

Introduction to new *Cochrane Handbook for Systematic Reviews of Interventions (Version 6)*

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Outline

- ❑ Introduction and background to the Handbook (Julian)
- ❑ General structure and opening sections (James)
- ❑ Core quantitative topics (Julian)
- ❑ Specific perspectives on reviews (James)
- ❑ Some further topics (Julian)
- ❑ Online-only materials and closing remarks (James)



[30 March 1994]

SECTION VI:

**PREPARING AND MAINTAINING
SYSTEMATIC REVIEWS
(The Cochrane Collaboration Tool Kit)**

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Acknowledgements:

Kay Dickersin, Andrew Herxheimer and Chris Silagy were developed this Section of the Handbook and share whatever blame) for the progress that has been made in developing it. It has been reviewed by the members of the Steering Group who made suggestions. The Advisory Board for the Tool Kit is composed of relevant Cochrane Methods Groups. Doug Altman and Ken and Ron Akelhurst (health economics), and David Moher (the members of their groups have helped guide the Tool Kit's development. Forming Methods Groups, (such as the one being organized by Iain Clarke on reviews using individual patient data) will help guide the Tool Kit. We are very grateful for the help of all those who have particularly like to acknowledge the help of Sally Hunt for her financial support for developing the first edition of the Tool Kit. Provincial Hospitals Trust, the Oxford Regional Health Authority Programme (England).

**The Cochrane Collaboration Handbook
Version 3.0
(compiled December 1996)**

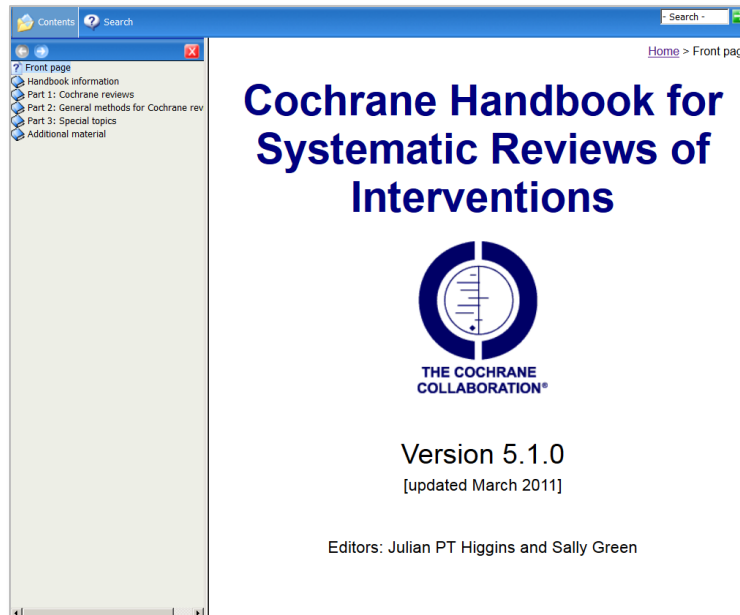
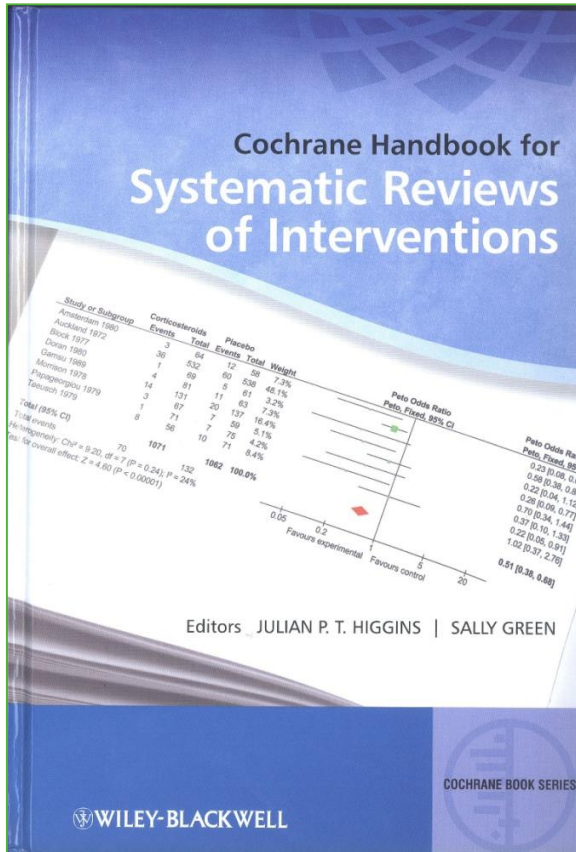
Contents

About the Handbook
What's new?

1. INTRODUCTION
2. FORMAT OF A COCHRANE REVIEW
3. DEVELOPING A PROTOCOL
4. FORMULATING THE PROBLEM
5. LOCATING AND SELECTING STUDIES
6. CRITICAL APPRAISAL OF STUDIES
7. COLLECTING DATA
8. ANALYSING AND PRESENTING RESULTS
9. INTERPRETING RESULTS
10. IMPROVING AND UPDATING REVIEWS
11. REVIEWS USING INDIVIDUAL PATIENT DATA

**Cochrane
Reviewers'
Handbook 4.0**

Updated July 1999



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★★★★★ 4.8 out of 5 stars ▾



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Lea

★★★★★ **Five Stars**

26 June 2017

Format: Hardcover | **Verified Purchase**

quick and good quality

Helpful

Comment | Report



Ashleigh

★★★★☆ **Four Stars**

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Very thorough

Helpful

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7 customer reviews

★★★★☆ 4.4 out of 5 stars ▾



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Top Reviews ▾

 Michael Smith★★★★☆ **Good review, though too advanced for beginners**

July 28, 2017

Format: Hardcover | **Verified Purchase**

This is a very good book for systematic review (basically the gold standard), but **my wife didn't find it as useful** as she had hoped because it was a little too advanced for her.


[Helpful](#)[Comment](#)[Report abuse](#) kinnickinnick★★★★★ **A worthwhile reference and study guide**

September 17, 2015

Format: Hardcover | **Verified Purchase**

An excellent reference for pharmaceutical/medical writers as well as researchers in medicine and public health, possibly along with a good text on meta-analysis.

One person found this helpful

[Helpful](#)[Comment](#)[Report abuse](#) what2bee★★★★☆ **just dull. That is the reason for the 3 stars**

September 9, 2015

Format: Hardcover | **Verified Purchase**

This is the standard for meta-analyses. It is fairly thorough, just dull. That is the reason for the 3 stars. It is probably wrong to expect this to be something other than dull. Recent changes are available on the Cochrane web site.


[Helpful](#)[Comment](#)[Report abuse](#)

Target audience

- ❑ **Cochrane Review authors and editors**
 - Traditionally many authors were novices at research, but not any more
- ❑ Non-Cochrane systematic review authors
- ❑ Researchers into methodology of systematic reviews
- ❑ Students
- ❑ Users of Cochrane Reviews





 [book] Cochrane handbook for systematic reviews of
interventions

Sep 26th 2008, DOI: 10.1002/9780470712184

Julian P. T. Higgins, Sally Green

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.

82 REFERENCES 36,540
CITATIONS*

RELATED
PUBLICATIONS

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Known citations

| Journal | # | Journal | # |
|-----------------------------|---------------|--------------------------------|---------------|
| CDSR | 3,858 | <i>Int J Nurs Stud</i> | 61 |
| All other journals | 16,385 | <i>J Affect Disorders</i> | 61 |
| <i>PloS One</i> | 803 | <i>Complement Ther Med</i> | 60 |
| <i>BMJ Open</i> | 448 | <i>Aliment Pharm Therap</i> | 59 |
| <i>Systematic Reviews</i> | 396 | <i>Arch Phys Med Rehab</i> | 59 |
| <i>J Clin Epidemiol</i> | 213 | <i>Evid Based Child Health</i> | 58 |
| <i>BMJ</i> | 194 | <i>Clin Psychol Rev</i> | 56 |
| <i>Int J Cardiol</i> | 134 | <i>Obesity Reviews</i> | 55 |
| <i>BMC Med Res Methodol</i> | 95 | <i>Lancet</i> | 52 |
| <i>Brit J Sport Med</i> | 94 | <i>Critical Care</i> | 52 |
| <i>BMC Public Health</i> | 85 | <i>Ann Intern Med</i> | 51 |
| <i>Evid Based Compl Alt</i> | 80 | <i>Brit J Anaesth</i> | 51 |
| <i>Sports Medicine</i> | 79 | <i>J Dent</i> | 51 |
| <i>Int J Surg</i> | 76 | <i>Brit J Psychiat</i> | 51 |
| <i>Am J Sport Med</i> | 69 | <i>BMC Med</i> | 49 |
| <i>Scientific Reports</i> | 69 | <i>Health Technol Assess</i> | 49 |
| <i>Pediatrics</i> | 63 | TOTAL JOURNAL ARTICLES | 20,243 |

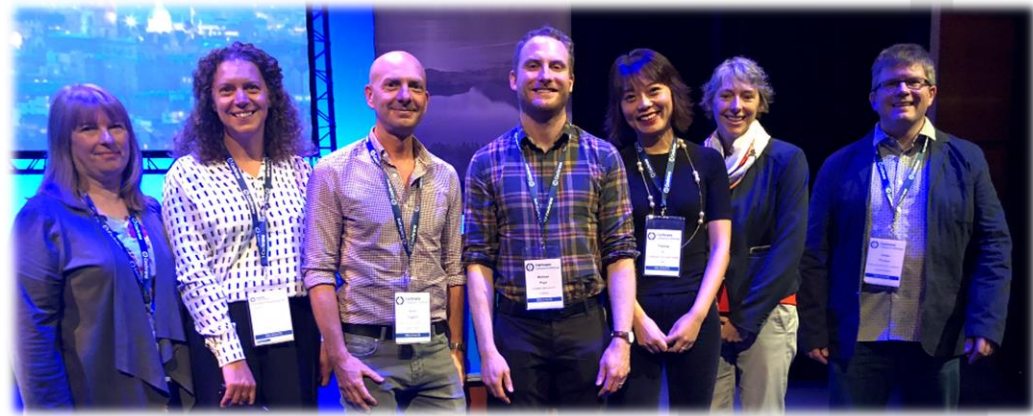
Development of the new version

- Planning started in 2009 between Julian and Sally Green
 - direct correspondence with all CRGs
 - fleshed out a plan
 - instigated updates with Methods Groups or other authors

- Slow progress
 - change of editorial team in 2012
 - MECIR developed and integrated into version 5.2 (released June 2017)
 - recruited a new team...



The team



❑ Numerous contributing authors and Methods Groups

- ❑ Julian Higgins (Senior editor)
- ❑ James Thomas (Senior editor)
- ❑ Tianjing Li (Associate scientific editor)
- ❑ Matt Page (Associate scientific editor)
- ❑ Vivian Welch (Associate scientific editor)
- ❑ Miranda Cumpston (Implementation editor)
- ❑ Jackie Chandler (Managing editor)
- ❑ Laura Mellor (Editorial assistant)



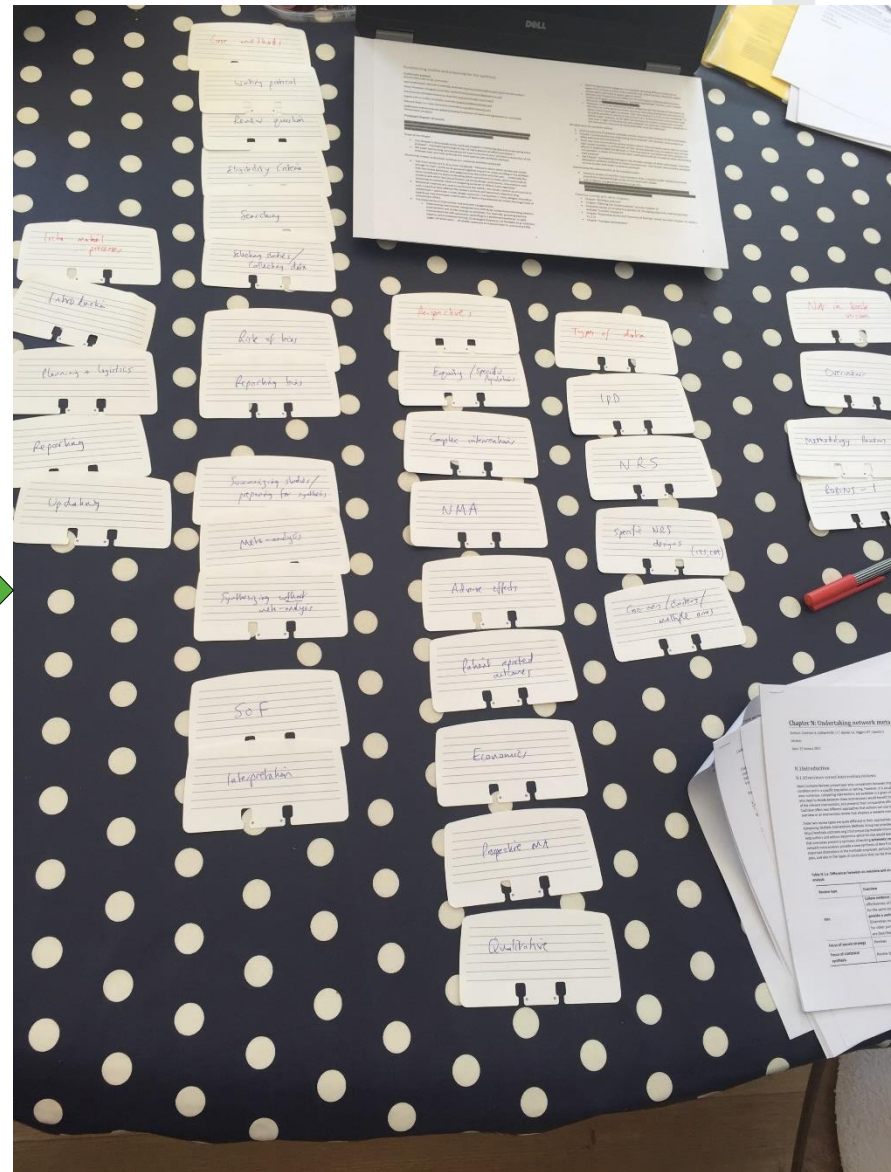
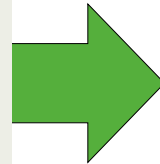
General structure

James Thomas



Planning version 6

- Part 1: Cochrane reviews
 - 1 Introduction
 - 2 Preparing a Cochrane review
 - 3 Maintaining reviews: updates, amendments and feedback
 - 4 Guide to the contents of a Cochrane protocol and review
- Part 2: General methods for Cochrane reviews
 - 5 Defining the review question and developing criteria for including studies
 - 6 Searching for studies
 - 7 Selecting studies and collecting data
 - 8 Assessing risk of bias in included studies
 - 9 Analysing data and undertaking meta-analyses
 - 10 Addressing reporting biases
 - 11 Presenting results and 'Summary of findings' tables
 - 12 Interpreting results and drawing conclusions
- Part 3: Special topics
 - 13 Including non-randomized studies
 - 14 Adverse effects
 - 15 Incorporating economics evidence
 - 16 Special topics in statistics
 - 17 Patient-reported outcomes
 - 18 Reviews of individual patient data
 - 19 Prospective meta-analysis
 - 20 Qualitative research and Cochrane reviews
 - 21 Reviews in public health and health promotion
 - 22 Overviews of reviews
- Additional material



From version 5 to 6

Part 1: Cochrane Reviews

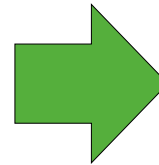
- Chapter 1: Introduction
- Chapter 2: Planning and preparation of a Cochrane review
- Chapter 3: Maintaining reviews: updates, amendments and feedback
- Chapter 4: Guide to the contents of a Cochrane protocol and review

Part 2: General methods for Cochrane Reviews

- Chapter 5: Defining the review question and developing criteria for including studies
- Chapter 6: Searching for studies
- Chapter 7: Selecting studies and collecting data
- Chapter 8: Assessing risk of bias in included studies
- Chapter 9: Analysing data and undertaking meta-analyses
- Chapter 10: Addressing reporting biases [PDF] new
- Chapter 11: Completing 'Summary of findings' tables and grading the confidence in or quality of the evidence
- Chapter 12: Interpreting results and drawing conclusions

Part 3: Special topics

- Chapter 13: Including non-randomized studies
- Chapter 14: Adverse effects
- Chapter 15: Incorporating economics evidence
- Chapter 16: Special topics in statistics
- Chapter 17: Patient-reported outcomes
- Chapter 18: Reviews of individual patient data
- Chapter 19: Prospective meta-analysis
- Chapter 20: Qualitative research and Cochrane reviews
- Chapter 21: Reviews in public health and health promotion
- Chapter 22: Overviews of reviews



- Chapter I: Introduction
- Chapter II: Planning a Cochrane review
- Chapter III: Reporting a review
- Chapter IV: Updating a review
- Chapter V: Overviews of reviews

Online

From version 5 to 6

Part 1: Cochrane Reviews

Chapter 1: Introduction

Chapter 2: Planning and preparation of a Cochrane review

Chapter 3: Maintaining reviews: updates, amendments and feedback

Chapter 4: Guide to the contents of a Cochrane protocol and review

Part 2: General methods for Cochrane Reviews

Chapter 5: Defining the review question and developing criteria for including studies

Chapter 6: Searching for studies

Chapter 7: Selecting studies and collecting data

Chapter 8: Assessing risk of bias in included studies

Chapter 9: Analysing data and undertaking meta-analyses

Chapter 10: Addressing reporting biases [PDF] new

Chapter 11: Completing 'Summary of findings' tables and grading the confidence in or quality of the evidence

Chapter 12: Interpreting results and drawing conclusions

Part 3: Special topics

Chapter 13: Including non-randomized studies

Chapter 14: Adverse effects

Chapter 15: Incorporating economics evidence

Chapter 16: Special topics in statistics

Chapter 17: Patient-reported outcomes

Chapter 18: Reviews of individual patient data

Chapter 19: Prospective meta-analysis

Chapter 20: Qualitative research and Cochrane reviews

Chapter 21: Reviews in public health and health promotion

Chapter 22: Overviews of reviews

Core methods

1. Starting a review
2. Determining the scope of the review and the questions it will address
3. Defining the criteria for including studies and how they will be grouped for the synthesis
4. Searching for and selecting studies
5. Collecting data
6. Choosing effect measures and computing estimates of effect
7. Considering bias and conflicts of interest among the included studies
8. Assessing risk of bias in a randomized trial
9. Summarizing studies and preparing for the synthesis
10. Analysing data and undertaking meta-analyses
11. Undertaking network meta-analyses
12. Synthesizing and presenting findings using other methods
13. Assessing risk of bias due to missing results in a synthesis
14. Completing 'Summary of findings' tables and grading the certainty of the evidence
15. Interpreting results and drawing conclusions

From version 5 to 6

Part 1: Cochrane Reviews

Chapter 1: Introduction

Chapter 2: Planning and preparation of a Cochrane review

Chapter 3: Maintaining reviews: updates, amendments and feedback

Chapter 4: Guide to the contents of a Cochrane protocol and review

Part 2: General methods for Cochrane Reviews

Chapter 5: Defining the review question and developing criteria for including studies

Chapter 6: Searching for studies

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Chapter 9: Analysing data and undertaking meta-analyses

Chapter 10: Addressing reporting biases [PDF] new

Chapter 11: Completing 'Summary of findings' tables and grading the confidence in or quality of the evidence

Chapter 12: Interpreting results and drawing conclusions

Part 3: Special topics

Chapter 13: Including non-randomized studies

Chapter 14: Adverse effects

Chapter 15: Incorporating economics evidence

Chapter 16: Special topics in statistics

Chapter 17: Patient-reported outcomes

Chapter 18: Reviews of individual patient data

Chapter 19: Prospective meta-analysis

Chapter 20: Qualitative research and Cochrane reviews

Chapter 21: Reviews in public health and health promotion

Chapter 22: Overviews of reviews (now online Chapter V)

Specific perspectives in reviews

16. [Equity and specific populations](#)

17. [Intervention complexity](#)

18. [Patient reported outcomes](#)

19. [Adverse effects](#)

20. [Economics evidence](#)

21. [Qualitative evidence](#)

Other topics

22. [Prospective approaches to cumulating evidence](#)

23. [Including variants on randomized trials](#)

24. [Including non-randomized studies](#)

25. [Assessing risk of bias in a non-randomized study](#)

26. [Individual participant data](#)

Core methods

1. Starting a review
2. Determining the scope of the review and the questions it will address
3. **Defining the criteria for including studies and how they will be grouped for the synthesis**
4. Searching for and selecting studies
5. Collecting data
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7. Considering bias and **conflicts of interest among the included studies**
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Specific perspectives in reviews

16. **Equity and specific populations**
17. **Intervention complexity**
18. Patient reported outcomes
19. Adverse effects
20. Economics evidence
21. Qualitative evidence

Other topics

22. **Prospective approaches to cumulating evidence**
23. Including variants on randomized trials
24. Including non-randomized studies
25. **Assessing risk of bias in a non-randomized study**
26. Individual participant data

About Cochrane Reviews

- I. Introduction
- II. Planning a Cochrane Review
- III. Reporting a review
- IV. Updating a review
- V. Overviews of Reviews

Methodological expectations of Cochrane Intervention reviews (MECIR)



Opening sections

James Thomas



Starting a review

- ❑ Why do a systematic review?
- ❑ What is the review question?
- ❑ Who should do a systematic review?
 - Involving consumers and other stakeholders
- ❑ The importance of reliability
- ❑ Protocol development
- ❑ Data management and quality assurance



Determining the scope of the review and the questions it will address

- ❑ Rationale for well-formulated questions
- ❑ Aims of reviews of interventions
- ❑ Defining the scope of the review question
 - Consideration of the review's PICO
 - Broad vs narrow reviews; 'lumping' vs 'splitting'
- ❑ Ensuring the review addresses the right questions
 - Using priority-setting exercises to define review questions
 - Engaging stakeholders; considering issues relating to equity
- ❑ Methods and tools for structuring the review
 - Logic models
 - Economic data

The three stages of PICO

- ❑ The **review PICO** (planned at the protocol stage) is the PICO on which eligibility of studies is based (what will be included and what excluded from the review).
- ❑ The **PICO for each synthesis** (also planned at the protocol stage) defines the question that each specific synthesis aims to answer, determining how the synthesis will be structured, specifying planned comparisons (including intervention and comparator groups, any grouping of outcome and population subgroups).
- ❑ The **PICO of the included studies** (determined at the review stage) is what was actually investigated in the included studies.

Defining the criteria for including studies and how they will be grouped for synthesis

- ❑ Articulation of the review and comparison PICO
 - Defining type of participants: which people and populations?
 - Defining interventions and how they will be grouped
 - Defining which comparisons will be made
 - Selecting, prioritizing and grouping review outcomes
- ❑ Determining which study designing to include
 - Randomized trials & non-randomized studies
- ❑ Eligibility based on publication status and language

Table 3.2.b: A process for planning intervention groups for synthesis

| Step | Considerations | Examples |
|--|--|--|
| 1. Identify intervention characteristics that may modify the effect of the intervention. | <p>Consider whether differences in interventions characteristics might modify the size of the intervention effect importantly. Content-specific research literature and expertise should inform this step.</p> <p>The <u>TIDieR</u> checklist – a tool for describing interventions – outlines the characteristics across which an intervention might differ (Hoffmann et al 2014). These include ‘what’ materials and procedures are used, ‘who’ provides the intervention, ‘when and how much’ intervention is delivered. The <u>iCAT-SR</u> tool provides equivalent guidance for complex interventions (Lewin et al 2017).</p> | <p>Exercise interventions differ across multiple characteristics, which vary in importance depending on the review.</p> <p>In a review of exercise for osteoporosis, whether the exercise is weight-bearing or non-weight-bearing may be a key characteristic, since the mechanism by which exercise is thought to work is by placing stress or mechanical load on bones (Howe et al 2011).</p> <p>Different mechanisms apply in reviews of exercise for knee osteoarthritis (muscle strengthening), falls prevention (gait and balance), cognitive function (cardiovascular fitness).</p> <p>The differing mechanisms might suggest different ways of grouping interventions (e.g. by intensity, mode of delivery) according to potential modifiers of the intervention effects.</p> |

Searching for and selecting studies

- General issues
 - The role of the information specialist / librarian
 - Minimising bias
- Sources to search
 - Bibliographic databases; trials registers; regulatory agency sources and clinical study reports
- Designing search strategies
 - Sensitivity vs precision; controlled vocabularies; identifying fraudulent studies / retracted publications
- Selecting studies
 - Software and new technologies



Core quantitative topics (bias, statistics etc)

Julian Higgins



Collecting data

- ❑ Collecting data from clinical study reports
- ❑ Semi-automation
 - “At the time of writing, we cannot recommend a specific tool for automating data extraction for routine systematic review production”
- ❑ Dealing with suspicions of misconduct



Effect measures

- ❑ A new chapter on effect measures
- ❑ Mostly a re-arrangement of existing material
- ❑ Includes computations to get data into the right format (SDs from P values, etc)
- ❑ Additional content on other effect measures for continuous outcomes (e.g. ratio of means)



Risk of bias

- ❑ Chapter 7: Considering bias and conflicts of interest among the included studies
 - ❑ Chapter 8: Assessing risk of bias in a randomized trial
 - ❑ Chapter 13: Assessing risk of bias due to missing results in a synthesis
-
- ❑ Chapter 24: Including non-randomized studies
 - ❑ Chapter 25: Assessing risk of bias in a non-randomized study

RoB 2



| RoB 1 | RoB 2 |
|---|--|
| Outcome-based assessment | Result-based assessment |
| Random sequence generation <i>(selection bias)</i> | Bias arising from the randomization process |
| Allocation concealment <i>(selection bias)</i> | |
| Blinding of participants and personnel <i>(performance bias)</i> | Bias due to deviations from intended interventions |
| Incomplete outcome data <i>(attrition bias)</i> | Bias due to missing outcome data |
| Blinding of outcome assessment <i>(detection bias)</i> | Bias in measurement of the outcome |
| Selective reporting <i>(reporting bias)</i> | Bias in selection of the reported result |
| Other bias | <i>[Not available]</i> |
| <i>[Not available]</i> | Overall bias |

Risk of bias for a parallel group trial with interest in the effect of assignment to intervention

| | | | |
|--|--|----------------------------|---------------|
| Bias arising from the randomization process | 1.1 Was the allocation sequence random? | NI | [Description] |
| | 1.2 Was the allocation sequence concealed until participants were enrolled and randomized? | NI | [Description] |
| | 1.3 Did baseline differences between intervention groups suggest a problem with the comparability of the groups? | NI | [Description] |
| | Risk of bias judgement | Low / High / Some concerns | [Support] |
| | Optional: What is the predicted direction of bias arising from the randomization process? | | [Rationale] |
| Bias due to deviations from intended interventions | 2.1 Were participants aware of their assigned intervention during the trial? | Y / PY / PN / N / NI | [Description] |
| | 2.2 Were carers and people delivering the interventions aware of participants' allocated intervention during the trial? | Y / PY / PN / N / NI | [Description] |
| | 2.3 If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context? | NA / Y / PY / PN / N / NI | [Description] |
| | 2.4 If Y/PY to 2.3: Were these deviations from intended intervention balanced between intervention groups? | NA / Y / PY / PN / N / NI | [Description] |
| | 2.5 If N/PN/NI to 2.4: Were these deviations likely to have affected the outcome? | / NI | [Description] |
| | 2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention? | NI | [Description] |
| | 2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the deviations from intended interventions? | / NI | [Description] |
| | Risk of bias judgement | Low / High / Some concerns | [Support] |
| | Optional: What is the predicted direction of bias due to deviations from intended interventions? | | [Rationale] |
| Bias due to missing outcome data | 3.1 Were outcome data available for all, or nearly all, participants randomized? | Y / PY / PN / N / NI | [Description] |
| | 3.2 Were participants who were missing outcome data similar to those who were not? | NA / Y / PY / PN / N | [Description] |
| | 3.3 Were participants who were missing outcome data similar to those who were not on its true value? | NA / Y / PY / PN / N / NI | [Description] |
| | 3.4 Were participants who were missing outcome data similar to those who were not on its true value? | NA / Y / PY / PN / N / NI | [Description] |
| | Risk of bias judgement | Low / High / Some concerns | [Support] |
| | Optional: What is the predicted direction of bias due to missing outcome data? | | [Rationale] |
| Bias in measurement of the outcome | 4.1 Were the outcome measurements assessed in a similar way in both intervention groups? | Y / PY / PN / N / NI | [Description] |
| | 4.2 Were the outcome measurements assessed in a similar way in both intervention groups? | Y / PY / PN / N / NI | [Description] |
| | 4.3 If Y/PY/NI to 4.1: Could assessment of the outcome have been influenced by knowledge of the intervention received by study participants? | | [Description] |
| | 4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of the intervention received by study participants? | | [Description] |
| | 4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of the intervention received by study participants? | | [Description] |
| | Risk of bias judgement | Low / High / Some concerns | [Support] |
| | Optional: What is the predicted direction of bias in measurement of the outcome? | | [Rationale] |
| Bias in selection of the reported result | 5.1 Was the trial analysed in accordance with a pre-specified plan that was finalized before the results were available? | | [Description] |
| | 5.2 ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain? | | [Description] |
| | 5.3 ... multiple analyses of the data? | Y / PY / PN / N / NI | [Description] |
| | Risk of bias judgement | Low / High / Some concerns | [Support] |
| | Optional: What is the predicted direction of bias in selection of the reported result? | | [Rationale] |
| Overall bias | Risk of bias judgement | Low / High / Some concerns | [Support] |
| | Optional: What is the overall predicted direction of bias? | | [Rationale] |

“Signalling questions”
Answers Y / PY / N / PN / NI

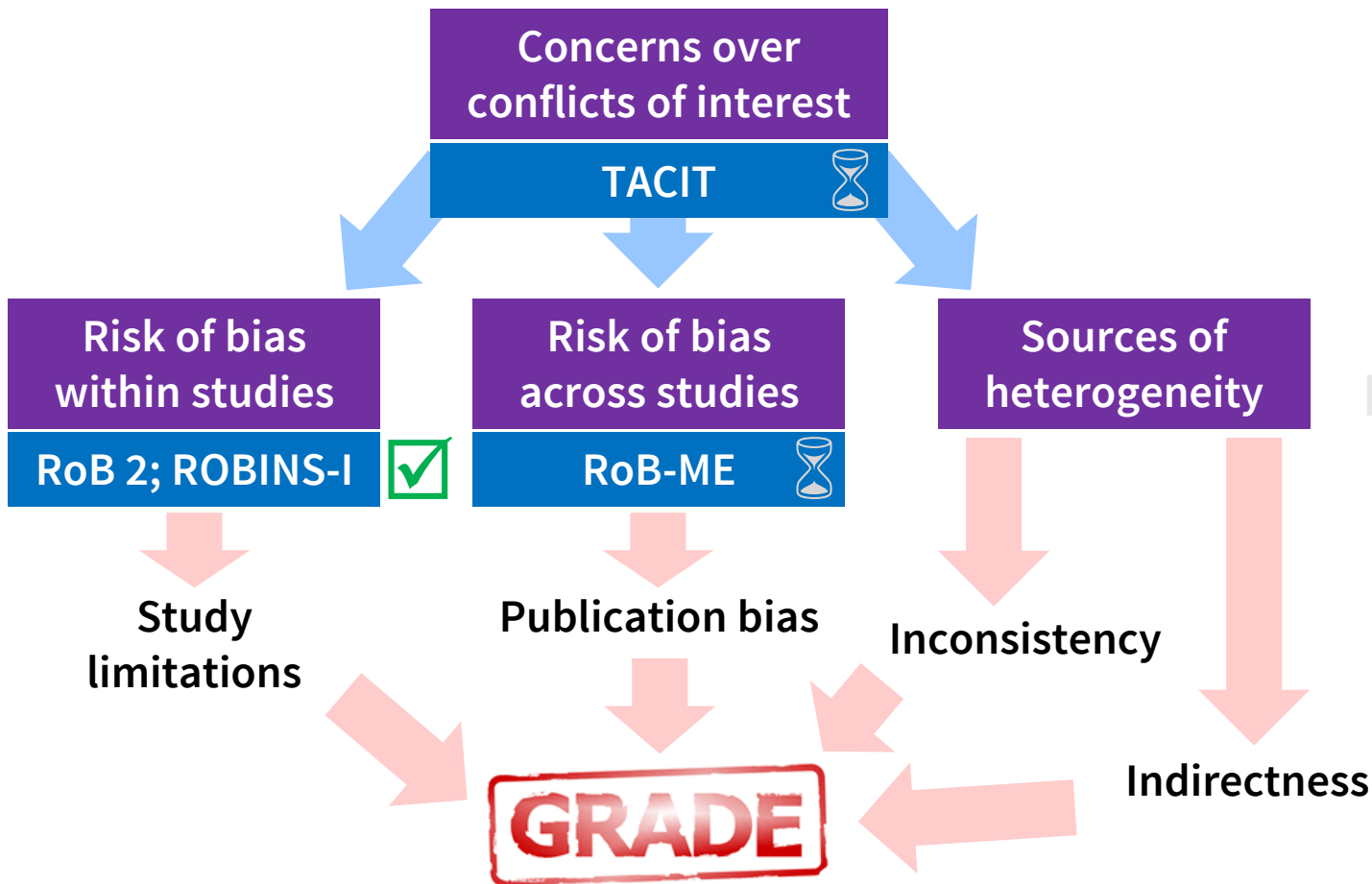
Risk of bias judgments
Low risk of bias, Some concerns,
High risk of bias

Distinction between effect of assignment to intervention and effect of adhering to intervention

Selection of reported result more specific than previous ‘selective reporting’ domain
Non-reporting not addressed

Overall risk of bias
Determined by ‘worst’ domain

Direction of travel



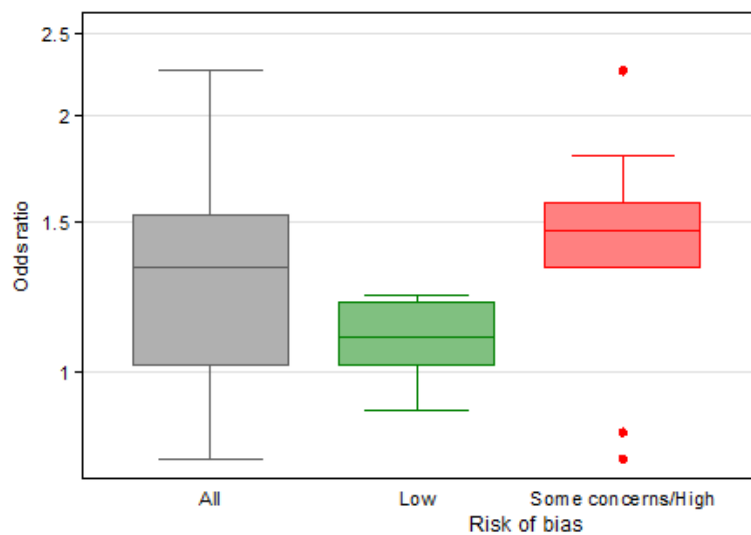
Meta-analysis and its alternatives

- New guidance on
 - fixed-effect vs random-effects models
 - interpreting random-effects meta-analysis using prediction intervals
 - better methods for random-effects meta-analysis
 - synthesis when meta-analysis can't (or shouldn't) be done
 - simple statistical tests
 - methods to avoid (e.g. vote counting statistical significance)
 - structured tables and plots

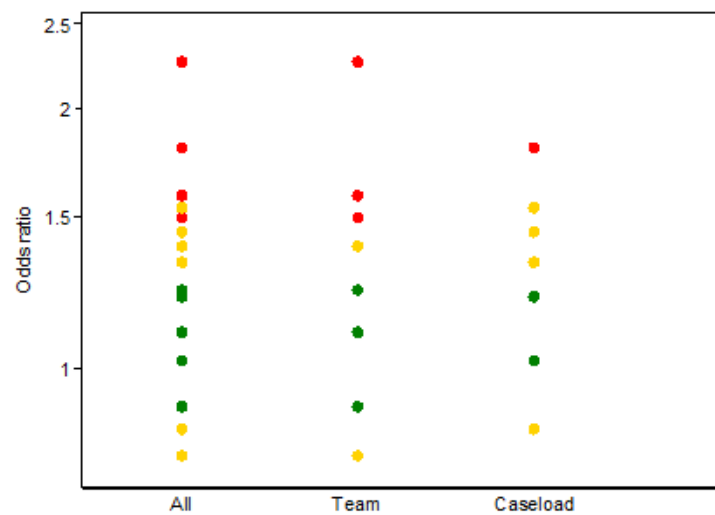
Awaiting
implementation
in RevMan



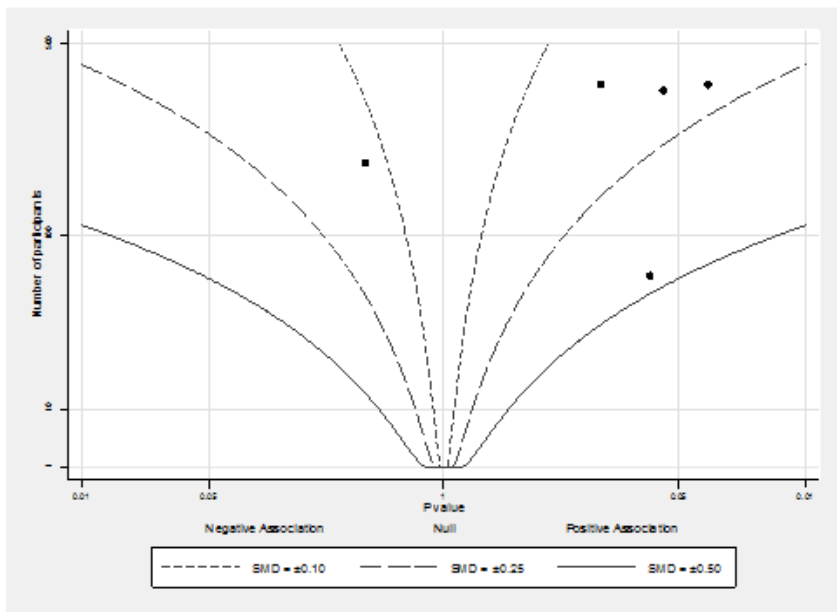
(A)



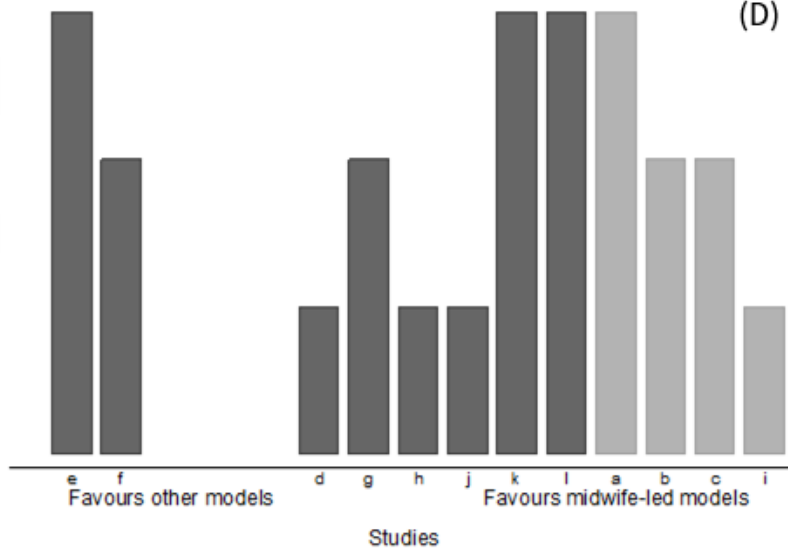
(B)



(C)



(D)



Network meta-analysis and indirect comparisons

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Record Title "interventions for"

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Cochrane Protocols 356
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Cochrane Database of Systematic Reviews
Issue 1 of 12, January 2019

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Nursing interventions for smoking cessation
 Virginia Hill Rice, Laura Heath, Jonathan Livingstone-Banks, Jamie Hartmann-Boyce
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Interventions for emergency contraception
 Jie Shen, Yan Che, Emily Showell, Ke Chen, Linan Cheng
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Interventions for acne scars
 Rania Abdel Hay, Khalid Shalaby, Hesham Zaher, Vanessa Hafez, Ching-Chi Chi, Sandra Dimitri, Ashraf F Nabhan, Alison M Layton
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Specific perspectives on reviews

James Thomas



Equity and specific populations

- Defining health equity
 - (i.e. the absence of avoidable and unfair differences in health)
 - Using logic models and theories of change to articulate hypotheses about equity
 - Consideration of study designs and outcomes
- Consideration of equity throughout the review



Intervention complexity

- ❑ Intervention complexity, rather than ‘complex intervention’
- ❑ Three ways of understanding complexity
 - Number of intervention components
 - Interactions between components / context
 - The wider system within which the intervention is introduced
- Chapter mainly focuses on the first two
- Considers complexity throughout the review process, using a Cochrane review as an example

Patient-reported outcomes

- Introduction to patient-reported outcomes (PROs)
 - What are PROs?
 - Why use PROs?
- Consideration of PROs throughout the review process with a particular focus on:
 - Measurement
 - Reliability
 - Validity
 - Responsiveness
 - Reporting bias
 - How to select which PRO measure to use



Adverse effects

- ❑ All reviews should try to consider adverse aspects of interventions
- ❑ This is particularly important when evidence on the potential for harm may affect treatment or policy decisions
- ❑ Adverse effects data are not always handled with as much rigour as primary beneficial outcomes
- ❑ Authors need to consider issues such as inadequate monitoring and incomplete reporting
- ❑ The inclusion of non-randomized studies may be required if adverse effects are to be properly investigated
- ❑ The chapter gives guidance on this issue throughout the review process

Economics evidence

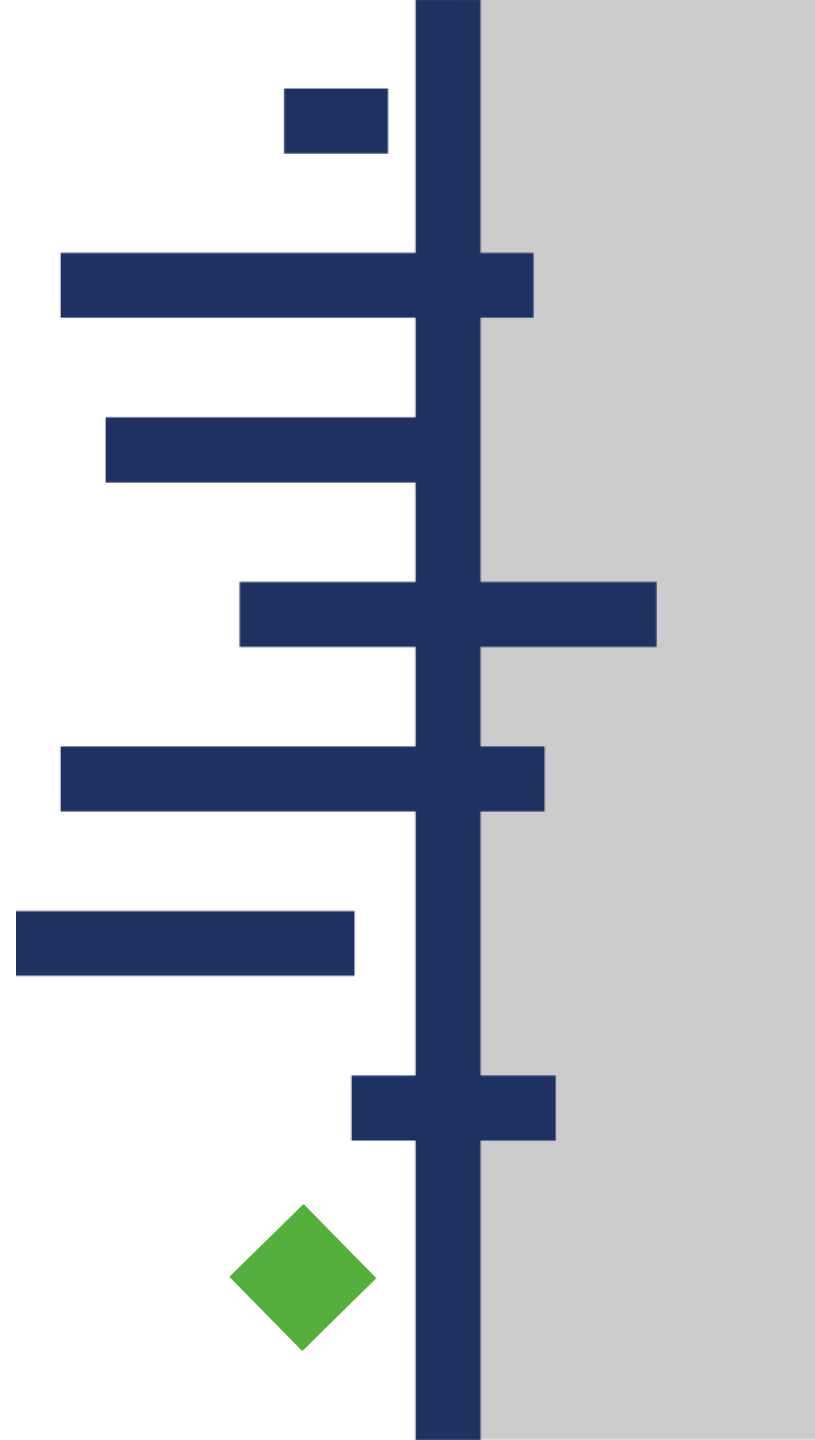
- ❑ Policy and practice decisions often need to be taken in the light of evidence about the (relative) costs of interventions
- ❑ Optimal decisions require best evidence on cost-effectiveness
- ❑ There are two possible methodological frameworks:
 - Brief economic commentary
 - Integrated full systematic review of economic evidence
- ❑ Chapter gives detailed guidance on how to construct brief economic commentaries in Cochrane reviews.
- ❑ Aims to provide guidance without requiring support from health economist
- ❑ Is a ‘minimal framework’ for including an economic perspective and we are currently discussing with the group where and how to include guidance on full integrated systematic reviews of economic evidence

Qualitative research and Cochrane Reviews

- ❑ How a qualitative evidence synthesis can add value
 - Understanding intervention complexity
 - Contextual variations
 - Implementation
 - Stakeholder preferences and experiences
- ❑ How a mixed-method / multicomponent design can be used to integrate a QES with a corresponding intervention review or within a single review
- ❑ Provides guidance throughout the review process – also signposts other key resources

Further topics

Julian Higgins



Prospective approaches to accumulating evidence

- New chapter covering
 - evidence surveillance and signals for updating
 - ‘living’ systematic reviews
 - prospectively planned meta-analyses
 - sequential approaches to meta-analysis
 - “Formal sequential meta-analysis approaches are discouraged for updated meta-analyses in most circumstances within the Cochrane context. They should not be used for the main analyses, or to draw main conclusions”



Non-standard trial designs and non-randomized studies

- ❑ Chapter 23: Including variants on randomized trials
 - cluster-randomized trials
 - cross-over trials
 - more than two treatment arms
- ❑ Chapter 24: Including non-randomized studies
- ❑ Chapter 25: Assessing risk of bias in a non-randomized study
 - ROBINS-I: core considerations for
 - follow-up studies
 - before-after studies (including interrupted time series)
 - controlled before-after studies



Online-only materials and closing remarks

James Thomas



Online chapters

- Introduction
- Planning a Cochrane Review
- Reporting a review
- Updating a review
- Overviews of Reviews



Overviews of Reviews

- ❑ What is a Cochrane Overview of Reviews?
- ❑ Specific characteristics:
 - Sufficiently up-to-date
 - Sufficiently homogeneous in terms of their PICO
 - Sufficiently homogeneous in terms of what and how outcome data are presented
 - Sufficiently low risk of bias or high methodological quality
- ❑ When a Cochrane Overview of Reviews is needed / appropriate
- ❑ Detailed methods for conducting a Cochrane Overview of Reviews



What happens next?

- Submission of book to Wiley later this week
- All chapters go up on intranet (PDFs) later this week
- Copy edits from Wiley get implemented
- Copy-edited version turned into open browseable version
- Book published later this year

- Anything can be implemented now (possibly CRG-dependent)
- Some methods to be implemented in RevMan Web



Thank you

Julian Higgins
James Thomas

Trusted evidence.
Informed decisions.
Better health.

