Designing and Assessing the Feasibility of a Randomised Controlled Trial of Bilateral Cochlear Implants in Adults

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For about two years we have been running a project which looks at whether we can do a clinical trial for a very large piece of research on bilateral cochlear implants for adults. As it is not a clinical trial itself but lays the foundation for a future trial it is called a foundation study.

The updated NICE guidance does not recommend bilateral implants for adults but it does not say that they do not provide benefits. They agreed that they do provide additional benefits over one implant. In particular they quoted input from patients themselves which said that two implants can help reduce listening difficulties and improve spatial hearing, that is whether the sound comes from this side or that side, so that they can help reduce listening effort and fatigue and can provide benefits to overall health and wellbeing. NICE want us to measure quality of life - health and wellbeing – not how good someone is on a test of speech understanding or sound localisation.

The question is can we do that? As the trial will cost money and will need the support of the companies the answer to this question is important. Will patients agree to take part and will they agree to be randomised so that whether they get one or two implants will be outside their control. This is necessary as the quality of life of people who have one implant needs to be compared with people who have two and, in order to measure this, the participants need to be willing to complete questionnaires.

The size of the trial, or how many patients are needed, is another matter that has to be resolved. If a big change is expected only a few are needed but if it is only a small and subtle difference many more need to be recruited.

A survey of candidates, existing implant users and clinical professionals has already been done. There were people awaiting an implant, people who had only been implanted a few weeks and people who had been using their implants for a long time. There were also unilateral and bilateral implant users. Almost 100 cochlear implant users and 40 health care professionals took part. Many issues came up. Only patients who were considered suitable for two implants would be randomised to get one or two. Both the clinical team and the patient would have to agree to this. Residual hearing is a huge issue as many people are unsure about which ear to go for. Should they have the poorer ear implanted and have a hearing aid in the better ear and so on. Another point that arose is that there is no really good accessible information about the benefits and risks of two implants versus one. A website with videos of people who have two implants or one implant talking about their experiences and the issues they have to deal with might help.

We asked participants two key questions. The first was do you think adult candidates would consider participating in the clinical trial. The health care professionals were a little more optimistic about the trial but in general three quarters of the implant users and clinicians thought that people would consider participating in the trial. About two thirds of the implant users and candidates in the survey would themselves have considered participating in the clinical trial.

The second part of the study involved screening adults who were going through the assessment pathway. Five auditory implant programmes were involved: Nottingham, St Thomas', Manchester and Southampton. To date they have screened nearly 350 candidates who were eligible for two implants and could participate in the trial. The acceptance level was sufficient to support a subsequent trial. All this happened in six months but we have yet to complete the analysis of the quality of life data.

There is a study management team and a steering group with an independent chair and independent members to oversee how we do the study. Our patient representative on the study management team is Richard Byrnes of the NCIUA.