A systematic review and meta-analysis assessing the effectiveness of alternative listening devices to conventional hearing aids in adults with hearing loss.

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**List of acronyms and abbreviations.**

ALDs: Assistive listening devices

BKB-SIN: Bamford-Kowal-Bench Speech-in-Noise test

CI: Confidence intervals

COSI: Client Oriented Scale of Improvement

CPHI: Communication Profile for the Hearing Impaired

FM: Frequency modulation

GHABP: Glasgow Hearing Aid Benefit Profile

HA: Hearing aid

HINT: Hearing in Noise Test

IOI-HA: International Outcome Inventory for Hearing Aids

MD: Mean difference

OTC: Over-the-counter

PICOS: Participants, Intervention(s), Comparators, Outcomes, and Study designs

PRISMA: Preferred Reporting Items for Systematic reviews and Meta-analyses Protocols

PSAP: Personal sound amplification products

QoL: Quality of life

RCT: Randomised controlled trials

SMD: standardised mean difference

SRT: Speech reception threshold

SSQ: Speech, Spatial and Qualities of Hearing Scale
Declaration of interest

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Abstract

**Objective.** Recent technological advances have led to a rapid increase in alternative listening devices to conventional hearing aids. The aim was to systematically review the existing evidence to assess the effectiveness of alternative listening devices in adults with mild and moderate hearing loss.

**Design.** A systematic search strategy of the scientific literature was employed, reported in accordance with the Preferred Reporting Items for Systematic reviews and Meta-analyses (PRISMA) checklist.

**Study sample.** Eleven studies met eligibility for inclusion: two studies evaluated personal sound amplification products, and nine studies assessed remote microphone systems (frequency modulation, Bluetooth, wireless).

**Results.** The evidence in this review suggests that alternative listening devices improve behavioural measures of speech intelligibility relative to unaided and/or aided conditions. Evidence for whether alternative listening devices improve self-reported outcomes is inconsistent. The evidence was judged to be of poor to good quality and subject to bias due to limitations in study design.

**Conclusions.** Our overall recommendation is that high-quality evidence (i.e. randomised controlled trials) is required to demonstrate the effectiveness of alternative listening devices. Such evidence is not currently available and is necessary to guide healthcare commissioners and policymakers when considering new service delivery models for adults with hearing loss.

**Review registration.** Prospective Register of Systematic Reviews (PROSPERO), CRD4201502958.
Introduction

Acoustic amplification provided by hearing aids is currently the primary clinical management strategy for adults with mild and moderate hearing loss. Hearing aids have been shown to improve hearing-specific health-related quality of life, general health-related quality of life, and listening abilities (Ferguson et al., 2017). However, two out of three people who would benefit from using hearing aids do not take them up (Davis et al., 2007). For those who do obtain hearing aids, estimates of non-use vary from 3% to 24% (Ferguson et al., 2017). People with hearing loss report that they are concerned or embarrassed that hearing aids will make them look old and that they will be treated differently by others (Barker et al., 2017; Heffernan et al., 2016; Wallhagen, 2010). For these reasons, alternative devices to hearing aids and alternative service delivery models should be considered as a potential means to increase patient choice, accessibility to and acceptability of hearing services for people with hearing loss that currently do not, or cannot, access hearing aids.

Whether new technologies can replace hearing aids has been ranked by patients and the public as the fifth topmost research priority for adults with mild to moderate hearing loss (Henshaw et al., 2015). Indeed, advances in technology have led to a rapid increase of alternative devices to conventional hearing aids. Here, we define alternative listening devices as standalone products that provide amplification of sound (e.g. Smartphone hearing aid applications; personal sound amplification products; hearables), as well as assistive listening devices (ALDs) that amplify and transmit sound directly into hearing aids (e.g. Smartphone-connected hearing aids; remote microphone systems). Many alternative listening devices can link wirelessly to Smartphone technologies, allowing users to adjust and personalise their hearing settings (e.g. gain, frequency response) in different listening situations at their own
convenience via an application (or app), and without the need to visit a qualified clinician (Taylor, 2015).

Existing evidence is mixed in terms of whether alternative listening devices are a suitable management strategy for hearing loss. For example, ‘mid-range’ (US$100-$500) personal sound amplification products (PSAPs), a type of ‘direct-to-consumer’ hearing device, have been shown to provide comparable electroacoustic characteristics (i.e. meet gain and output targets using National Acoustic Laboratories prescriptive procedures) to hearing aids (Callaway & Punch, 2008). By comparison, other products defined as ‘low-cost’ (<US$100) may be of limited benefit and potentially damaging to residual hearing due to over-amplification (Callaway & Punch, 2008; Chan & McPherson, 2015). Smartphone-based ‘hearing aid’ apps have also been shown to provide similar levels of amplification, improved speech-in-noise performance, and greater self-reported benefit in comparison to hearing aids (Amlani et al., 2013). Remote microphone systems have also been shown to improve hearing outcomes, but may require additional audiological support for optimal use (Boothroyd, 2004).

To date, no systematic review has evaluated whether alternative listening devices are a clinically effective intervention for people with mild and moderate hearing loss. A systematic review with meta-analysis provides the gold-standard evidence-base to inform future feasibility and effectiveness trials of alternative listening devices. This approach is consistent with the Medical Research Council’s guidelines for evaluating complex healthcare interventions (Medical Research Council, 2006). The primary objective of this study, therefore, was to review and synthesise the existing body of evidence to assess the effectiveness of alternative listening devices to conventional hearing aids.
Methods

Prior to commencing the systematic review, the protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) (registration number, CRD42015029582) and published in a peer-reviewed publication (Maidment et al., 2016). Methods are reported according to the Preferred Reporting Items for Systematic reviews and Meta-analyses (PRISMA) checklist (Moher et al., 2009).

Eligibility criteria

The criteria for inclusion in the review were specified in terms of participants, intervention, comparators, outcomes, and study designs (PICOS) as follows:

Participants

Adults (≥18 years) with a mild and moderate hearing loss (average hearing threshold across octave frequencies 0.25-4 kHz ≥20 and ≤70 dB HL (British Society of Audiology, 2011). Studies that included both children (<18 years) and adults were not included unless data were reported separately. If the hearing thresholds were not specified, the study author was contacted for further clarification. If hearing threshold data was not reported and could not be obtained, studies were included where the mean average hearing threshold reported fell within the range of either mild (between 20 to 40 dB HL) or moderate hearing loss (between 41 to 70 dB HL). Bilateral and unilateral sensorineural, conductive and mixed hearing losses were included.
**Intervention(s)**

An alternative listening device to a conventional hearing aid was considered to be non-medical standalone product (e.g. Smartphone app, PSAP, hearable) or an assistive listening device that provides additional functionality to a conventional hearing aid (e.g. remote microphone system; Smartphone-connected hearing aid whereby the Smartphone can be used as a remote microphone and/or allows manipulation of gain and frequency response via an app). An alternative listening device should aim to improve hearing and communication outcomes in people with hearing loss, specifically via the amplification of external sound sources.

**Comparators**

The comparisons of interest were either passive (e.g. unaided) or active control (e.g. conventional hearing aid). A conventional hearing aid was defined as a device that detects and amplifies sound, delivering an amplified acoustic signal via air conduction to the external auditory canal on the same side that the signals are detected, irrespective of where it is worn (behind-the-ear, in-the-ear or receiver-in-the-canal). Studies evaluating analogue hearing aids were excluded.

**Outcomes**

As the aim of the review was to assess the clinical-effectiveness of alternative listening devices, studies were restricted to outcomes associated with the consequences of hearing loss. There were no restrictions as to the duration of follow-up. Primary outcomes included one or more of the following: (i) behavioural measures of speech intelligibility (e.g. intelligibility of syllables, words or sentences presented in quiet or in noise); (ii) hearing-specific health-related quality of life (QoL), where participation was the key domain, measured using any
self-reported questionnaire (e.g. Hearing Handicap Inventory for the Elderly: Ventry & Weinstein, 1982); and (iii) adverse effects of patient, reported as pain, discomfort, tenderness, skin irritation or ear infection as a consequence of device fitting. Secondary outcomes included any of the following self-reported outcomes: (i) General health-related QoL (e.g. Health Utilities Index Mark 3: Furlong et al., 2001); (ii) listening ability (e.g. Abbreviated Profile of Hearing Aid Benefit: Cox & Alexander, 1995); (iii) cognition (e.g. working memory); (iv) feasibility (e.g. usability, adherence); (v) adverse effect of noise-induced hearing loss (e.g. due to over-amplification from inappropriate hearing aid fitting).

**Study designs**

Retrospective or prospective studies, randomised controlled trials, non-randomised controlled trials, before and after studies were included. Articles reporting expert opinions, practice guidelines, case reports, case series, conference abstracts and book chapters were excluded.

**Search strategy**

An initial literature search was conducted by a medical information specialist (Farhad Shokraneh, University of Nottingham) on April 2nd 2016. Searches were last updated on March 7th 2018 to ensure that any newly published studies were included. The following databases were searched: CINAHL (via EBSCO host), Cochrane Library, EMBASE (via Ovid SP), MEDLINE (via Ovid SP), PubMed, Scopus, Citations Indexes of Web of Science, ISRCTN Registry, ClinicalTrials.Gov, and WHO International Clinical Trials Registry Platform. Supplemental 1 provides full electronic search strategies for all databases. All database searches were completed in one day and with no time, language, document type, or publication status limitations. The search terms were collected based on free text and
controlled vocabularies (Medical Subject Headings, Excerpta Medica Tree, and CINHAL Headings), expert opinion, literature review, and checking the test search results.

Additional information was identified manually through snowballing of the reference lists from included studies, as well as screening of related articles by shortlisted authors to identify any relevant articles that may not have been returned by the initial database searches. Contact with study authors was not necessary to ascertain whether any studies were ongoing.

**Study selection**

Two investigators (DM, AB) independently screened all identified references to decide eligibility according to the PICOS criteria by reading the title and/or abstract. The full text was obtained for articles that appeared to meet eligibility or where there was any uncertainty (i.e. insufficient information to make a clear decision). We did not need to contact study authors for additional information to resolve questions concerning eligibility. Discrepancies were resolved through discussion between investigators.

**Data collection process**

A standardised data collection form constructed via Covidence (www.covidence.org) was used, which included study details (e.g. sponsorship source, country, setting), author’s contact details (name, institution, email, postal address), study design, population (inclusion/exclusion criteria, baseline characteristics), interventions (and comparators), and outcomes. Prior to starting the review, detailed guidance notes were devised by DM and were piloted by DM and AB to ensure consistency. Data collection was conducted by DM and AB independently, but in duplicate for every included record. Where necessary, study authors were contacted to resolve any uncertainties and to obtain any missing data. If data could not
be obtained and were only presented in graphical form, the results were estimated from figures using WebPlotDigitizer (http://arohatgi.info/WebPlotDigitizer/app/). Disagreements about numerical data extracted from figures were discussed and resolved by averaging.

**Risk of bias in individual studies**

DM and AB independently assessed risk of bias of each included study with the Cochrane risk of bias tool (Higgins & Green, 2011), which rates the studies as ‘high risk’, ‘low risk’ or ‘unclear risk’ in the following six domains: sequence generation, allocation concealment, blinding of participants and personnel, blinding outcome assessors, incomplete outcome data, selective outcome reporting, and other sources of bias (e.g. influence of funders). As all included studies were non-randomised, the Downs and Black (1998) checklist, which consists of 27 criteria, was used to assess study quality. Criterion 27 was adapted to consider whether or not a power calculation was performed rather than whether there was sufficient power to detect a clinically meaningful change, as there is a lack of consensus regarding clinically meaningful change in hearing loss outcome measurement (Barker et al., 2016). All answers were scored 0 (‘no’ or ‘unable to determine) or 1 (‘yes’), with the exception of criterion 5 (‘Are the distributions of principal confounders in each group of subjects to be compared clearly described?’), which was scored 0 (‘no’), 1 (‘partially’) or 2 (‘yes’). The total maximum score was 28, with study quality rated as excellent (26-28), good (20-25), fair (15-19) or poor (≤14) (Hooper et al., 2008).

**Data synthesis**

Included studies were reviewed in order to determine whether their data were suitable for inclusion in the meta-analyses. Meta-analyses were only performed when studies were broadly comparable in terms of study design, interventions, and outcomes. For continuous
data, where the studies used the same outcome measure, mean differences (MDs) were calculated with 95% confidence intervals (CI). If different outcome measures were employed, effect sizes were calculated as standardised mean differences (SMDs) in which the mean difference between conditions was divided by the pooled standard deviation (between-group) or by the standard deviation of the differences (within-group). Heterogeneity in effect sizes across studies was examined using the $I^2$ statistic and its significance was tested using a $\chi^2$ test. This approach to quantifying heterogeneity provided a value from 0 to 100%, with low (0%-40%), medium (41%-60%), and high (61%-100%) ranges (Higgins & Green, 2011). In the absence of meta-analysis, primary and secondary outcomes were assessed at the individual study level through narrative synthesis (Popay et al., 2006).

**Deviations from the published protocol**

Although we pre-specified that the data would be subjected to both random and fixed effects models, we opted to only use a random-effects meta-analysis. A random effects approach was considered most appropriate based on an assumption that effect sizes would vary across studies, not only because they used different samples of participants (as assumed in a fixed effect approach) but also due to differences in assessment methodologies employed. In addition, we stated previously that we would not pool studies if $I^2$ exceeded 60%, suggestive of high heterogeneity (Higgins & Thompson, 2002). However, although heterogeneity was high, which was to be expected due to differences across studies, we thought it useful to illustrate the pooled data for comparable studies irrespective of heterogeneity, but took this into account when interpreting the data.
Results

A total of 2,198 records were identified for screening. Following the removal of 1,060 duplicate publications, 1,138 records were subjected to a three-stage screening process (Figure 1). The full texts of 149 articles that passed the initial title and abstract screen were retrieved. A total of 138 articles were not judged to have met inclusion criteria and were excluded. Eleven studies were included in the review.

Supplemental 2 summarises the characteristics of the 11 studies included in the review. Two categories of alternative listening device (i.e. intervention) were evaluated, (i) PSAPs (n=2); and (ii) remote microphone systems (n=9). All studies were before-after comparisons, with participants acting as their own control. Comparators included unaided, conventional hearing aids alone, or another alternative listening device. Four studies assessed outcomes at a range of follow-up durations, from one month (Sacco et al., 2016) to one year (Chisolm et al., 2007). For studies that were sufficiently similar in terms of interventions and outcomes, meta-analyses were performed. Narrative synthesis (Popay et al., 2006) are reported where meta-analyses were not possible.

PSAPs

Speech intelligibility

Two eligible studies (n=73 participants) assessed six different PSAPs. Sacco et al. (2016) evaluated the TEO First listening device (Tinteo, Personal Sound Society), classified by the authors as an ‘over-the-counter’ hearing device. Reed et al. (2017) assessed five different PSAPs, which varied in terms of the purchase price as of 4th July 2017.
**PSAPs vs. unaided.** Summary effects and forest plots are provided in Table 1 and Figure 2 respectively. Overall performance across both studies was better when using a PSAP relative to unaided conditions (Figure 2A). Heterogeneity was low ($I^2=0\%$). To provide a conservative estimate of effect, performance in Reed et al.’s (2017) study was pooled across all five included PSAPs. However, Reed et al. (2017) also showed that, in comparison to unaided, performance was superior for PSAPs that were priced ≥US$299.99 (Reed et al., 2017).

**PSAPs vs. hearing aids.** Only one study (n=42 participants) compared PSAPs with conventional hearing aids (Reed et al., 2017). This showed an effect favouring hearing aids compared to PSAPs that were priced ≤US$269.99. However, performance did not differ statistically between hearing aids and PSAPs that were priced ≥US$299.99.

**Hearing-specific health-related QoL**

Hearing-specific health-related QoL was only reported by Sacco et al (2016) (n=31 participants), who administered the Glasgow Hearing Aid Benefit Profile (GHABP) handicap subscales. Handicap scores reported as percentage change, decreased for the TEO First device relative to unaided handicap for following two items, (i) having a conversation without background noise (-9.6 %, $p=0.018$), and (ii) having a conversation with several people (-16.2%, $p=0.008$).

**Listening ability**

Listening abilities were only reported by Sacco et al (2016), whereby statistically significant decreases in GHABP residual disability subscale scores (percentage change) were found for the TEO First device compared to unaided disability for the following four items: (i) watching television (-18.5%, $p=0.011$), (ii) having a conversation without background noise
(-16.5%, $p=0.002$), (iii) having a conversation in noisy background (-17.1%, $p=0.027$), and
(iv) having a conversation with several people (-20%, $p=0.014$).

**Feasibility**

Sacco et al. (2016) assessed device acceptability using a six-point Likert scale, from zero
(‘worst’) to five (‘best’). Mean scores ranged from 1.8 ($SD=1.4$) for ‘satisfaction when using
the noisy setting’, to 3.2 ($SD=1.6$) for ‘ease of use’. The authors conclude that overall
acceptability of the TEO First device was low-to-moderate. Mean duration of use was also
measured, with participants reporting average daily use of 60 minutes. Feasibility was not
reported by Reed (2017).

**Adverse effects**

Sacco et al. (2016) explicitly reported that ‘no adverse events were observed’ during the
course of the study. Adverse effects were not reported by Reed (2017).

**Remote microphone systems**

**Speech intelligibility**

Six studies tested speech intelligibility. Summary effects and forest plots are provided in
Table 1 and Figure 2 respectively. For all meta-analyses, heterogeneity was high ($I^2\geq80.3\%$),
and statistically significant ($p\leq0.024$).

*Hearing aids+FM system vs. Unaided.* Three studies (Lewis et al., 2004; Lewis et al.,
2010; Rodemerk & Galster, 2015) (n=61 participants) showed that performance favoured the
hearing aids+FM system compared to unaided (Figure 2B).
**Hearing aids+FM system vs. Hearing aid alone.** Two studies (Lewis et al., 2004; Rodemerk & Galster, 2015) (n=51 participants) showed that performance favoured the hearing aids+FM system compared to hearing aids alone (Figure 2C).

**Hearing aids+FM system vs. FM microphone only.** Three studies (Rodemerk & Galster, 2015; Lewis et al., 2010; Norrix et al., 2016) (n=36 participants) showed that while performance favoured FM microphone only compared to hearing aids+FM system, the pooled effect was not significant (Figure 2D).

**Hearing aids+FM system vs. Hearing aids+2.4GHz system.** Two studies (Rodemerk & Galster, 2015; Thibodeau, 2014) (n=27 participants) showed conflicting results, with one favouring hearing aids+FM (Rodemerk & Galster, 2015) and the other favouring hearing aids+2.4GHz system (Thibodeau, 2014) (Figure 2E).

**Hearing aids+Bluetooth system vs. Hearing aids alone.** Two studies (Rodemerk & Galster, 2015; Kim et al., 2014) (n=46 participants) showed performance favoured the hearing aids+Bluetooth system relative to the when the hearing aid was used alone (Figure 2F).

**Remote microphone only mode vs. Unaided or hearing aid alone.** Only one study (n=16 participants) compared speech intelligibility across four different remote microphone systems (FM, Bluetooth, 900MHz wireless, 2.4GHz wireless) (Rodemerk & Galster, 2015). All systems in microphone-only mode significantly improved performance relative to both unaided and hearing aid alone conditions (p<0.001). The magnitude of this effect did not differ statically between systems.

**Hearing-specific health-related QoL**

There was no robust evidence as to whether remote microphone systems improved self-reported hearing-specific health-related QoL.
**Hearing aids+FM system vs. Hearing aids alone.** Only one study, using the MarkeTrak VI survey, compared the hearing aids+FM system and hearing aids alone (Chisolm et al., 2007). No statistically significant differences were found (six weeks, n=36, Z=0.68, p=0.499; one year, n=30, Z=0.71, p=0.489).

**Hearing aids+Bluetooth accessories vs. Hearing aids alone.** Only one study (n=12 participants), using the International Outcome Inventory for Hearing Aids (IOI-HA, Cox & Alexander, 2002), compared hearing aids+Bluetooth accessories to hearing aids alone (Smith & Davis, 2014). A statistically significant improvement favouring hearing aids+Bluetooth accessories was found for residual participation restrictions (Z=2.12, p=0.034).

**Listening ability**

There was no robust evidence as to whether remote microphone systems improved self-reported listening abilities.

**Hearing aids+FM system vs. Hearing aids alone.** Two studies (Chisolm et al., 2007; Lewis et al., 2005) (n=59 participants), using different variants of the Communication Profile for the Hearing Impaired (CPHI, Demorest & Erdman, 1987), showed that listening abilities were significantly better (p≤0.03) for the hearing aids+FM system compared to hearing aids alone for social, work, home situations.

**Hearing aids+Bluetooth accessories vs. Hearing aids alone.** Only one study (n=12 participants), using the IOI-HA, GHABP, and the Speech, Spatial and Qualities of Hearing Scale (SSQ, Gatehouse & Noble, 2004) (n=12 participants), compared listening abilities between hearing aids+Bluetooth accessories and hearing aids alone (Smith & Davis, 2014). Statistically significant improvements favouring hearing aids+Bluetooth accessories were found for residual activity limitations (Z=2.24, p =0.025) and residual disability (Z=2.55, p=0.011) subscales (IOI-HA, GHABP). No statistically significant differences (p≤0.374)
across all sub-scales were found between conditions when listening abilities were measured using the SSQ.

*Feasibility*

Three different studies assessed the following feasibility domains: (i) satisfaction (Chisolm et al., 2007); (ii) preferences (Thibodeau, 2014); and (iii) usability (Smith & Davis, 2014).

*Hearing aids+FM system vs. Hearing aids alone.* Using the MarkeTrak VI survey, Chisolm et al. (2007) found statistically significant improvements favouring the hearing aids+FM system for satisfaction in ‘noisy’ listening situations (e.g. restaurant, large group, leisure activities) (six weeks, n=36, Z=3.10, *p*=0.002; one year, n=30, Z=2.27, *p*=0.007) and ‘ability to hear soft sounds’ (six weeks, n=36, Z=3.31, *p*=0.001; one year, n=30, Z=3.25, *p*=0.001).

*Hearing aids+FM system vs. Hearing aids+2.4GHz system.* Thibodeau (2014) (n=10 participants) found that all participants reported that they preferred using hearing aids+2.4GHz wireless system compared to hearing aids+FM system.

*Hearing aids+Bluetooth accessories vs. Hearing aids alone.* Smith and Davis (2014) (n=12 participants) observed that the majority of participants (exact data not reported) reported that Bluetooth accessories ‘quite easy’ to use, and improved the quality of sound when viewing the TV and using a cell phone.

*Risk of bias assessment*

Using the Cochrane risk of bias tool (Higgins & Green, 2011), all studies were judged to be high risk with regard to selection bias (i.e. random sequence generation, allocation concealment) due to the nature of the before-after study design (Table 2). Risk of performance (blinding of participants/personnel) and detection bias (blinding of outcome
assessment) was judged to be high for ten and eight studies respectively, as no blinding procedures were reported. Studies were judged to be low risk if blinding was stated, although it should be acknowledged that blinding in before-after studies is not always strictly possible as a consequence of this study design. The risk of attrition bias due to incomplete outcome data was judged to be low for all studies as there was no attrition in nine studies. In the remaining two studies, while attrition ranged from 16.67% (Chisolm et al., 2007) to 25% (Smith & Davis, 2014) at the one year and 12 week follow-up respectively, reasons for incomplete outcome data were considered to be clearly reported in each article, increasing confidence that missing data had no undue influence on the results. With the exception of Reed et al. (2017), risk of reporting bias (selective outcome reporting) was judged to be high for all studies, as numerical values were not sufficiently reported and/or were only provided for statistically significant results. In terms of risk of other bias, with the exception of three studies (Kim et al., 2014; Norrix et al., 2016; Reed et al., 2017), this was judged to be unclear for seven studies because of financial support from the manufacturer of the device(s) being evaluated. For one study (Smith & Davis, 2014), an author acted as a consultant for a hearing aid manufacturer. For these reasons, potential vested interest could have posed a threat to validity.

**Quality assessment**

Scores on the Downs and Black (1998) checklist ranged from 13 (Smith & Davis, 2014) to 21 (Sacco et al., 2016) out of a possible total of 28, indicative of a poor to good level of quality respectively. In terms of ‘reporting’, with the exception of one study (Sacco et al., 2016), adverse effects as a consequence of the intervention were not reported by any study. Whether participants were representative of the target population from which they were recruited (i.e. ‘external validity’) was also uncertain for the majority of study, as sufficient detail was often
lacking to make a clear judgement. In terms of ‘internal validity’ (e.g. randomisation, blinding), lower quality ratings arose because no studies randomised participants to intervention groups. Furthermore, only one study attempted to blind study participants to the intervention they received (Thibodeau, 2014). Similarly, a power calculation was reported for only one study to determine sample size (Rodemerk & Galster, 2015).

**Discussion**

In the current review, the scientific literature examining the effectiveness of alternative listening devices in adults with mild to moderate hearing loss was systematically searched. Eleven studies met eligibility for inclusion, two studies evaluated PSAPs and nine assessed remote microphone systems (FM, Bluetooth, wireless). The majority of studies primarily examined behavioural measures of speech intelligibility in noise. Self-reported hearing-specific QoL, listening ability, and feasibility (i.e. usability, adherence, acceptability) were also evaluated, but to a lesser extent. There were some outcomes of potential interest that were not measured (i.e. cognition, general health-related QoL, adverse effects). Follow-up ranged from one month (Sacco et al., 2016) to one year (Chisolm et al., 2007), with no long-term follow-up greater than one year. There was considerable heterogeneity, whereby interventions and outcomes varied greatly across studies. The evidence was judged to be of poor to good quality, and subject to bias mainly due to limitations in study design.

**Speech intelligibility**

For speech intelligibility performance, data pooled across two studies demonstrated that there was a beneficial effect of PSAPs in improving performance compared to unaided conditions (Reed et al., 2017; Sacco et al., 2016). Findings reported by Reed et al. (2017) further suggest
that this effect may be dependent on the cost of the PSAP assessed, whereby PSAPs that were priced ≥ US$299.99 improved speech intelligibility performance relative to unaided, and did not differ statistically from hearing aids. A potential explanation for this finding may reside in existing evidence showing that higher priced PSAPs provide comparable electroacoustic characteristics to hearing aids (Callaway & Punch, 2008). However, the extent to which these variables (i.e. price and/or electroacoustic characteristics) impact patient-reported outcomes for PSAPs remains to be established.

Similarly, speech intelligibility performance was superior for remote microphone systems used in conjunction with hearing aids (FM, Bluetooth, wireless) relative to both unaided and hearing aids alone (Kim et al., 2014; Lewis et al., 2004; Lewis et al., 2010; Norrix et al., 2016; Rodemerk & Galster, 2015). While we can be confident in the direction of the effect, due to high heterogeneity, the pooled effect size estimates could change with further evidence. Heterogeneity between studies most likely arose as a consequence of differences in assessment methodologies. In future, there should be greater consistency in the outcome measures used to assess speech intelligibility in adults with hearing loss. Standardised measurement procedures should be employed across studies so that they can be appropriately combined to enable direct comparison of effect sizes.

**Self-reported hearing-specific QoL, listening abilities and feasibility**

Outcome measures used to assess self-reported hearing-specific QoL, listening abilities and feasibility varied considerably across studies, as did duration of follow-up. This not only limited direct comparison, but may also help to explain why the pattern of results was inconsistent across studies. On this basis, there is no robust evidence as to whether alternative listening devices included in this review improve these outcomes, or if the improvements
observed are specific to the device, situations specified and/or outcome measures employed in each study. As a consequence, we suggest that the same self-report outcome measures should be consistently applied across studies, which should be appropriately sensitive and tap into the behavioural domains that they aim to reflect (Heinrich et al., 2016; Ferguson et al., 2014; 2017). There is a clear need for the development of a core outcome set in audiological rehabilitation research (Barker et al., 2015; Ferguson et al., 2017). In addition, longer follow-up durations greater than one-year would improve the certainty in the results, providing a better estimate of potential long-term benefit (Barker et al., 2016; Ferguson et al., 2017).

**Study quality and risk of bias**

The quality of the evidence included in this review was judged to be poor to good and subject to bias. The design of all studies was classified as ‘observational’ (i.e. before-after comparison), with no studies employing a separate control group. As a result, confidence in the effect size estimates are limited, as the true effects may be different. It cannot be known with certainty whether the effects seen are due to the devices, rather than due to regression to the mean or external factors affecting all participants. Further high-quality evidence is, therefore, required to improve confidence in the effect size estimates.

It should be noted that no studies assessing Smartphone-connected hearing aids or Smartphone ‘hearing aid’ apps met the inclusion criteria during the article screening process. We are aware of at least one non-peer reviewed publication that has evaluated Smartphone hearing aid apps compared to conventional hearing aids (Amlani et al., 2013). This study was not detected in the current review because it was published in an industry-related magazine (i.e. the grey literature). Inclusion of the grey literature could have provided a broader review of the available evidence. However, we opted to exclude databases of the grey literature in
our pre-specified search strategy because there is no agreed method of extracting and synthesising evidence obtained from this literature in a clear and transparent way. This would also reduce, though not eliminate, the likelihood of including poor quality studies. Two of the study authors (DM, MF) worked collaboratively with the UK NIHR Horizon Scanning and Intelligence Centre to review new and emerging technologies for hearing loss (NIHR Horizon Scanning Research & Intelligence Centre, 2017). Together with the current systematic review, and Cochrane review on hearing aids for mild to moderate hearing loss (Ferguson et al., 2017), all three reviews provide up-to-date high-level evidence of a wide range of listening devices.

**Review limitations**

A potential limitation of this review, as well as the field more generally, is that there is no consensus in terms of audiometric descriptors across different countries and organisations. In this review we used the audiometric descriptors for mild to moderate hearing loss, based on pure-tone air-conduction thresholds established by the British Society of Audiology (2011). An average hearing threshold in the better hearing ear across octave frequencies 0.25-4 kHz that are $\geq 20$ and $\leq 40$ dB HL is defined as ‘mild’, and $\geq 41$ and $\leq 70$ dB HL as ‘moderate’. Other definitions adopt different frequency ranges and intensity cut-offs, such as the World Health Organisation definitions, whereby average thresholds across 0.5-4 kHz between 26 and 40 dB HL is defined as ‘mild’, and 41 to 60 dB HL as ‘moderate’ hearing loss (Mathers et al., 2000). In addition, individual hearing threshold data were seldom reported for all included studies, and could not be made available by the study authors for logistical reasons. Although unlikely, included studies could have included some participants with more severe degrees of hearing loss. Nevertheless, in accordance with our published protocol (Maidment
et al., 2016), studies were verified as eligible for inclusion because the mean average hearing threshold always fell within the pre-specified range.

**Research recommendations**

On the basis of this review, further high-quality evidence, namely randomised controlled trials (RCTs), is needed to evaluate whether alternative listening devices are a clinically- and cost-effective intervention for adults living with hearing loss. This is in-line with a research recommendation for hearing loss assessment and management specified by the UK National Institute for Clinical Excellence (2018). Such research has also been identified as a high-priority need in the US (Humes et al., 2017; National Academies of Science, 2016), given that alternative listening devices could enable new service delivery models (e.g. direct-to-consumer, over-the-counter). Moreover, there have been recent legislative changes in the United States, with the introduction of the Over-the-Counter (OTC) Hearing Aid Act of 2017, which aim to improve accessibility and affordability of hearing-healthcare for adults. High-quality evidence, therefore, is needed as a priority in this area. In a recently published randomised, double-blind, placebo-controlled clinical trial (Humes et al., 2017), hearing aids fitted by an audiologist (i.e. ‘audiology best practices’) and hearing aids fitted using an OTC model resulted in similar effect sizes for measures of speech recognition and hearing aid benefit. Nevertheless, satisfaction and percentage likely to purchase hearing aids post-trial were lower for the OTC model, potentially attributable to the lack of audiological interaction during the provision of the hearing aids (Humes et al., 2017). It has been proposed that adults living with hearing loss may require optional assistance to successfully use alternative listening devices that do not require a hearing healthcare professional in terms of device fitting and/or fine-tuning (Keidser and Convery, 2016). In support, the results of our mixed-methods usability study, completed following this systematic review, suggest that people
living with hearing loss would like greater instruction to use and adjust alternative listening
devices themselves (Maidment & Ferguson, 2017; in press). Remotely-delivered information
is one means of providing such assistance, and has been shown to successfully supplement
the provision of hearing aids, resulting in improved outcomes (Kramer et al., 2005; Ferguson
et al., 2016; Thorén et al., 2014). Therefore, we recommend that this concept be incorporated
in the design of future effectiveness trials.

Conclusions
In summary, the evidence included in this review suggests that alternative listening devices
improve behavioural measures of speech intelligibility relative to unaided and/or
conventional hearing aids. There is no robust evidence as to whether alternative listening
devices improve self-reported outcomes. Furthermore, the evidence was judged to be poor to
good quality and subject to bias due to limitations in study design. On this basis, we argue
that high-quality studies (i.e. RCTs) investigating the clinical- and cost-effectiveness of
alternative listening devices are needed in this area. Such evidence, though currently
unavailable, is necessary to guide healthcare commissioners and policymakers when
considering new service delivery pathways to benefit adults living with hearing loss.
Moreover, given that this field is likely to continue to develop in new and unexpected ways,
we envisage that the current systematic review will require updating, and it is our intention to
do so in two to three years. These rapid developments reflect the innovative nature of the
field, which not only has the potential to transform hearing healthcare service delivery in the
future, but also increase the likelihood that people will seek and use amplification to
successfully manage their hearing loss.
Acknowledgments

The authors would like to thank Farhad Shokraneh (Medical Information Specialist, University of Nottingham) for devising the search strategy.
Table 1. Summary effects of speech intelligibility for comparable studies included in the review. CI = confidence interval; FM = frequency modulation; MD = mean difference; SMD = standardised mean difference.

<table>
<thead>
<tr>
<th>Study</th>
<th>N</th>
<th>MD/SMD</th>
<th>95% CI</th>
<th>Z</th>
<th>p</th>
<th>Heterogeneity</th>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>( \chi^2 ) (df)</td>
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<tr>
<td><strong>PSAPs vs. Unaided</strong></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Reed et al (2017)</td>
<td>42</td>
<td>-0.24</td>
<td>-0.55, 0.06</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Sacco et al (2016)</td>
<td>31</td>
<td>-0.41</td>
<td>-0.77, -0.04</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Total</td>
<td>73</td>
<td>-0.31</td>
<td>-0.55, -0.07</td>
<td>-2.58</td>
<td>&lt;0.01</td>
<td>0.45 (1)</td>
</tr>
<tr>
<td><strong>Hearing aids+FM system vs. Unaided</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lewis et al (2004)</td>
<td>45</td>
<td>-25.10*</td>
<td>-27.11, -23.09</td>
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<td>-</td>
<td>-</td>
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<tr>
<td>Lewis et al (2010)</td>
<td>10</td>
<td>-8.60*</td>
<td>-11.73, -5.47</td>
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<td>-</td>
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<tr>
<td>Rodemerk &amp; Galster (2015)</td>
<td>16</td>
<td>-14.80*</td>
<td>-16.80, -12.80</td>
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<td>-</td>
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<tr>
<td>Total</td>
<td>71</td>
<td>-16.22*</td>
<td>-25.64, -6.81</td>
<td>-3.38</td>
<td>&lt;0.001</td>
<td>92.42 (2)</td>
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<td><strong>Hearing aids+FM system vs. Hearing aids alone</strong></td>
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<td></td>
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<tr>
<td>Lewis et al (2004)</td>
<td>45</td>
<td>-20.44*</td>
<td>-22.07, -18.81</td>
<td>-</td>
<td>-</td>
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<td>Rodemerk &amp; Galster (2015)</td>
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<td>-14.00*</td>
<td>-16.52, -11.48</td>
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<tr>
<td>Total</td>
<td>61</td>
<td>-17.29*</td>
<td>-23.60, -10.99</td>
<td>-5.37</td>
<td>&lt;0.001</td>
<td>17.62 (1)</td>
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<td><strong>Hearing aids+FM system vs. FM-only mode</strong></td>
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<tr>
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<td>0.68</td>
<td>-0.01, 1.36</td>
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<td>-</td>
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<tr>
<td>Norrix et al (2016)</td>
<td>10</td>
<td>2.80</td>
<td>1.42, 4.17</td>
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<td>-</td>
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<tr>
<td>Rodemerk &amp; Galster (2015)</td>
<td>16</td>
<td>0.36</td>
<td>-0.14, 0.87</td>
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<td>Total</td>
<td>36</td>
<td>1.15</td>
<td>-0.22, 2.52</td>
<td>1.65</td>
<td>0.10</td>
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<tr>
<td><strong>Hearing aids+FM system vs. Hearing aids+2.4GHz system</strong></td>
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<tr>
<td>Rodemerk &amp; Galster (2015)</td>
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<td>-1.55</td>
<td>-2.28, -0.82</td>
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<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Thibodeau (2014)</td>
<td>11</td>
<td>0.40</td>
<td>-0.22, 1.01</td>
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<td>-</td>
<td>-</td>
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<tr>
<td>Total</td>
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<td>-0.57</td>
<td>-2.48, 1.34</td>
<td>-0.58</td>
<td>0.56</td>
<td>16.09 (1)</td>
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<td><strong>Hearing aids+Bluetooth system vs. Hearing aids alone</strong></td>
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<td>Kim et al (2014)</td>
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<td>-4.79, -2.75</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<tr>
<td>Rodemerk &amp; Galster (2015)</td>
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<td>-2.20</td>
<td>-3.11, -1.29</td>
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<tr>
<td>Total</td>
<td>46</td>
<td>-2.97</td>
<td>-4.50, -1.43</td>
<td>-3.79</td>
<td>&lt;0.001</td>
<td>5.08 (1)</td>
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</tbody>
</table>

*MDs reported, as studies used the same outcome measure. SMDs are reported for all other meta-analyses. SMDs calculated as the mean difference between conditions divided by the by the standard deviation of the differences (within group).*
Table 2. Review authors’ judgements using Downs and Black (1998) checklist to assess study quality for each included study, whereby higher scores indicate superior study quality (total maximum score of 28). Risk of bias was assessed using the Cochrane risk of bias tool: A. sequence generation; B. allocation concealment C. blinding of participants and personnel; D. blinding of outcome assessors; E. incomplete outcome data; F. selective outcome reporting; G. other sources of bias.

<table>
<thead>
<tr>
<th>Study</th>
<th>Study quality</th>
<th>Risk of bias</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>B</td>
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<tr>
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<td>High</td>
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<tr>
<td>Lewis et al (2005)</td>
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</tr>
<tr>
<td>Chisolm et al (2007)</td>
<td>19 (fair)</td>
<td>High</td>
</tr>
<tr>
<td>Lewis et al (2010)</td>
<td>18 (fair)</td>
<td>High</td>
</tr>
<tr>
<td>Rodemerk &amp; Galster (2015)</td>
<td>16 (fair)</td>
<td>High</td>
</tr>
<tr>
<td>Thibodeau (2014)</td>
<td>16 (fair)</td>
<td>High</td>
</tr>
<tr>
<td>Reed et al (2017)</td>
<td>15 (fair)</td>
<td>High</td>
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<tr>
<td>Norrix et al (2016)</td>
<td>14 (poor)</td>
<td>High</td>
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<td>Kim et al (2014)</td>
<td>13 (poor)</td>
<td>High</td>
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<tr>
<td>Smith &amp; Davis (2014)</td>
<td>13 (poor)</td>
<td>High</td>
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References


Figure Legends

Figure 1. Selection of studies for the systematic review based on Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram.
Figure 2. Summary of the random effects meta-analyses for speech intelligibility: A. PSAPs vs. unaided; B. Hearing aids+FM system vs. Unaided; C. Hearing aids+FM system vs. Hearing aids alone; D. Hearing aids+FM system vs. FM microphone only; E. Hearing aids+FM system vs. Hearing aids+2.4GHz system; F. Hearing aids+Bluetooth system vs. Hearing aids alone. Black squares = summery effect size of each study for speech intelligibility. Error bars = 95% confidence intervals (CI) for the summery effects. Diamond = overall effect size, lateral points indicate 95% CI for overall effect estimate.
A. CINAHL
S4 S1 AND S2 AND S3
S3 (MH "Wireless Communications") OR (MH "Smartphone") OR (MH "Mobile Applications") ) OR TI Digital OR TI ( Alternative* or Premium or Smartphone* or "Smart Phone" or "Smart Phones" or iPhone or Wireless or "FM System" or "Frequency Modulation" or Bluetooth or "Assistive Listening" or "Mobile App" or "Mobile Apps" or "Mobile Application" or "Mobile Applications" or "Self-Fitting" ) OR AB ( Alternative* or Premium or Smartphone* or "Smart Phone" or "Smart Phones" or iPhone or Wireless or "FM System" or "Frequency Modulation" or Bluetooth or "Assistive Listening" or "Mobile App" or "Mobile Apps" or "Mobile Application" or "Mobile Applications" or "Self-Fitting" )
S2 (MH "Hearing Aids") OR (MH "Hearing Aid Fitting") OR TI ((Auditory or Hearing or Amplif* or Listening or Audible or Hearable or Aural or Audio*) and (Prosthes* or Device* or Aid or Aids or Product or Products)) or "Ear Mold" or "Ear Molds" or Conventional or Unaided or "No Treatment" or "Control Group" or "Usual Care" or "Waiting List" or Waitlist or "Treatment as Usual" or "Usual Treatment" or Routine or "Care as Usual"
S1 (MH "Mobile Applications") OR TI ( Hypoacus* or "Hearing Loss" or "Hearing Losses" or "Hearing Impairment" or "Hearing Impairments" or Deaf* or "Hearing Problem" or "Hearing Problems") OR AB ( Hypoacus* or "Hearing Loss" or "Hearing Losses" or "Hearing Impairment" or "Hearing Impairments" or Deaf* or "Hearing Problem" or "Hearing Problems")

B. ClinicalTrials.Gov
Advanced Search
Conditions: Hearing OR Deafness
Interventions: (Hearing OR Ear Mold OR Auditory OR Amplified OR Amplifier OR Listening OR Audible OR Hearable OR Aural OR Audio) AND (Device OR Devices Aid OR Aids OR Product OR Products)

C. Cochrane Library
#1 MeSH descriptor: [Hearing Loss] explode all trees
#2 (Hypoacus* or "Hearing Loss" or "Hearing Losses" or "Hearing Impairment" or "Hearing Impairments" or Deaf* or "Hearing Problem" or "Hearing Problems");ti,ab
#3 #1 or #2
#4 MeSH descriptor: [Hearing Aids] this term only
#5 ((Auditory or Hearing or Amplif* or Listening or Audible or Hearable or Aural or Audio*) and (Prosthes* or Device* or Aid or Aids or Product or Products)) or "Ear Mold" or "Ear Molds" or Conventional or Unaided or
"No Treatment" or "Control Group" or "Usual Care" or "Waiting List" or Waitlist or "Treatment as Usual" or "Usual Treatment" or Routine or "Care as Usual"):ti,ab
#6 #4 or #5
#7 MeSH descriptor: [Wireless Technology] explode all trees
#8 MeSH descriptor: [Smartphone] explode all trees
#9 MeSH descriptor: [Mobile Applications] explode all trees
#10 Digital:ti
#11 (Alternative* or Premium or Smartphone* or "Smart Phone" or "Smart Phones" or iPhone or Wireless or "FM System" or "Frequency Modulation" or Bluetooth or "Assistive Listening" or "Mobile App" or "Mobile Apps" or "Mobile Application" or "Mobile Applications" or "Self-Fitting"):ti,ab
#12 #7 or #8 or #9 or #10 or #11
#13 #3 and #6 and #12

D. EMBASE
1. Exp Hearing Impairment/ OR (Hypoacus* OR "Hearing Loss" OR "Hearing Losses" OR "Hearing Impairment" OR "Hearing Impairments" OR Deaf* OR "Hearing Problem" OR "Hearing Problems").ti,ab.
2. Hearing Aid/ OR Air Conduction Hearing Aid/ OR Assistive Listening Device/ OR Exp Bone Conduction Hearing Aid/ OR Hearing Aid Analysis System/ OR Hearing Aid Calibrator/ OR Master Hearing Aid/ OR Tactile Hearing Aid/ OR Tinnitus Masker/ OR Transcutaneous Air Conduction Hearing Aid/ OR Wireless Air Conduction Hearing Aid/ OR ((Auditory OR Hearing OR Amplif* OR Listening OR Audible OR Hearable OR Aural OR Audio*) AND (Prosthes* OR Device* OR Aid OR Aids OR Product OR Products)) OR "Ear Mold" OR "Ear Molds" OR Conventional OR Unaided OR "No Treatment" OR "Control Group" OR "Usual Care" OR "Waiting List" OR Waitlist OR "Treatment as Usual" OR "Usual Treatment" OR Routine OR "Care as Usual").ti,ab.
3. Wireless Communication/ OR Mobile Application/ OR Digital:ti. OR (Alternative* OR Premium OR Smartphone* OR "Smart Phone" OR "Smart Phones" OR iPhone OR Wireless OR "FM System" OR "Frequency Modulation" OR Bluetooth OR "Assistive Listening" OR "Mobile App" OR "Mobile Apps" OR "Mobile Application" OR "Mobile Applications" OR "Self-Fitting").ti,ab.
4. Crossover-Procedure/ OR Double-Blind Procedure/ OR Randomized Controlled Trial/ OR Single-Blind Procedure/ OR Exp "Clinical Trial (Topic)"/ OR Exp Controlled Study/ OR Exp Cohort Analysis/ OR (Random* OR Factorial* OR Crossover* OR "Cross Over" OR Placebo* OR (Doubl* adj Blind*) OR (Singl* adj Blind*) OR Assign* OR Allocat* OR Volunteer*).mp. OR (Groups OR Nonrandomi?d OR Trial* OR "Quasi Experimental" OR Placebo OR RCT* OR "Before After" OR "Before and After" OR "CBA Study" OR "CBA Studies" OR Cohort OR Concurrent OR Incidence OR "Follow Up" OR Followup OR Longitudinal OR Prospective OR Retrospective OR "Case Control" OR "Case Comparison" OR "Case Compeer" OR "Case Base" OR Retrospective).ti,ab.
5. 1 and 2 and 3 and 4

E. ISRCTN
Advanced Search
Condition: Hearing

**F. MEDLINE**

Exp Hearing Loss/ OR (Hypoacus* OR "Hearing Loss" OR "Hearing Losses" OR "Hearing Impairment" OR "Hearing Impairments" OR Deaf* OR "Hearing Problem" OR "Hearing Problems").ti,ab.

Hearing Aids/ OR (((Auditory OR Hearing OR Amplif* OR Listening OR Audible OR Hearable OR Aural OR Audio*) AND (Prosthes* OR Device* OR Aid OR Aids OR Product OR Products)) OR "Ear Mold" OR "Ear Molds" OR Conventional OR Unaided OR "No Treatment" OR "Control Group" OR "Usual Care" OR "Waiting List" OR "Treatment as Usual" OR "Usual Treatment" OR Routine OR "Care as Usual").ti,ab.

Exp Wireless Technology/ OR Exp Smartphone/ OR Exp Mobile Applications/ OR Digital.ti. OR (Alternative* OR Premium OR Smartphone* OR "Smart Phone" OR "Smart Phones" OR iPhone OR Wireless OR "FM System" OR "Frequency Modulation" OR Bluetooth OR "Assistive Listening" OR "Mobile App" OR "Mobile Apps" OR "Mobile Application" OR "Mobile Applications" OR "Self-Fitting").ti,ab.

Exp Clinical Trials as Topic/ OR Exp Non-Randomized Controlled Trials as Topic/ OR Exp Cross-Over Studies/ OR Exp Controlled Before-After Studies/ OR Exp Cohort Studies/ OR Exp Case-Control Studies/ OR (Randomized Controlled Trial OR Controlled Clinical Trial OR Pragmatic Clinical Trial OR Clinical Trial OR Observational Study OR Multicenter Study).pt. OR (Randomi?ed OR Nonrandomi?d OR Randomly OR Placebo OR Trial* OR Groups).ab. OR Drug Therapy.fs. OR ("Quasi Experimental" OR Placebo OR RCT* OR "Cross Over" OR Crossover OR "Before After" OR "Before and After" OR "CBA Study" OR "CBA Studies" OR Cohort OR Concurrent OR Incidence OR "Follow Up" OR Followup OR Longitudinal OR Prospective OR Retrospective OR "Case Control" OR "Case Comparison" OR "Case Compeer" OR "Case Base" OR Retrospective).ti,ab. NOT (Animals NOT (Humans and Animals)).sh.

1 and 2 and 3 and 4

**G. PubMed**


**H. WHO ICTRP**

Advanced Search

Recruitment Status is All

Condition: Hearing OR Deafness

Intervention: (Hearing OR Ear Mold OR Auditory OR Amplified OR Amplifier OR Listening OR Audible OR Hearable OR Aural OR Audio) AND (Device OR Devices Aid OR Aids OR Product OR Products)
**Supplemental 2.** Characteristics of included studies. FM = Frequency modulation; HA = Hearing aid; PTA = Pure tone average.

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<thead>
<tr>
<th>Reference</th>
<th>Participants</th>
<th>Intervention/comparator</th>
<th>Outcomes</th>
<th>Setting &amp; design</th>
<th>Follow-up duration(s)</th>
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</thead>
<tbody>
<tr>
<td><strong>1. Personal sound amplification products (PSAPs)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Sacco et al (2016) France</td>
<td>N=31 (17 F; 14 M) Mean age=78.9y (SD=9.7) Mean PTA=47.74 dB HL</td>
<td>Unaided TEO First</td>
<td>Speech intelligibility: Speech audiometry in quiet and noise <strong>Hearing-specific QoL:</strong> Glasgow Hearing Aid Benefit Profile (Gatehouse, 1999) <strong>Listening ability:</strong> Glasgow Hearing Aid Benefit Profile (Gatehouse, 1999) <strong>Feasibility:</strong> Self-reported acceptability; Average daily time of use Adverse effects</td>
<td>Clinical Before-after comparison</td>
<td>1 month</td>
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<tr>
<td><strong>2. Remote microphone systems</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chisolm et al (2007) USA</td>
<td>N=36 (all M) Mean age= 79y (68-80) Mean PTA=69.7 dB HL Report no evidence of retro-cochlear pathology</td>
<td>BTE digital or analogue hearing aids (Phonak) alone Hearing aids+FM system (Phonak Microlink)</td>
<td>Hearing-specific QoL: MarkeTrak VI survey <strong>Listening ability:</strong> Client Oriented Scale of Improvement (Dillon et al., 1997); Communication Profile for the Hearing Impaired (Demorest &amp; Erdman, 1987)</td>
<td>Clinical Before-after comparison</td>
<td>6 weeks &amp; 1 year</td>
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<tr>
<td>Kim et al (2014) South Korea</td>
<td>N=30 (15 F; 15 M) Mean age= 57.2y (21-76) Mean PTA=33.17 dB HL</td>
<td>Hearing aids+Bluetooth® system (BioSoundLab, Seoul, Korea): (i) conventional (i.e. free-field acoustic signal transmission) (ii) wireless mode (i.e. directed wireless speech signal transmission)</td>
<td>Speech intelligibility: Word and sentence recognition (Jang et al., 2008) in quiet and noise.</td>
<td>Laboratory Before-after comparison</td>
<td>Immediately post-comparison</td>
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<td>Lewis et al (2004) USA</td>
<td>N=35 (17 F; 18 M) Median age= 73y (24-84) Mean PTA=43.1 dB HL</td>
<td>Unaided BTE digital hearing aids (Phonak) alone: (i) omnidirectional mode (ii) directional mode Hearing aids+FM system (Phonak Microlink) (i) monaural (ii) binaural</td>
<td>Speech intelligibility: Hearing In Noise Test (Nilsson et al., 1994)</td>
<td>Clinical Before-after comparison Randomized order</td>
<td>Immediately post-comparison</td>
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<td>Lewis et al (2005) USA</td>
<td>N=23 (10 F; 13 M) Median age= 73y (34-81) Mean PTA=55.2 dB HL</td>
<td>BTE digital hearing aids alone (Phonak) Hearing aids+FM system (Phonak Microlink)</td>
<td>Listening ability: Communication Profile for the Hearing Impaired (Demorest &amp; Erdman, 1987)</td>
<td>Clinical Before-after comparison Randomized order Experimenter blinding</td>
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<td>Gender</td>
<td>Mean Age</td>
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</tr>
<tr>
<td>Smith &amp; Davis (2014)</td>
<td>UK</td>
<td>N=12 (4 F; 8 M)</td>
<td></td>
<td>56y (SD=18.9)</td>
<td>65.9 dB HL</td>
</tr>
<tr>
<td>Thibodeau (2014)</td>
<td>USA</td>
<td>N=11 (8 F; 3 M)</td>
<td></td>
<td>16-78y</td>
<td>58.4 dB HL</td>
</tr>
</tbody>
</table>