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exposed to noise (Protocol)		

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Cochrane Database of Systematic Reviews 2021, Issue 10. Art. No.: CD015066.

DOI: 10.1002/14651858.CD015066.

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#### [Intervention Protocol]

# Effects of hearing protection field attenuation estimation systems and associated training on the level of noise attenuation in workers exposed to noise

Thais C Morata<sup>1</sup>, Wei Gong<sup>2</sup>, Christina Tikka<sup>3</sup>, Alessandra Samelli<sup>4</sup>, Jos H Verbeek<sup>5</sup>

<sup>1</sup>National Institute for Occupational Safety and Health (NIOSH), Cincinnati, OH, USA. <sup>2</sup>Division of Field Studies and Engineering, National Institute for Occupational Safety and Health (NIOSH), Cincinnati, OH, USA. <sup>3</sup>Department of Public and Occupational Health, Amsterdam UMC, University of Amsterdam, Amsterdam, Netherlands. <sup>4</sup>Department of Physical Therapy, Speech Therapy and Occupational Therapy, Universidade de São Paulo, São Paulo, Brazil. <sup>5</sup>Cochrane Work, Department of Public and Occupational Health, Amsterdam UMC, University of Amsterdam, Amsterdam, Netherlands

Contact address: Thais C Morata, tmorata@cdc.gov.

**Editorial group:** Cochrane Work Group.

**Publication status and date:** New, published in Issue 10, 2021.

**Citation:** Morata TC, Gong W, Tikka C, Samelli A, Verbeek JH. Effects of hearing protection field attenuation estimation systems and associated training on the level of noise attenuation in workers exposed to noise (Protocol). *Cochrane Database of Systematic Reviews* 2021, Issue 10. Art. No.: CD015066. DOI: 10.1002/14651858.CD015066.

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#### **ABSTRACT**

# **Objectives**

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

The first objective of this review is to assess the effects of field attenuation estimation systems and associated training on noise exposure at the ear and adherence to hearing protection use. A secondary objective is to assess whether the effects of field attenuation estimation systems differ according to age, gender, earplug type, and HPD use experience.



#### BACKGROUND

Noise is an environmental agent that impacts several aspects of health and well-being. High noise levels can cause irreversible damage to hearing and trigger other auditory symptoms, including tinnitus and hyperacusis. Less intense levels can cause annoyance, sleep disturbance, negative cardiovascular and immunological outcomes, and other stress-mediated effects in both children and adults (Morata 2005). Noise has long been recognised as an occupational hazard, even before industrialisation, and evidence of the extent of the burden it represents to society has continued to accumulate over time (ACGIH 2018; Teixeira 2021). Noise-induced hearing loss, increased injury risk (ACGIH 2018), and cardiovascular disease are three adverse work-related conditions receiving increased attention (Teixeira 2021).

A 2021 systematic review conducted as part of the Global Burden of Disease (GBD) initiative examined population-representative surveys on hearing loss prevalence from 1990 to 2019 (GBD 2019 Hearing Loss Collaborators). It reported an estimate of 1.57 billion (95% uncertainty interval 1.51 to 1.64) people globally with hearing loss in 2019, which corresponds to one in five individuals (20.3% (19.5 to 21.1)). Differences in prevalence between countries were attributed to differences in healthcare access and quality, but also to the prevalence of occupational noise exposure. By 2019, 7 million (4.76 to 10.1) years lived with disability (YLDs) were attributable to occupational noise exposure. The GBD group has identified noise-reduction strategies as one of the urgently needed multidisciplinary actions to improve hearing health care.

The relevance of hazardous noise exposure in the workplace to the prevalence of acquired hearing loss has been recognised for decades (ISO 1999: 2013; Nelson 2005; WHO 1997). This recognition prompted not only research but also the development and implementation of public health policy, early intervention and preventive programmes (Suter 2017; Themann 2019). Numerous countries require industry to comply with governmental regulatory requirements to control hazardous noise exposures and implement hearing conservation programmes. The evidence on reducing risks from various workplace hazards favours controlling the source of exposures (primary prevention). In practice, however, in the case of noise, the most common attempt to reduce exposure consists of distributing hearing protection devices (HPDs) (Themann 2013a). A 2017 Cochrane Review on the effectiveness of interventions to prevent work-related hearing loss identified specific strategies that have shown effectiveness in reducing workplace noise, such as the implementation of stricter legislation and the need for training in the proper use of earplugs and earmuffs to reduce noise exposure to safe levels. However, the overall quality of the evidence for the effectiveness of hearing loss prevention programs in preventing hearing loss was low, and there was limited follow-up of participants receiving training for insertion of earplugs (Tikka 2017). The authors concluded that further research is likely to have an important impact and could modify the conclusions reached. Later, Sayler and colleagues reported that of 14 metal manufacturing plants, the 4 reporting higher expenditures in training and having conducted fit testing of hearing protectors for at least 5 years had the lowest percentages of age-corrected standard threshold shifts, and lower 10-year average high-frequency hearing loss rates (Sayler 2018).

#### **Description of the condition**

Long-term exposure to noise levels greater than 80 dB(A) is associated with an increased risk of hearing loss. The risk increases with noise level and can ultimately lead to hearing impairment. The impairment is characterised by a limitation in situational awareness, as well as in the capacity to engage in conversation in meetings or social activities. Hearing difficulties can therefore become a significant barrier in establishing or maintaining emotional relationships. Such outcomes have prompted studies which reported the association between hearing loss and depression, cognitive decline, increased hospitalisations and healthcare costs, and mortality (see reviews by Basner 2014; Themann 2019). Workers with hearing loss have higher rates of absenteeism; may be at increased risk of work-related injuries; and are more likely to be underemployed or unemployed (Dzhambov 2017; Kerr 2017; Themann 2013b). The condition is permanent, and there is no effective treatment for it. However, the risk of noiseinduced hearing loss can be greatly minimised if noise is reduced to below 80 dB(A) (NIOSH 1998).

Despite decades of study, workplace interventions, and regulations, noise-induced hearing loss is consistently amongst the most common self-reported occupational illnesses or injuries (Nelson 2005). Information is also available for self-reported hearing difficulty and tinnitus amongst workers and non-workers ( Masterson 2016a) and disability-adjusted life years (Masterson 2016b). A 4-kilohertz audiometric 'notch', a decrease in hearing acuity at the frequency of 4 kHz, is understood to be one of the first signs of noise-induced hearing loss (Nelson 2005). Worldwide, 16% of disabling hearing loss in adults is attributed to occupational noise. Leigh 1999 calculated a global annual incidence of noiseinduced hearing loss of 1,628,000 cases, which means an annual incidence rate of almost two new cases per 1000 older workers. The risk for work-related hearing loss is present in more economic sectors than originally anticipated. As discussed by Themann 2019, industry- and occupation-specific estimates indicate risk in unexpected sectors, such as transportation and warehousing and real estate. Workers outside manufacturing are rarely offered preventive interventions such as risk assessment, audiometric testing, or access to hearing protection.

The probability of hearing impairment defined as the binaural puretone average (PTA) hearing threshold level greater than 25 dB for selected frequencies in individuals not exposed to noise at the ages of 35 and 65 is estimated to be 10% and 55%, respectively, because it increases naturally with age, even if as a surrogate for other risk factors (Prince 1997). Long-term exposure to noise levels beyond 80 dB(A) carries an excess risk of hearing loss, which increases with the noise level and can ultimately lead to hearing impairment (ISO 2018; Prince 1997).

# **Description of the intervention**

A Cochrane Review on the effectiveness of interventions to prevent work-related hearing loss concluded that the use of HPDs in a well-implemented hearing loss prevention programme was associated with less hearing loss, but that instruction on how to insert plugs into the ears was key to their effectiveness in noise reduction (Tikka 2017). Since the mid-1970s, laboratory studies have used many forms of hearing protection fit-test technology to investigate the actual acoustic attenuation hearing protectors provided, often to inexperienced users. Technology for the measurement of the



noise attenuation obtained by individual workers has become commercially available in the past decade, and research has accompanied the implementation of this technology (Byrne 2018; Voix 2021). Fit testing can be achieved by asking a worker to insert their usual ear plugs and then test what their hearing acuity is. This is then repeated without hearing protection. The difference in hearing acuity with and without hearing protection indicates the actual obtained attenuation.

Different technologies will allow for the estimation of personal attenuation, which are presented in similar ways. Current methods used in the field to estimate a personal attenuation rating (PAR) are: real-ear attenuation at threshold (REAT, ISO 2018), microphone in the real-ear (MIRE, ANSI 2018), and the alternating binaural loudness balance under headphones (Voix 2021). The REAT measures the difference in the minimum level one can detect a sound when wearing and when not wearing a hearing protector. The MIRE measures the difference between the sound pressure levels in the ear canal with and without an earplug in place (result expressed as insertion loss) and the difference of sound pressure levels outside or underneath the HPD, referred to as noise reduction (NR). For the alternating binaural loudness balance, the individual is asked to indicate with and without earplugs when the loudness between ears is balanced (Rimmer 1997). Each of the different fit-test methods combines the attenuation measurements at different frequencies to determine a PAR for the individual who is tested. Some fit-test systems may also present visual cues such as pass/fail indicator lights. The intervention of the fit test per se is aimed at helping an individual worker achieve his/her needed attenuation level with a particular protector. Achieving desired attenuation requires the correct use of HPDs. This has prompted the development and incorporation of an educational component to fit-testing interventions (Voix 2021).

This review will include interventions consisting of fit testing of personal HPDs, by the various existing methods (REAT, MIRE, loudness balance) and instructions/training associated with the use of HPDs. We will include studies using as comparators no intervention, a sham intervention, or an alternative intervention.

#### How the intervention might work

Technically, most protectors can attenuate the noise exposure enough to enable hearing loss prevention. In practice, this theoretical reduction is often not achieved because of improper application of the devices (Berger 1983; Murphy 2011). Earplugs can be especially difficult to insert due to the small dimensions of the ear canal or lack of skills to do it properly. HPD fit tests measure the discrepancy between the theoretical and the practical noise attenuation of hearing protection. If there is a discrepancy, the worker will be instructed in better application skills. The fit-test can thus lead to better application skills and a better attenuation of the noise exposure at the ear. Fit-test systems use either a physical measurement (also called objective) or psychophysical measurement (also called subjective) to test either a standard HPD or a surrogate HPD worn by users. Fit-test systems may calculate an attenuation measurement value or a PAR, or both, or simply indicate a pass/fail answer based on achieving a minimum required attenuation value (ANSI 2018).

The fit-test intervention per se is aimed at helping an individual worker achieve his/her needed attenuation level with a particular protector. This is accomplished in part by giving the worker an

objective experience or parameters of what the proper insertion feels like and what attenuation sounds like. Achieving desired attenuation requires proper selection and use of HPDs, which has prompted the incorporation of instructions/training components to the fit-test intervention. The main argument put forth for the adoption of this technology is that it may result in lower noise exposures at the ear when wearing HPDs due to a correct and consistent use of hearing protection, one that delivers the needed attenuation. It has been suggested that it may prompt greater adherence to hearing protection use, as a consequence of the objective experience and from an improved sense of self-efficacy (Schulz 2011; Stephenson 2011).

Better noise attenuation whilst wearing hearing protection and better adherence to hearing protection use could eventually lead to less hearing loss amongst workers (Sayler 2018).

# Why it is important to do this review

There is uncertainty regarding the effects of this incipient technology and associated training on the adherence to hearing protection use and the attenuation of noise levels at the ear. A review of these initial practices has the potential to guide not only future research but also contribute to the identification of implementation strategies that can lead to the protection of workers from noise exposure.

#### **OBJECTIVES**

The first objective of this review is to assess the effects of field attenuation estimation systems and associated training on noise exposure at the ear and adherence to hearing protection use. A secondary objective is to assess whether the effects of field attenuation estimation systems differ according to age, gender, earplug type, and HPD use experience.

# METHODS

# Criteria for considering studies for this review

# Types of studies

We will include (cluster) randomised controlled trials ((c)RCT), controlled before-after studies (CBA), and interrupted time-series (ITS), irrespective of their publication status.

Evaluations of hearing loss prevention interventions can be biased by factors that affect noise exposure. Randomisation is the best protection against such bias. Cluster-randomisation, in which whole companies or departments are randomly assigned to the intervention and control group, is a way to replace randomisation at the individual level whilst still leading to bias reduction.

As randomisation is difficult to perform in the context of the working environment with multiple stakeholders, we will also include CBA studies, where the outcome was measured at least once before and once after the intervention in both the intervention and the control group.

We will include ITS studies, in which the outcome has been measured at least three times before and three times after the intervention in one group of study participants (EPOC 2012; Ramsay 2003).



Finally, we will include studies that used uncontrolled before-and-after studies (BA), or case series designs (uncontrolled longitudinal study), where observations are made on a series of individuals, usually all receiving the same intervention, before and after an intervention but with no control group (non-randomised controlled study (NRS) designs) (Reeves 2021). We will only use these studies as comparators with the included studies in the Discussion section of the review, but not in the Authors' conclusions. The lack of a control group in such studies makes it difficult to determine if the effects can be attributed to the intervention.

# **Types of participants**

We will include studies conducted with adult workers at workplaces exposed to noise levels of more than 80 dB(A) as a time-weighted average over a period of an entire work shift or working day or part of the work shift, and who underwent an objective measurement of the attenuation offered by HPDs of any kind to prevent noise-induced hearing loss. In the case of studies including only a subset of relevant participants, we may combine the results from different subpopulations in the same synthesis, examining whether a given subdivision explains variation (heterogeneity) amongst the intervention effects.

# **Types of interventions**

We will include studies that have evaluated a specific field attenuation estimation system (FAES) intended to assure appropriate PAR level by hearing protection devices (HPDs). To be included, an FAES intervention should consist of the following elements: 1) physical or psychophysical measurement of noise attenuation at the ear, or both; and 2) measure the PAR of an HPD or indicate a pass/fail fit of an HPD to achieve a specific noise attenuation threshold. We will include interventions consisting of fit testing of personal HPDs, by various methods (REAT, MIRE, Fit-Testing) and instructions/training associated with the use of HPDs, on one or more of the following topic areas: noise exposure, proper use of HPDs, individual attenuation needs, and personal attenuation ratings.

Studies will be eligible if the FAES evaluation was conducted with or without an accompanying training, whether it was part of a work-related hearing loss prevention programme or not. We will include interventions provided as part of corporate safety and health programmes, by either in-house personnel or third parties. We will exclude laboratory studies, as it is difficult to assess if their results can be applied to real-world situations.

We will include studies that meet the following criteria:

- intervention is provided for individuals;
- outcome data are available before (once) and after intervention;
- · the intervention effect is estimated by change over time;
- the methods used control for confounding by observed covariates;
- individuals are grouped based on the outcome;
- · assessment of the outcome; and
- outcome variables measured before the intervention are included (Reeves 2021).

We will exclude studies on other types of interventions, such as engineering controls to reduce or eliminate the source of the noise, changing materials, processes or workplace layout (NIOSH

1997), and administrative control measures that involve changing work practices.

#### Types of outcome measures

We will include one outcome: change in noise exposure at the ear obtained through hearing protection. We will use change values of the primary outcomes, the change in the outcome between before and after the implementation of the intervention. We will do so because the evidence is composed mostly of non-randomised studies, and this will correct for differences in baseline values.

Noise exposure at the ear due to the use of HPD may be measured with either MIRE, REAT, or loudness balance technologies.

We will evaluate immediate (same day), short-term (until six months follow-up), and long-term effects (longer than six months follow-up).

#### **Primary outcomes**

We will include studies that directly measured the change in noise exposure at the ear obtained through hearing protection either as the difference in PAR levels (dB) or the difference in rates of workers who achieve the needed attenuation from their HPDs. Group mean differences in PAR and in pass rate (and their 95% confidence intervals) will be the approach used to examine their impact. Noise attenuation inside the hearing protection that results in levels equal to or less than 80 dB(A) will be considered as achievement of a no-excess risk outcome. We will include studies regardless of the frequencies measured (Hz). All outcomes may be measured either as long- or short-term, or immediately following intervention effects, depending on the follow-up time of the study. We will include studies reporting measurements for either a specific facility or a specific worker.

# **Secondary outcomes**

Change in the proportion of workers who wear hearing protection.

# Search methods for identification of studies

We will conduct systematic searches for RCTs, CBA studies, ITS studies, and field attenuation estimation systems uncontrolled before-and-after studies. We will use no restrictions on language, publication year, or publication status.

#### **Electronic searches**

We will search the following databases. The search strategy is shown in Appendix  ${\bf 1}$ 

- the Cochrane Central Register of Controlled Trials (CENTRAL);
- MEDLINE (Ovid) 1946 to present;
- Embase (Ovid) 1988 to present;
- PsycINFO (Ovid) 1806 to present;
- CINAHL (EBSCOhost) (Cumulative Index to Nursing and Allied Health Literature);
- · Scopus; and
- NIOSHTIC-2.

# **Searching other resources**

An Information Specialist from the US Centers for Disease Control and Prevention with experience in systematic reviews advised the



review authors on the strategy and search terms, tailored and ran initial trial searches, and will run all electronic searches to be included in the review. In order to identify further published, unpublished, conference presentations, dissertations and theses, and ongoing trials, we will search the Trip database, NHS Evidence-Ear, Nose, Throat and Audiology (formerly NLH ENT & Audiology Specialist Library) to retrieve existing systematic reviews that may be relevant to this systematic review, so that we can scan their reference lists for additional studies. We will search the ORCID, Google Scholar, and ResearchGate pages of principal investigators identified from relevant publications, as well as the terms directly associated with the interventions of interest.

# **Data collection and analysis**

We will use Covidence for managing abstract and full-text screening and collecting data on study characteristics and outcomes extracted from the included studies (Covidence).

#### **Selection of studies**

We will conduct the selection of eligible studies in two stages using the review management program Covidence (Covidence). First, three review authors (TM, WG, and AS) will independently screen the titles and abstracts of all potentially relevant studies identified by our systematic search and exclude studies that clearly do not fulfil the inclusion criteria. The same review authors will code each study as 'include' (eligible or potentially eligible) or 'exclude'. At this stage we will exclude all references that clearly do not fulfil our inclusion criteria or that do fulfil our exclusion criteria.

At the second stage, we will retrieve the full-text study reports or publications for all references coded as 'include' at the first stage, and one review author (TM) will assess the full texts for eligibility and identify studies for inclusion in the review. Other review authors (WG, AS, CT) will do part of the same assessment independently so that all full-text reports are assessed independently by two review authors. Any disagreements will be resolved through discussion or by consulting a third review author (JV) if required to make a final decision.

We will record reasons for exclusion of studies deemed ineligible at the full-text stage in a 'Characteristics of excluded studies' table. We will identify and exclude duplicates and collate multiple reports of the same study so that each study, rather than each report, is the unit of interest in the review. We will record the selection process in sufficient detail to complete a PRISMA study flow diagram.

If our systematic searches identify studies conducted by authors of this review, we will avoid conflicts of interest by having all decisions concerning inclusion and exclusion made by review authors not involved in the study.

# **Data extraction and management**

We will use Covidence for collecting data on study characteristics and outcomes extracted from the included studies (Covidence). Two review authors (WG, TM) will extract study characteristics using the data collection form from the Cochrane Review 'Interventions to prevent occupational noise-induced hearing' (Tikka 2017).

We will collect information on methods, study design and setting (including industrial sector, occupation, and country), participant characteristics (including age, gender, type of workplace), study

eligibility criteria, details of the interventions given, outcomes assessed, source of study funding and any conflicts of interest reported by the investigators. For RCTs, we are interested in the effect of the assignment to the intervention.

Three review authors in pairs (WG, TM, AS) will independently extract outcome data from included studies. We will note in the 'Characteristics of included studies' table if outcome data are not reported in a useable way. Any disagreements will be resolved by consensus or by involving a third review author (JV). One review author (WG) will contact the study authors if key information is missing and transfer the data into the Review Manager Web (RevMan Web 2020). We will double-check that data have been entered correctly by comparing the data presented in the systematic review with the study reports. A second review author (TM) will spot-check study characteristics for accuracy against the trial report. Should we include studies published in one or more languages in which our author team is not proficient, we will arrange for a native speaker or someone sufficiently qualified in each foreign language to fill in a data extraction form for us.

#### Assessment of risk of bias in included studies

We will use the RoB 2 tool to assess risk of bias for randomised and cluster-randomised trials (Higgins 2021). Pairs of review authors will independently assess the risk of bias of the studies using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2021). Any disagreements will be resolved by discussion or by deferment to a third review author (CT). We will grade each potential risk of bias as high, some concerns, or low, and provide a quote from the study report together with a justification for our judgement in the risk of bias table. For randomised studies, we will summarise the risk of bias judgements across different studies for each of the following risk of bias domains.

- Bias arising from the randomisation process
- Bias due to deviations from intended interventions
- Bias due to missing outcome data
- Bias in measurement of the outcome
- · Bias in selection of the reported result

We will consider blinding separately for different key outcomes where necessary (by each of the different study outcomes and timing of the intervention). Where information on risk of bias relates to unpublished data or correspondence with a trialist, we will note this in the risk of bias table. We will consider bias arising from the randomisation process, from deviations from the intended interventions, and in measurement of the outcomes to be key domains for RCTs and cluster-RCTs, and bias due to confounding, in selection of participants into the study, and in measurement of outcomes to be key domains for non-RCTs. We will judge a study to have a high risk of bias overall if one or more key domains are judged to have a high risk of bias. Conversely, we will judge a study to have a low risk of bias overall if all key domains are judged to have a low risk of bias. When considering treatment effects, we will take into account the risk of bias for the studies that contribute to that outcome.

For assessing the risk of bias in CBA studies, we will use the Risk Of Bias In Non-randomised Studies of Interventions (ROBINS-I) tool (Sterne 2016). Our target trial against which we will assess the risk of bias would be a trial in which noise-exposed are assigned to HPD fit-testing, followed by receiving the results and



training or HPD fit testing with no results or training. We will consider the following variables as potential confounders: previous experience with field attenuation estimation systems and HPD training received, for which we expect studies to have adjusted in the design or in the analysis because these variables are related to the obtained personal attenuation rating. We will assess follow-up training or instructions as co-interventions that could differ between intervention and control group and have an impact on the primary outcome. We will first use the signalling questions as prescribed in the ROBINS-I tool, and then assess the risk of bias if these questions indicate a potential risk of bias. We will assess the following risk of bias domains.

- · Bias due to confounding
- · Bias in selection of participants into the study
- Bias in classification of interventions
- Bias due to deviations from the intended interventions
- Bias due to missing data
- Bias in measurement of outcomes
- Bias in selection of the reported result

We will judge the risk of bias of CBA studies in all of the above domains to be low, high, or unclear.

For ITS studies, we will use the risk of bias criteria developed by the Cochrane Effective Practice and Organisation of Care (EPOC) group (EPOC 2012), as follows.

- · Was the intervention independent of other changes?
- Was the shape of the intervention effect prespecified?
- Was the intervention unlikely to affect data collection?
- Was knowledge of the allocated interventions adequately prevented during the study?
- Were incomplete outcome data adequately addressed?
- · Was the study free from selective outcome reporting?
- Was the study free from other risks of bias?

# Overall risk of bias at study level

We will judge a study to have a high risk of bias overall when one or more domains are judged to have a high risk of bias. Conversely, we will judge a study to have a low risk of bias overall when all domains are judged to have a low risk of bias.

When considering treatment effects, we will take into account the risk of bias for the studies that contribute to that outcome.

# Assessment of bias in conducting the systematic review

We will conduct the review according to this published protocol and report any deviations from it in the 'Differences between protocol and review' section of the systematic review.

#### **Measures of treatment effect**

We will enter the outcome data for each study into the data tables in Review Manager Web 2020 to calculate the treatment effects. We will use risk ratios (RRs) for dichotomous outcomes, and mean differences (MDs) or standardised mean differences (SMDs) for continuous outcomes or other type of data as reported by the authors of the studies.

If only effect estimates and their 95% confidence intervals (CIs) or standard errors are reported in studies, we will enter these data into Review Manager Web using the generic inverse-variance method (RevMan Web 2020). We will ensure that higher scores for continuous outcomes have the same meaning for a given outcome, or we will explain the direction to the reader and report where the directions were reversed if this was necessary. If the results cannot be entered in either way, we will describe them in the 'Characteristics of included studies' table or enter the data into Additional tables.

We will recalculate a mean change difference from the pooled effect size using the median standard deviation of the included studies in the formula: (pooled mean change = pooled effect size \* median standard deviation).

We will calculate SMDs for the estimation of effect sizes for direct comparisons using the same index of effect. When samples sizes are small, the calculations can be positively biased and will need to be corrected (Durlak 2009).

For ITS studies, we will extract data from the original papers and reanalyse them according to the recommended methods for analysis of ITS designs for inclusion in systematic reviews (Ramsay 2003). We will use the standardised change in level and change in slope as effect measures.

For CBAs, we will report odds ratios (ORs) and MDs or SMDs, using baseline data for comparison. We will look for visual evidence of heterogeneity in forest plots and statistical evidence of heterogeneity using the Chi<sup>2</sup> test and the degree of heterogeneity quantified using the I<sup>2</sup> statistic, where populations, interventions, and outcomes are sufficiently similar to permit meta-analysis (Elfeky 2020).

# **Unit of analysis issues**

For studies that employ a cluster-randomised design and that report sufficient data to be included in the meta-analysis but do not make an allowance for the design effect, we will calculate the design effect based on a fairly large assumed intracluster correlation of 0.10. We base this assumption of 0.10 as being a realistic estimate by analogy to studies about implementation research (Campbell 2001). We will follow the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* for the calculations (Deeks 2021).

When cross-over trials report continuous outcomes with which the authors have not reported a paired analysis, we will perform a paired analysis based on a reported or imputed correlation between the outcomes of the intervention and the control condition (Higgins 2021). For dichotomous outcomes, we will adjust the CIs for the paired analysis according to Elbourne 2002.

#### Dealing with missing data

We will contact the investigators or study sponsors in order to verify key study characteristics and to obtain missing numerical outcome data where possible (e.g. when a study is identified as abstract only). Where this is not possible, and the missing data are thought to introduce serious bias, we will explore the impact of including such studies in the overall assessment of results by a sensitivity analysis.



If numerical outcome data are missing, such as standard deviations or correlation coefficients, and they cannot be obtained from the authors, we will calculate them from other available statistics such as P values, according to the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2021).

# **Assessment of heterogeneity**

We will assess the clinical homogeneity of the results of the included studies based on similarity of population, intervention, outcome, and follow-up. Methodological heterogeneity may arise from: study design, type of participants included, types of interventions included, definition of outcomes of interest, or methods of measuring outcomes (Deeks 2021). We will not combine results from studies with different study designs. We will consider the following participants as sufficiently similar to combine studies: workers exposed to noise levels of more than 80 dB(A) as a time-weighted average over a period of an entire work shift or working day or part of the work shift who are required to wear hearing protection.

We will consider the following interventions and comparisons as sufficiently similar to combine studies:

- interventions which consisted of the use of FAES to measure PAR level (noise attenuation at-the-ear (in dB), by type of HPDs (foam, premolded, and muffs);
- interventions which consisted of the use of FAES to calculate rates of workers who achieve the needed attenuation from their HPDs.

The follow-up training after the initial fit test must have occurred at the same time for studies to be combined (either immediate, short term, or long term). We will also use the types of intervention (accompanying training or no training, of different types of training) to determine heterogeneity.

We will then test for statistical heterogeneity by means of the I<sup>2</sup> statistic as presented in the meta-analysis graphs generated by the Review Manager Web (Deeks 2021; RevMan Web 2020). If this test statistic is greater than 50%, we will consider there to be substantial heterogeneity between studies (Deeks 2021).

### **Assessment of reporting biases**

We will attempt to assess publication bias. Funnel plots (and the tests used for examining funnel plot asymmetry) may help to identify evidence of non-reporting biases in cases where protocols or trials register records are unavailable for most studies (Page 2021).

# **Data synthesis**

We will pool data from studies deemed sufficiently homogeneous regarding interventions, participants, and settings. If more than one study provides useable data in any single comparison, we will perform meta-analysis. We will use a random-effects model because we believe that the type of intervention and study designs included will always lead to heterogeneity. We will recalculate a mean change difference from the pooled effect size using the median standard deviation of the included studies in the formula: (pooled mean change = pooled effect size \* median standard deviation).

Where multiple trial arms are reported in a single trial, we will include only the relevant arms. If two comparisons (in-person training versus online training) are combined in the same meta-analysis, we will halve the control group to avoid double-counting.

# Subgroup analysis and investigation of heterogeneity

We plan to carry out the following subgroup analyses: by age, gender, earplug type, and HPD use experience for the earplug performance.

We will use the following outcomes in subgroup analyses: difference between initial and final PARs in dB or the difference in rates of workers who achieve the needed attenuation from their HPDs, and duration of follow-up.

We will use the Chi<sup>2</sup> test to test for subgroup interactions in Review Manager Web (RevMan Web 2020).

# **Sensitivity analysis**

We will perform sensitivity analysis defined a priori to assess the robustness of our conclusions. This will involve studies with low risk of bias versus studies with high risk of bias. A sensitivity analysis will aim to evaluate if decisions made in the process of obtaining our conclusions did not misguide findings from the systematic review. The issues suitable for sensitivity analysis will be only identified during the review process where the individual peculiarities of the studies under investigation are known. Sensitivity analysis may involve undertaking the meta-analysis twice, if the eligibility of some studies in the meta-analysis is dubious because they do not contain full details.

# Summary of findings and assessment of the certainty of the evidence

We will create summary of findings tables for only the main comparisons (difference in PAR or pass rate before versus after intervention (immediate, short term, and long term)) that are of most interest to decision makers. We will report all outcomes for these comparisons. We will use the five GRADE considerations (study limitations, consistency of effect, imprecision, indirectness, and publication bias) to assess the certainty of a body of evidence as it relates to the studies that contribute data to the meta-analyses for the prespecified outcomes. Two review authors (WG, TM) will independently perform the GRADE assessments and compare their results. We will use the methods and recommendations described in Chapter 12 of the *Cochrane Handbook for Systematic Reviews of Interventions* (McKenzie 2021), employing GRADEpro GDT software (GRADEpro GDT). We will justify all decisions to down- or upgrade the certainty of the evidence using footnotes.

We will base our conclusions on the studies with designs at lowest risk of bias, such as RCTs. If there is no difference in risk of bias across designs, we will use all of the available studies for our conclusions.

# ACKNOWLEDGEMENTS

We thank Mr Erik Kateman, from Solcon, the Netherlands, for his help with the identification of the scope of this protocol. We thank Julitta Boschman, Managing Editor, and Jan Hoving, Co-ordinating Editor, from Cochrane Work Review Group for their help in the early stages of the current protocol. We thank Drs Regina Tangerino



de Souza Jacob and Liliane Teixeira for their peer review of the protocol, as well as the copy editor, Lisa Winer.

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the National

Institute for Occupational Safety and Health, Centers for Disease Control and Prevention. The mention of any company or product does not constitute endorsement by the National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.



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# **APPENDICES**

# Appendix 1. Search strategy

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Database	Strategy		
Medline	Noise, Occupational/ OR ((noise OR hearing OR sound exposure*) AND (occupation* OR work-related OR worker* OR job* OR industry OR industrial OR employment)).ti,ab,kf.		
(Ovid) 1946-	AND		
	(((noise* OR hearing) ADJ5 (attenuation OR dampen* OR suppress* OR cancel* OR reduc* OR diminish*)) OR protective equipment OR protective device* OR protector* OR control* OR (loss ADJ3 prevent*) OR (hearing ADJ3 conserv*) OR (hearing ADJ3 protect*) OR ear muff* OR earmuff* OR ear plug* OR earplug* OR ear defender*).ti,ab,kf.		
	AND		
	(field attenuation* OR personal attenuation* OR attenuation rating* OR attenuation estimate* OR attenuation threshold OR PARS OR PAR OR noise dosimetry OR real ear* OR REAT OR FAES OR fit test* OR (field ADJ3 test*) OR field microphone* OR (field ADJ3 attenuation) OR fit check* OR validation system* OR E-A-Rfit OR estimation system* OR evaluation OR assessment* OR protection level* OR training).ti,ab,kf.		
Embase	Industrial noise/ OR ((noise OR hearing OR sound exposure*) AND (occupation* OR work-related OR		
(Ovid)	worker* OR job* OR industry OR industrial OR employment)).ti,ab,kw.		
1988-	AND		



(Continued)

(((noise\* OR hearing) ADJ5 (attenuation OR dampen\* OR suppress\* OR cancel\* OR reduc\* OR diminish\*)) OR protective equipment OR protective device\* OR protector\* OR control\* OR (loss ADJ3 prevent\*) OR (hearing ADJ3 conserv\*) OR (hearing ADJ3 protect\*) OR ear muff\* OR earmuff\* OR ear plug\* OR ear defender\*).ti,ab,kw.

#### AND

(field attenuation\* OR personal attenuation\* OR attenuation rating\* OR attenuation estimate\* OR attenuation threshold OR PARS OR PAR OR noise dosimetry OR real ear\* OR REAT OR FAES OR fit test\* OR (field ADJ3 test\*) OR field microphone\* OR (field ADJ3 attenuation) OR fit check\* OR validation system\* OR E-A-Rfit OR estimation system\* OR evaluation OR assessment\* OR protection level\* OR training).ti,ab,kw.

NOT pubmed/medline

#### **PsycINFO**

(Ovid)

1806-

exp "Noise Levels (Work Areas)"/ OR ((noise OR hearing OR sound exposure\*) AND (occupation\* OR work-related OR worker\* OR job\* OR industry OR industrial OR employment)).ti,ab,hw.

#### AND

(((noise\* OR hearing) ADJ5 (attenuation OR dampen\* OR suppress\* OR cancel\* OR reduc\* OR diminish\*)) OR protective equipment OR protective device\* OR protector\* OR control\* OR (loss ADJ3 prevent\*) OR (hearing ADJ3 conserv\*) OR (hearing ADJ3 protect\*) OR ear muff\* OR earmuff\* OR ear plug\* OR ear defender\*).ti,ab,hw.

#### AND

(field attenuation\* OR personal attenuation\* OR attenuation rating\* OR attenuation estimate\* OR attenuation threshold OR PARS OR PAR OR noise dosimetry OR real ear\* OR REAT OR FAES OR fit test\* OR (field ADJ3 test\*) OR field microphone\* OR (field ADJ3 attenuation) OR fit check\* OR validation system\* OR E-A-Rfit OR estimation system\* OR evaluation OR assessment\* OR protection level\* OR training).ti,ab,hw.

#### **Cochrane Library**

((noise OR hearing OR "sound exposure\*") AND (occupation\* OR work-related OR worker\* OR job\* OR industry OR industrial OR employment)):ti,ab

#### AND

(((noise\* OR hearing) NEAR/5 (attenuation OR dampen\* OR suppress\* OR cancel\* OR reduc\* OR diminish\*)) OR "protective equipment" OR "protective device\*" OR protector\* OR control\* OR (loss NEAR/3 prevent\*) OR (hearing NEAR/3 conserv\*) OR (hearing NEAR/3 protect\*) OR "ear muff\*" OR earmuff\* OR "ear plug\*" OR earplug\* OR "ear defender\*"):ti,ab

#### AND

("field attenuation\*" OR "personal attenuation\*" OR "attenuation rating\*" OR "attenuation estimate\*" OR "attenuation threshold" OR PARS OR PAR OR "noise dosimetry" OR "real ear\*" OR REAT OR FAES OR "fit test\*" OR (field NEAR/3 test\*) OR "field microphone\*" OR (field NEAR/3 attenuation) OR "fit check\*" OR "validation system\*" OR E-A-Rfit OR "estimation system\*" OR evaluation OR assessment\* OR "protection level\*" OR training):ti,ab

# **CINAHL**

# (EBSCOhost)

((noise OR hearing OR "sound exposure\*") AND (occupation\* OR work-related OR worker\* OR job\* OR industry OR industrial OR employment))

# AND

(((noise\* OR hearing) N5 (attenuation OR dampen\* OR suppress\* OR cancel\* OR reduc\* OR diminish\*)) OR "protective equipment" OR "protective device\*" OR protector\* OR control\* OR (loss N3 prevent\*) OR (hearing N3 conserv\*) OR (hearing N3 protect\*) OR "ear muff\*" OR earmuff\* OR "ear plug\*" OR earplug\* OR "ear defender\*")

AND



(Continued)	("field attenuation*" OR "personal attenuation*" OR "attenuation rating*" OR "attenuation estimate*" OR "attenuation threshold" OR PARS OR PAR OR "noise dosimetry" OR "real ear*" OR REAT OR FAES OR "fit test*" OR (field N3 test*) OR "field microphone*" OR (field N3 attenuation) OR "fit check*" OR "validation system*" OR E-A-Rfit OR "estimation system*" OR evaluation OR assessment* OR "protection level*" OR training)  Exclude Medline records
Scopus	TITLE-ABS((noise OR hearing OR "sound exposure*") W/10 (occupation* OR work-related OR work-er* OR job* OR industry OR industrial OR employment)) AND TITLE-ABS(((noise* OR hearing) W/5 (attenuation OR dampen* OR suppress* OR cancel* OR reduc* OR diminish*)) OR "protective equipment" OR "protective device*" OR protector* OR control* OR (loss W/3 prevent*) OR (hearing W/3 conserv*) OR (hearing W/3 protect*) OR "ear muff*" OR earmuff* OR "ear plug*" OR earplug* OR "ear defender*") AND TITLE-ABS("field attenuation*" OR "personal attenuation*" OR "attenuation rating*" OR "attenuation estimate*" OR "attenuation threshold" OR PARs OR PAR OR "noise dosimetry" OR "real ear*" OR REAT OR FAES OR "fit test*" OR (field W/3 test*) OR "field microphone*" OR (field W/3 attenuation) OR "fit check*" OR "validation system*" OR E-A-Rfit OR "estimation system*" OR evaluation OR assessment* OR "protection level*" OR training)
NIOSHTIC-2	Noise OR hearing OR sound exposure
	AND
	attenuation OR dampen* OR suppress* OR cancel* OR reduc* OR diminish* OR protect* OR control* OR prevent* OR conserv* OR ear muff OR earmuff OR ear plug OR earplug OR ear defender
	AND
	field attenuation OR personal attenuation OR attenuation rating OR attenuation estimate OR at-

Notes: Duplicates were identified using the EndNote automated 'find duplicates' function with preference set to match on title, author, and year, and removed from your EndNote library. There will likely be additional duplicates found that EndNote was unable to detect.

tenuation threshold OR PARs OR PAR OR noise dosimetry OR real ear\* OR REAT OR FAES OR fit test\* OR field test\* OR field microphone\* OR fit check\* OR validation system\* OR E-A-Rfit OR estimation

# CONTRIBUTIONS OF AUTHORS

Conceiving the protocol: TM, CT, WG, AS

Designing the protocol: all authors

Co-ordinating the protocol: TM

Designing the search strategies: all authors

Writing the protocol: TM, WG

Providing general advice on the protocol: JV

Securing funding for the protocol: TM

Performing previous work that was the foundation of the current study: WG, AS, CT

system\*

# **DECLARATIONS OF INTEREST**

Thais Morata: none known
Wei Gong: none known



Christina Tikka: none known

Alessandra Samelli: none know

Jos Verbeek: none known

# SOURCES OF SUPPORT

#### **Internal sources**

National Institute for Occupational Safety and Health, USA
 Contract #75D30120P07102 with Synergy America for expertise and co-authorship for Ms Wei Gong.

#### **External sources**

· Cochrane Work, formerly known as Cochrane Occupational Safety and Health Review Group, Netherlands

Provided support in kind.

Finnish Institute of Occupational Health, Finland

Provided support in kind.

• Universidade de São Paulo, Brazil

Provided support in kind.

• National Institute for Occupational Safety and Health, USA

Provided support in kind.