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Psychosocial interventions for smoking cessation in people with coronary heart disease (Protocol)

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[Intervention Protocol]

Psychosocial interventions for smoking cessation in people with coronary heart disease

Lorenzo Righi[1], Jürgen Barth[2], Cristian Baicus[3], Julia A Critchley[4], Ioana Daha[5], Martha McCarey[1], Erik von Elm[6]

[1]Cochrane Switzerland and Center for Primary Care and Public Health (Unisanté), University of Lausanne, Lausanne, Switzerland. [2]Barth Academic Writing, Bern, Switzerland. [3]Internal Medicine, Colentina University Hospital, Carol Davila University of Medicine and Pharmacy, Bucharest, Romania. [4]Population Health Research Institute, St George's School of Health and Medical Sciences, City St George's, University of London, London, UK. [5]Cardiology, Colentina University Hospital, Carol Davila University of Medicine and Pharmacy, Bucharest, Romania. [6]Cochrane Switzerland and Cochrane Germany Foundation, Freiburg, Germany

Contact: Erik von Elm, erik.vonelm@cochrane.de.

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ABSTRACT

Objectives

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

Primary objective

- To examine the benefits and harms of different types of psychosocial interventions for smoking cessation in people with CHD.

Secondary objectives

- To examine the benefits and harms of psychosocial interventions aimed solely at smoking cessation compared with multi-risk factor interventions for smoking cessation in people with CHD.
- To examine the benefits and harms of brief (duration of < one month) compared to extended (duration of ≥ one month) psychosocial interventions for smoking cessation in people with CHD.
- To explore whether using a validated biochemical assessment versus a self-report of abstinence moderates the effectiveness of smoking cessation interventions in people with CHD.
- To assess the equity of psychosocial interventions for smoking cessation in people with CHD.

BACKGROUND

Description of the condition

Smoking is a major and independent risk factor for coronary heart disease (CHD) [1, 2]. Smokers have a considerably higher risk of myocardial infarction (MI) and of cardiovascular diseases overall compared to non-smokers [1, 3, 4, 5]. Smokers have an increased risk of CHD even if they smoke only one cigarette per day [6].

After a first cardiac event, smokers are at increased risk of a second event; for example, restenosis of a coronary artery [7, 8, 9]. People who quit smoking after a CHD diagnosis reduce their risk of death from cardiovascular disease by more than one-third; they also reduce their risk of non-fatal myocardial infarction and non-fatal stroke [9]. However, many smokers do not quit even after a CHD diagnosis or resume smoking after an acute-care hospitalisation for a cardiovascular event or other health condition [10, 11].

Description of the intervention and how it might work

Psychosocial interventions for smoking cessation can be differentiated from psychopharmacological interventions (such as antidepressants) and substance replacement treatment strategies (such as nicotine replacement therapy (NRT)). Psychosocial interventions may include elements of behavioural therapy, which is based on learning theory. They include learning strategies for coping with situations that could induce smoking, offering incentives for abstinence, and increasing people's motivation to stop smoking. Psychosocial interventions may use combinations of in-person counselling, motivational support, or advice from health professionals or other trained persons, with or without providing printed or digital educational materials. Such interventions can be provided in two ways: singly, with a focus on smoking cessation, or as part of a multi-risk factor intervention also targeting other risk factors such as obesity or sedentarism (e.g. in a more comprehensive cardiac rehabilitation programme).

For the purpose of this review, we distinguish the following five types of interventions: (1) in-person (face-to-face) interventions; (2) interventions using telemedicine; (3) telephone support, including encouraging communication; (4) digital support using digital applications, in particular on smartphones, to encourage or monitor smoking cessation; and (5) self-help by providing information on how to quit smoking. These interventions are often combined with pharmacological treatments, as the integration of behavioural support with pharmacotherapy has been shown to be effective, especially when smokers are recruited through healthcare settings [12].

Indeed, evidence shows that behavioural interventions can significantly improve smoking cessation outcomes, even when used without pharmacological support [13]. Individual counselling is more effective than minimal behavioural interventions (risk ratio (RR) 1.57, 95% confidence interval (CI) 1.40 to 1.77) [14]. Advice from health professionals showed beneficial effects on smoking cessation. Brief advice from a physician was effective for quitting (RR 1.66, 95% CI 1.42 to 1.94), with somewhat larger point estimates with more intensive interventions (defined as an initial consultation of more than 20 minutes, use of materials other than a leaflet, or more than one follow-up visit) (RR 1.86, 95% CI 1.60 to 2.15) [15]. Counselling by nurses was less effective but still showed positive results (RR 1.29, 95% CI 1.21 to 1.38) [16]. Interventions delivered by community pharmacy personnel also seemed beneficial (RR 2.30, 95% CI 1.33 to 3.97), but the evidence was of low certainty [17]. Telephone support might improve the cessation rate due to continuous personal contact. Telephone counselling was more effective than less intensive interventions such as educational self-help materials only; as a single intervention it increased the cessation rate by 38% (RR 1.38, 95% CI 1.19 to 1.61) [18]. Using video instead of telephone for counselling did not seem to be beneficial [19]. Automated text messaging may result in greater quit rates than minimal smoking cessation support (RR 1.54, 95% CI 1.19 to 2.00) [20]. Interactive and tailored internet-based interventions appear to be more effective than passive strategies (RR 1.15, 95% CI 1.01 to 1.30) [21]. Providing printed self-help materials is probably the easiest intervention to carry out, and when compared with no intervention, it is moderately effective in helping smokers to quit (RR 1.19, 95% CI 1.03 to 1.37) [22].

Smoking cessation interventions were effective in hospitalised persons (RR 1.37, 95% CI 1.27 to 1.48), according to a recent Cochrane review [23]. Its authors stressed the importance of at least one follow-up contact to maintain abstinence. This finding is in line with another Cochrane review on nursing interventions for smoking cessation, which pointed out the need for follow-up contact [16].

Why it is important to do this review

This is a protocol update for a Cochrane review first published in 2008 [24], and subsequently updated in 2015 [25].

Smoking is one of the risk factors of the general population associated with the highest levels of mortality and disability worldwide [26]. Behavioural support for smoking cessation can increase quit rates at six months or longer in the general population [13]. National and international guidelines on the management of people with CHD emphasise the importance of changes in health behaviour as a key component of secondary prevention. The most recent European and American guidelines recommend psychosocial interventions to quit smoking, along with other strategies, including nicotine replacement therapy and medications. These guidelines underline the importance of assessing smoking status and offering adequate interventions for smoking cessation in people with CHD [27, 28, 29, 30, 31]. Usually, psychosocial interventions for secondary prevention start during acute care hospitalisation and are continued after discharge. Consequently, they differ from interventions used to support smoking cessation in the general population. The technological developments of recent years have broadened the spectrum of available interventions that fall within the scope of this review; for example, the use of automated text messages or interactive apps on smartphones. Increasingly, such digital support interventions go beyond smoking cessation and address multiple risk factors. Whether their use may also be harmful remains unclear so far.

Previous versions of this review showed that psychosocial interventions are effective in increasing abstinence at six to 12 months. However, a benefit could only be shown for extended interventions lasting more than one month. Whether their type (i.e. mode of delivery) moderates effectiveness remained unclear. Further, studies with long-term follow-up were scarce, and the quality of the earlier studies was very limited. It is therefore critical to synthesise the currently available evidence on the benefit and potential harm of intervention strategies for smoking cessation in

people with CHD. We aim to update this body of evidence using current Cochrane review methodology.

OBJECTIVES

Primary objective

- To examine the benefits and harms of different types of psychosocial interventions for smoking cessation in people with CHD.

Secondary objectives

- To examine the benefits and harms of psychosocial interventions aimed solely at smoking cessation compared with multi-risk factor interventions for smoking cessation in people with CHD.
- To examine the benefits and harms of brief (duration of < one month) compared to extended (duration of ≥ one month) psychosocial interventions for smoking cessation in people with CHD.
- To explore whether using a validated biochemical assessment versus a self-report of abstinence moderates the effectiveness of smoking cessation interventions in people with CHD.
- To assess the equity of psychosocial interventions for smoking cessation in people with CHD.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials on psychosocial interventions for smoking cessation in people with CHD, which assess smoking status at least six months after the baseline assessment. We will include cluster-RCTs. We will exclude cross-over studies and studies using inappropriate (not truly random) strategies of allocating interventions (sometimes called 'quasi-randomised' studies).

We will impose no restrictions on language and year of publication. We will include studies published as full articles in peer-reviewed journals. We will also assess unpublished and ongoing studies for eligibility.

Types of participants

Eligible studies will have enroled people with CHD including those with myocardial infarction, chronic coronary syndrome, or who underwent coronary artery bypass surgery or percutaneous transluminal coronary angioplasty (International Classification of Diseases 10 codes I20 to I25). Participants must be current smokers and use cigarettes or any other combustible tobacco product. If not all participants were smokers, aggregated data for this subgroup must be reported separately.

We will include studies that also recruited people with other cardiovascular diseases if at least 80% of participants suffered from CHD. Studies in people with any comorbidities will be eligible. We will include community-based studies with participants self-identifying as having CHD. We will include studies in hospitalised people with various somatic diagnoses only if outcome data from the subgroup of participants with CHD are reported separately. We will exclude studies with insufficient information about the participants' somatic diagnoses. We will not apply any age restriction. However, we anticipate that our review is unlikely to identify eligible studies in children or adolescents with CHD.

In the included studies, initial smoking status will need to be assessed either by a validated biochemical measure or self-report.

If it is unclear whether a subgroup of trial participants meets our inclusion criteria, we will contact the authors and ask for clarification and provision of the aggregated outcome data. In case of non-response, we will exclude the study, and indicate this in our review.

Types of interventions

We will include any psychosocial intervention with the goal of changing smoking behaviour in people with CHD. Such interventions may include printed or digital self-help materials on strategies for quitting smoking, more specific counselling either in person or remotely (e.g. phone support or telemedicine); may be provided by health professionals or other trained individuals; and may be initiated during hospitalisation or later. The psychosocial intervention could be provided either as a stand-alone (i.e. focusing on smoking cessation) or as a multi-risk factor intervention also targeting other risk factors such as obesity or sedentarism (e.g. in a more comprehensive cardiac rehabilitation programme).

We will exclude studies that are solely evaluating pharmacological interventions (including NRT). We will include studies investigating combinations of psychosocial and pharmacological interventions. Further, we will exclude studies on non-pharmacological interventions without a distinct psychological component (e.g. studies focusing on exercise or physiotherapy). We will include studies on hypnotherapy. Eligible interventions could have been delivered during a stay in acute care or cardiac rehabilitation or in the community. They could have been provided in group or individual settings.

The psychosocial interventions will be grouped according to their components into the following non-exclusive categories: (1) in-person interventions, (2) telemedicine, (3) phone support, (4) digital support, and (5) self-help. These five categories may be extended or modified based on the nature of the included studies. In addition, we will classify interventions as either specific (i.e. focused on smoking cessation) or multi-risk factor (i.e. if other risk factors were also addressed). These two categories are mutually exclusive.

We will classify the duration of the psychosocial interventions using a modified definition from another Cochrane review [23]: (1) single initial contact lasting one hour or less, no additional support; (2) one or more contacts lasting more than one hour in total, no additional support within one month; (3) any initial contact plus additional support within one month; (4) any initial contact plus additional support between one month and six months; and (5) any initial contact plus additional support after six months. We will regard interventions in categories 1 to 3 as 'brief', and those in categories 4 and 5 as 'extended'.

For digital support interventions, the duration will correspond to the time period during which participants used the digital support tool for the intervention, if available. For multi-risk factor interventions, we will consider the total time of all intervention

components as it will be difficult to determine the time spent specifically on smoking cessation.

Eligible control interventions will be either usual care (with participants being allowed to seek support for smoking cessation but without a structured referral or waiting list) or non-specific interventions (e.g. provision of educational material on health issues).

We will base comparisons on the five types of psychosocial interventions (as defined above) versus usual care or non-specific interventions (combined). This will result in a total of five comparisons in the main analysis. Analysing different types of interventions separately will help identify which intervention approaches are most effective for smoking cessation in this particular group. Additionally, the included interventions vary in organisational complexity and cost, making it important to understand their relative effectiveness when optimising resource allocation.

Outcome measures

Critical outcomes

Smoking status, either self-reported or assessed by validated biochemical measurement (e.g. carbon monoxide) at a minimum of six months after baseline assessment. This outcome is dichotomous (non-smoker versus smoker). If both self-report and biochemical measurement are available, outcome data based on the latter will be preferred in the main analysis. We will not exclude otherwise eligible studies that do not report participants' smoking status at baseline or follow-up. If the intervention targeted smoking (e.g. amongst other health behaviours) but smoking status at baseline or follow-up was not reported, we will contact the authors and ask for clarification.

Important outcomes

We will extract any descriptive or quantitative information about adverse events specifically related to the study interventions. For instance, this may include instances of stress or anxiety caused by these interventions. Further, for some participants, the attention from staff while trying to quit smoking might be a positive experience they do not want to relinquish, thus preventing them from completing smoking cessation.

Search methods for identification of studies

Electronic searches

Previous versions of this review searched the Cochrane Central Register of Controlled Trials (CENTRAL, Issue 12, 2012) on *The Cochrane Library*, MEDLINE (OVID, 1950 to January week 1 2013), Embase (OVID, 1980 to 2013 week 1), and PsycINFO (OVID, 1806 to January week 2 2013) to January 2013. We will update these searches for the period from 1 January 2013 to the present, using a revised search strategy (Supplementary material 1). For this revision, we reviewed and optimised the syntax for the different databases, and we added terms for controlled vocabulary and free text searches to cover the concepts of cardiac rehabilitation and acute coronary syndrome. The German-language database PSYNDEX has been searched from 1977 to June 2003 in previous review versions. Conference Proceedings Citation Index - Science (CPCI-S) on Web of Science (Thomson Reuters) has been searched from 1990 to June 2013 in previous review versions; we will use the revised search strategy for Web of Science (Core Collection). We also added a search string for Google Scholar.

We incorporated the sensitivity-maximizing RCT filter into the search strategy of the last review version for MEDLINE and adapted it for Embase, PsycINFO, and Web of Science [32].

Searching other resources

We will search the *Cochrane Database of Systematic Reviews* for systematic reviews on smoking cessation and the reference lists of included studies to identify additional eligible studies.

For the first version of this review, the authors searched for eligible studies in other reviews [33, 34, 35, 36, 37], and handsearched relevant journals from 1998 to 2003 (*Annals of Internal Medicine*, *Archives of Internal Medicine*, *BMJ*, *Psychology and Health*, *Health Psychology*, *Tobacco Control*).

Data collection and analysis

We will follow the standard methodology for Cochrane intervention reviews, as recommended in the *Cochrane Handbook for Systematic Reviews of Interventions* [38].

Selection of studies

Three review authors (LR, MM, EvE) will work in pairs to screen titles and abstracts of potentially eligible studies using Covidence [39]. To enhance the screening, we will use the Cochrane RCT Classifier, an algorithm developed by the Evidence for Policy & Practice Information (EPPI) Centre and built into Covidence, which predicts whether identified studies potentially report on RCTs. We will retrieve the full-text articles of potentially eligible studies. Again, working independently, pairs of review authors (LR, MM, EvE) will screen the articles for inclusion. We will resolve any disagreements at both stages through discussion, and consult a third review author if we cannot reach consensus. If there are multiple publications from one study, we will collate them. If the information from the retrieved publications is insufficient to decide on study selection, we will contact the authors and ask for clarification.

We will report detailed numbers of reports and studies from the different stages of study selection with reasons for in-/exclusion in a PRISMA flow chart [40].

Data extraction and management

Three review authors (LR, MM, EvE) will work in pairs using Covidence to extract data from the studies newly identified in this update. We will resolve differences by consensus or, if needed, by consultation with a third review author. From the included studies, we will extract information on the eligibility criteria, design, setting, characteristics and number of participants at baseline, distribution by population characteristics (including gender, ethnicity, and age), methods and timing of follow-up, and sources of study funding. We will extract information about study interventions in sufficient detail and classify them as described in Types of interventions. We will specify our decision-making rationale, especially if studies used combined interventions. We plan to conduct online training for all review authors to ensure that we define and use the criteria for types of interventions consistently.

For the studies included in the previous review versions, we will seek any relevant data on population characteristics and

concomitant NRTs that have not already been extracted from the original publications, and add these data to that already contained in Review Manager [41].

We will extract any information on biochemical validation of smoking status. If studies used cotinine levels in urine or other standardised procedures to assess smoking status, we will regard this as a validated outcome assessment. If studies used self-report or peer-report to assess smoking status, we will regard it as a non-validated outcome assessment.

We will extract outcome data from follow-up time points at six months, one year, and the longest available follow-up (> one year), including summary dichotomous data for each group. If multiple variables are reported for abstinence, we will record which definition of abstinence was used and rank continuous or sustained abstinence above point prevalence measures, in line with published recommendations [42].

The review authors involved in the data extraction stage will customise the data extraction form in Covidence and pilot it on at least one newly included study.

Risk of bias assessment in included studies

Three review authors (LR, MM, EvE) will work in pairs to assess the risk of bias in all previously included and newly identified studies using the Cochrane Risk of Bias 1 tool [43]. Review authors will not assess any study in which they have been involved. We will also consider the guidance by the former Cochrane Tobacco Addiction Group [44]. The bias domains to be assessed for each study as either high, low, or unclear risk are:

- random sequence generation (selection bias);
- allocation concealment (selection bias);
- blinding of outcome assessment (detection bias);
- incomplete outcome data (attrition bias);
- selective reporting of outcomes.

Because blinding of participants and study personnel is not possible in RCTs of psychosocial interventions, we will not assess the risk of performance bias at study level but will consider this as an overall source of bias when interpreting the findings.

We will resolve any differences by consensus or, if needed, by consultation with a third review author. We will contact study authors for any missing information that may be required to assess the risk of bias.

Measures of treatment effect

We will use the extracted numbers of study participants with smoking / non-smoking status in intervention and control groups at the time of follow-up to calculate risk ratios (RR) with 95% confidence intervals for individual studies as well as for pooled estimates. A RR with a lower bound of confidence interval greater than 1 will indicate superiority of the intervention group over the control group.

For adverse events, it is highly unlikely that a pooled measure of effect, such as an odds ratio or risk ratio, can be calculated, given the nature of psychosocial interventions. Nevertheless, we will report on any data on adverse events from the included studies if available.

Unit of analysis issues

We will examine at which level the randomisation took place in the included studies. For cluster-RCTs, we will aim to account for any clustering effects and unit of analysis errors. For multi-arm studies, we will determine which intervention groups are relevant for the review update, and for any particular meta-analysis, and extract outcome data accordingly.

For both individual and cluster-RCTs, we will follow the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* [45].

Dealing with missing data

We will seek any missing information or outcome data from the studies newly identified for this update from the study authors, with one reminder in case of initial non-response. For our main analysis, we will use the data of complete cases as reported by the study authors for the three follow-up time points. In a separate analysis, we will assume that participants lost to follow-up were still smokers at the follow-up time point (see Sensitivity analysis).

Reporting bias assessment

We will update the funnel plot published in the previous review version to assess small study effects.

Synthesis methods

We will use a random-effects model to pool the study data because we expect heterogeneity in the included studies. We will use forest plots to depict the results of meta-analyses.

We will use the extracted outcome data for both a completer (per-protocol) analysis and an intention-to-treat (ITT) analysis. The completer analysis will be the main analysis and include only data from study participants for which follow-up information on smoking status was reported by the study authors. If study information is unclear, we will classify the outcome data in the same way as for the completer analysis.

Investigation of heterogeneity and subgroup analysis

We will consider the clinical and methodological heterogeneity of the included studies with regard to important characteristics, such as study design, interventions, populations, and outcome measures. We will assess statistical heterogeneity by examining the forest plots visually and by calculating the Chi^2 heterogeneity test (with $P \leq 0.10$ as the threshold for rejection of the null hypothesis of homogeneity) and the I^2 statistics. The range of I^2 values is between 0% and 100%, with higher values indicating a larger proportion of heterogeneity between trials than would be expected by chance alone. Values between 0% and 40% indicate low heterogeneity; 30% to 60% moderate heterogeneity, 50% to 90% substantial heterogeneity, and 75% to 100% considerable heterogeneity [46]. We will assess heterogeneity prior to any synthesis of the included studies. We will only conduct meta-analyses if the included studies are sufficiently similar with regard to both clinical and methodological heterogeneity.

To explore the clinical diversity of the included studies, we aim to conduct subgroup analyses and to test subgroup differences as outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* [46]. We plan the following subgroup analyses:

- percentage of participants with concomitant NRT (with cut-offs for the purpose of this analysis at 25%, 50%, and 75%);
- interventions aimed solely at smoking cessation versus multi-risk factor interventions; and
- brief interventions (duration < one month) versus extended interventions (duration ≥ one month).

We consider these subgroup analyses important because they may provide a more nuanced understanding of the benefit of different psychosocial intervention strategies for smoking cessation in people with CHD. First, studies vary in the frequency of concomitant NRT use. The respective subgroup analysis may help differentiate between the benefits of NRT and of psychosocial interventions, and provide insights into possible interactions. Second, specific interventions aimed solely at smoking cessation may differ significantly from those with a more holistic approach – for example, addressing multiple risk factors in a digital support tool or comprehensive rehabilitation programme – in both their nature and potential benefit. Lastly, analysing whether extended interventions are more effective than brief interventions can inform the design of future interventions and help balance effectiveness and feasibility.

If meta-analysis is not possible, we will consider existing guidance such as the Synthesis Without Meta-analysis (SWiM) guideline to summarise study data [47].

Equity-related assessment

To assess the equity of psychosocial interventions for smoking cessation in people with CHD, we will extract any outcome data for relevant subgroups of participants reported by the included studies. In particular, we aim to determine whether any of the PROGRESS-Plus factors [48], such as gender, ethnicity, and place of residence, have been considered for analysis in the included studies. We will extract any definition of age groups used to analyse differences in effectiveness. We anticipate that few studies will have reported separate effect estimates for equity-related subgroups, and that this assessment will be exploratory. Where possible, we will summarise the equity-related information narratively.

Sensitivity analysis

We will conduct sensitivity analyses according to the following criteria:

- studies with validated versus non-validated smoking status;
- studies with low risk of bias versus all studies (i.e. excluding studies with high or unclear risk of bias);
- assuming that study participants with missing data due to loss to follow-up were still smokers (worst-case scenario).

Certainty of the evidence assessment

We will assess the certainty of included evidence for the critical review outcome 'smoking status', according to the GRADE approach, taking into account the following criteria: risk of bias, inconsistency, indirectness, imprecision, and publication bias [49].

For each comparison, three review authors (LR, MM, EvE) will work in pairs to rate the certainty of evidence for the outcome as high, moderate, low, or very low, using the online tool GRADEpro GDT [50]. We will resolve any discrepancies by consensus or by consulting a third review author, if needed. Review authors will not be involved in any GRADE assessment that uses outcome data from a study in which they have been involved.

We will present the results of this assessment in summary of findings (SoF) tables, as described in the *Cochrane Handbook for Systematic Reviews of Interventions* [51]. We will create the SoF tables for the outcome 'smoking status' for the following comparisons:

- in-person interventions versus usual care or non-specific interventions;
- telemedicine interventions versus usual care or non-specific interventions;
- phone support interventions versus usual care or non-specific interventions;
- digital support interventions versus usual care or non-specific interventions; and
- self-help interventions versus usual care or non-specific interventions.

Assuming that most studies will report on follow-up at 12 months, we intend to create SoF tables for this time point. If the included studies more frequently report one of the two other prespecified follow-up time points (i.e. six months or longest available follow-up), we will reassess and present an additional SoF table.

Consumer involvement

Consumers have not been involved in the drafting of the protocol of this review update. We will seek advice from consumer representatives if relevant questions arise during the conduct of this review and later dissemination of our findings.

SUPPLEMENTARY MATERIALS

Supplementary materials are available with the online version of this article: 10.1002/14651858.CD016093.

Supplementary material 1 Search strategies

ADDITIONAL INFORMATION

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Editorial and peer-reviewer contributions

Cochrane Central Editorial Service supported the authors in the development of this protocol.

The following people conducted the editorial process for this article:

- Sign-off Editor (final editorial decision): Jamie Brown, University College London, UK;
- Managing Editor (selected peer reviewers, provided editorial guidance to authors, edited the article): Sue Marcus, Cochrane Central Editorial Service;
- Editorial Assistant (conducted editorial policy checks, collated peer-reviewer comments and supported editorial team): Justin Mann, Cochrane Central Editorial Service;

- Copy Editor (copy editing and production): Faith Armitage, Cochrane Central Production Service;
- Peer-reviewers (provided comments and recommended an editorial decision): Joseph Grech, Institute of Applied Sciences, Malta College of Arts, Science and Technology (clinical/content review); Phil Käding (consumer review); Clare Miles, Evidence Production and Methods Directorate (methods review); Jo Platt, Central Editorial Information Specialist (search review). An additional peer reviewer provided clinical/content peer review but chose not to be publicly acknowledged.

Contributions of authors

LR drafted the protocol, updated the cited literature and revised the search strategy. EvE drafted the protocol and revised the search strategy.

All other authors commented on the protocol draft, provided critical input, and approved the final version.

Two authors involved in the previous versions of this review (2008 and 2015) are no longer included as authors: Jürgen Bengel and Tiffany Jacob. Some of the content retained in this update reflects their contributions.

Declarations of interest

All authors: no commercial or non-commercial conflicts of interest relevant to this review.

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Internal sources

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External sources

- External funding, Other

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Registration and protocol

Cochrane approved the proposal for this review update in December 2023.

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Data, code and other materials

As part of the published Cochrane review, the following is made available for download for users of the Cochrane Library: full search strategies for each database.

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