

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)	Feasibility and Acceptability of Training Community Health Workers in Ear and Hearing Care in Malawi: A cluster randomised controlled trial
AUTHORS	Mulwafu, W; Kuper, Hannah; Viste, Asgaut; Goplen, Frederik K.

VERSION 1 - REVIEW

REVIEWER	Shelly Chadha World Health Organization
REVIEW RETURNED	20-Mar-2017

GENERAL COMMENTS	<p>1. The strengths and limitations of the paper are given together. They should be listed separately.</p> <p>2. The paper refers to the number of persons screened by the trained persons and those identified with ear and hearing problems. It also mentions that these were examined by specialists. However, it does not provide a measure of accuracy/concurrence of diagnosis made by trained CHWs compared with that of specialists. This information is very relevant and should be included.</p>
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REVIEWER	Dr Derek Hoare University of Nottingham, UK
REVIEW RETURNED	29-Apr-2017

GENERAL COMMENTS	<p>The randomised study involves training community health workers to identify and refer for hearing disorders. The primary outcome was change in health worker knowledge of hearing disorders and this was assessed by questionnaire and compared to knowledge of untrained health workers. The manuscript is well written and provides an interesting insight into the Malawi hearing healthcare system. As the primary interest is in the feasibility of training I would suggest for this manuscript that more emphasis is placed on two important findings. Firstly, whilst there is an overall statistical improvement in correct answers demonstrating learning of those trained in hearing healthcare, on some modules of the training, particularly ear canal, middle ear, and assessing hearing and counselling, there is no improvement or even a reduced score on the knowledge questionnaire. This should be explored in more detail with due consideration as to how the training could be improved, in conjunction with the feedback of the trainees. Second, about 15% of patients referred did not have a hearing loss. This issue has obvious cost implications and so it should be explored or considered why the</p>
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'false' referral rate was so high and again, how this might be reduced in the future.

Additional specific comments:

P3L3 – the outcome measure needs to be described briefly in the abstract to make “correct answers” meaningful to the reader.

P5L28 – here it is not specifically ‘ear disease and hearing loss’ that is being referred to, I would suggest it is ‘untreated ear disease and hearing difficulties’.

P5L34 – It would be useful to have here some more brief details on CHWs and what health scenarios they are generally more familiar with.

P6L15 – This implies that the CHWs were trained to treat simple ear disease which I don't think is the case? Please clarify.

P7L52 – it is not clear what the power calculation is based on. Was it simply a feasibility estimate? What does a change of 15 of the primary outcome measure signify? Is this your feasibility criterion? How was it chosen?

P7L54 – suggest ‘change’ here as opposed to ‘improvement’.

P8L6 – this line is unclear to me, I do not understand what is the relationship between CHW and the MHSAs?

P9 – training: was there any practical training in otoscopy? How was practical skill assessed?

P12L5-9 – please clarify what was being tested in these comparisons.

P13L11 – suggest a new paragraph and subheading from ‘Test scores...’ to clarify this as primary outcome. Here also, what was defined as the criterion for feasibility?

P22L20 – I do not understand this quote, some clarification of meaning needed.

P22L34 – who is the ‘chief’ referred to here?

Total referrals listed as 1739 and 1730 in text and Figure 1 respectively.

General comment:

Would minimise use of non-standard abbreviations, many in the manuscript are unhelpful.

Suggest wording in the table headings are consistent with the text – i.e. use ‘screening camp’ or ‘examination camp’ consistently to avoid confusion.

VERSION 1 – AUTHOR RESPONSE

1 The paper refers to the number of persons screened by the trained persons and those identified with ear and hearing problems. It also mentions that these were examined by specialists. However, it does not provide a measure of accuracy/concurrence of diagnosis made by trained CHWs compared with that of specialists. This information is very relevant and should be included. We have mentioned as a limitation that the accuracy of CHWs was not compared to specialists. However, only 22% of people referred did not have an ear and hearing disorder, showing that the CHWs were reasonably competent and correct referral. This is now highlighted in the discussion.

2 Firstly, whilst there is an overall statistical improvement in correct answers demonstrating learning of those trained in hearing healthcare, on some modules of the training, particularly ear canal, middle ear, and assessing hearing and counselling, there is no improvement or even a reduced score on the knowledge questionnaire. This should be explored in more detail with due consideration as to how the training could be improved, in conjunction with the feedback of the trainees. We note in the discussion that there was no change in knowledge about the middle ear or assessing hearing and counselling, and that these modules need to be improved in future training sessions. Unfortunately, we do not have the capacity now to explore this in detail with the trainees.

2 Second, about 15% of patients referred did not have a hearing loss. This issue has obvious cost implications and so it should be explored or considered why the 'false' referral rate was so high and again, how this might be reduced in the future. We estimate that approximately 22% of people examined at the screening camp did not have an ear or hearing disorder. We believe that this is a relatively low false referral rate, and now describe it as such in the discussion. There is room for improvement, of course, and we have now suggested that the emphasis on training in future should focus on identification of the normal patients

2 P3L3 – the outcome measure needs to be described briefly in the abstract to make "correct answers" meaningful to the reader. The outcomes have been described

2 P5L28 – here it is not specifically 'ear disease and hearing loss' that is being referred to, I would suggest it is 'untreated ear disease and hearing difficulties'. We have made the change suggested by the editor.

2 P5L34 – It would be useful to have here some more brief details on CHWs and what health scenarios they are generally more familiar with. Each HSA in Malawi is assigned to a catchment area of approximately 1,000 inhabitants and its associated health facility, covering a radius of eight kilometers except in district-defined hard-to-reach catchment areas. HSAs track pregnancies, births, and deaths using their Village Health Registers (VHRs), conduct health talks and vaccinations. This description is now included in the methods.

2 P6L15 – This implies that the CHWs were trained to treat simple ear disease which I don't think is the case? Please clarify. "The leading causes of hearing impairment in Sub-Saharan Africa are believed to be middle ear disease and impacted wax, and are therefore easily amenable to identification, prevention and treatment'. This sentence does not refer to CHWs only. Have added the word identification to signify the role played by CHWs

2 P7L52 – it is not clear what the power calculation is based on. Was it simply a feasibility estimate? What does a change of 15 of the primary outcome measure signify? Is this your feasibility criterion? How was it chosen? The sample size calculation were estimated for a change in knowledge level between baseline and follow up in the intervention group. However, no published data could be found for the likely mean and variance of pre-test training scores. We therefore modelled different scenarios and conservatively estimated the change in score of 15 with a standard deviation of 15.

However, these estimates are speculative and perhaps not needed for a feasibility study, and so this section has been removed.

2 P7L54 – suggest 'change' here as opposed to 'improvement'. This has been changed

2 P8L6 – this line is unclear to me, I do not understand what is the relationship between CHW and the

MHSAs? HSAs are the formal CHWs in Malawi. This has been clarified in the methods, and throughout we now refer to CHWs rather than HSAs.

2 P9 – training: was there any practical training in otoscopy? How was practical skill assessed? There was training in Otoscopy (specified page 9), but practical skills were not assessed, which is now mentioned as a limitation. The primary aim was to enable them to identify common pathologies like wax and discharge, which is a fairly easy task. However, in a possible higher level course in the future, it would be a good idea to test both manual and diagnostic skills.

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P12L5-9 – please clarify what was being tested in these comparisons. We tested whether or not there was an increase in the number of patients seen in health centres. This is now clarified in the text.

2 P13L11 – suggest a new paragraph and subheading from ‘Test scores...’ to clarify this as primary outcome. Here also, what was defined as the criterion for feasibility? Will start new paragraph.

2 P22L20 – I do not understand this quote, some clarification of meaning needed. Solar powered otoscopes requiring sunshine to charge. This is now clarified in the text.

2 P22L34 – who is the ‘chief’ referred to here? This is the Traditional Chief of the village, and this is now specified in the text.

2 Total referrals listed as 1739 and 1730 in text and Figure 1 respectively. Correct number is 1739. This has been corrected in the text in the discussion

2 Would minimise use of non-standard abbreviations, many in the manuscript are unhelpful. We have now taken out the abbreviation for HSA, HC, VHR, PEHCTR, CSOM, VHW, IEC

2 Suggest wording in the table headings are consistent with the text – i.e. use ‘screening camp’ or ‘examination camp’ consistently to avoid confusion. We have changed table headings to screening camps so that it is consistent with the text

VERSION 2 – REVIEW

REVIEWER	Derek Hoare University of Nottingham, UK
REVIEW RETURNED	18-Jun-2017

GENERAL COMMENTS	<p>P37L30 - spell out LMICs here.</p> <p>P41- the new study outcomes section needs more detail of how each outcome was evaluated. Please provide description of the primary outcome measure, how many questions, question style etc. More detail about the secondary outcome needed also; was the measure of interest percentage correct?</p> <p>P46L35 - move (national language of Malawi) to first use of Chichewa.</p>
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VERSION 2 – AUTHOR RESPONSE

P37L30 - spell out LMICs here. This has been spelt out

P41- the new study outcomes section needs more detail of how each outcome was evaluated. Please provide description of the primary outcome measure, how many questions, question style etc. More detail about the secondary outcome needed also; was the measure of interest percentage correct? More details have been added

P46L35 - move (national language of Malawi) to first use of Chichewa. This has been done

VERSION 3 - REVIEW

REVIEWER	Derek Hoare University of Nottingham, UK
REVIEW RETURNED	26-Jul-2017

GENERAL COMMENTS	P40L39 - spell out three. P43L9 - need a space after Chichewa P59L13 - suggest 'important to' instead of 'a good idea'.
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