Author’s response to reviews

Title: Comparison of the benefits of cochlear implantation versus contra-lateral routing of signal hearing aids in adult patients with single-sided deafness: study protocol for a prospective within-subject longitudinal trial

Authors:

Pádraig T Kitterick (padraig.kitterick@nottingham.ac.uk)
Gerard M O'Donoghue (gerard.o'donoghue@nottingham.ac.uk)
A Mark Edmondson-Jones (mark.edmondson-jones@nottingham.ac.uk)
Andrew Marshall (andrew.marshall@nuh.nhs.uk)
Ellen Jeffs (ellen.jeffs@nuh.nhs.uk)
Louise Craddock (louise.craddock@uhb.nhs.uk)
Alison Riley (alison.riley@uhb.nhs.uk)
Kevin Green (kevin.green@cmft.nhs.uk)
Martin O'Driscoll (martin.odriscoll@cmft.nhs.uk)
Dan Jiang (d.jiang.uk@gmail.com)
Terry Nunn (terry.nunn@gstt.nhs.uk)
Shakeel Saeed (shakeel.saeed@ucl.ac.uk)
Wanda Aleksy (wanda.aleksy@uclh.nhs.uk)
Bernhard U Seeber (seeber@tum.de)

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To the editor,

Please find enclosed a revised manuscript reporting the protocol for our clinical trial entitled “Comparison of the benefits of cochlear implantation versus contra-lateral routing of signal hearing aids in adult patients with single-sided deafness: study protocol for a prospective within-subject longitudinal trial”. We have revised the manuscript to address the requests of the two anonymous reviewers. Each of the requests is listed below with our response in italic font.

Reviewer 1

1. Overall, there is nothing structurally wrong with the trial or the paper but I do wonder what is so excitingly new about this trial compared to what has already been done in the study by Arndt et al. (2009).

   Note: In our response, we assume that the reviewer is referring to Arndt et al. (2011) as cited in our manuscript as we could not identify a study by Arndt et al published in 2009.

   We identify 5 primary differences between our study and that of Arndt et al. which we assert are noteworthy:

   1. Arndt et al.’s inclusion criteria defined participants as those for whom a CROS or a BAHA had already failed to provide sufficient benefit prior to entering the study. The inclusion criteria for our study do not specify that participants should have already failed to benefit from a CROS. Instead, insufficient benefit is determined as part of the study protocol using a specific device and standard fitting procedure. The results of our study, particularly the outcomes from the 3-month CROS trial, will therefore be more readily generalizable to the wider set of individuals who present with an acquired single-sided deafness in the clinic rather than just to the subset of patients who have already been found to receive insufficient benefit from a CROS.

   In addition, the Methods/Design section has been revised to provide this justification for the duration of the CROS follow-up period, as follows: “The duration of the CROS trial (3 months) was chosen in consultation with clinical colleagues from several UK audiology services to ensure that (a) it was of sufficient duration to allow the benefits from CROS to emerge; (b) any benefits from CROS would have stabilised; and (c) self-reported benefits would be based on patients’ experience of CROS use rather than any pre-conceived expectations (whether positive or negative).”

   3. Participants in Arndt et al. indicated their localisation responses by selecting one of 7 loudspeakers separated by 30 degrees which were visible to the participant. In contrast, participants in our study will indicate the location of sounds by adjusting the position of a
visual marker with high precision (< 1 degree azimuth) while the set of possible locations are unknown to them. The use of this measurement method will: a) provide far more precise estimates of the localisation ability of participants compared to that of Arndt et al; and b) provide a better estimate of real-world localisation performance in which patients do not localise by choosing from one of several known locations.

The Sound Localisation sub-section in the ‘Primary Outcome Measures’ section has been revised to clarify the precision of the method, as follows: “The task of participants will be to indicate the perceived location of the sound by moving a visual pointer projected onto the curtain. The position of the visual pointer will be adjusted using a computer-controlled trackball mouse and with a precision exceeding one degree of visual angle.”

4. Arndt et al. assessed localisation performance in a sound-treated room. In our study, localisation performance will be assessed under anechoic conditions and under simulated reverberant conditions. This approach will allow the effects of reverberation on localisation performance to be determined separately from the ability to localise under ideal conditions.

The Sound Localisation sub-section in the ‘Primary Outcome Measures’ section has been revised to highlight the utility of our method, as follows: “The ratio between the direct and reverberant sound will be varied to simulate different room characteristics from anechoic (no reflections) to highly-reverberant. Localisation accuracy in anechoic conditions will reflect the ability of participants to access and use monaural spectral cues and inter-aural cues under ideal listening conditions. Comparison of localisation in anechoic conditions and in reverberant conditions will identify the level of reverberation that participants can tolerate while maintaining accuracy.”

5. Arndt et al. observed ceiling effects for some spatial configurations of speech and noise when assessing speech perception using the HSM sentence test. While an adaptive sentence test in noise which avoids such ceiling effects was used, it was only administered unaided and 6-months after cochlear implantation and not after CROS/BAHA use. Our study will administer adaptive tests of speech perception in noise at baseline, after 3 months of CROS use, and after 9 months of CI use.

The ‘Speech understanding in noise’ sub-section of the ‘Primary Outcome Measures’ section has been revised to clarify that our method avoids floor and ceiling effects, as follows: “SRTs will be measured using an adaptive procedure to avoid floor and ceiling effects by varying the level of the speech and noise from trial to trial based on the accuracy with which the participant recalls keywords in the sentences.”

2. The study as it is designed as such may have one important flaw, and that is the way that the normal hearing ear is occluded. The paper doesn’t say how the speech is presented (FF or via headphones), but I suspect in FF, but it says that speech is presented at 70dB. A combination of an earplug and a circumaural muffler would only give you a masking of about 40dB max., which will mean the good hearing ear will still hear 30dB if you present speech at 70dB. If I am getting this wrong, please explain better in the paper.

We have revised the manuscript to clarify that BKB sentences are presented in the soundfield when performing the initial assessment of the normal-hearing ear, as follows: “Two lists of Bamford-Kowal-Bench (BKB) sentences will be presented at 70 dB Sound
Pressure Level from a loudspeaker positioned in front of the patient while their normal hearing ear is occluded using a combination of an earplug and a circumaural muffler.

We share the concern of the reviewer that it is important to adequately assess the impaired ear function and we acknowledge that the combination of an earplug and circumaural muffler may be insufficient to attenuate the sentences below threshold in the normal-hearing ear. This issue is addressed in the ‘Inclusion Criteria’ section, as follows: “If the percentage of keywords reported correctly is 50% or greater [when using an earplug and circumaural muffler], performance will be reassessed using two different BKB lists while the function of the normal hearing ear is further degraded using a combination of a masking noise presented at 50 dB(A) via an insert tube-phone and a circumaural muffler.”

The use of masking noise at 50 dB(A) in combination with a circumaural muffler would be expected to severely limit the contribution of the normal-hearing ear. It was felt that if a participant could still report 50% or more key words correctly under these conditions, then there would be sufficient uncertainty over the level of function in the impaired ear to justify their exclusion from the study.

Reviewer 2

1. I would recommend a little additional information on the CROS system, which is reported as standard care for single-sided deafness in the UK. Does this refer to conventional (air conduction) only or also include quasi-transcranial and transcranial bone conduction CROS systems?

We have revised the ‘Contra-lateral Routing of Signals’ sub-section of the ‘Interventions’ section to emphasise that the CROS system is a conventional air conduction system, as follows: “The CROS hearing aid comprises a conventional acoustic hearing aid and a remote microphone. The remote microphone is worn on the impaired ear and the hearing aid is worn on the non-impaired ear. Sounds arriving at the impaired ear are picked up by the remote microphone and sent via a wireless link to the hearing aid which delivers the sounds via air conduction to the non-impaired ear. The acoustic coupling for the hearing aid is selected to have the smallest possible impact on the sound arriving at the non-impaired ear.”

2. Please provide reference(s) if there is evidence for the statement below to indicate that some patients with SSD who are eligible candidates for a BAHA do not choose the device: “The placement of a permanent bone-anchored abutment through the skin may also be unacceptable to some patients.”

We have revised the Background section to provide a citation for the statement about patient preferences for the placement of the abutment, as follows: “Poor localisation ability has been cited by patients as a factor which contributes to their decision not to receive a BAHA as have cosmetic concerns about the placement of a permanent bone-anchored abutment through the skin [17].”

3. p. 3. End of 1st paragraph, methods section. The secondary endpoints are clearly stated and it would be useful to have the primary endpoints identified briefly in this section as well, i.e., sound localisation and speech recognition.
The 1st paragraph of the Methods/Design section has been revised to state the primary endpoints, as follows: “The primary endpoints are the assessments of sound localisation and speech understanding in noise at baseline, after CROS aiding, and after cochlear implantation."

4. I found myself looking for how ‘minimal benefit from a hearing aid’ will be determined. There is a good description in the section under ‘Exclusion criteria’ which I would suggest moving to the above section when the notion is first introduced.

The two paragraphs which previously followed the exclusion criteria and which outline how minimal benefit from a hearing aid will be assessed have now been moved to within the Inclusion Criteria section.

5. I wondered if any consideration has been given to prior experience with a CROS configuration or if this is an exclusion criterion.

We acknowledge that we neglected to specify whether previous CROS use would affect candidacy for inclusion. An additional paragraph has been added to the Inclusion Criteria section addressing this issue, as follows: “Participants may have previous experience with using a CROS system. However, participants must have ceased use of any CROS system prior to entry into the study so that they may be evaluated in their unaided state during the baseline phase.”

6. It would be useful to know the duration of the trial period with amplification. Also, this section falls under ‘exclusion’ criteria but in fact these patients would qualify for the study – I suggest a subheading or slight re-organization to avoid confusion.

We have revised the manuscript to clarify the duration of the trial period with amplification, as follows: “If the necessary gain can be provided and the prescription can be achieved, the patient will undergo a trial of a hearing aid at their local audiology centre before speech perception is assessed in their best-aided condition as described above. The duration of the trial will vary according to local practice but will last for a minimum of four weeks.”

In response to issue 4 above, the text relating to the trial period with amplification has been moved to the Inclusion Criteria section for clarity and to avoid confusion.

7. There is no mention of rehabilitation being provided during the period of CROS system use. The post-cochlear implant intervention process is more clearly described; rehabilitation costs are covered by Cochlear Europe. It is important to know whether patients will be seen more than once with the CROS device, for example, for fine-tuning and encouragement as they would be for a cochlear implant. Given that the acceptance rate is known to be quite low for patients fit with CROS systems, there is a risk that patients will not use the device, particularly since they presumably know that they are later being fit with a cochlear implant.

We acknowledge that insufficient detail was provided on follow-up after CROS fitting and then steps taken to minimise non-use. The Contra-lateral Routing of Signals sub-section in the Interventions section has been revised accordingly, as follows: “At the time of fitting, participants will be encouraged to use the CROS system for as long as possible each day...”
and to record the number of hours of use in their user diary each day. Participants will attend a follow-up appointment after one month of CROS use during which their initial usage will be assessed, additional encouragement will be given, and the fitting adjusted as required.”

We also note that patients who display insufficient motivation to complete all trial activities including the CROS trial will be excluded according to the exclusion criteria “Unwillingness of the subject to comply with all of the trial requirements”.

8. The ‘practice period’ with a cochlear implant is substantially longer (approx. 8 months after speech processor fitting) than with the CROS configuration. It would be helpful if the authors could comment on the rationale for the short period. Is any period of adjustment needed for listeners to adjust to wearing a CROS system?

The Methods/Design section has been revised to provide additional information on the differences in the duration of the CROS and CI follow-up periods, as follows: “The duration of the CROS trial (3 months) was chosen in consultation with clinical colleagues from several UK audiology services to ensure that (a) it was of sufficient duration to allow ample time for benefits from CROS to emerge; (b) any benefits from CROS would have stabilised; and (c) self-reported benefits would be based on patients’ experience of CROS use rather than any pre-conceived expectations (whether positive or negative). The duration of the cochlear implantation follow-up period (9 months) was chosen based on data from previous studies which have suggested that a large proportion of the benefit from cochlear implantation is achieved within the first 9 months and additional benefits emerge at a slower rate over the course of several years (Tyler et al., 1997; Ruffin et al., 2007)”.

9. Please state whether the testing is administered using recorded material and if the test is BKB sentences or other test material.

We have revised the Primary Outcome Measures section to provide further details about the materials used for the localisation test, as follows: “On each trial, a short pre-recorded speech segment will be presented from one of several loudspeakers positioned in the frontal plane and behind an acoustically-transparent curtain. Speech segments will be short isophonemic words (Boothroyd, 1968) spoken by a male talker with a British accent.”

We have revised the Primary Outcome Measures section to provide further details about the materials used for the speech understanding in noise test, as follows: “Sentences will be drawn from a recording of the IEEE sentence corpus (Rothauser et al., 1969) spoken by a female talker with a British accent. The masking noise will be generated to match the long-term average spectrum of the sentences.”

Thank you for considering our manuscript for publication.

Yours sincerely,
On behalf of my fellow authors,
Dr Pádraig Kitterick