

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	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.
AUTHORS	Cullington, Helen; Kitterick, Pdraig; DeBold, Lisa; Weal, Mark; Clarke, Nicholas; Newberry, Eva; Aubert, Lisa

VERSION 1 - REVIEW

REVIEWER	<p>Ariane Laplante-Lévesque Research Area Manager, eHealth Eriksholm Research Centre Oticon A/S Denmark</p> <p>Associate Professor (adj) Department of Behavioural Sciences and Learning Linköping University Sweden</p> <p>My employer, Oticon A/S, has the same owner as Oticon Medical, a cochlear implant manufacturer and a competitor to Cochlear Ltd.</p> <p>Cochlear Ltd is the employer of two of the authors.</p>
REVIEW RETURNED	16-Feb-2016

GENERAL COMMENTS	<p>This is a review of the manuscript titled "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". This interesting manuscript presents the protocol of a feasibility RCT to precede a RCT of remote care vs standard care for adults with cochlear implants. Below are some comments to improve an already very good manuscript.</p> <ul style="list-style-type: none">- The research questions / hypotheses of the feasibility RCT vs the RCT could be more clearly expressed and differentiated. Describe what the feasibility RCT is finding out and contrast with what the RCT is finding out. The points Lancaster et al (2004), Arain et al (2010) and/or the National Institute of Health Research make regarding feasibility / pilot trials can help in giving a needed focus on the research questions / hypotheses of the feasibility RCT itself.- The benefits reported throughout the manuscript are relevant. When first introduced (page 5, lines 30-...), it would help to frame the benefits within a health economic evaluation theory
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	<p>perspective.</p> <ul style="list-style-type: none"> - Page 5, lines 13-14: Not clear why the number of pensioners is relevant here. - Page 6-7: This section presents standard care and the intervention, which is very relevant: introduce the purpose of this section. - Page 6, line 23: Minor comment: The Action on Hearing Loss Hearing Check was indeed available on its website, but not in the Apple Store, when I checked on 16 February 2015. - Page 9, line 20: Is this the only computer / internet eligibility criterion? Nothing about system version / internet speed? - Page 9, line 37: Could describe minimisation approach to randomisation (= adaptive stratified randomisation) and provide reference. - Page 10, lines 25-31: Acoustic presentation (through the processor microphone) or through direct audio input (through a cable)? - Page 11, lines 43-51: The measures would benefit from a description, including the construct they measure, their previous use in hearing care (if not hearing-specific), and their reported sensitivity to change. - Page 13, line 20-22: Information important to understanding this section comes on the following page. Consider introducing this part of the Methods earlier. - Throughout: Check spelling, punctuation, and referencing, eg page 6 line 10 should read "recognition" instead of "reognition". - Throughout: Consider using people-first language.
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REVIEWER	Robert Eikelboom Ear Science Institute Australia, Subiaco, Western Australia, Australia
REVIEW RETURNED	17-Feb-2016

GENERAL COMMENTS	<p>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.</p> <p>First author: Helen Cullington</p> <p>This manuscript is prepared as the protocol for a RCT of study on alternative methods of providing care of hearing implant recipients over a long-term (6 months).</p> <p>This planned collaborative study will take place in the UK, and involve clinical and research units at the University of Southampton, an academic/research unit at the National Institute for Health Research, Cochlear Europe (a unit of the hearing implant</p>
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	<p>manufacturer Cochlear), and a business school unit. In addition, an anonymous user at the clinical unit is listed as an author. The collection of this skills and interests is a great asset to this project.</p> <p>The rationale for the study is argued well by the authors and well referenced. The authors have provided a thorough and credible description of their research plan; ethics approval has already been received, and recruitment has commenced (almost complete at the time of writing).</p> <p>Specific comments:</p> <p>Page 5, line 13: Comma between the two references? Other places as well.</p> <p>Page 5, line 13: I'm not sure 'pensioners' is an adequate term to define a cohort in the population which is probably meant to convey something about age and the ageing population.</p> <p>Page 5, line 30: Is there a suitable reference for the clinical protocols for followup appointments? I accept that the list is not inclusive of everything that may occur.</p> <p>Page 5, line 35: Consider including the word 'a' or 'the' in front of the word 'clinic'; it may be a localised variation in English, but without either of these words, 'clinic' becomes a proper noun.</p> <p>Page 5, line 52: The term 'telemedicine' is not really introduced.</p> <p>Reference #10 probably needs a URL: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/465062/Work_Stream_1.1_Final.pdf</p> <p>Page 6, line 10: Please confirm at BKB is conducted in the UK in quiet and in noise (update: on pages 11 and 12 this is confirmed; should it be mentioned here?). I understand that BKB tested in noise is most common, but that CI candidates will often fail to get a score; in this case tests like CNC words and phonemes are used.</p> <p>Page 6, line 21: References 21 and 22 need more information.</p> <p>Page 6, line 57: This section on rehabilitation is quite short, and seeing 'Many clinical resources are devoted to rehabilitation' some more information is warranted. 'the new sound can be difficult to get used to.' is just a brief nod to a complex issue; here, too, some detail on the issues faced by CI recipients, especially as some of these may be addressed by remote consultations or other technological interventions. Any references for this section?</p> <p>Page 6, line 12: Is a reminder a reasonable expectation? Is there a reference available to the statements in this paragraph?</p> <p>Page 6, line 23: Should that be 'will be randomised' rather than 'are randomised'?</p> <p>Page 7, line 15: The word 'around' would normally be avoided in scientific paper. See this link: http://blog.amamanualofstyle.com/2012/09/14/around-about-approximately/ I suggest using the word 'approximately'.</p>
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	<p>Page 8, line 29: see comment above regarding the word 'around'. In any case, in this instance I suggest replacing 'around 30 to 50' with 'between 30 to 50'.</p> <p>Page 8, line 29: Third sentence should start something like this: "A sample size of 60 was selected..."</p> <p>Page 9 line 12: Will there be equal numbers of people with non-Cochlear© cochlear implants in the control and study groups?</p> <p>Page 10, line 31: Does "but can do it at any time.' mean at any time in months 1 and 6, or 'and at any other time during the six months.?" By the way, the purpose of doing the TDT at home is as yet unclear; I assume this will be revealed further in the manuscript. Why is this a meaningful outcome measure? Can the TDT be done in a free field in an environment which the ambient noise is not controlled?</p> <p>Page 10, line 42: See comment re line 31 above.</p> <p>Page 10, line 46: 'will receive' or 'may receive'? i.e. will you insist on it?</p> <p>Page 11, line 7: "...who may not be used to the Internet..." is there a better wording for this?</p> <p>Page 11, line 8: Will the registering of the score be automatic from the Action in Hearing Loss site, or will the participant have to enter the result(s)? What is appropriate feedback?</p> <p>Page 11, line 11: 'log in'- I know what you mean, but the wording could be tightened.</p> <p>Page 11, line 12: Reminders to do what?</p> <p>Page 11, line 16: How are you going to manage bi-lateral implantees? Will both be part of the project?</p> <p>Page 11, line 53: Does this information below elsewhere? It's not an outcome measure.</p> <p>Page 12, line 44: The purpose and nature of the focus groups is not clear.</p> <p>Page 13, line 17: Preference of what?</p> <p>Page 13, line 20: Preference of what? Not clear why 3 interviews are required. The inclusion of clinicians as study participants is revealed only here. How is this part of the aim? The measure should be included in the methodology. Besides 3 interviews, why 10 clinicians? Are they audiologists only? (update – found the information further down.)</p> <p>I can see these are important steps in the study, but they are not well described.</p> <p>Page 13, line 26: This is useful information, especially for the future RCT. However, should that not be formally part of the study aims and methodology? If they are important questions, it will be important to make sure that these data are collected formally and accurately. As it is, some of these four terms are not clear as to what they are.</p>
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	<p>Page 14, line 9: This is also a good inclusion in the study, but also is revealed late in the piece. This and the above should be mentioned in the introduction.</p> <p>Page 14, line 50: Invitation will be sent to all staff involved; how will the 10 be selected?</p> <p>Page 15, line 8. Missing fullstop.</p> <p>Page 16, line 22: provide abbreviation in heading, or define PPI in the next line.</p> <p>How was the service user identified? What will be her/his role?</p> <p>References: Please check that DOI should or should not be included. Furthermore, some references would be more complete with a URL; for example, I could not find any reference to #21.</p> <p>Figure 1: although it conveys what it should, the selection of background colours in the boxes should be reviewed. A more subtle selection may be more appropriate. The text in the boxes with the dark purple and blue colours does not contrast well.</p>
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VERSION 1 – AUTHOR RESPONSE

Thank you very much to the two reviewers for spending such a lot of time on our manuscript and giving detailed and informative comments. I have used track changes in the revised upload, and have made comments below each point. I have preceded all my comments with % for clarity:

- The research questions / hypotheses of the feasibility RCT vs the RCT could be more clearly expressed and differentiated. Describe what the feasibility RCT is finding out and contrast with what the RCT is finding out. The points Lancaster et al (2004), Arain et al (2010) and/or the National Institute of Health Research make regarding feasibility / pilot trials can help in giving a needed focus on the research questions / hypotheses of the feasibility RCT itself.

% thank you. I have added further details under Trial design in Methods and Analysis.

- The benefits reported throughout the manuscript are relevant. When first introduced (page 5, lines 30-...), it would help to frame the benefits within a health economic evaluation theory perspective. % we will not be evaluating health economics in this trial although it will be included in the later study. Clarified in benefits paragraph now.

- Page 5, lines 13-14: Not clear why the number of pensioners is relevant here.

% I was trying to imply that more older people = more hearing-impaired people. I have clarified now in the manuscript.

- Page 6-7: This section presents standard care and the intervention, which is very relevant: introduce the purpose of this section.

% I have now included subheadings of 'The standard clinical pathway' and 'The intervention' in the Introduction.

- Page 6, line 23: Minor comment: The Action on Hearing Loss Hearing Check was indeed available

on its website, but not in the Apple Store, when I checked on 16 February 2015.

% oh that is weird. It is definitely in the app store; I just checked online now. Here is the link to it:
<https://itunes.apple.com/gb/app/hearing-check/id485312957?mt=8>

- Page 9, line 20: Is this the only computer / internet eligibility criterion? Nothing about system version / internet speed?

% this is the only criterion. We wanted to keep it as broad as possible; it will be valuable to see if anyone ends up struggling due to hardware.

- Page 9, line 37: Could describe minimisation approach to randomisation (= adaptive stratified randomisation) and provide reference.

% thank you. We have put much more detail in and included some references.

- Page 10, lines 25-31: Acoustic presentation (through the processor microphone) or through direct audio input (through a cable)?

% they can do either - clarified in manuscript

- Page 11, lines 43-51: The measures would benefit from a description, including the construct they measure, their previous use in hearing care (if not hearing-specific), and their reported sensitivity to change.

% thanks, have added much more detail under 'Baseline measures' now, although there is insufficient room for more detail about their psychometric properties.

- Page 13, line 20-22: Information important to understanding this section comes on the following page. Consider introducing this part of the Methods earlier.

% Both reviewers commented that this information occurred too late, so I have moved the Paragraph 'Staff change management assessment' earlier in the manuscript.

- Throughout: Check spelling, punctuation, and referencing, eg page 6 line 10 should read "recognition" instead of "reognition".

% thank you. Have spell checked again.

- Throughout: Consider using people-first language.

% thanks for picking me up on this. Have changed all occurrences of cochlear implant users to people using cochlear implants/people with cochlear implants

Reviewer: 2

Robert Eikelboom

Ear Science Institute Australia, Subiaco, Western Australia, Australia.

Specific comments:

Page 5, line 13: Comma between the two references? Other places as well.
% my references are handled by EndNote using the BMJ style, and I notice in other articles in the journal, there are not commas between references.

Page 5, line 13: I'm not sure 'pensioners' is an adequate term to define a cohort in the population which is probably meant to convey something about age and the ageing population.
% I have clarified now in the manuscript, and changed it to 'people of retirement age'

Page 5, line 30: Is there a suitable reference for the clinical protocols for followup appointments? I accept that the list is not inclusive of everything that may occur.
% reference to quality standard added

Page 5, line 35: Consider including the word 'a' or 'the' in front of the word 'clinic'; it may be a localised variation in English, but without either of these words, 'clinic' becomes a proper noun.
% I think in the UK we would use 'the clinic' or 'clinic' interchangeably. However I want the paper to be readable to people outside the UK, so I have added 'the' several times

Page 5, line 52: The term 'telemedicine' is not really introduced.
% changed to 'the use of technology to assist self-care'

Reference #10 probably needs a URL:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/465062/Work_Stream_1.1_Final.pdf
% added

Page 6, line 10: Please confirm at BKB is conducted in the UK in quiet and in noise (update: on pages 11 and 12 this is confirmed; should it be mentioned here?). I understand that BKB tested in noise is most common, but that CI candidates will often fail to get a score; in this case tests like CNC words and phonemes are used.
% I have added 'in quiet and noise'. You are right that BKB sentences are not a great measure - most potential CI users get 0% before CI and 100% after CI! Probably a discussion for elsewhere!

Page 6, line 21: References 21 and 22 need more information.
% added that these are MSc theses

Page 6, line 57: This section on rehabilitation is quite short, and seeing 'Many clinical resources are devoted to rehabilitation' some more information is warranted. 'the new sound can be difficult to get used to.' is just a brief nod to a complex issue; here, too, some detail on the issues faced by CI recipients, especially as some of these may be addressed by remote consultations or other technological interventions. Any references for this section?
% added a couple of references. the word limit probably precludes too much more info

Page 6, line 12: Is a reminder a reasonable expectation? Is there a reference available to the

statements in this paragraph?

% I do think a reminder could come in the future - perhaps on the remote control. I have added references to both maintenance and upgrades.

Page 6, line 23: Should that be 'will be randomised' rather than 'are randomised'?

% yes, thanks. Changed

Page 7, line 15: The word 'around' would normally be avoided in scientific paper. See this link: <http://blog.amamanualofstyle.com/2012/09/14/around-about-approximately/> I suggest using the word 'approximately'.

% really interesting blog comment. I have replaced around with approximately three times.

Page 8, line 29: see comment above regarding the word 'around'. In any case, in this instance I suggest replacing 'around 30 to 50' with 'between 30 to 50'.

% done.

Page 8, line 29: Third sentence should start something like this: "A sample size of 60 was selected..."

% done.

Page 9 line 12: Will there be equal numbers of people with non-Cochlear© cochlear implants in the control and study groups?

% that is what the randomisation aims for: see paragraph Randomisation. I have added more detail.

Page 10, line 31: Does "but can do it at any time." mean at any time in months 1 and 6, or 'and at any other time during the six months.'? By the way, the purpose of doing the TDT at home is as yet unclear; I assume this will be revealed further in the manuscript. Why is this a meaningful outcome measure? Can the TDT be done in a free field in an environment which the ambient noise is not controlled?

% The users can do the test either by direct connect or in the sound field (now clarified in the manuscript). I have clarified when they can do the test. The purpose of doing the TDT at home is now clarified under 'Feasibility outcomes'.

Page 10, line 42: See comment re line 31 above.

% clarified

Page 10, line 46: 'will receive' or 'may receive'? i.e. will you insist on it?

% no, no insisting, have changed to may.

Page 11, line 7: "...who may not be used to the Internet..." is there a better wording for this?

% have improved

Page 11, line 8: Will the registering of the score be automatic from the Action in Hearing Loss site, or will the participant have to enter the result(s)? What is appropriate feedback?

% detail added

Page 11, line 11: 'log in' - I know what you mean, but the wording could be tightened.

% improved

Page 11, line 12: Reminders to do what?

% detail added

Page 11, line 16: How are you going to manage bi-lateral implantees? Will both be part of the project?

% yes, bilateral users can take part (see Inclusion criteria). I have added 'month and year of FIRST implant surgery'. They are given advice to test themselves using their usual configuration (usually bilateral). There is also provision in CIRCA to cater for people with different sound processors on each ear. I haven't added this detail into the manuscript.

Page 11, line 53: Does this information below elsewhere? It's not an outcome measure.

% deleted the part about training and having self-mapping activated. It's not an outcome measure, and it's obvious people will be trained!

Page 12, line 44: The purpose and nature of the focus groups is not clear.

% 'in order to collect qualitative preference and experience data' added

Page 13, line 17: Preference of what?

% clarified in manuscript

Page 13, line 20: Preference of what? Not clear why 3 interviews are required. The inclusion of clinicians as study participants is revealed only here. How is this part of the aim? The measure should be included in the methodology. Besides 3 interviews, why 10 clinicians? Are they audiologists only? (update – found the information further down.)

% preference of what is clarified in manuscript. Clinician assessment is mentioned in the abstract (Methods and analysis).

Both reviewers commented that this information occurred too late, so I have moved the Paragraph 'Staff change management assessment' earlier in the manuscript.

Within the 'staff change management assessment' paragraph, we have mentioned that repeated interviews with the same people will provide insights into how things change and evolve. I have now added 'capturing data near the beginning, middle and end of project ...'. Sample size of 10 now explained in manuscript.

I can see these are important steps in the study, but they are not well described.

Page 13, line 26: This is useful information, especially for the future RCT. However, should that not be formally part of the study aims and methodology? If they are important questions, it will be important to make sure that these data are collected formally and accurately. As it is, some of these four terms are not clear as to what they are.

% feasibility outcomes are mentioned in the abstract. More detail is now included under 'Trial design'. Brevity of article precludes too much more detail. Attrition has been explained (drop-out), and more detail given on recruitment and adherence.

Page 14, line 9: This is also a good inclusion in the study, but also is revealed late in the piece. This and the above should be mentioned in the introduction.

%thanks. Have added a sentence to last paragraph of Introduction (The intervention).

Page 14, line 50: Invitation will be sent to all staff involved; how will the 10 be selected?

% great point, thanks. Have added a sentence at the end of Staff recruitment.

Page 15, line 8. Missing fullstop.

% added, well spotted

Page 16, line 22: provide abbreviation in heading, or define PPI in the next line.

% thanks, have put abbreviation in heading (careless of me)

How was the service user identified? What will be her/his role?

% more detail given in PPI section. Role described in Author Contributions. We wanted to include various stakeholders in team (Explained now in PPI section).

References: Please check that DOI should or should not be included. Furthermore, some references would be more complete with a URL; for example, I could not find any reference to #21.

% BMJ instructions for authors suggest that the DOI should ideally be included in the citation. I don't have all the DOIs - editor: should I attempt to find them all please?

I have added more detail on reference 21. More detail and more urls included too.

I also noticed that reference number citations are supposed to be after punctuation, so I have moved them all!

Figure 1: although it conveys what it should, the selection of background colours in the boxes should be reviewed. A more subtle selection may be more appropriate. The text in the boxes with the dark purple and blue colours does not contrast well.

% box fills made paler in order to show the text better

VERSION 2 – REVIEW

REVIEWER	Ariane Laplante-Lévesque Eriksholm Research Centre, Oticon A/S, Denmark Linköping University, Sweden
REVIEW RETURNED	My employer, Oticon A/S, is owned by William Demant Holding, which also owns a cochlear implant manufacturer (Oticon Medical).

GENERAL COMMENTS	I was Reviewer 1 in the previous round of reviews. The authors have successfully addressed my comments.
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REVIEWER	Robert Eikelboom Ear Science Institute Australia, Australia
REVIEW RETURNED	29-Mar-2016

<p>GENERAL COMMENTS</p>	<p>Second review</p> <p>The authors have carefully attended to all the comments provided in the first review. I have a few more minor comments:</p> <p>Page 6, line 42: comma after 'However'.</p> <p>Page 9, line 45: 'minimisation' to be consistent with the other two instances of the word in this paragraph.</p> <p>Page 10 line 41 (was page 11, line 8): Still not clear on how the Action on Hearing Loss data is captured by the study.</p> <p>Page 10 Line 44: 'self-testing' rather than 'self testing'</p> <p>Page 10 Line 45: The Triplet Digit Test is centred on the signal to noise ratio; if participants opt for direct input into their processor (excluding the background noise, as stated here), is this using the test for a different purpose than it was intended, and now result in some form of threshold test? Further I assume one would want to compare results over time; would the same mode of testing be required each time?</p> <p>Page 12 line 8: Sharepoint may be unknown to the reader; perhaps '(Microsoft Corporation, Redmond, WA, USA)' should perhaps be added to the text.</p> <p>Page 14 line 8: minor point – inconsistent use of fullstop at end of items in bullet pointed lists.</p> <p>Page 15 line 5: 'randomisation'? The only instance of '...iz...' spelling in the manuscript, other than the one on Page 9 and in reference titles.</p> <p>Page 15 lines 15 onwards: query only - should information about the methodology be part of the hypotheses? The last secondary hypothesis in particular has probably too much information about the method.</p> <p>Figure 1 is much improved; the lines and arrows do not meet cleanly and evenly – some touch the line of the box, some are over the line, some have a gap between the end/arrow and the line.</p> <p>Comment on comment by other reviewer: The Apple store may restrict access to apps based on location; I can see it (in Australia).</p>
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VERSION 2 – AUTHOR RESPONSE

Thank you again to the reviewers for their time, expertise and attention to detail. For clarity, reviewer comments below are preceded with ***, and my replies are written below each comment:

*** Page 6, line 42: comma after 'However'.
done

***Page 9, line 45: 'minimisation' to be consistent with the other two instances of the word in this paragraph.
well spotted! Changed

***Page 10 line 41 (was page 11, line 8): Still not clear on how the Action on Hearing Loss data is captured by the study.

I have clarified in text now at end of Remote and self-monitoring paragraph as follows '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.'

***Page 10 Line 44: 'self-testing' rather than 'self testing'
Done

***Page 10 Line 45: The Triplet Digit Test is centred on the signal to noise ratio; if participants opt for direct input into their processor (excluding the background noise, as stated here), is this using the test for a different purpose than it was intended, and now result in some form of threshold test? Further I assume one would want to compare results over time; would the same mode of testing be required each time?

Oh, I'm so sorry! The test is still in noise, I just meant that they could reduce home environmental sounds, like dog barking, children talking etc. I have clarified in manuscript now. Also have clarified about qualitative data only ie it doesn't matter if they use the same mode of testing each time.

***Page 12 line 8: Sharepoint may be unknown to the reader; perhaps '(Microsoft Corporation, Redmond, WA, USA)' should perhaps be added to the text.
Done

***Page 14 line 8: minor point – inconsistent use of fullstop at end of items in bullet pointed lists. I'm sorry, I couldn't see a full stop in any bullet pointed lists - happy for this to be changed in editing if someone finds it!

***Page 15 line 5: 'randomisation'? The only instance of '...iz...' spelling in the manuscript, other than the one on Page 9 and in reference titles.
Changed

***Page 15 lines 15 onwards: query only - should information about the methodology be part of the hypotheses? The last secondary hypothesis in particular has probably too much information about the method.
Thanks, have changed the last secondary hypothesis to exclude methodology details.

***Figure 1 is much improved; the lines and arrows do not meet cleanly and evenly – some touch the line of the box, some are over the line, some have a gap between the end/arrow and the line.

Thanks, I think I have it perfectish now!

VERSION 3 - REVIEW

REVIEWER	RH Eikelboom Ear Science Institute Australia, Australia; Ear Sciences Centre, School of Surgery, The University of Western Australia, Australia; School of Speech-Language Pathology and Audiology, University of
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	Pretoria, South Africa.
REVIEW RETURNED	22-Apr-2016

GENERAL COMMENTS	All my review comments have been addressed, and looking forward to seeing the paper in press.
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