Template for Update- no new studies

Review information

Review type: Intervention

Authors

Anna Hobson[1]

[1]Cochrane Pain, Palliative & Supportive Care Group, Pain Research Unit, Oxford, UK

Citation example: Hobson A. Template for Update- no new studies. Cochrane Database of Systematic Reviews , Issue . Art. No.: . DOI: .

This document is an abridged version of the MECIR template document for updates. This is to support the completion of an update for which there are no new studies.

Cochrane Handbook:

3.4.2.2 Updating reviews when no new studies are found (read online here)

When no new studies meeting the selection criteria are found, the review update will simply require that this finding be recorded in the relevant sections of the review. Revision of the text of the review will be required in the following sections:

1. Search methods (to ensure the appropriate 'Date of search' is recorded);
2. Description of studies in the Results section (to revise numbers of identified, screened and excluded studies if relevant);
3. Results (to ensure any dates are appropriate);
4. 'Authors' conclusions' (particularly if there is an ongoing need for further research);
5. Abstract and 'Plain language summary'.

In addition to revision of the text of the review, authors will need to ensure that the relevant date fields are correct and reflect the updated status of the review (see Section 3.3), and the 'What's new' table is completed (see Section 3.5).

In order to alert readers of the review to the fact that they are reading an updated version, a sentence can be added to the Background section of the Abstract stating that this is an update of a Cochrane review (with the earlier version cited) and including the year the review was originally published and the dates of any previous updates. In the Background section of the review itself, this sentence can be expanded to include discussion of the findings of the original review.

Finally, it is important to check that nothing else in the review is out of date (e.g. references to other Cochrane reviews which may have been updated, information about prevalence or incidence of the condition of interest, statements like 'recently, in 1998, it was shown that …', 'next year, in 2002, there will be …'). If there are changes or additions to the Acknowledgements and 'Declarations of interest' sections of the review these should be revised.

PaPaS: Suggestions for wording are added in relevant sections marked with a '*'.

A few points to remember:

- Style: Use the past tense and active voice.
- All the authors listed on the Cochrane Review see and approve this version and take full responsibility for the accuracy of the contents. If an original author will no longer be contributing, please ensure they are added to the Acknowledgements section. Ask your CRG to remove the author from the byline (this needs to be done centrally).
- Complete a validation check in RevMan (File menu > Reports > Validation report), and make corrections where possible.
- Complete a spell check in RevMan (Tools menu > Check spelling).
- Proofread the Cochrane Review carefully in accordance with the Cochrane Style Guide Basics.
- Use either UK or US English consistently throughout the review (e.g. either 'randomised' or 'randomized')
- Explain all acronyms and abbreviations (e.g. World Health Organization (WHO)).
- Spell in full all numbers at the beginning of a sentence, and those up to and including nine. For numbers 10 and higher, and all numbers in tables, please use numerals.
- Include a space before and after each unit of measurement or mathematical symbol (e.g. 5 mL, P = 0.03)

Contact person

Anna Hobson

Managing Editor
Cochrane Pain, Palliative & Supportive Care Group
Pain Research Unit
The Churchill Hospital
Old Road
Oxford

OX3 7LE
UK

E-mail: anna.hobson@ndcn.ox.ac.uk

Dates

Assessed as Up-to-date:	Not provided
Date of Search:	Not provided
Next Stage Expected:	Not provided
Protocol First Published:	Not specified
Review First Published:	Not specified
Last Citation Issue:	Not specified

Assessed as up to date and Date of search: both should state the date of the most recent search. Must reflect what is written in the review text. Most recent search must have occurred in the last 12 months (cannot publish if search older than 12 months).

Next stage expected: usually date 'Assessed as up to date' plus two years. If updating can be postponed (e.g. because it is unlikely that new evidence will come to light) a longer time period can be agreed in collaboration with PaPaS CRG and your review can be stabilised.

What's new

Date	Event	Description
16 October 2014	Updated	* Two events in the 'What's new' section must be completed for **all updates**. 'Updated'. This review has been updated to include the results of a new search [and risk of bias tables and a summary of findings table have been added].
16 October 2014	New citation: conclusions not changed	'New citation: conclusions not changed': No new studies were identified. **OR** 'New citation: conclusions changed': Conclusions were strengthened due to the application of updated methods etc...'

Two events in the 'What's new' section must be completed for **all updates**.

All previous events need to moved to 'History' (right click on the event title in What's New in the left-hand panel in RevMan).

All updates will have a new citation. The Cochrane editorial and publishing policy resource states, 'Since April 2012, all updated Cochrane Reviews receive a new citation so that the wording of the abstracts is always consistent between the CDSR and MEDLINE and other databases. This applies to all updated Cochrane Reviews because at the very least any update will include a new 'search date'. Citations to updates should be given even when a new search reveals no new trials, and when there are no edits made to the Cochrane Review apart from updating the search. Every time a Cochrane Review receives a new citation, the previously cited version is archived in the CDSR alongside the current version (see the 'Other Versions' tab).'

Read the policy in full here.

History

Date	Event	Description

Abstract

Background

* Include an introductory sentence: 'This is an updated version of the original Cochrane review published in Issue [X, Year], on [Title]'.

Objectives

* Suggested wording: 'To assess the effects of [intervention or comparison] for [health problem] for/in [types of people, disease or problem and setting if specified]'. Should match what is in the main review text.

Search methods

* Add to the existing text: 'For the original/previous version of the review, [*keep original text*]. For this update, we searched for relevant studies from [DATE] to [DATE].'

Selection criteria

Data collection and analysis

Main results

* Suggested wording: 'For the original/previous version of the review, [*keep original text*]. For this update, we did not identify any additional studies for inclusion.'

* This section needs to clearly state a) what the original review found, b) what the update found, and c) if there are any differences between the two.

Authors' conclusions

* Add to the existing text: 'Since publication of the original/previous version of this review, no new studies were found and our conclusions remain [unchanged/strengthened].'

Plain language summary

[Plain language title]

[Summary text]

*Please check that your PLS meets the current standards. Please acknowledge the original/previous review as well as the results of this update.

PaPaS: PLS criteria, proposed by Professor Andrew Moore:

Condition: A sentence or two about the condition under study.

Intervention: A sentence or two about the intervention(s) under study.

Found: What was found, mainly in terms of the number of studies and patients, but including outcomes or other appropriate or important topics.

Work: What was the effect of the intervention in terms of benefit. For benefit we use the simple odds (X in 10) of getting a benefit that is important to patients, with and without using the intervention. The reason for using simple offs as a numerical is because research on understanding shows that this is most accessible to most people (see Arthritis Res Ther. 2008;10(1):R20 for a systematic review).

Harm: What was the effect of the intervention in terms of harm. What harm, and what was the risk – usually here we stick with X in 10 because the issue of RCTs is common and irreversible harm, but obviously it can be Y in 1000 or 10000 if the review discusses rare , serious, and irreversible harm.

Next up: What next? New trials?

Background

*Add text, 'This review is an update of a previously published review in The Cochrane Database of Systematic Reviews [Issue X, Year] on [Title]'.

*Check that the references are up to date in this section.

Description of the condition

Description of the intervention

How the intervention might work

Why it is important to do this review

Objectives

*Suggested wording: 'To assess the effects of [intervention or comparison] for [health problem] for/in [types of people, disease or problem and setting if specified]'. Should match what is in the Abstract.

Methods

Criteria for considering studies for this review

Types of studies

Types of participants

Types of interventions

Types of outcome measures

Primary outcomes

Secondary outcomes

Search methods for identification of studies

* Suggested wording: 'For the original/previous version of the review, [*keep original text*]. For this update, we searched for relevant studies from [DATE] to [DATE]'.

Electronic searches

* PaPaS suggested wording. Ensure any restrictions in the search strategy on publication date, publication format or language are justified.

'We searched the following databases without language restrictions.

- The Cochrane Central Register of Controlled Trials (CENTRAL) (via the Cochrane Library) [Issue, Year]
- MEDLINE (via Ovid) [dates]
- EMBASE (via Ovid) [dates]
- [Other] [dates]

'Medical subject headings (MeSH) or equivalent and text word terms were used. There were no language restrictions. Searches were tailored to individual databases, and adapted from those used in the original/previous review. The search strategy for the original/previous review for MEDLINE is in Appendix X, and the updated search strategy for this version is in Appendix Y. [*Ensure these link correctly*]'

Searching other resources

* PaPaS suggested wording: For the original review and this update, we searched the metaRegister of controlled trials (mRCT) (www.controlled-trials.com/mrct), clinicaltrials.gov (www.clinicaltrials.gov) and the WHO International Clinical Trials Registry Platform (ICTRP) (http://apps.who.int/trialsearch/) for ongoing trials. In addition, reference lists of reviews and retrieved articles were checked for additional studies and citation searches were performed on key articles. Experts in the field were contacted for unpublished and ongoing trials. Authors were contacted for additional information.

Data collection and analysis

Selection of studies

Data extraction and management

*Ensure the latest version of RevMan is referenced (RevMan 2012, version 5.3).

Assessment of risk of bias in included studies

*Ensure this section follows the latest standards. See MECIR in right-hand panel in RevMan, and PaPaS recommended wording below.

'Two authors [XX, ZZ] independently assessed risk of bias for each study, using the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011) and adapted from those used by the Cochrane Pregnancy and Childbirth Group, with any disagreements resolved by discussion. We completed a 'Risk of bias' table for each included study using the Risk of bias tool in RevMan (RevMan 2012).

'We assessed the following for each study:

- Random sequence generation (checking for possible selection bias). We will assess the method used to generate the allocation sequence as: low risk of bias (any truly random process, e.g. random number table; computer random number generator); unclear risk of bias (method used to generate sequence not clearly stated). Studies using a non-random process (e.g. odd or even date of birth; hospital or clinic record number) will be excluded.
- Allocation concealment (checking for possible selection bias). The method used to conceal allocation to interventions prior to assignment determines whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment. We will assess the methods as: low risk of bias (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes); unclear risk of bias (method not clearly stated). Studies that do not conceal allocation (e.g. open list) will be excluded.
- Blinding of outcome assessment (checking for possible detection bias). We will assess the methods used to blind study participants and outcome assessors from knowledge of which intervention a participant received. We will assess the methods as: low risk of bias (study states that it was blinded and describes the method used to achieve blinding, e.g. identical tablets; matched in appearance and smell); unclear risk of bias (study states that it was blinded but does not provide an adequate description of how it was achieved). Studies that were not double-blind will be excluded.
- Incomplete outcome data (checking for possible attrition bias due to the amount, nature and handling of incomplete outcome data). We will assess the methods used to deal with incomplete data as: low risk (< 10% of participants did not complete the study and/or used ‘baseline observation carried forward’ analysis); unclear risk of bias (used 'last observation carried forward' analysis); high risk of bias (used 'completer' analysis).
- Size of study (checking for possible biases confounded by small size). We will assess studies as being at low risk of bias (≥ 200 participants per treatment arm); unclear risk of bias (50 to 199 participants per treatment arm); high risk of bias (< 50 participants per treatment arm).'

Measures of treatment effect

Unit of analysis issues

Dealing with missing data

Assessment of heterogeneity

Assessment of reporting biases

Data synthesis

Subgroup analysis and investigation of heterogeneity

Sensitivity analysis

Results

Description of studies

* Please include a flow chart of the number of references identified in the searches, both for the original version[s] of the review, and the latest search. See Figure 1 for template (Figure 1).

Results of the search

*Add to the existing text: Since publication of the original/previous version of this review, no new studies were found.

* This section needs to clearly state a) what the original review found, b) what the update found, and c) if there are any differences between the two.

Included studies

Excluded studies

Risk of bias in included studies

* Ensure that two Risk of bias summary graphs are included- see Figure 2 and Figure 3, and ensure links are correct.

Allocation (selection bias)

Blinding (performance bias and detection bias)

Incomplete outcome data (attrition bias)

Selective reporting (reporting bias)

Other potential sources of bias

Effects of interventions

Discussion

*Add to the existing text: Since publication of the original/previous version of this review, no new studies were found.

* This section needs to clearly state a) what the original review found, b) what the update found, and c) if there are any differences between the two.

Summary of main results

Overall completeness and applicability of evidence

Quality of the evidence

* Please check that the current standards are applied here, i.e. High/Low, not Yes/No.

Potential biases in the review process

Agreements and disagreements with other studies or reviews

* Check that the references in this section are up to date.

Authors' conclusions

Implications for practice

*Add to the existing text: 'Since publication of the original/previous version of this review, no new studies were found.'

Implications for research

* Current requirements stipulate that detailed recommendations for future research should be provided. If recommending further research, structure this section to address the nature of evidence required, including population and size, intervention comparison, outcomes of interest, and type of study.

Acknowledgements

* Acknowledge those people who contributed to the update but are not named as authors, and include the reasons for acknowledging each person. Ensure permission has been granted from all the people named to include them in this section.

* Acknowledge people who contributed to previous versions of the review, but did not participate in the update.

All PaPaS reviews must contain the following wording:

Cochrane Review Group funding acknowledgement: The National Institute for Health Research (NIHR) is the largest single funder of the Cochrane PaPaS Group. Disclaimer: The views and opinions expressed therein are those of the authors and do

not necessarily reflect those of the NIHR, National Health Service (NHS) or the Department of Health.

Contributions of authors

* Ensure this section is relevant to this update, not the previous version.

Declarations of interest

- Must be completed separately for each author, noting present or past affiliations or other involvement in any organization or entity with an interest in the review's findings that might 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, please state e.g. 'XY has no known conflicts of interest to declare that are relevant to the development of this protocol'.
- The DoI statements must be identical to the declarations in each electronic 'Conflicts of Interest' form, which will be circulated by the editorial team upon receipt of the first draft.
- The Cochrane Collaboration has recently updated its Commercial Sponsorship Policy (2014). Please ensure this section is fully compliant. See the policy in full online or contact PaPaS for further information.

Commercial funding of reviews or authors

[Taken from http://www.cochrane.org/organisational-policy-manual/appendix-5-commercial-sponsorship-policy, accessed 10/10/2014.]

The intent of clauses 1-5 is to ensure the independence of Cochrane reviews by making sure there is no bias associated with commercial conflicts of interest in the conduct of Cochrane reviews.

1. *Cochrane reviews cannot be funded or conducted by commercial sponsors or commercial sources with a real or potential vested interest in the findings of a specific review.*
2. *Individuals who are employed by a company that has a real or potential financial interest in the outcome of the review (including but not limited to drug companies or medical device manufacturers), or who hold or have applied for a patent related to the review are prohibited from being Cochrane review authors. In most cases, employment would be characterised by the affiliation statement made by the author at the title registration, protocol or review stage of the review. Any questions about what constitutes "employment by a company with a financial interest" should be referred to the funding arbiter.*
3. *Authors who in the last 3 years have received financial support from commercial sponsors or sources who have a real or potential financial interest in the findings of the review, but who are not covered by the restriction above should declare these interests at the earliest possible stage in the editorial process. Such financial support may include remuneration from a consultancy, grants, fees, fellowships, support for sabbaticals, royalties, stocks from pharmaceutical companies, advisory board membership or otherwise. In such cases, at the funding arbiter's discretion, and only where a majority of the review authors and lead author have no relevant COIs, it may be possible for an author who has a declared interest as listed in the previous sentence to be a Cochrane review author.*
4. *Editors with conflicts of interest with a given product/drug/non-drug intervention should not undertake peer review or be a contact editor, or provide sign-off on a review that involves that product, drug, non-drug intervention or a competing intervention. Co-ordinating Editors with conflicts of interest should assign the relevant review to another editor within their group. Editors are prohibited from being employees of a pharmaceutical company or medical device manufacturer.*
5. *Peer reviewers should be asked to declare COI using the ICMJE framework.*

Differences between protocol and review

Published notes

Characteristics of studies

Characteristics of included studies

Test 2011

Methods	test
Participants	test
Interventions	test
Outcomes	test
Notes	test

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	test
Allocation concealment (selection bias)	Low risk	test
Blinding of participants and personnel (performance bias)	Unclear risk	test
Blinding of outcome assessment (detection bias)	Unclear risk	test
Incomplete outcome data (attrition bias)	High risk	test
Selective reporting (reporting bias)	Unclear risk	test
Other bias	Unclear risk	test
Size	Unclear risk	test

Footnotes

Characteristics of excluded studies

Footnotes

Characteristics of studies awaiting classification

Footnotes

Characteristics of ongoing studies

Footnotes

Summary of findings tables

Additional tables

References to studies

Included studies

Test 2011

Excluded studies

Studies awaiting classification

Add relevant studies here.

Ongoing studies

Add relevant studies here.

Other references

Additional references

Add any ‘additional references’ you have identified to the appropriate References section in RevMan which may be suitable for bringing the background up to date.

Other published versions of this review

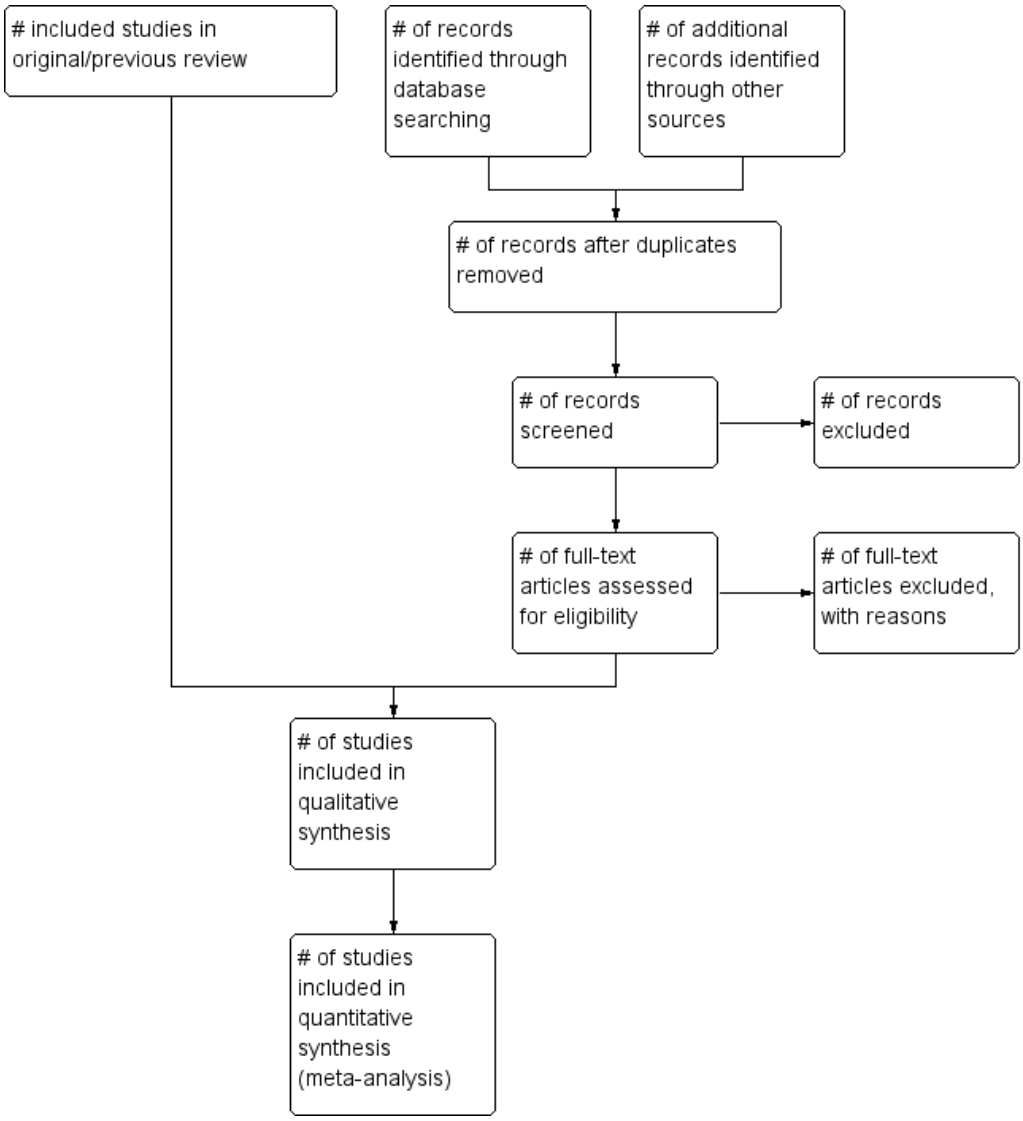
Include a reference to the originally published Cochrane version in the reference section under ‘Other versions of this review’.

Classification pending references

Data and analyses

Figures

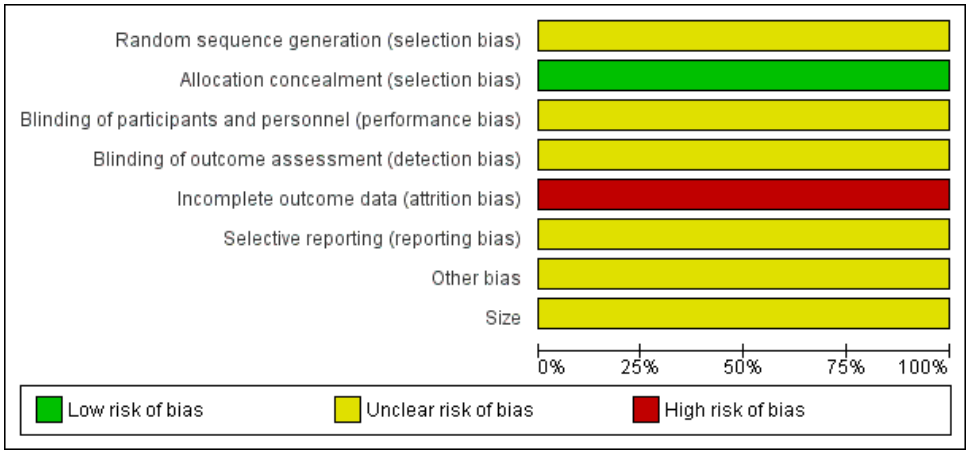
Figure 1



Caption

~Study flow diagram.

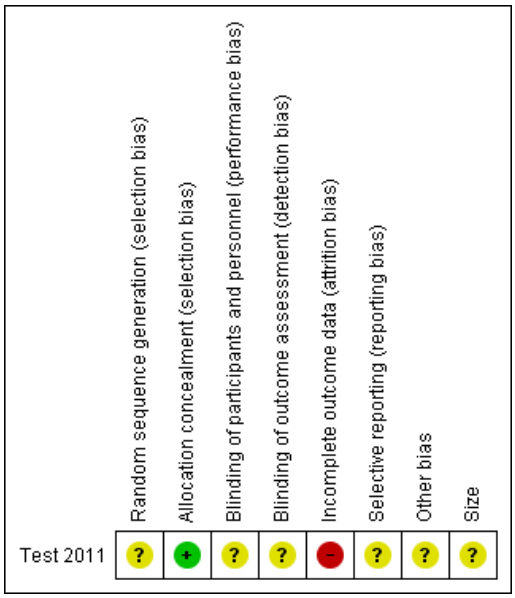
Figure 2



Caption

Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

Figure 3



Caption

Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

Sources of support

Internal sources

- No sources of support provided

External sources

- No sources of support provided

Feedback

Appendices

1 [Search strategies for the previous review]

Test

2 [Search strategies for the update if different]

Test