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# BMJ Open

## Feasibility of Training Community Health Workers in Ear and Hearing Care in Malawi: A Cluster Randomised Controlled Trial

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3 **Feasibility of training Community Health Workers in Ear and Hearing Care in Malawi: A**  
4 **cluster randomised controlled trial**  
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## Abstract

### OBJECTIVE:

To assess the feasibility of training community health workers (CHWs) in ear and hearing care, and their ability to identify patients with ear and hearing disorders.

### DESIGN:

cluster randomised controlled trial (RCT).

### SETTING:

Health Centres (HCs) in Thyolo district, Malawi.

### PARTICIPANTS:

Ten HCs participated, 5 intervention HCs (29 CHWs) and 5 control HCs (28 CHWs).

### INTERVENTION:

Intervention CHWs received training in Primary Ear and Hearing Care, while among control CHWs training was delayed for 6 months. Both groups were given a pre-test that assessed knowledge about ear and hearing care, only the intervention group was given the post-test on the third day of training. Intervention group was given one month to identify patients with ear and hearing disorders in their communities, and these people were screened for hearing disorders by ENT clinical specialists.

### OUTCOME MEASURES:

Knowledge of ear and hearing care among CHWs after the training, number of patients with ear or hearing disorders identified by CHWs and number recorded at health centres during routine activities.

### RESULTS:

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3 The average overall correct answers increased from 55% to 68% (95% CI 65-71) in the  
4 intervention group ( $p<0.001$ ). A total of 1,739 patients with potential ear and hearing disorders  
5 were identified by CHWs and 860 patients attended the screening camps, of whom 400 had  
6 hearing loss (73 patients determined through bilateral fail on Oto-acoustic Emissions, 327  
7 patients through audiometry). Where cause could be determined, the most common cause of ear  
8 and hearing disorders was chronic suppurative otitis media followed by impacted wax.  
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## 14 15 16 17 18 **CONCLUSIONS:** 19

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21 Training was effective in improving the knowledge of CHW in ear and hearing care in Malawi  
22 and allowing them to identify patients with ear and hearing disorders. This intervention could be  
23 scaled up to other CHWs in LMICs.  
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31 **TRIAL REGISTRATION NUMBER: P.11/14/1659**  
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## 33 34 **Strengths and limitations of this study** 35

- 36 • Structured framework was used to assess the feasibility and acceptability of the  
37 intervention to train CHWs in primary ear and hearing care
- 38 • The training and screening camps were led by an ENT surgeon, and drew on tools  
39 prepared by the WHO
- 40 • Through focus group discussions with CHWs, we explored the reasons why people did  
41 not attend at the screening camp. In-depth interviews with people who did not attend  
42 screening camps could have provided additional information.
- 43 • The impact of the training on number of recorded patients at the health centres was  
44 evaluated
- 45 • Roles and responsibilities of CHWs is different in different countries. Therefore,  
46 generalization of these findings to other settings must be done with caution.  
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- Although the cost of the training is reported, the full cost of the intervention, taking into account costs of referrals and final treatment, was not assessed.

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## Introduction

Hearing loss is the most common sensory disability and its prevalence is increasing globally with population ageing.<sup>1</sup> According to the World Health Organisation (WHO), an estimated 360 million people, or 5.3% of the world's population, are living with disabling hearing impairment.<sup>2</sup> Data for Sub-Saharan Africa are sparse, but the prevalence of hearing impairment may be even higher in this region.<sup>3</sup> 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 treatment and prevention<sup>4</sup>.

Ear and hearing problems can cause life-long difficulties. They may have profound effect on the ability of individuals to communicate with others, on their education, and on their ability to obtain and keep employment<sup>5</sup>. Furthermore, hearing loss also impacts negatively on social relationships and may lead to stigmatization<sup>6</sup>. Consequently, ear and hearing problems are likely to produce substantial economic burdens on individuals, communities and countries.<sup>7</sup>

The high prevalence of ear diseases and hearing loss in Sub-Saharan Africa is at least partly due to the severe shortage of health workers including audiologists, and of resources for hearing aid provision, support and aural rehabilitation programmes<sup>8</sup>. Educating Community Health Workers (CHWs) about ear disease and hearing loss can help to fill these gaps in settings with a scarcity of health workers. CHWs are members of the communities where they work, selected by the communities, answerable to the communities for their activities, and have shorter training than professional clinical workers.<sup>9</sup>

The role of CHWs may be particularly important in controlling ear and hearing problems. Effective interventions against ear and hearing problems include ear wax removal, treatment of chronic suppurative otitis media (CSOM) and provision of hearing aids. These interventions can be implemented at the primary level by trained CHWs and have the potential for a major impact on the burden of ear disease and hearing loss when used on large scale.<sup>10,11</sup> However, most low and middle income countries do not have CHWs trained in Primary Ear and Hearing Care (PEHC).<sup>12</sup>

Malawi is a setting where CHWs can potentially make an important contribution to controlling ear and hearing problems. There are only two ENT Surgeons for a population of more than 17

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3 million, and only 25 ENT Clinical Officers.<sup>13</sup>. Data are limited, but a study among children  
4 showed a high prevalence of hearing loss, with an estimated 1,800 children per million  
5 population with hearing impairment from avoidable causes that could be treated through  
6 provision of basic primary level ear and hearing care, in particular wax and middle ear disease.<sup>14</sup>  
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11 The aim of this study was to assess the feasibility of training CHWs to provide primary level ear  
12 and hearing care, including: identification of patients with ear and hearing disorders, referral of  
13 patients to services, and treatment of simple ear conditions.  
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## **Methods**

### *Ethical approval*

Ethical approval was provided by the College of Medicine Research Ethics Committee in Malawi. The study was evaluated and found exempt from review by the Norwegian Regional Committee for Medical and Health Research Ethics (2016/1472 REC South East, Section D).

### *Study design*

An intervention study was undertaken to assess the feasibility of training CHWs in primary ear and hearing care. A group of CHW were selected, and half the participants were randomized to receive training in primary ear and hearing care, while for the remainder training was delayed for six months.

### **Setting**

Thyolo district was selected as the study area. Thyolo is a tea-growing district with a population of approximately 460 000, mainly Lomwe people. It is situated about 30 km away from Blantyre, where the only dedicated Ear, Nose and Throat (ENT) Unit in Malawi is located. The district hospital is one of eight district hospitals which has an ENT Clinical Officer, who has been working in Thyolo for two years. Within this district there are 33 health centres. Each Health Centre is supported by about 10 CHWs and serves a catchment area of approximately 14 000 people.

### **Sample size**

Power analysis was based on inclusion of 6 HSAs for each of 10 HCs. We expected 90% power to detect a difference of 15 in the mean scores. For the untrained CHWs we, expected the improvement to be zero. The design effect was estimated to be 1.25.

## **Subjects**

CHWs were selected among Malawian Health Surveillance Assistants. These form a cadre of 10,500 frontline health workers employed by the Ministry of Health and comprise 30% of the health workforce in Malawi<sup>15</sup>. Each is expected to serve about 1000 people, receives 12 weeks of training and has important roles in providing care, promoting community participation in health care activities and in promoting disease surveillance services at the community level. Prior to this study, they had not received any training in primary ear and hearing care.

A list of all the 33 health centres together with all the names of the CHWs in Thyolo district was compiled with the help of the District Health Environmental Office in Thyolo district. Using a Random Number Generator, we selected 10 health centres for inclusion in the trial (Figure 1); we then randomly allocated five health centres to the intervention group and five health centres to the Control group. Using the Random Number Generator, we selected 6 CHWs (out of approximately 10 CHW) per Health Centre. Consequently, a total of 30 intervention CHWs and 30 control CHWs were selected.

## **Consent and pre-test**

The selected CHWs were called up for a briefing at a central location, with intervention and control groups meeting separately. They were briefed on the study and written consent was taken from them to be part of the study after they had received details of what participation involved. Data collected from the CHWs included age, sex and years of formal education. They were administered a pre-test questionnaire containing the questions from the first 6 modules of the intermediate level WHO Primary Ear and Hearing Care Trainer's Manual (10 questions per module)<sup>16</sup> The participants in the control group were assured of the training after 6 months.

## **Training for intervention group**

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3 The training lasted three days and was undertaken by an ENT Surgeon and two ENT Clinical  
4 Officers. The two ENT Clinical Officers each had 18 months of training in ENT and had  
5 participated in a primary ear and hearing care course. A training curriculum and manual was  
6 developed in English by local experts (1 Audiologist, 3 Audiological Officers, 3 ENT Clinical  
7 Officers and 1 ENT Surgeon). The training manual was based on both the Basic and Intermediate  
8 Manual of WHO Primary Ear and Hearing Care Training Resources (PEHCTR).<sup>16</sup>  
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17 The first part of the training focused on knowledge about ear and hearing disorders. Training  
18 emphasized the structure and function of the ear, causes of hearing impairment and their  
19 management and levels of hearing impairment. Next, the training focused on skills training,  
20 including: 1) History taking in patient with ear and hearing disorders, 2) Ear examination, 3)  
21 Steps in doing otoscopy, 4) Steps in doing voice tests, 5) Assessment of hearing in children.  
22 Training methods included lectures, posters of ear and hearing disorders, flip charts, and  
23 demonstrations, practical of voice tests, discussion and group work. Training was done both in  
24 English and Chichewa. At the end of the training, each CHW was given a training manual that  
25 contained the key points of training and which could be referred to when needed. They were also  
26 given Arclight Otoscopes (WJW Ltd, Liverpool, UK), to allow ear examination.  
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36 The participants were given a post-test questionnaire on the third day of training, using the same  
37 questionnaire as in pre-test. The participants were also asked how their opinions about the length  
38 of training and whether or not they felt comfortable in identifying people with ear and hearing  
39 disorders.  
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### **Mobilization of patients by Community Health Workers**

After training, each CHW in the intervention group was given one month to identify, list and refer patients with ear and hearing disorders from their own village to their corresponding health centre. First, the CHW met with the Village Headman, village development committee members and village health committee members to explain in detail about the programme. Next, the CHW met with the community members to explain about the programme and to schedule dates for screening of the community members. CHWs were asked to use multiple methods in their identification (door to door, school screenings, health education, church/mosque announcements). CHWs took history, did otoscopy and voice tests as a way of identifying community members with ear and hearing disorders. CHWs created a list of patients they suspected of having ear and hearing disorders in their community.

Identified patients with suspected ear disorder or hearing loss were asked to come to the scheduled screening camps, which took place at the five health centres of Bvumbwe, Chimaliro, Chisoka, Changata and Gombe.

### **Screening Camps**

The listed patients were asked to come to the health centre in their catchment area together with their CHW. A team of 6 people (One ENT Surgeon, One ENT Clinical Officer, Queen Elizabeth Central Hospital (QECH) Audiological Officers and two research assistants) from the ENT Department at QECH in Blantyre traveled to all the five health centres in Thyolo to conduct the screening camps

All patients underwent otoscopy, pure tone audiometry, transient evoked otoacoustic emissions (TEOAEs) and tympanometry performed by one of two audiological officers.

- Otoscopy was performed on all patients using the Heine Mini 2000 (HEINE Optotechnik, Herrsching, Germany).
- Audiometry was performed in all patients aged >4 years who were able to cooperate in a quiet room using the KUDUwave 5000 audiometer (eMoyoDotnet (Pty) Ltd, Randburg,

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3 South Africa). Thresholds were obtained at frequencies of .5, 1, 2 and 4 kHz according to  
4 WHO recommendations. Pure tone average (PTA) was calculated based on these four  
5 frequencies. Hearing impairment was defined as PTA > 25dB in the better ear.  
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- 8 - TEOAEs were measured in subjects aged less than 4 years and those who were not able  
9 to cooperate for audiometry. TEOAEs were tested using the Sentiero handheld device  
10 (PATH Medical Solutions, Guymark, UK) and assessed in each ear at frequencies  
11 between 1000 and 4000 kHz. Results were graded as 'pass' (indicating normal hearing)  
12 or 'fail' (indicating impaired hearing).  
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- 14 - Tympanometry was done in all patients using Tympanometer S/N P 99 0556, Grason-  
15 Stadler, USA.  
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21 Data was recorded on the WHO/PBD Ear and Hearing Disorders Survey Form.  
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26 Patients with ear wax had this removed on site by ENT Clinicians. Those with discharging ears  
27 had ear toilet and were given ciprofloxacin ear drops. Those with bigger wet perforations had  
28 Candiderm (Beclomethasone Dipropionate, Clotrimazole, and Gentamicin Sulphate) inserted in  
29 the middle ear. All patients with chronic otitis media (active or inactive) were referred to QECH.  
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32 Recorded data of patients with ear and hearing disorders at the health centres were collected at  
33 baseline (one month data before the study), at three months and six months after intervention.  
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### 40 **Qualitative data collection**

41 Focus Group Discussions (FGDs) were undertaken by a research assistant in three of the five  
42 health centres (Chimaliro, Bvumbwe and Chisoka). The guided discussions asked CHWs about  
43 their impressions on training, and challenges faced when identifying people with ear and hearing  
44 disorders.  
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### 50 **Data analysis**

51 Data were analysed using Stata version 13. Tests for normality were done using SPSS version  
52 21. All the scores were tested for normal distribution using the Shapiro-Wilk test. We conducted  
53 an independent t-test to determine the difference in the mean knowledge scores between the  
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3 intervention and control groups and paired t-test in the intervention group before and after the  
4 training. For all procedures, alpha was set at 0.05. Paired t-test and chi square statistic were used  
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6 to compare number of patients seen at baseline to those seen at three months and six months in  
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8 both intervention and control groups.  
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12 Transcripts from each focus group discussions were generated and translated into English, and  
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14 those transcripts were examined for recurring themes and patterns through open coding and  
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16 qualitative content analysis. Nvivo 11 was used for coding the data.  
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## RESULTS

A total of 57 CHWs were included, 28 in the control arm and 29 in the intervention arm. Intervention and control CHWs were similar in terms of proportion of males (59% vs 54%), mean age (37 years, range 28-51 vs 38 years, range 29-55), and proportion who had 10 years or more of formal education (56% vs 54%). Test scores are shown in table 1. In the pre-test questionnaire, the intervention group scored slightly lower ( $p < 0.05$ ) than the control group, i.e. 55% (95% CI 52-58) compared to 58% (95% CI 56-60%). After training, the mean score for the post-test in the intervention group increased to 68% (SD 1.18, 95% CI 65-71), showing a statistically significant improvement from baseline ( $p < 0.001$ ).

**TABLE 1: Proportion of CHWs who answered correctly in the six different modules**

Module	Proportion of questions answered correctly:			Significance (paired t- test pre- vs post-test)
	Control group pre-test (n=28)	Intervention group pre-test (n=29)	Intervention group post-test (n=29)	
Structure and function of the ear	58%	61%	82%	0.0000
Hearing impairment and deafness: causes and prevention	52%	53%	78%	0.0000
The outer ear: examine, treat and refer	59%	53%	74%	0.0000
The ear canal: examine, diagnose and clean	54%	47%	57%	0.0349
The middle ear: examine, diagnose and treat	55%	48%	52%	0.2763



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Assessing hearing and counselling	72%	69%	66%	0.1650
<b>ALL MODULES</b>	<b>58%</b>	<b>55%</b>	<b>68%</b>	<b>0.0000</b>

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8 The majority of the CHWs (67%) said that the length of the training was right, while 33%  
9 thought that it was too short. In dealing with patients with ear and hearing disorders, 52%  
10 reported that they felt comfortable and 48% very comfortable after the training. None of the  
11 CHWs reported feeling uncomfortable. Overall, the average cost of training one CHW was  
12 \$189, including trainer's costs (\$33), trainee's stipend (\$64), training supplies (\$61) and travel  
13 costs (\$31).  
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22 After training, the CHWs identified and referred a total of 1,739 patients with suspected ear  
23 disorder or hearing loss. Of these, only 860 patients (49%) attended the screening camp. Of those  
24 attending, 67.2% were female and mean age was 23 years (range 2 months to 90 years).  
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28 TEOAEs were obtained for subjects below 4 years and those who were not able to cooperate for  
29 audiometry. Out of 860 patients attending the screening camp, 249 patients had TEOAEs, 592  
30 audiometry, and for 19 it was not possible to undertake either audiometry or TEOAE.  
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37 Out of the 592 patients that underwent audiometry, 327 (55%) had hearing impairment defined  
38 as PTA > 25 dB in the better hearing ear (Table 2). Of the 265 subjects without hearing  
39 impairment according to this definition, 115 had unilateral hearing loss while 152 subjects had  
40 normal hearing (PTA ≤ 25 dB) in both ears. Of those who underwent TEOAE, 73 patients (30  
41 %) had bilateral fail. Consequently, of the 841 who were screened, 400 (48%) were found to  
42 have a hearing impairment. The rest had either unilateral hearing loss (n = 115), normal hearing  
43 but with ear disorders (n = 148) or normal hearing without ear disorder (n = 184).  
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**Table 2. Categories of hearing impairment reported as Pure-Tone Average of 0.5, 1, 2 and 4 kHz in the better hearing ear**

Hearing impairment category (dB)	Children (<18 years)		Adults ( <u>≥ 18 years</u> )	
	Number of subjects	%	Number of subjects	%
Normal ( $\leq 25$ )	149	60.3	116	33.6
Slight (26-40)	73	29.6	119	34.5
Moderate (41-60)	19	7.7	74	21.5
Severe (61-80)	4	1.6	23	6.7
Profound ( $>80$ )	2	0.8	13	3.8
<b>TOTAL</b>	247	100	345	100

The causes of ear and hearing disorders were determined by an ENT Surgeon and ENT Clinical Officer (Table 3). It was not possible to determine the cause for one in three ears with an ear and hearing disorder for adults. For those conditions that we were able to determine the cause, the majority were caused by CSOM and Impacted Wax. Impacted Wax was removed on site and no further action was required.

**Table 3: Causes of ear and hearing disorders among participants who attended the examination camp**

ear conditions	<18 years		>18 years	
	Total number of ears	%	Total number of ears	%
Wax	89	9.2	122	16.2
Foreign Body	8	0.8	1	0.1
Otitis Externa	3	0.3	1	0.1
Acute Otitis Media	23	2.4	11	1.5
Chronic Suppurative Otitis Media	165	17.0	110	14.6
OME	36	3.7	45	6.0
Dry Perforation	5	0.5	14	1.9
Infectious Diseases	22	2.3	8	1.1
Genetic Diseases	8	0.8	3	0.4
Non-Infectious Diseases	4	0.4	22	2.9
Undetermined Causes	124	12.8	250	33.2
Not tested	36	3.7	2	0.3
Normal ear and hearing	445	46.0	<b>163</b>	21.7
<b>Total</b>	<b>968</b>	100.0	<b>752</b>	100.0

Table 4 presents further action required for patients with ear and hearing disorders. The majority of the patients were given medication but were asked to be followed up by the ENT Clinical Officer at the district hospital. Those requiring hearing aid evaluation and surgery referral (mainly for tympano-mastoid surgery), were referred to a tertiary hospital of Queen Elizabeth Central.

**Table 4: Further actions needed for patients with ear and hearing disorders who attended the examination camp**

Action needed	Children (<18 years)		Adults ( <u>≥ 18 years</u> )	
	Number	%	Number	%
Medication	110	20.8	90	22.3
Hearing Aid Evaluation	86	16.2	146	36.2
Language and speech rehabilitation	3	0.6	0	0.0
Special Needs Education	14	2.6	1	0.2
Vocational training	4	0.8	0	0.0
Surgery referral	49	9.2	42	10.4

	264	49.8	124	30.8
<b>*TOTAL</b>	<b>530</b>	<b>100</b>	<b>403</b>	<b>100</b>

\*Out of total actions (not patients)

Table 5 shows the patients with ear and hearing disorders recorded at the ten health centres, comparing intervention and control groups at baseline, third and sixth months. Although the numbers recorded are small, there were more patients seen at baseline, third month and sixth month in the intervention group as compared to the control group. There was no difference in referral rates at baseline and 3 months or 6 months (paired t-test and Chi square:  $p > 0.05$ ).

**Table 5: Patients with ear and hearing disorders recorded at the ten health centres**

	<u>Baseline</u>	<u>3rd month</u>	<u>6th month</u>
<b><u>INTERVENTION GROUP</u></b>			
<u>Chimaliro</u>	<u>28</u>	<u>8</u>	<u>26</u>
<u>Chisoka</u>	<u>7</u>	<u>13</u>	<u>8</u>
<u>Changata</u>	<u>14</u>	<u>7</u>	<u>5</u>
<u>Gombe</u>	<u>11</u>	<u>6</u>	<u>2</u>
<u>Bvumbwe</u>	=	=	=
<b><u>Total (%)</u></b>	<b><u>60 (88)</u></b>	<b><u>34 (85)</u></b>	<b><u>41(77)</u></b>
<b><u>Mean</u></b>	<b><u>15</u></b>	<b><u>1.5</u></b>	<b><u>10.3</u></b>
<b><u>P-value</u></b>		<b><u>0.3098</u></b>	<b><u>0.1570</u></b>
<b><u>CONTROL GROUP</u></b>			
<u>Satemwa</u>	2	3	2
<u>Nansonia</u>	1	0	0
<u>Zoa</u>	5	1	5
<u>Ntambanyama</u>	0	2	5
<u>Nsabwe</u>	-	-	-
<b><u>Total (%)</u></b>	<b>8 (12)</b>	<b>6 (15)</b>	<b>12 (23)</b>

<b>Mean</b>	2	1.5	3
<b>P-value</b>		0.7306	0.5137

‘-’ data was not collected for the two health centres

## **FINDINGS FROM FOCUS GROUP DISCUSSIONS**

Three main themes emerged from the focus group discussions: training of CHWs and other health workers, identification of patients and problems faced in the mobilization of patients.

### **Training of HSAs and other health workers**

Overall, the training was felt to be successful, however there was an expressed need to expand the training for CHWs to include medical assistants and other health workers in health facilities in their areas. As one trainee put it:

*“It is only a few of us who have received this training, therefore I feel that those other remaining HSA’s and other health workers should also get the training, so that the other remaining communities should be assisted”*

There were issues concerning the complexity of the diagrams used in the training manual, as the participants found these difficult to understand.

*“Do you see that, these words written about the anatomy of the ear, but when I now come to the real ear and ask what’s this. For me to find the part, according to the way the picture looks like, I cannot manage to identify that, because the picture and the real ear are two different things, eeh but, the manual has been helpful.”*

There was also a request for more practice, rather than theory, particularly with respect to diagnosis of conditions.

*‘I feel that if only we had trainings where we could also have practicals, it would have been helpful’*

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13 Identification of participants  
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15 A number of problems were encountered by the CHWs in the identification of participants with  
16 ear disorders or hearing loss and these included failure of the otoscopes:  
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20 *“Like at the beginning, when using the otoscope, maybe you may have prepared to go out for*  
21 *work, you happen to find that it is cloudy, there are showers, whereby you couldn't have charged*  
22 *the device”*  
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26 On the other hand, other participants were happy with the equipment.  
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28 *“This work shows that this doesn't require expensive instruments or instruments that are hard to*  
29 *purchase, that's what I observed, those are my views’.*  
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33 Others reported on particular methods that helped in the identification of patients, such as the  
34 involvement of the chief to legitimize the work.  
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52 Problems faced with mobilization of patients for screening camps  
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3 A number of problems were encountered by the CHWs, and these included poor weather  
4 conditions, belief in different deities so that people would rather go and receive prayers than  
5 meet health personnel, lack of support from the village heads and competing ongoing events that  
6 were a distraction (e.g. the free distribution of fertilizer coupons).  
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11 *'Whenever we could go to the field just as my friend has said it, it used to be very hard because*  
12 *whenever we could go to the field and happen to get to the venue, it would be found that people*  
13 *could have gone for registration (for fertilizer coupons) just the way it happens during this time*  
14 *to register for coupons in the village, and were supposed to stay in the village and wait for them'*  
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## 20 21 **DISCUSSION**

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24 The Primary Ear and Hearing training increased the knowledge and confidence of CHWs in ear  
25 and hearing care, an area of health care in which they had not previously been trained. The  
26 trained CHW demonstrated their ability to identify patients with ear and hearing disorders, both  
27 through outreach and as part of routine practice. They identified 1,730 people with potential ear  
28 or hearing disorders of whom 860 attended a screening, and almost half (400) had significant  
29 hearing loss and a further 115 had unilateral hearing loss. More patients with ear and hearing  
30 disorders were recorded at the health centres in the intervention group as compared to the control  
31 group. Although the number of CHWs who were trained per health centre was small, this is  
32 encouraging as it can be scaled up. Furthermore, the training was relatively cheap (\$189 per  
33 CHW trained) and well received by the participants.  
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43 Successful integration of ear and hearing care into primary health care requires resources, to  
44 raise awareness, train CHWs, and provide equipment and medications at the health centre.  
45 Important lessons can also be learnt from the study and the existing literature in considering  
46 whether and how to scale up the Primary Ear and Hearing training.  
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53 *Were CHW the appropriate target for training?*  
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This study showed that trained CHWs proved to be a valuable resource in mobilizing patients with ear and hearing disorders. This is in contrast to what Kalua et al showed that other community Key Informants (e.g. village volunteers) were much better at identifying blind children than CHWs.<sup>17</sup> In that study, CHWs reported lack of time as a major constraint in identifying blind children, and it is well known that CHWs are often over-loaded with many competing tasks.. Although, we did not compare with other cadres of community like village volunteers, we found that the number of patients with potential hearing loss identified by CHWs were still large.

### *Was the length of training sufficient?*

Most of the CHWs were happy with the length of the training while few would like it to have been extended. The cost of training of our training was an average of \$189 per health worker. Kyabayinze in Uganda showed that the average cost per health worker of the one day training was \$101 (range \$92-112) with the main cost drivers being trainee travel and per diems<sup>18</sup>. One of the ways of reducing the cost of training is to reduce the length of the training, which would require further testing. In Mental health and Blindness, they have successfully conducted one day training sessions.<sup>19</sup> However, reducing the length of training was against the expressed wishes of the CHWs.

### *Were the CHW able to identify people with ear and hearing disorders?*

CHWs were able to identify people with ear and hearing disorders both within the community and in the clinics.

Although the CHWs were able to identify about 1,730 patients, only 860 patients appeared for screening. The major reason given for non attendance was that most clients went to receive free fertilizer coupons. Other barriers in ear and hearing care need to be explored in more detail, and could include difficulties in accessing care, limited engagement of communities and inadequate support from health systems<sup>20</sup>. Muller et al reported that of the 84 trained Village Health Workers (VHWs) in Primary Eye Care, only 13 (15%) brought patients to the health centres and the main reason suggested for the difference was lack of motivation among VHWs.<sup>19</sup>

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6 Resources may be required to pay for transport reimbursements for patients to travel from their  
7 villages to the health centre since there is clearly a large unmet need for services among people  
8 in the communities.  
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14 *Were the CHWs appropriately equipped?*  
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17 Equipping CHWs with a tool like an Arclight Otoscopes may have improved the diagnostic  
18 accuracy especially for Impacted Wax and CSOM. There is need to do more research on the  
19 provision of diagnostic and therapeutic primary ear and hearing care services by CHWs and  
20 general health workers at frontline health facilities. With the advent of a lot of software  
21 applications for audiometry<sup>21</sup>, there is need to look at the feasibility of equipping the CHWs with  
22 the tool. Furthermore, research is needed as to which therapeutic approaches are appropriate at  
23 primary level. For instance, primary health care workers are often taught to do dry mopping for  
24 wet perforations. Among our patients with wet perforations, a number of them had dead house  
25 flies in the ears which may have been difficult to remove with dry mopping alone. Evidence is  
26 also needed as to whether or not ear syringing may be useful for these sort of conditions.  
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38 In summary, in line with the Malawi Government guidelines on task shifting to CHWs<sup>22</sup>, the  
39 following tasks in ear and hearing care are recommended for CHWs. There are 1) Information,  
40 Education and Communication( IEC) on ear and hearing disorders, 2) Identification of cases for  
41 referral, 3) Follow- up of cases for treatment adherence, 4) Support and Counselling of families  
42 on ear and hearing disorders. All these tasks are based on the assumption that the CHWs have  
43 been trained in ear and hearing care and that equipment like Otoscopes are made available to  
44 them.  
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52 There are important strengths to the study. It used a structured framework to assess the feasibility  
53 and acceptability of the intervention to train CHW in primary ear and hearing care. The training  
54 and screening camps were led by an ENT surgeon, and drew on tools prepared by the WHO.  
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There are also limitations to consider. It was not possible to explore in detail why people did not attend at the screening camp. We only conducted FGDs with CHWs. In-depth interviews with people who did not attend the screening camps could have provided more information. Furthermore, the impact of training CHW in PEHC on their routine clinical activities was not fully evaluated, nor the impact on the number of diagnoses and referrals made of ear and hearing disorders at the primary care level on reducing the burden at the secondary and tertiary levels. We are aware that roles and responsibilities of CHWs is different in different countries. Therefore generalization of these findings to other settings must be done with caution.

## Conclusions

The training was effective in improving the knowledge of CHW in ear and hearing care in Malawi and allowing them to identify people in the community requiring ENT services. Based on the success of this study, training of CHWs and their identification of patients with ear and hearing disorders, could be scaled up in Malawi and tested in other low and middle income countries.

**Contributorship statement:** WM, HK, and FG designed the study. HK and FG helped with data analysis and drafting of the manuscript. WM conducted the study in Malawi, did data collection, data analysis and drafting of the manuscript. AV helped to draft and revise the manuscript. All authors read and approved the final manuscript.

**Competing interests:** None declared

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**Data sharing statement:** No additional data are available

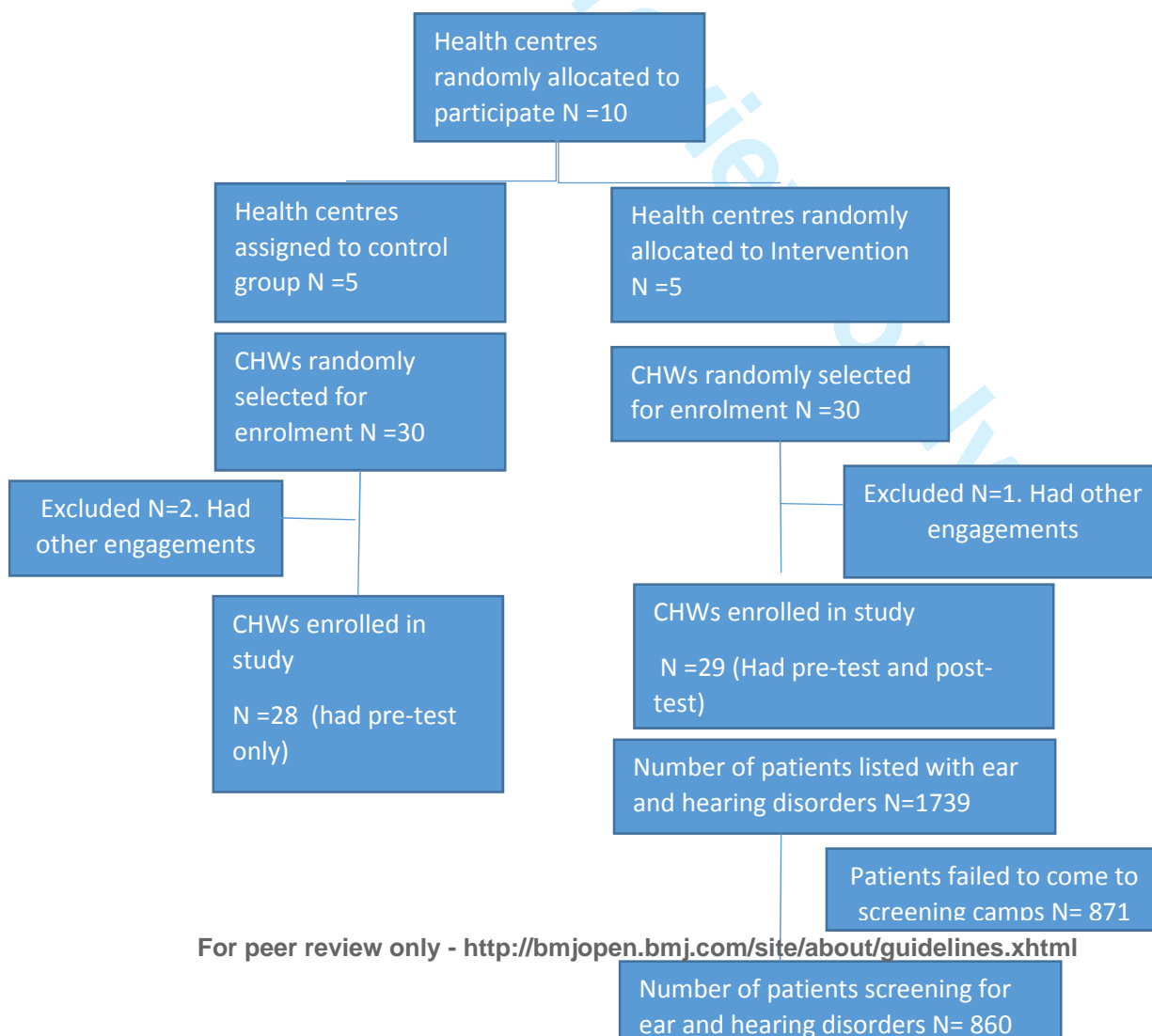
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Figure 1: Flow of participants through the study



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# CONSORT 2010 checklist of information to include when reporting a randomised trial\*

Section/Topic	Item No	Checklist item	Reported on page No
<b>Title and abstract</b>			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
<b>Introduction</b>			
Background and objectives	2a	Scientific background and explanation of rationale	5 & 6
	2b	Specific objectives or hypotheses	6
<b>Methods</b>			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	7 & 8
	4b	Settings and locations where the data were collected	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8,9,10 & 11
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9,10 & 11
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
<b>Randomisation:</b>			
Sequence generation	8a	Method used to generate the random allocation sequence	8
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	8
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	8
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	12
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
<b>Results</b>			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	8
	13b	For each group, losses and exclusions after randomisation, together with reasons	13
Recruitment	14a	Dates defining the periods of recruitment and follow-up	11
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	13
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	13
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	13
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	13-20
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	13-20
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
<b>Discussion</b>			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	25
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	23-25
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	23-25
<b>Other information</b>			
Registration	23	Registration number and name of trial registry	3
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	26

\*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org).

# BMJ Open

## Feasibility and Acceptability of Training Community Health Workers in Ear and Hearing Care in Malawi: A cluster randomised controlled trial

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2017-016457.R1
Article Type:	Research
Date Submitted by the Author:	30-May-2017
Complete List of Authors:	Mulwafu, W; College of Medicine Blantyre Malawi, Surgery Kuper, Hannah; The London School of Hygiene & Tropical Medicine, Clinical Research Viste, Asgaut; Haukeland Universitetssjukehus Goplen, Frederik K.; Haukeland Universitetssjukehus
<b>Primary Subject Heading</b>:	Ear, nose and throat/otolaryngology
Secondary Subject Heading:	Ear, nose and throat/otolaryngology
Keywords:	ear and hearing disorders, training, community health workers

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Manuscripts

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3 **Feasibility and Acceptability of Training Community Health Workers in Ear and Hearing**  
4 **Care in Malawi: A cluster randomised controlled trial**  
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## Abstract

### OBJECTIVE:

To assess the feasibility and acceptability of training community health workers (CHWs) in ear and hearing care, and their ability to identify patients with ear and hearing disorders.

### DESIGN:

Cluster randomised controlled trial (RCT).

### SETTING:

Health Centres in Thyolo district, Malawi.

### PARTICIPANTS:

Ten health centres participated, 5 intervention (29 CHWs) and 5 control (28 CHWs).

### INTERVENTION:

Intervention CHWs received 3 days of training in Primary Ear and Hearing Care, while among control CHWs training was delayed for 6 months. Both groups were given a pre-test that assessed knowledge about ear and hearing care, only the intervention group was given the post-test on the third day of training. Intervention group was given one month to identify patients with ear and hearing disorders in their communities, and these people were screened for hearing disorders by ENT clinical specialists.

### OUTCOME MEASURES:

Primary outcome measure was improvement in knowledge of ear and hearing care among CHWs after the training. Secondary outcome measures were number of patients with ear or hearing disorders identified by CHWs and number recorded at health centres during routine activities, and the perceived feasibility and acceptability of the intervention.

## RESULTS:

The average overall correct answers increased from 55% to 68% (95% CI 65-71) in the intervention group ( $p < 0.001$ ). A total of 1,739 patients with potential ear and hearing disorders were identified by CHWs and 860 patients attended the screening camps, of whom 400 had hearing loss (73 patients determined through bilateral fail on Oto-acoustic Emissions, 327 patients through audiometry). Where cause could be determined, the most common cause of ear and hearing disorders was chronic suppurative otitis media followed by impacted wax. The intervention was perceived as feasible and acceptable to implement.

## CONCLUSIONS:

Training was effective in improving the knowledge of CHW in ear and hearing care in Malawi and allowing them to identify patients with ear and hearing disorders. This intervention could be scaled up to other CHWs in LMICs.

**TRIAL REGISTRATION NUMBER:** PACTR201705002285194

### Strengths and limitations of this study

- Structured framework was used to assess the feasibility and acceptability of the intervention to train CHWs in primary ear and hearing care
- The training and screening camps were led by an ENT surgeon, and drew on tools prepared by the WHO
- Through focus group discussions with CHWs, we explored the reasons why people did not attend at the screening camp. In-depth interviews with people who did not attend screening camps could have provided additional information.
- Roles and responsibilities of CHWs is different in different countries. Therefore, generalization of these findings to other settings must be done with caution.

- Although the cost of the training is reported, the full cost of the intervention, taking into account costs of referrals and final treatment, was not assessed.

For peer review only

## Introduction

Hearing loss is the most common sensory disability and its prevalence is increasing globally with population ageing.<sup>1</sup> According to the World Health Organisation (WHO), an estimated 360 million people, or 5.3% of the world's population, are living with disabling hearing impairment.<sup>2</sup> Data for Sub-Saharan Africa are sparse, but the prevalence of hearing impairment may be even higher in this region.<sup>3</sup> 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 treatment and prevention.<sup>4</sup>

Ear and hearing problems can cause life-long difficulties. They may have profound effect on the ability of individuals to communicate with others, on their education, and on their ability to obtain and keep employment.<sup>5</sup> Furthermore, hearing loss also impacts negatively on social relationships and may lead to stigmatization.<sup>6</sup> Consequently, ear and hearing problems are likely to produce substantial economic burdens on individuals, communities and countries.<sup>7</sup>

The high prevalence of ear diseases and hearing loss in Sub-Saharan Africa is at least partly due to the severe shortage of health workers including audiologists, and of resources for hearing aid provision, support and aural rehabilitation programmes.<sup>8</sup> Educating Community Health Workers (CHWs) about ear disease and hearing loss can help to fill these gaps in settings with a scarcity of specialist health workers. CHWs are members of the communities where they work, selected by the communities, answerable to the communities for their activities, and have shorter training than specialist health workers.<sup>9</sup>

The role of CHWs may be particularly important in controlling ear and hearing problems. Effective interventions against ear and hearing problems include ear wax removal, treatment of chronic suppurative otitis media and provision of hearing aids. These interventions can be implemented at the primary level by trained CHWs and have the potential for a major impact on the burden of ear disease and hearing loss when used on large scale.<sup>10,11</sup> However, most low and middle income countries do not have CHWs trained in Primary Ear and Hearing Care (PEHC).<sup>12</sup>

Malawi is a setting where CHWs can potentially make an important contribution to controlling ear and hearing problems. There are only two ENT Surgeons for a population of more than 17 million, and only 25 ENT Clinical Officers.<sup>13</sup> Data are limited, but a study among children



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3 showed a high prevalence of hearing loss, with an estimated 1,800 children per million  
4 population with hearing impairment from avoidable causes that could be treated through  
5 provision of basic primary level ear and hearing care, in particular wax and middle ear disease.<sup>14</sup>  
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9 The aim of this study was to assess the feasibility and acceptability of training CHWs to provide  
10 primary level ear and hearing care, including: identification of patients with ear and hearing  
11 disorders, referral of patients to services, and treatment of simple ear conditions.  
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## **Methods**

### *Ethical approval*

Ethical approval was provided by the College of Medicine Research Ethics Committee in Malawi. The study was evaluated and found exempt from review by the Norwegian Regional Committee for Medical and Health Research Ethics (2016/1472 REC South East, Section D).

### *Study design*

An intervention study was undertaken to assess the feasibility and acceptability of training CHWs in primary ear and hearing care. A group of CHW were selected, and half the participants were randomized to receive training in primary ear and hearing care, while for the remainder training was delayed for six months.

### *Study outcomes*

Primary outcome measure was improvement in knowledge of ear and hearing care among CHWs after the training. Secondary outcome measures were number of patients with ear or hearing disorders identified by CHWs and number recorded at health centres, and the perceived feasibility and acceptability of the intervention.

## **Setting**

Thyolo district was selected as the study area. Thyolo is a tea-growing district with a population of approximately 460 000, mainly Lomwe people. It is situated about 30 km away from Blantyre, where the only dedicated Ear, Nose and Throat (ENT) Unit in Malawi is located. The district hospital is one of eight district hospitals which has an ENT Clinical Officer, who has been working in Thyolo for two years. Within this district there are 33 health centres. Each Health Centre is supported by about 10 CHWs and serves a catchment area of approximately 14 000 people.

## **Subjects**

CHWs were selected among Malawian Health Surveillance Assistants, which is the formal cadre of CHWs in Malawi. These form a cadre of 10,500 frontline health workers employed by the Ministry of Health and comprise 30% of the health workforce in Malawi.<sup>15</sup> Each Health Surveillance Assistant 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. They track pregnancies, births, and deaths using their Village Health Registers, conduct health talks and vaccinations. Each receives 12 weeks of training and has important roles in providing care, promoting community participation in health care activities and in promoting disease surveillance services at the community level. Prior to this study, they had not received any training in primary ear and hearing care.

A list of all the 33 health centres together with all the names of the CHWs in Thyolo district was compiled with the help of the District Health Environmental Office in Thyolo district. Using a Random Number Generator, we selected 10 health centres for inclusion in the trial (Figure 1); we then randomly allocated five health centres to the intervention group and five health centres to the Control group. Using the Random Number Generator, we selected 6 CHWs (out of approximately 10 CHW) per Health Centre. Consequently, a total of 30 intervention CHWs and 30 control CHWs were selected.

## **Consent and pre-test**

The selected CHWs were called up for a briefing at a central location, with intervention and control groups meeting separately. They were briefed on the study and written consent was taken from them to be part of the study after they had received details of what participation involved.

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3 Data collected from the CHWs included age, sex and years of formal education. They were  
4 administered a pre-test questionnaire containing the questions from the first 6 modules of the  
5 intermediate level WHO Primary Ear and Hearing Care Trainer's Manual (10 questions per  
6 module).<sup>16</sup> The participants in the control group were assured of the training after 6 months.  
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### 14 **Training for intervention group**

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16 The training lasted three days and was undertaken by an ENT Surgeon and two ENT Clinical  
17 Officers. The two ENT Clinical Officers each had 18 months of training in ENT and had  
18 participated in a primary ear and hearing care course. A training curriculum and manual was  
19 developed in English by local experts (1 Audiologist, 3 Audiological Officers, 3 ENT Clinical  
20 Officers and 1 ENT Surgeon). The training manual was based on both the Basic and Intermediate  
21 Manual of WHO Primary Ear and Hearing Care Training Resources.<sup>16</sup>  
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30 The first part of the training focused on knowledge about ear and hearing disorders. Training  
31 emphasized the structure and function of the ear, causes of hearing impairment and their  
32 management and levels of hearing impairment. Next, the training focused on skills training,  
33 including: 1) History taking in patient with ear and hearing disorders, 2) Ear examination, 3)  
34 Steps in doing otoscopy, 4) Steps in doing voice tests, 5) Assessment of hearing in children.  
35 Training methods included lectures, posters of ear and hearing disorders, flip charts, and  
36 demonstrations, practical of voice tests, discussion and group work. Training was done both in  
37 English and Chichewa. At the end of the training, each CHW was given a training manual that  
38 contained the key points of training and which could be referred to when needed. They were also  
39 given Arclight Otoscopes (WJW Ltd, Liverpool, UK), to allow ear examination.  
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48 The participants were given a post-test questionnaire on the third day of training, using the same  
49 questionnaire as in pre-test. The participants were also asked how their opinions about the length  
50 of training and whether or not they felt comfortable in identifying people with ear and hearing  
51 disorders.  
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### **Mobilization of patients by Community Health Workers**

After training, each CHW in the intervention group was given one month to identify, list and refer patients with suspected ear and hearing disorders from their own village to their corresponding health centre. First, the CHW met with the Village Headman, village development committee members and village health committee members to explain in detail about the programme. Next, the CHW met with the community members to explain about the programme and to schedule dates for screening of the community members. CHWs were asked to use multiple methods in their identification (door to door, school screenings, health education, church/mosque announcements). CHWs took history, did otoscopy and voice tests as a way of identifying community members with ear and hearing disorders. CHWs created a list of patients they suspected of having ear and hearing disorders in their community.

Identified patients with suspected ear disorder or hearing loss were asked to come to the scheduled screening camps, which took place at the five health centres of Bvumbwe, Chimaliro, Chisoka, Changata and Gombe.

### **Screening Camps**

The listed patients were asked to come to the health centre in their catchment area together with their CHW. A team of 6 people (One ENT Surgeon, One ENT Clinical Officer, Queen Elizabeth Central Hospital (QECH) Audiological Officers and two research assistants) from the ENT Department at QECH in Blantyre traveled to all the five health centres in Thyolo to conduct the screening camps.

All patients underwent otoscopy, pure tone audiometry, transient evoked otoacoustic emissions (TEOAEs) and tympanometry performed by one of two audiological officers.

- Otoscopy was performed on all patients using the Heine Mini 2000 (HEINE Optotechnik, Herrsching, Germany).
- Audiometry was performed in all patients aged >4 years who were able to cooperate in a quiet room using the KUDUwave 5000 audiometer (eMoyoDotnet (Pty) Ltd, Randburg,

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3 South Africa). Thresholds were obtained at frequencies of .5, 1, 2 and 4 kHz according to  
4 WHO recommendations. Pure tone average (PTA) was calculated based on these four  
5 frequencies. Hearing impairment was defined as PTA > 25dB in the better ear.  
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- 8 - TEOAEs were measured in subjects aged less than 4 years and those who were not able  
9 to cooperate for audiometry. TEOAEs were tested using the Sentiero handheld device  
10 (PATH Medical Solutions, Guymark, UK) and assessed in each ear at frequencies  
11 between 1000 and 4000 kHz. Results were graded as 'pass' (indicating normal hearing)  
12 or 'fail' (indicating impaired hearing).  
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14 - Tympanometry was done in all patients using Tympanometer S/N P 99 0556, Grason-  
15 Stadler, USA.  
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21 Data was recorded on the WHO/PBD Ear and Hearing Disorders Survey Form.  
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26 Patients with ear wax had this removed on site by ENT Clinicians. Those with discharging ears  
27 had ear toilet and were given ciprofloxacin ear drops. Those with bigger wet perforations had  
28 Candiderm (Beclomethasone Dipropionate, Clotrimazole, and Gentamicin Sulphate) inserted in  
29 the middle ear. All patients with chronic otitis media (active or inactive) were referred to QECH.  
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33 Recorded data of patients with ear and hearing disorders at the health centres were collected at  
34 baseline (one month data before the study), at three months and six months after intervention.  
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### 40 **Qualitative data collection**

41 We used the consolidated criteria for reporting qualitative studies (COREQ) checklist to report our  
42 methods and results<sup>17</sup>. Focus Group Discussions (FGDs) were undertaken by a female research  
43 assistant in three of the five health centres (Chimaliro, Bvumbwe and Chisoka). In each health  
44 centre, we chose a quiet room where the discussion were conducted. The CHWs involved in the  
45 FGDs were purposively selected. There were a total of 17 CHWs (9 females and 8 Males) who  
46 participated in the three FGDs, each including 5-6 participants. The female research assistant  
47 was not involved in quantitative data collection or analysis to reduce the possibility of bias. We  
48 conducted the FGDs using semi-structured interview guide. The guided discussions asked CHWs  
49 about their impressions on training, and challenges faced when identifying people with ear and  
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3 hearing disorders. Each FGDs took approximately 45 minutes. The discussions were in  
4 Chichewa (national language of Malawi). FGDs were audio-recorded.  
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### 10 11 12 13 14 **Data analysis**

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17 Data were analysed using Stata version 13. Tests for normality were done using SPSS version  
18 21. All the scores were tested for normal distribution using the Shapiro-Wilk test. We conducted  
19 an independent t-test to determine the difference in the mean knowledge scores between the  
20 intervention and control groups and paired t-test in the intervention group before and after the  
21 training. For all procedures, alpha was set at 0.05. Paired t-test and chi square statistic were used  
22 to compare number of patients seen at baseline in the health centres to those seen at three months  
23 and six months in both intervention and control groups.  
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31 Transcripts from each focus group discussions were generated and translated into English, and  
32 those transcripts were examined for recurring themes and patterns through open coding and  
33 qualitative content analysis. Nvivo 11 was used for coding the data.  
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## RESULTS

A total of 57 CHWs were included, 28 in the control arm and 29 in the intervention arm.

Intervention and control CHWs were similar in terms of proportion of males (59% vs 54%), mean age (37 years, range 28-51 vs 38 years, range 29-55), and proportion who had 10 years or more of formal education (56% vs 54%).

Test scores are shown in table 1. In the pre-test questionnaire, the intervention group scored slightly lower (55%, 95% CI 52-58%) compared to the control group (58%, 95% CI 56-60%;  $p < 0.05$ ). After training, the mean score for the post-test in the intervention group increased to 68% (95% CI 65-71%), showing a statistically significant improvement from baseline ( $p < 0.001$ ).

There was also improvements in knowledge for the individual modules, except for the module on the inner ear, and assessment and counselling.



**TABLE 1: Proportion of CHWs who answered correctly in the six different modules**

Module	Proportion of questions answered correctly:			Significance (paired t- test pre- vs post-test)
	Control group pre-test (n=28)	Intervention group pre-test (n=29)	Intervention group post-test (n=29)	
Structure and function of the ear	58%	61%	82%	<0.0001
Hearing impairment and deafness: causes and prevention	52%	53%	78%	<0.0001
The outer ear: examine, treat and refer	59%	53%	74%	<0.0001
The ear canal: examine, diagnose and clean	54%	47%	57%	0.03
The middle ear: examine, diagnose	55%	48%	52%	0.28

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and treat				
Assessing hearing and counselling	72%	69%	66%	0.17
<b>ALL MODULES</b>	<b>58%</b>	<b>55%</b>	<b>68%</b>	<b>&lt;0.0001</b>

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8 The majority of the CHWs (67%) said that the length of the training was right, while 33%  
9 thought that it was too short. In dealing with patients with ear and hearing disorders, 52%  
10 reported that they felt comfortable and 48% very comfortable after the training. None of the  
11 CHWs reported feeling uncomfortable. Overall, the average cost of training one CHW was  
12 \$189, including trainer's costs (\$33), trainee's stipend (\$64), training supplies (\$61) and travel  
13 costs (\$31).  
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22 After training, the CHWs identified and referred a total of 1,739 patients with suspected ear  
23 disorder or hearing loss. Of these, only 860 patients (49%) attended the screening camp. Of those  
24 attending, 67.2% were female and mean age was 23 years (range 2 months to 90 years).  
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30 TEOAEs were obtained for subjects below 4 years and those who were not able to cooperate for  
31 audiometry. Out of 860 patients attending the screening camp, 249 patients had TEOAEs, 592  
32 audiometry, and for 19 it was not possible to undertake either audiometry or TEOAE. Out of the  
33 592 patients that underwent audiometry, 327 (55%) had hearing impairment defined as PTA > 25  
34 dB in the better hearing ear (Table 2). Of the 265 subjects without hearing impairment according  
35 to this definition, 115 had unilateral hearing loss while 152 subjects had normal hearing (PTA ≤  
36 25 dB) in both ears. Of those who underwent TEOAE, 73 patients (30 %) had bilateral fail.  
37 Consequently, of the 841 who were screened, 400 (48%) were found to have a hearing  
38 impairment. The rest had either unilateral hearing loss (n = 115, 14%), normal hearing but with  
39 ear disorders (n = 148, 18%) or normal hearing without an ear disorder (n = 184, 22%).  
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**Table 2. Categories of hearing impairment reported as Pure-Tone Average of 0.5, 1, 2 and 4 kHz in the better hearing ear among participants attending the screening camp**

Hearing impairment category (dB)	Children (<18 years)		Adults ( <u>≥ 18 years</u> )	
	Number of subjects	%	Number of subjects	%
Normal ( $\leq 25$ )	149	60.3	116	33.6
Slight (26-40)	73	29.6	119	34.5
Moderate (41-60)	19	7.7	74	21.5
Severe (61-80)	4	1.6	23	6.7
Profound ( $>80$ )	2	0.8	13	3.8
<b>TOTAL</b>	247	100	345	100

The causes of ear and hearing disorders were determined by an ENT Surgeon and ENT Clinical Officer (Table 3). It was not possible to determine the cause for one in three ears with an ear and hearing disorder for adults. For those conditions that we were able to determine the cause, the majority were caused by Chronic Suppurative Otitis Media and Impacted Wax. Impacted Wax was removed on site and no further action was required.

**Table 3: Causes of ear and hearing disorders among participants who attended the screening camp**

ear conditions	<18 years		>18 years	
	Total number of ears	%	Total number of ears	%
Wax	89	9.2	122	16.2
Foreign Body	8	0.8	1	0.1
Otitis Externa	3	0.3	1	0.1
Acute Otitis Media	23	2.4	11	1.5
Chronic Suppurative Otitis Media	165	17.0	110	14.6
Otitis Media with Effusion	36	3.7	45	6.0
Dry Perforation	5	0.5	14	1.9
Infectious Diseases	22	2.3	8	1.1
Genetic Diseases	8	0.8	3	0.4
Non-Infectious Diseases	4	0.4	22	2.9
Undetermined Causes	124	12.8	250	33.2
Not tested	36	3.7	2	0.3
Normal ear and hearing	445	46.0	<b>163</b>	21.7

<b>Total</b>	<b>968</b>	<b>100.0</b>	<b>752</b>	<b>100.0</b>
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Table 4 presents further action required for patients with ear and hearing disorders. The majority of the patients were given medication on the spot, but were asked to be followed up by the ENT Clinical Officer at the district hospital. Those requiring hearing aid evaluation and surgery referral (mainly for tympano-mastoid surgery), were referred to a tertiary hospital of QECH.

**Table 4: Further actions needed for patients with ear and hearing disorders who attended the screening camp**

<b>Action needed</b>	<b>Children (&lt;18 years)</b>		<b>Adults (&gt; 18 years)</b>	
	<b>Number</b>	<b>%</b>	<b>Number</b>	<b>%</b>
Medication	110	20.8	90	22.3
Hearing Aid Evaluation	86	16.2	146	36.2
Language and speech rehabilitation	3	0.6	0	0.0
Special Needs Education	14	2.6	1	0.2
Vocational training	4	0.8	0	0.0
Surgery referral	49	9.2	42	10.4

	264	49.8	124	30.8
<b>*TOTAL</b>	<b>530</b>	<b>100</b>	<b>403</b>	<b>100</b>

\*Out of total actions (not patients)

Table 5 shows the patients with ear and hearing disorders recorded at the ten health centres, comparing intervention and control groups at baseline, third and sixth months. Although the numbers recorded are small, there were more patients seen at baseline, third month and sixth month in the intervention group as compared to the control group. There was no difference in referral rates at baseline and 3 months or 6 months (paired t-test and Chi square:  $p > 0.05$ ).

**Table 5: Patients with ear and hearing disorders recorded at the ten health centres**

	<b><u>Baseline</u></b> <b><u>(one month pre</u></b> <b><u>intervention)</u></b>	<b><u>3rd month after</u></b> <b><u>intervention</u></b>	<b><u>6th month after</u></b> <b><u>intervention</u></b>
<b><u>INTERVENTION</u></b> <b><u>GROUP</u></b>			
<u>Chimaliro</u>	<u>28</u>	<u>8</u>	<u>26</u>
<u>Chisoka</u>	<u>7</u>	<u>13</u>	<u>8</u>
<u>Changata</u>	<u>14</u>	<u>7</u>	<u>5</u>
<u>Gombe</u>	<u>11</u>	<u>6</u>	<u>2</u>
<u>Bvumbwe</u>	=	=	=
<b><u>Total (%)</u></b>	<b><u>60 (88)</u></b>	<b><u>34 (85)</u></b>	<b><u>41(77)</u></b>
<b><u>Mean</u></b>	<b><u>15</u></b>	<b><u>1.5</u></b>	<b><u>10.3</u></b>
<b><u>P-value</u></b>		<b><u>0.31</u></b>	<b><u>0.16</u></b>
<b><u>CONTROL GROUP</u></b>			
<u>Satemwa</u>	<u>2</u>	<u>3</u>	<u>2</u>
<u>Nansonia</u>	<u>1</u>	<u>0</u>	<u>0</u>
<u>Zoa</u>	<u>5</u>	<u>1</u>	<u>5</u>
<u>Ntambanyama</u>	<u>0</u>	<u>2</u>	<u>5</u>
<u>Nsabwe</u>	-	-	-
<b><u>Total (%)</u></b>	<b><u>8 (12)</u></b>	<b><u>6 (15)</u></b>	<b><u>12 (23)</u></b>

<b>Mean</b>	2	1.5	3
<b>P-value</b>		0.73	0.51

‘-‘ data was not collected for the two health centres

### **FINDINGS FROM FOCUS GROUP DISCUSSIONS**

Three main themes emerged from the focus group discussions: training of CHWs and other health workers, identification of patients and problems faced in the mobilization of patients.

#### *Training of CHWs and other health workers*

Overall, the training was felt to be successful, however there was an expressed need to expand the training for CHWs to include medical assistants and other health workers in health facilities in their areas. As one trainee put it:

*“It is only a few of us who have received this training, therefore I feel that those other remaining HSA’s and other health workers should also get the training, so that the other remaining communities should be assisted”*

There were issues concerning the complexity of the diagrams used in the training manual, as the participants found these difficult to understand.

*“Do you see that, these words written about the anatomy of the ear, but when I now come to the real ear and ask what’s this? For me to find the part, according to the way the picture looks like, I cannot manage to identify that, because the picture and the real ear are two different things, eeh but, the manual has been helpful.”*

There was also a request for more practice, rather than theory, particularly with respect to diagnosis of conditions.



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*'I feel that if only we had trainings where we could also have practicals, it would have been helpful'*

### Identification of participants

A number of problems were encountered by the CHWs in the identification of participants with ear disorders or hearing loss and these included failure of the otoscopes, which were solar powered and so reliant on sunshine for charging:

*"Like at the beginning, when using the otoscope, maybe you may have prepared to go out for work, you happen to find that it is cloudy, there are showers, whereby you couldn't have charged the device"*

On the other hand, other participants were happy with the equipment.

*"This work shows that this doesn't require expensive instruments or instruments that are hard to purchase, that's what I observed, those are my views'.*

Others reported on particular methods that helped in the identification of patients, such as the involvement of the traditional chief of the village to legitimize the work.

### Problems faced with mobilization of patients for screening camps

A number of problems were encountered by the CHWs, and these included poor weather conditions, belief in different deities so that people would rather go and receive prayers than meet health personnel, lack of support from the village heads and competing ongoing events that were a distraction (e.g. the free distribution of fertilizer coupons).

*'Whenever we could go to the field just as my friend has said it, it used to be very hard because whenever we could go to the field and happen to get to the venue, it would be found that people*

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*could have gone for registration (for fertilizer coupons) just the way it happens during this time to register for coupons in the village, and were supposed to stay in the village and wait for them'*

## **DISCUSSION**

The Primary Ear and Hearing training increased the knowledge and confidence of CHWs in ear and hearing care, an area of health care in which they had not previously been trained. The trained CHW demonstrated their ability to identify patients with ear and hearing disorders, both through outreach and as part of routine practice. They identified 1,739 people with potential ear or hearing disorders of whom 860 attended a screening, and almost half (400) had significant hearing loss and a further 115 had unilateral hearing loss. There was little change, however, in the patients with ear and hearing disorders were recorded at the health centres after the intervention. The trainees perceived that the intervention was feasible and acceptable. Although the number of CHWs who were trained per health centre was small, these positive findings are encouraging as it can be scaled up. Furthermore, the training was relatively cheap (\$189 per CHW trained) and well received by the participants.

Successful integration of ear and hearing care into primary health care requires resources, to raise awareness, train CHWs, and provide equipment and medications at the health centre. Important lessons can also be learnt from the study and the existing literature in considering whether and how to scale up the Primary Ear and Hearing training.

*Were CHW the appropriate target for training?*

This study showed that trained CHWs proved to be a valuable resource in mobilizing patients with ear and hearing disorders. This is in contrast to what Kalua et al showed that other community Key Informants (e.g. village volunteers) were much better at identifying blind children than CHWs.<sup>18</sup> In that study, CHWs reported lack of time as a major constraint in

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3 identifying blind children, and it is well known that CHWs are often over-loaded with many  
4 competing tasks. Although, we did not compare with other cadres of community like village  
5 volunteers, we found that the number of patients with potential hearing loss identified by CHWs  
6 were still large.  
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### 10 11 12 *Was the content of the training appropriate?*

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15 There was an improvement in the knowledge of ear and hearing disorders among CHWs overall,  
16 showing that the training was appropriate. However, there was no improvement in knowledge  
17 about the middle ear or assessing hearing and counselling. Further improvement of these  
18 modules is needed to ensure that the material is at the right level for CHWs. About 22% of the  
19 patients examined at the screening camps did not have an ear and hearing disorder. We consider  
20 this to be a relatively low false-positive rate, showing that the CHWs were reasonably competent  
21 at identifying people with hearing loss. There is still room for improvement, however, and a  
22 further emphasis on future training should focus on normal ear anatomy and more practical  
23 sessions on normal ears. The CHWs were trained in otoscopy, but their practical skills were not  
24 assessed. The primary aim was to enable them to identify common pathologies like wax and discharge.  
25 However, in a possible higher level course in the future, it would be a good idea to test both manual and  
26 diagnostic skills.  
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### 40 41 *Was the length of training sufficient?*

42 Most of the CHWs were happy with the length of the training while few would like it to have  
43 been extended. The cost of training of our training was an average of \$189 per health worker.  
44 Kyabayinze in Uganda showed that the average cost per health worker of the one day training  
45 was \$101 (range \$92-112) with the main cost drivers being trainee travel and per diems.<sup>19</sup> One  
46 of the ways of reducing the cost of training is to reduce the length of the training, which would  
47 require further testing. In Mental health and Blindness, they have successfully conducted one day  
48 training sessions.<sup>20</sup> However, reducing the length of training was against the expressed wishes of  
49 the CHWs.  
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*Were the CHW able to identify people with ear and hearing disorders?*

CHWs were able to identify people with ear and hearing disorders both within the community and in the clinics. However, the accuracy of diagnosis made by CHWs compared with that of ENT specialist was not measured, which is a limitation.

Although the CHWs were able to identify about 1,739 patients, only 860 patients appeared for screening. The major reason given for non attendance was that most clients went to receive free fertilizer coupons. Other barriers in ear and hearing care need to be explored in more detail, and could include difficulties in accessing care, limited engagement of communities and inadequate support from health systems<sup>21</sup>. Muller et al reported that of the 84 trained Village Health Workers in Primary Eye Care, only 13 (15%) brought patients to the health centres and the main reason suggested for the difference was lack of motivation among Village Health Workers.<sup>20</sup>

Resources may be required to pay for transport reimbursements for patients to travel from their villages to the health centre since there is clearly a large unmet need for services among people in the communities.

*Were the CHWs appropriately equipped?*

Equipping CHWs with a tool like an Arclight Otoscopes may have improved the diagnostic accuracy especially for Impacted Wax and Chronic Suppurative Otitis Media.

There is need to do more research on the provision of diagnostic and therapeutic primary ear and hearing care services by CHWs and general health workers at frontline health facilities. With the advent of a lot of software applications for audiometry<sup>22</sup>, there is need to look at the feasibility of equipping the CHWs with the tool. Furthermore, research is needed as to which therapeutic approaches are appropriate at primary level. For instance, primary health care workers are often taught to do dry mopping for wet perforations. Among our patients with wet perforations, a number of them had dead house flies in the ears which may have been difficult to remove with dry mopping alone. Evidence is also needed as to whether or not ear syringing may be useful for these sort of conditions.

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6 In summary, in line with the Malawi Government guidelines on task shifting to CHWs<sup>23</sup>, the  
7 following tasks in ear and hearing care are recommended for CHWs. There are 1) Information,  
8 Education and Communication on ear and hearing disorders, 2) Identification of cases for  
9 referral, 3) Follow- up of cases for treatment adherence, 4) Support and Counselling of families  
10 on ear and hearing disorders. All these tasks are based on the assumption that the CHWs have  
11 been trained in ear and hearing care and that equipment like Otosopes are made available to  
12 them.  
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21 There are important strengths to the study. It used a structured framework to assess the feasibility  
22 and acceptability of the intervention to train CHW in primary ear and hearing care. The training  
23 and screening camps were led by an ENT surgeon, and drew on tools prepared by the WHO.  
24 There are also limitations to consider. It was not possible to explore in detail why people did not  
25 attend at the screening camp. We only conducted FGDs with CHWs. In-depth interviews with  
26 people who did not attend the screening camps could have provided more information.  
27 Furthermore, the impact of training CHW in PEHC on their routine clinical activities was not  
28 fully evaluated, nor the impact on the number of diagnoses and referrals made of ear and hearing  
29 disorders at the primary care level on reducing the burden at the secondary and tertiary levels.  
30 We are aware that roles and responsibilities of CHWs is different in different countries.  
31 Therefore generalization of these findings to other settings must be done with caution.  
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#### 44 **Conclusions**

45 The training was effective in improving the knowledge of CHW in ear and hearing care in  
46 Malawi and allowing them to identify people in the community requiring ENT services. Based  
47 on the success of this study, training of CHWs and their identification of patients with ear and  
48 hearing disorders, could be scaled up in Malawi and tested in other low and middle income  
49 countries.  
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3 **Contributorship statement:** WM, HK, and FG designed the study. HK and FG helped with data  
4 analysis and drafting of the manuscript. WM conducted the study in Malawi, did data collection,  
5 data analysis and drafting of the manuscript. AV helped to draft and revise the manuscript. All  
6 authors read and approved the final manuscript.  
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12 **Competing interests:** None declared  
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17 programme with the University of Bergen. Funding for this research came from the NORHED  
18 Surgery project (QZA-0484, MWI-13/0030)  
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25 **Data sharing statement:** No additional data are available  
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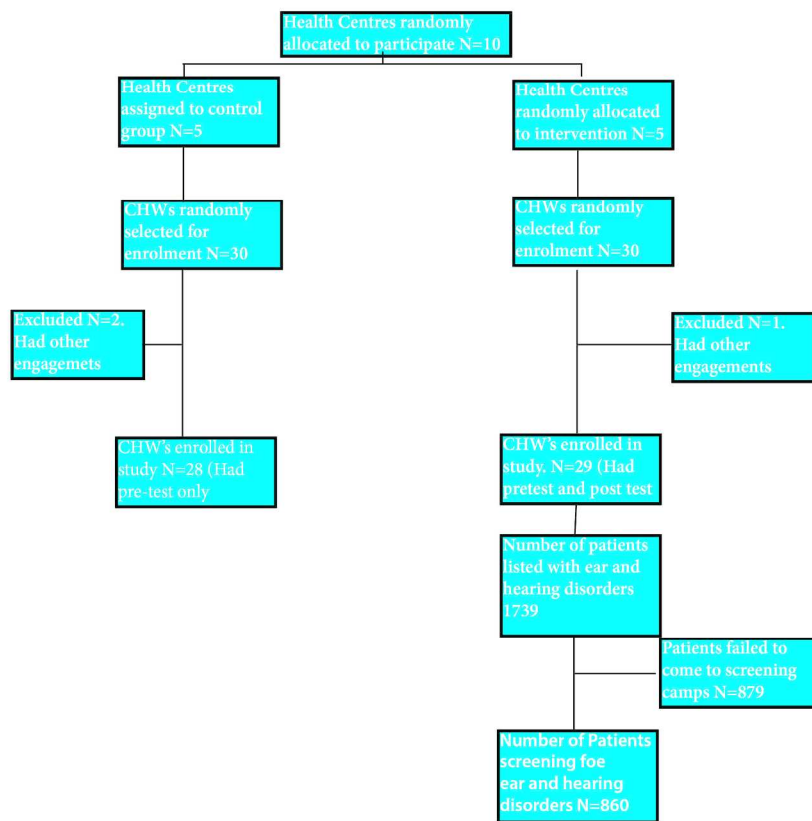


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For peer review only

Figure 1: Flow of participants through the study



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## CONSORT 2010 checklist of information to include when reporting a randomised trial\*

Section/Topic	Item No	Checklist item	Reported on page No
<b>Title and abstract</b>			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
<b>Introduction</b>			
Background and objectives	2a	Scientific background and explanation of rationale	5 & 6
	2b	Specific objectives or hypotheses	6
<b>Methods</b>			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	7 & 8
	4b	Settings and locations where the data were collected	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8,9,10 & 11
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9,10 & 11
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
<b>Randomisation:</b>			
Sequence generation	8a	Method used to generate the random allocation sequence	8
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	8
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	8
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	

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2		assessing outcomes) and how	
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4		11b If relevant, description of the similarity of interventions	
5	Statistical methods	12a Statistical methods used to compare groups for primary and secondary outcomes	12
6		12b Methods for additional analyses, such as subgroup analyses and adjusted analyses	
7			
8	<b>Results</b>		
9	Participant flow (a	13a For each group, the numbers of participants who were randomly assigned, received intended treatment, and	8
10	diagram is strongly	were analysed for the primary outcome	
11	recommended)	13b For each group, losses and exclusions after randomisation, together with reasons	13
12	Recruitment	14a Dates defining the periods of recruitment and follow-up	11
13		14b Why the trial ended or was stopped	
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15	Baseline data	15 A table showing baseline demographic and clinical characteristics for each group	13
16	Numbers analysed	16 For each group, number of participants (denominator) included in each analysis and whether the analysis was	13
17		by original assigned groups	
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19	Outcomes and	17a For each primary and secondary outcome, results for each group, and the estimated effect size and its	13
20	estimation	precision (such as 95% confidence interval)	
21		17b For binary outcomes, presentation of both absolute and relative effect sizes is recommended	13-20
22	Ancillary analyses	18 Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing	13-20
23		pre-specified from exploratory	
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25	Harms	19 All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
26			
27	<b>Discussion</b>		
28	Limitations	20 Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	25
29	Generalisability	21 Generalisability (external validity, applicability) of the trial findings	23-25
30	Interpretation	22 Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	23-25
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32	<b>Other information</b>		
33	Registration	23 Registration number and name of trial registry	3
34	Protocol	24 Where the full trial protocol can be accessed, if available	
35	Funding	25 Sources of funding and other support (such as supply of drugs), role of funders	26
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\*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org).

# BMJ Open

## Feasibility and Acceptability of Training Community Health Workers in Ear and Hearing Care in Malawi: A cluster randomised controlled trial

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2017-016457.R2
Article Type:	Research
Date Submitted by the Author:	06-Jul-2017
Complete List of Authors:	Mulwafu, W; College of Medicine Blantyre Malawi, Surgery Kuper, Hannah; The London School of Hygiene & Tropical Medicine, Clinical Research Viste, Asgaut; Haukeland Universitetssjukehus Goplen, Frederik K.; Haukeland Universitetssjukehus
<b>Primary Subject Heading</b>:	Ear, nose and throat/otolaryngology
Secondary Subject Heading:	Ear, nose and throat/otolaryngology
Keywords:	ear and hearing disorders, training, community health workers

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Manuscripts

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3 **Feasibility and Acceptability of Training Community Health Workers in Ear and Hearing**  
4 **Care in Malawi: A cluster randomised controlled trial**  
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## Abstract

### OBJECTIVE:

To assess the feasibility and acceptability of training community health workers (CHWs) in ear and hearing care, and their ability to identify patients with ear and hearing disorders.

### DESIGN:

Cluster randomised controlled trial (RCT).

### SETTING:

Health Centres in Thyolo district, Malawi.

### PARTICIPANTS:

Ten health centres participated, 5 intervention (29 CHWs) and 5 control (28 CHWs).

### INTERVENTION:

Intervention CHWs received 3 days of training in Primary Ear and Hearing Care, while among control CHWs training was delayed for 6 months. Both groups were given a pre-test that assessed knowledge about ear and hearing care, only the intervention group was given the post-test on the third day of training. Intervention group was given one month to identify patients with ear and hearing disorders in their communities, and these people were screened for hearing disorders by ENT clinical specialists.

### OUTCOME MEASURES:

Primary outcome measure was improvement in knowledge of ear and hearing care among CHWs after the training. Secondary outcome measures were number of patients with ear or hearing disorders identified by CHWs and number recorded at health centres during routine activities, and the perceived feasibility and acceptability of the intervention.



**RESULTS:**

The average overall correct answers increased from 55% to 68% (95% CI 65-71) in the intervention group ( $p < 0.001$ ). A total of 1,739 patients with potential ear and hearing disorders were identified by CHWs and 860 patients attended the screening camps, of whom 400 had hearing loss (73 patients determined through bilateral fail on Oto-acoustic Emissions, 327 patients through audiometry). Where cause could be determined, the most common cause of ear and hearing disorders was chronic suppurative otitis media followed by impacted wax. The intervention was perceived as feasible and acceptable to implement.

**CONCLUSIONS:**

Training was effective in improving the knowledge of CHW in ear and hearing care in Malawi and allowing them to identify patients with ear and hearing disorders. This intervention could be scaled up to other CHWs in Low Middle Income Countries.

**TRIAL REGISTRATION NUMBER:** PACTR201705002285194

**Strengths and limitations of this study**

- Structured framework was used to assess the feasibility and acceptability of the intervention to train CHWs in primary ear and hearing care
- The training and screening camps were led by an ENT surgeon, and drew on tools prepared by the WHO
- Through focus group discussions with CHWs, we explored the reasons why people did not attend at the screening camp. In-depth interviews with people who did not attend screening camps could have provided additional information.
- Roles and responsibilities of CHWs is different in different countries. Therefore, generalization of these findings to other settings must be done with caution.

- Although the cost of the training is reported, the full cost of the intervention, taking into account costs of referrals and final treatment, was not assessed.

For peer review only

## Introduction

Hearing loss is the most common sensory disability and its prevalence is increasing globally with population ageing.<sup>1</sup> According to the World Health Organisation (WHO), an estimated 360 million people, or 5.3% of the world's population, are living with disabling hearing impairment.<sup>2</sup> Data for Sub-Saharan Africa are sparse, but the prevalence of hearing impairment may be even higher in this region.<sup>3</sup> 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 treatment and prevention.<sup>4</sup>

Ear and hearing problems can cause life-long difficulties. They may have profound effect on the ability of individuals to communicate with others, on their education, and on their ability to obtain and keep employment.<sup>5</sup> Furthermore, hearing loss also impacts negatively on social relationships and may lead to stigmatization.<sup>6</sup> Consequently, ear and hearing problems are likely to produce substantial economic burdens on individuals, communities and countries.<sup>7</sup>

The high prevalence of ear diseases and hearing loss in Sub-Saharan Africa is at least partly due to the severe shortage of health workers including audiologists, and of resources for hearing aid provision, support and aural rehabilitation programmes.<sup>8</sup> Educating Community Health Workers (CHWs) about ear disease and hearing loss can help to fill these gaps in settings with a scarcity of specialist health workers. CHWs are members of the communities where they work, selected by the communities, answerable to the communities for their activities, and have shorter training than specialist health workers.<sup>9</sup>

The role of CHWs may be particularly important in controlling ear and hearing problems. Effective interventions against ear and hearing problems include ear wax removal, treatment of chronic suppurative otitis media and provision of hearing aids. These interventions can be implemented at the primary level by trained CHWs and have the potential for a major impact on the burden of ear disease and hearing loss when used on large scale.<sup>10,11</sup> However, most low and middle income countries do not have CHWs trained in Primary Ear and Hearing Care (PEHC).<sup>12</sup>

Malawi is a setting where CHWs can potentially make an important contribution to controlling ear and hearing problems. There are only two ENT Surgeons for a population of more than 17 million, and only 25 ENT Clinical Officers.<sup>13</sup> Data are limited, but a study among children

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3 showed a high prevalence of hearing loss, with an estimated 1,800 children per million  
4 population with hearing impairment from avoidable causes that could be treated through  
5 provision of basic primary level ear and hearing care, in particular wax and middle ear disease.<sup>14</sup>  
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9 The aim of this study was to assess the feasibility and acceptability of training CHWs to provide  
10 primary level ear and hearing care, including: identification of patients with ear and hearing  
11 disorders, referral of patients to services, and treatment of simple ear conditions.  
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## **Methods**

### *Ethical approval*

Ethical approval was provided by the College of Medicine Research Ethics Committee in Malawi. The study was evaluated and found exempt from review by the Norwegian Regional Committee for Medical and Health Research Ethics (2016/1472 REC South East, Section D).

### *Study design*

An intervention study was undertaken to assess the feasibility and acceptability of training CHWs in primary ear and hearing care. A group of CHW were selected, and half the participants were randomized to receive training in primary ear and hearing care, while for the remainder training was delayed for six months.

### *Study outcomes*

Primary outcome measure was improvement in knowledge of ear and hearing care among CHWs after the training. CHWs were given sixty multiple choice questions from the first six modules of the WHO Primary Ear and Hearing Care Trainer's Manual<sup>15</sup>. Secondary outcome measures were number of patients with ear or hearing disorders identified by CHWs and number recorded at health centres, and the perceived feasibility and acceptability of the intervention. The records at the health centres were examined at baseline (before training) and after training, the records were examined at 3 months and six months .

## **Setting**

Thyolo district was selected as the study area. Thyolo is a tea-growing district with a population of approximately 460 000, mainly Lomwe people. It is situated about 30 km away from Blantyre, where the only dedicated Ear, Nose and Throat (ENT) Unit in Malawi is located. The district hospital is one of eight district hospitals which has an ENT Clinical Officer, who has been working in Thyolo for two years. Within this district there are 33 health centres. Each Health

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3 Centre is supported by about 10 CHWs and serves a catchment area of approximately 14 000  
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5 people.  
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### 14 15 **Subjects** 16

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18 CHWs were selected among Malawian Health Surveillance Assistants, which is the formal cadre  
19 of CHWs in Malawi.. These form a cadre of 10,500 frontline health workers employed by the  
20 Ministry of Health and comprise 30% of the health workforce in Malawi.<sup>16</sup> Each Health  
21 Surveillance Assistant in Malawi is assigned to a catchment area of approximately 1,000 inhabitants and  
22 its associated health facility, covering a radius of eight kilometers except in district-defined hard-to-  
23 reach catchment areas. They track pregnancies, births, and deaths using their Village Health Registers ,  
24 conduct health talks and vaccinations. Each receives 12 weeks of training and has important roles in  
25 providing care, promoting community participation in health care activities and in promoting  
26 disease surveillance services at the community level. Prior to this study, they had not received  
27 any training in primary ear and hearing care.  
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39 A list of all the 33 health centres together with all the names of the CHWs in Thyolo district was  
40 compiled with the help of the District Health Environmental Office in Thyolo district. Using a  
41 Random Number Generator, we selected 10 health centres for inclusion in the trial (Figure 1); we  
42 then randomly allocated five health centres to the intervention group and five health centres to  
43 the Control group. Using the Random Number Generator, we selected 6 CHWs (out of  
44 approximately 10 CHW) per Health Centre. Consequently, a total of 30 intervention CHWs and  
45 30 control CHWs were selected.  
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### 55 **Consent and pre-test** 56 57 58 59 60

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3 The selected CHWs were called up for a briefing at a central location, with intervention and  
4 control groups meeting separately. They were briefed on the study and written consent was taken  
5 from them to be part of the study after they had received details of what participation involved.  
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7 Data collected from the CHWs included age, sex and years of formal education. They were  
8 administered a pre-test questionnaire containing the questions from the first 6 modules of the  
9 intermediate level WHO Primary Ear and Hearing Care Trainer's Manual (10 questions per  
10 module).<sup>15</sup> The participants in the control group were assured of the training after 6 months.  
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### 20 **Training for intervention group**

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22 The training lasted three days and was undertaken by an ENT Surgeon and two ENT Clinical  
23 Officers. The two ENT Clinical Officers each had 18 months of training in ENT and had  
24 participated in a primary ear and hearing care course. A training curriculum and manual was  
25 developed in English by local experts (1 Audiologist, 3 Audiological Officers, 3 ENT Clinical  
26 Officers and 1 ENT Surgeon). The training manual was based on both the Basic and Intermediate  
27 Manual of WHO Primary Ear and Hearing Care Training Resources .<sup>15</sup>  
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36 The first part of the training focused on knowledge about ear and hearing disorders. Training  
37 emphasized the structure and function of the ear, causes of hearing impairment and their  
38 management and levels of hearing impairment. Next, the training focused on skills training,  
39 including: 1) History taking in patient with ear and hearing disorders, 2) Ear examination, 3)  
40 Steps in doing otoscopy, 4) Steps in doing voice tests, 5) Assessment of hearing in children.  
41 Training methods included lectures, posters of ear and hearing disorders, flip charts, and  
42 demonstrations, practical of voice tests, discussion and group work. Training was done both in  
43 English and Chichewa(national language of Malawi). At the end of the training, each CHW was  
44 given a training manual that contained the key points of training and which could be referred to  
45 when needed. They were also given Arlight Otoscopes (WJW Ltd, Liverpool, UK), to allow ear  
46 examination.  
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56 The participants were given a post-test questionnaire on the third day of training, using the same  
57 questionnaire as in pre-test. The participants were also asked how their opinions about the length  
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3 of training and whether or not they felt comfortable in identifying people with ear and hearing  
4 disorders.  
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### 10 11 12 **Mobilization of patients by Community Health Workers** 13

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15 After training, each CHW in the intervention group was given one month to identify, list and  
16 refer patients with suspected ear and hearing disorders from their own village to their  
17 corresponding health centre. First, the CHW met with the Village Headman, village development  
18 committee members and village health committee members to explain in detail about the  
19 programme. Next, the CHW met with the community members to explain about the programme  
20 and to schedule dates for screening of the community members. CHWs were asked to use  
21 multiple methods in their identification (door to door, school screenings, health education,  
22 church/mosque announcements). CHWs took history, did otoscopy and voice tests as a way of  
23 identifying community members with ear and hearing disorders. CHWs created a list of patients  
24 they suspected of having ear and hearing disorders in their community.  
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33 Identified patients with suspected ear disorder or hearing loss were asked to come to the  
34 scheduled screening camps, which took place at the five health centres of Bvumbwe, Chimaliro,  
35 Chisoka, Changata and Gombe.  
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### 42 **Screening Camps** 43

44 The listed patients were asked to come to the health centre in their catchment area together with  
45 their CHW. A team of 6 people (One ENT Surgeon, One ENT Clinical Officer, Queen Elizabeth  
46 Central Hospital (QECH) Audiological Officers and two research assistants) from the ENT  
47 Department at QECH in Blantyre traveled to all the five health centres in Thyolo to conduct the  
48 screening camps.  
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53 All patients underwent otoscopy, pure tone audiometry, transient evoked otoacoustic emissions  
54 (TEOAEs) and tympanometry performed by one of two audiological officers.  
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- 4 - Otoscopy was performed on all patients using the Heine Mini 2000 (HEINE Optotechnik, Herrsching, Germany).
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- 8 - Audiometry was performed in in all patients aged >4 years who were able to cooperate in
- 9 a quiet room using the KUDUwave 5000 audiometer (eMoyoDotnet (Pty) Ltd, Randburg,
- 10 South Africa). Thresholds were obtained at frequencies of .5, 1, 2 and 4 kHz according to
- 11 WHO recommendations. Pure tone average (PTA) was calculated based on these four
- 12 frequencies. Hearing impairment was defined as PTA > 25dB in the better ear.
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- 14 - TEOAEs were measured in subjects aged less than 4 years and those who were not able
- 15 to cooperate for audiometry. TEOAEs were tested using the Sentiero handheld device
- 16 (PATH Medical Solutions, Guymark, UK) and assessed in each ear at frequencies
- 17 between 1000 and 4000 kHz. Results were graded as 'pass' (indicating normal hearing)
- 18 or 'fail' (indicating impaired hearing).
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- 20 - Tympanometry was done in all patients using Tympanometer S/N P 99 0556, Grason-
- 21 Stadler, USA.
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28 Data was recorded on the WHO/PBD Ear and Hearing Disorders Survey Form.

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33 Patients with ear wax had this removed on site by ENT Clinicians. Those with discharging ears

34 had ear toilet and were given ciprofloxacin ear drops. Those with bigger wet perforations had

35 Candiderm (Beclomethasone Dipropionate, Clotrimazole, and Gentamicin Sulphate) inserted in

36 the middle ear. All patients with chronic otitis media (active or inactive) were referred to QECH.

37 Recorded data of patients with ear and hearing disorders at the health centres were collected at

38 baseline (one month data before the study), at three months and six months after intervention.

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### 47 **Qualitative data collection**

48 We used the consolidated criteria for reporting qualitative studies (COREQ) checklist to report our

49 methods and results<sup>17</sup>. Focus Group Discussions (FGDs) were undertaken by a female research

50 assistant in three of the five health centres (Chimaliro, Bvumbwe and Chisoka). In each health

51 centre, we chose a quiet room where the discussion were conducted. The CHWs involved in the

52 FGDs were purposively selected. There were a total of 17 CHWs (9 females and 8 Males) who

53 participated in the three FGDs, each including 5-6 participants. The female research assistant

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3 was not involved in quantitative data collection or analysis to reduce the possibility of bias. We  
4 conducted the FGDs using semi-structured interview guide. The guided discussions asked CHWs  
5 about their impressions on training, and challenges faced when identifying people with ear and  
6 hearing disorders. Each FGDs took approximately 45 minutes. The discussions were in  
7 Chichewa. FGDs were audio-recorded.  
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### 20 **Data analysis**

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22 Data were analysed using Stata version 13. Tests for normality were done using SPSS version  
23 21. All the scores were tested for normal distribution using the Shapiro-Wilk test. We conducted  
24 an independent t-test to determine the difference in the mean knowledge scores between the  
25 intervention and control groups and paired t-test in the intervention group before and after the  
26 training. For all procedures, alpha was set at 0.05. Paired t-test and chi square statistic were used  
27 to compare number of patients seen at baseline in the health centres to those seen at three months  
28 and six months in both intervention and control groups.  
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36 Transcripts from each focus group discussions were generated and translated into English, and  
37 those transcripts were examined for recurring themes and patterns through open coding and  
38 qualitative content analysis. Nvivo 11 was used for coding the data.  
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## RESULTS

A total of 57 CHWs were included, 28 in the control arm and 29 in the intervention arm.

Intervention and control CHWs were similar in terms of proportion of males (59% vs 54%), mean age (37 years, range 28-51 vs 38 years, range 29-55), and proportion who had 10 years or more of formal education (56% vs 54%).

Test scores are shown in table 1. In the pre-test questionnaire, the intervention group scored slightly lower (55%, 95% CI 52-58%) compared to the control group (58%, 95% CI 56-60%;  $p < 0.05$ ). After training, the mean score for the post-test in the intervention group increased to 68% (95% CI 65-71%), showing a statistically significant improvement from baseline ( $p < 0.001$ ).

There was also improvements in knowledge for the individual modules, except for the module on the inner ear, and assessment and counselling.

**TABLE 1: Proportion of CHWs who answered correctly in the six different modules**

Module	Proportion of questions answered correctly:			Significance (paired t-test pre- vs post-test)
	Control group pre-test (n=28)	Intervention group pre-test (n=29)	Intervention group post-test (n=29)	
Structure and function of the ear	58%	61%	82%	<0.0001
Hearing impairment and deafness: causes and prevention	52%	53%	78%	<0.0001
The outer ear: examine, treat and refer	59%	53%	74%	<0.0001
The ear canal: examine, diagnose and clean	54%	47%	57%	0.03
The middle ear: examine, diagnose	55%	48%	52%	0.28

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and treat				
Assessing hearing and counselling	72%	69%	66%	0.17
<b>ALL MODULES</b>	<b>58%</b>	<b>55%</b>	<b>68%</b>	<b>&lt;0.0001</b>

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8 The majority of the CHWs (67%) said that the length of the training was right, while 33%  
9 thought that it was too short. In dealing with patients with ear and hearing disorders, 52%  
10 reported that they felt comfortable and 48% very comfortable after the training. None of the  
11 CHWs reported feeling uncomfortable. Overall, the average cost of training one CHW was  
12 \$189, including trainer's costs (\$33), trainee's stipend (\$64), training supplies (\$61) and travel  
13 costs (\$31).  
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22 After training, the CHWs identified and referred a total of 1,739 patients with suspected ear  
23 disorder or hearing loss. Of these, only 860 patients (49%) attended the screening camp. Of those  
24 attending, 67.2% were female and mean age was 23 years (range 2 months to 90 years).  
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30 TEOAEs were obtained for subjects below 4 years and those who were not able to cooperate for  
31 audiometry. Out of 860 patients attending the screening camp, 249 patients had TEOAEs, 592  
32 audiometry, and for 19 it was not possible to undertake either audiometry or TEOAE. Out of the  
33 592 patients that underwent audiometry, 327 (55%) had hearing impairment defined as PTA > 25  
34 dB in the better hearing ear (Table 2). Of the 265 subjects without hearing impairment according  
35 to this definition, 115 had unilateral hearing loss while 152 subjects had normal hearing (PTA ≤  
36 25 dB) in both ears. Of those who underwent TEOAE, 73 patients (30 %) had bilateral fail.  
37 Consequently, of the 841 who were screened, 400 (48%) were found to have a hearing  
38 impairment. The rest had either unilateral hearing loss (n = 115, 14%), normal hearing but with  
39 ear disorders (n = 148, 18%) or normal hearing without an ear disorder (n = 184, 22%).  
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**Table 2. Categories of hearing impairment reported as Pure-Tone Average of 0.5, 1, 2 and 4 kHz in the better hearing ear among participants attending the screening camp**

Hearing impairment category (dB)	Children (<18 years)		Adults ( <u>≥ 18 years</u> )	
	Number of subjects	%	Number of subjects	%
Normal ( $\leq 25$ )	149	60.3	116	33.6
Slight (26-40)	73	29.6	119	34.5
Moderate (41-60)	19	7.7	74	21.5
Severe (61-80)	4	1.6	23	6.7
Profound ( $>80$ )	2	0.8	13	3.8
<b>TOTAL</b>	247	100	345	100

The causes of ear and hearing disorders were determined by an ENT Surgeon and ENT Clinical Officer (Table 3). It was not possible to determine the cause for one in three ears with an ear and hearing disorder for adults. For those conditions that we were able to determine the cause, the majority were caused by Chronic Suppurative Otitis Media and Impacted Wax. Impacted Wax was removed on site and no further action was required.

**Table 3: Causes of ear and hearing disorders among participants who attended the screening camp**

ear conditions	<18 years		>18 years	
	Total number of ears	%	Total number of ears	%
Wax	89	9.2	122	16.2
Foreign Body	8	0.8	1	0.1
Otitis Externa	3	0.3	1	0.1
Acute Otitis Media	23	2.4	11	1.5
Chronic Suppurative Otitis Media	165	17.0	110	14.6
Otitis Media with Effusion	36	3.7	45	6.0
Dry Perforation	5	0.5	14	1.9
Infectious Diseases	22	2.3	8	1.1
Genetic Diseases	8	0.8	3	0.4
Non-Infectious Diseases	4	0.4	22	2.9
Undetermined Causes	124	12.8	250	33.2
Not tested	36	3.7	2	0.3
Normal ear and hearing	445	46.0	<b>163</b>	21.7



<b>Total</b>	<b>968</b>	<b>100.0</b>	<b>752</b>	<b>100.0</b>
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Table 4 presents further action required for patients with ear and hearing disorders. The majority of the patients were given medication on the spot, but were asked to be followed up by the ENT Clinical Officer at the district hospital. Those requiring hearing aid evaluation and surgery referral (mainly for tympano-mastoid surgery), were referred to a tertiary hospital of QECH.

**Table 4: Further actions needed for patients with ear and hearing disorders who attended the screening camp**

<b>Action needed</b>	<b>Children (&lt;18 years)</b>		<b>Adults (&gt; 18 years)</b>	
	<b>Number</b>	<b>%</b>	<b>Number</b>	<b>%</b>
Medication	110	20.8	90	22.3
Hearing Aid Evaluation	86	16.2	146	36.2
Language and speech rehabilitation	3	0.6	0	0.0
Special Needs Education	14	2.6	1	0.2
Vocational training	4	0.8	0	0.0
Surgery referral	49	9.2	42	10.4

	264	49.8	124	30.8
<b>*TOTAL</b>	<b>530</b>	<b>100</b>	<b>403</b>	<b>100</b>

\*Out of total actions (not patients)

Table 5 shows the patients with ear and hearing disorders recorded at the ten health centres, comparing intervention and control groups at baseline, third and sixth months. Although the numbers recorded are small, there were more patients seen at baseline, third month and sixth month in the intervention group as compared to the control group. There was no difference in referral rates at baseline and 3 months or 6 months (paired t-test and Chi square:  $p > 0.05$ ).

**Table 5: Patients with ear and hearing disorders recorded at the ten health centres**

	<b><u>Baseline</u></b> <b><u>(one month pre</u></b> <b><u>intervention)</u></b>	<b><u>3rd month after</u></b> <b><u>intervention</u></b>	<b><u>6th month after</u></b> <b><u>intervention</u></b>
<b><u>INTERVENTION</u></b> <b><u>GROUP</u></b>			
<u>Chimaliro</u>	<u>28</u>	<u>8</u>	<u>26</u>
<u>Chisoka</u>	<u>7</u>	<u>13</u>	<u>8</u>
<u>Changata</u>	<u>14</u>	<u>7</u>	<u>5</u>
<u>Gombe</u>	<u>11</u>	<u>6</u>	<u>2</u>
<u>Bvumbwe</u>	=	=	=
<b><u>Total (%)</u></b>	<b><u>60 (88)</u></b>	<b><u>34 (85)</u></b>	<b><u>41(77)</u></b>
<b><u>Mean</u></b>	<b><u>15</u></b>	<b><u>1.5</u></b>	<b><u>10.3</u></b>
<b><u>P-value</u></b>		<b><u>0.31</u></b>	<b><u>0.16</u></b>
<b><u>CONTROL GROUP</u></b>			
<u>Satemwa</u>	<u>2</u>	<u>3</u>	<u>2</u>
<u>Nansonia</u>	<u>1</u>	<u>0</u>	<u>0</u>
<u>Zoa</u>	<u>5</u>	<u>1</u>	<u>5</u>
<u>Ntambanyama</u>	<u>0</u>	<u>2</u>	<u>5</u>
<u>Nsabwe</u>	-	-	-
<b><u>Total (%)</u></b>	<b><u>8 (12)</u></b>	<b><u>6 (15)</u></b>	<b><u>12 (23)</u></b>

<b>Mean</b>	2	1.5	3
<b>P-value</b>		0.73	0.51

‘-‘ data was not collected for the two health centres

### **FINDINGS FROM FOCUS GROUP DISCUSSIONS**

Three main themes emerged from the focus group discussions: training of CHWs and other health workers, identification of patients and problems faced in the mobilization of patients.

#### *Training of CHWs and other health workers*

Overall, the training was felt to be successful, however there was an expressed need to expand the training for CHWs to include medical assistants and other health workers in health facilities in their areas. As one trainee put it:

*“It is only a few of us who have received this training, therefore I feel that those other remaining HSA’s and other health workers should also get the training, so that the other remaining communities should be assisted”*

There were issues concerning the complexity of the diagrams used in the training manual, as the participants found these difficult to understand.

*“Do you see that, these words written about the anatomy of the ear, but when I now come to the real ear and ask what’s this? For me to find the part, according to the way the picture looks like, I cannot manage to identify that, because the picture and the real ear are two different things, eeh but, the manual has been helpful.”*

There was also a request for more practice, rather than theory, particularly with respect to diagnosis of conditions.

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*'I feel that if only we had trainings where we could also have practicals, it would have been helpful'*

### Identification of participants

A number of problems were encountered by the CHWs in the identification of participants with ear disorders or hearing loss and these included failure of the otoscopes, which were solar powered and so reliant on sunshine for charging:

*"Like at the beginning, when using the otoscope, maybe you may have prepared to go out for work, you happen to find that it is cloudy, there are showers, whereby you couldn't have charged the device"*

On the other hand, other participants were happy with the equipment.

*"This work shows that this doesn't require expensive instruments or instruments that are hard to purchase, that's what I observed, those are my views'.*

Others reported on particular methods that helped in the identification of patients, such as the involvement of the traditional chief of the village to legitimize the work.

### Problems faced with mobilization of patients for screening camps

A number of problems were encountered by the CHWs, and these included poor weather conditions, belief in different deities so that people would rather go and receive prayers than meet health personnel, lack of support from the village heads and competing ongoing events that were a distraction (e.g. the free distribution of fertilizer coupons).

*'Whenever we could go to the field just as my friend has said it, it used to be very hard because whenever we could go to the field and happen to get to the venue, it would be found that people*

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*could have gone for registration (for fertilizer coupons) just the way it happens during this time to register for coupons in the village, and were supposed to stay in the village and wait for them'*

## **DISCUSSION**

The Primary Ear and Hearing training increased the knowledge and confidence of CHWs in ear and hearing care, an area of health care in which they had not previously been trained. The trained CHW demonstrated their ability to identify patients with ear and hearing disorders, both through outreach and as part of routine practice. They identified 1,739 people with potential ear or hearing disorders of whom 860 attended a screening, and almost half (400) had significant hearing loss and a further 115 had unilateral hearing loss. There was little change, however, in the patients with ear and hearing disorders were recorded at the health centres after the intervention. The trainees perceived that the intervention was feasible and acceptable. Although the number of CHWs who were trained per health centre was small, these positive findings are encouraging as it can be scaled up. Furthermore, the training was relatively cheap (\$189 per CHW trained) and well received by the participants.

Successful integration of ear and hearing care into primary health care requires resources, to raise awareness, train CHWs, and provide equipment and medications at the health centre. Important lessons can also be learnt from the study and the existing literature in considering whether and how to scale up the Primary Ear and Hearing training.

*Were CHW the appropriate target for training?*

This study showed that trained CHWs proved to be a valuable resource in mobilizing patients with ear and hearing disorders. This is in contrast to what Kalua et al showed that other community Key Informants (e.g. village volunteers) were much better at identifying blind children than CHWs.<sup>18</sup> In that study, CHWs reported lack of time as a major constraint in

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3 identifying blind children, and it is well known that CHWs are often over-loaded with many  
4 competing tasks. Although, we did not compare with other cadres of community like village  
5 volunteers, we found that the number of patients with potential hearing loss identified by CHWs  
6 were still large.  
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### 10 11 12 *Was the content of the training appropriate?*

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15 There was an improvement in the knowledge of ear and hearing disorders among CHWs overall,  
16 showing that the training was appropriate. However, there was no improvement in knowledge  
17 about the middle ear or assessing hearing and counselling. Further improvement of these  
18 modules is needed to ensure that the material is at the right level for CHWs. About 22% of the  
19 patients examined at the screening camps did not have an ear and hearing disorder. We consider  
20 this to be a relatively low false-positive rate, showing that the CHWs were reasonably competent  
21 at identifying people with hearing loss. There is still room for improvement, however, and a  
22 further emphasis on future training should focus on normal ear anatomy and more practical  
23 sessions on normal ears. The CHWs were trained in otoscopy, but their practical skills were not  
24 assessed. The primary aim was to enable them to identify common pathologies like wax and discharge.  
25 However, in a possible higher level course in the future, it would be a good idea to test both manual and  
26 diagnostic skills.  
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### 40 41 *Was the length of training sufficient?*

42 Most of the CHWs were happy with the length of the training while few would like it to have  
43 been extended. The cost of training of our training was an average of \$189 per health worker.  
44 Kyabayinze in Uganda showed that the average cost per health worker of the one day training  
45 was \$101 (range \$92-112) with the main cost drivers being trainee travel and per diems.<sup>19</sup> One  
46 of the ways of reducing the cost of training is to reduce the length of the training, which would  
47 require further testing. In Mental health and Blindness, they have successfully conducted one day  
48 training sessions.<sup>20</sup> However, reducing the length of training was against the expressed wishes of  
49 the CHWs.  
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3 *Were the CHW able to identify people with ear and hearing disorders?*

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5 CHWs were able to identify people with ear and hearing disorders both within the community  
6 and in the clinics. However, the accuracy of diagnosis made by CHWs compared with that of  
7 ENT specialist was not measured, which is a limitation.  
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11 Although the CHWs were able to identify about 1,739 patients, only 860 patients appeared for  
12 screening. The major reason given for non attendance was that most clients went to receive free  
13 fertilizer coupons. Other barriers in ear and hearing care need to be explored in more detail, and  
14 could include difficulties in accessing care, limited engagement of communities and inadequate  
15 support from health systems<sup>21</sup>. Muller et al reported that of the 84 trained Village Health  
16 Workers in Primary Eye Care, only 13 (15%) brought patients to the health centres and the main  
17 reason suggested for the difference was lack of motivation among Village Health Workers.<sup>20</sup>  
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21 Resources may be required to pay for transport reimbursements for patients to travel from their  
22 villages to the health centre since there is clearly a large unmet need for services among people  
23 in the communities.  
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27 *Were the CHWs appropriately equipped?*

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29 Equipping CHWs with a tool like an Arclight Oscopes may have improved the diagnostic  
30 accuracy especially for Impacted Wax and Chronic Suppurative Otitis Media.  
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34 There is need to do more research on the provision of diagnostic and therapeutic primary ear and  
35 hearing care services by CHWs and general health workers at frontline health facilities. With the  
36 advent of a lot of software applications for audiometry<sup>22</sup>, there is need to look at the feasibility of  
37 equipping the CHWs with the tool. Furthermore, research is needed as to which therapeutic  
38 approaches are appropriate at primary level. For instance, primary health care workers are often  
39 taught to do dry mopping for wet perforations. Among our patients with wet perforations, a  
40 number of them had dead house flies in the ears which may have been difficult to remove with  
41 dry mopping alone. Evidence is also needed as to whether or not ear syringing may be useful for  
42 these sort of conditions.  
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6 In summary, in line with the Malawi Government guidelines on task shifting to CHWs<sup>23</sup>, the  
7 following tasks in ear and hearing care are recommended for CHWs. There are 1) Information,  
8 Education and Communication on ear and hearing disorders, 2) Identification of cases for  
9 referral, 3) Follow-up of cases for treatment adherence, 4) Support and Counselling of families  
10 on ear and hearing disorders. All these tasks are based on the assumption that the CHWs have  
11 been trained in ear and hearing care and that equipment like Otoscopes are made available to  
12 them.  
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21 There are important strengths to the study. It used a structured framework to assess the feasibility  
22 and acceptability of the intervention to train CHW in primary ear and hearing care. The training  
23 and screening camps were led by an ENT surgeon, and drew on tools prepared by the WHO.  
24 There are also limitations to consider. It was not possible to explore in detail why people did not  
25 attend at the screening camp. We only conducted FGDs with CHWs. In-depth interviews with  
26 people who did not attend the screening camps could have provided more information.  
27 Furthermore, the impact of training CHW in PEHC on their routine clinical activities was not  
28 fully evaluated, nor the impact on the number of diagnoses and referrals made of ear and hearing  
29 disorders at the primary care level on reducing the burden at the secondary and tertiary levels.  
30 We are aware that roles and responsibilities of CHWs is different in different countries.  
31 Therefore generalization of these findings to other settings must be done with caution.  
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#### 44 **Conclusions**

45 The training was effective in improving the knowledge of CHW in ear and hearing care in  
46 Malawi and allowing them to identify people in the community requiring ENT services. Based  
47 on the success of this study, training of CHWs and their identification of patients with ear and  
48 hearing disorders, could be scaled up in Malawi and tested in other low and middle income  
49 countries.  
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4 **Contributorship statement:** WM, HK, and FG designed the study. HK and FG helped with data  
5 analysis and drafting of the manuscript. WM conducted the study in Malawi, did data collection,  
6 data analysis and drafting of the manuscript. AV helped to draft and revise the manuscript. All  
7 authors read and approved the final manuscript.  
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12 **Competing interests:** None declared  
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17 programme with the University of Bergen. Funding for this research came from the NORHED  
18 Surgery project (QZA-0484, MWI-13/0030)  
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25 **Data sharing statement:** No additional data are available  
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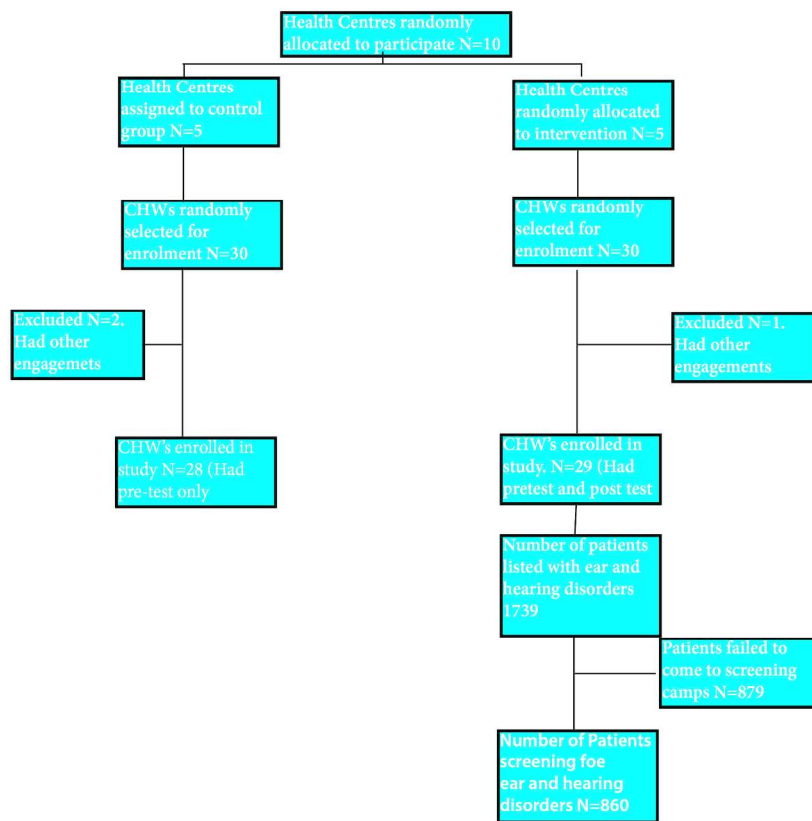
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48 Figure 1: Flow of participants through the study  
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Figure 1: Flow of participants through the study



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## CONSORT 2010 checklist of information to include when reporting a randomised trial\*

Section/Topic	Item No	Checklist item	Reported on page No
<b>Title and abstract</b>			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
<b>Introduction</b>			
Background and objectives	2a	Scientific background and explanation of rationale	5 & 6
	2b	Specific objectives or hypotheses	6
<b>Methods</b>			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	7 & 8
	4b	Settings and locations where the data were collected	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8,9,10 & 11
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9,10 & 11
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
<b>Randomisation:</b>			
Sequence generation	8a	Method used to generate the random allocation sequence	8
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	8
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	8
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	

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2		assessing outcomes) and how	
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4		11b If relevant, description of the similarity of interventions	
5	Statistical methods	12a Statistical methods used to compare groups for primary and secondary outcomes	12
6		12b Methods for additional analyses, such as subgroup analyses and adjusted analyses	
7			
8	<b>Results</b>		
9	Participant flow (a	13a For each group, the numbers of participants who were randomly assigned, received intended treatment, and	8
10	diagram is strongly	were analysed for the primary outcome	
11	recommended)	13b For each group, losses and exclusions after randomisation, together with reasons	13
12	Recruitment	14a Dates defining the periods of recruitment and follow-up	11
13		14b Why the trial ended or was stopped	
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15	Baseline data	15 A table showing baseline demographic and clinical characteristics for each group	13
16	Numbers analysed	16 For each group, number of participants (denominator) included in each analysis and whether the analysis was	13
17		by original assigned groups	
18			
19	Outcomes and	17a For each primary and secondary outcome, results for each group, and the estimated effect size and its	13
20	estimation	precision (such as 95% confidence interval)	
21		17b For binary outcomes, presentation of both absolute and relative effect sizes is recommended	13-20
22	Ancillary analyses	18 Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing	13-20
23		pre-specified from exploratory	
24			
25	Harms	19 All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
26			
27	<b>Discussion</b>		
28	Limitations	20 Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	25
29	Generalisability	21 Generalisability (external validity, applicability) of the trial findings	23-25
30	Interpretation	22 Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	23-25
31			
32	<b>Other information</b>		
33	Registration	23 Registration number and name of trial registry	3
34	Protocol	24 Where the full trial protocol can be accessed, if available	
35	Funding	25 Sources of funding and other support (such as supply of drugs), role of funders	26
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38 \*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also

39 recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials.

40 Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org).

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