Hearing aids for mild to moderate hearing loss in adults (Protocol)

Ferguson MA, Kitterick PT, Edmondson-Jones M, Hoare DJ

Ferguson MA, Kitterick PT, Edmondson-Jones M, Hoare DJ. Hearing aids for mild to moderate hearing loss in adults. 
DOI: 10.1002/14651858.CD012023.

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Hearing aids for mild to moderate hearing loss in adults

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Editorial group: Cochrane ENT Group.
Publication status and date: Edited (no change to conclusions), published in Issue 12, 2015.


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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To evaluate the effectiveness of hearing aids for mild to moderate hearing loss in adults who have been prescribed at least one hearing aid.

BACKGROUND

Description of the condition

Hearing loss is the most prevalent sensory deficit (Mathers 2000); it represents a major public health issue with substantial economic and societal costs. Untreated, adult hearing loss results in communication difficulties that can lead to social isolation and withdrawal, depression and reduced quality of life (Davis 2007). Hearing loss is also associated with an increased risk of dementia (Lin 2011).

According to the World Health Organization hearing loss is the 13th most common global disease burden and the third leading cause of years living with disease (WHO 2008). Disabling hearing loss is estimated to affect 360 million persons globally (5.3% of the world’s population) (WHO 2012a). The prevalence of hearing loss increases with age (Akeroyd 2014), and given the ageing society it is predicted that by 2030 adult-onset hearing loss will be the seventh largest disease burden, above diabetes and human immunodeficiency virus (HIV) (WHO 2008).

Epidemiological data suggest that the majority of cases of hearing loss in adults are sensorineural (92%) and bilateral (94.8%) (Cruickshanks 1998). There are numerous definitions of hearing loss across different countries and organisations (Timmer 2015). In this review, hearing loss is defined according to pure-tone thresholds averaged across 0.5 kHz, 1.0 kHz, 2.0 kHz and 4.0 kHz in the better-hearing ear, consistent with the World Health Organization grades of hearing impairment (Mathers 2000). The majority of hearing losses (92%) are those that are defined as mild or moderate (AuHL 2015). Mild (or slight) hearing loss is indicated as 26 to 40 dB hearing level (HL) and described as the ability to hear and repeat words spoken in a normal voice at one metre. Moderate hearing loss is indicated as 41 to 60 dB HL and described as the ability to hear and repeat words using a raised voice at one metre (Mathers 2000). In addition to a loss of hearing sensitivity, there may be additional sensory deficits of temporal and spectral pro-
Hearing aids for mild to moderate hearing loss in adults (Protocol)

Description of the intervention

There are no effective medical or surgical treatments for mild to moderate sensorineural hearing loss (Chisolm 2007), so the main clinical intervention is the use of acoustic hearing aids (Kochkin 2009). It was estimated in 2012 that 11 million hearing aids were sold worldwide (Kirkwood 2013). Hearing aids detect and amplify sound and deliver an amplified acoustic signal via air conduction to the external auditory canal on the same side as the signals are detected. Hearing aids are described according to where they are worn (e.g. behind-the-ear, in-the-ear, in-the-canal, completely-in-the-canal) or classified by their technology (i.e. analogue, digitally programmable analogue or digital hearing aids) (Dillon 2012).

Hearing aids are typically fitted by healthcare professionals who have been trained in audiology or the dispensing of hearing aids. Hearing aid fittings can be unilateral or bilateral and they are typically programmed according to the user’s pure-tone hearing thresholds using hearing aid prescription formulae (Mueller 2005). Changes to the hearing aid programme may be made according to subjective preference for sound quality, such as the perceived loudness of sounds (McArdle 2005). Hearing aid orientation that includes information on hearing aid use and care, expectations and limitations is typically offered as usual care (Boothroyd 2007; Recse 2005).

The use of a hearing aid to amplify sounds does not necessarily restore hearing function. Frequency response characteristics of hearing aids, distortions arising from peak clipping, poor clarity or loudness of speech can all have an impact on successful listening (Dillon 2012). As hearing aids amplify all sounds, not just speech sounds, their use can lead to continued communication difficulties following hearing aid fitting, particularly in noisy backgrounds (Picou 2013). These and other reasons can lead to non-use of hearing aids (McCormack 2013), with estimates of non-use varying from 5% to 40%. Additional interventions may be used to promote the use of hearing aids in people with hearing loss (Barker 2014).

How the intervention might work

The primary function of hearing aids is to amplify and improve the audibility of sounds, and speech in particular. However, improving the audibility of sounds or speech signals forms only one element within the broader concept of rehabilitating a person with hearing loss, where the overall aim is to reduce the negative consequences of hearing loss and improve communication. In order to communicate effectively, an individual needs to access the acoustic information (hearing, a passive process), employ attention and intention (listening, an active process), correctly interpret the acoustic and linguistic information (comprehension, a unidirectional process) and use and transmit this information effectively (communication, a bidirectional process) (Kiessling 2003). These processes can be mapped onto the International Classification of Functioning, Disability and Health (ICF, WHO 2001), which provides a theoretical framework upon which to measure the success of amplification using hearing aids.

Based on the ICF Core Set (Danemark 2013), the goal of amplification with hearing aids where there is mild to moderate hearing loss is to reduce the auditory deficits associated with body functions and structures, thereby reducing activity limitations and participation restrictions (Chisolm 2007; Kiessling 2003). Improvements in the ability of a patient with hearing aids to detect and discriminate sounds and speech can be measured by acoustic outcomes (e.g. free-field threshold and speech audiometry). The consequences of these improvements in terms of activities and participation can then be measured by patient-reported outcomes such as self report questionnaires, which can be defined as either disease-specific (e.g. hearing) or generic (e.g. health-related quality of life). Generic health-related quality of life measures generally show limited benefit from hearing aids as they lack sensitivity to the consequences of hearing loss (Joore 2002; Joore 2003; Stark 2004). There is, however, some evidence that the Health Utilities Index Mark 3 (HUI3) is useful (Barton 2004; Davis 2007). Currently, there is a lack of consensus on the optimal set of outcome measures to use in hearing research (Granberg 2014).

Why it is important to do this review

Hearing aids are routinely offered and fitted for people with hearing loss. It might seem axiomatic that such an intervention is bound to be associated with an improvement in a patient’s ability to hear and to communicate, but is this true? If there is an improvement in a patient’s ability to hear and communicate, how big an improvement is it? There is little high-level evidence to answer these questions and to inform discussions around the effectiveness of hearing aids, their provision within a population and the approach to be taken by those who might fund such provision.

There are no recent or ongoing systematic reviews that provide the high-level evidence to inform clinical decision-making on this important topic. A previous systematic review of the published evidence included randomised controlled trials (RCTs) and non-randomised trials published up to August 2004 that met specific criteria. It sought to address a specific objective: to determine if the use of hearing aids compared to the non-use of hearing aids resulted in improvements in health-related quality of life for adults with sensorineural hearing loss using disease-specific and generic instruments (Chisolm 2007). There were only two RCTs suitable for inclusion at that time, limiting the generalisability of the findings and the robustness of the conclusions.

This review will not compare the evidence for the bilateral versus unilateral fitting of hearing aids, for which there is an ongoing
OBJECTIVES

To evaluate the effectiveness of hearing aids for mild to moderate hearing loss in adults who have been prescribed at least one hearing aid.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials and quasi-randomised studies, where the unit of analysis is the individual participant. We will use the first treatment period of cross-over trials and treat this as a parallel-arm trial, providing the study reporting permits.

Types of participants

Adults (≥ 18 years old) with mild or moderate hearing loss, as defined by pure-tone thresholds in the better-hearing ear averaged across four frequencies (0.5 kHz, 1.0 kHz, 2.0 kHz and 4.0 kHz) of 26 to 40 dB HL (mild hearing loss) and 41 to 60 dB HL (moderate hearing loss). In the absence of confirmation that all participants in a study meet these criteria (i.e. where participant-level data are not reported or cannot be obtained), we will include studies where the reported participant characteristics for the mean four-frequency average fall within the range for either mild or moderate hearing loss, as described above. If a mean frequency average is offered for a combination of frequencies other than 0.5 kHz, 1.0 kHz, 2.0 kHz and 4.0 kHz, we will use studies where the reported value falls between 26 to 40 dB HL (mild hearing loss) and 41 to 60 dB HL (moderate hearing loss). If only qualitative descriptions of mild and moderate hearing loss are given with no supporting audiometric data, we will include such studies but will not include them in the meta-analysis.

Types of interventions

Acoustic hearing aids, irrespective of where they are worn or the type of technology (analogue or digital). We will exclude hearing aids or implantable devices whose primary purpose is to deliver bone conduction sound or those that detect and deliver sound via air conduction to the contralateral ear.

The comparisons of interest are hearing aids versus either a passive control (no intervention, waiting list control; we will pool these in meta-analysis) or an active control that involves:

- information/education only, listening tactics and communication training (we will pool these in meta-analysis);
- assistive listening devices; or
- auditory training (we will analyse these second two in separate meta-analyses).

We will not consider studies where the intervention is delivered in a group setting.

Types of outcome measures

We will analyse these outcomes in the review, but we will not use them as a basis for including or excluding studies. We will analyse the data at the trial endpoint, with a subgroup analysis to compare different trial endpoints.

Primary outcomes

- Hearing-specific health-related quality of life, where participation is the key domain. This will be measured using self report questionnaires. If multiple questionnaires are used, we propose a ranked hierarchy of instruments whereby we will identify the primary outcome based on the following in order of importance:
  - Hearing Handicap Inventory for the Elderly (HHIE; Ventry 1982) or HHI for Adults (HHIA; Newman 1990), if the HHIE is not used;
  - Quantified Denver Scale of Communication (QDS; Tuley 1990);
  - Auditory Disability Preference - Visual Analog Scale (ADPI-VAS; Joore 2002); and
  - any questionnaire not specified above that is relevant to hearing-specific health-related quality of life.

- Adverse effect: pain. This may be reported by the patient as pain, discomfort, tenderness or skin irritation, or may be reported as occurrence of ear infection as a consequence of hearing aid fitting.

Secondary outcomes

- Health-related quality of life. A ranked hierarchy of self report outcome measures is proposed in the following order:
  - Health Utilities Index Mark 3 (HUI-3; Furlong 2001);
  - EQ-5D (Rabin 2001);
  - SF-36 (Ware 1992), or if not reported other short forms of the SF-36;
  - Glasgow Benefit Inventory (GBI; Robinson 1996);
  - World Health Organization Disability Assessment Schedule (WHODAS; WHO 2012b);
Search methods for identification of studies

The Cochrane ENT Trials Search Co-ordinator will conduct systematic searches for randomised controlled trials and controlled clinical trials. There will be no language, publication year or publication status restrictions. We may contact original authors for clarification and further data if trial reports are unclear and we will arrange translations of papers where necessary.

Electronic searches

Published, unpublished and ongoing studies will be identified by searching the following databases from their inception:

- Cochrane Register of Studies (CRS) ENT Trials Register (search to date);
- Cochrane Central Register of Controlled Trials (CENTRAL, current issue);
- Ovid MEDLINE (1946 to date);
- Ovid MEDLINE (In-Process & Other Non-Indexed Citations);
- PubMed (as a top up to searches in Ovid MEDLINE);
- Ovid EMBASE (1974 to date);
- EBSCO CINAHL (1982 to date);
- Ovid CAB abstracts (1910 to date);
- LILACS (search to date);
- KoreaMed (search to date);
- IndMed (search to date);
- PakMediNet (search to date);
- Web of Knowledge, Web of Science (1945 to date);
- CNKI (searched via Google Scholar to date);
- ClinicalTrials.gov (www.clinicaltrials.gov) (search via the CRS to date);
- ICTR (search to date);
- ISRCTN (www.isrctn.com) (search to date);
- Google Scholar (search to date).

The subject strategies for databases will be modelled on the search strategy designed for CENTRAL (Appendix 1). Where appropriate, these will be combined with subject strategy adaptations of the highly sensitive search strategy designed by Cochrane for identifying randomised controlled trials and controlled clinical trials (as described in the Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0, Box 6.4.b. (Handbook 2011)).

Searching other resources

We will scan the reference lists of identified publications for additional trials and contact trial authors if necessary. In addition, the Trials Search Co-ordinator will search PubMed, TRIPdatabase, The Cochrane Library and Google to retrieve existing systematic reviews relevant to this systematic review, so that we can scan their reference lists for additional trials. We will search for conference abstracts using the Cochrane ENT Trials Register and EMBASE.

Data collection and analysis

Selection of studies

Material downloaded from electronic sources will include details of author, institution or journal of publication and abstract. MF, DH and Fiona Barker (FB) will independently screen each study against the criteria for including studies to determine their eligibility for inclusion in the review. Where the decision about any one study is not unanimous among the screening authors, we will acquire the full article for further inspection. Once the full articles are obtained, we will decide whether the studies meet the review criteria. We will make a final decision by consensus.

Data extraction and management

MF and FB will independently extract data from the articles. We will record the extracted data on a review-specific form that we will develop and assess for suitability through pilot testing prior to independent data extraction. Where data to be extracted are also described in the text of an article, whether in the main body or in a table, PK will resolve discrepancies between the two independent extractions. Where data to be extracted are also described graphically in an article, we will use the average of the two independent extractions provided there is agreement regarding their derivation (see also Dealing with missing data).

Information to be extracted will include: trial design, setting, methods of randomisation and blinding, power, inclusion and exclusion criteria, type of intervention and control, time since hearing aid fitting, and duration of follow-up, outcome measures and statistical tests.
Assessment of risk of bias in included studies

MF and PK will undertake assessment of the risk of bias of the included trials independently, with the following taken into consideration, as guided by the Cochrane 'Risk of bias' tool in RevMan 5.3:
- sequence generation;
- allocation concealment;
- blinding of (i) participants and study personnel (performance bias), and (ii) outcome assessment (detection bias);
- incomplete outcome data;
- selective outcome reporting; and
- other sources of bias.

We will use the Cochrane 'Risk of bias' tool in RevMan 5.3, which involves describing each of these domains as reported in the trial and then assigning a judgement about the risk of bias on the outcomes measured as a result of each entry: 'low', 'high' or 'unclear' risk of bias.

Measures of treatment effect

We will express the size of the difference in treatment effect between a treatment group and a control group at a trial endpoint in terms of the standardised mean difference (SMD). The calculation of the effect size will use the pooled standard deviation. We will also report the 95% confidence interval (CI) for each SMD. An effect size greater than 0 indicates that a larger treatment effect was observed in the treatment group relative to the control group. For binary data, including adverse effects, we will preferably express the treatment effects as risk ratios (RR).

Unit of analysis issues

The unit of analysis will be the participant. We do not anticipate that participant-level data will generally be available, but suitable summary statistics should be provided. As stated above, in the case of cross-over trials we will only include the first period.

Dealing with missing data

We will make efforts to contact the corresponding author of an included study to obtain any missing data. Where data can only be estimated by reading off plots, we will achieve this as detailed in the Data extraction and management section. If standard deviations are not reported or provided by the authors we will estimate standard deviations in RevMan 5.3 using available data, such as standard errors, 95% CIs, P values and t values. If data are not available for subgroups of interest then we will request these data from study authors; likewise if data, for example, standard deviations (or error bars on plots) are not available. Where missing data cannot be obtained, we will describe the methodology used to account for these missing data and investigate the mechanism by which data might be missing (e.g. whether missing completely at random). Where possible, we will perform analysis on an available case analysis basis, unless this is not feasible given the use of imputation in individual studies. If possible, we will report the extent of the missing data within studies.

Assessment of heterogeneity

We will assess heterogeneity among treatment effect sizes using RevMan 5.3, and we will express this in terms of the I^2 statistic. We will assess statistical significance using a Chi^2 test with K-1 degrees of freedom. We will quantify heterogeneity in terms of the I^2 statistic with low, medium and high ranges of 0% to 40%, 41% to 60% and 61% to 100%, respectively.

Assessment of reporting biases

We will assess publication bias by examining a funnel plot in which the size of treatment effects is plotted against their variability. We will quantify deviation from the expected symmetrical pattern by calculating the number of studies required to achieve symmetry using the ‘trim and fill’ method.

Data synthesis

We will conduct random-effects meta-analyses of the SMDs using RevMan 5.3, as we anticipate significant heterogeneity across treatment effects between studies. For each meta-analysis, we will report a summary effect size estimate in terms of the SMD (and where appropriate risk ratio) together with its 95% CI. We will calculate summary effects using the generic inverse variance procedure.
Subgroup analysis and investigation of heterogeneity

If heterogeneity is identified we will use subgroup analyses to assess possible sources. These factors will include age at hearing aid fitting, sex and degree of hearing loss (i.e. mild or moderate). Degree of hearing loss will be based on the better ear hearing thresholds averaged across 0.5 kHz, 1.0 kHz, 2.0 kHz and 4.0 kHz and we will classify this as mild and moderate for hearing thresholds between 26 to 40 dB hearing level (HL) and 41 to 60 dB HL, respectively. Where studies do not report separately by subgroup, or do not fall completely within one particular subgroup, we will allocate studies to a subgroup where there is evidence that a majority of participants fall within that group. Age will be defined as older adults (> 55 years) and younger adults (<= 55 years). If a study includes only one sex, we propose that those studies go entirely into one subgroup, and if a study reports males and females separately they can contribute to both subgroups of an analysis. If, however, a study only reports a mixed group, then we will remove this from the analysis. Time between fitting and trial endpoint may also represent a source of heterogeneity and so a subgroup analysis will also compare trials with endpoints at up to three months, over three months to six months and six months or more.

Sensitivity analysis

We will perform sensitivity analyses to informally test the robustness of assumptions from the data. We will use sensitivity analyses where there is any uncertainty regarding any aspect of the included studies in terms of randomisation (random/quasi-random), missing data (greater than 30% at the primary endpoint) and description of hearing loss (mild/moderate).

GRADE and 'Summary of findings'

PK and DH will use the GRADE approach to independently rate the overall quality of evidence for each outcome. MF will then review the ratings and discuss any disagreements with PK and DH, involving other authors as required until a consensus is reached. The quality of evidence reflects how confident we are that an estimate of effect is correct. We will apply this to our interpretation of results. The four possible ratings are: high, moderate, low or very low. A rating of high-quality evidence implies confidence in the estimate of effect and that further research is very unlikely to change our confidence in the estimate. If a study is rated as very low quality this would imply that the estimate of effect is very uncertain.

The GRADE approach rates evidence from RCTs that do not have serious limitations as high quality. However, several factors can lead to the downgrading of the evidence to moderate, low or very low. The degree of downgrading is determined by the seriousness of the these factors: study limitations (risk of bias), inconsistency, indirectness of evidence, imprecision and publication bias. We will include a 'Summary of findings' table (Handbook 2011), and we will use the GRADE considerations to separately assess the quality of the body of evidence for each intervention and primary outcome, and to draw conclusions about the quality of evidence in the review. We will include the following outcomes in the 'Summary of findings' table: hearing-specific health-related quality of life, health-related quality of life, listening ability and adverse effects.

Acknowledgements

This project was supported by the National Institute for Health Research, via Cochrane Infrastructure, Cochrane Programme Grant or Cochrane Incentive funding to Cochrane ENT. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the Systematic Reviews Programme, NIHR, NHS or the Department of Health.

We acknowledge Helen Henshaw who helped to conceive the review question. We would also like to acknowledge Lee Yee Chong for methodological support and advice and Samantha Faulkner who designed the search strategy (Cochrane ENT).

References

Akeroyd 2014

AoHL 2015

Barker 2014

Barton 2004
Barton GR, Bankart J, Davis AC, Summerfield QA. Comparing utility scores before and after hearing-aid
Hearing aids for mild to moderate hearing loss in adults (Protocol)

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McArdle 2005

McCormack 2013

Mueller 2005

Newman 1990

Picou 2013

Rabin 2001

Reese 2005

RevMan 2014 [Computer program]

Robinson 1996

Stark 2004

Timmer 2015

Tuley 1990

Ventry 1982

Ware 1992

WHO 2001

WHO 2008

WHO 2012a

WHO 2012b

* Indicates the major publication for the study
APPENDICES

Appendix 1. CENTRAL search strategy

#1 MeSH descriptor: [Hearing Loss] explode all trees
#2 MeSH descriptor: [Persons With Hearing Impairments] explode all trees
#3 hearing near (loss or impair*)
#4 deaf*
#5 #1 or #2 or #3 or #4
#6 MeSH descriptor: [Hearing Aids] this term only
#7 "hearing aid*" or hearing-aid* or "hearing device*" or "hearing instrument*" or "hearing system*"
#8 hearing near (loss or impair*) near (amplif* or aided or unaided)
#9 #6 or #7 or #8
#10 #5 and #9

WHAT'S NEW

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CONTRIBUTIONS OF AUTHORS

MF conceived the review question. MF wrote the protocol and co-ordinated comments from the authors and reviewers.

PK contributed substantially to the 'Data collection and analysis' sections and provided advice on content relating to Cochrane review protocols.

MEJ contributed substantially to the 'Data collection and analysis' sections and provided statistical advice.

PK and MEJ provided general feedback on the protocol.

DH commented substantially on the initial proposal and critically reviewed the protocol manuscript.

Fiona Barker was not an author of the protocol but will join the review as a co-author for the full review.

DECLARATIONS OF INTEREST

Melanie Ferguson: none known.

Mark Edmondson-Jones: none known.

Pádraig T Kitterick: NHBRU has received financial support from Cochlear Europe Ltd. and support in kind from Phonak UK Ltd. to conduct a multicentre clinical trial of cochlear implantation in single-sided deafness co-ordinated by PTK. PTK has accepted the hospitality of Cochlear Europe Ltd. to attend and speak at national and international scientific meetings.

Derek Hoare: none known.
**SOURCES OF SUPPORT**

**Internal sources**
- National Institute for Health Research, UK.
MF, PK, MEJ and DH are funded by the National Institute for Health Research (NIHR) Biomedical Research Unit Programme, however the views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health

**External sources**
- National Institute for Health Research, UK.
Infrastructure funding for Cochrane ENT