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)

Version: 2
Date: 20 February 2014

Author's response to reviews: see over
20 February 2014

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 would be grateful if you would consider this manuscript for publication in the journal *BMC Ear, Nose & Throat Disorders*. We have addressed each of your requests in turn below.

**Ethics and Funding**

The trial has received ethical approval from the National Research Ethics Committee, East Midlands Nottingham - 2, Nottingham, UK (study reference number 12/EM/0378). *I confirm that documents providing evidence of ethical approval have been forwarded to BMCSeriesEditorial@biomedcentral.com.*

Research costs for the trial are being met by an infrastructure funding grant awarded by the UK National Institute for Health Research (NIHR) to the Nottingham Hearing Biomedical Research Unit. *I confirm that documents providing evidence of funding approval from the NIHR have been forwarded to BMCSeriesEditorial@biomedcentral.com.*

The cochlear implant devices and implant-related treatment costs are being funded through an industry grant from a manufacturer of cochlear implants, Cochlear Europe Ltd. The CROS systems are being donated by the manufacturer, Phonak Group Limited. *I confirm that documents providing evidence of funding approval from Cochlear Europe Ltd and Phonak Group Ltd have been forwarded to BMCSeriesEditorial@biomedcentral.com.* I also confirm that the contributions from both companies have been declared in the ‘Competing interests’ section of the manuscript.

**Justification of commercial funding/assistance**

The contribution of Cochlear Europe Ltd is justified by the fact that providing cochlear implants to patients is costly not only during the course of this study (e.g. device, surgery, rehabilitation) but also for the lifetime of the patient (e.g. device upgrades, failures, explantation). We feel that it is therefore appropriate that all those who stand to benefit from the research should contribute towards the high costs of conducting the study; i.e. not only the UK National Health Service but also the device manufacturer.

The contribution of Phonak Group Ltd is justified by the need to ensure that all patients in the trial receive identical devices which represent the state-of-the-art in order to both (a) maximise patient benefit from standard care, and (b) minimise variability in how standard care is delivered to such a small (but well-powered) sample.

**Study status**

*I confirm that the study is currently ongoing.* Recruitment into the trial has not yet been completed and all patients are still being followed-up. No data analysis has been performed to date. The status of the study is listed in the section ‘Trial status’ in the manuscript.
Related Articles

I confirm that the results of this study have not been published or submitted for publication.

Revisions to previous version

The manuscript has been revised to ensure that all sources of funding/assistance, including the contributions from commercial organizations, are listed under the ‘competing interests’ section of the manuscript. The manuscript has also been revised to (1) add a missing affiliation to the last author; and to (2) name an additional member of the research team in the acknowledgements section.

Thank you for considering our manuscript for publication.

Yours sincerely,
On behalf of my fellow authors,

Dr Pádraig Kitterick