

1 **Does probe-tube verification of real-ear hearing aid amplification**  
2 **characteristics improve outcomes in adult hearing aid users? A protocol for**  
3 **a systematic review**

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1 **ABSTRACT**

2 **Introduction:** Using a probe-tube microphone to measure and adjust the real-ear  
3 performance of the hearing aid to match the prescription target is recommended and widely  
4 used in clinical practice. Hearing aid fitting software can approximately match the  
5 amplification characteristics of the hearing aid to the prescription without real-ear  
6 measurements (REM), but using REM improves the match to the prescribed target. What is  
7 unclear is if the improved match results in a better patient-reported outcome. The primary  
8 objective of this review is to determine whether the use of REM improves patient-reported  
9 outcomes in adult hearing aid users.

10 **Methods and analysis:** The review's methods are in accordance with Preferred Reporting  
11 Items for Systematic Reviews and Meta-Analyses (PRISMA-P) guidelines. MEDLINE,  
12 EMBASE, PsycINFO, CINAHL, Web of Science and CENTRAL via Cochrane Library will  
13 be searched to identify relevant studies. The review's population of interest will include  
14 adults with any degree of sensorineural or mixed hearing loss who have been prescribed with  
15 acoustic hearing aids. The included studies should compare REM fitting to the initial fit  
16 provided by the manufacturer's fitting software. Hearing-specific health-related quality of life  
17 is the primary outcome but secondary outcomes include self-reported listening ability, speech  
18 recognition scores, generic health-related quality of life, hours of use, number of required  
19 follow-up sessions and adverse events. Randomised and non-randomised controlled trials will  
20 be included. The risk of bias in the included studies will be evaluated using Down and  
21 Black's checklist. The quality of the overall evidence will be assessed using the Grading of  
22 Recommendations, Assessment, Development and Evaluations (GRADE) tool.

23 **Ethics and dissemination:** Ethical approval will not be sought because this systematic  
24 review will only retrieve and analyse data from published studies. Review results will be  
25 published in a peer-reviewed journal and presented at relevant scientific conferences.

26 **PROSPERO registration number:** CRD42020166074

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## 1 **Strengths and limitations of the study:**

- 2 • This review will be first to synthesise data that compare two commonly used  
3 approaches to fit hearing aids to prescription targets (i.e. initial-fit and real-ear  
4 measurements).
- 5 • A variety of outcome measures will be used to compare these two approaches.
- 6 • The implications of this review are important for the emerging category of over-  
7 the-counter and direct-to-consumer hearing aids that do not involve real-ear  
8 measures.
- 9 • We will include only studies that compare these fitting approaches among adults  
10 with sensorineural hearing loss, because children and those with other types of  
11 hearing loss may require different amplification characteristics.
- 12 • Grey literature will not be included (i.e. conference abstracts and theses).

## 13 **INTRODUCTION**

14 Hearing loss is the most prevalent sensory deficit, affecting more than a fifth of the world's  
15 population<sup>1 2</sup>. Untreated hearing loss reduces peoples' ability to communicate effectively,  
16 which could lead to social isolation, depression and decreased health-related quality of life<sup>3</sup>.  
17 Hearing loss is associated with an increased risk of cognitive decline and dementia but  
18 causality is unknown<sup>4</sup>. The rate of unemployment among individuals with hearing loss is  
19 higher than that of the general population, costing the UK economy about £25 billion  
20 annually in terms of lost economic output<sup>5</sup>.

21 The most prevalent type of hearing loss in adults is sensorineural loss, accounting for more  
22 than 90% of all adults with hearing loss in the UK<sup>6</sup>. The primary intervention for permanent  
23 hearing loss is the use of acoustic hearing aids<sup>7</sup>. These devices are designed to restore  
24 audibility of low-level sounds, maximise intelligibility of conversational level sounds, and  
25 maintain comfortability for loud sounds<sup>8</sup>. Hearing aids reduce the handicap caused by mild  
26 and moderate hearing loss (e.g. decreased health-related quality of life)<sup>9</sup>.

27 In the UK, hearing aids are fitted and prescribed by state-registered hearing health  
28 professionals. The selection of the most appropriate hearing aid is based on a combination of  
29 audiometric and non-audiometric factors (e.g., hearing threshold levels, type of hearing loss,  
30 physical capabilities of the patient and patient preference, respectively). The optimal

1 amplification characteristics for each hearing aid user are specified according to validated  
2 prescription formulae (e.g. National Acoustic Laboratories Non-Linear 2)<sup>10</sup>, which takes into  
3 account the patient-specific data (e.g. gender, language and type and degree of hearing loss)  
4 to personalise hearing aid output. Modern hearing aid software can approximate the  
5 amplification characteristics and the use of this approach for hearing aid fitting is known as  
6 initial-fit. A real-ear measurement (REM), which is a tool that can be used to accurately  
7 measure the output of a hearing aid when it is coupled to the individual's ear via a soft probe-  
8 tube microphone<sup>8</sup>, can also be used to guide the adjustment of the output of the hearing aid so  
9 that it matches the proposed amplification target that was provided by the validated  
10 prescription formula.

11 Numerous studies have shown that the amplification characteristics approximated by the  
12 hearing aid software are inaccurate and significantly deviate from prescription targets<sup>11-13</sup>.  
13 These studies also suggest that the use of REMs can improve matches with prescription  
14 targets. Given the available evidence, using REMs, to verify the output of hearing aids and  
15 achieve better matches with prescription targets, has been endorsed by the British Society of  
16 Audiology<sup>14</sup> and most international hearing organisations (e.g. American Speech-Language-  
17 Hearing Association)<sup>15</sup>. Nevertheless, it remains unclear if improved matching to prescription  
18 targets result in better outcomes.

19 Using REMs to match hearing aid output to prescription targets requires valuable clinical  
20 time, which could otherwise be used to deliver alternative health and hearing services (e.g.,  
21 identifying and addressing other hearing problems).

## 22 **Rationale**

23 There is no published systematic review examining the evidence on whether the use of REM  
24 improves patient-reported outcomes in adult hearing aid users. Determining the effectiveness  
25 of hearing aids fitted using REM would help decision-makers and stakeholders either to  
26 continue recommending or to abandon routine use of REM during adult hearing aid fittings.  
27 This is an urgent knowledge gap for both stakeholders and clinicians, given that the cost of  
28 the REM system is relatively high and it consumes a large amount of clinicians' valuable  
29 time. The findings have implications for the emerging category of over-the-counter or direct-  
30 to-consumer hearing aids. If fitting hearing aids using REM does not benefit patients, then  
31 one of the potential obstacles to people fitting their own hearing aids is overcome. However,

1 if it is found to be beneficial, decision-makers should continue recommending the use of  
2 REMs until other reliable fitting approaches have evolved.

### 3 **Objectives**

4 The objective of this review is to systematically evaluate the current evidence on whether the  
5 use of REMs to match the hearing aid's output to one of the validated prescription targets  
6 improves outcomes in adult hearing aid users.

## 7 **METHOD AND ANALYSIS**

8 The protocol of this systematic review has been pre-registered with the International  
9 Prospective Register of Systematic Reviews (PROSPERO; CRD42020166074). The  
10 systematic review's method are reported in accordance with Preferred Reporting Items for  
11 Systematic review and Meta-Analyses (PRISMA-P) guidelines<sup>16</sup>.

### 12 **Eligibility criteria**

13 The inclusion and exclusion criteria for studies are reported in accordance with participants,  
14 interventions, comparators, outcomes and study designs (PICOS) elements.

#### 15 *Participants*

16 Participants will include adults ( $\geq 18$  years old) with any specified degree of sensorineural or  
17 mixed hearing loss. Studies that report only a qualitative description of age and threshold of  
18 hearing will also be included. If both children and adults are included in a clinical trial, the  
19 study will be excluded unless the data were interpreted and reported independently.

20 Participants with other types of hearing loss (i.e. conductive or fluctuating hearing loss) will  
21 be excluded.

#### 22 *Interventions*

23 The intervention that will be included is conventional acoustic hearing aids that were  
24 programmed to a prescription target using a real-ear measurement system. Assistive listening  
25 devices, hearables personal sound amplification products, and direct-to-consumer hearing  
26 devices will be excluded. Implantable devices (e.g. cochlear implants), bone conduction  
27 hearing aids or contralateral routing of sounds hearing aids will also be excluded.

1 *Comparators*

2 The comparisons of interest are hearing aids that are programmed to the manufacturers'  
3 approximation of the wearers hearing loss without REMs (i.e. initial fit approach).

4 *Outcomes*

5 The primary outcomes of interest is hearing-specific health-related quality of life (e.g.  
6 Hearing Handicap Inventory for the Elderly)<sup>17</sup>. Secondary outcomes of interest are self-  
7 reported listening ability (e.g. Abbreviated Profile of Hearing Aid Benefit)<sup>18</sup>, general benefit  
8 of hearing aids (e.g. International Outcomes Inventory for Hearing Aids)<sup>19</sup>, speech  
9 recognition in quiet or noisy environments, generic health-related quality of life, hours of use  
10 per day, number of required follow-up care sessions (i.e. for further fine-tuning) and adverse  
11 events (e.g. noise-induced hearing loss).

12 *Study designs*

13 Randomised controlled trials and non-randomised controlled trials will be included. Case  
14 reports, conference abstracts, book chapters, dissertations, theses, reviews and clinical  
15 guidelines will be excluded.

16 **Information sources**

17 Studies that meet the aforementioned eligibility criteria will be identified using a systematic  
18 search strategy of the following databases: MEDLINE, EMBASE, PsycINFO, CINAHL,  
19 Web of Science and CENTRAL via Cochrane Library. No search restrictions will be applied  
20 in terms of the publication's language, status and year.

21 The reference lists of the included publications will be manually scanned to identify further  
22 studies. Using Google Scholar "cited by" feature, publications that have cited any of the  
23 included studies will be screened to identify additional relevant articles. Prior to analysis, the  
24 searches will be repeated to identify any other relevant studies if there is a significant delay  
25 between searches and a manuscript's submission for publication (> 6 months).

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## 1 **Search strategy**

2 The search protocol and methods will be developed by a medical information specialist from  
3 Systematic Review Solutions Limited. The included search terms will be based on experts'  
4 opinion, free text and controlled terms from Medical Subject Headings (MeSH), Excerpta  
5 Medica Tree (EMTREE) and CINAHL headings. The search terms will include many free  
6 text terms because truncations may not work well with phrases (e.g. Hearing difficult\* might  
7 not capture Hearing difficulties). The search strategies for all databases are reported in  
8 Appendix 1.

## 9 **Study records**

### 10 *Data management*

11 Search results, including titles, authors' details, publication years, publication journals and  
12 abstracts, will be extracted to EndNote X9 Reference Management software (Clarivate  
13 Analytics, 2018). The same software will also be used to remove any duplicates prior to the  
14 initial screening. Next, IA will export the title and abstracts of all identified articles into an  
15 Excel spreadsheet so that they can be easily screened against the eligibility criteria. The  
16 reason for any article's exclusion can also be documented and assessed by KJM and HD.  
17 Each article will be assigned a unique number that is linked to the full details of the article.

### 18 *Selection process*

19 The title and abstract of all identified studies will be screened independently by IA and KJM  
20 to determine eligibility for inclusion. A further inspection will be used when there is a  
21 discrepancy between the two investigators; this will include assessing the full article. Any  
22 disagreement will be resolved by discussion and/or by consulting with the third author (HD).  
23 The full text will be retained and inspected by IA and KJM for all articles that match the  
24 inclusion criteria. Any disagreements will be resolved via discussion or by consulting the  
25 third author. Following PRISMA- recommendations<sup>20</sup>, a flow diagram will be used to  
26 present the study selection process.

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1 *Data collection process and data items*

2 IA and KJM will independently extract the data from the included studies. Should any  
3 discrepancies arise, these will be resolved through discussion or consultation with the third  
4 author (HD). The data will be extracted in a pre-designed data extraction form adapted from  
5 the Cochrane Handbook<sup>21</sup>. The extracted data will include but will not be limited to authors  
6 (year), methods, participants, intervention and outcomes (see Table 1). Data presented on  
7 graphical forms will be extracted using an online extraction tool (e.g., WebPlotDigitizer;  
8 <https://automeris.io/WebPlotDigitizer>) when necessary.

**Table 1 Data items**

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General information	Authors (year)
	Title
Method	Study design
	Total study duration
	Sequence generation
	Sequence concealment
	Blinding
Participants	Total number
	Country / Setting
	Age
	Sex
	Inclusion and exclusion criteria
Intervention	Intervention group
	Comparator group
Outcome	Primary outcome
	Secondary outcome(s)
Funding source	
Declaration of interest	
Notes	

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9 **Risk of bias in individual studies**

10 The assessment of the risk of bias will be conducted independently by IA, KJM and HD. Any  
11 disagreements will be resolved using a majority decision. Given the limited number of



1 randomised controlled trials in the field of audiology, it is anticipated that most of the  
2 extracted studies will be non-randomised controlled trials; therefore, the Downs and Black<sup>22</sup>  
3 checklist will be used because it is easy to administer, has a well-established validity and  
4 reliability and can be used to assess the methodological quality of both randomised and non-  
5 randomised studies. Because knowledge of the clinically important differences in hearing aid  
6 outcomes is lacking, scoring for the final item (number 27) will be modified based on  
7 whether or not the power calculation was performed. That is, one point will be awarded if the  
8 calculation was conducted and zero points if it was not. Consequently, the maximum score  
9 will be 28. Articles scoring 26–28, 20–25, 15–19 and < 14 will be regarded as having  
10 excellent, good, fair and poor quality, respectively. The assessment of the risk of bias will be  
11 conducted by the primary and secondary authors independently.

## 12 **Data synthesis**

13 A meta-analysis will be conducted if enough data are available (i.e. more than one study). If  
14 the included studies used the same continuous outcome measures, the mean differences will  
15 be calculated with the 95% confidence interval (CI). When different outcome measures are  
16 used, the standardised mean difference will be measured along with 95% CI. If the included  
17 studies used similar dichotomous outcome measures, the risk ratio will be calculated. If the  
18 statistical heterogeneity is low, fixed-effect meta-analyses will be computed; otherwise, only  
19 the random-effect meta-analysis will be calculated. For each meta-analysis, the effect size  
20 estimate will be calculated using the generic inverse of variance. The effect estimate will be  
21 reported along with its 95% CI. Forest plots will be used to present these results.

22 Asymmetrical distribution of continuous outcomes (i.e. skewed data) will be assessed by  
23 subtracting the lowest possible value from the mean and then dividing it by the SD. A ratio  
24 below 2 or 1 either suggests or indicates a skewed distribution, respectively<sup>23</sup>. Skewed data  
25 will be log-transformed where possible to reduce the skew distribution. Randomised and non-  
26 randomised controlled trials will be synthesised separately.

27 If meta-analysis is not appropriate, the risk of bias of each individual study will be assessed  
28 and the findings will be systematically reported

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## 1 **Assessment of reporting bias**

2 The existence of publication bias will be visually inspected using a funnel plot of the study  
3 size or precision as a function of intervention effect estimates.

## 4 **Assessment of heterogeneity**

5 The percentage of variability between studies' outcomes that is due to heterogeneity rather  
6 than random error will be computed using an  $I^2$  statistic. Given that the absolute threshold of  
7  $I^2$  is meaningless, the results will be interpreted as either low (0–40%), medium (41–60%) or  
8 high (61–100%) heterogeneity.

## 9 **Dealing with missing data**

10 The corresponding authors will be contacted, where necessary, if any of the data are missing.  
11 Data that are only presented in graphical forms will be extracted using the detailed method  
12 explained in the section titled Data collection process and data items. In case the standard  
13 deviations (SDs) are missing and cannot be obtained from the corresponding authors, they  
14 will be estimated from the available data (e.g. 95% CI and standard errors). The reasons for  
15 the missing data will be assessed to identify whether they are missing at random or not.

## 16 **Subgroup analysis**

17 When possible, subgroup analysis will be performed to determine whether age (i.e.  $\leq 55$  or  $>$   
18  $55$  years), severity of hearing loss and experience with hearing aids (i.e. first-time vs.  
19 experienced users) are possible sources of heterogeneity.

## 20 **Confidence in cumulative estimate**

21 The quality of each outcome measure will be rated as high, moderate, low or very low using a  
22 well-developed assessment tool, the Grading of Recommendations, Assessment,  
23 Development and Evaluations tool (GRADE)<sup>24</sup>. The quality rating assigned to each outcome  
24 measure reflects our level of confidence as to the veracity of the drawn estimate effect. The  
25 GRADE tool takes into account five principal domains: study limitations (e.g. blinding and  
26 allocation concealment), inconsistency (e.g., variabilities in effect size), indirectness (e.g.  
27 differences in population), and imprecision (e.g. broad CI) and publication bias (e.g. selective

1 reporting of positive outcomes). Randomised controlled trials without serious shortcomings  
2 will be rated as high-quality evidence. That is, our confidence level is high enough to  
3 conclude that the true effect is close to the drawn estimate effect. Conversely, non-  
4 randomised control trials (e.g. observational studies) will be assigned a low rating. In other  
5 words, the estimated effect may vary considerably from the true estimate of the effect.  
6 However, the assigned rating to randomised and non-randomised controlled trials could be  
7 subject to either upgrading or downgrading by either one or two points on the basis of the  
8 seriousness of the above-mentioned assessment domains. A thorough discussion of these  
9 factors can be found in Schünemann et al (2013)<sup>25</sup>. IA and KJM will carry out the assessment  
10 independently and disagreements will be resolved by discussion and/or by consulting HD.

### 11 **Sensitivity analysis**

12 Sensitivity analysis will be administered to assess the robustness of the pooled estimates.  
13 That is, studies with a very high risk of bias (i.e., those that scored less than 14 points on the  
14 Downs and Black checklist) will be removed from quantitative synthesis.

### 15 **Patient and Public Involvement**

16 Patients and the public were not formally involved in the development of the research  
17 question and outcomes. However, a summary of the review results will be made available to  
18 the public through the website of The Manchester Center for Audiology and Deafness  
19 (ManCAD).

### 20 **ETHICS AND DISSEMINATION**

21 Ethical approval will not be sought because this systematic review will only retrieve and  
22 analyse data from published studies. Review results will be published in a peer-reviewed  
23 journal, presented at relevant scientific conferences and disseminated on social media.

24 **Contributor** IA is the guarantor of this review. IA developed and prepared the review  
25 protocol. The search procedure has been developed by a medical information specialist from  
26 Systematic Review Solutions Limited. KJM and HD contributed to the development of  
27 inclusion and exclusion criteria, search strategy and assessment of the risk of bias. KJM and  
28 HD also critically reviewed and provided feedback on earlier versions of the protocol. This  
29 manuscript has been approved by all contributors.

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3 **Competing interest** None declared.

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