DEVELOPING A PROTOCOL

CMSG REVIEW AUTHOR RESOURCE PACK

Cochrane Musculoskeletal Review Group (CMSG)
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Congratulations, your title has been registered by the Cochrane Musculoskeletal Group!

The next step in the development of your systemic review is to prepare a protocol. The protocol outlines the plan for review and should describe the rationale for the review; the objectives; and the methods that will be used to locate, select and critically appraise studies, and to collect and analyze data from the included studies.

Several resources have been included with this letter, which will guide you in developing your protocol. Please review all of the instructions and suggestions given within each document.

- **Cochrane Handbook for Systematic Reviews of Interventions**
  - Designed to help you make appropriate decisions about the methods you use in your review

- **Cochrane Style Guide**
  - A guide that ensures all Cochrane protocols, reviews and documents are in Cochrane format

- **CMSG Protocol Checklist**
  - Please complete this checklist before submitting your protocol

Please do not forget to regularly refer to the *Cochrane Handbook for Systematic Reviews of Interventions* (www.cochrane-handbook.org) to ensure that the required Cochrane standards are being achieved.

I hope these resources assist you in preparing your protocol for submission. When you are ready to submit your protocol for editorial approval, please check it into Archie and send an email to the editorial base to inform them that it is ready for approval. Once submitted, you will be notified within a few weeks about the editorial status of your protocol.

Please do not hesitate to contact me at any time should you require further clarification or assistance.

Best regards,

Elizabeth Ghogomu and Renea Johnston,
Managing Editors (Ottawa and Australia Editorial Bases)
On behalf of:
The Cochrane Musculoskeletal Group
Email: cmsg@uottawa.ca and renea.johnston@med.monash.edu.au

THE COCHRANE HANDBOOK FOR SYSTEMATIC REVIEWS OF INTERVENTIONS

The Cochrane Handbook for Systematic Reviews of Interventions is the official document that describes in detail the process of preparing and maintaining Cochrane systematic reviews on the effects of healthcare interventions. The current version of the Handbook is 5.0.1 (updated September 2008). It is available in various formats:

- Printable version
- Browsable version online
- Browsable version from the help menu in RevMan 5

It has a new structure, with 21 chapters divided into three parts.

- **Part 1**, relevant to all reviews, introduces Cochrane reviews, covering their **planning and preparation**, and their **maintenance and updating**, and ends with a **guide to the contents** of a Cochrane review or protocol.

- **Part 2**, relevant to all reviews, provides guidance on preparing reviews, covering **eligibility criteria**, **searching**, **collecting data**, **within-study bias**, **analyzing data**, **reporting bias**, **presenting** and **interpreting results**.

- **Part 3**, relevant to some reviews only, addresses special topics, including particular considerations in addressing **adverse effects**, meta-analysis with **non-standard study designs** and using **individual participant data**. This part has *new* chapters on incorporating **economic evaluations**, **non-randomized studies**, **qualitative research**, **patient-reported outcomes** in reviews, and reviews in **health promotion and public health**. A final chapter describes the new review type of **Overviews of reviews**.

To access the *Handbook* online please visit:
http://www.cochrane-handbook.org/

If you have any questions about the *Handbook*, please feel free to email cmsg@uottawa.ca or renea.johnston@med.monash.edu.au

COCHRANE STYLE GUIDE

As well as using the Cochrane Style Guide, remember to think about the **reader** when writing your Cochrane protocol, review, or document. You can help the reader by:

(1) Writing in the active (not the passive) voice, for example "we extracted data" (not "the data were extracted");

(2) Using short sharp sentences (get to the point quickly);

(3) Letting someone else read your review (they may give you tips on how to make it easier to read or tell you if it doesn't make sense);

(4) Using plain English (you don't have to use complicated language to talk about science);

(5) Writing protocols in the future tense ("we will search") and reviews in the past tense ("we searched"); and

(6) Being consistent in your choice of punctuation and spelling.

Need more Cochrane style guidance??
Please download the free "Cochrane Style Guide" at
http://www.cochrane.org/style/home.htm

Also available from the help menu in Review Manager 5

PROTOCOL CHECKLIST

Please do not send us any protocols until you have checked them against this checklist!

The completed checklist should be emailed to the editorial base when you send an email to let us know you have checked in the review for editorial approval.

Please run the Validation Report button in RevMan (File>Reports>Validation Report) to ensure there are no errors with your RevMan file.

Title of protocol:

General:

- ☐ Have you proof-read the protocol?
- ☐ Have you given the protocol to someone else to proof-read, preferably someone who is not an expert in the field?
- ☐ Have you run a spell-check? (included in RevMan)
- ☐ Is the structure logical and easy to follow?
- ☐ Is the style such that the protocol is comprehensible for the non-expert?
- ☐ Have you explained technical terms?
- ☐ Have you avoided clinical jargon?
- ☐ Have you added references to substantiate statements?

Titles:

- ☐ Have you checked your title against the Cochrane title recommendations?

Contact details:

- ☐ Have you added the contact details of all authors and the contact person?

Dates:

- ☐ Have you indicated the date for next stage expected (that is when the completed review is due)?

Background:

- ☐ Have you defined the condition of interest?
- ☐ Have you explained what is known about the aetiology of the condition?
- ☐ Have you talked about incidence?
- ☐ Have you discussed management options, including the intervention of interest?
- ☐ Have you discussed what is known about the mechanism of action of the intervention?
- ☐ Have you stated the overall aim of your review?
- ☐ Have you referenced any appropriate Cochrane reviews that relate to this topic?

Objectives:

- ☐ Have you restricted these to the main objectives, in terms of PICO (population, intervention, comparison, and outcome)?

Types of Studies:

- ☐ Have you considered different types of RCT study designs (if appropriate)?
- ☐ Have you specified a desirable trial duration?

Types of participants:

- ☐ Have you defined acceptable diagnostic criteria?

Types of interventions:

- ☐ Have you listed comparison interventions?

Types of outcome measures:

- ☐ Have you considered all the outcome measures you consider relevant (rather than those you think you may find)?
- ☐ Have you defined what your major and secondary outcome measures are?
- ☐ Have you listed possible adverse effects?
- ☐ Have you defined outcome measures?

Search strategy:

- ☐ Have you listed the Cochrane Central Register of Controlled Trials (CENTRAL) as a source of trials?

☐ Have you considered searching other relevant electronic databases other than Medline (e.g. CINAHL, EMBASE)?
☐ Have you included searches of reference lists of trials, reviews, and relevant textbooks?
☐ Have you considered doing some handsearching, e.g. of relevant conference proceeding or journals not already handsearched for CENTRAL?
☐ Have you considered contacting experts for information on additional trials?
☐ Have you developed a strategy for identifying and using unpublished information?
☐ Have you written out your whole electronic search strategy as a structured list?

Methods:
☐ Have you discussed trials selection, risk of bias assessment of trials, data extraction and data analysis?

☐ Have you stated how you will resolve any differences in opinion between the authors?
☐ Have you referred to the risk of bias domains from Chapter 8 of the Handbook and stated how you will use the different criteria (e.g. in a sensitivity analysis)? Have you considered how you will summarize the results of your assessment of risk of bias?
☐ Have you stated how you will summarise continuous and dichotomous data (if appropriate)?
☐ Have you stated which model and which summary measure you will use in the meta-analysis (i.e. random effects or fixed effects)?
☐ Have you explained how you will assess and deal with heterogeneity?
☐ Have you specified possible subgroups of interest?
☐ Have you specified possible sensitivity analyses of interest?
☐ Have you stated how you will use the GRADE approach to grade the quality of the evidence related to each of the main outcomes?
☐ Have you stated how you will present the main results of the review in summary of findings tables?

Acknowledgements:
☐ Have you included the reason(s) for acknowledging people?

Contribution of authors:
☐ Have you listed the contributions each author made to the protocol in this section of RevMan?

Declaration of interest:
☐ Have you filled in this section?
☐ Have you or your co-authors done a trial in the field or are you planning one?
☐ Did you receive any funding from the pharmaceutical industry for this review ? Note: the Cochrane Collaboration has a policy on Commercial Sponsorship; see http://www.cochrane.org/docs/commercial_sponsorship_revised.htm

References/Citations:
☐ Are reference IDs in the correct format and listed alphabetically when more than one reference? (e.g. Smith 1983; UKPDS 1990)
☐ Have you checked the spelling in your references?
☐ Do all the citations in the text appear as links?
☐ Are the citations in the text separated by semicolons?
☐ Have you used ‘et al’ in a reference only for more than six authors?
☐ Are all the journal names written out in full?
☐ Have you double-checked the format of the references?