

Writing a protocol

Trusted evidence.
Informed decisions.
Better health.

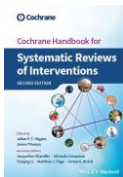


Steps of a Cochrane Review

1. define the question
→ register title
2. **plan eligibility criteria**
3. **plan methods**
→ publish protocol
4. search for studies
5. apply eligibility criteria
6. collect data
7. assess studies for risk of bias
8. analyse and present results
9. interpret results and draw conclusions
10. improve and update review

Session outline

- **rationale for writing a protocol**
- structure of a protocol for a Cochrane Review



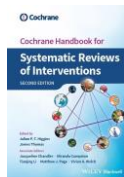
See Chapter II and Chapter 1 of the Handbook

Rationale for protocols

- systematic reviews involve judgements
 - e.g. question definition, eligibility, outcome measures
 - retrospective research - decisions should not be based on known results
- decide and document methods in advance
 - reduce impact of bias
 - allow peer review
 - reduce duplication
 - plan tasks and allocate resources
- published in the Cochrane Library
- published review will contain a link to your protocol

Session outline

- rationale for writing a protocol
- **structure of a Cochrane protocol**



See Chapter III of the Handbook



[Go to old article view](#)

PDF



Info



References

Cochrane Database of Systematic Reviews

Short versus long feeding interval for bolus feedings in very preterm infants

New

Protocol

Intervention

Nor Rosidah Ibrahim , Hans Van Rostenberghe, Jacqueline J Ho

First published: 17 August 2016

Editorial Group: [Cochrane Neonatal Group](#)DOI: [10.1002/14651858.CD012322](#) [View/save citation](#)Cited by: 0 articles  [Citation tools](#)

Abstract

This is the protocol for a review and there is no abstract. The objectives are as follows:

- To determine the most effective and safest feeding interval for bolus feeding for very preterm infants (less than 32 weeks' gestation at birth).
- To assess whether short feeding intervals (such as one or two hours) compared with long feeding intervals (such as three or four hours) improve the time to full feeding and growth in very preterm infants.
 - Subgroup analysis will address birthweight, gestational age, type of feeding, different short and long feeding intervals and other differences in the feeding protocol such as volume of daily increment and prior use of MEF.
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Default view

Full text



- Dashboard
- Review information <
- Text >
- Abstract <
- Plain language summary
- Background >
 - Description of the co...
 - Description of the in...
 - How the interventio...
 - Why it is important t...
- Objectives
- Methods <
- Results <
- Discussion <
- Authors' conclusions <
- Studies <
- Other references <

Background

Add Note

Description of the condition

Add Note

Description of the intervention

Add Note

How the intervention might work

Add Note

Why it is important to do this review

Add Note

Authors

- must affirm that they:
 - made substantial contribution to:
 - the conception and design of review, or
 - the acquisition, analysis, or interpretation of data for the work
 - drafted the review or provided critical comments on intellectual content
 - approved the final version to be published
 - agree to be accountable for all aspects of the work
- specific contributions listed in ‘Contribution of authors’ section
- individuals, groups or both
- order of authors relative to their contribution
- institutional affiliations will be published

Contact person

- responsible for:
 - organising review team
 - communicating with Cochrane
 - monitoring progress with agreed timeline
 - submitting completed protocol/review
 - communicating feedback to co-authors
 - ensuring updates are prepared
- usually the lead author
- full contact details will be published



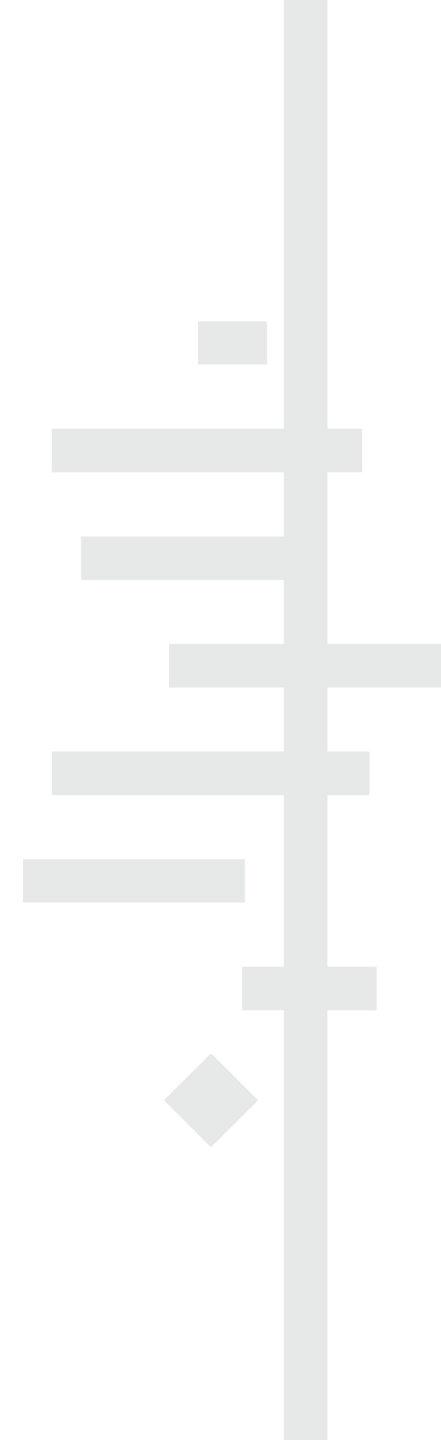
Writing your protocol

- accessible language
 - easy to read and understand by someone who is not an expert
- future tense, active voice
- use the Cochrane Style Manual
 - <http://community.cochrane.org/style-manual>
- terminology, statistics, spelling, references, formatting, etc.



Background

- put the review in context with the existing body of knowledge
 - description of the condition and its significance
 - description of the intervention
 - how the intervention might work
 - why it is important to do the review



Objectives

- a precise statement of the primary objective
- usually one sentence
- may also include specific objectives relating to different
 - participant groups
 - comparisons of interventions
 - outcome measures

To assess the effects of [*intervention or comparison*]
for [*health problem*]
for/in [*types of people, disease or problem and setting if specified*].

Methods

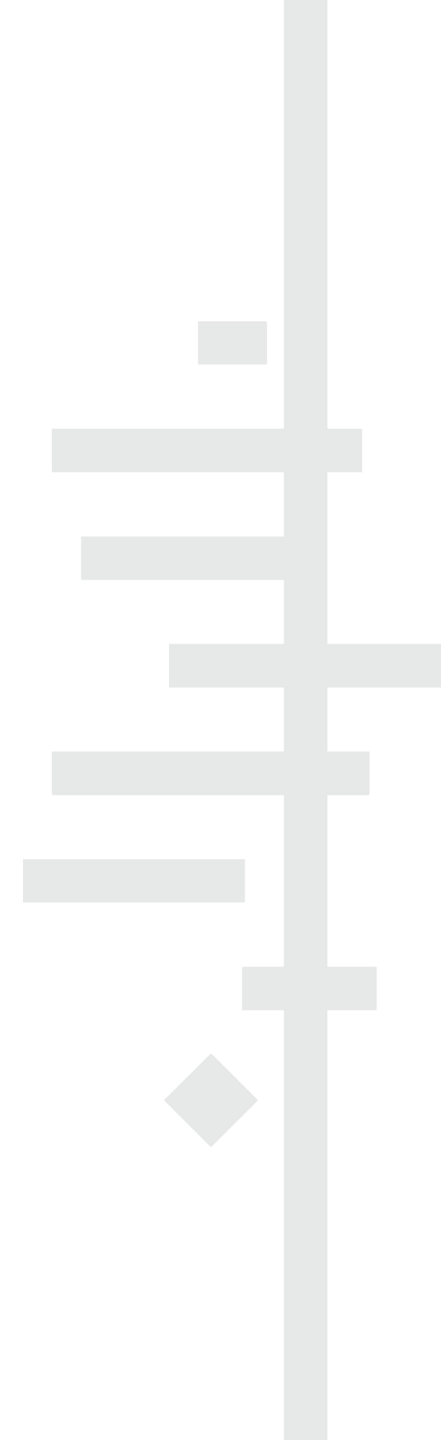
- plan what you will do before you start
 - minimise bias
 - divide work among review authors and establish timeline
 - enough detail so that the decisions and methods could be replicated
- select methods likely to deliver the best evidence on which to base decisions
 - consult your Cochrane Group - they may have a standard template
- anticipate that a useful number of studies will be found
 - may be the case in future updates, if not now



Methods

- eligibility criteria
- outcomes
- searching
- data collection
- risk of bias assessment
- analysis
- summarising findings

To be covered in more detail...



Standards

- MECIR: Methodological Expectations for Cochrane Intervention Reviews
<http://methods.cochrane.org/mecir>
- cover conduct and reporting
- most mandatory, some highly desirable
- consistent with PRISMA standards for reporting systematic reviews

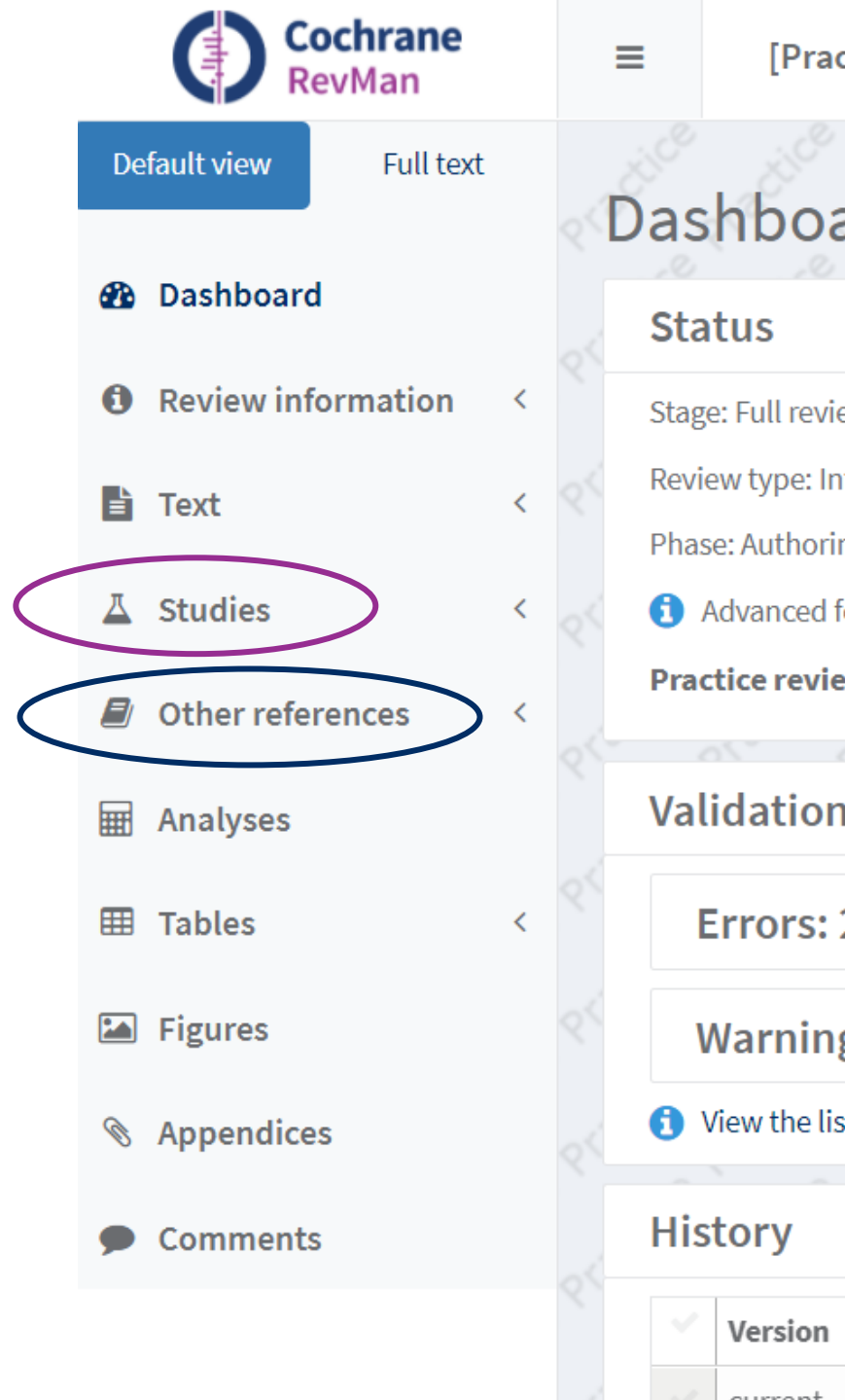
Methodological Expectations of Cochrane Intervention Reviews (MECIR)
Standards for the conduct and reporting of new Cochrane Intervention Reviews, reporting of protocols and the planning, conduct and reporting of updates

Julian PT Higgins, Toby Lasserson, Jackie Chandler, David Tovey, James Thomas, Ella Flemyng and Rachel Churchill



Studies and references

- Studies
 - included or excluded from your review
 - not used for protocol
- Other references
 - all protocol references
e.g. Background, Methods



The screenshot shows the Cochrane RevMan interface. At the top right, the Cochrane RevMan logo is visible. Below it, there are two tabs: 'Default view' (selected) and 'Full text'. A navigation menu is displayed on the left side, listing various sections: Dashboard, Review information, Text, Studies, Other references, Analyses, Tables, Figures, Appendices, and Comments. The 'Studies' and 'Other references' items are circled in purple and blue respectively. On the right side, there is a 'Dashboard' section with a 'Status' box containing information about the review stage, type, and phase. Below that is a 'Validation' section with 'Errors' and 'Warnings' boxes. At the bottom right, there is a 'History' section with a table showing the current version.

Cochrane RevMan

Default view Full text

Dashboard

Review information <

Text <

Studies <

Other references <

Analyses

Tables <

Figures

Appendices

Comments

Dashboard

Status

Stage: Full review

Review type: In

Phase: Authoring

Advanced f

Practice review

Validation

Errors: 2

Warning

View the lis

History

Version
current

Additional information

- acknowledgements
- contributions of authors
- declarations of interest
- sources of support
- any additional tables or appendices



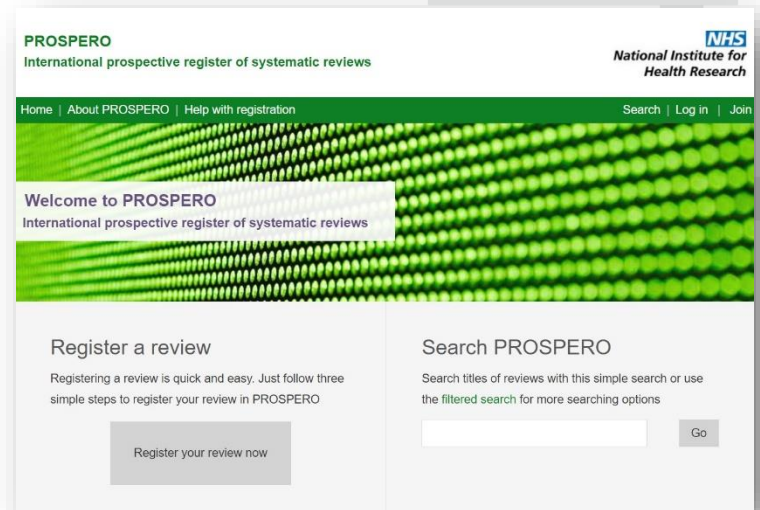
When your protocol is complete

- check the details
 - spell check, validation check, Cochrane Group checklist
- submit for editorial approval
- expect internal and peer review
 - ME, Editor(s), Statistical Editor, peer referees, consumer
 - like any journal, may take several months
- when it has been approved
 - complete License for Publication & Declaration of Interest forms
 - commence review
 - will be published immediately



PROSPERO

- international database of prospectively registered systematic reviews in health and social care
- all Cochrane protocols automatically uploaded to PROSPERO
- <http://www.crd.york.ac.uk/PROSPERO/>



PRISMA-P protocol reporting standards

- Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P)
- <http://prisma-statement.org/Extensions/Protocols.aspx>

Take home message

- published protocols are a requirement for Cochrane Reviews, designed to minimise bias
- write your protocol so that readers can understand in detail what you plan to do
- follow the standard structure available in RevMan



References

- Cumpston M, Chandler J. **Chapter II: Planning a Cochrane Review.** In: Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, Welch VA (editors). Cochrane Handbook for Systematic Reviews of Interventions, 2019. Available from <https://training.cochrane.org/handbook/current/chapter-ii>
- Lasserson TJ, Thomas J, Higgins JP. **Chapter 1: Starting a review.** In: Higgins JP, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, Welch VA (editors). Cochrane Handbook for Systematic Reviews of Interventions, 2019. Available from <https://training.cochrane.org/handbook/current/chapter-01>
- Page MJ, Cumpston M, Chandler J, Lasserson T. **Chapter III: Reporting the review.** In: Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, Welch VA (editors). Cochrane Handbook for Systematic Reviews of Interventions, 2019. Available from <https://training.cochrane.org/handbook/current/chapter-iii>

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