Electronically Published SUMJ - 007

Published online: July 2012

Grewal R & Irwin J (2012). Innovative ways hearing aids can be improved for clinical use: Literature Review

Innovative ways hearing aids can be improved for clinical use A Literature Review

Ravinder Grewal (4th year MBChB) & John Irwin (Consultant in Audiological Medicine)
Correspondence to: Ravinder Grewal : R.S.Grewal@dundee.ac.uk

ABSTRACT

Background:
Hearing aids have been vastly improved since the introduction of digital technology. However, there are several areas exist where further development can take place. There is currently no literature review focusing upon these potential hearing aid developments for patients with hearing problems.

Objectives: To research aspects of hearing aids that can be further improved and evaluate the effectiveness of using head-related transfer functions by comparing headphone and sound-field standardised scores in terms of sound localisation.

Search strategy: 'MEDLINE', 'Web of Science', a manual library search and reference lists of relevant articles were searched up to and including January 2011

Selection criteria: Studies were included if they were randomised control trials and included only human participants. Data collection and analysis: One author selected relevant trials, assessed methodological quality and extracted data with supervision.

Main results: A quantitative meta-analysis was deemed inappropriate due to heterogeneity in outcome measures. Seven papers featured evidence of potential further enhancements to hearing aids that included direct and indirect improvements. Localisation techniques to improve hearing aid testing were discussed which improve hearing aid use indirectly. Further improvement to wireless abilities, stronger yet smaller digital signal processors (DSP) chips, a greater number of channels and complex algorithms featured as direct hearing aid improvement techniques.

Conclusions: For innovated sound localisation techniques to be implemented clinically, it is essential that this area is researched further. Otherwise, hearing aid technology will develop and sound localisation techniques will be over-shadowed by more direct improvements despite the very real clinical and cost-effective improvements that localisation techniques may have upon patient hearing.

Key Words: Audiological Medicine; Hearing Aids; Literature Review ENT

Introduction

Hearing loss affects every aspect of our lives, especially personal and professional relationships. This can give rise to stress that may negatively impact all aspects of life. To counter these effects, devices such as cochlear implantations and hearing aids have been developed. At present, there has not been a systematic literature review on the topic of improving hearing aids for clinical use. This systematic literature review will highlight how hearing aids have developed and how further they can be improved especially in under researched areas such as localisation ability.

How Hearing Aids Have Developed

In the past (mid-1660s), sophisticated hearing aid devices were not available and ear trumpets/horns were used to amplify sounds.[1] These devices had obvious limitations as all frequencies were amplified around the same level whilst the extent of amplification was limited. In the early 1900s the first hearing aid was developed and this was followed by vast improvements throughout the years; ranging recently from the innovation of analogue to digital hearing aids.

Current Hearing Aid Technology

At present digital hearing aids is the preferred intervention when a patient has a hearing loss with the following exceptions. Firstly, when a patient presents with significantly impaired outer and/or middle ear function, as bone-anchored devices are preferred. Secondly, if patients present with profound hearing loss particularly in children, cochlear implantation is preferred, as documented by the National Institute of Clinical Excellence guideline.[2] Digital hearing aids have many advantages to their analogue counter-part. The main advantage is that tuning the hearing aid to a patient's hearing thresholds can be much more accurate rather than the trial and error technique used in analogue hearing aid fitting. This also prevents patients from manually altering their hearing aid tuning settings by mistake as this cannot be done on a digital hearing aid unless it is plugged into a computer with the appropriate software. Other improvements consist of digital feedback reduction, digital noise reduction, digital speech enhancement, digital microphones and increased comfort associated with improved wide-dynamic range algorithms to prevent high-intensity sounds causing discomfort. Recent market data states that 71% of hearing aid users express overall satisfaction of their hearing aids.[3] This percentage has most likely been increased due to the implementation of digital hearing aids.[4] However, patients that have had analogue hearing aids for a long time sometimes dislike their new digital hearing aids as they can sound very different and may never sound like the hearing aid they were used to.

How Hearing Aids Work

Simply put, all hearing aids work by amplifying sound in frequencies where the patient has lost natural amplification and/or sensitivity. To do this, a hearing aid must have four basic parts consisting of a *microphone*, *amplifier*, *speaker* and *battery*. The microphone picks up sound, converts it to an electronic signal that is amplified by the amplifier and then sent to the speaker. The speaker converts the sound back to an acoustic wave of which the ear is familiar with, whilst the battery powers these three components. Different hearing aids exist depending on one's hearing loss and associated problems. There are three types of hearing loss; sensorineural, conductive and mixed:

* Sensorineural hearing loss- implies a loss of hearing in the inner ear or higher up in brain function (for example- brainstem). Approximately 90% of patients have sensorineural hearing loss to some degree.[2]

* A conductive hearing loss- is anything outside of the inner ear, i.e. either the middle or outer ear and a

* Mixed hearing loss- consists of a mixture of both.

The areas of the ear discussed above are shown in Fig 1.

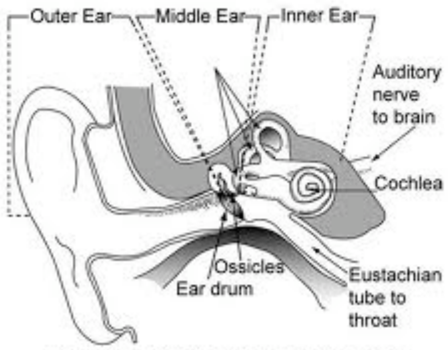

Figure 1: The Outer, Middle, and Inner Ear

Figure 1 shows a clear illustration of the ear and for one to understand how hearing aids work is important that one understands how we hear at least a basic level. In essence, sound arrives from the environment to the outer ear. The outer ear plays a role in localisation and amplification of sound. Sound then travels and resonates through the ear canal (external auditory meatus) as a passage to the ear-drum (tympanic membrane). The tympanic membrane vibrates and allows the middle ear bones (ossicles) to vibrate at the oval window adjacent to the cochlear. The cochlear is a spiral shaped structure that allows for the mechanical form of sound energy to be converted to electrical energy. It contains vast amounts of outer hair cells that amplify and manipulate sound similar to channels featured on a hearing aid as well as inner hair cells that act as a transducer to electrical energy. The inner hair cells allow sound to be sent to the brain via the auditory nerve (cranial nerve VIII) once the outer hair cells have manipulated sound. Damage to either these structures can cause types of hearing loss. The type of hearing loss along with other audiological issues determines which hearing aid is more suitable to each patient.

For example, a patient with a severe conductive loss and/or frequent ear discharge will benefit from sound being bypassed by the damaged outer/middle ear. This can be implemented via the use of a bone-anchored hearing aid (BAHA) i.e. a hearing device attached to the mastoid bone that transmits sound directly to the skull and inner ear (fig 2). For the more common type of hearing loss (sensorineural hearing loss), behind-the ear hearing aids are mostly used as they have many advantages over other types e.g. ease of use, clarity of sound and cost-effectiveness.

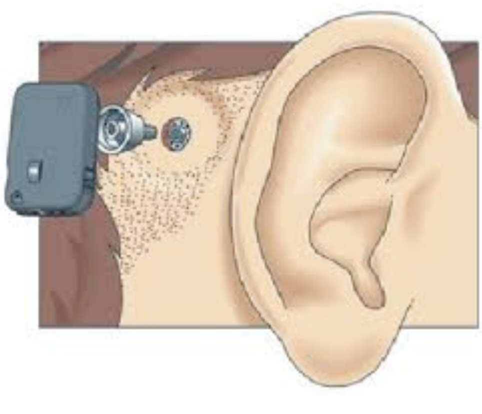

Figure 2: BAHA placed on the mastoid bone

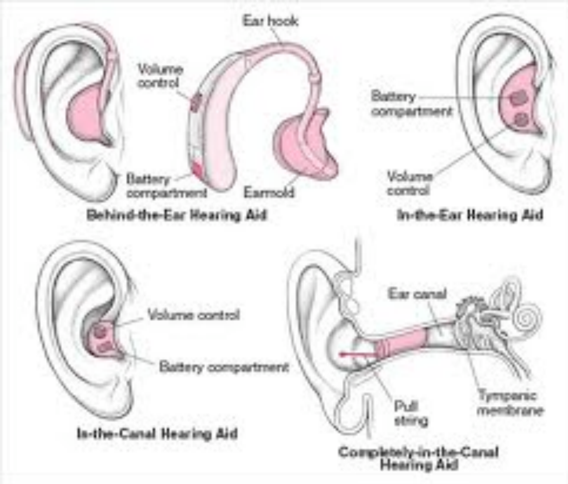

Figure 3: Highlighting different types of hearing aid

Improving Hearing Aid Technology

Current hearing aid improvements are vast and are currently well researched. Some of the recent innovations in the last couple years consist of smaller light-weight hearing aids, wireless hearing aids that connect with many house hold electrical devices, open-ear hearing aids, more powerful behind the-ear hearing aids and sophisticated background noise reduction algorithms.[4] However, one key area of localising sounds effectively rather than just directly improving sound quality does not feature significantly in current improvements. Localising sounds effectively improves speech intelligibility and safety.[5-12] Speech intelligibility can be defined as the amount one can discriminate between sounds of spoken words i.e. the quality of speech heard by a hearing aid. It is greatly affected by the number of channels a hearing aid has. The term channels refer to components manipulating sound in a hearing aid just as our outer hair cells manipulate sound in the cochlear. This is achieved by accurate binaural hearing (two sided hearing). Factors that affect binaural hearing include the head shadow effect and spectral cues.

The head shadow effect arises when a region of reduced amplitude of a sound occurs due to the head's obstruction. The obstruction may result in sound attenuation and cause filtering effects that may result in poorer sound localisation.[13] Spectral cues are a generic term that also takes in account of the pinna and torso as well as the head. In addition to spectral cues, the auditory system exploits differences in inter-aural time and intensities to aid localisation.[14] An inter-aural time difference (ITD) is defined as the difference in arrival times of a sound wave at both ears. Similarly, an inter-aural level difference (ILD) is defined as the amplitude difference generated between both ears by a sound in the free field. These differences occur because in a sound field, sound waves are reflected by many different surfaces that have varied impedance properties. The result is distortion due to constructive and deconstructive interferences. To eliminate such factors, a free field would be preferred although this is practically impossible due to acoustic, cost and time constraints. This is the significant reason why patients undergo pure tone audiometry via headphones to test their hearing. Headphones have their own problems such as a perception loss of around 3db that occurs because of the headphones masking the ear.[5] Furthermore, spatial hearing that occurs in a sound field is fundamentally more natural than using headphones.[15-16] This is due to headphones not being able to take in account for the head shadow effect and spectral cues i.e. some patients with significantly different sized heads will not have accurate hearing aid settings as headphones do not take in account for this as sound is played directly inside the ear. Audiologists will often test hearing aid/cochlear implant patients with their devices on and with the aid of head-related transfer function (HRTF) data, to improve accuracy in the diagnosis and subsequent treatment of a child with hearing loss. The HRTF can be defined as the size difference of one's head that reflects sound waves before arriving inside the ear canal.[10]

This systematic literature review will look into whether such improvements of sound localisation have currently been clinically effective. There has currently been no such review undertaken after reviewing the literature.

Methodology

This systematic literature review will research whether innovative ways in improving hearing aid technology have been fully utilised. A thorough methodology was put into practice to identify high-quality evidence regarding improving hearing aid technology. This methodology is consistent with the systematic literature review recommendations of the Cochrane Back Review Group[16] that is similar to the 1994 Agency for Health Care Policy and Research (AHCPR) guideline and National Institute of Occupational Safety and Health guideline. It was intended to perform a meta-analysis of the isolated studies.

Literature search

One researcher carried out the search. A search of two relevant database; MEDLINE (via OVID search) and Web of Science, was conducted up to and including January 2011 by using the following search terms: (hearing) AND; (improvement OR localization) AND (aid). These were used since other databases clearly had no articles listed on the topic. The literature search was restricted to papers published in English. The search retrieved 505 abstracts that were read by RG. The primary author applied inclusion and exclusion criteria (discussed below) to include and exclude studies as appropriate.

Eight studies were then found and were critically appraised in relation to evidence-based practice guidelines for the categorisation of medical studies.

Additional papers

An additional 3 papers were obtained from references contained in the references list of those papers selected for the initial review from the above search methodology. Furthermore, the search was extended by contacting experts in the field of medical research for additional papers. No extra papers relating to current research were found.

Inclusion-Criteria

Studies were included if they involved humans only, discussed technological improvements in relation to digital hearing aids and were written in the English language. Studies required the primary purpose of the paper to further develop hearing aid use through their intervention. Studies that had patients with no hearing difficulties were selected on the basis to test localisation scores fairly between participants with the use of HRTFs. This would help derive whether such techniques will improve hearing aid tests thus, improving hearing aid use indirectly.

Exclusion-Criteria

Studies were excluded if they included non-human participants or had a small sample size (less than 5). Studies that were not related to providing hearing aids with further improvement were also ruled out before being appraised by a format similar to the AHCPR guideline. Other studies were excluded if they regarded improvements of analogue hearing aids.

The search strategy isolated eleven potential papers for a meta-analysis remained and this was dependent on a critical appraisal.

Assessing the validity and quality of the studies

The study validity for systematic literature reviews can be defined as "the degree to which its design and conduct are likely to prevent systematic errors of bias."[17] A simplistic approach towards the assessment of validity of studies included in this review was made via using criteria suggested in the Cochrane Handbook.[16] Each paper was assessed and rated according to criteria of low, moderate or high risk of bias. Studies that were regarded as high risk were not included in the review.

In addition to validity, a thorough read through each of the 8 retrieved studies and 3 additional articles was carried out to filter the most relevant studies. The studies were scored similar to the recommendations of the Cochrane Back Review Group (appendix 1 and 2). The criteria that have been proposed for scoring evidence can be found in table 1. In addition, the final methodological cut off threshold for inclusion of studies inevitably depended on the overall quality of the literature retrieved; as a result, a flexible approach was used.

Table 1 - Criteria for evidence scoring

Criteria		**Score**
Evidence Level	I	2
	II	1
	III-IV	0
Sample size	0-5	Discarded
	6-9	1
	10-19	2
	20+	3
Patient history		1
Human participants		1
Clinical Relevance	No	Discarded
	Limited	0
	Yes	1
Scores associated with hearing improvement due to hearing aid technology not currently implemented		1

Data presentation

As a consequence of heterogeneous content and the broad range of different types of hearing aid improvement listed, a meta-analysis for this literature review would be inappropriate. Therefore, a quantitative analysis will be used only across papers that have homogenous outcome measures accompanied by a qualitative approach.

Results

The methodological assessment showed that 9 papers had high scores however; the criterion score is set at a score of 6 due to consistency with the Cochrane Back Review Group (appendix 1). [16] This reduced the number of papers to 7 papers (table 2). Studies highlighted in blue were included in further analysis.

Table 2 - Validity and strength of the evidence scores

Publications	Validity risk	Score*
Cameron et.al. (2006)	Low	7
Danhauer (2009)	Low	6
Edwards (2007)	Low	6
MacDonald and Tran (2008)	Low	6
Schlegel (1994)	Low	6
Wightman and Kistler (1989a)	Low	6
Wightman and Kistler (1989b)	Low	6
Begault and Wenzel (1993)	Moderate	5
Wenzel et.al. (1993)	Low	5
Sivonen and Ellermeier (2006)	Low	4
Zotkin et.al. (2006)	Low	2

** Score = Evidence level score; higher the number indicates a stronger evidence level*

Excluded studies

Four studies were excluded because they contained evidence of being; irrelevant to improving hearing aid technology, contained solely improvements that have already been applied clinically, inefficient sample size and irrelevance to hearing.

Ongoing studies

No ongoing studies were found in terms of improving hearing aid use via sound localisation strategies.

Risk of bias in included strategies

No risk of bias was isolated as each study (except one[4]) included randomisation and appeared to have an appropriate and strong methodology (defined by Cochrane standards).

Characteristics of the selected papers

Clinical efficacy of each study varies as highlighted by the given evidence-based scores. Sample sizes varied significantly; the lowest sample size was 24 and the highest was 223. This skewed the evidence-based scores for each study. The outcome measures of the studies were heterogeneous thus, making it difficult to conduct a quantitative meta-analysis.

Homogenous content across papers included potential clinical applications in the improvement of hearing aids. Outcome measures differed across papers (Table 3); five papers[6-8; 11-12] had objective outcome measures that showed the benefit of implementing patients head-related transfer function (size of their head) into hearing aids as this has not currently been implemented in hearing aids provided by the NHS. One paper also had objective[3] measures but revealed that a wide variety of improvements in hearing aid technology would provide significant benefit. The last paper[4] has subjective outcome measures and looked into the recent innovation of wireless technology followed by new innovative ways to improve digital chip technology.

Quantitative analysis of studies

A quantitative analysis via programs such as SPSS cannot be carried out due to the vast difference in outcome measures noted in each study.

Table 3: Summary of outcome measures used between studies

Publications	Incorporation of new technology	Improving existing technology
Cameron et.al. (2006)	Localisation techniques	Improved background noise reduction
Danhauer (2009)	n/a	Multi-channel hearing aid improvement
Edwards (2007)	Hearing aids that automatically switch between programs New algorithms in processing sound	Digital chip technology and wireless improvements
MacDonald and Tran (2008)	Localisation techniques	n/a
Schlegel (1994)	Localisation techniques	n/a
Wightman and Kistler (1989a)	Localisation techniques	n/a
Wightman and Kistler (1989b)	Localisation techniques	n/a

Key: HAI = Hearing aid improvement

Other-factors

Factors that may affect validity in results include age, hearing/localisation ability, and gender. Hearing screening varied across studies. Four studies screened hearing via audiometry. Hearing screening varied in criteria across studies. In two studies, hearing thresholds had to be better than 15 dB HL and in two studies 20 dB HL with the remaining studies not being clear about this threshold. Specific age groups were not given in three papers although the remaining papers listed a diverse range of age groups, overall ranging from 15-42 years of age. Five papers used a similar ratio of gender. For the remaining papers, either the data was not given or there were more females than males.

Discussion

The results showed that it was possible to analyse the papers based on similar outcome measures that include whether localisation strategies would be significantly helpful in clinical use and whether there is room for improvement incorporating such techniques into improved wireless, multi-channel hearing aids and digital chip technology.

Improving existing technology

Innovative ways hearing aid technology can be further improved consisted of:

1) Further improving the use of wireless technology
2) More powerful DSP chips as seen in new generation mobile/cell phones
3) Hearing aids with a greater number of channels and improved intelligibility
4) Improving background noise reduction

At present, digital wireless technology has become a fairly new concept that has improved the quality of life to hard of hearing patients.[3-4] The technology is not limited to assisted devices and loop systems to operate. It has been further developed so that patient's with binaural hearing aids work together in signal processing to improve sound localisation. Furthermore, wireless technology allows for hearing aids to be connected to a vast array of devices and making hearing aids Bluetooth compatible can further enhance this. Such compatibility would allow for connectivity to many devices such as mobile phones, mp3 players and computers effortlessly. The reason why the extensive use of Bluetooth has not been implemented in the National Health Service is due to power consumption (reduced battery life) difficulties that arise with such technology.[3] This problem can be solved in the future as wireless chips become smaller and use less power.[3] In addition, such advances in today's' technology have been successful, such as the development of mobile phone technology that uses smaller more powerful chips. It is also likely that wireless chip sizes in hearing aids will also become smaller but the down side is that cost may increase.

Another advancement discussed in isolated papers included improved intelligibility of hearing aids. However, this may well be a costly advancement. Currently hearing aid dispensers and audiologists spend a significant amount of time fine-tuning hearing aids in hearing aid fitting and review sessions. The time and effort expended by clinicians in this endeavour could be reduced if the hearing aid itself learned better feedback cancellation via the users' response.[3-4] Feedback cancellation is a major issue in perceived sound quality via hearing aids.[3-4] Another improvement that has positive pilot studies is improving accuracy in testing for auditory processing disorders in children especially for children who require hearing aids.[6] Headphones can be used that provide background masking noise in a three dimensional environment in addition to pure tones. This has been found to increase accuracy in the obtained hearing thresholds.[6] This indirectly improves hearing aid use by making use of more accurate hearing thresholds and delivering a more accurate prescription.

Localisation improvements to speech intelligibility

Testing localisation scores with the use of HRTF data (individualised and non-individualised) was the predominant method of assessing clinical efficacy.[7-8; 11-12] One study noted the significant inaccuracy of testing sound localisation/natural perception of sound with the use of non-individualised HRTF data.[8] This means that this paper suggests that not using individualised HRTF data that is characteristic of the participant will cause a significant decrease in accuracy of sound localisation scores.[12] Another problem found in two of the seven papers was inter-ear[11] and inter-aural[12] individual differences between participants. Inter ear differences may have occurred, as the HRTF used may have been similar to some participants more so than others. Inter aural differences were arguably negligible to cause a significant problem in sound field emulation.

Can non-individualised HRTFs seek clinical approval in the NHS where non-individualised HRTFs take the population's average pinna and head shape into consideration in sound localisation? This important question can be answered in this systematic literature review to an extent. The majority of studies showed good accuracy in sound localisation with the use of non-individualised HRTF. In one study the use of non-individualised HRTF data has been used to create an audiology based test to help increase accuracy of obtaining thresholds with patient's who may have an auditory processing disorder.[6] In addition, there is a chronological pattern that emerges as later studies show better use of non-individualised HRTFs. A variety of factors can account for this however; the innovation of new technology is likely to be the case as different equipment was used amongst studies in 1990-2009 and also, this was an era where headphone clarity increased as better technology developed quickly.

Overview of data extraction

Multiple ways were used in obtaining high quality relevant studies for a potential analysis. An extensive search was carried out with the use of databases such as MEDLINE and Web of Science as the latter database is not restricted to just allied health and biomedicine papers. Research in this area was done mostly on non-humans and therefore, it can be argued that to include this in the inclusion criteria might have benefited the results. However, after careful analysis, it can be argued that to include non-human participants may have skewed results. The outcome measures found across papers were problematic due to heterogeneity and thus, a quantitative statistical analysis via programs such as SPSS was absent. In addition, the results of this systematic literature review should be interpreted cautiously for a variety of reasons. For example, this review is based on a small number of studies as many others were rigorously filtered out. Sample sizes varied throughout each paper and it was difficult to establish how many participants were involved in one paper.[3] Thus, the efficacy of each paper varies. Publication bias may also have been apparent if trials with negative results were suppressed in the published literature thus, leaving mostly small, yet positive studies to include in the review.

Conclusions

Implication to practice and research

Like many other electrical devices, the initial innovation of digital hearing aids showed vast improvements, giving rise to many benefits as discussed in this literature review. It is likely that improvements to hearing aids will expand as more powerful DSP chips are being developed. Furthermore, hearing tests and subsequent hearing aid prescriptions can be improved with the use of individualised or non-individualised HRTFs. Such techniques have been over-shadowed by less complicated methods. For HRTFs to be put in use clinically, it is clear that greater quality research on either the implementation of individualised HRTF or the minimisation, of any negative aspects that the use of non-individualised HRTF may have should be carried out. In addition, if this under-researched area is ever to obtain clinical approval, it is imperative that a large randomised-controlled study should be carried out.

Otherwise, hearing aid technology will develop and such localisation techniques will be over-shadowed by more direct improvements such as increased connectivity and enhanced intelligibility despite the very real clinical improvements that localisation techniques may have upon patient-hearing.

References

[1] A F. Jahn, J Santos-Sacchi. (2001). Physiology of the Ear. Singular; 2nd edition. Columbia.

[2] Hearing impairment - cochlear implants, NICE Technology Appraisal Guidance (January 2009); Cochlear implants for severe to profound deafness in children and adults

[3] Danhauer, J. L, Johnson, C. E, Williams, V.A. (2009). Hearing aid outcomes: Effects of gender and experience on patients' use and satisfaction. JAAA. 20: 422–432.

[4] Edwards, B. (2007). The future of hearing aid technology. Trends in amplification 11: 31-45

[5] Begault, D. R., Wenzel, E. M. (1993). Headphone localization of speech. Human Factors: The Journal of the Human Factors and Ergonomics Society. Volume 35(2), pp. 361-376(16)

[6] Cameron, S., Dillon, H., Newall, P. (2006). Development and evaluation of the listening in spatialized noise test. Ear Hearing. 27, 30-42.

[7] MacDonald, J. A., Tran, P.K. (2008). The effect of head-related transfer function measurement methodology on localization performance in spatial audio. Human Factors: The Journal of the Human Factors and Ergonomics Society. 50(2), pp. 256-263(8)

[8] Schlegel, P. A. (1994). “Azimuth estimates by human subjects under free-field and headphone conditions.”Audiology. 33(2): pp. 93-116

[9] Sivonen, V. P., Ellermeier, W. (2006). “Directional loudness in an anechoic sound field, head-related transfer functions, and binaural summation),” The Journal of the Acoustical Society of America, 119(5), pp. 2965-2980.

[10] Wenzel, E. M., Arruda, M., Kistler, D. J., Wightman, F. L. (1993). Localization using nonindividualized head-related transfer functions. Journal of the Acoustical Society of America 94(1): 111–123.

[11] Wightman, F. L., Kistler, D. J. (1989a). “Headphone simulation of free-field listening: I. Stimulus synthesis,” Journal of the Acoustical Society of America. 85, pp. 858–867.

[12] Wightman, F. L., Kistler, D. J. (1989b). Headphone simulation of free-field listening: II. Psychophysical validation. Journal of the Acoustical Society of America. 85, pp. 616-617, 868-878.

[13] van Hoesel, R. J. (2004). Exploring the benefits of bilateral cochlear implants. Audiology and Neuro-Otology. 9. 234–246.

[14] Blauert, J. (1983). Spatial Hearing: The Psychophysics of Human Sound Localization. MIT Press. Cambridge. pp 49-50.

[15] Yost, W. A., Popper, A. N., Fay, R. R. (2008). Auditory Perception of Sound Sources. Springer, New York. pp. 222.

[16] Mulrow and Oxman. (1996). Cochrane Handbook for Systematic Reviews of Interventions. The Cochrane Collaboration. Available from www.cochrane-handbook.org
[17] Moher, D., Olkin, I., 1995. Meta-analysis of randomized controlled trials. A concern for standards. JAMA. 274, pp. 1962–1964.

Appendix

Appendix 1: Summary of the hierarchy of evidence on the effectiveness of health care interventions based on criteria developed by the Centre for Reviews and Dissemination (CRD).

Type of potential bias	**Definition and indicators of the presence of bias**
Selection	Systematic differences between intervention and control groups. Those determining the eligibility of participants should have no previous knowledge of the treatment assignment. Allocation into treatment groups should be performed by a randomisation process conducted independently of the recruitment team, and with controls to ensure that the randomisation process cannot be decoded. Selection processes that are liable to selection bias include:
	Evidence-based categorization of medical studies
	Ia - Evidence from meta-analysis of randomised controlled trials
	Ib - Evidence from at least one randomised controlled trial
	IIa - Evidence from at least one controlled study without randomisation
	IIb - Evidence from at least one other type of quasi-experimental study
	III - Evidence from non-experimental descriptive studies, such as comparative studies, correlation studies, and case–control studies
	IV - Evidence from expert committee reports or opinions or clinical experience of respected authorities, or both.
Performance	Systematic differences in care provided apart from the intervention being evaluated. The blinding of those providing and receiving care can protect against performance bias. Whilst blinding is desirable, it should be noted that not all interventions can be provided in this way (for example, it is obvious to the patient whether they have been interviewed by a care coordinator or not).
Attrition	Systematic differences in withdrawals from the trial across follow-up. This form of bias may threaten the validity of the study if one group deviates from the designated treatment, or individuals withdraw from one of the treatment groups.
Detection	Systematic differences in outcome assessment. The blinding of the treatment allocation from those assessing the study outcomes (as well as the participants themselves) can limit detection bias, although this is not always possible if participants are aware of their treatment allocation. Bias may also arise through the selective reporting of study results.

Appendix 2: Criteria for assessing the validity of studies included in a systematic review

Risk of bias	**Relationship to individual criteria**	**Definition**
Low risk	Plausible bias unlikely to significantly alter the results	All of the criteria met
Moderate risk	Plausible bias that raises some doubt about the results	One or more criteria partially met