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Have cochlear implant; won't have to travel. Introducing telemedicine to people using cochlear implants

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ABSTRACT

Purpose: This paper describes a planned project to design, implement, and evaluate remote care for adults using cochlear implants and compare their outcomes with those following the standard care pathway.

Method: Sixty people with cochlear implants will be recruited and randomized to either the remote care group or a control group. The remote care group will use new tools for 6 months: remote and self-monitoring, self-adjustment of device, and a personalized online support tool. The main outcome measure is patient empowerment, with secondary outcomes of hearing and quality of life stability, patient and clinician preference, and use of clinic resources.

Conclusion: The clinical trial ends in summer 2016. Remote care may offer a viable method of follow-up for some adults with cochlear implants.

At the end of 2014, 41% of the world were using the internet (The World Bank, 2015). Half of the world's population now has at least one mobile phone account. By 2020 it is predicted that around 60% of the global population will have a mobile subscription (GSMA, 2015). The proliferation of internet connectivity and use opens up new possibilities for health care delivered remotely via the internet. In the past few years, we have seen the introduction of wearable technology: smart watches, fitness monitors, activity trackers, smart glasses, etc. However to find wearable technology we need look no further than the hundreds of thousands of people with cochlear implants worldwide – already wearing a technologically-advanced device all their waking hours.

In order to maintain scalability of cochlear implant services, some changes are needed due to:

1) Increasing patient numbers. Currently around 50,000 cochlear implant surgeries occur each year globally (Hochmair, 2013). Approximately 500,000 people use cochlear implants worldwide (estimated from NIDCD, 2014); this represents almost a tripling of numbers in the last 7 years (Peters, Wyss, & Manrique, 2010). This large increase is likely due to better awareness of the benefits of cochlear implantation (among hearing-impaired people and referrers), more market penetration worldwide, expanding candidacy criteria, and ageing populations worldwide (World Health Organisation, 2016). Can we continue to offer the same level of service to this ever-increasing population of people using implants? Will funding for cochlear implants also triple in 7 years?

2) Patient preference. People using cochlear implants and their families would generally welcome telemedicine and more involvement in their hearing care (Cullington, 2013; Tsay, 2013). Focus groups held during design of this project revealed that some people with cochlear implants want to adjust their own mapping in a real world environment rather than in a sound-treated test room, they want to be able to test their own hearing and device when convenient for them, and would like more patient-centered care. With only few cochlear implant centers, many patients live far from their center which may necessitate a whole day lost from work, childcare, education, etc. to attend a routine appointment. For example in the United Kingdom there are 19 cochlear implant centers caring for more than 13,000 (BCIG, 2015) people using implants spread over a land area of around 94,000 square miles resulting in some people having a journey of several hours. The 60 participants in this project live between 5 and 156 miles from their cochlear implant center with a mean distance of 42 miles (standard deviation = 31 miles). The

situation is worse in other countries with more geographically dispersed populations, where the access to a cochlear implant audiologist may be highly variable (McElveen et al., 2010).

3) Current pathway is not patient-centered. The current care pathway for adults using cochlear implants typically involves annual visits after surgery for the whole of the patient's life. Most implant centers 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; hearing deterioration is found which the patient had not noticed. This can usually be remedied by replacing equipment; if the patient had realized, they could have done this themselves at home. Making this care pathway patient-centered instead (no more routine appointments – only attend clinic when needed) may provide a more efficient service and allow more timely identification of issues.

This paper describes a pilot project to introduce patient-centered remote clinical care to adults using cochlear implants. There is evidence to show a significant improvement in outcomes when patients use self-management tools (Panagioti et al., 2014). Furthermore, patients who are activated and involved in their care have better health outcomes (Hibbard, Greene, Shi, Mittler, & Scanlon, 2015; Mosen et al., 2007).

METHOD

Patient and public involvement (PPI) has been a large feature of the design of this project. A member of the research team uses a cochlear implant, and two additional service users are members of the project Steering Group. Local and national publicity (website, twitter, presentations, newsletter articles, letters, emails, and social media) has resulted in around 100 people with cochlear implants willing to help design and plan the research. These patients have been involved in focus groups, reviewing materials remotely, and design of a new questionnaire.

This project will design, introduce, and evaluate a triple approach to remote care: remote and self-monitoring, self-adjustment of device, and an online support tool. Sixty adults with cochlear implants will be recruited to participate in a 6 month clinical trial: they will be randomized to a remote care group using the new tools (n = 30) or to a control group following the usual care pathway (n = 30). The standard pathway involves routine follow-up appointments offered to the patient on a clinic-led schedule. As this is an innovative pilot study, no formal power calculations were done; sample sizes of between 30 and 50 are suggested (Browne, 1995; Sim & Lewis, 2012). Sixty participants was selected (30 in each group) in order to gather a range of different service users' experiences. The inclusion criteria are:

- Person using a 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

Remote and self-monitoring

Remote care trial participants will access an online speech-in-noise test based on the Triple Digit Test (Smits, Kapteyn, & Houtgast, 2004) with good correlation to clinic tests (Agyemang-Prempeh, 2012). This will be accessed via a custom interface maintained by Action on Hearing Loss.
Patients will be required to do self-testing at least in months 1 and 6 of the clinical trial, but can do it at any time.

Self-adjustment of device

Only participants using Cochlear devices (CI500 series, CI422 or CI24RE devices using CP800 or CP900 series processors) will be able to participate in device self-adjustment using Remote Assistant Fitting. This allows the patient to do adjustment of programming with equivalent hearing outcomes to audiologist-led sessions (Botros, Banna, & Maruthurkkara, 2013). 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 (upgrade of external equipment usually happens every 5 years) will be sent the upgrade by mail to their home rather than coming into the clinic.

Online support tool

- The research team will design a new online cochlear implant support tool using LifeGuide (Williams, Yardley, & Wills, 2013); LifeGuide is an open source software that allows intervention designers with no experience of programming to create interactive web-based interventions. This will be an iterative process incorporating feedback from service users and clinicians at all stages. The online support tool will include equipment help and information, troubleshooting, goal-setting, rehabilitation, help with music and telephone use, and a method of ordering replacement equipment. The online support tool will also give feedback on the participant's Triple Digit Test result.

Outcome measures

Primary outcome measure

- Change in patient activation measured using the Patient Activation Measure (PAM®) (Hibbard, Stockard, Mahoney, & Tusler, 2004) and a custom-designed cochlear implant patient empowerment measure (CI-EMP) in both the remote care and control groups (Kitterick, Fackrell, & Cullington, 2016).

Secondary outcome measures

- Stability of hearing measured by change in speech recognition measured using BKB sentences (Bench, Kowal, & Bamford, 1979), the Triple Digit Test, the Speech, Spatial and Qualities of Hearing (SSQ) questionnaire (Gatehouse & Noble, 2004).

- Stability of quality of life measured by change in quality of life using the Health Utilities Index (HUI) mark 3 (Feeny, Furlong, Boyle, & Torrance, 1995)
- Patient preference measured qualitatively from focus groups and feedback
- Clinician preference measured qualitatively from interviews
- Information will also be collected regarding the number and nature of clinic contacts in both groups, and any adverse events associated with remote care.

Analysis

To comply with recommendations for pilot studies, analysis will be mainly descriptive.(Lancaster, Dodd, & Williamson, 2004). 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. Clinician and participant feedback, use of clinic resources (number and type of appointments) and feasibility outcomes will be reported and analyzed qualitatively.

DISCUSSION

As this paper describes a planned project, no results are available yet. The 6 month clinical begun in January 2016. This project will introduce remote care to a group of 30 adults with cochlear implants and compare their outcomes with a control group following the standard pathway**.** 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

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 this analysis is outside the scope of this project.

Offering remote care tools may offer significant benefit to some patients, but as with all treatments, one size will not fit all. One method of differentiating suitable patients may be to use the newly-developed CI-EMP questionnaire at a routine clinical appointment (perhaps at 1 year after implantation). The results of this measure of empowerment may be discussed between the patient and clinician in order to decide together which care pathway is most appropriate. An assessment of the patient's readiness to use

technology to manage their care may also be required, by using an additional questionnaire (Gurupur et al., 2016).

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CONFLICT OF INTERESTS STATEMENT

The first author (HC) performs occasional private consultancy work for the cochlear implant company Cochlear Europe. Kitterick is in receipt of grant funding from Cochlear Europe for a multi-center trial of cochlear implantation in patients with unilateral deafness and for a feasibility study of a new implantable hearing implant. University of Southampton receives research consultancy funding from Advanced Bionics.

This paper summarizes an oral presentation made at the 2nd International Meeting on Internet and Audiology, 2015. Similar work was also presented at the 12th European Symposium Pediatric Cochlear Implant 2015 and has subsequently been accepted as a protocol paper in BMJ Open (Cullington et al., 2016).

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