely to increase rapidly: only approximately 5% of eligible people in the UK have received an implant,[3] and the number of people of retirement age is projected to increase by 28% by 2035[4] meaning a further increase in the number of hearing-impaired people. Cochlear implant care in the UK is provided at one of 19 tertiary centres involving assessment, surgery, and a resource-intensive acute phase of device adjustment and rehabilitation. These centres may be several hours away from the patient's home necessitating travel expense, time off work and family disruption. Currently UK implant centres review patients on a clinic-led schedule; this means that review appointments can occur that provide little benefit to the patient. Conversely when some patients attend a routine appointment, there is hearing deterioration which the patient had not noticed. This is often remedied by replacing equipment that the patient could have done at home. Making this care pathway patient-centred instead may provide a more efficient and effective service and allow more timely identification of issues.

When a patient attends a long-term follow-up appointment, the following tasks may be done: speech recognition testing, device adjustment, rehabilitation, equipment check and troubleshooting, and provision of replacement or upgraded equipment. We propose that at least some of these tasks could be done by the patient themselves at home, and that people using cochlear implants should only attend the clinic when there is clinical need (no more routine appointments). Potential benefits for the patient are:

- more stable hearing (problems identified and resolved quicker)
- better hearing (ability to fine tune when away from clinic)
- convenience of not travelling to routine appointments
- reduction of travel cost and time, time off work and disruption to family life
- increased confidence to manage own hearing
- greater equality in service delivery (same level of service regardless of distance from clinic)

It may also mean that the clinic has greater resources (time, money, space) to see complex cases and the expanding population of new patients; although health economics analysis will not occur in this trial. People using cochlear implants and their families would generally like to take a more active role in their care and welcome the use of technology to assist self-care.[5 6] The NHS has a strong commitment to supporting self-care for people with long-term conditions[7] with 'the vision of a citizen-centred, digitally-

enabled, health and social care system'.[8] Evidence shows a significant improvement in outcomes when patients use self-management tools[9] and those who are activated and involved in their care tend to have better health outcomes.[10 11]

**The standard clinical care pathway**

*Speech recognition testing*

The main speech recognition measure used in UK clinics is Bamford-Kowal-Bench (BKB) sentences[12] in quiet and noise; these are usually performed in a sound-treated room in the clinic by experienced clinicians, although there are some reports of testing remotely using an assistant at a remote location and video conferencing facilities.[13 14] Speech perception in noise testing using digits has been developed;[15] digits are highly familiar stimuli and are usually known by people with even basic language skills. Digit testing requires a closed set response and thus is suitable for self-testing over the telephone or internet[16 17] and has a minimal learning effect.[18] The test correlates well with speech recognition in noise with sentences in people using cochlear implants.[19-22] A digit test in English is freely available online at the Action on Hearing Loss website[23] and also as an application for mobile devices (Action on Hearing Loss Hearing Check).

*Device adjustment*

In order to provide benefit to a hearing-impaired person, the levels of electrical stimulation need to be individually adjusted for both soft and loud sounds on up to 22 electrode contacts in the cochlea. The levels can change as the person using a cochlear implant becomes more used to listening, more experienced at doing the task and as physiological changes occur. Most cochlear implant centres offer frequent appointments in the first few months following implantation and annual adjustment appointments thereafter.[24] Device adjustment usually occurs in the clinic in a sound-treated room, led by an experienced clinician. Several centres are now offering remote device programming.[13 25-32] However these reports continue to use a clinician-centred model involving the patient attending a centre closer to their home where an assistant is present, and the cochlear implant centre clinician leading the session using video conferencing and remote desktop connection.

People using cochlear implants have commented that they would like to be able to adjust their device parameters in their own home or work environment, rather than just in the sound-treated clinic room.[5] The company Cochlear® have introduced a self-fitting paradigm (Remote Assistant Fitting) using the speech processor remote control that patients already have. This allows adjustment of programming to be

done by the patient at any time and anywhere with equivalent hearing outcomes to audiologist-led sessions.[33]

*Rehabilitation*

Many clinical resources are devoted to rehabilitation after people receive a cochlear implant; the new sound can be difficult to get used to. Rehabilitation appointments are frequent in the first year and may be offered annually thereafter.[34] Computer-based auditory training completed by the patient at home can significantly improve their speech recognition.[35]

*Equipment troubleshooting/repairs/spares provision/upgrades*

Cochlear implant speech processors are complex; some parts need regular replacement in order to keep the device in optimum condition.[36] No reminder is given on the device. Many NHS cochlear implant centres offer an upgraded speech processor approximately every 5 years, requiring a clinic visit.[34]

**The intervention**

This paper describes the protocol for a feasibility project to design, introduce and evaluate a patient-centred remote care approach for adults using cochlear implants long-term. This is necessary preparatory work for a fully powered randomised controlled trial (RCT) that will be extended across the UK. It is a prospective RCT whereby 60 patients will be randomised to either a control group (usual clinical care) or a remote care group where they are given access to new remote care tools. The patients in the remote care group will monitor their hearing at home, and some can fine-tune their hearing to suit their own real-world environment. Their other needs will be met through a personalised online support tool. Assessment of frontline staff perceptions of remote care will also be formally evaluated using repeated interviews with 10 staff members at the start, midpoint and end of the project. Empowering the patient to self-care at home could enable better and more stable hearing and a more convenient and accessible service.

## METHODS AND ANALYSIS

### Trial design

This will be a two-arm feasibility RCT involving 60 adults with cochlear implants with at least 6 months device experience in a 6 month clinical trial of remote care (see Figure 1 flow chart). This feasibility trial will inform a later fully powered RCT and will be used to estimate characteristics of the outcome measures, follow-up rates, adherence, willingness of participants to be randomised, and the number of eligible and willing participants. The later substantive RCT will aim to answer the question 'Is remote care an acceptable and effective method of caring for adults using cochlear implants?' using more participants and a longer time scale.

### Setting and participants

The trial will be conducted at the University of Southampton Auditory Implant Service (USAIS): a tertiary treatment centre mostly funded by NHS referrals. The study sponsor is the University of Southampton. The funder (The Health Foundation) and sponsor have not contributed towards the study protocol. Some anonymised data will be analysed at the University of Nottingham. Participants will not necessarily be USAIS patients.

### Proposed sample size

No formal power calculations were done as this is a feasibility trial to plan a later RCT. The literature suggests sample sizes between 30 and 50 for a feasibility trial.[36 37] Sixty participants was selected (30 in each group) in order to gather a range of different service users' experiences of the remote care tools and to estimate the effect size on the primary outcome measure.

### Recruitment

Potential participants will be sent a covering letter and the Participant Information Sheet several weeks before consenting. The clinical trial will begin in January 2016. There has been much interest in the project among people using cochlear implants in the UK, so adequate enrollment to reach target size is not of concern.

The Principal Investigator (PI) (Cullington) will access the USAIS clinical database and contact patients who fulfil the inclusion criteria, excepting those who have indicated that they do not wish to receive research invitations. Information will also be placed in the USAIS waiting room.

An advertisement will be placed on the USAIS website (www.AIS.southampton.ac.uk) from the date of ethical approval to the end of recruitment. A link will be tweeted from @UoS_AIS and @CIRemoteCare once a week from study ethical approval to end of recruitment. Details of the study will be placed on the National Cochlear Implant Users' Association website.

Patients from other centres may respond to the advertisement; we will obtain participants' permission to notify individual teams if their patients are involved.

**Inclusion criteria**

- Person using cochlear implant (any device, unilateral or bilateral) for at least 6 months
- Living in the UK
- Aged 18 years or more
- Able to give informed consent
- Sufficient English to understand study documentation and participate in testing
- Access to a computer or device with internet access

**Exclusion criteria**

- Those that do not fulfil the inclusion criteria plus any medical condition or known disability that would limit their capacity to use the online support tool

**Randomisation**

Participants who consent to the study will be allocated to the remote care pathway or the standard care pathway at the baseline visit by the PI using minimization software.[37] Minimisation seeks to achieve a balance across the arms of a trial on one or more pre-defined patient characteristics.[38 39] The minimisation will balance the following factors:

- CI user less than a year or more than a year
- Gender
- Distance from the clinic (local or non-local i.e. within 20 miles or more than 20 miles away)
- Device (Cochlear or not)
- Ability to use Cochlear Remote Assistant Fitting (or not)

The approach will use biased coin minimisation with a base probability of 0.7. Imbalance between the groups will be quantified using the marginal balance method.[40]

**Blinding**

It will not be possible to blind participants to which group they are in. Baseline measures will be completed before allocation. Efforts will be made to blind clinicians to which group the participant belongs when they perform exit measures. Where possible, blinded measures will be passed to the University of Nottingham for analysis.

**Interventions**

*Control group: standard clinical care pathway*

Participants in the control group will continue with their usual care pathway; they will not have access to remote care. They will be asked to attend twice for this project: baseline and exit measures.

*Intervention group: remote care*

Those randomised into the treatment group (remote care group) will receive cochlear implant care remotely for 6 months. Clinic appointments will be given if required, and participants must still adhere to any medical check-ups with the cochlear implant surgeon. Participants may access the tools as often as they wish (minimum twice required for project) and can use them wherever they wish (at home, at a friend's house, at the library etc.). Remote care will comprise:

1 Remote and self-monitoring

Remote care trial participants will access a password-protected online speech recognition test based on the Triple Digit Test (TDT). The site is provided and maintained by Action on Hearing Loss. Participants will listen to sets of three digits in background noise and type in the numbers they hear. Participants will be required to do self testing at least in months 1 and 6, but can do it at any time during the six months. They will be advised that they can do the hearing test using a direct connection from the computer sound card to their speech processor (with the advantage of excluding background noise) or they can listen via speakers (with the advantage of testing their whole hearing system including the microphone).

2 Self-adjustment of device (Remote Assistant Fitting)

Only those people using cochlear implants with newer Cochlear devices (CI500 series, CI422 or CI24RE devices using CP800 or CP900 series processors) will be able to participate in the self-adjustment of

device; the other manufacturers do not have these tools yet. Participants will use Remote Assistant Fitting to adjust their device programming at any time anywhere. Patients will be required to do self-adjustment at least in months 1 and 6, but can do it at any time during the six months.

Those patients in the trial who are eligible for a processor upgrade will receive the upgrade at home rather than coming into the clinic. This will apply to users of all devices.

3 Online support tool

The research team will design a new online support tool for adults with cochlear implants using LifeGuide.[41] LifeGuide is an open source software platform that allows the development and trialling of interactive web-based interventions. This will be an iterative process incorporating feedback from service users at all stages, including focus groups of adults with cochlear implants. The online support tool (Cochlear Implant Remote Care, CIRCA) will incorporate personalised equipment help and information, troubleshooting, rehabilitation, goal-setting, help with music and telephone use and a method of ordering replacement equipment in an easy format to people who may be inexperienced Internet users. It will also store the TDT speech recognition test result entered by the participant and provide a comparison with the baseline test and appropriate feedback (no significant change or significantly worse: contact the centre). Participants will be given a unique user name to log in to this support tool; they can access it at any time. They will have the option to include a mobile phone number if they wish to receive reminder text messages for speech processor maintenance and study information.

The participant will enter the following:

- name they would like to be called
- email address
- main speech processor
- month and year of first implant surgery
- date microphone cover and rechargeable batteries were changed (if appropriate)
- year of birth (optional)
- first part of postcode (optional)
- born deaf or lost hearing (optional)
- mobile phone number (optional)

**Staff change management assessment**

Moving to remote care represents a significant change to cochlear implant centre staff; feedback will be obtained throughout from clinicians using a SharePoint feedback site, discussions at centre meetings, the project steering group, and informal discussions. A formal change evaluation will also occur. Interviews will be conducted with 10 members of the multidisciplinary team at three month intervals over a period of six months, (i.e. 0, 3, 6 months). Capturing data near the beginning, middle and end of the project will enable us to better capture the on-going and iterative relationships between perceptions and learning and how these change in response to leadership, social context and decision-making processes over time.[42] Interviews will be carried out in the work place or over the phone in accordance with the guidelines and codes of conduct recommended by both the British and American Psychological Societies.[43 44] Repeated interviews with the same individuals will provide insights into how the nature and content of challenges of telehealth implementation and acceptance are changing and evolving as part of a dynamic process. Examining and understanding staff responses to the change will optimise the chance of the change being sustainable.

The following information will be collected from staff:

- Age (in 10 year age bands)
- Gender
- Role in team
- Number of years working in cochlear implant centre

*Staff recruitment*

Ten staff members who work with adults using cochlear implants at USAIS will be recruited. An email will be sent to all eligible staff enclosing the Staff Participant Information Sheet. This information will also be placed on the staff SharePoint site. Any staff member working at USAIS in a clinical role with adults with implants will be eligible to take part, including staff who support patient equipment needs. A sample size of 10 was chosen in order to provide a variety of differing professions and viewpoints. If more than 10 people want to take part, participants will be selected in order to provide a balance of different clinical roles.

**Outcome measures**

*Baseline measures*

All participants will undergo the following baseline measures after signing the consent form:

- speech recognition testing (BKB sentences in quiet and noise and Triple Digit Test, TDT).
- Patient Activation Measure® (PAM®)
- the Speech, Spatial and Qualities of Hearing questionnaire (SSQ)
- quality of life questionnaire: Health Utilities Index (HUI) mark 3

The speech recognition testing is described under the earlier section 'Standard clinical care pathway'. The PAM® is a well-validated generic measure of patient activation that evaluates the knowledge, skills, beliefs and behaviours that patients have for self-management of their long-term condition.[45 46] It has been used extensively in over 200 peer-reviewed published studies.[47] The SSQ is a 49-item questionnaire measuring self-reported hearing disability over three domains: difficulties understanding speech in different situations, localising and tracking sounds, and ease of listening and naturalness of sound.[48] The HUI mark 3 (HUI3) is a multi-attribute health status classification system evaluating eight domains of vision, hearing, speech, ambulation, dexterity, emotion, cognition and pain.[49]
The following information will be collected on both the control group and remote care group during the clinical trial:

- Number and nature of clinic contacts and visits (including non-attendance)
- Repair logs
- Age
- Gender
- Postcode (to calculate distance to clinic) – Postcode data will be used once only in order to calculate the distance to the clinic and will then be destroyed
- Cochlear implant device and speech processor
- Highest formal educational qualifications
- Which cochlear implant centre takes care of the participant

All staff will be reminded to document all contact with patients as usual. Additionally in the remote care group, logs of their interaction with the remote care tools will be stored to assess adherence and utility.

*Exit measures (summer 2016)*

All participants will undergo the following exit measures:

- speech recognition testing (BKB sentences in quiet and noise and TDT)

- PAM®
- SSQ questionnaire
- HUI3

Travel expenses will be paid for both baseline and exit measure visits. The day of the exit measures will be considered to be the day the participants exit from the trial.

Participants in the remote care group will be asked to attend a focus group on the day of their exit measures in order to collect qualitative preference and experience data. Focus groups will be audio recorded and transcribed. A small number of participants in the remote care group will be asked if they would be willing to be videoed talking about remote care. These videos will be stored securely on a University of Southampton password-protected network using just the participant's ID. They will be used in presentations to report and promote the research.

*Primary outcome measure*

- Change (from day of entry into study to 6 months after remote care introduced) in patient activation measured using the PAM®

*Secondary outcome measures*

- 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 TDT, the SSQ questionnaire in both the control and treatment arms
- 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 measured using the HUI3 in both the control and treatment arms
- Patient preference for and experience of remote care in treatment arm reported qualitatively from feedback in online support tool and focus groups
- Clinician preference for and experience of remote care measured qualitatively from three interviews with up to 10 members of clinical staff

*Feasibility outcomes*

- Recruitment (number of eligible and willing participants)
- Attrition (drop-out) and bias

- Adherence to protocol
- Acceptability of randomization to service users
- Willingness and ability to use remote care tools (hearing test, Remote Assistant Fitting, online support tool)

**Hypotheses**

*Primary*

- 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 PAM®.

*Secondary*

- There will be no more deterioration in hearing in the remote care group compared to the control group, measured using speech recognition (BKB, TDT) and the SSQ questionnaire.
- There will be no more deterioration in quality of life in the remote care group compared to the control group, measured using the HUI3.
- Service users (patients) will feel positive about remote care, measured qualitatively from feedback in online support tool and in focus groups.
- Clinicians will feel positive about remote care, measured qualitatively from three interviews with up to 10 members of clinical staff.

**Data handling**

Data will be managed according to the University of Southampton Research Data Management Policy (RDMP). An individual study Data Management Plan is stored on the University network. Stored data will be coded and anonymised, will not include name or address information and will be stored securely: all electronic data will be password protected. Hard copy data will be stored in a locked filing cabinet in a secure office. The University provides secure storage for all active research data (http://library.soton.ac.uk/researchdata/unistorage). The data are regularly backed up and a copy of the back up is regularly off-sited to a secure location for disaster recovery purposes. Research data will be kept for at least 10 years in line with University of Southampton policy.

Metadata records for the data (and published outputs) will also be maintained on the the University of Southampton Institutional Research Repository (ePrints). Each deposit can be assigned a unique Digital

Object Identifier (DOI) via the DataCite scheme, allowing it to be cited in publications. No personal data or identifiable data will be included in the data stored in the repository. This will be in accordance with the university's data security policy (http://www.calendar.soton.ac.uk/sectionIV/dppolicy.pdf) and the requirements of the Data Protection Act (1998).

The terms of the PAM® licence specify that up to 250 participants can be tested until August 2016. Non-personally identifiable individual data must be shared with Insignia. The data shared shall include individual level data records containing answers to each of the PAM® questions, and if captured i) demographic variables, health status and condition variables ii) specific outcome variables including health behaviours, self-management behaviours and whether patients using PAM® improved the self-management aspects of their health care and iii) the PAM® materials' effect on or relationship to patient health care utilisation and costs. Such data shall be reported to Insignia in an electronic format in approximately September 2016.

A data monitoring committee is not required due to the short period of follow-up and minimal project risks.

**Trial organisation and monitoring**

The trial is led by the PI (HC). Monthly research team meetings will be held. We have formed a Steering Group, with the remit of reflecting on the process and governance of the project including adverse events monitoring. The Steering Group comprises three USAIS clinicians, the USAIS Director, the PI, a consultant on change management (NC) and two service users (patients). It will meet at least three times.

**Data analysis plan**

To comply with recommendations, analysis will be mainly descriptive.[50] Scores on the PAM® (primary outcome), quality of life and hearing results will be compared between the two groups (control and remote care group), although statistical analysis of any differences will be interpreted with caution as no formal power calculation was in place, and will primarily be used to estimate effect sizes. Analysis will focus on whether the generic PAM® is sensitive enough to show change, or whether a condition-specific empowerment measure needs to be developed. Clinician and participant feedback, use of clinic resources (number and type of appointments) and feasibility outcomes will be reported and analysed qualitatively. IBM SPSS Statistics 21 will be used.

**Public and patient involvement, PPI**

The research team has a strong commitment to PPI; a member of the research team is a service user. This service user was known to the Principal Investigator to be interested in remote care, and has served on the USAIS Governance Group. The research team contains representatives from the main stakeholders: patient, clinician, cochlear implant company. Two additional service users are on the project Steering Group. Local and national publicity (website, twitter, presentation to National Cochlear Implant Users' Association, newsletter articles, letters, emails, Yahoo group) have already invited help in designing the research.

## ETHICS AND DISSEMINATION

Ethical approval was received from North West – Greater Manchester South Research Ethics Committee (15/NW/0860) and University of Southampton Research Governance Office (ERGO 15329).

### Ethics

Participation is entirely voluntary and it has been stressed to patients that if they do not participate, this will not affect their usual clinical care in any way. Written informed consent will be taken from all participants by the PI who has regular GCP (Good Clinical Practice) training. Participants are free to withdraw at any point without giving a reason. A risk analysis has been approved by the University of Southampton.

The PI will inform paticipants during the trial if any new information comes to light which may affect their willingness to participate.

### Confidentiality

Linked anonymity will be used. Participants will be assigned a unique identifier on enrollment. All results will be stored using only this ID. The lookup table will be stored on a password-protected University of Southampton network in a password-protected file separate from the study results, and will be accessible only to the research team.

Adults with cochlear implants are still rare in the general population (approximately 0.01% of the UK population). BMJ reporting guidelines will be followed: we will not report three or more indirect identifiers (for example place of treatment, sex, rare disease or treatment, age) for any individuals.[51]

### Dissemination

Research results will be presented locally, nationally and internationally. Dissemination will include but not be limited to peer-reviewed research publications both online and in print, conference and meeting presentations, posters, newsletter articles, website reports, and social media. In order to inform people with cochlear implants of the results, information will be sent to the National Cochlear Implant Users' Association and other patient groups, and the USAIS patient newsletter. Participants will be offered the opportunity to receive a summary of the findings.

## CONCLUSION

This will be the first RCT of a triple approach to remote care for people using cochlear implants. The study results will inform further work on a larger scale roll out of cochlear implant remote care in the UK.

## TRIAL STATUS

At the time of writing (January 2016), 58 participants have been enrolled.

## ACKNOWLEDGEMENTS

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## REFERENCES


1. Wilson BS, Dorman MF. Cochlear implants: current designs and future possibilities. J Rehabil Res Dev 2008;**45**(5):695-730.
2. BCIG. Annual update 2014-2015 2015 [Available from: http://www.bcig.org.uk/wp-content/uploads/2015/12/CI-activity-2015.pdf.
3. Ear Foundation. Cochlear implants http://www.earfoundation.org.uk/files/download/1221. In: Ear Foundation information sheet, ed., 2016.
4. Office for National Statistics. [Archived content] National population projections, 2010-based statistical bulletin http://webarchive.nationalarchives.gov.uk/20160105160709/http://ons.gov.uk/ons/rel/npp/national-population-projections/2010-based-projections/index.html, 2011.
5. Cullington HE. What do our service users really want? [poster]. British Cochlear Implant Group Annual Conference. Ayrshire, 2013.
6. Tsay IA. Using a patient-driven software tool for programming multiple cochlear implant patients simultaneously in a telemedicine setting. Thesis (PhD). University of Colorado at Denver, 2013.
7. NHS. Five year forward view. In: NHS, ed., 2014.
8. National Information Board. Personalised Health and Care 2020. Work stream 1.1: Enable me to make the right health and care choices: providing patients and the public with digital access to health and care information and transactions https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/442834/Work_Stream_1_1.pdf, 2015.
9. Panagioti M, Richardson G, Small N, et al. Self-management support interventions to reduce health care utilisation without compromising outcomes: a systematic review and meta-analysis. BMC Health Serv Res 2014;**14**:356.
10. Hibbard JH, Greene J, Shi Y, et al. Taking the long view: how well do patient activation scores predict outcomes four years later? Med Care Res Rev 2015;**72**(3):324-37.
11. Mosen DM, Schmittdiel J, Hibbard J, et al. Is patient activation associated with outcomes of care for adults with chronic conditions? J Ambul Care Manage 2007;**30**(1):21-9.
12. Bench J, Kowal A, Bamford J. The BKB (Bamford-Kowal-Bench) sentence lists for partially-hearing children. Br J Audiol 1979;**13**(3):108-12.
13. Hughes ML, Goehring JL, Baudhuin JL, et al. Use of telehealth for research and clinical measures in cochlear implant recipients: a validation study. J Speech Lang Hear Res 2012;**55**(4):1112-27.
14. Goehring JL, Hughes ML, Baudhuin JL, et al. The effect of technology and testing environment on speech perception using telehealth with cochlear implant recipients. J Speech Lang Hear Res 2012;**55**(5):1373-86.
15. Smits C, Kapteyn TS, Houtgast T. Development and validation of an automatic speech-in-noise screening test by telephone. Int J Audiol 2004;**43**:15-28.
16. Smits C, Houtgast T. Results from the Dutch speech-in-noise screening test by telephone. Ear Hear 2005;**26**(1):89-95.
17. Smits C, Merkus P, Houtgast T. How we do it: The Dutch functional hearing-screening tests by telephone and internet. Clin Otolaryngol 2006;**31**(5):436-40.
18. Smits C, Theo Goverts S, Festen JM. The digits-in-noise test: assessing auditory speech recognition abilities in noise. J Acoust Soc Am 2013;**133**(3):1693-706.
19. Mahafzah M. The Triple Digit Test: a self-test of speech perception in cochlear implant users. Thesis (MSc). University of Southampton, 2013.
20. Aidi T. The Triple Digit Test: A validity and feasibility study. Thesis (MSc). University of Southampton, 2015.
21. Kaandorp MW, Smits C, Merkus P, et al. Assessing speech recognition abilities with digits in noise in cochlear implant and hearing aid users. Int J Audiol 2015;**54**(1):48-57.
22. Agyemang-Prempeh A. Telemedicine in cochlear implants: a new way of conducting long term patient follow-up. Thesis (MSc). University of Southampton, 2012.
23. Action on Hearing Loss. Check your hearing 2015 [Available from: http://www.actiononhearingloss.org.uk/your-hearing/look-after-your-hearing/check-your-hearing/take-the-check.aspx.
24. Vaerenberg B, Smits C, De Ceulaer G, et al. Cochlear Implant Programming: A Global Survey on the State of the Art. The Scientific World Journal 2014;**2014**:1-12.

25. Eikelboom RH, Jayakody DM, Swanepoel DW, et al. Validation of remote mapping of cochlear implants. J Telemed Telecare 2014;**20**(4):171-77.
26. Kuzovkov V, Yanov Y, Levin S, et al. Remote programming of MED-EL cochlear implants: users' and professionals' evaluation of the remote programming experience. Acta Otolaryngol 2014;**134**(7):709-16.
27. McElveen JT, Jr., Blackburn EL, Green JD, Jr., et al. Remote Programming of Cochlear Implants: A Telecommunications Model. Otol Neurotol 2010;**31**(7):1035-40.
28. Ramos A, Rodriguez C, Martinez-Beneyto P, et al. Use of telemedicine in the remote programming of cochlear implants. Acta Otolaryngol 2009;**129**(5):533-40.
29. Rodriguez C, Ramos A, Falcon JC, et al. Use of telemedicine in the remote programming of cochlear implants. Cochlear Implants Int 2010;**11 Suppl 1**:461-4.
30. Wesarg T, Wasowski A, Skarzynski H, et al. Remote fitting in Nucleus cochlear implant recipients. Acta Otolaryngol 2010;**130**(12):1379-88.
31. Wasowski A, Skarzynski PH, Lorens A, et al. Remote fitting of cochlear implant system. Cochlear Implants Int 2010;**11 Suppl 1**:489-92.
32. Samuel PA, Goffi-Gomez MV, Bittencourt AG, et al. Remote programming of cochlear implants. Codas 2014;**26**(6):481-6.
33. Botros A, Banna R, Maruthurkkara S. The next generation of Nucleus((R)) fitting: a multiplatform approach towards universal cochlear implant management. Int J Audiol 2013;**52**(7):485-94.
34. Muller J, Raine CH. Quality standards for adult cochlear implantation. Cochlear Implants Int 2013;**14 Suppl 2**:S6-12.
35. Fu QJ, Galvin J, Wang X, et al. Effects of auditory training on adult cochlear implant patients: a preliminary report. Cochlear Implants Int 2004;**5 Suppl 1**:84-90.
36. Cochlear.com. Nucleus 6 care and maintenance accessed 01/03/2016 [Available from: http://www.cochlear.com/wps/wcm/connect/us/recipients/nucleus-6/nucleus-6-basics/care-and-maintenance.
37. Saghaei M, Saghaei S. Implementation of an open-source customizable minimization program for allocation of patients to parallel groups in clinical trials. J Biomedical Science and Engineering 2011;**4**:734-39.
38. Taves DR. Minimization: a new method of assigning patients to treatment and control groups. Clin Pharmacol Ther 1974;**15**(5):443-53.
39. Pocock SJ, Simon R. Sequential treatment assignment with balancing for prognostic factors in the controlled clinical trial. Biometrics 1975;**31**(1):103-15.
40. Han B, Enas NH, McEntegart D. Randomization by minimization for unbalanced treatment allocation. Stat Med 2009;**28**(27):3329-46.
41. Introduction to the LifeGuide: software facilitating the development of interactive behaviour change internet interventions. The Society for the Study of Artificial Intelligence and Simulation of Behaviour; 2009; Edinburgh.
42. Pettigrew AM. Context and action in the transformation of the firm. J Manage Stud 1987; **24**(6):649-70.
43. American Pyschological Association. Ethical principles of Psychologists and code of conduct. , 2002.
44. British Psychological Society. Code of Ethics and Governance. 2009.
45. Hibbard JH, Mahoney ER, Stockard J, et al. Development and testing of a short form of the patient activation measure. Health Serv Res 2005;**40**(6 Pt 1):1918-30.
46. Hibbard JH, Stockard J, Mahoney ER, et al. Development of the Patient Activation Measure (PAM): conceptualizing and measuring activation in patients and consumers. Health Serv Res 2004;**39**(4 Pt 1):1005-26.
47. Insignia Health. http://www.insigniahealth.com/products/pam-survey [
48. Gatehouse S, Noble W. The Speech, Spatial and Qualities of Hearing Scale (SSQ). Int J Audiol 2004;**43**(2):85-99.
49. Feeny D, Furlong W, Boyle M, et al. Multi-attribute health status classification systems. Health Utilities Index. Pharmacoeconomics 1995;**7**(6):490-502.
50. Lancaster GA, Dodd S, Williamson PR. Design and analysis of pilot studies: recommendations for good practice. J Eval Clin Pract 2004;**10**(2):307-12.
51. Hrynaszkiewicz I, Norton ML, Vickers AJ, et al. Preparing raw clinical data for publication: guidance for journal editors, authors, and peer reviewers. BMJ 2010;**340**:c181.

## AUTHOR CONTRIBUTIONS

Cullington, Kitterick, DeBold, Weal, Clarke, Newberry and Aubert made substantial contributions to the conception and design of the work, revised it critically for intellectual content and approved the final manuscript. They agree to be accountable for their work. Cullington leads the work and takes overall responsibility for the manuscript. Kitterick was involved in all aspects. DeBold and Aubert were responsible for the incorporation of the parts of the protocol specific to Cochlear devices; Weal worked especially on the LifeGuide parts; Newberry gave particular input to PPI; Clarke was responsible for the staff assessment components.

FUNDING STATEMENT

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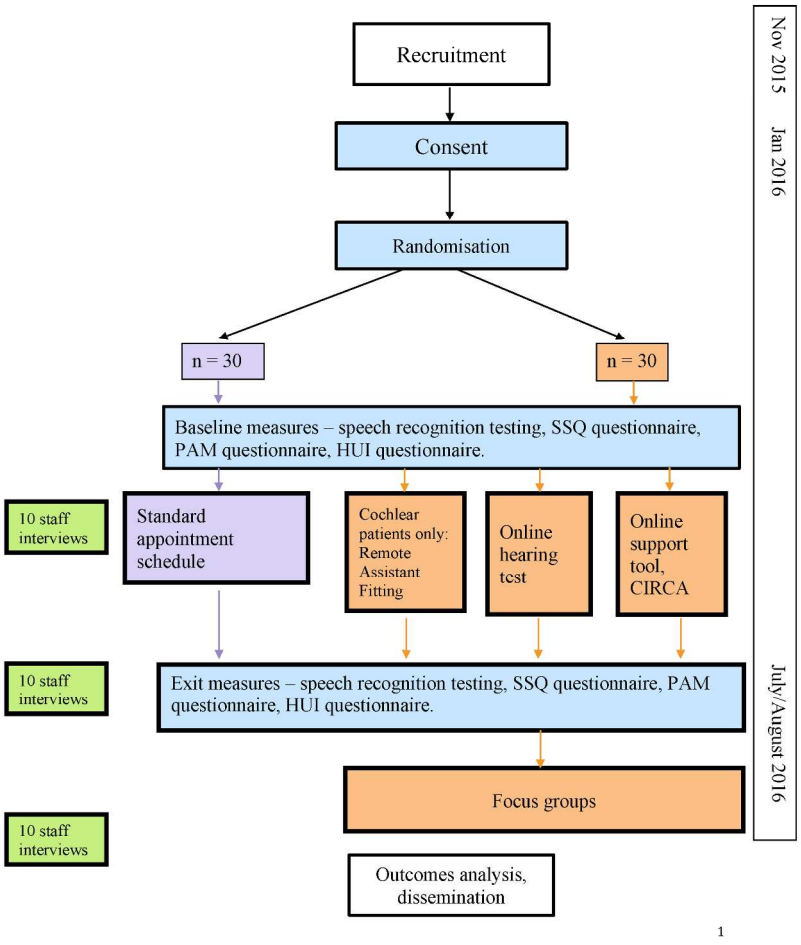
COMPETING INTERESTS STATEMENT

The PI, Cullington, performs occasional private consultancy work for the cochlear implant company Cochlear Europe.

Dr. Cullington reports grants from The Health Foundation, during the conduct of the study; other from Cochlear Europe, other from Advanced Bionics, grants from British Society of Audiology, grants from Healthcare Quality Improvement Partnership, other from Cochlear Europe, other from MED-EL, other from Advanced Bionics, grants from Oticon, personal fees from Maney publishers, outside the submitted work; .
Dr Kitterick reports grants from The Health Foundation during the conduct of this study; grant from Cochlear Europe, grant from Phonak, grant from British Society of Audiology.




Flow chart of project. Items in blue apply to all enrolled cochlear implant users, purple: control group only, orange: remote care group only, green: staff.
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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

| Section/item | Item No | Description | Addressed on page number |
|---|---|---|---|
| **Administrative information** | | | |
| Title | 1 | Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym | _____1_____ |
| Trial registration | 2a | Trial identifier and registry name. If not yet registered, name of intended registry | _____3_____ |
| | 2b | All items from the World Health Organization Trial Registration Data Set | _in registry entry_ |
| Protocol version | 3 | Date and version identifier | N/A for article_ |
| Funding | 4 | Sources and types of financial, material, and other support | _____8,23_____ _ |
| Roles and responsibilities | 5a | Names, affiliations, and roles of protocol contributors | _____1-2____ |
| | 5b | Name and contact information for the trial sponsor | _____8____ |
| | 5c | Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities | _____8_____ |
| | 5d | Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) | _____8, 14_____ |

| | | | |
|---|---|---|---|
| **Introduction** | | | |
| Background and rationale | 6a | Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention | 5-7 |
| | 6b | Explanation for choice of comparators | |
| Objectives | 7 | Specific objectives or hypotheses | 13-14 |
| Trial design | 8 | Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) | 8 |
| **Methods: Participants, interventions, and outcomes** | | | |
| Study setting | 9 | Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained | 8 |
| Eligibility criteria | 10 | Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) | 9 |
| Interventions | 11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | 10-11 |
| | 11b | Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) | N/A |
| | 11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) | 12 |
| | 11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | 10 |
| Outcomes | 12 | Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended | 12-13 |
| Participant timeline | 13 | Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) | Figure 1 |

| | | | |
|---|---|---|---|
| Sample size | 14 | Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations | 8 |
| Recruitment | 15 | Strategies for achieving adequate participant enrolment to reach target sample size | 8 |
| **Methods: Assignment of interventions (for controlled trials)** | | | |
| Allocation: | | | |
| Sequence generation | 16a | Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions | 9 |
| Allocation concealment mechanism | 16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned | 9 |
| Implementation | 16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | 9 |
| Blinding (masking) | 17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | 9 |
| | 17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial | |
| **Methods: Data collection, management, and analysis** | | | |
| Data collection methods | 18a | Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol | 11-14 |
| | 18b | Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols | |

| | | | |
|---|---|---|---|
| Data management | 19 | Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol | _____15_____ |
| Statistical methods | 20a | Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol | _____16_____ |
| | 20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | _____ |
| | 20c | Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) | _____ |
| **Methods: Monitoring** | | | |
| Data monitoring | 21a | Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed | ____15_____ |
| | 21b | Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial | _____ |
| Harms | 22 | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct | _____16-17____ |
| Auditing | 23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor | _____ |
| **Ethics and dissemination** | | | |
| Research ethics approval | 24 | Plans for seeking research ethics committee/institutional review board (REC/IRB) approval | _____17_____ |
| Protocol amendments | 25 | Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) | _____ |

| | | | |
|---|---|---|---|
| Consent or assent | 26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | ____17_____ |
| | 26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | ___N/A_____ |
| Confidentiality | 27 | How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial | _____17___ |
| Declaration of interests | 28 | Financial and other competing interests for principal investigators for the overall trial and each study site | _____24_____ |
| Access to data | 29 | Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators | ____15____ |
| Ancillary and post-trial care | 30 | Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation | _____ |
| Dissemination policy | 31a | Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions | _____17_____ |
| | 31b | Authorship eligibility guidelines and any intended use of professional writers | _____ |
| | 31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | _____ |
| **Appendices** | | | |
| Informed consent materials | 32 | Model consent form and other related documentation given to participants and authorised surrogates | _____ |
| Biological specimens | 33 | Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable | ____N/A_____ _ |

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

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



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

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## ABSTRACT

### Introduction

Many resources are required to provide post-operative 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 speech recognition testing, information, self-rehabilitation, advice, equipment training and troubleshooting.

The main outcome measure is patient activation. Secondary outcomes are stability and quality of hearing, stability of quality of life, clinic resources, patient and clinician experience, and any adverse events associated with remote care. We will examine the acceptability of remote care to service users and clinicians, the willingness of participants to be randomised, and attrition rates. We will estimate numbers required to plan a fully powered RCT.

### Ethics and dissemination

Ethical approval was received from North West – Greater Manchester South Research Ethics Committee (15/NW/0860) and the University of Southampton Research Governance Office (ERGO 15329).
Results will be disseminated in the clinical and scientific communities and also to the patient population via peer-reviewed research publications both online and in print, conference and meeting presentations, posters, newsletter articles, website reports, and social media.
Trial registration number ISRCTN 14644286

**Strengths and limitations of this study**

- This will be the first RCT of a triple approach to remote care for people using cochlear implants
- No formal power calculations were done as this is the first study of its kind and acts as a feasibility RCT
- The generic Patient Activation Measure® 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 all neural prostheses;[1] they can provide hearing to people with severe to profound deafness. Approximately 1,200 people receive a cochlear implant in the United Kingdom (UK) each year.[2] The total number of people with implants is approximately 14,000 in the UK and 600,000 worldwide.[3] Numbers are likely to increase rapidly: only approximately 5% of eligible people in the UK have received an implant,[3] and the number of people of retirement age is projected to increase by 28% by 2035[4] meaning a further increase in the number of hearing-impaired people. Cochlear implant care in the UK is provided at one of 19 tertiary centres involving assessment, surgery, and a resource-intensive acute phase of device adjustment and rehabilitation. These centres may be several hours away from the patient's home necessitating travel expense, time off work and family disruption. Currently UK implant centres review patients on a clinic-led schedule; this means that review appointments can occur that provide little benefit to the patient. Conversely when some patients attend a routine appointment, there is hearing deterioration which the patient had not noticed. This is often remedied by replacing equipment that the patient could have done at home. Making this care pathway patient-centred instead may provide a more efficient and effective service and allow more timely identification of issues.

When a patient attends a long-term follow-up appointment, the following tasks may be done: speech recognition testing, device adjustment, rehabilitation, equipment check and troubleshooting, and provision of replacement or upgraded equipment. We propose that at least some of these tasks could be done by the patient themselves at home, and that people using cochlear implants should only attend the clinic when there is clinical need (no more routine appointments). Potential benefits for the patient are:

- more stable hearing (problems identified and resolved quicker)
- better hearing (ability to fine tune when away from clinic)
- convenience of not travelling to routine appointments
- reduction of travel cost and time, time off work and disruption to family life
- increased confidence to manage own hearing
- greater equality in service delivery (same level of service regardless of distance from clinic)

It may also mean that the clinic has greater resources (time, money, space) to see complex cases and the expanding population of new patients; although health economics analysis will not occur in this trial. People using cochlear implants and their families would generally like to take a more active role in their care and welcome the use of technology to assist self-care.[5 6] The NHS has a strong commitment to supporting self-care for people with long-term conditions[7] with 'the vision of a citizen-centred, digitally-

enabled, health and social care system'.[8] Evidence shows a significant improvement in outcomes when patients use self-management tools[9] and those who are activated and involved in their care tend to have better health outcomes.[10 11]

**The standard clinical care pathway**

*Speech recognition testing*

The main speech recognition measure used in UK clinics is Bamford-Kowal-Bench (BKB) sentences[12] in quiet and noise; these are usually performed in a sound-treated room in the clinic by experienced clinicians, although there are some reports of testing remotely using an assistant at a remote location and video conferencing facilities.[13 14] Speech perception in noise testing using digits has been developed;[15] digits are highly familiar stimuli and are usually known by people with even basic language skills. Digit testing requires a closed set response and thus is suitable for self-testing over the telephone or internet[16 17] and has a minimal learning effect.[18] The test correlates well with speech recognition in noise with sentences in people using cochlear implants.[19-22] A digit test in English is freely available online at the Action on Hearing Loss website[23] and also as an application for mobile devices (Action on Hearing Loss Hearing Check).

*Device adjustment*

In order to provide benefit to a hearing-impaired person, the levels of electrical stimulation need to be individually adjusted for both soft and loud sounds on up to 22 electrode contacts in the cochlea. The levels can change as the person using a cochlear implant becomes more used to listening, more experienced at doing the task and as physiological changes occur. Most cochlear implant centres offer frequent appointments in the first few months following implantation and annual adjustment appointments thereafter.[24] Device adjustment usually occurs in the clinic in a sound-treated room, led by an experienced clinician. Several centres are now offering remote device programming.[13 25-32] However, these reports continue to use a clinician-centred model involving the patient attending a centre closer to their home where an assistant is present, and the cochlear implant centre clinician leading the session using video conferencing and remote desktop connection.

People using cochlear implants have commented that they would like to be able to adjust their device parameters in their own home or work environment, rather than just in the sound-treated clinic room.[5] The company Cochlear® have introduced a self-fitting paradigm (Remote Assistant Fitting) using the speech processor remote control that patients already have. This allows adjustment of programming to be

done by the patient at any time and anywhere with equivalent hearing outcomes to audiologist-led sessions.[33]

*Rehabilitation*

Many clinical resources are devoted to rehabilitation after people receive a cochlear implant; the new sound can be difficult to get used to. Rehabilitation appointments are frequent in the first year and may be offered annually thereafter.[34] Computer-based auditory training completed by the patient at home can significantly improve their speech recognition.[35]

*Equipment troubleshooting/repairs/spares provision/upgrades*

Cochlear implant speech processors are complex; some parts need regular replacement in order to keep the device in optimum condition.[36] No reminder is given on the device. Many NHS cochlear implant centres offer an upgraded speech processor approximately every 5 years, requiring a clinic visit.[34]

**The intervention**

This paper describes the protocol for a feasibility project to design, introduce and evaluate a patient-centred remote care approach for adults using cochlear implants long-term. This is necessary preparatory work for a fully powered randomised controlled trial (RCT) that will be extended across the UK. It is a prospective RCT whereby 60 patients will be randomised to either a control group (usual clinical care) or a remote care group where they are given access to new remote care tools. The patients in the remote care group will monitor their hearing at home, and some can fine-tune their hearing to suit their own real-world environment. Their other needs will be met through a personalised online support tool. Assessment of frontline staff perceptions of remote care will also be formally evaluated using repeated interviews with 10 staff members at the start, midpoint and end of the project. Empowering the patient to self-care at home could enable better and more stable hearing and a more convenient and accessible service.

## METHODS AND ANALYSIS

### Trial design

This will be a two-arm feasibility RCT involving 60 adults with cochlear implants with at least 6 months device experience in a 6 month clinical trial of remote care (see Figure 1 flow chart). This feasibility trial will inform a later fully powered RCT and will be used to estimate characteristics of the outcome measures, follow-up rates, adherence, willingness of participants to be randomised, and the number of eligible and willing participants. The later substantive RCT will aim to answer the question 'Is remote care an acceptable and effective method of caring for adults using cochlear implants?' using more participants and a longer time scale.

### Setting and participants

The trial will be conducted at the University of Southampton Auditory Implant Service (USAIS): a tertiary treatment centre mostly funded by NHS referrals. The study sponsor is the University of Southampton. The funder (The Health Foundation) and sponsor have not contributed towards the study protocol. Some anonymised data will be analysed at the University of Nottingham. Participants will not necessarily be USAIS patients.

### Proposed sample size

No formal power calculations were done as this is a feasibility trial to plan a later RCT. The literature suggests sample sizes between 30 and 50 for a feasibility trial.[36 37] Sixty participants was selected (30 in each group) in order to gather a range of different service users' experiences of the remote care tools and to estimate the effect size on the primary outcome measure.

### Recruitment

Potential participants will be sent a covering letter and the Participant Information Sheet several weeks before consenting. The clinical trial will begin in January 2016. There has been much interest in the project among people using cochlear implants in the UK, so adequate enrollment to reach target size is not of concern.

The Principal Investigator (PI) (Cullington) will access the USAIS clinical database and contact patients who fulfil the inclusion criteria, excepting those who have indicated that they do not wish to receive research invitations. Information will also be placed in the USAIS waiting room.

An advertisement will be placed on the USAIS website (www.AIS.southampton.ac.uk) from the date of ethical approval to the end of recruitment. A link will be tweeted from @UoS_AIS and @CIRemoteCare once a week from study ethical approval to end of recruitment. Details of the study will be placed on the National Cochlear Implant Users' Association website.

Patients from other centres may respond to the advertisement; we will obtain participants' permission to notify individual teams if their patients are involved.

**Inclusion criteria**

- Person using cochlear implant (any device, unilateral or bilateral) for at least 6 months
- Living in the UK
- Aged 18 years or more
- Able to give informed consent
- Sufficient English to understand study documentation and participate in testing
- Access to a computer or device with internet access

**Exclusion criteria**

- Those that do not fulfil the inclusion criteria plus any medical condition or known disability that would limit their capacity to use the online support tool

**Randomisation**

Participants who consent to the study will be allocated to the remote care pathway or the standard care pathway at the baseline visit by the PI using minimisation software.[37] Minimisation seeks to achieve a balance across the arms of a trial on one or more pre-defined patient characteristics.[38 39] The minimisation will balance the following factors:

- CI user less than a year or more than a year
- Gender
- Distance from the clinic (local or non-local i.e. within 20 miles or more than 20 miles away)
- Device (Cochlear or not)
- Ability to use Cochlear Remote Assistant Fitting (or not)

The approach will use biased coin minimisation with a base probability of 0.7. Imbalance between the groups will be quantified using the marginal balance method.[40]

**Blinding**

It will not be possible to blind participants to which group they are in. Baseline measures will be completed before allocation. Efforts will be made to blind clinicians to which group the participant belongs when they perform exit measures. Where possible, blinded measures will be passed to the University of Nottingham for analysis.

**Interventions**

*Control group: standard clinical care pathway*

Participants in the control group will continue with their usual care pathway; they will not have access to remote care. They will be asked to attend twice for this project: baseline and exit measures.

*Intervention group: remote care*

Those randomised into the treatment group (remote care group) will receive cochlear implant care remotely for 6 months. Clinic appointments will be given if required, and participants must still adhere to any medical check-ups with the cochlear implant surgeon. Participants may access the tools as often as they wish (minimum twice required for project) and can use them wherever they wish (at home, at a friend's house, at the library etc.). Remote care will comprise:

1 Remote and self-monitoring

Remote care trial participants will access a password-protected online speech recognition test based on the Triple Digit Test (TDT). The site is provided and maintained by Action on Hearing Loss. Participants will listen to sets of three digits in background noise and type in the numbers they hear. Participants will be required to do self-testing at least in months 1 and 6, but can do it at any time during the six months. They will be advised that they can do the hearing test using a direct connection from the computer sound card to their speech processor (with the advantage of excluding distracting home environmental noise) or they can listen via speakers (with the advantage of testing their whole hearing system including the microphone). Participants will be encouraged to experiment with different processor settings and programs and redo the test whenever they want. Although the number of times participants take the test will be recorded, the data captured will be qualitative only: participants' preference and experience of being able to test their hearing at home.

2 Self-adjustment of device (Remote Assistant Fitting)

Only those people using cochlear implants with newer Cochlear devices (CI500 series, CI422 or CI24RE devices using CP800 or CP900 series processors) will be able to participate in the self-adjustment of device; the other manufacturers do not have these tools yet. Participants will use Remote Assistant Fitting to adjust their device programming at any time anywhere. Patients will be required to do self-adjustment at least in months 1 and 6, but can do it at any time during the six months.

Those patients in the trial who are eligible for a processor upgrade will receive the upgrade at home rather than coming into the clinic. This will apply to users of all devices.

3 Online support tool

The research team will design a new online support tool for adults with cochlear implants using LifeGuide.[41] LifeGuide is an open source software platform that allows the development and trialling of interactive web-based interventions. This will be an iterative process incorporating feedback from service users at all stages, including focus groups of adults with cochlear implants. The online support tool (Cochlear Implant Remote Care, CIRCA) will incorporate personalised equipment help and information, troubleshooting, rehabilitation, goal-setting, help with music and telephone use and a method of ordering replacement equipment in an easy format to people who may be inexperienced Internet users. It will also store the TDT speech recognition test result entered by the participant and provide a comparison with the baseline test and appropriate feedback (no significant change or significantly worse: contact the centre). Participants will be given a unique user name to log in to this support tool; they can access it at any time. They will have the option to include a mobile phone number if they wish to receive reminder text messages for speech processor maintenance and study information.

The participant will enter the following:

- name they would like to be called
- email address
- main speech processor
- month and year of first implant surgery
- date microphone cover and rechargeable batteries were changed (if appropriate)
- year of birth (optional)
- first part of postcode (optional)
- born deaf or lost hearing (optional)
- mobile phone number (optional)

**Staff change management assessment**

Moving to remote care represents a significant change to cochlear implant centre staff; feedback will be obtained throughout from clinicians using a SharePoint (Microsoft Corporation, Redmond, WA, USA) feedback site, discussions at centre meetings, the project steering group, and informal discussions. A formal change evaluation will also occur. Interviews will be conducted with 10 members of the multidisciplinary team at three month intervals over a period of six months, (i.e. 0, 3, 6 months). Capturing data near the beginning, middle and end of the project will enable us to better capture the on-going and iterative relationships between perceptions and learning and how these change in response to leadership, social context and decision-making processes over time.[42] Interviews will be carried out in the work place or over the phone in accordance with the guidelines and codes of conduct recommended by both the British and American Psychological Societies.[43 44] Repeated interviews with the same individuals will provide insights into how the nature and content of challenges of telehealth implementation and acceptance are changing and evolving as part of a dynamic process. Examining and understanding staff responses to the change will optimise the chance of the change being sustainable.

The following information will be collected from staff:

- Age (in 10 year age bands)
- Gender
- Role in team
- Number of years working in cochlear implant centre

*Staff recruitment*

Ten staff members who work with adults using cochlear implants at USAIS will be recruited. An email will be sent to all eligible staff enclosing the Staff Participant Information Sheet. This information will also be placed on the staff SharePoint site. Any staff member working at USAIS in a clinical role with adults with implants will be eligible to take part, including staff who support patient equipment needs. A sample size of 10 was chosen in order to provide a variety of differing professions and viewpoints. If more than 10 people want to take part, participants will be selected in order to provide a balance of different clinical roles.

**Outcome measures**

*Baseline measures*

All participants will undergo the following baseline measures after signing the consent form:

- speech recognition testing (BKB sentences in quiet and noise and Triple Digit Test, TDT).
- Patient Activation Measure® (PAM®)
- the Speech, Spatial and Qualities of Hearing questionnaire (SSQ)
- quality of life questionnaire: Health Utilities Index (HUI) mark 3

The speech recognition testing is described under the earlier section 'Standard clinical care pathway'. The PAM® is a well-validated generic measure of patient activation that evaluates the knowledge, skills, beliefs and behaviours that patients have for self-management of their long-term condition.[45 46] It has been used extensively in over 200 peer-reviewed published studies.[47] The SSQ is a 49-item questionnaire measuring self-reported hearing disability over three domains: difficulties understanding speech in different situations, localising and tracking sounds, and ease of listening and naturalness of sound.[48] The HUI mark 3 (HUI3) is a multi-attribute health status classification system evaluating eight domains of vision, hearing, speech, ambulation, dexterity, emotion, cognition and pain.[49]
The following information will be collected on both the control group and remote care group during the clinical trial:

- Number and nature of clinic contacts and visits (including non-attendance)
- Repair logs
- Age
- Gender
- Postcode (to calculate distance to clinic) – Postcode data will be used once only in order to calculate the distance to the clinic and will then be destroyed
- Cochlear implant device and speech processor
- Highest formal educational qualifications
- Which cochlear implant centre takes care of the participant

All staff will be reminded to document all contact with patients as usual. Additionally in the remote care group, logs of their interaction with the remote care tools will be stored to assess adherence and utility.

*Exit measures (summer 2016)*

All participants will undergo the following exit measures:

- speech recognition testing (BKB sentences in quiet and noise and TDT)

- PAM®
- SSQ questionnaire
- HUI3

Travel expenses will be paid for both baseline and exit measure visits. The day of the exit measures will be considered to be the day the participants exit from the trial.

Participants in the remote care group will be asked to attend a focus group on the day of their exit measures in order to collect qualitative preference and experience data. Focus groups will be audio recorded and transcribed. A small number of participants in the remote care group will be asked if they would be willing to be videoed talking about remote care. These videos will be stored securely on a University of Southampton password-protected network using just the participant's ID. They will be used in presentations to report and promote the research.

*Primary outcome measure*

- Change (from day of entry into study to 6 months after remote care introduced) in patient activation measured using the PAM®

*Secondary outcome measures*

- 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 TDT, the SSQ questionnaire in both the control and treatment arms
- 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 measured using the HUI3 in both the control and treatment arms
- Patient preference for and experience of remote care in treatment arm reported qualitatively from feedback in online support tool and focus groups
- Clinician preference for and experience of remote care measured qualitatively from three interviews with up to 10 members of clinical staff

*Feasibility outcomes*

- 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 (hearing test, Remote Assistant Fitting, online support tool)

**Hypotheses**

*Primary*

- 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 PAM®.

*Secondary*

- There will be no more deterioration in hearing in the remote care group compared to the control group, measured using speech recognition (BKB, TDT) and the SSQ questionnaire.
- There will be no more deterioration in quality of life in the remote care group compared to the control group, measured using the HUI3.
- Service users (patients) will feel positive about remote care, measured qualitatively from feedback in online support tool and in focus groups.
- Clinicians will feel positive about remote care, measured qualitatively from interviews with clinical staff.

**Data handling**

Data will be managed according to the University of Southampton Research Data Management Policy (RDMP). An individual study Data Management Plan is stored on the University network. Stored data will be coded and anonymised, will not include name or address information and will be stored securely: all electronic data will be password protected. Hard copy data will be stored in a locked filing cabinet in a secure office. The University provides secure storage for all active research data (http://library.soton.ac.uk/researchdata/unistorage). The data are regularly backed up and a copy of the back up is regularly off-sited to a secure location for disaster recovery purposes. Research data will be kept for at least 10 years in line with University of Southampton policy.

Metadata records for the data (and published outputs) will also be maintained on the the University of Southampton Institutional Research Repository (ePrints). Each deposit can be assigned a unique Digital

Object Identifier (DOI) via the DataCite scheme, allowing it to be cited in publications. No personal data or identifiable data will be included in the data stored in the repository. This will be in accordance with the university's data security policy (http://www.calendar.soton.ac.uk/sectionIV/dppolicy.pdf) and the requirements of the Data Protection Act (1998).

The terms of the PAM® licence specify that up to 250 participants can be tested until August 2016. Non-personally identifiable individual data must be shared with Insignia. The data shared shall include individual level data records containing answers to each of the PAM® questions, and if captured i) demographic variables, health status and condition variables ii) specific outcome variables including health behaviours, self-management behaviours and whether patients using PAM® improved the self-management aspects of their health care and iii) the PAM® materials' effect on or relationship to patient health care utilisation and costs. Such data shall be reported to Insignia in an electronic format in approximately September 2016.

A data monitoring committee is not required due to the short period of follow-up and minimal project risks.

**Trial organisation and monitoring**

The trial is led by the PI (HC). Monthly research team meetings will be held. We have formed a Steering Group, with the remit of reflecting on the process and governance of the project including adverse events monitoring. The Steering Group comprises three USAIS clinicians, the USAIS Director, the PI, a consultant on change management (NC) and two service users (patients). It will meet at least three times.

**Data analysis plan**

To comply with recommendations, analysis will be mainly descriptive.[50] Scores on the PAM® (primary outcome), quality of life and hearing results will be compared between the two groups (control and remote care group), although statistical analysis of any differences will be interpreted with caution as no formal power calculation was in place, and will primarily be used to estimate effect sizes. Analysis will focus on whether the generic PAM® is sensitive enough to show change, or whether a condition-specific empowerment measure needs to be developed. Clinician and participant feedback, use of clinic resources (number and type of appointments) and feasibility outcomes will be reported and analysed qualitatively. IBM SPSS Statistics 21 will be used.

**Public and patient involvement, PPI**

The research team has a strong commitment to PPI; a member of the research team is a service user. This service user was known to the Principal Investigator to be interested in remote care, and has served on the USAIS Governance Group. The research team contains representatives from the main stakeholders: patient, clinician, cochlear implant company. Two additional service users are on the project Steering Group. Local and national publicity (website, twitter, presentation to National Cochlear Implant Users' Association, newsletter articles, letters, emails, Yahoo group) have already invited help in designing the research.

## ETHICS AND DISSEMINATION

Ethical approval was received from North West – Greater Manchester South Research Ethics Committee (15/NW/0860) and University of Southampton Research Governance Office (ERGO 15329).

### Ethics

Participation is entirely voluntary and it has been stressed to patients that if they do not participate, this will not affect their usual clinical care in any way. Written informed consent will be taken from all participants by the PI who has regular GCP (Good Clinical Practice) training. Participants are free to withdraw at any point without giving a reason. A risk analysis has been approved by the University of Southampton.

The PI will inform paticipants during the trial if any new information comes to light which may affect their willingness to participate.

### Confidentiality

Linked anonymity will be used. Participants will be assigned a unique identifier on enrollment. All results will be stored using only this ID. The lookup table will be stored on a password-protected University of Southampton network in a password-protected file separate from the study results, and will be accessible only to the research team.

Adults with cochlear implants are still rare in the general population (approximately 0.01% of the UK population). BMJ reporting guidelines will be followed: we will not report three or more indirect identifiers (for example place of treatment, sex, rare disease or treatment, age) for any individuals.[51]

### Dissemination

Research results will be presented locally, nationally and internationally. Dissemination will include but not be limited to peer-reviewed research publications both online and in print, conference and meeting presentations, posters, newsletter articles, website reports, and social media. In order to inform people with cochlear implants of the results, information will be sent to the National Cochlear Implant Users' Association and other patient groups, and the USAIS patient newsletter. Participants will be offered the opportunity to receive a summary of the findings.

## CONCLUSION

This will be the first RCT of a triple approach to remote care for people using cochlear implants. The study results will inform further work on a larger scale roll out of cochlear implant remote care in the UK.

## TRIAL STATUS

At the time of writing (January 2016), 58 participants have been enrolled.

## ACKNOWLEDGEMENTS

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## REFERENCES


1. Wilson BS, Dorman MF. Cochlear implants: current designs and future possibilities. J Rehabil Res Dev 2008;**45**(5):695-730.
2. BCIG. Annual update 2014-2015 2015 [Available from: http://www.bcig.org.uk/wp-content/uploads/2015/12/CI-activity-2015.pdf.
3. Ear Foundation. Cochlear implants http://www.earfoundation.org.uk/files/download/1221. In: Ear Foundation information sheet, ed., 2016.
4. Office for National Statistics. [Archived content] National population projections, 2010-based statistical bulletin http://webarchive.nationalarchives.gov.uk/20160105160709/http://ons.gov.uk/ons/rel/npp/national-population-projections/2010-based-projections/index.html, 2011.
5. Cullington HE. What do our service users really want? [poster]. British Cochlear Implant Group Annual Conference. Ayrshire, 2013.
6. Tsay IA. Using a patient-driven software tool for programming multiple cochlear implant patients simultaneously in a telemedicine setting. Thesis (PhD). University of Colorado at Denver, 2013.
7. NHS. Five year forward view. In: NHS, ed., 2014.
8. National Information Board. Personalised Health and Care 2020. Work stream 1.1: Enable me to make the right health and care choices: providing patients and the public with digital access to health and care information and transactions https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/442834/Work_Stream_1_1.pdf, 2015.
9. Panagioti M, Richardson G, Small N, et al. Self-management support interventions to reduce health care utilisation without compromising outcomes: a systematic review and meta-analysis. BMC Health Serv Res 2014;**14**:356.
10. Hibbard JH, Greene J, Shi Y, et al. Taking the long view: how well do patient activation scores predict outcomes four years later? Med Care Res Rev 2015;**72**(3):324-37.
11. Mosen DM, Schmittdiel J, Hibbard J, et al. Is patient activation associated with outcomes of care for adults with chronic conditions? J Ambul Care Manage 2007;**30**(1):21-9.
12. Bench J, Kowal A, Bamford J. The BKB (Bamford-Kowal-Bench) sentence lists for partially-hearing children. Br J Audiol 1979;**13**(3):108-12.
13. Hughes ML, Goehring JL, Baudhuin JL, et al. Use of telehealth for research and clinical measures in cochlear implant recipients: a validation study. J Speech Lang Hear Res 2012;**55**(4):1112-27.
14. Goehring JL, Hughes ML, Baudhuin JL, et al. The effect of technology and testing environment on speech perception using telehealth with cochlear implant recipients. J Speech Lang Hear Res 2012;**55**(5):1373-86.
15. Smits C, Kapteyn TS, Houtgast T. Development and validation of an automatic speech-in-noise screening test by telephone. Int J Audiol 2004;**43**:15-28.
16. Smits C, Houtgast T. Results from the Dutch speech-in-noise screening test by telephone. Ear Hear 2005;**26**(1):89-95.
17. Smits C, Merkus P, Houtgast T. How we do it: The Dutch functional hearing-screening tests by telephone and internet. Clin Otolaryngol 2006;**31**(5):436-40.
18. Smits C, Theo Goverts S, Festen JM. The digits-in-noise test: assessing auditory speech recognition abilities in noise. J Acoust Soc Am 2013;**133**(3):1693-706.
19. Mahafzah M. The Triple Digit Test: a self-test of speech perception in cochlear implant users. Thesis (MSc). University of Southampton, 2013.
20. Aidi T. The Triple Digit Test: A validity and feasibility study. Thesis (MSc). University of Southampton, 2015.
21. Kaandorp MW, Smits C, Merkus P, et al. Assessing speech recognition abilities with digits in noise in cochlear implant and hearing aid users. Int J Audiol 2015;**54**(1):48-57.
22. Agyemang-Prempeh A. Telemedicine in cochlear implants: a new way of conducting long term patient follow-up. Thesis (MSc). University of Southampton, 2012.
23. Action on Hearing Loss. Check your hearing 2015 [Available from: http://www.actiononhearingloss.org.uk/your-hearing/look-after-your-hearing/check-your-hearing/take-the-check.aspx.
24. Vaerenberg B, Smits C, De Ceulaer G, et al. Cochlear Implant Programming: A Global Survey on the State of the Art. The Scientific World Journal 2014;**2014**:1-12.

25. Eikelboom RH, Jayakody DM, Swanepoel DW, et al. Validation of remote mapping of cochlear implants. J Telemed Telecare 2014;**20**(4):171-77.
26. Kuzovkov V, Yanov Y, Levin S, et al. Remote programming of MED-EL cochlear implants: users' and professionals' evaluation of the remote programming experience. Acta Otolaryngol 2014;**134**(7):709-16.
27. McElveen JT, Jr., Blackburn EL, Green JD, Jr., et al. Remote Programming of Cochlear Implants: A Telecommunications Model. Otol Neurotol 2010;**31**(7):1035-40.
28. Ramos A, Rodriguez C, Martinez-Beneyto P, et al. Use of telemedicine in the remote programming of cochlear implants. Acta Otolaryngol 2009;**129**(5):533-40.
29. Rodriguez C, Ramos A, Falcon JC, et al. Use of telemedicine in the remote programming of cochlear implants. Cochlear Implants Int 2010;**11 Suppl 1**:461-4.
30. Wesarg T, Wasowski A, Skarzynski H, et al. Remote fitting in Nucleus cochlear implant recipients. Acta Otolaryngol 2010;**130**(12):1379-88.
31. Wasowski A, Skarzynski PH, Lorens A, et al. Remote fitting of cochlear implant system. Cochlear Implants Int 2010;**11 Suppl 1**:489-92.
32. Samuel PA, Goffi-Gomez MV, Bittencourt AG, et al. Remote programming of cochlear implants. Codas 2014;**26**(6):481-6.
33. Botros A, Banna R, Maruthurkkara S. The next generation of Nucleus((R)) fitting: a multiplatform approach towards universal cochlear implant management. Int J Audiol 2013;**52**(7):485-94.
34. Muller J, Raine CH. Quality standards for adult cochlear implantation. Cochlear Implants Int 2013;**14 Suppl 2**:S6-12.
35. Fu QJ, Galvin J, Wang X, et al. Effects of auditory training on adult cochlear implant patients: a preliminary report. Cochlear Implants Int 2004;**5 Suppl 1**:84-90.
36. Cochlear.com. Nucleus 6 care and maintenance accessed 01/03/2016 [Available from: http://www.cochlear.com/wps/wcm/connect/us/recipients/nucleus-6/nucleus-6-basics/care-and-maintenance.
37. Saghaei M, Saghaei S. Implementation of an open-source customizable minimization program for allocation of patients to parallel groups in clinical trials. J Biomedical Science and Engineering 2011;**4**:734-39.
38. Taves DR. Minimization: a new method of assigning patients to treatment and control groups. Clin Pharmacol Ther 1974;**15**(5):443-53.
39. Pocock SJ, Simon R. Sequential treatment assignment with balancing for prognostic factors in the controlled clinical trial. Biometrics 1975;**31**(1):103-15.
40. Han B, Enas NH, McEntegart D. Randomization by minimization for unbalanced treatment allocation. Stat Med 2009;**28**(27):3329-46.
41. Introduction to the LifeGuide: software facilitating the development of interactive behaviour change internet interventions. The Society for the Study of Artificial Intelligence and Simulation of Behaviour; 2009; Edinburgh.
42. Pettigrew AM. Context and action in the transformation of the firm. J Manage Stud 1987; **24**(6):649-70.
43. American Pyschological Association. Ethical principles of Psychologists and code of conduct. , 2002.
44. British Psychological Society. Code of Ethics and Governance. 2009.
45. Hibbard JH, Mahoney ER, Stockard J, et al. Development and testing of a short form of the patient activation measure. Health Serv Res 2005;**40**(6 Pt 1):1918-30.
46. Hibbard JH, Stockard J, Mahoney ER, et al. Development of the Patient Activation Measure (PAM): conceptualizing and measuring activation in patients and consumers. Health Serv Res 2004;**39**(4 Pt 1):1005-26.
47. Insignia Health. http://www.insigniahealth.com/products/pam-survey [
48. Gatehouse S, Noble W. The Speech, Spatial and Qualities of Hearing Scale (SSQ). Int J Audiol 2004;**43**(2):85-99.
49. Feeny D, Furlong W, Boyle M, et al. Multi-attribute health status classification systems. Health Utilities Index. Pharmacoeconomics 1995;**7**(6):490-502.
50. Lancaster GA, Dodd S, Williamson PR. Design and analysis of pilot studies: recommendations for good practice. J Eval Clin Pract 2004;**10**(2):307-12.
51. Hrynaszkiewicz I, Norton ML, Vickers AJ, et al. Preparing raw clinical data for publication: guidance for journal editors, authors, and peer reviewers. BMJ 2010;**340**:c181.

## AUTHOR CONTRIBUTIONS

Cullington, Kitterick, DeBold, Weal, Clarke, Newberry and Aubert made substantial contributions to the conception and design of the work, revised it critically for intellectual content and approved the final manuscript. They agree to be accountable for their work. Cullington leads the work and takes overall responsibility for the manuscript. Kitterick was involved in all aspects. DeBold and Aubert were responsible for the incorporation of the parts of the protocol specific to Cochlear devices; Weal worked especially on the LifeGuide parts; Newberry gave particular input to PPI; Clarke was responsible for the staff assessment components.

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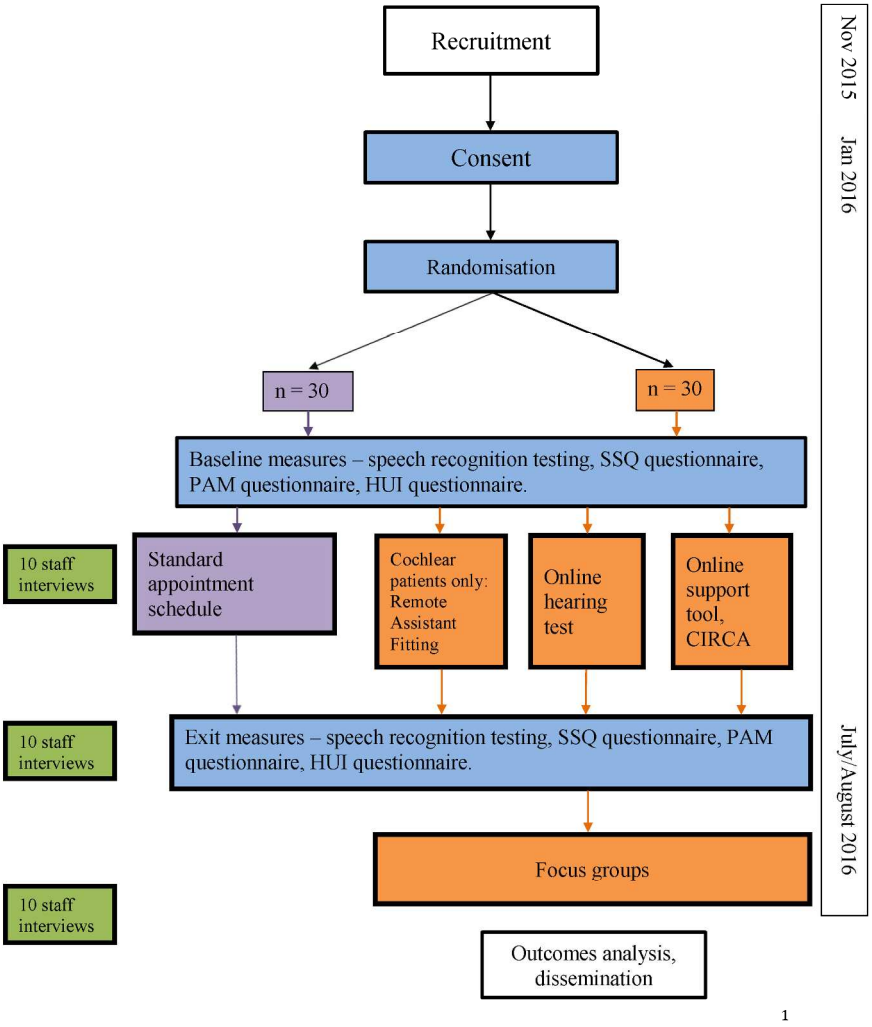
COMPETING INTERESTS STATEMENT

The PI, Cullington, performs occasional private consultancy work for the cochlear implant company Cochlear Europe.




Flow chart of project. Items in blue apply to all enrolled cochlear implant users, purple: control group only, orange: remote care group only, green: staff.
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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

| Section/item | Item No | Description | Addressed on page number |
|---|---|---|---|
| **Administrative information** | | | |
| Title | 1 | Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym | _____1_____ |
| Trial registration | 2a | Trial identifier and registry name. If not yet registered, name of intended registry | _____3_____ |
| | 2b | All items from the World Health Organization Trial Registration Data Set | _in registry entry_ |
| Protocol version | 3 | Date and version identifier | N/A for article_ |
| Funding | 4 | Sources and types of financial, material, and other support | _____8,23_____ _ |
| Roles and responsibilities | 5a | Names, affiliations, and roles of protocol contributors | _____1-2____ |
| | 5b | Name and contact information for the trial sponsor | _____8____ |
| | 5c | Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities | _____8_____ |
| | 5d | Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) | _____8, 14_____ |

| | | | |
|---|---|---|---|
| **Introduction** | | | |
| Background and rationale | 6a | Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention | 5-7 |
| | 6b | Explanation for choice of comparators | |
| Objectives | 7 | Specific objectives or hypotheses | 13-14 |
| Trial design | 8 | Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) | 8 |
| **Methods: Participants, interventions, and outcomes** | | | |
| Study setting | 9 | Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained | 8 |
| Eligibility criteria | 10 | Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) | 9 |
| Interventions | 11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | 10-11 |
| | 11b | Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) | N/A |
| | 11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) | 12 |
| | 11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | 10 |
| Outcomes | 12 | Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended | 12-13 |
| Participant timeline | 13 | Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) | Figure 1 |

| | | | |
|---|---|---|---|
| Sample size | 14 | Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations | 8 |
| Recruitment | 15 | Strategies for achieving adequate participant enrolment to reach target sample size | 8 |
| **Methods: Assignment of interventions (for controlled trials)** | | | |
| Allocation: | | | |
| Sequence generation | 16a | Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions | 9 |
| Allocation concealment mechanism | 16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned | 9 |
| Implementation | 16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | 9 |
| Blinding (masking) | 17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | 9 |
| | 17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial | |
| **Methods: Data collection, management, and analysis** | | | |
| Data collection methods | 18a | Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol | 11-14 |
| | 18b | Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols | |

| | | | |
|---|---|---|---|
| Data management | 19 | Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol | _____15_____ |
| Statistical methods | 20a | Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol | _____16_____ |
| | 20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | _____ |
| | 20c | Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) | _____ |
| **Methods: Monitoring** | | | |
| Data monitoring | 21a | Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed | ____15_____ |
| | 21b | Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial | _____ |
| Harms | 22 | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct | _____16-17____ |
| Auditing | 23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor | _____ |
| **Ethics and dissemination** | | | |
| Research ethics approval | 24 | Plans for seeking research ethics committee/institutional review board (REC/IRB) approval | _____17_____ |
| Protocol amendments | 25 | Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) | _____ |

| | | | |
|---|---|---|---|
| Consent or assent | 26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | ____17_____ |
| | 26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | ___N/A_____ |
| Confidentiality | 27 | How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial | _____17___ |
| Declaration of interests | 28 | Financial and other competing interests for principal investigators for the overall trial and each study site | _____24_____ |
| Access to data | 29 | Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators | ____15____ |
| Ancillary and post-trial care | 30 | Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation | _____ |
| Dissemination policy | 31a | Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions | _____17_____ |
| | 31b | Authorship eligibility guidelines and any intended use of professional writers | _____ |
| | 31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | _____ |
| **Appendices** | | | |
| Informed consent materials | 32 | Model consent form and other related documentation given to participants and authorised surrogates | _____ |
| Biological specimens | 33 | Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable | ____N/A_____ _ |

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.