Cochrane Menstrual Disorders & Subfertility Group

Cochrane Intervention Protocol – checklist for authors

This checklist is designed to help you (the authors) complete your Cochrane Protocol before you submit it for editorial and peer review. Please complete each item in the checklist before checking your Cochrane Protocol into Archie, and email the completed checklist to: Helen Nagels, Managing Editor, at Cochrane.MDSG@auckland.ac.nz.

There is a ‘Notes’ section at the end of the form to alert the editorial team to the reason for any incomplete checks.

**Cochrane Protocol title:**

**Contact person:**

**Date:**

# General

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| 1.1 |  | All authors have seen and approved this version of the protocol and take full responsibility for the accuracy of its contents and order of authors |
| 1.2 |  | All relevant headings in RevMan have been activated and all sections completed |
| 1.3 |  | RevMan validation check has been completed (File menu > Reports > Validation report) |
| 1.4 |  | Spelling has been checked in RevMan (Tools menu > Check spelling) |
| 1.5 |  | The text is clearly written and all technical and medical terms are explained for non-expert readers. |

# Title and review information

(see Cochrane 2011 Handbook [Section 4.2](http://www.mrc-bsu.cam.ac.uk/cochrane/handbook/index.htm#chapter_4/4_2_title_and_review_information_or_protocol_information.htm))

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| 2.1 |  | Title is the same as the registered title, unless a change has been agreed with the CRG. |
| 2.2 |  | ‘Date next stage expected’ field is filled in, estimating when the Cochrane Review will be completed. |

# Background

(see Cochrane Handbook [Section 4.5](http://www.mrc-bsu.cam.ac.uk/cochrane/handbook/index.htm#chapter_4/4_5_ii_background.htm))

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| 3.1 |  | The condition or health issue to be addressed is described, including how it occurs, where it occurs, who is affected (including high risk groups, vulnerable/disadvantaged groups), diagnosis, symptoms and consequences. |
| 3.2 |  | The intervention is described, 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 |  | Any likely differences in the use or outcomes of the intervention for specific populations (e.g. children, vulnerable/disadvantaged groups) are described, and those populations have been defined where necessary. |
| 3.4 |  | There is a description of how the intervention might work to achieve the desired outcomes. |
| 3.5 |  | There is an explanation of why it is important to do this Cochrane Review in the context of the factors described above. |
| 3.6 |  | All facts, figures and statements are supported with references. |
| 3.7 |  | Other Cochrane Reviews relevant to this topic are cited. |

# Objectives

(see Cochrane Handbook [Section 4.5](http://www.mrc-bsu.cam.ac.uk/cochrane/handbook/index.htm#chapter_4/4_5_iii_objectives.htm))

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| 4.1 |  | The objective should, where possible, be 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]’. |

# Methods

(see Cochrane Handbook [Section 4.5](http://www.mrc-bsu.cam.ac.uk/cochrane/handbook/index.htm#chapter_4/4_5_iv_methods.htm))

## 5.1 Style

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| 5.1.1 |  | The future tense and active voice are used. |

## 5.2 Criteria for considering studies for this Cochrane Review

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| **Types of studies** | | |
| 5.2.1 |  | Study designs are included that are consistent with the objectives of the Cochrane Review, and the CRG has approved these designs. |
| **Types of interventions** | | |
| 5.2.2 |  | Comparators for the intervention are listed 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** | | |
| 5.2.3 |  | The outcomes you plan to report in the Cochrane Review are listed, and it is clear whether any of the outcomes listed are required as part of the eligibility criteria for including studies. |
| 5.2.4 |  | Primary and secondary outcomes are identified. |
| 5.2.5 |  | Adverse effects are included among the outcomes to be reported. |
| 5.2.6 |  | Outcomes relevant to special populations (e.g. learning outcomes for children, process outcomes for reaching disadvantaged groups) have been considered for inclusion. |
| 5.2.7 |  | Appropriate methods of measuring each outcome (e.g. validated tools, meaningful process measures) and appropriate time points for measurement are described. |
| 5.2.8 |  | The minimally important difference or threshold for appreciable change for each outcome has been considered. |
| 5.2.9 |  | Maximum of seven important outcomes, including adverse effects, have been selected to be included in the Summary of findings table(s) when the Cochrane Review is complete (see Cochrane Handbook [Section 11.5.2](http://www.mrc-bsu.cam.ac.uk/cochrane/handbook/index.htm#chapter_11/11_5_2_selecting_outcomes_for_summary_of_findings_tables.htm)). |

## 5.3 Search methods for identification of studies

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| 5.3.1 |  | The CRG Trials Search Co-ordinator has been consulted regarding development of the 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, language or publication type. |

## 5.4 Data collection and analysis

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| **Selection of studies** | | | |
| 5.4.1 |  | | Statement made that at least two authors will conduct selection of studies for inclusion in the Cochrane Review, and a strategy for resolving disagreements described. |
| **Data extraction and management** | | | |
| 5.4.2 |  | | Methods for extracting and managing data (e.g. using a data collection form) are described. |
| **Assessment of risk of bias in included studies** | | | |
| 5.4.3 | |  | Statement made that at least two authors will conduct the assessment of risk of bias, and a strategy for resolving disagreements described. |
| 5.4.4 | |  | Methods are consistent with [Chapter 8](http://www.mrc-bsu.cam.ac.uk/cochrane/handbook/index.htm#chapter_8/8_assessing_risk_of_bias_in_included_studies.htm) of the Cochrane Handbook, and the CRG has approved any additional items. |
| 5.4.5 | |  | 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) has been described. |
| **Measures of treatment effect** | | | |
| 5.4.6 | |  | The measures of effect that will be used to measure outcomes (e.g. odds ratio, risk ratio, mean difference) have been described. |
| **Unit of analysis issues** | | | |
| 5.4.7 | |  | If the Cochrane Review is likely to identify study designs such as crossover trials and cluster-randomised trials, analysis of these designs to avoid unit-of-analysis errors has been described. |
| **Dealing with missing data** | | | |
| 5.4.8 | |  | A strategy for dealing with missing data and following intention-to-treat principles, if appropriate, has been described. |
| **Assessment of heterogeneity** | | | |
| 5.4.9 | |  | A strategy for assessing clinical and statistical heterogeneity, and determining whether meta-analysis is appropriate, has been described. |
| **Assessment of reporting biases** | | | |
| 5.4.10 | |  | A strategy for assessing reporting biases has been described. If funnel plots will be used, it is clear that asymmetric funnel plots are not necessarily caused by publication bias. |
| **Data synthesis** | | | |
| 5.4.11 | |  | The methods that will be used for meta-analysis, and how results will be synthesised if meta‑analysis is not appropriate, have been described. |
| 5.4.12 | |  | If the Cochrane Review will include non-randomised studies, the analysis of these studies has been described. |
| **Subgroup analysis and investigation of heterogeneity** | | | |
| 5.4.13 | |  | Planned subgroup analyses, including analysis of the effects in vulnerable/disadvantaged populations where possible, have been described. |
| **Sensitivity analysis** | | | |
| 5.4.14 | |  | 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) have been described. |

# Acknowledgements

(see Cochrane Handbook [Section 4.5](http://www.mrc-bsu.cam.ac.uk/cochrane/handbook/index.htm#chapter_4/4_5_viii_acknowledgements.htm))

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

# Contributions of authors

(see Cochrane Handbook [Section 4.5](http://www.mrc-bsu.cam.ac.uk/cochrane/handbook/index.htm#chapter_4/4_5_ix_contributions_of_authors.htm))

|  |  |  |
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| 7.1 |  | Each author’s contribution to the design and development of the Cochrane Protocol has been described. |

# Declarations of interest

(see Cochrane Handbook [Section 4.5](http://www.mrc-bsu.cam.ac.uk/cochrane/handbook/index.htm#chapter_4/4_5_x_declarations_of_interest.htm))

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| 8.1 |  | Declaration completed for each author, noting present or past affiliations that 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. |

# Tables (Additional tables only – NO results should appear in the protocol)

(see Cochrane Handbook [Section 4.6.7](http://www.mrc-bsu.cam.ac.uk/cochrane/handbook/index.htm#chapter_4/4_6_7_additional_tables.htm))

|  |  |  |
| --- | --- | --- |
| 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’. |

# 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 ([www.cochrane.org/style/home.htm](http://www.cochrane.org/style/home.htm)). In particular, please check the following items:

## 10.1 In the text

|  |  |  |
| --- | --- | --- |
| 10.1.1 |  | Check made that a link has been created wherever a reference citation ID appears in the text of the Cochrane Protocol using the ‘Insert Link’ tool. |
| 10.1.2 |  | Reference citation IDs and links in the text are grouped in alphabetical or chronological order, surrounded by round brackets and separated by semi-colons. |

## In the reference lists

(see Cochrane Handbook [Section 4.7](http://www.mrc-bsu.cam.ac.uk/cochrane/handbook/index.htm#chapter_4/4_7_studies_and_references.htm))

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| **References to studies** | | |
| 10.2.1 |  | None are included in the Cochrane Protocol. |
| **Additional references** | | |
| 10.2.2 |  | Reference citation IDs are in the correct format (first author or group abbreviation and year of publication, e.g. Smith 1983 or UKPDS 1990) |
| 10.2.3 |  | Each journal title is included in full, with no abbreviations. |
| 10.2.4 |  | Each reference display has been checked to remove unnecessary punctuation. |
| 10.2.5 |  | Where applicable, the first six authors listed before using ‘et al.’ |
| 10.2.6 |  | Page numbers are written correctly (e.g. 354-7). |
| 10.2.7 |  | In any references to web pages, the date accessed is included. |
| **Other published versions of this review** | | |
| 10.2.8 |  | References to any previous or derivative published versions of this Cochrane Protocol are included. |

# Sources of support

(see Cochrane Handbook [Section 4.10](http://www.mrc-bsu.cam.ac.uk/cochrane/handbook/index.htm#chapter_4/4_10_sources_of_support_to_the_review.htm))

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| 11.1 |  | All sources of funding and in-kind support are listed, including internal sources (e.g. the home institution of any author) and external sources (e.g. grant funding). |

# Appendices

(see Cochrane Handbook [Section 4.12](http://www.mrc-bsu.cam.ac.uk/cochrane/handbook/index.htm#chapter_4/4_12_appendices.htm))

|  |  |  |
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| 12.1 |  | The titles of any appendices are clear and informative. |

# Style

(see Cochrane Style Guide at [www.cochrane.org/style/home.htm](http://www.cochrane.org/style/home.htm))

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| --- | --- | --- |
| 13.1 |  | The Cochrane Protocol has been proofread carefully in accordance with the [Cochrane Style Guide Basics](http://www.cochrane.org/training/authors-mes/cochrane-style-guide/cochrane-style-guide-basics). |
| 13.2 |  | If additional subheadings have been added, the appropriate Heading Style has been selected using the drop‑down box on the RevMan toolbar. |
| 13.3 |  | Either UK or US English is used consistently throughout the review (e.g. either ‘randomised’ or ‘randomized’) |
| 13.4 |  | All acronyms and abbreviations have been explained (e.g. World Health Organization (WHO)). |
| 13.5 |  | Numbers up to and including nine are written as words, and numbers 10 or higher as numerals (excluding those at the start of a sentence and numbers appearing in tables or figures). |
| 13.6 |  | A space is included before and after each unit of measurement or mathematical symbol (e.g. 5 mL, P = 0.03) |

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| Amended Cochrane Protocols (see Cochrane Handbook [Chapter 3](http://www.mrc-bsu.cam.ac.uk/cochrane/handbook/index.htm#chapter_3/3_maintaining_reviews_updates_amendments_and_feedback.htm))  If you are submitting an amendment to an already published Cochrane Protocol, please address these additional criteria: | | |
| 14.1 |  | An event has been added in the ‘What’s New’ section to describe all relevant changes since the last published version of the Cochrane Protocol. |
| 14.2 |  | In the ‘What’s New’ section, you have selected whether the new version is an Amendment or New Citation Version, and the selection is consistent with [Section 3.2](http://www.mrc-bsu.cam.ac.uk/cochrane/handbook/index.htm#chapter_3/3_2_some_important_definitions.htm) of the Handbook. |
| 14.3 |  | The methods of the Cochrane Protocol have been updated to reflect the latest guidance in the Cochrane Handbook. |
| 14.4 |  | 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. |

# 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: