

Intervention Cochrane Protocol: Checklist for authors

This checklist is designed to help you (the authors) complete your Cochrane Protocol to an acceptable standard before you submit it for editorial and peer review. **Please complete each item in the checklist before submitting your Cochrane Protocol for editorial review, and email or fax the completed checklist to the Review Group's Managing Editor.** The editorial team may return your Cochrane Protocol to you if the form is incomplete or not received. There is a 'Notes' section at the end of the form to alert the editorial team to the reason for any incomplete checks.

Cochrane Review title:

Contact person:

Date:

1. General

- 1.1 All the authors listed on the Cochrane Protocol have seen and approved this version and take full responsibility for the accuracy of the contents.
- 1.2 Incorporated any standard text provided by your Cochrane Review Group (CRG).
- 1.3 Activated the relevant headings and subheadings in RevMan and completed each section.
- 1.4 Completed a validation check in RevMan (File menu > Reports > Validation report), and made corrections where possible. There should be no errors or warnings reported when you submit your draft.
- 1.5 Completed a spell check in RevMan (Tools menu > Check spelling).
- 1.6 The text is clearly written and all technical and medical terms are explained for non-expert readers.

2. Title and review information

(see Cochrane Handbook Section 4.2)

- 2.1 Title is the same as the registered title, unless a change has been agreed with the CRG.
- 2.2 Authors are listed in the correct order and have agreed to the order in which they are listed.
- 2.3 Names and details of all authors and the contact person appear correctly, or the CRG has been notified of any necessary corrections.
- 2.4 Completed the 'Date next stage expected' field, estimating when the Cochrane Review will be completed.

3. Background

(see Cochrane Handbook Section 4.5)

- 3.1 Described the condition or health issue to be addressed, including how it occurs, where it occurs, who is affected (including high risk groups, vulnerable/disadvantaged groups), diagnosis, symptoms and consequences.
- 3.2 Described the intervention, including for whom it is intended, its context in usual practice, comparison interventions, the treatment regimen or intervention components, and known adverse effects.
- 3.3 Described any likely differences in the use or outcomes of the intervention for specific populations (e.g. children, vulnerable/disadvantaged groups), and have defined those populations where necessary.
- 3.4 Described how the intervention might work to achieve the desired outcomes.

- 3.5 Explained why it is important to do this Cochrane Review in the context of the factors described above.
- 3.6 Supported all facts, figures and statements with references.
- 3.7 Cited other Cochrane Reviews relevant to this topic.
- 3.8 Avoided the use of plagiarised text.

4. Objectives

(see Cochrane Handbook Section 4.5)

- 4.1 Where possible, phrased as 'To assess the effects of [intervention or comparison] for [health problem] for/in [types of people, disease or problem and setting if specified]'.
- 4.2 If relevant, stated explicitly as secondary objectives any specific questions being addressed by the review, such as those relating to particular participant groups, intervention comparisons or outcomes.
- 4.3 If health economics evidence and/or qualitative research evidence is being reviewed, stated this explicitly in the Objectives.

5. Methods

(see Cochrane Handbook Section 4.5)

5.1 Style

- 5.1.1 Used the future tense and active voice (ie. 'We will conduct searches...' rather than 'Searches will be conducted...')

5.2 Criteria for considering studies for this Cochrane Review

Types of studies

- 5.2.1 Included study designs that are consistent with the objectives of the Cochrane Review, and the CRG has approved these designs. (Note, the inclusion of study designs beyond RCTs must be justified explicitly).
- 5.2.2 If studies are excluded on the basis of publication status or language, explained and justified this.

Types of participants

- 5.2.3 Stated eligibility criteria for participants, including any criteria around location, setting, diagnosis or definition of condition and demographic factors, and how studies including subsets of relevant participants are handled.

Types of interventions

- 5.2.4 Stated eligibility criteria for interventions, including any criteria around delivery, dose, duration, intensity, co-interventions and characteristics of complex interventions.
- 5.2.5 Listed comparators for the intervention that are consistent with the objectives of the Cochrane Review (e.g. comparison with a placebo addresses a different objective from comparison with an active intervention).

Types of outcome measures

- 5.2.6 Listed the outcomes you plan to report in the Cochrane Review, and it is clear whether any of the outcomes listed are required as part of the eligibility criteria for including studies.
- 5.2.7 Identified clearly which are primary and which are secondary outcomes.
- 5.2.8 Included adverse effects among the outcomes to be reported.
- 5.2.9 Considered including outcomes relevant to special populations (e.g. learning outcomes for children, process outcomes for reaching disadvantaged groups).
- 5.2.10 Described appropriate methods of measuring each outcome (e.g. validated tools, meaningful process measures) and appropriate time points for measurement.
- 5.2.11 Defined in advance how outcome measures will be selected when there are several possible measures (e.g. multiple definitions, assessors or scales).
- 5.2.12 Considered the minimally important difference or threshold for appreciable change for each outcome.
- 5.2.13 Selected a maximum of seven important outcomes, including adverse effects, to be included in the 'Summary of findings' table(s) when the Cochrane Review is complete (see Cochrane Handbook Section 11.5.2).

5.3 Search methods for identification of studies

- 5.3.1 Consulted the CRG Trials Search Co-ordinator regarding development of the MEDLINE search strategy.
- 5.3.2 Search strategy is consistent with the inclusion criteria for the Cochrane Review, including the types of studies to be included.
- 5.3.3 Search incorporates appropriate sources (e.g. subject-specific databases, trials registers, contact with experts, references and citations, handsearching).
- 5.3.4 Search strategy is not limited by year of publication (unless there is justification for this), language or publication type.
- 5.3.5 If review has specific eligibility criteria to include additional studies such as studies of adverse effects, health economics evidence or qualitative evidence, described search methods for identifying such studies.

5.4 Data collection and analysis

Selection of studies

- 5.4.1 Stated that at least two authors will work independently to select studies for inclusion in the Cochrane Review, and described a strategy for resolving disagreements.

Data extraction and management

- 5.4.2 Described methods for extracting and managing data (e.g. using a data collection form which has been piloted; using at least two people working independently to extract study characteristics, and describing a strategy for resolving disagreements).
- 5.4.3 Listed the types of information that will be sought from reports of included studies
- 5.4.4 Described attempts that will be made to obtain or clarify missing data from individuals or organisations.

Assessment of risk of bias in included studies

- 5.4.5 Stated that at least two authors will conduct the assessment of risk of bias, and described a strategy for resolving disagreements.
- 5.4.6 Methods are consistent with Chapter 8 of the Cochrane Handbook, and the CRG has approved any additional items. Justified any deviations from the 'Risk of Bias' tool.
- 5.4.7 Described a strategy for using the risk of bias assessment in interpreting the results of the Cochrane Review (e.g. narrative description, stratified analysis, exclusion of high risk trials from analysis).

Measures of treatment effect

- 5.4.8 Described the measures of effect that will be used to measure outcomes (e.g. odds ratio, risk ratio, mean difference) for each type of data (e.g. dichotomous, continuous, other).

Unit of analysis issues

- 5.4.9 If the Cochrane Review is likely to identify study designs such as crossover trials and cluster-randomised trials, described analysis of these designs to avoid unit-of-analysis errors.

Dealing with missing data

- 5.4.10 Described a strategy for dealing with missing data and following intention-to-treat principles, if appropriate.

Assessment of heterogeneity

- 5.4.11 Described a strategy for assessing clinical and statistical heterogeneity, and determining whether meta-analysis is appropriate.

Assessment of reporting biases

- 5.4.12 Described a strategy for assessing reporting biases. If funnel plots will be used, it is clear that asymmetric funnel plots are not necessarily caused by publication bias.

Data synthesis

- 5.4.13 Described the methods that will be used for meta-analysis, and how results will be synthesised if meta-analysis is not appropriate.
- 5.4.14 If the Cochrane Review will include non-randomised studies, or non-standard randomised trials, described the analysis of these studies.
- 5.4.15 If the Cochrane Review will draw on analyses performed outside RevMan, referenced the software and command/macro/program used.

Subgroup analysis and investigation of heterogeneity

- 5.4.16 Described planned subgroup analyses, including analysis of the effects in vulnerable/disadvantaged populations where possible, and provided a rationale for each.

Sensitivity analysis

- 5.4.17 Described planned sensitivity analyses to determine whether conclusions are robust to decisions made during the review process (e.g. choice of meta-analysis method, exclusion of studies from analysis).

'Summary of findings' table

- 5.4.18 Described methods for planned 'Summary of findings' table/s (or for assessing the quality of the body of evidence).

Ensuring relevance to decisions in health care

- 5.4.19 Described methods for ensuring the review's relevance to healthcare decision-making

6. Acknowledgements

(see Cochrane Handbook Section 4.5)

- 6.1 Acknowledged those people who contributed to the Cochrane Protocol but are not named as authors, and included the reasons for acknowledging each person.
- 6.2 Permission has been granted from all the people named to include them in this section.

7. Contributions of authors

(see Cochrane Handbook Section 4.5)

- 7.1 Described each author's contribution to the design and development of the Cochrane Protocol.

8. Declarations of interest

(see Cochrane Handbook Section 4.5)

- 8.1 Completed for each author, noting present or past affiliations that may lead to a real or perceived conflict of interest, including whether authors are investigators on studies likely to be included in the review. If no potential conflicts are identified for a particular author, "None known" has been stated.

9. Tables (Additional tables)

(see Cochrane Handbook Section 4.6.7)

- 9.1 Each table has a brief and informative heading.
- 9.2 Included links to each table from the appropriate part of the main text.
- 9.3 Included explanations of any abbreviations in footnotes.
- 9.4 If footnotes are used, these are referenced in the text using superscript letters (e.g. ^a).
- 9.5 Where possible, non-essential tables moved to the 'Appendices'.

10. References

All sources of information in the Cochrane Protocol must be appropriately referenced to prevent plagiarism. Reference citation IDs and the reference list must be consistent with the Cochrane Style Guide

(<http://www.cochrane.org/training/cochrane-style-resource>). In particular, please check the following items:

10.1 In the text

- 10.1.1 Checked that a link has been created wherever a reference citation ID appears in the text of the Cochrane Protocol using the 'Find and Mark Links' tool.
- 10.1.2 Grouped reference citation IDs and links in the text in alphabetical or chronological order, surrounded by round brackets and separated by semi-colons.

10.2 In the reference lists

(see Cochrane Handbook Section 4.7)

References to studies

- 10.2.7 None included in the Cochrane Protocol.

Additional references

- 10.2.1 Reference citation IDs are in the correct format (first author or group abbreviation and year of publication, e.g. Smith 1983 or UKPDS 1990)
- 10.2.2 Included each journal title in full, with no abbreviations.
- 10.2.3 Checked how each reference is displayed to remove unnecessary punctuation.
- 10.2.4 Where applicable, listed the first six authors before using 'et al.'
- 10.2.5 Written the page numbers correctly (e.g. 354-7).
- 10.2.6 Included the date accessed in any references to web pages.

Other published versions of this review

- 10.2.8 Included references to any previous or derivative published versions of this Cochrane Protocol.

11. Figures

(see Cochrane Handbook Section 4.9 and the RevMan User Guide for specifications on size and resolution)

- 11.1 Permission received to reproduce any figures included in the Cochrane Protocol.
- 11.2 Each figure has a brief caption describing the purpose of the figure, and acknowledging its source.
- 11.3 All figures used are scaled so that a reader can see the complete picture within the RevMan window.
- 11.4 All figures are of a sufficient resolution and quality for publication.

12. Sources of support

(see Cochrane Handbook Section 4.10)

- 12.1 Listed all sources of funding and in-kind support, including internal sources (e.g. the home institution of any author) and external sources (e.g. grant funding), and specified what they are supporting (eg. Author salary, infrastructure).

13. Appendices

(see Cochrane Handbook Section 4.12)

- 13.1 The titles of any appendices are clear and informative.

14. Style

(see Cochrane Style Guide at <http://www.cochrane.org/training/cochrane-style-resource>)

- 14.1 Proofread the Cochrane Protocol carefully in accordance with the [Cochrane Style Guide Basics](#).
- 14.2 If additional subheadings have been added, the appropriate Heading Style has been selected using the drop-down box on the RevMan toolbar.
- 14.3 Used either UK or US English consistently throughout the review (e.g. either 'randomised' or 'randomized')
- 14.4 Explained all acronyms and abbreviations (e.g. World Health Organization (WHO)).
- 14.5 Written numbers up to and including nine as words, and numbers 10 or higher as numerals (excluding those at the start of a sentence and numbers appearing in tables or figures).
- 14.6 Included a space before and after each unit of measurement or mathematical symbol (e.g. 5 mL, P = 0.03)

15. Amended Cochrane Protocols

(see Cochrane Handbook Chapter 3)

If you are submitting an amendment to an already published Cochrane Protocol, please address these additional criteria:

- 15.1 Added an event in the 'What's New' section to describe all relevant changes since the last published version of the Cochrane Protocol.
- 15.2 In the 'What's New' section, selected whether the new version is an Amendment or New Citation Version, and the selection is consistent with Section 3.2 of the Handbook.
- 15.3 Updated the methods of the Cochrane Protocol to reflect the latest guidance in the Cochrane Handbook.

15.4 If you received any feedback on your Cochrane Protocol via *The Cochrane Library*, you have included the comments received and your response in the 'Feedback' section.

16. Queries or notes for the CRG editorial team

List here any notes for the editorial team, including difficulties with completing any of the checklist items: