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Unilateral versus bilateral hearing aids for bilateral hearing impairment in adults (Protocol)

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[Intervention Protocol]

Unilateral versus bilateral hearing aids for bilateral hearing impairment in adults

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

To assess the effects of bilateral versus unilateral hearing aids in adults with a bilateral hearing impairment.

BACKGROUND

Description of the condition

Acquired hearing loss is a common adult condition, affecting 16% of the adult UK population aged 18 to 80 years. The incidence increases markedly with age with 37% of those aged 61 to 70 years and 60% of those aged 71 to 80 years having a bilateral hearing loss (Davis 1989; Davis 1994). A review of the world epidemiology literature in 2000 suggested that globally 360 million adults have a 'disabling' loss in the better ear (> 40 dB HL) (Mathers 2000). In most people the hearing loss is sensorineural and due to the loss of hair cells in both inner ears, as opposed to a conductive hearing loss that is due to middle or external ear pathology (Browning 1992). In the majority of cases the loss of hair cells occurs with ageing, leading to a bilateral 'age-related' hearing loss that affects both ears to the same degree (Davis 1989; Davis 1994). This is not the case with conductive hearing loss where the pathology often affects one or both ears to a different extent. Age-related sensorineural hearing loss is often combined with a conductive hearing loss (mixed hearing loss).

The level of disability caused by hearing loss is mainly determined by the hearing in the better hearing ear as assessed by pure-tone audiometry. From the audiogram the average of the thresholds of detection at four frequencies (0.5 kHz, 1 kHz, 2 kHz and 4 kHz) is calculated and compared with the adult categories of normal (0 to 20 dB HL), mild (21 to 40 dB HL), moderate (41 to 70 dB HL), severe (71 to 95 dB HL) and profound (> 90 dB HL) (WHO 1991).

Middle ear surgery has a potential role in a very small proportion of patients with a pure conductive impairment, which is most frequently unilateral. Profound hearing loss can be managed with cochlear implants. Mild, moderate and severe sensorineural hearing loss is primarily managed with hearing aids. The fitting of hearing aids constitutes the majority of the workload of audiology departments with an estimated 10.8 million aids being sold each

year, based on a survey of manufacturers of hearing aids (Kirkwood 2013). Forty-five per cent of these were sold in Europe, 29% in America and 26% in the rest of the world. However, this figure grossly underestimates the potential usage of hearing aids, as the majority (80%) of adults aged 55 to 74 years who have a disabling hearing loss do not use aids (McCormack 2013).

Description of the intervention

Hearing aids

In this review, all participants receive hearing aids as the main intervention; the comparison is between one aid fitted to one specific ear and the fitting of aids to both ears.

Hearing aids amplify the sound reaching the ear. They can be either digital or analogue instruments. With either technology the degree of amplification of the hearing aid complex can be programmed to suit the characteristics of the patient's hearing loss as assessed with a pure-tone audiogram. Aids can vary in where they are positioned: in-the-canal, in-the-ear, behind-the-ear and body-worn. Patient choice is one important factor that determines which is used, but the degree of hearing impairment is another. Hearing aids can also have features such as directional microphones, which are helpful in face-to-face conversation. There is considerable variation in patients' listening requirements. Some require amplification only when listening to the television, for example, whilst others have multiple requirements such as the need to hear in varying background noise and with multiple speakers.

Most patients with sensorineural hearing loss have a reduced dynamic range and many hearing aids incorporate compression systems. These can be adjusted so that soft sounds are audible without loud sounds being uncomfortable. To date, however, hearing aids cannot directly compensate for other things that usually accompany sensorineural hearing loss, such as a reduced ability to distinguish different frequencies. This may restrict or limit their benefit.

Hearing aids are thought to be most suitable for patients with a pure tone average of $\geq$ 25 dB HL to 70 dB HL. When hearing loss is greater than 70 dB HL, alternative options such as cochlear implants may be more suitable.

The provision of hearing aids varies widely in different health services and resource settings. In some places hearing aids (either one or two) are provided 'free' to the patient, funded by the local health care providers. In others, aids are only available to those who can pay for them. In both systems there are cost implications when two aids are provided rather than one.

When two aids are being considered, there are at least two alternative approaches:

- fit one aid then consider an aid for the other ear later;
- fit two aids from the beginning and leave it to the patient to use two, one or no aids.

Those who use hearing aids - or their carers - need sufficient manual dexterity to position the aid in the ear, to switch it on, to maintain it (for example, clean it) and, for some hearing aids, to make programme button and/or volume control changes. Some people find some of these things difficult.

How the intervention might work

Bilateral hearing aids

In normal hearing people, there is general benefit in having two ears rather than one. A binaural system enables the listener to determine from which side the sound is coming (lateralisation). This allows the head to be turned towards the sound source and, as a result, the source of the sound can be localised. This helps a listener when attending to specific sounds, for example speech in the presence of background noise (Bronkhorst 2015).

In the light of this, it is easy to assume that patients with binaural hearing aids will be able to function more 'normally' than those with only one aid. However, as we mention above, amplification does not produce 'normal' hearing and those processes that produced a patient's sensorineural hearing loss (especially ageing) may also impact on the way sound is processed and understood.

Possible benefits of bilateral amplification include the following:

- An improved ability to localise sound.
- So-called 'binaural loudness summation', where an equivalent sound pressure level is perceived as louder when presented binaurally.
- The assurance of better-ear listening. In some situations, one of the ears will be presented with a clearer signal of interest; having both ears aided theoretically allows patients to take advantage of all situations.
- Some hearing aid users suffer from ear infections and related problems, requiring them to leave an aid out of the affected ear for several days or weeks. Having the option to use aids in both ears can be helpful in these circumstances.

On the other hand, a potential disadvantage of binaural aiding is 'binaural interference', where the patient's speech recognition is poorer when presented in both ears rather than just one.

In summary, whilst there are theoretical reasons why binaural aids might work better than a single aid, based on an idea that this restores a patient to a more 'normal' situation, there remains uncertainty about this. There are also several practical issues relating to the use of two aids rather than one that may also impact on the outcomes of binaural aiding.

Why it is important to do this review

The existence of two main strategies for fitting hearing aids (bilateral *versus* unilateral) for patients with bilateral hearing loss has

arisen due to uncertainty about the relative benefits to patients and cost-effectiveness. There is a lack of understanding of the factors leading to non-use of aids. This is true of those who use a single aid as well as those with two aids (McCormack 2013).
These fitting strategies may lead to one of several outcomes:

- abandonment of the use of one or both hearing aids altogether;
- satisfaction and continued use of one or both aids;
- continued use of one aid but abandonment of the second; or
- a desire to try a second aid by those fitted with only one.

Finally, whether the use of one or two hearing aids prevails depends on many patient characteristics (audiometric, lifestyle and expectations), the method of hearing aid fitting and the rehabilitative approach. The interplay of these factors is not well understood.
In the absence of strong evidence of the prognostic factors that can specifically predict patient preference and outcomes, evidence from randomised controlled trials on the relative effectiveness of bilateral versus unilateral fitting is important to guide practice. We have not identified any previous systematic review therefore a Cochrane Review to evaluate the effects of unilateral versus bilateral hearing aids for bilateral hearing impairment is warranted.

OBJECTIVES

To assess the effects of bilateral versus unilateral hearing aids in adults with a bilateral hearing impairment.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs). This includes:

- parallel-group study designs, where patients are randomised to unilateral or bilateral aids; or
- cross-over study designs for the order of fitting of unilateral/bilateral aids for each patient; or
- cluster-randomised trials, where randomisation is done by practice or setting (the number of randomised groups must be more than two);
- quasi-randomised trials, because only a small number of trials is expected.

Types of participants

We will include studies if the participants meet the following criteria:

- adults (over 18 years);
- with a bilateral hearing impairment and both ears suitable for hearing aids.

We will exclude studies from the review if a *majority* of the participants have one or more of the following characteristics:

- although asymmetric hearing impairment will not be excluded, if a patient has one ear that is audiometrically normal or one ear that has a profound or total loss conventional hearing aids are not appropriate for them;
- active external or middle ear disease;
- previous experience of using a hearing aid.

Types of interventions

The comparison of interest is:

- fitting of two versus one ear-level acoustic hearing aids.

We will exclude implants, body-worn aids and bone-conduction hearing aids.
We will apply no minimum duration of use or follow-up as an inclusion criterion, but we will consider these as part of the GRADE evidence evaluation for indirectness of evidence.

Types of outcome measures

We will analyse the following outcomes in the review, but we will not use them as a basis for including or excluding studies.

Primary outcomes

- Patient preference for unilateral versus bilateral aids.
- Hearing-specific health-related quality of life (e.g. Hearing Handicap Inventory for the Elderly (HHIE), Hearing Handicap Inventory for Adults (HHIA), Auditory Disability Preference - Visual Analogue Scale (ADPI-VAS), Quantified Denver Scale of communication (QDS), Device Orientated Subjective Outcome Scale)*.
- Adverse effects (pain, infection).

Secondary outcomes

- Usage of hearing aids (e.g. data logging, battery consumption) for the duration of the trial (Laplante-Levesque 2014).
- Health-related quality of life (Health Utilities Index Mark 3 (HUI-3), the Glasgow Benefit Inventory (GBI), EQ-5D, SF-36, the World Health Organization (WHO) Disability Assessment Schedule (WHO-DAS), Self Evaluation of Life Function (SELF)*.

- Listening ability (e.g. Abbreviated Profile of Hearing Aid Benefit (APHAB), Speech, Spatial and Qualities of Hearing Scale (SSQ), Glasgow Hearing Aid Benefit profile)*.
- Audiometric benefit measured as binaural loudness summation.
- Outcome reported by carer or 'communication partner'**.
- Annoyance, measured using patient-reported outcome measures**.
- Sound localisation as measured by laboratory tests**.
- Speech in noise detection as measured by laboratory tests**.

* For the generic health-related quality of life instruments, only the HUI-3 and the Glasgow Benefit Inventory (GBI) are expected to have the sensitivity to distinguish the effectiveness of hearing aids. It will be essential that there is supporting evidence that questionnaires chosen to measure an outcome have been shown to be responsive to the provision of hearing aids and have the potential to differentiate between the benefits of binaural versus monaural fitting of aids. However, due to the lack of known validated questionnaires for this purpose, we will collect data from any questionnaire not specified above if relevant or validated.
** These additional outcomes were included as part of a collaboration with a NICE guideline committee and will not be included in the 'Summary of findings' table of this review.

Search methods for identification of studies

The Cochrane ENT Information Specialist, in conjunction with the NICE Information Specialist, 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:
- the Cochrane Register of Studies ENT Trials Register (search to date);
- the Cochrane Central Register of Controlled Trials (CENTRAL, current issue);
- Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) (1946 to date);
- Ovid EMBASE (1974 to date);
- EBSCO CINAHL (1982 to date);
- LILACS (search to date);
- KoreaMed (search to date);
- Web of Knowledge, Web of Science (1945 to date);
- ClinicalTrials.gov, www.clinicaltrials.gov (search via the Cochrane Register of Studies to date);
- World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) (search to date);
- Google Scholar (search to date).

The subject strategies for databases will be modelled on the search strategy designed for Ovid MEDLINE, Ovid Embase and CENTRAL in 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 Information Specialists will search Ovid MEDLINE, Ovid Embase and the *Cochrane Library* to retrieve existing systematic reviews relevant to this systematic review, so that we can scan their reference lists for additional trials.

Data collection and analysis

Selection of studies

At least two authors will independently screen the titles and abstracts of the papers found by the searches against the criteria for inclusion. We will then retrieve and independently review the full text of the potentially eligible papers to determine if they meet the inclusion criteria for the review. We will resolve any differences by discussion and consensus, with the involvement of a third author for clinical or methodological input.

Data extraction and management

At least two authors will independently extract the data from each trial using a standardised data extraction form (Appendix 2). If any essential data are missing from a study then one author will contact the authors of the papers to request the additional information. We will try to identify multiple publications for included studies and, if a study has more than one publication, we will retrieve all publications to ensure complete extraction of data. If differences are found between publications of a study, we will contact the original authors for clarification. We will use data from the main paper(s) if no further information is found.
Where there are discrepancies in the data extracted by different review authors, we will check these against the original reports and resolve differences by discussion and consensus, with the involvement of a third author or a methodologist where appropriate. We will contact the original study authors for clarification or for missing data whenever possible.

For each trial we will document the following information:

- Methods: study design (cross-over, parallel etc.), randomisation method, unit of randomisation, blinding method, duration of follow-up.
- Participants: setting, number of participants entered and analysed, age and sex, inclusion and exclusion criteria, levels of hearing impairment.
- Type of intervention: type of hearing aids fitted during the study, duration of each intervention, use of additional intervention, details of model, type of mould used and fitting strategy. We will record the rehabilitation strategy used (such as the ability to position the aid and mould in the ear and to use the controls).
- Outcomes: assessment method, time point of data collection.
- Funding sources and declarations of interest.

In addition, we will also extract baseline information on prognostic factors (often called 'predictors' in trials) or effect modifiers that may affect preferences and outcomes of the study. For this review, this includes:

- levels or severity of hearing impairment;
- presence of asymmetric hearing loss;
- whether participants had previous experience of hearing aid use;
- cognitive impairment;
- visual impairment;
- presence of tinnitus.

For the outcomes of interest to the review, we will extract the findings of the studies on an available case analysis basis; i.e. we will include data from all patients available at the time points based on the treatment randomised whenever possible, irrespective of compliance or whether patients had received the treatment as planned.

In addition to extracting pre-specified information about study characteristics and aspects of methodology relevant to risk of bias, we will extract the following summary statistics for each trial and each outcome:

- For continuous data: the mean values, standard deviations and number of patients for each treatment group. We will prioritise using change from baseline data whenever available. Where change data are not available, we will use the mean and standard deviation of each group at the end of the study. We will analyse data from measurement scales as continuous data.
- For binary data: the numbers of participants experiencing an event and the number of patients assessed at the time point.
- For ordinal scale data: if the data appear to be approximately normally distributed or if the analysis that the investigators performed suggests parametric tests were appropriate, then we will treat the outcome measures as continuous data. Alternatively, if data are available, we may convert into binary data.

Where studies report data at multiple time points, we will only extract the longest available data or end of the study data.

Assessment of risk of bias in included studies

GGB and PH will undertake assessment of the risk of bias of the included trials independently, with the following taken into consideration, as guided by the*Cochrane Handbook for Systematic Reviews of Interventions* (Handbook 2011):

- sequence generation;
- allocation concealment;
- blinding;
- incomplete outcome data;
- selective outcome reporting; and
- other sources of bias (validity and sensitivity of questionnaires and measurement methods used to measure the outcomes).

We will use the Cochrane 'Risk of bias' tool in RevMan 5.3 (RevMan 2014), which involves describing each of these domains as reported in the trial and then assigning a judgement about the adequacy of each entry: 'low', 'high' or 'unclear' risk of bias. For other sources of bias, we will only consider the issue of validity and sensitivity of questionnaires as a high risk of bias if there is evidence or a strong rationale to believe that the lack of sensitivity will bias the results towards 'no difference', or the type of measure is unfairly favourable/unfavourable to either of the treatments. We will revisit and discuss disagreements with all authors until consensus is reached.

Measures of treatment effect

We will summarise dichotomous data as risk ratios (RR) with 95% confidence intervals (95% CI). For the key outcomes that we will present in the 'Summary of findings' table, we will also express the results as absolute numbers based on the pooled results and compared to the assumed risk. We may also calculate the number needed to treat to benefit (NNTB) using the pooled results. The assumed baseline risk is typically either (a) the median of the risks of the control groups in the included studies, this being used to represent a 'medium-risk population' or, alternatively, (b) the average risk of the control groups in the included studies is used as the 'study population' (Handbook 2011). If a large number of studies are available, and where appropriate, we may also present additional data based on the assumed baseline risk in (c) a low-risk population and (d) a high-risk population.

For continuous outcomes, we will summarise the treatment effect as the mean difference (MD) with 95% CI or as the standardised mean difference (SMD) with 95% CI if different scales have been used to measure the same outcome. We will provide a clinical interpretation of the SMD values.

We will dichotomise or analyse ordinal data as a continuous outcome, depending on the outcome and whether the scale can be expected to be normally distributed.

Unit of analysis issues

Cross-over studies

In addition to simple parallel randomised controlled trials (where the unit of randomisation is at the individual level), another possible design is a cross-over trial where patients are randomised to different fitting arrangements during different phases of the trial. If cross-over studies are found and included, our analyses will take into account the 'paired' nature of the data across different phases whenever possible (Elbourne 2002). If these data are not available, we will analyse only the first phase of the study. By analysing only the first phase, carry-over effects are avoided.

If both of the above options are unavailable, we will consider using the data at the end of the trial and note the risk of bias. Since this is a stable condition, we do not expect a patient's condition to fluctuate and hearing aids will only have an effect while they are in use. Any 'cross-over effect' is likely to be due to adaptation and experience of using of hearing aids. Using the end of study data is also reflective of clinical practice protocols where patients may be started with one or two hearing aids fitted and then try a different combination.

Cluster-randomised studies

For cluster-randomised trials, where patients may be randomised to either unilateral or bilateral fitting depending on the location or unit of practice, the unit of randomisation will be the unit or practice rather than the individual. For these designs, we will use the approximate analyses detailed in Chapter 16 of the *Cochrane Handbook for Systematic Reviews of Interventions* to either inflate the standard error or calculate the effective sample sizes (Handbook 2011).

Dealing with missing data

To obtain any missing data we will make efforts to contact the corresponding author to request this. In the event of missing data we will perform an available case analysis.

If standard deviation data are not available, we will approximate these using the standard estimation methods from P values, standard errors or 95% CIs, if these are reported, as detailed in the*Cochrane Handbook for Systematic Reviews of Interventions* (Handbook 2011). If it is impossible to estimate these, we will contact the study authors.

Apart from imputations for missing standard deviations, we will conduct no other imputations. We will extract and analyse all data using the available case analysis method.

Assessment of heterogeneity

We will assess clinical heterogeneity (which may be present even in the absence of statistical heterogeneity) by examining the included studies for potential differences between them in the types of participants recruited, interventions or controls used and outcomes measured.

We will assess statistical heterogeneity by visually inspecting the forest plots and considering the Chi^2 test (with the threshold for significant heterogeneity being an associated P value below 0.1). We will also express heterogeneity in terms of the I^2 statistic, which calculates the percentage of variability that is due to heterogeneity rather than chance with low, medium and high ranges of 20% to 40%, 41% to 60% and 61% to 100%, respectively (Handbook 2011).

Assessment of reporting biases

We will assess reporting bias as between-study publication bias and within-study outcome reporting bias.

Outcome reporting bias (within-study reporting bias)

We will assess within-study reporting bias by comparing the outcomes reported in the published report against the study protocol, whenever this can be obtained. If the protocol is not available, we will compare the outcomes reported to those listed in the methods section. If results are mentioned but not reported adequately in a way that allows analysis (e.g. the report only mentions whether the results were statistically significant or not), bias in a meta-analysis is likely to occur. We will seek further information from the study authors. If no further information can be found, we will note this as being a 'high' risk of bias. Quite often there will be insufficient information to judge the risk of bias; we will note this as an 'unclear' risk of bias (Handbook 2011).

Publication bias (between-study reporting bias)

We will assess funnel plots if sufficient trials (more than 10) are available for an outcome. If we observe asymmetry of the funnel plot, we will conduct more formal investigation using the methods proposed by Egger 1997.

Data synthesis

We will conduct all meta-analyses using Review Manager 5.3 (RevMan 2014). For dichotomous data, we plan to analyse treatment differences as a risk ratio (RR) calculated using the Mantel-Haenszel method. We will analyse time-to-event data using the generic inverse variance method.

For continuous outcomes, if all the data are from the same scale, we may pool mean values obtained at follow-up with change outcomes and report this as a MD. However, if the SMD has to be used as an effect measure, we will not pool change and endpoint data.

When statistical heterogeneity is low, random-effects versus fixed-effect methods yield trivial differences in treatment effects. However, when statistical heterogeneity is high, the random-effects method provides a more conservative estimate of the difference.

Subgroup analysis and investigation of heterogeneity

A number of factors could affect the relative benefit of binaural versus monaural hearing aids. If heterogeneity is detected, we will assess this using the following subgroup analyses, including:

- type of hearing aid;
- age;
- sex;
- severity of hearing loss - degree of hearing loss will be based on the better ear hearing threshold average as classified earlier;
- asymmetry of loss;
- cognitive impairment;
- visual impairment;
- presence of tinnitus with hearing loss;
- first time users of hearing aid.

We will conduct some subgroup analyses regardless of whether statistical heterogeneity is observed, as these are widely suspected to be potential effect modifiers. For this review, this will be the type of hearing aid. We will present the main analyses of this review according to type of hearing aid. We will present all other subgroup analysis results in tables.

When studies have a mixed group of patients, we will analyse the study as one of the subgroups (rather than as a mixed group) if more than 80% of patients belong to one category.

Sensitivity analysis

We will carry out sensitivity analyses to determine whether the findings are robust to the decisions made in the course of identifying, screening and analysing the trials. We plan to conduct sensitivity analysis for the following factors, whenever possible:

- impact of model chosen: fixed-effect versus random-effects model;
- risk of bias of included studies: excluding studies with high risk of bias (we define these as studies that have a high risk of allocation concealment bias and a high risk of attrition bias (overall loss to follow-up of > 20%, differential follow-up observed);
- how outcomes were measured: we will investigate the impact of including data where the validity of the measurement is unclear.

If any of these investigations finds a difference in the size of the effect or heterogeneity, we will mention this in the 'Effects of interventions' section.

GRADE and 'Summary of findings' table

Two authors will independently use the GRADE approach to rate the overall quality of evidence using GRADEpro GDT (https://gradepro.org/). The quality of evidence reflects the extent to which we are confident that an estimate of effect is correct and we will apply this in the interpretation of results. There are four possible ratings: high, moderate, low and very low. A rating of high quality of evidence implies that we are confident in our estimate of effect and that further research is very unlikely to change our confidence in the estimate of effect. A rating of very low quality implies that any estimate of effect obtained 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 these factors:

- study limitations (risk of bias);
- inconsistency;
- indirectness of evidence;
- imprecision; and
- publication bias.

For this review, we have identified the duration of use of hearing aids before outcome assessment as being important, as it will take some time before patients can adjust and fully benefit from the devices fitted. Therefore, for any outcomes where the duration of use is less than eight weeks, we will downgrade the evidence for indirectness. We will also consider downgrading in cases where the technology used in the hearing aids used in the study is no longer reflective of currently available hearing aids.

We will include a 'Summary of findings' table, constructed according to the recommendations described in Chapter 10 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Handbook 2011). We will include the following outcomes in the 'Summary of findings' table:

- Patient preference for unilateral versus bilateral aids.
- Hearing-specific health-related quality of life.
- Adverse effects (pain, infection).
- Usage of hearing aids (e.g. data logging, battery consumption) for the duration of the trial.
- Health-related quality of life.
- Listening ability.
- Audiometric benefit measured as binaural loudness summation.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. Draft search strategies

MEDLINE (Ovid)	Embase (Ovid)	CENTRAL
1 exp Hearing Loss/ 2 (hearing adj2 (loss* or impair* or partial* or deficit* or deteriorat* or degenerat* or diminish* or difficult* or disabilit* or hard or one side* or unilateral)).ti,ab 3 deaf*.ti,ab. 4 (hypoacus* or presbycus* or presbyacus* or sociocus* or nosocus* or anacus*).ti,ab 5 Persons With Hearing Impairments/ 6 or/1-5 7 letter/ 8 editorial/ 9 news/ 10 exp historical article/ 11 Anecdotes as Topic/ 12 comment/ 13 case report/ 14 (letter or comment*).ti. 15 or/7-14 16 randomized controlled trial/ or random*.ti,ab. 17 15 not 16 18 animals/ not humans/ 19 Animals, Laboratory/ 20 exp animal experiment/ 21 exp animal model/ 22 exp Rodentia/ 23 (rat or rats or mouse or mice).ti. 24 or/17-23 25 6 not 24 26 Hearing Aids/ 27 "Correction of Hearing Impairment"/is [Instrumentation] 28 (hearing adj (aid* or instrument*)).ti,ab. 29 (ear mold* or earmold* or ear mould* or earmould* or amplif*).ti,ab 30 or/26-29 31 (contralateral or bilateral* or binaural or unilateral* or monoaural or (bi adj3 lateral*) or (uni adj3 lateral*) or bimodal).ti,ab 32 ((both or two or one or left or right or	1 exp *hearing impairment/ 2 (hearing adj2 (loss* or impair* or partial* or deficit* or deteriorat* or degenerat* or diminish* or difficult* or disabilit* or hard or one side* or unilateral)).ti,ab 3 deaf*.ti,ab. 4 (hypoacus* or presbycus* or presbyacus* or sociocus* or nosocus* or anacus*).ti,ab 5 or/1-4 6 letter.pt. or letter/ 7 note.pt. 8 editorial.pt 9 case report/ or case study/ 10 (letter or comment*).ti. 11 or/6-10 12 randomized controlled trial/ or random*.ti,ab. 13 11 not 12 14 animals/ not humans/ 15 nonhuman/ 16 exp animal experiment/ 17 exp Experimental Animal/ 18 animal model/ 19 exp Rodent/ 20 (rat or rats or mouse or mice).ti. 21 or/13-20 22 5 not 21 23 Hearing Aid/ 24 (hearing adj (aid* or instrument*)).ti,ab. 25 (ear mold* or earmold* or ear mould* or earmould* or amplif*).ti,ab 26 or/23-25 27 (contralateral or bilateral* or binaural or unilateral* or monoaural or (bi adj3 lateral*) or (uni adj3 lateral*) or bimodal).ti,ab 28 ((both or two or one or left or right or single or double) adj3 (side* or ear or ears or fitting*)).ti,ab 29 27 or 28 30 26 and 29	#1 [mh "hearing loss"] #2 (hearing near/2 (loss* or impair* or partial* or deficit* or deteriorat* or degenerat* or diminish* or difficult* or disabilit* or hard or one side* or unilateral)):ti,ab #3 deaf*:ti,ab #4 (hypoacus* or presbycus* or presbyacus* or sociocus* or nosocus* or anacus*):ti,ab #5 [mh ^"persons with hearing impairments"] #6 {or #1-#5} #7 [mh ^"Hearing Aids"] #8 MeSH descriptor: [Correction of Hearing Impairment] this term only and with qualifier(s): [Instrumentation - IS] #9 (hearing next (aid* or instrument*)):ti,ab #10 (ear next mold* or earmold* or ear next mould* or earmould* or amplif*):ti,ab #11 {or #7-#10} #12 (contralateral or bilateral* or binaural or unilateral* or monoaural or (bi near/3 lateral*) or (uni near/3 lateral*) or bimodal):ti,ab #13 ((both or two or one or left or right or single or double) near/3 (side* or ear or ears or fitting*)):ti,ab #14 #12 or #13 #15 #11 and #14 #16 ((both or two or one or left or right or single or double) near/3 (aid* or instrument*)):ti,ab #17 #15 or #16 #18 #6 and #17

(*Continued*)

single or double) adj3 (side* or ear or ears or fitting*)).ti,ab 33 31 or 32 34 30 and 33 35 ((both or two or one or left or right or single or double) adj3 (aid* or instrument*)).ti,ab 36 34 or 35 37 25 and 36 38 randomized controlled trial.pt. 39 controlled clinical trial.pt. 40 randomi#ed.ti,ab. 41 placebo.ab. 42 randomly.ti,ab. 43 Clinical Trials as topic.sh. 44 trial.ti 45 or/38-44 46 37 and 45	31 ((both or two or one or left or right or single or double) adj3 (aid* or instrument*)).ti,ab 32 30 or 31 33 22 and 32 34 random*.ti,ab. 35 factorial*.ti,ab. 36 (crossover* or cross over*).ti,ab. 37 ((doubl* or singl*) adj blind*).ti,ab. 38 (assign* or allocat* or volunteer* or placebo*).ti,ab. 39 crossover procedure/ 40 single blind procedure/ 41 randomized controlled trial/ 42 double blind procedure/ 43 or/34-42 44 33 and 43	

Appendix 2. Data extraction form

REF ID:	Study title:
Date of extraction:	Extracted by:

General comments/notes (internal for discussion):

FLOW CHART OF TRIAL:

	Group A (Intervention)	Group B (Comparison)
No of people screened		
No. of participants randomised - all		
No. randomised to each group		
No. receiving treatment as allocated		

(*Continued*)

No. not receiving treatment as allocated - Reason 1 - Reason 2		
No. dropped out (no available follow-up data for any outcome)		
No. excluded from analysis[1] (for all outcomes) - Reason 1 - Reason 2		

[1]This should be the people who received the treatment and were therefore not considered 'dropouts' but were excluded from all analyses (e.g. because the data could not be interpreted or the outcome was not recorded for some reason)

Information to go into 'Characteristics of included studies' table:

Methods	X arm, double/single/non-blinded, [multicentre] parallel-group/cross-over/cluster-RCT, with x duration of treatment and x duration of follow-up
Participants	**Location:** country, no. of sites etc. **Setting of recruitment and treatment:** **Sample size:** • **Number randomised:** x in intervention, y in comparison • **Number completed:** x in intervention, y in comparison **Participant (baseline) characteristics:** • Age: • Gender: • Main diagnosis: *[as stated in paper]* Other important effect modifiers: • Hearing loss status: • Degree of asymmetry: **Inclusion criteria:** **Exclusion criteria:**
Interventions	**Intervention (n = x):** (hearing aid name, type of hearing aid, how this was fitted, hearing aid style, whether volume control is allowed) **Comparator group (n = y)**: Use of additional interventions (common to both treatment arms):
Outcomes[1]	Outcomes of interest in this review ***1. Hearing-specific health-related quality of life*** • Hearing Handicap Inventory for the Elderly (HHIE) or HHI for Adults (HHIA) • Quantified Denver Scale of Communication (QDS) • Auditory Disability Preference - Visual Analogue Scale (ADPI-VAS)

(*Continued*)

	• Device Orientated Subjective Outcome Scale • Any questionnaire not specified above that is relevant ***2. Listening ability*** • Abbreviated Profile of Hearing Aid Benefit (APHAB) • Speech, Spatial and Qualities of Hearing (SSQ) • Glasgow Hearing Aid Benefit Profile (GHABP) disability subscale • Any questionnaire not specified above that is relevant ***3. Adverse effects: pain, infection, etc.*** ***4. Patient preference*** Secondary outcomes/important outcomes ***5. Outcomes reported by carer or 'communication partner' [add information on how this was measured]*** ***6. Usage of hearing aids [add information on how this was measured]*** ***7. Health-related quality of life (generic scale)*** • Health Utilities Index Mark 3 (HUI-3) • EQ-5D • SF-36 • Glasgow Benefit Inventory (GBI) • WHO Disability Assessment Schedule (WHO-DAS) • Self-Evaluation of Life Function (SELF) • Any questionnaire mot specified above that is relevant ---------- ***8. Annoyance scale in patient-reported outcome measures [add information on how this was measured]*** ***9. Sound localisation as measured by laboratory tests [add information on how this was measured]*** ***10. Speech in noise detection as measured by laboratory tests [add information on how this was measured]***
Funding sources	"No information provided"/"None declared"/State source of funding
Declarations of interest	"No information provided"/"None declared"/State conflict
Notes	

[1]DELETE all the outcomes that have not been reported in the study, leaving behind only the outcomes that are reported by the study.

FINDINGS OF STUDY

CONTINUOUS OUTCOMES

Results (continuous data table)							Results (continu
Outcome	Group A - Bilateral			Group B - Unilateral			Other summary stats/Notes
	Mean	SD	N	Mean	SD	N	Mean difference (95% CI), P values etc.

(*Continued*)

Hearing-specific health-related quality of life • Hearing Handicap Inventory for the Elderly (HHIE) or HHI for Adults (HHIA) • Quantified Denver Scale of Communication (QDS) • Auditory Disability Preference - Visual Analogue Scale (ADPI-VAS) • Device Orientated Subjective Outcome Scale							
Listening ability • Abbreviated Profile of Hearing Aid Benefit (APHAB) • Speech, Spatial and Qualities of Hearing (SSQ) • Glasgow Hearing Aid Benefit Profile (GHABP) disability subscale							

(*Continued*)

Patient preference (add information on how this was recorded)							
Usage of hearing aids (add information on how this was recorded)							
Health-related quality of life (generic scale) • Health Utilities Index Mark 3 (HUI-3) • EQ-5D • SF-36 • Glasgow Benefit Inventory (GBI) • WHO Disability Assessment Schedule (WHO-DAS) • Self-Evaluation of Life Function (SELF) • Any questionnaire mot specified above that is relevant							
Outcomes reported by carer or 'communication partner'							

(*Continued*)

Sound localisation as measured by laboratory tests							
Speech in noise detection as measured by laboratory tests							
Comments:							Comments:

Appendix 3. 'Risk of bias' table template

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High/unclear/low risk	Quote: Comment:
Allocation concealment (selection bias)	High/unclear/low risk	Quote: Comment:
Blinding of participants and personnel (performance bias)	High/unclear/low risk	Quote: Comment:
Blinding of outcome assessment (detection bias)	High/unclear/low risk	Quote: Comment:
Incomplete outcome data (attrition bias)	High/unclear/low risk	Quote: Comment:
Selective reporting (reporting bias)	High/unclear/low risk	Quote: Comment:
Other bias	High/unclear/low risk	Quote: Comment:
Other bias: insensitive/non-validated instrument?	High/unclear/low risk	Quote: Comment:

CONTRIBUTIONS OF AUTHORS

George Browning: conceiving, designing and co-ordinating the review, providing a clinical perspective, writing the protocol.

Patrick Howell: providing a clinical perspective, writing the protocol.

William M Whitmer: designing the review, providing a clinical perspective, writing the protocol.

Saoussen Ftouh: providing a methodological perspective, writing the protocol.

Lee Yee Chong: providing a methodological perspective, writing the protocol.

Graham Naylor: providing a clinical perspective, writing the protocol, providing general advice on the review.

DECLARATIONS OF INTEREST

George G Browning: none known.

Patrick Howell: none known.

William M Whitmer: none known.

Saoussen Ftouh: none known.

Lee Yee Chong: none known.

Graham Naylor: none known.

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Staff time

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