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Addressing Risk of Bias 2 implementation

April Governance Meeting (Krakow)
3 April 2019

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Aims of the session

- Provide an overview of the new Risk of Bias tool (RoB 2).
- Provide a case-study and practical advice on using RoB 2 within a Cochrane Review.
- Provide information on the pilot and roll-out.
- Highlight changes to RevMan Web.
- Highlight proposals for RoB 2 output in the Cochrane Library.
- Get your feedback on priorities for tools, guidance, training and support.

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Session overview (9:00-10:30)

01	**The Risk of Bias 2 (RoB 2) tool - structure and differences to RoB 1** Presented by Julian Higgins, University of Bristol and Cochrane Bias Methods Group
02	**Using RoB 2 - the Mental Health First Aid Review case study** Presented by Rachel Richardson, Network Research Fellow, Abdomen and Endocrine Network
03	**Data collection for RoB 2 - changes to the data collection form** Presented by Kerry Dwan, Statistical Editor

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Session overview (11:00-12:30)

04 **RoB 2 piloting and roll-out**
Presented by Toby Lasserson, Senior Editor

05 **Implementation in RevMan Web**
Presented by Rebecka Hall, Product Owner of RevMan

06 **Implementation in Cochrane Library**
Presented by Toby Lasserson, Senior Editor

07 **Tools, guidance, training and support: group exercise and feedback**
Presented by Ella Flemyng, Methods Implementation Coordinator

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Key messages before we begin

- 2019 will involve piloting and testing technology, processes and software.
- 2019 will involve developing tools, training, guidance and support.
- Platform and system dependencies related to full implementation.
- RoB 2 roll-out will likely be staggered.
- You can start using RoB 2 in Cochrane Reviews today, but you don’t have to.

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The Risk of Bias 2 tool

Julian Higgins
University of Bristol, UK
Cochrane Bias Methods Group

Brief overview of the RoB 2 tool

- Funders
  - Development supported by the UK Medical Research Council Network of Hubs for Trials Methodology Research (MR/L004933/1- N61)
  - Support also from a Cochrane Methods Innovation Fund grant

Brief overview of the RoB 2 tool

- Contributors
  - Core group:
    - Julian Higgins, Jelena Savović, Matthew Page, Asbjørn Hróbjartsson, Isabelle Boutron, Barney Reeves, Roy Elbers, Jonathan Sterne
  - Working Group members:
    - Doug Altman, Natalie Blencowe, Mike Campbell, Christopher Cates, Rachel Churchill, Mark Corbett, Nicky Cullum, Francois Curtin, Amy Drahota, Sandra Eldridge, Jonathan Emberson, Bruno Giraudeau, Jeremy Grimshaw, Sharea Ijaz, Miguel Hernán, Sally Hopewell, Asbjørn Hróbjartsson, Peter Jüni, Jamie Kirkham, Toby Lasserson, Tianjing Li, Stephen Senn, Sasha Shepperd, Ian Shrier, Nandi Siegfried, Lesley Stewart, Kate Tilling, Ian White, Penny Whiting
  - And:
    - Henning Keinke Andersen, Vincent Cheng, Mike Clarke, Jon Deeks, Daniela Junqueira, Alexandra McAleenan, Geraldine Macdonald, Richard Morris, Mona Nasser, Nishith Patel, Jani Ruotsalainen, Holger Schünemann, Jayne Tierney

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Bias is not the same as…

Imprecision

- random error due to sampling variation
- reflected in the confidence interval

Quality

- bias can occur in well-conducted studies
- not all methodological flaws introduce bias

Reporting

- good methods may have been used but not well reported

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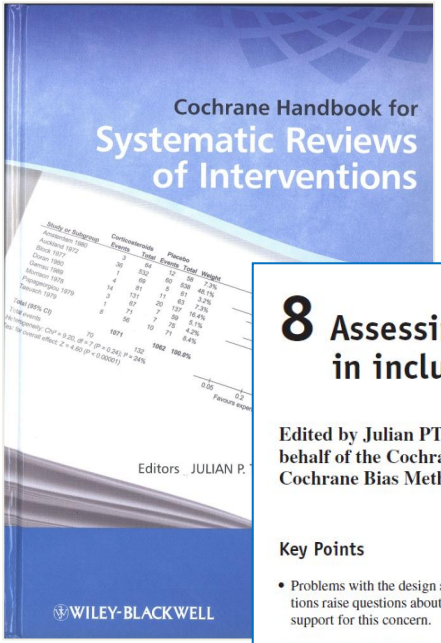
BMJ 2011; 343: d5928



8 Assessing risk of bias in included studies

Edited by Julian PT Higgins and Douglas G Altman on behalf of the Cochrane Statistical Methods Group and the Cochrane Bias Methods Group

Key Points

- Problems with the design and execution of individual studies of healthcare interventions raise questions about the validity of their findings; empirical evidence provides support for this concern.
- An assessment of the validity of studies included in a Cochrane review should emphasize the risk of bias in their results, i.e. the risk that they will overestimate or underestimate the true intervention effect.
- Numerous tools are available for assessing methodological quality of clinical trials. We recommend against the use of scales yielding a summary score.
- The Cochrane Collaboration recommends a specific tool for assessing risk of bias in each included study. This comprises a description and a judgement for each entry in a 'Risk of bias' table, where each entry addresses a specific feature of the study. The judgement for each entry involves answering a question, with answers 'Yes' indicating low risk of bias, 'No' indicating high risk of bias, and 'Unclear' indicating either lack of information or uncertainty over the potential for bias.

RESEARCH METHODS & REPORTING

The Cochrane Collaboration's tool for assessing risk of bias in randomised trials

Julian P T Higgins,[1] Douglas G Altman,[2] Peter C Gøtzsche,[3] Peter Jüni,[4] David Moher,[5 6] Andrew D Oxman,[7] Jelena Savović,[8] Kenneth F Schulz,[9] Laura Weeks,[5] Jonathan A C Sterne,[8] Cochrane Bias Methods Group Cochrane Statistical Methods Group

Flaws in the design, conduct, analysis, and reporting of randomised trials can cause the effect of an intervention to be underestimated or overestimated. The Cochrane Collaboration's tool for assessing risk of bias aims to make the process clearer and more accurate

Randomised trials, and systematic reviews of such trials, provide the most reliable evidence about the effects of healthcare interventions. Provided that there are enough participants, randomisation should ensure that participants in the intervention and comparison groups are similar with respect to both known and unknown prognostic factors. Differences in outcomes of interest between the different groups can then in principle be ascribed to the causal effect of the intervention.[1]

Causal inferences from randomised trials can, however, be undermined by flaws in design, conduct, analyses, and reporting, leading to underestimation or overestimation of the true intervention effect (bias).[2] However, it is usually impossible to know the extent to which biases have affected the results of a particular trial.

Systematic reviews aim to collate and synthesise all studies that meet prespecified eligibility criteria[3] using methods that attempt to minimise bias. To obtain reliable conclusions, review authors must carefully consider the potential limitations of the included studies. The notion of study "quality" is not well defined but relates to the extent to which its design, conduct, analysis, and presentation were appropriate to answer its research question. Many tools for assessing the quality of randomised trials are available, including scales (which score the trials) and checklists (which assess trials without producing a score).[4-7] Until recently, Cochrane reviews used a variety of these tools, mainly checklists.[8] In 2005 the Cochrane Collaboration's methods groups embarked on a new strategy for assessing the quality of randomised trials. In this paper we describe the collaboration's new risk of bias assessment tool, and the process by which it was developed and evaluated.

SUMMARY POINTS

Systematic reviews should carefully consider the potential limitations of the studies included

The Cochrane Collaboration has developed a new tool for assessing risk of bias in randomised trials

The tool separates a judgment about risk of bias from a description of the support for that judgment, for a series of items covering different domains of bias

Development of risk assessment tool

In May 2005, 16 statisticians, epidemiologists, and review authors attended a three day meeting to develop the new tool. Before the meeting, JPTH and DGA compiled an extensive list of potential sources of bias in clinical trials. The items on the list were divided into seven areas: generation of the allocation sequence; concealment of the allocation sequence; blinding; attrition and exclusions; other generic sources of bias; biases specific to the trial design (such as crossover or cluster randomised trials); and biases that might be specific to a clinical specialty. For each of the seven areas, a nominated meeting participant prepared a review of the empirical evidence, a discussion of specific issues and uncertainties, and a proposed set of criteria for assessing protection from bias as adequate, inadequate, or unclear, supported by examples.

During the meeting decisions were made by informal consensus regarding items that were truly potential biases rather than sources of heterogeneity or imprecision. Potential biases were then divided into domains, and strategies for their assessment were agreed, again by informal consensus, leading to the creation of a new tool for assessing potential for bias. Meeting participants also discussed how to summarise assessments across domains, how to illustrate assessments, and how to incorporate assessments into analyses and conclusions. Minutes of the meeting were transcribed from an audio recording in conjunction with written notes.

After the meeting, pairs of authors developed detailed criteria for each included item in the tool and guidance for assessing the potential for bias. Documents were shared and feedback requested from the whole working group (including six who could not attend the meeting). Several email iterations took place, which also incorporated feedback from presentations of the proposed guidance at various meetings and workshops within the Cochrane Collaboration and from

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Foam dressings for venous leg ulcers

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "Subjects were randomised in blocks of six to one of the two treatment groups using sequentially numbered, sealed opaque envelopes." Comment: sequence generation not reported.
Allocation concealment (selection bias)	Low risk	Quote: "Subjects were randomised in blocks of six to one of the two treatment groups using sequentially numbered, sealed, opaque envelopes." Comment: allocation process adequate.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "Because the study was not blinded, secondary absorbent dressing and peri ulcer treatments used were at the discretion of the investigator." Comment: stated as not being blinded.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Quote: "Because the study was not blinded, secondary absorbent dressing and peri ulcer treatments used were at the discretion of the investigator." Comment: stated as not being blinded.
Incomplete outcome data (attrition bias) All outcomes	High risk	Comment: numbers withdrawing and reasons reported by group (Group 1: 14/60 (23%); Group 2: 5/58 (9%)) but a higher proportion of participants withdrew from Group 2 and analysis not undertaken as ITT.
Selective reporting (reporting bias)	Unclear risk	Comment: although all trial outcomes described in the published report are in the supplied RCT protocol, it was unclear from the published report what the primary outcomes were (maceration in the protocol). A secondary outcome of 'ability to adapt' in the protocol (translated from Danish) is not identifiable in the published report.

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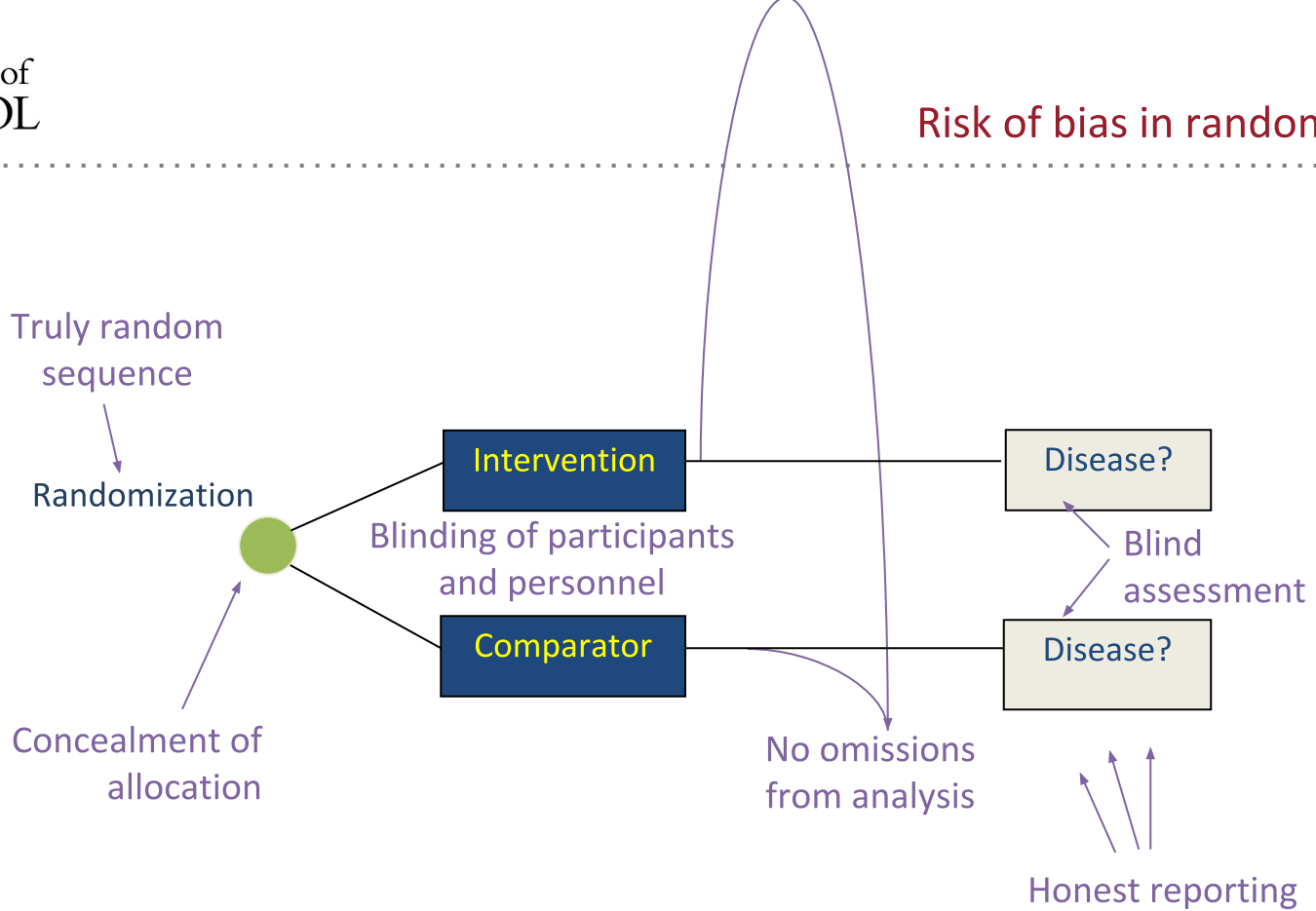
Risk of bias in randomized trials



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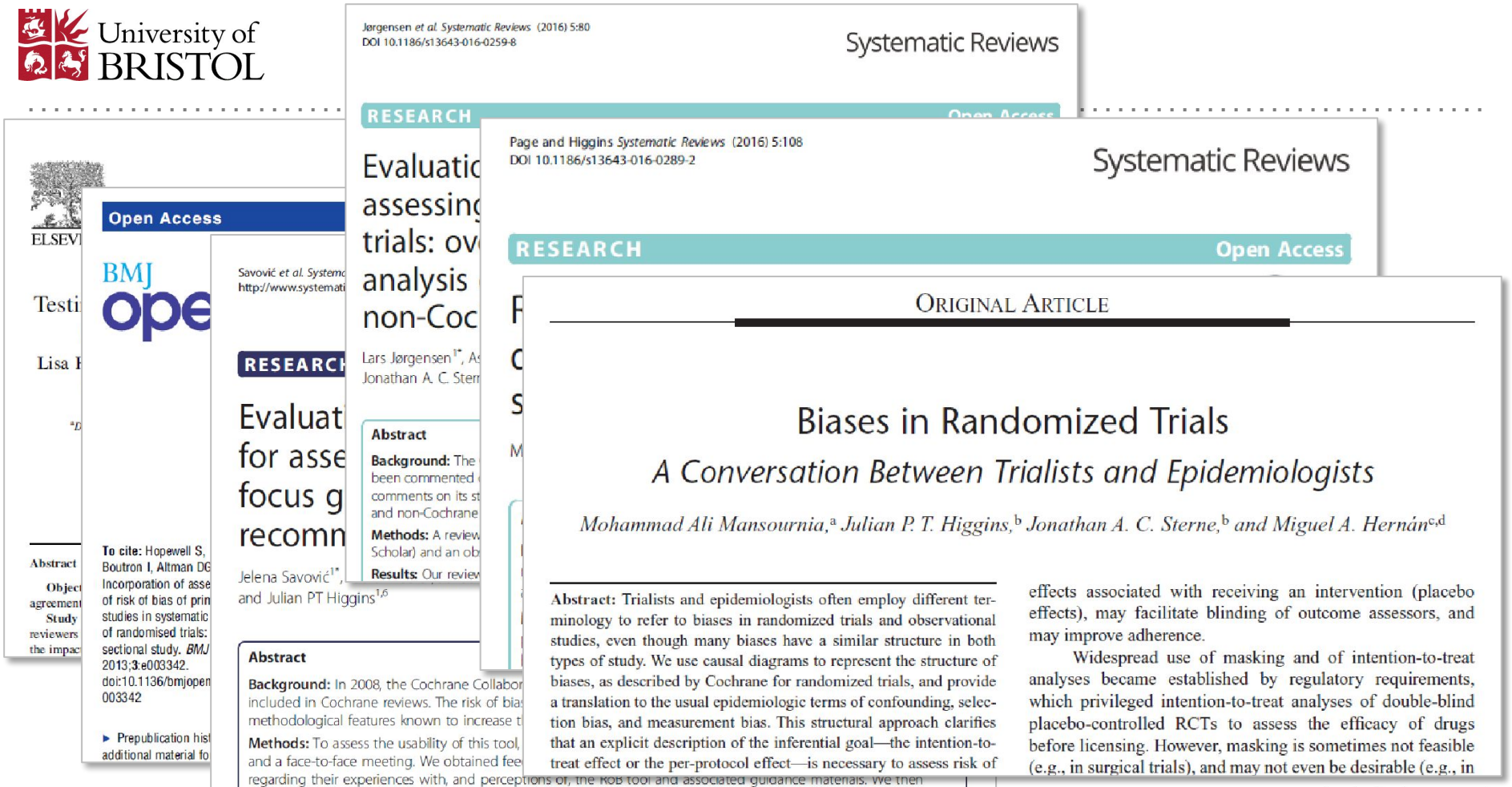

Jørgensen et al. Systematic Reviews (2016) 5:80
DOI 10.1186/s13643-016-0259-8

Systematic Reviews

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Page and Higgins Systematic Reviews (2016) 5:108
DOI 10.1186/s13643-016-0289-2

Systematic Reviews

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ORIGINAL ARTICLE

Biases in Randomized Trials

A Conversation Between Trialists and Epidemiologists

Mohammad Ali Mansournia,[a] Julian P. T. Higgins,[b] Jonathan A. C. Sterne,[b] and Miguel A. Hernán[c,d]

Abstract: Trialists and epidemiologists often employ different terminology to refer to biases in randomized trials and observational studies, even though many biases have a similar structure in both types of study. We use causal diagrams to represent the structure of biases, as described by Cochrane for randomized trials, and provide a translation to the usual epidemiologic terms of confounding, selection bias, and measurement bias. This structural approach clarifies that an explicit description of the inferential goal—the intention-to-treat effect or the per-protocol effect—is necessary to assess risk of

effects associated with receiving an intervention (placebo effects), may facilitate blinding of outcome assessors, and may improve adherence.

Widespread use of masking and of intention-to-treat analyses became established by regulatory requirements, which privileged intention-to-treat analyses of double-blind placebo-controlled RCTs to assess the efficacy of drugs before licensing. However, masking is sometimes not feasible (e.g., in surgical trials), and may not even be desirable (e.g., in

Why a new version?

- More **accurate**
  - more comprehensive
  - more guidance and structure to improve consistency
  - versions appropriate to cluster-randomized trials, cross-over trials
- More **usable**
  - clearer guidance, in-built help in reaching judgements
- More **current**
  - incorporates developments in the science (particularly missing data, unblinded trials)
- More **useful**
  - overall risk of bias judgement feeds into sensitivity analyses/exploration of heterogeneity
  - allied to ROBINS-I for non-randomized studies

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RoB 1 to RoB 2: bias domains

RoB 1	RoB 2
Random sequence generation (*selection bias*)	Bias arising from the randomization process
Allocation concealment (*selection bias*)	
Blinding of participants and personnel (*performance bias*)	Bias due to deviations from intended interventions
Incomplete outcome data (*attrition bias*)	Bias due to missing outcome data
Blinding of outcome assessment (*detection bias*)	Bias in measurement of the outcome
Selective reporting (*reporting bias*)	Bias in selection of the reported result
Other bias	N/A
N/A	Overall bias

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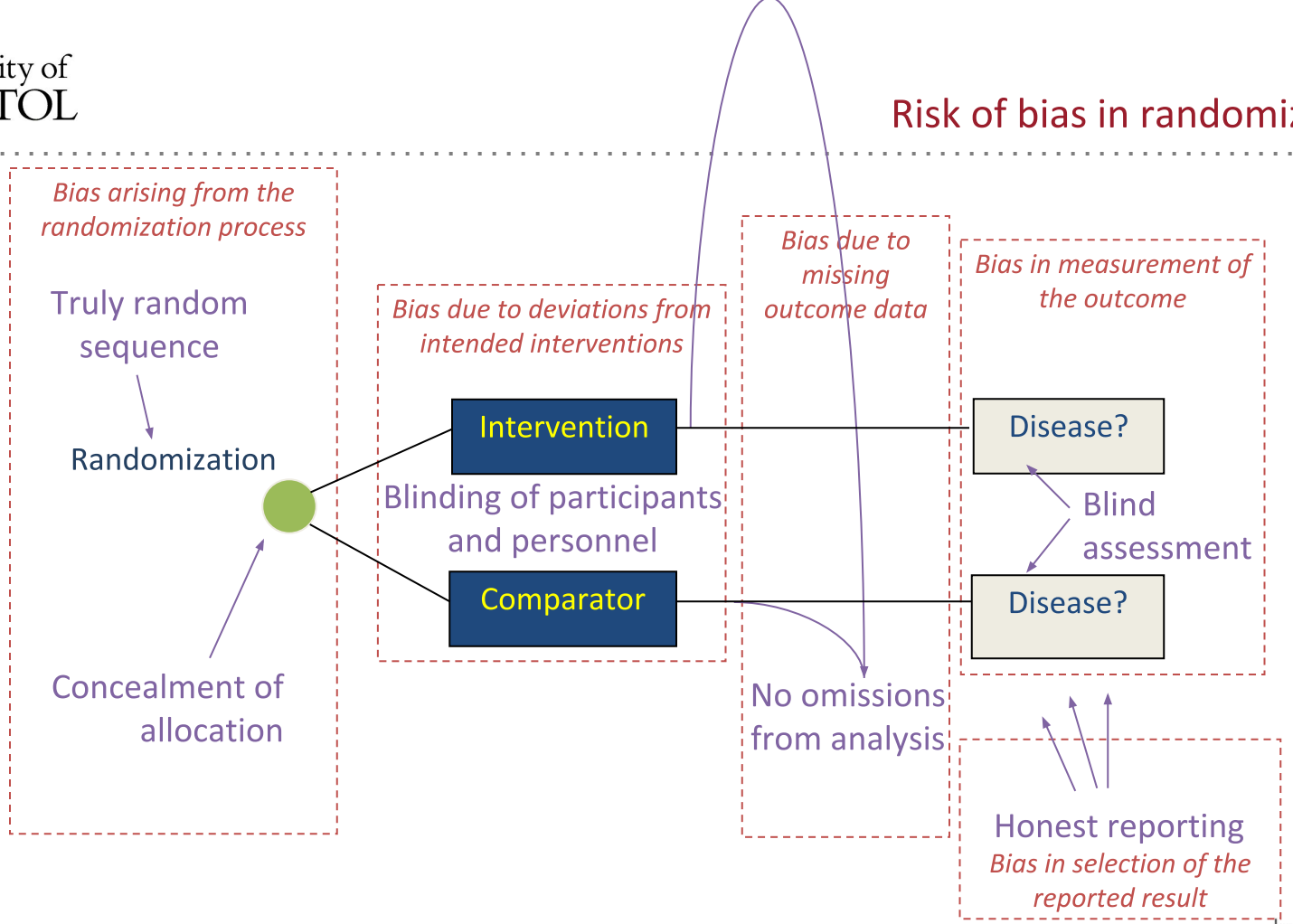
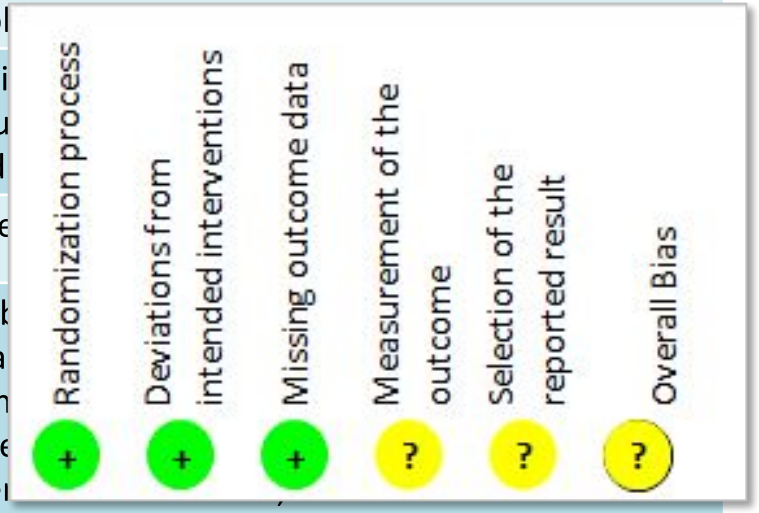
Risk of bias in randomized trials



RoB 2 example output

Domain	Judgement	Support for judgement
Bias arising from the randomization process	**Low**	Allocation sequence was adequately generated and concealed, and baseline imbalances appear to be compatibl
Bias due to deviations from intended interventions	**Low**	More pati group sou this could
Bias due to missing outcome data	**Low**	Data were
Bias in measurement of the outcome	**Some concerns**	Pain/disab were awa participan either inte assessmer that this was likely.
Bias in selection of the reported result	**Some concerns**	Unclear if the reported analysis approach was pre-specified or influenced by the results.
Overall bias	**Some concerns**	



RoB 2: Bias domains

- All domains are mandatory

- No additional domains available (i.e. no 'Other bias' domain)
  - The domains in the tool should cover all potential issues

- Funding and vested interests will be addressed separately
  - TACIT (*Tool for Addressing Conflicts of Interest in Trials*) working group led by Asbjørn Hróbjartsson and Isabelle Boutron

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Signalling questions and judgements

- Reasonably factual **signalling questions** aim to facilitate judgements and increase transparency
  - **‘Yes’, ‘Probably yes’, ‘Probably no’, ‘No’, ‘No information’**

- **Risk of bias judgements** follow from answers to signalling questions (can be over-ridden)
  - **‘Low risk of bias’, ‘Some concerns’, ‘High risk of bias’**

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Example: Bias arising from the randomization process

1.1 Was the allocation sequence random? 1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	**Randomization methods**
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	**Additional evidence of problems**

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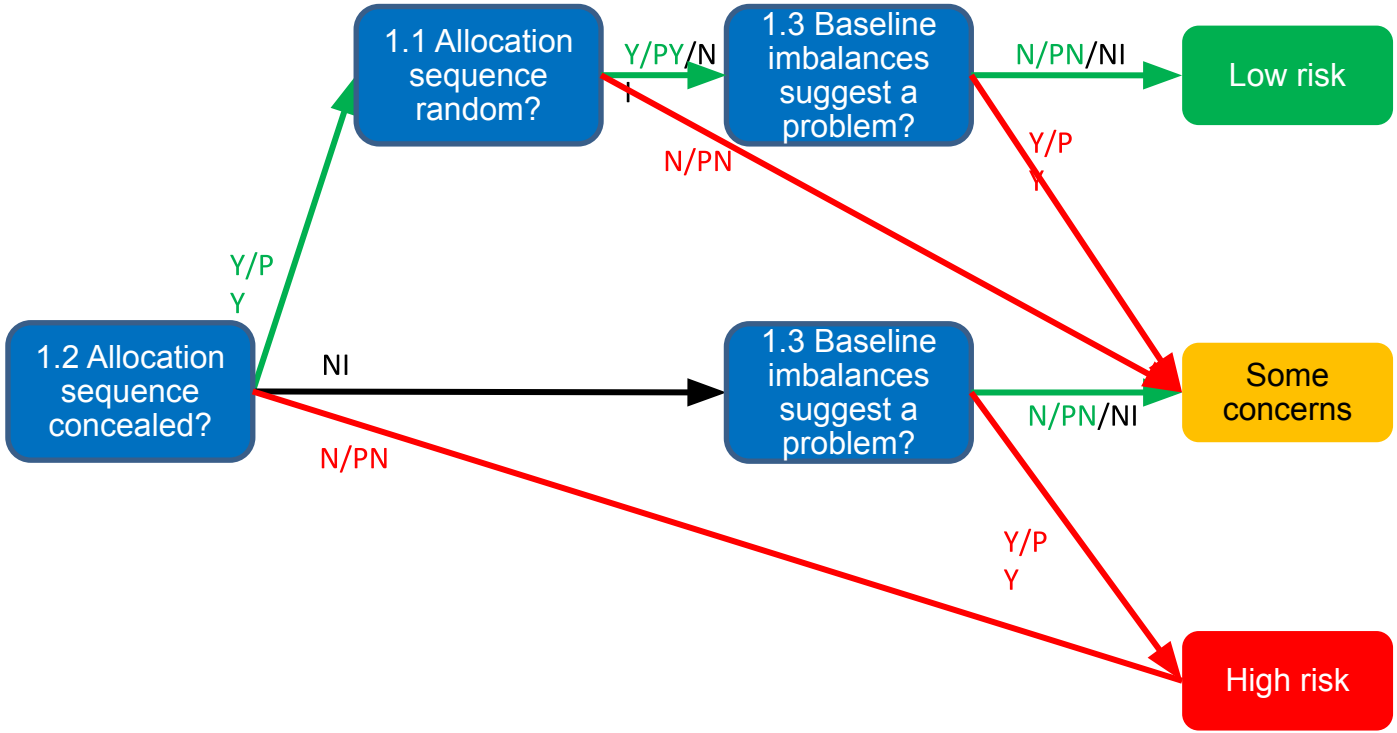
Example: Bias arising from the randomization process



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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?	Y / PY / PN / N / NI	[Description]
	1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	Y / PY / PN / N / NI	[Description]
	1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	Y / PY / PN / N / 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 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?	NA / Y / PY / PN / N / NI	[Description]
	2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Y / PY / PN / N / NI	[Description]
	2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	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 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 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	NA / Y / PY / PN / N	[Description]
	3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	NA / Y / PY / PN / N / NI	[Description]
	3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended 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 Was the method of measuring the outcome inappropriate?	Y / PY / PN / N / NI	[Description]
	4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	Y / PY / PN / N / NI	[Description]
	4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	Y / PY / PN / N / NI	[Description]
	4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	NA / Y / PY / PN / N / NI	[Description]
	4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?	NA / Y / PY / PN / N / NI	[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 unblinded outcome data were available for analysis?	Y / PY / PN / N / NI	[Description]
	Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
	5.2 ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	Y / PY / PN / N / NI	[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 bias due to selection of the reported results?		[Rationale]
Overall bias	**Risk of bias judgement**	Low / High / Some concerns	[Support]
	Optional: What is the overall predicted direction of bias for this outcome?		[Rationale]

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

- ☐ Journal article(s) with results of the trial
- ☐ Trial protocol
- ☐ Statistical analysis plan (SAP)
- ☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- ☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- ☐ "Grey literature" (e.g. unpublished thesis)
- ☐ Conference abstract(s) about the trial
- ☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- ☐ Research ethics application
- ☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- ☐ Personal communication with trialist
- ☐ Personal communication with the sponsor

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Overall risk of bias judgement

Low risk of bias	The study is judged to be at **low risk of bias for all domains** for this result.
Some concerns	The study is judged to be at **some concerns** in at least one domain for this result.
High risk of bias	The study is judged to be at **high risk of bias** in at least one domain for this result. OR The study is judged to have **some concerns** for **multiple domains** in a way that substantially lowers confidence in the result.

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Other key features of RoB 2

- **Result-based** assessments
  - Even more specific than outcome-based assessments
- Distinction between **effects of interest**
  - effect of **assignment** to intervention vs **adhering** to intervention
- Selective reporting focussed on reported result (not unreported results)

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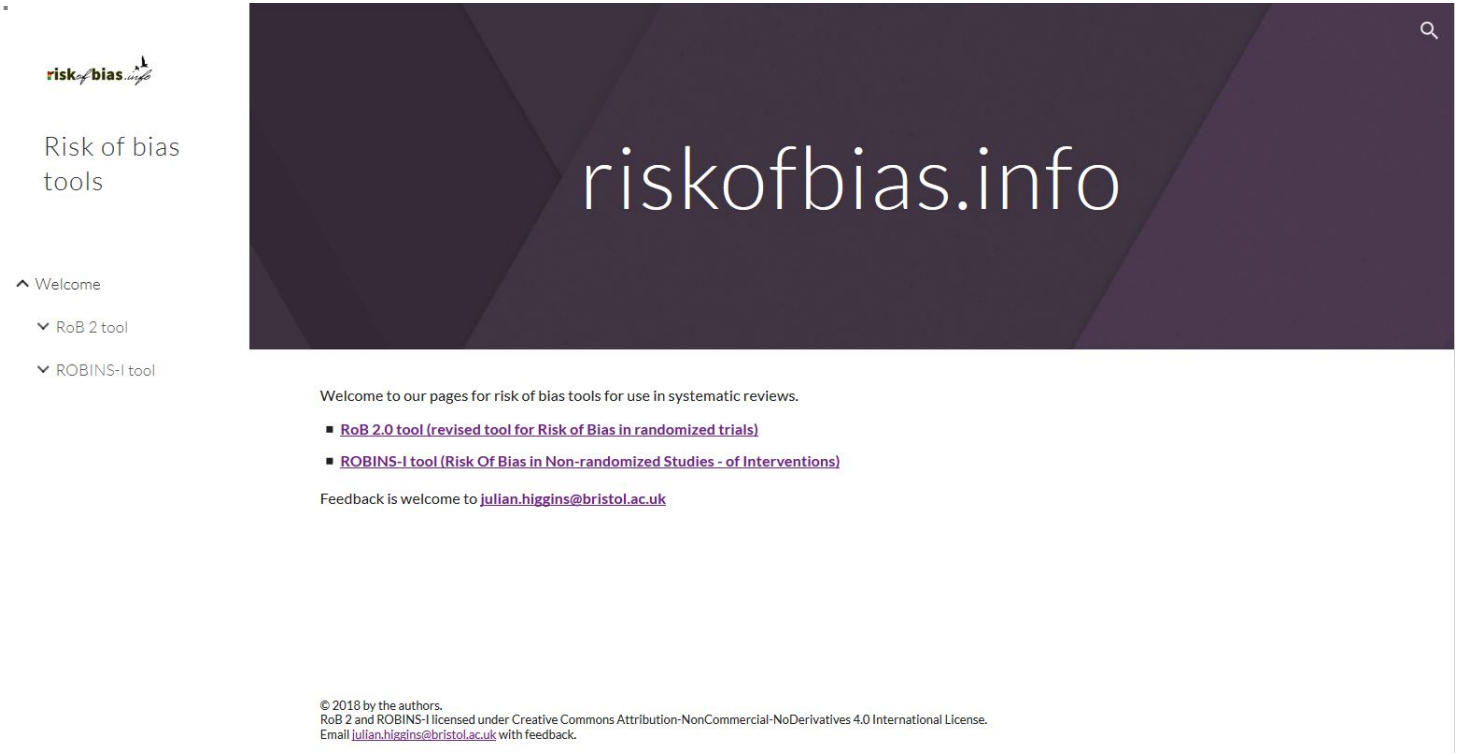
riskofbias.info



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Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the ROB2 Development Group

DRAFT 16 January 2019

Dedicated to Professor Douglas G Altman, whose contributions were of fundamental importance to development of risk of bias assessment in systematic reviews

Contents

Some practicalities

- How many results to assess per study?
  - We recommend a maximum of the outcomes in the Summary of Findings table
  - Usually somewhat fewer outcomes would be assessed
  - Many issues will be common to all results
    - software implementations should facilitate copying these from one assessment to another
- No result, no RoB assessment?
  - Yes - we think that's reasonable
  - But we can include assessments by adding outcome data as 'Other data'

- We have an Excel tool to implement RoB 2, and are developing a web-based system intended to link easily with RevMan, Covidence, etc

AutoSave Off | ROB 2_IRPG_2018_beta_v5.xlsm - Excel | Vincent Cheng

File Home Insert Draw Page Layout Formulas Data Review View Developer Add-ins Help Power Pivot Form Tell me Share Comments

Paste | Calibri 11 | Wrap Text | General | Conditional Formatting | Format as Table | Cell Styles | Insert | Delete | Format | AutoSum | Fill | Clear | Sort & Filter | Find & Select | Ideas

Clipboard | Font | Alignment | Number | Styles | Cells | Editing | Ideas

E8

RoB 2 Assessment Form	Summary	Figures	Populate Printing	Discrepancy Check
Instruction for the assessment form	Instruction for the summary	Instruction for the figure	Instruction for the populate printing	Instruction for the discrepancy check

1. General notices

1. Enable Macros before you start.
2. Each workbook can take a maximum of 300 assessments.
3. If the form is over-sized, please download the low resolution version.

2. Getting started with your first RoB 2 assessment

1. Click the 'Rob 2 Assessment Form' button to initialise the user form (note: the form will look slightly different in Microsoft Excel for Mac but functionality is not affected).
2. Give each assessment an 'Unique ID', and enter this in the relevant space on the form. The ID can be combination of letter and/or numbers.
3. Complete the assessment. Each domain of RoB 2 is on a separate tab in the form. Answers to the signalling questions can be selected from a drop-down menu, and there is space for justification for your answers.
4. Click the 'Save' button.

Tips:

- Double-clicking on the signalling question causes guidance on answering the signalling question to appear.
- RoB 2 has suggested risk of bias judgements for each domain based on the answers to the signalling questions. Clicking the 'Algorithm' button will cause suggested judgements to appear.
- There is box which enables you to input the weight a study has in the meta-analysis. This is set to 1.00 by default (each study has equal weighting), but can be edited to reflect the weight a study has in the meta-analysis. This is only relevant for the plots that can be created by clicking the 'Summary' button

Intro | Results | Summary | Figures | Print (ITT) | Print (PP) | Check

Ready Calculate 80%

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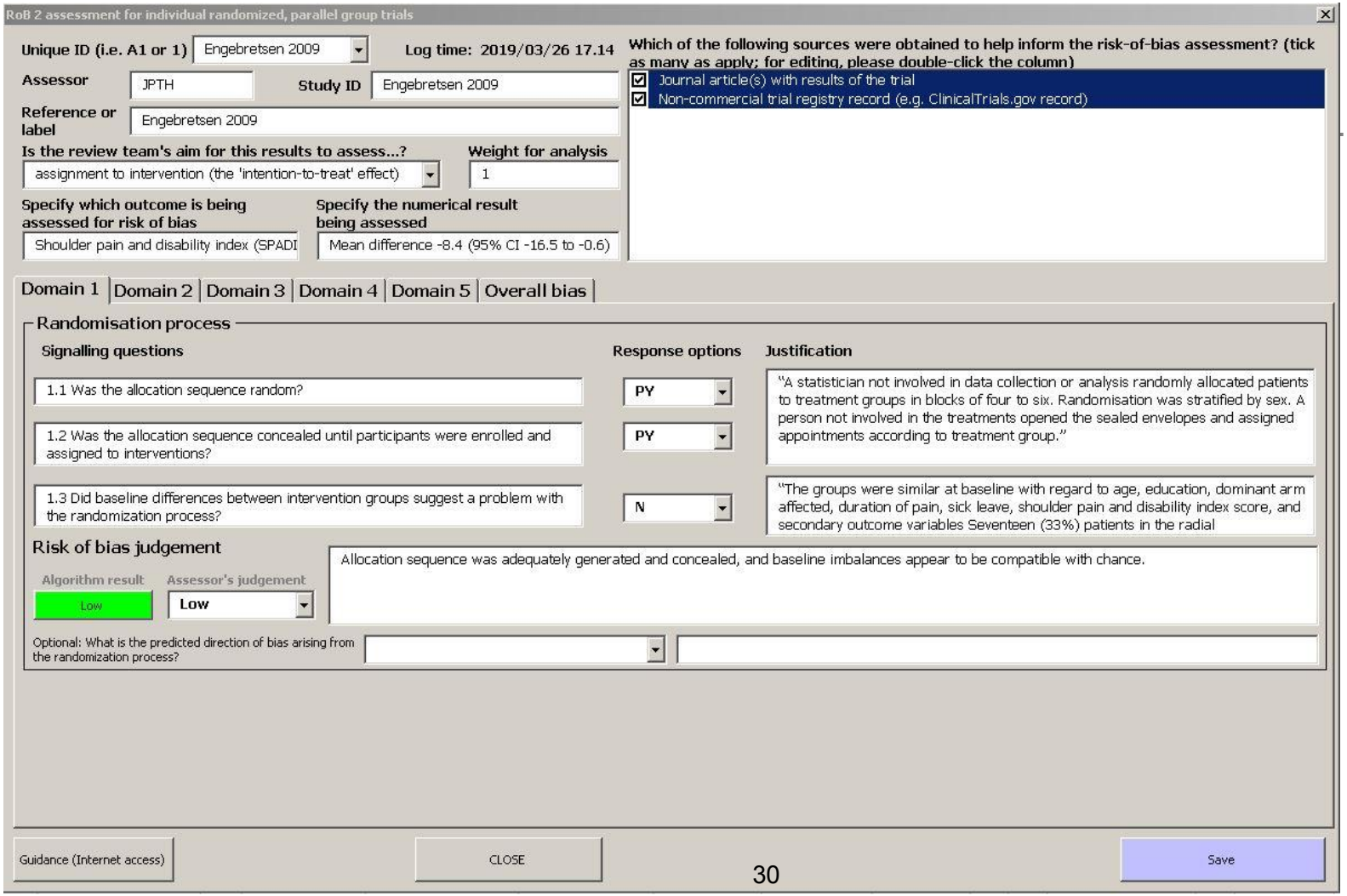
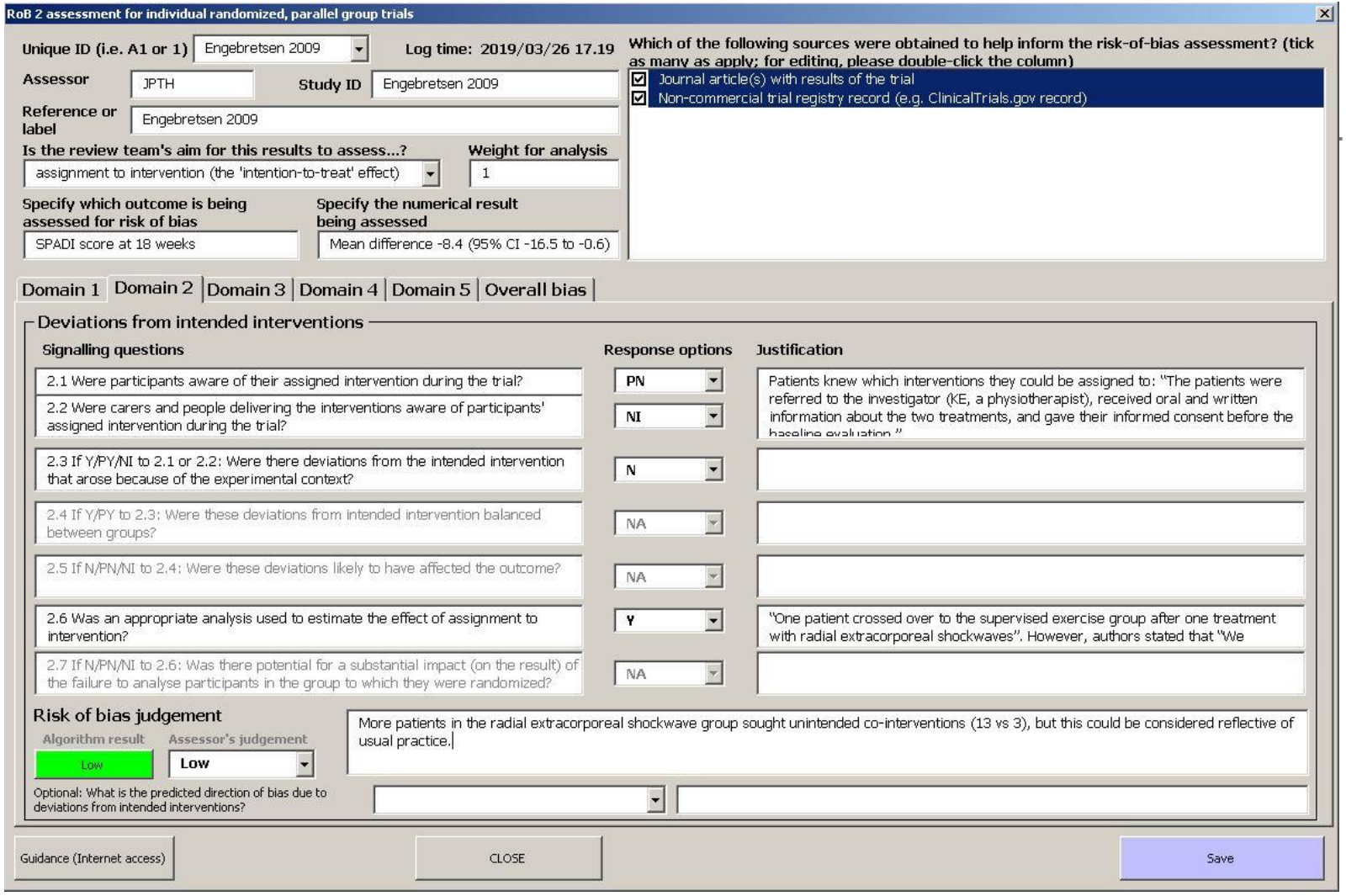

RoB 2 assessment for individual randomized, parallel group trials
Unique ID (i.e. A1 or 1)
Engebretsen 2009
Log time: 2019/03/26 17.14
Assessor
JPTH
Study ID
Engebretsen 2009
Reference or label
Engebretsen 2009
Is the review team's aim for this results to assess...?
assignment to intervention (the 'intention-to-treat' effect)
Weight for analysis
1
Specify which outcome is being assessed for risk of bias
Shoulder pain and disability index (SPADI
Specify the numerical result being assessed
Mean difference -8.4 (95% CI -16.5 to -0.6)
Which of the following sources were obtained to help inform the risk-of-bias assessment? (tick as many as apply; for editing, please double-click the column)
Journal article(s) with results of the trial
Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
Domain 1
Domain 2
Domain 3
Domain 4
Domain 5
Overall bias
Randomisation process
Signalling questions
Response options
Justification
1.1 Was the allocation sequence random?
PY
"A statistician not involved in data collection or analysis randomly allocated patients to treatment groups in blocks of four to six. Randomisation was stratified by sex. A person not involved in the treatments opened the sealed envelopes and assigned appointments according to treatment group."
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?
PY
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?
N
"The groups were similar at baseline with regard to age, education, dominant arm affected, duration of pain, sick leave, shoulder pain and disability index score, and secondary outcome variables Seventeen (33%) patients in the radial
Risk of bias judgement
Algorithm result
Low
Assessor's judgement
Low
Allocation sequence was adequately generated and concealed, and baseline imbalances appear to be compatible with chance.
Optional: What is the predicted direction of bias arising from the randomization process?
Guidance (Internet access)
CLOSE
Save


RoB 2 assessment for individual randomized, parallel group trials
Unique ID (i.e. A1 or 1)
Engebretsen 2009
Log time: 2019/03/26 17.19
Assessor
JPTH
Study ID
Engebretsen 2009
Reference or label
Engebretsen 2009
Is the review team's aim for this results to assess...?
assignment to intervention (the 'intention-to-treat' effect)
Weight for analysis
1
Specify which outcome is being assessed for risk of bias
SPADI score at 18 weeks
Specify the numerical result being assessed
Mean difference -8.4 (95% CI -16.5 to -0.6)
Which of the following sources were obtained to help inform the risk-of-bias assessment? (tick as many as apply; for editing, please double-click the column)
Journal article(s) with results of the trial
Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
Domain 1
Domain 2
Domain 3
Domain 4
Domain 5
Overall bias
Deviations from intended interventions
Signalling questions
Response options
Justification
2.1 Were participants aware of their assigned intervention during the trial?
PN
Patients knew which interventions they could be assigned to: "The patients were referred to the investigator (KE, a physiotherapist), received oral and written information about the two treatments, and gave their informed consent before the
2.2 Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?
NI
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?
N
2.4 If Y/PY to 2.3: Were these deviations from intended intervention balanced between groups?
NA
2.5 If N/PN/NI to 2.4: Were these deviations likely to have affected the outcome?
NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?
Y
"One patient crossed over to the supervised exercise group after one treatment with radial extracorporeal shockwaves". However, authors stated that "We
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?
NA
Risk of bias judgement
Algorithm result
Low
Assessor's judgement
Low
More patients in the radial extracorporeal shockwave group sought unintended co-interventions (13 vs 3), but this could be considered reflective of usual practice.
Optional: What is the predicted direction of bias due to deviations from intended interventions?
Guidance (Internet access)
CLOSE
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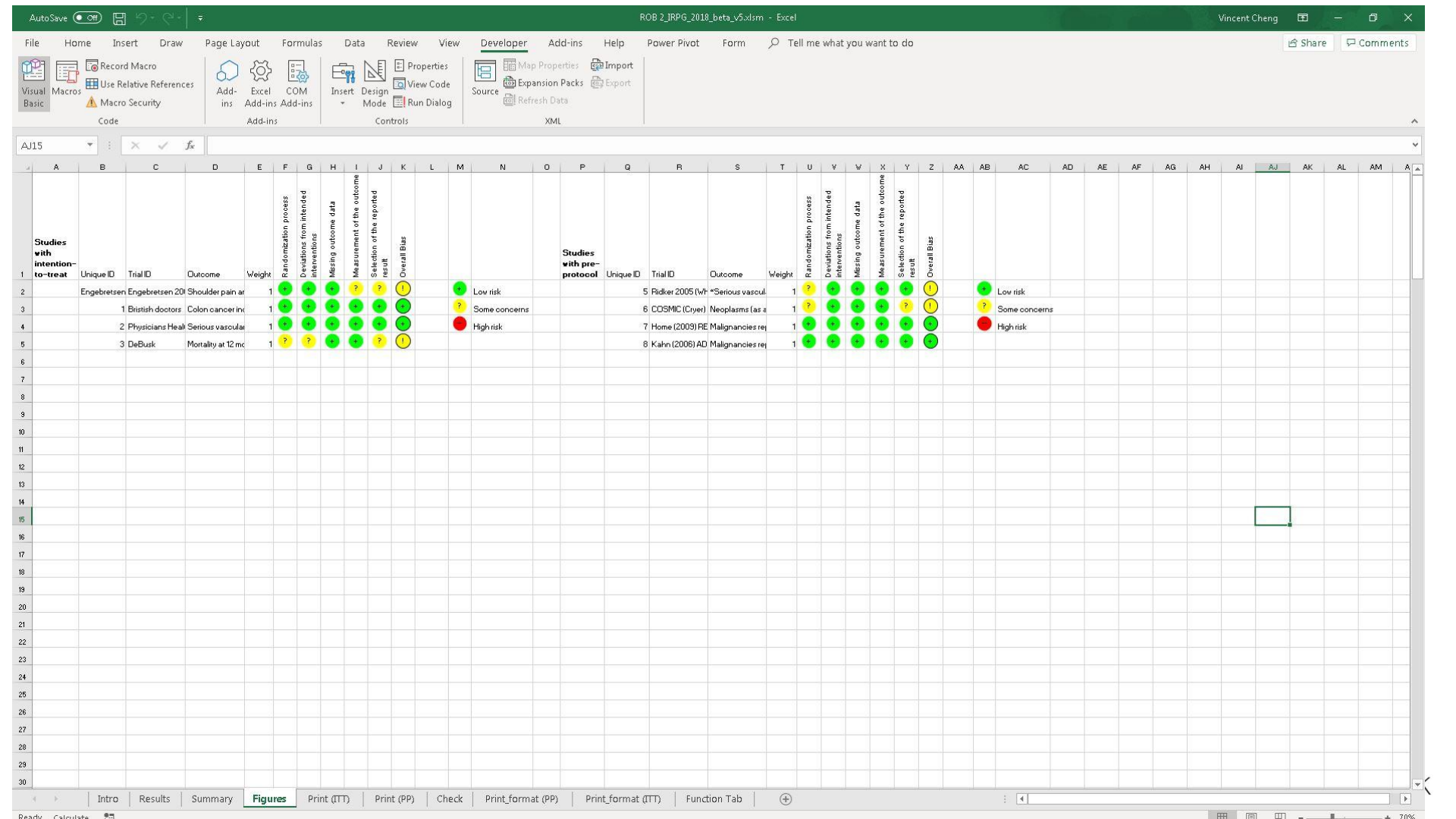
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Studies with intention-to-treat
Unique ID
Trial ID
Outcome
Weight
Randomization process
Deviations from intended interventions
Missing outcome data
Measurement of the outcome
Selection of the reported result
Overall Bias
Engebretsen
Engebretsen 20(
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Low risk
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Bristish doctors
Colon cancer inc
Some concerns
2
Physicians Healt
Serious vascular
High risk
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DeBusk
Mortality at 12 mc
Studies with pre-protocol
Ridker 2005 (WH
*Serious vascul
6
COSMIC (Cryer)
Neoplasms (as a
7
Home (2009) RE
Malignancies rep
8
Kahn (2006) AD
Malignancies rep
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Visual Basic | Macros | Record Macro | Use Relative References | Macro Security (Code)
Add-ins | Excel Add-ins | COM Add-ins (Add-ins)
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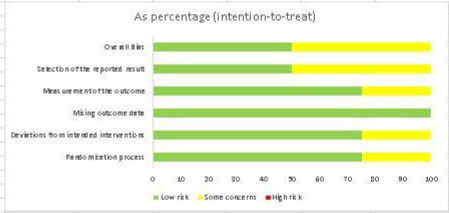
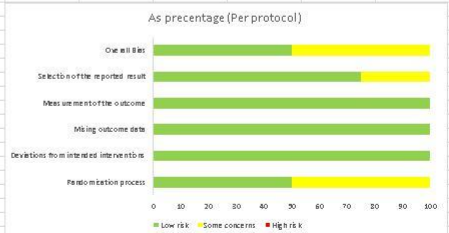
Source | Map Properties | Expansion Packs | Refresh Data | Import | Export (XML)

Q16

Unique ID	Reviewer	Study ID	Reference	Outcome	Result	Aim	Weight	Randomization process	Deviations from intended interventions	Missing outcome data	Measurement of the outcome	Selection of the reported result	Overall Bias
Engebretsen	JPTH	Engebretsen 20	Engebretsen 20	Shoulder pain a	Mean difference	assignment to in	1	Low	Low	Low	Some concerns	Some concerns	Some concerns
1	VC	Bristish doctors	Ridker 2005 (Wh	Colon cancer in	Numerical result	assignment to in	1	Low	Low	Low	Low	Low	Low
2	VC	Physicians Heal	COSMIC (Cryer)	Serious vascula	0.82 (95% CI 0.7	assignment to in	1	Low	Low	Low	Low	Low	Low
3	VC	DeBusk	Home (2009) RE	Mortality at 12 mo	4.1% (Interventic	assignment to in	1	Some concerns	Some concerns	Low	Low	Some concerns	Some concerns
5	AM	Ridker 2005 (Wh	Women's Health	*Serious vascul	See Figure 1in A	adhering to inte	1	Some concerns	Low	Low	Low	Low	Some concerns
6	AM	COSMIC (Cryer)	Cryer et al. (200	Neoplasms (as a	Table 2, 92/722,	adhering to inte	1	Some concerns	Low	Low	Low	Some concerns	Some concerns
7	AM	Home (2009) RE	Home (2010) Exp	Malignancies re	Table 2 in Home	adhering to inte	1	Low	Low	Low	Low	Low	Low
8	AM	Kahn (2006) AD	Home (2010) Exp	Malignancies re	Home (2010) Tal	adhering to inte	1	Low	Low	Low	Low	Low	Low

	Randomization process	Deviations from intended	Missing outcome data	Measurement of the outcome	Selection of the reported result	Overall Bias
Assignment to intervention (the 'intention-to-treat' effect)						
Total number of study = 4						
Low risk	75	75	100	75	50	50
Some concerns	25	25	0	25	50	50
High risk	0	0	0	0	0	0
Adhering to intervention (the 'per-protocol' effect)						
Total number of study = 4						
Low risk	50	100	100	100	75	50
Some concerns	50	0	0	0	25	50
High risk	0	0	0	0	0	0





Intro | Results | Summary | Figures | Print (ITT) | Print (PP) | Check | Print_format (PP) | Print_format (ITT) | Function Tab

Ready | 70%

Using RoB 2 - the Mental Health First Aid Review case study

Presented by Rachel Richardson
Network Research Fellow, Abdomen and Endocrine Network

Cochrane

Presentation outline

Cochrane

‘Mental Health First Aid as a tool for improving mental health and well-being’

Rachel Richardson, Holly Eve Dale, Lindsay Robertson, George Wellby, Dean McMillan, Rachel Churchill

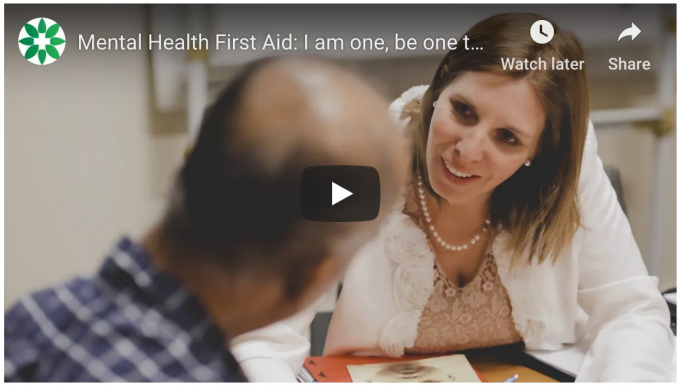
Cochrane

Mental Health First Aid

MENTAL HEALTH FIRST AID Australia

WELCOME TO **MENTAL HEALTH FIRST AID AUSTRALIA**

Each year **1 in 5 Australians** will experience a mental illness. Many people are not knowledgeable or confident to offer assistance. Physical first aid is accepted and widespread in our community, however most do not cover mental health problems. Mental Health First Aid (MHFA) teaches people the skills to help someone who they're concerned about.



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PICO for review

- Study design: RCTs
- Participants: any participants/any settings
- Interventions: MHFA trademarked course delivered in any format whether tailored to a particular group or not
- Comparators: waitlist control, no treatment control, alternative mental health literacy intervention, active or attention control

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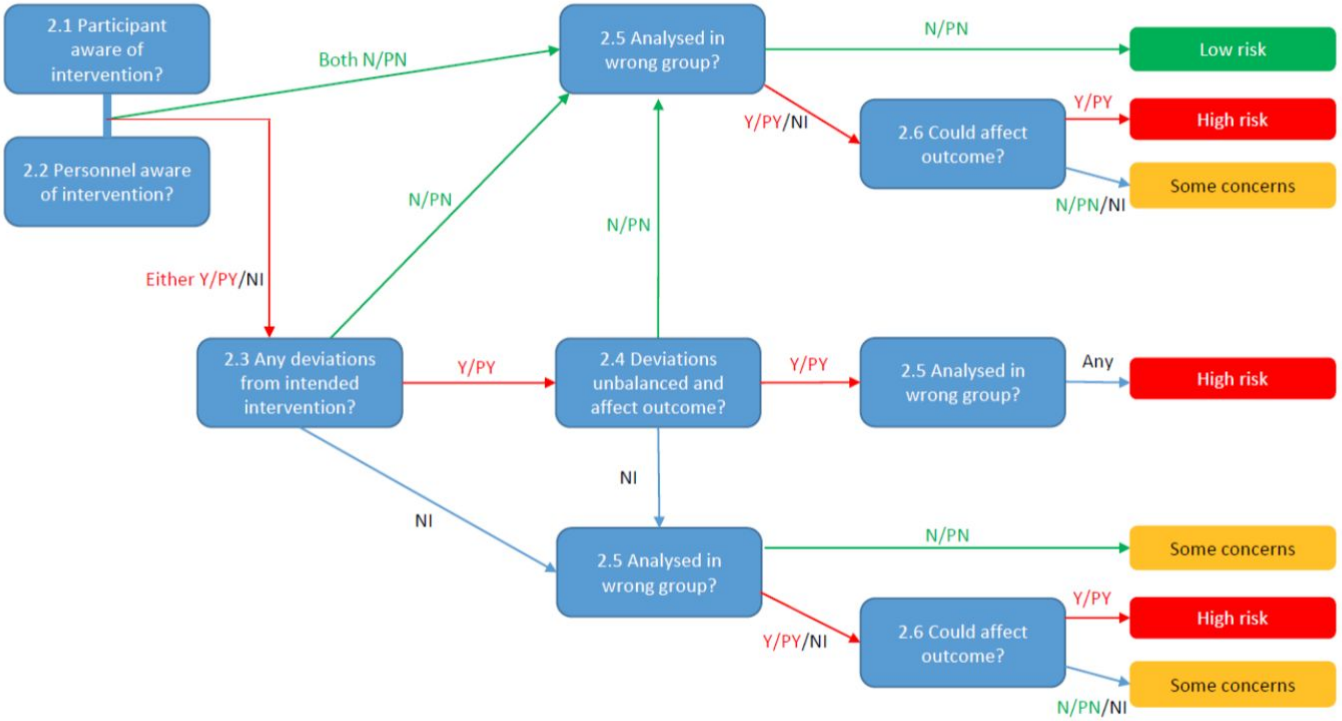
Primary outcomes

- Mental health and well-being of recipients (of MHFA), measured by a validated measure
- Mental health service usage, measured by objective service records
- Adverse effects of MHFA, for example, documented examples of inappropriate advice, adverse impacts on MH First Aiders

What worked well

		null / Unpredictable	
Bias due to deviations from intended interventions	2.1. Were participants aware of their assigned intervention during the trial?	Y / PY / PN / N / NI	
	2.2. Were carers and trial personnel aware of participants' assigned intervention during the trial?	Y / PY / PN / N / NI	
	2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention beyond what would be expected in usual practice?	NA / Y / PY / PN / N / NI	There was a low take-up of the online course in the intervention group. Authors state that 'twenty (74.1%) participants registered and created an account to access the MHFA eLearning course. Fourteen completed the introductory module; 13 completed the depression module; 12 completed the anxiety problems and eating disorders modules; with 11 completing all modules... 10 participants reported using the MHFA manual and/or supplementary booklet, and 11 watched and/or listened to all (n=6) or at least one (n=5) of the audio/visual media embedded within the eLearning course.' However this low take-up rate reflects how the intervention would work in day-to-day practice.
	2.4. If Y/PY to 2.3: Were these deviations from intended intervention unbalanced between groups *and* likely to have affected the outcome?	NA / Y / PY / PN / N / NI	
	2.5 Were any participants analysed in a group different from the one to which they were assigned?	Y / PY / PN / N / NI	
	2.6 If Y/PY/NI to 2.5: Was there potential for a substantial impact (on the estimated effect of intervention) of analysing participants in the wrong group?	NA / Y / PY / PN / N / NI	Not applicable
	Risk of bias judgement	Low / High / Some concerns	

Figure 2. Suggested algorithm for reaching risk of bias judgements for bias due to deviations from intended interventions (*effect of assignment to intervention*). This is only a suggested decision tree: all default judgements can be overridden by assessors.



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

Domain	Signalling questions	Response options	Description/Support for judgement
Bias arising from the randomization process	1.1 Was the allocation sequence random?	Y / PY / PN / N / NI	Students 'were randomly assigned to either the intervention or control group using computer generated automated randomisation and were notified of their intervention condition .... The computer generated randomisation and notification was implemented by a Research Assistant'
	1.2 Was the allocation sequence concealed until participants were recruited and assigned to interventions?	Y / PY / PN / N / NI	
	1.3 Were there baseline imbalances that suggest a problem with the randomization process?	Y / PY / PN / N / NI	No apparent baseline imbalances
	Risk of bias judgement	Low / High / Some concerns	
	Optional: What is the predicted direction of bias arising from the randomization process?	Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable	Not applicable

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No ‘other bias’

- Helpful to have all considerations specified
- No place for researcher allegiance/for profit bias

What didn’t work

Bias	Authors' judgement	Support for judgement
Bias arising from the randomisation process	Unclear risk	Some concerns. The authors report that 'random numbers were produced by a computer program and four clusters were randomly assigned to the intervention or control group (two clusters each group)'. It appears as if there was some pair-matching of clusters, as in each of the 5 institutions two clusters were created and then allocated randomly to intervention or control. It also appears that the clusters were combined to ensure clusters contained 9-18 participants. The number of participants in the intervention group (65) was considerably higher than the number in the control group (49).
Bias arising from the timing of identification and recruitment of individual participants in relation to timing of randomisation (CRCT)	Low risk	All the participants were identified before randomisation. However participants were invited to participate after randomisation of clusters. However, only 6 declined to participate. Baseline characteristics were balanced between the groups.
Bias due to deviations from intended interventions	Unclear risk	Some concerns. Participants and teachers aware of group allocation. There is no information about attrition from training, or fidelity to training model.
Bias due to missing outcome data	High risk	Attrition rates were high and there was greater attrition in the intervention group. ITT analyses carried out by the authors assumed that data were missing at random, which may not be the case.
Bias in measurement of the outcome Knowledge related outcomes	Unclear risk	
Bias in measurement of the outcome	High risk	As this was a subjective outcome it is likely that assessment would be influenced


Photo by Ocean Biggshott on Unsplash

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Outcome soup

Self reported contacts

WEMWBS

Perceived stigma

(Depression)

PHQ-9

Social distance (PTSD)

Beliefs about treatment

(Schizophrenia)

Knowledge Outcomes	Other Outcomes
Vignette recognition	Self-report mental health scales
Appropriate beliefs about helpfulness	Personal stigma
Knowledge quiz	Desire for social distance
	Self-reported contacts/help offered

MILITARY MEDICINE, 182, 1/2:e1576, 2017

Military Mental Health First Aid: Development and Preliminary Efficacy of a Community Training for Improving Knowledge, Attitudes, and Helping Behaviors

Nathaniel Vincent Mohatt, PhD†; Robert Boeckmann, PhD‡; Nicola Winkel, MPA*§; Dennis F. Mohatt, MA*; Jay Shore, MD†*

ABSTRACT Introduction: Persistent stigma, lack of knowledge about mental health, and negative attitudes toward treatment are among the most significant barriers to military service members and veterans seeking behavioral health care. With the high rates of untreated behavioral health needs among service members and veterans, identifying effective programs for reducing barriers to care is a national priority. This study adapted Mental Health First Aid (MHFA), an evidence-based program for increasing mental health knowledge, decreasing stigma, and increasing laypeople's confidence in helping and frequency of referring people in need, for military and veteran populations and pilot tested the adapted training program with 4 Army National Guard armories. Materials and Methods: A total of 176 community first responders (CFRs) participated in a comparative outcomes study, with 69 receiving the training and 107 participating in the control group. CFRs were individuals in natural positions within the Armory or home communities of

RoB for Mohatt 2017

Bias	Authors' judgement	Support for judgement
Bias arising from the randomisation process	High risk	No information is given on generation of the randomisation sequence, or on allocation concealment. There appears to be a baseline imbalance in terms of rurality. The armouries were matched on rurality. However 'of the intervention group, 50.7% were from a rural Armory, whereas 39.3% of the control group were from a rural Armory' There is no other information on baseline characteristics
Bias arising from the timing of identification and recruitment of individual participants in relation to timing of randomisation (CRCT)	High risk	There is a lack of information in the paper to judge the risk of bias in this domain. If participants were approached knowing their allocation, it is very likely that this affected recruitment. On balance, it is likely that recruitment happened after randomisation. Greater numbers were recruited in the control group than in the intervention group.
Bias due to deviations from intended interventions	Unclear risk	Some concerns. There is no information on attrition from training, or fidelity to the training model.
Bias due to missing outcome data	High risk	Attrition levels were very high. 22/69 were lost in the intervention group and 89/107 in the control group. The authors have not conducted an analysis to test the robustness of their findings to attrition.
Bias in measurement of the outcome Knowledge related outcomes	Unclear risk	
Bias in measurement of the outcome Other outcomes	High risk	As this was a subjective outcomes it is likely that assessment would be influenced by knowledge of the intervention received.
Bias in selection of the reported result	Low risk	There is no evidence of bias in this domain
Overall bias Knowledge related outcomes	Unclear risk	
Overall bias Other outcomes	High risk	High risk of bias in several domains.

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Conclusions

Cochrane

Data collection for RoB 2

Kerry Dwan
Statistical Editor, Cochrane

Data extraction options

Context: data extraction and RoB 2 based on written reports of trials (e.g. journal articles)

- Option 1: Assess RoB **separately** from data extraction
- Option 2: Assess RoB **while doing** data extraction
- Option 3: **Hybrid**: extract relevant information during data extraction, but assess RoB separately

Some notes on each of these…

Option 1: Assess RoB **separately** from data extraction

- Advantages
  - focus the mind on RoB
  - use the best software for data extraction and the best software for RoB
  - use the best personnel for data extraction and the best personnel for RoB

- Disadvantages
  - requires at least two ‘looks’ at the articles

Option 2: Assess RoB **while doing** data extraction

- Advantages
  - ‘one look’ at the paper [though unlikely in practice…]

- Disadvantages
  - currently no software to facilitate this

Option 3: **Hybrid**: extract relevant information during data extraction, but assess RoB separately

- Advantages
  - 'one look' at the paper [though unlikely in practice…]
  - use the best software for data extraction and the best software for RoB
  - use the best personnel for data extraction and the best personnel for RoB may be most efficient for multiple reports of the study

- Disadvantages
  - Probably the RoB assessment will require further looks at the paper

- The rest of the presentation addresses this third option
  - This is ongoing work

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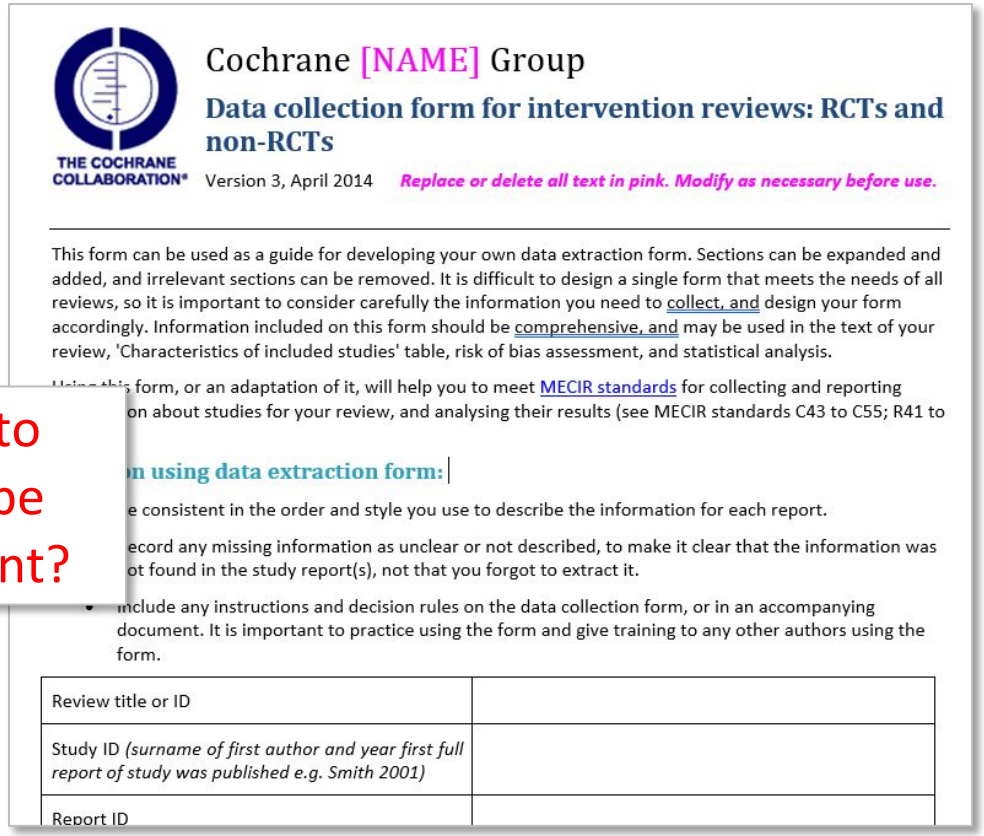


Cochrane [NAME] Group

Data collection form for intervention reviews: RCTs and non-RCTs

THE COCHRANE COLLABORATION®

Version 3, April 2014 *Replace or delete all text in pink. Modify as necessary before use.*

This form can be used as a guide for developing your own data extraction form. Sections can be expanded and added, and irrelevant sections can be removed. It is difficult to design a single form that meets the needs of all reviews, so it is important to consider carefully the information you need to collect, and design your form accordingly. Information included on this form should be comprehensive, and may be used in the text of your review, 'Characteristics of included studies' table, risk of bias assessment, and statistical analysis.

Using this form, or an adaptation of it, will help you to meet MECIR standards for collecting and reporting information about studies for your review, and analysing their results (see MECIR standards C43 to C55; R41 to

Information using data extraction form:

- Be consistent in the order and style you use to describe the information for each report.
- Record any missing information as unclear or not described, to make it clear that the information was not found in the study report(s), not that you forgot to extract it.
- Include any instructions and decision rules on the data collection form, or in an accompanying document. It is important to practice using the form and give training to any other authors using the form.

Review title or ID	
Study ID *(surname of first author and year first full report of study was published e.g. Smith 2001)*	
Report ID	

How might this be modified to collect information that will be useful for the RoB 2 assessment?

Risk of Bias assessment

(See Handbook Chapter 8. Additional domains may be added for non-randomised studies.)

Domain	Risk of bias Low High Unclear	Support for judgement *(include direct quotes where available with explanatory comments)*	Location in text or source *(pg & ¶/fig/table/other)*
Allocation concealment *(selection bias)*	☐ ☐ ☐		
Blinding of participants and personnel *(performance bias)*	☐ ☐ ☐	Outcome group: All/	
(if separate judgement by outcome(s) required)	☐ ☐ ☐	Outcome group:	
Blinding of outcome assessment *(detection bias)*	☐ ☐ ☐	Outcome group: All/	
(if separate judgement by outcome(s) required)	☐ ☐ ☐	Outcome group:	
Incomplete outcome data *(attrition bias)*	☐ ☐ ☐	Outcome group: All/	
(if separate		Outcome group:	

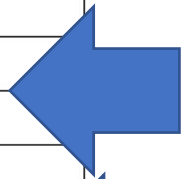
Drop this in favour of a dedicated tool

(e.g. Bristol's Excel or web-based system for now)

Some aspects are covered already

3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?	This question distinguishes between situations in which (i) missingness in the outcome could depend on its true value (assessed as 'Some concerns') from those in which (ii) it is likely that missingness in the outcome depended on its true value (assessed as 'High'). Four reasons for answering 'Yes' are: 1. Differences between intervention groups in the proportions of missing outcome data. If there is a difference between the effects of the experimental and comparator interventions on the outcome, and the missingness in the outcome is influenced by its true value, then the proportions of missing outcome data are likely to differ between intervention groups. Therefore, such a difference may indicate a risk of bias due to missing outcome data. For time-to-event-data, the analogue is that rates of censoring (loss to follow-up) differ between the intervention groups. 2. Reported reasons for missing outcome data provide evidence that missingness in the outcome depends on its true value; 3. Reported reasons for missing outcome data differ between the intervention groups; 4. The circumstances of the trial make it likely that missingness in the outcome depends on its true value. For example, in trials of interventions to treat schizophrenia it is widely understood that continuing symptoms make drop out more likely.

Results	Intervention		Comparison		
	No. with event	Total in group	No. with event	Total in group	
Any other results reported *(e.g. odds ratio, risk difference, CI or P value)*					
No. missing participants					
Reasons missing					
No. participants moved from other group					
Reasons moved					
Unit of analysis *(by individuals, cluster/groups or body*					



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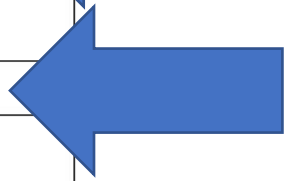

NB this is relevant to assessment in ‘Deviations from intended intervention’ domain

General Information

Date form completed *(dd/mm/yyyy)*	
Name/ID of person extracting data	
Reference citation	
Study author contact details	
Publication type *(e.g. full report, abstract, letter)*	
Notes:	

Some aspects can be added

General Information

Date form completed *(dd/mm/yyyy)*	
Name/ID of person extracting data	
Reference citation	
Trial registration details	
Study author contact details	
Which of the following sources were obtained? (tick as many as apply)	☐ Journal article(s) with results of the trial ☐ Trial protocol ☐ Statistical analysis plan (SAP) ☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record) ☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record) ☐ "Grey literature" (e.g. unpublished thesis) ☐ Conference abstract(s) about the trial ☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package) ☐ Research ethics application ☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research) ☐ Personal communication with trialist ☐ Personal communication with the sponsor

Characteristics of included studies

Methods

	Descriptions as stated in report/paper	Location in text or source *(pg & ¶/fig/table/other)*
Aim of study *(e.g. efficacy, equivalence, pragmatic)*		
Design *(e.g. parallel, crossover, non-RCT)*		
Unit of allocation *(by individuals, cluster/ groups or body parts)*		
Start date		
End date		

Some aspects can be added

Characteristics of included studies

Methods

	Descriptions as stated in report/paper	Location in text or source *(pg & ¶/fig/table/other)*
Aim of study *(e.g. efficacy, equivalence, pragmatic)*		
Design *(e.g. parallel, crossover, non-RCT)*		
Unit of allocation *(by individuals, cluster/ groups or body parts)*		
Sequence generation		
Allocation concealment		
Blinding of participants, carers and personnel		
Start date		

Participants

	Description *Include comparative information for each intervention or comparison group if available*	Location in text or source *(pg & ¶/fig/table/other)*
Population description *(from which study participants are drawn)*		
Setting *(including location and social context)*		
Inclusion criteria		
Exclusion criteria		
Method of recruitment of participants *(e.g. phone, mail, clinic patients)*		
Informed consent obtained	☐ Yes ☐ No ☐ Unclear	
Total no. randomised *(or total pop. at start of study for non-RCTs)*		
Clusters *(if applicable, no., type, no. people per cluster)*		
Baseline imbalances		

Some aspects can be amended slightly

Participants

	Description *Include comparative information for each intervention or comparison group if available*	Location in text or source *(pg & ¶/fig/table/other)*
Population description *(from which study participants are drawn)*		
Setting *(including location and social context)*		
Inclusion criteria		
Exclusion criteria		
Method of recruitment of participants *(e.g. phone, mail, clinic patients)*		
Informed consent obtained		
Total no. randomised *(or total pop. at start of study for non-RCTs)*		
Clusters *(if applicable, no., type, no. people per cluster)*		
Baseline imbalances *(note particularly if they might raise concerns about the randomization process)*		

Baseline imbalances *(note particularly if they might raise concerns about the randomization process)*

Other aspects are more challenging

2.3. If Y/PY/NI to 2.1 or 2.2: Were important co-interventions balanced across intervention groups?	Important co-interventions are the interventions or exposures: (1) that are inconsistent with the trial protocol; (2) that trial participants might receive with or after starting their assigned intervention; (3) that may be related to the intervention received; and (4) that are prognostic for the outcome. Bias will arise if there is imbalance in such co-interventions between the intervention groups.

This requires detailed information on the trial protocol, which is often not available in a trial report.

Review authors should try and articulate this – should they do it while extracting data?

(This applies only to the effect of adhering to intervention, so shouldn't be an issue for most)

Cochrane

Addressing RoB 2 implementation

PART 2 (11:00-12:30)

Cochrane

RoB 2 rollout

Presented by Toby Lasserson
Senior Editor (Methods)
Editorial and Methods Department

‘Successful implementation of ROB2 for all new reviews and updates **initiated** after the end of 2019’

Cochrane

Implementing methods

Nobody has all the answers

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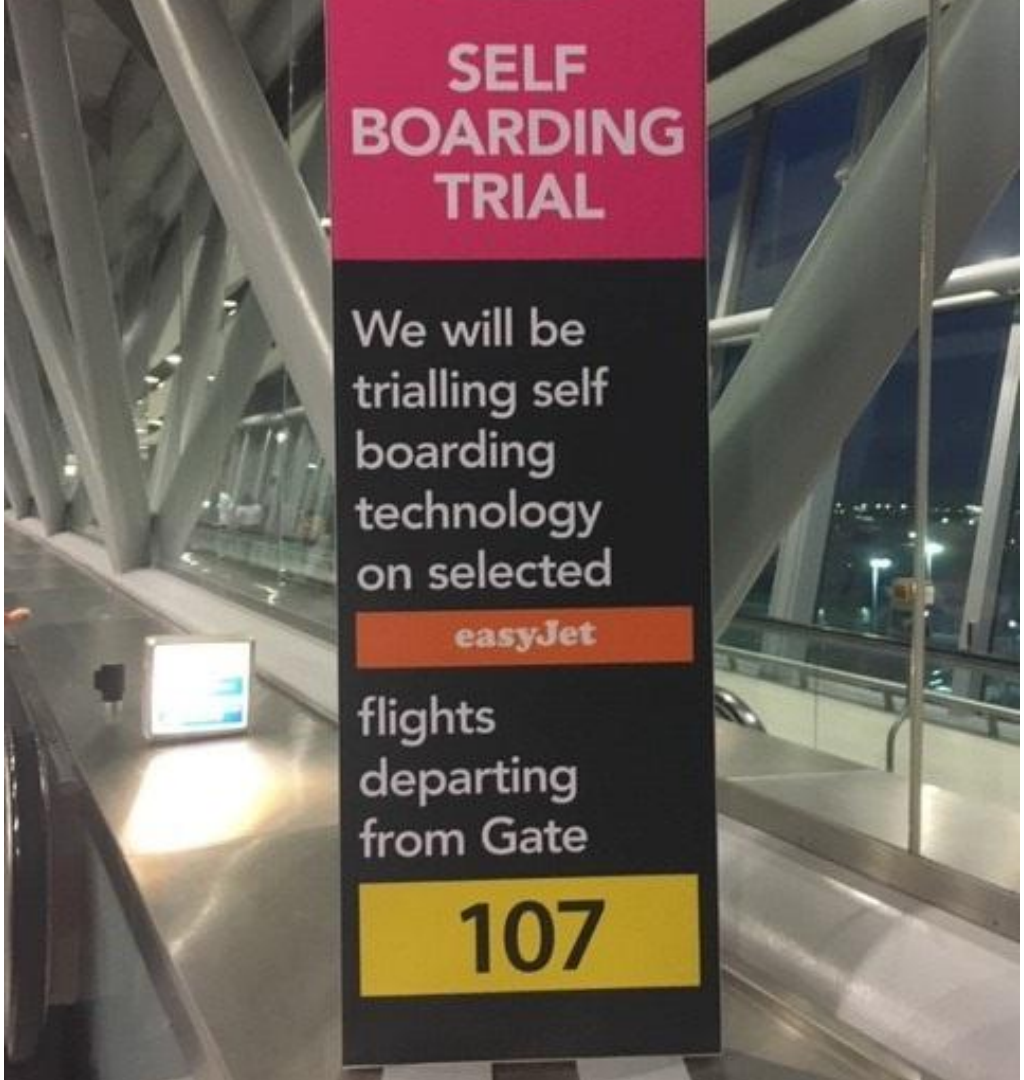
SELF BOARDING TRIAL
We will be trialling self boarding technology on selected
easyJet
flights departing from Gate
107

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Rollout

Last RoB rollout should teach us about how we do this in future

Technology has changed review process, learning & communication

Network structure offers opportunity to share practice & experiences

Quality assessment (pre-2008)

Allocation concealment	B

Limited to assessment of allocation concealment

Heterogeneity & little validity of aggregate scores (Jüni 1999)

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2008 - First RoB 1 table

Outcome reporting/other bias?

Risk of bias table

Item	Authors' judgement	Support for judgement
Adequate sequence generation?	Yes	Computer-generated randomisation schedule.
Allocation concealment?	Yes	Third party not involved with primary study.
Blinding?	Yes	Open label study design not a threat to primary outcomes in this review.
Incomplete outcome data addressed? OCS treated exacerbations	Unclear	ITT analysis described; no explicit details on how withdrawals were handled
Incomplete outcome data addressed? Hospital admission	Unclear	ITT analysis described; no explicit details on how withdrawals were handled

Differentiation between outcomes for attrition but not blinding?

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View on implementation from 1819

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View on implementation from 2019

Learning opportunities more varied

Evidence on implementation before deciding on rollout

Change in approach & potential impact on reviews should be reason for collaborative approach

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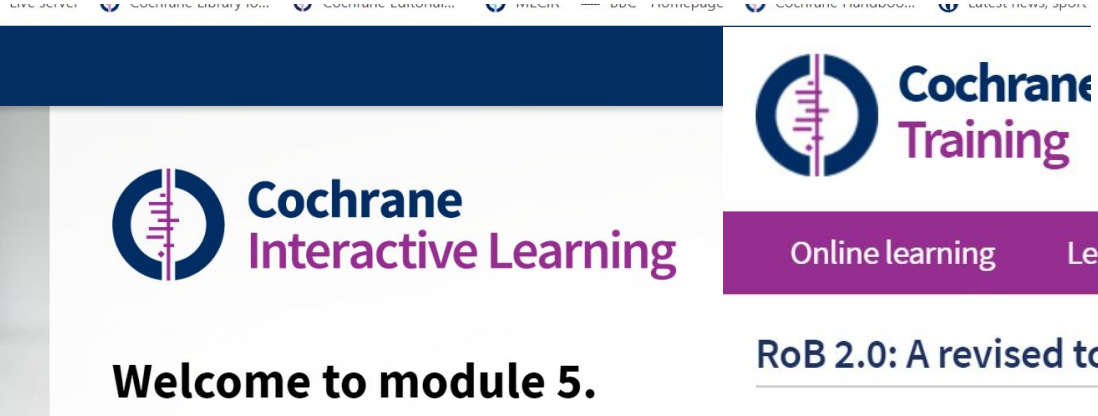
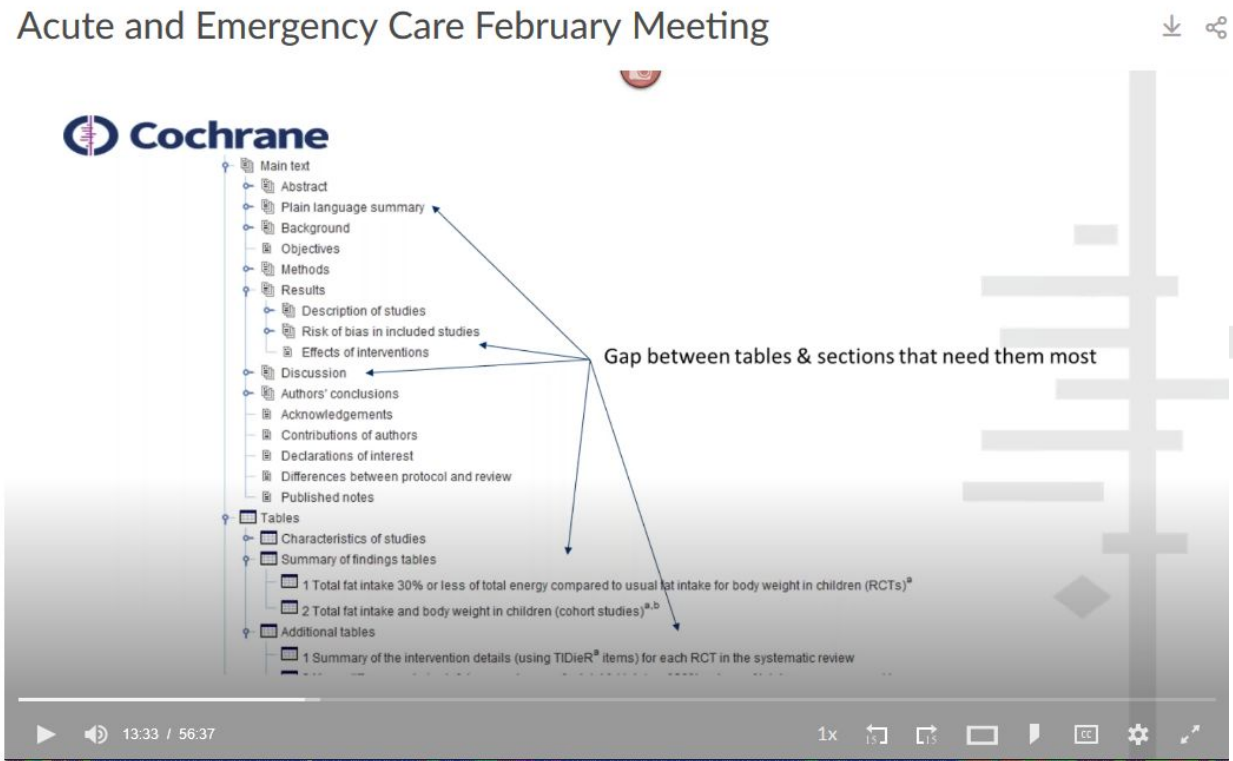
Training

F2F - 2019 Methods Training Event on RoB in Bristol

Interactive learning materials & SATMs



GoToMeeting changed my (working) life



RoB 2 pilot

Invite cohort of volunteer author teams to use RoB2 in RevMan Web

Regular check ins with dedicated methods & tech support from EMD & ITS; CRG & Network Eds welcome

Opportunity for CRG, Networks, CET work through challenges of adopting new method

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RoB 2 pilot

Gathering:

- Barriers/facilitators for terminology, process & technology
- How to store signalling questions
- Impact on other parts of review (GRADE - just RoB?)
- Examples
- Other review types can benefit

Identify & manage dependencies/risk

Inform development of considerations for protocols & updates

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Options to scale up from pilot

Extending rollout from initial cohort

Incremental within Networks?

- Targeted support for editors & authors
- Encourage enthusiastic adopters
- 2 changes in one (new method & software)

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Surgical Safety Checklist

World Health Organization | Patient Safety
A World Alliance for Safer Health Care

Before induction of anaesthesia

(with at least nurse and anaesthetist)

Has the patient confirmed his/her identity, site, procedure, and consent?
- ☐ Yes

Is the site marked?
- ☐ Yes
- ☐ Not applicable

Is the anaesthesia machine and medication check complete?
- ☐ Yes

Is the pulse oximeter on the patient and functioning?
- ☐ Yes

Does the patient have a:

Known allergy?
- ☐ No
- ☐ Yes

Difficult airway or aspiration risk?
- ☐ No
- ☐ Yes, and equipment/assistance available

Before skin incision

(with nurse, anaesthetist and surgeon)

- ☐ **Confirm all team members have introduced themselves by name and role.**
- ☐ **Confirm the patient's name, procedure, and where the incision will be made.**

Has antibiotic prophylaxis been given within the last 60 minutes?
- ☐ Yes
- ☐ Not applicable

Anticipated Critical Events

To Surgeon:
- ☐ What are the critical or non-routine steps?
- ☐ How long will the case take?
- ☐ What is the anticipated blood loss?

To Anaesthetist:
- ☐ Are there any patient-specific concerns?

To Nursing Team:
- ☐ Has sterility (including indicator results) been confirmed?
- ☐ Are there equipment issues or any concerns?

Is essential imaging displayed?

Before patient leaves operating room

(with nurse, anaesthetist and surgeon)

Nurse Verbally Confirms:
- ☐ The name of the procedure
- ☐ Completion of instrument, sponge and needle counts
- ☐ Specimen labelling (read specimen labels aloud, including patient name)
- ☐ Whether there are any equipment problems to be addressed

To Surgeon, Anaesthetist and Nurse:
- ☐ What are the key concerns for recovery and management of this patient?

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Implementation in RevMan Web

Presented by Rebecka Hall
Product Owner of RevMan
Information and Technology Services

Cochrane

Bias	Authors' judgement	Support for judgement
Bias arising from the randomisation process	Unclear risk	Some concerns. The authors report that 'random numbers were produced by a computer program and four clusters were randomly assigned to the intervention or control group (two clusters each group)'. It appears as if there was some pair-matching of clusters, as in each of the 5 institutions two clusters were created and then allocated randomly to intervention or control. It also appears that the clusters were combined to ensure clusters contained 9-18 participants. The number of participants in the intervention group (65) was considerably higher than the number in the control group (49).
Bias arising from the timing of identification and recruitment of individual participants in relation to timing of randomisation (CRCT)	Low risk	All the participants were identified before randomisation. However participants were invited to participate after randomisation of clusters. However, only 6 declined to participate. Baseline characteristics were balanced between the groups.
Bias due to deviations from intended interventions	Unclear risk	Some concerns. Participants and teachers aware of group allocation. There is no information about attrition from training, or fidelity to training model.
Bias due to missing outcome data	High risk	Attrition rates were high and there was greater attrition in the intervention group. ITT analyses carried out by the authors assumed that data were missing at random, which may not be the case.
Bias in measurement of the outcome Knowledge related outcomes	Unclear risk	
Bias in measurement of the outcome	High risk	As this was a subjective outcome it is likely that assessment would be influenced

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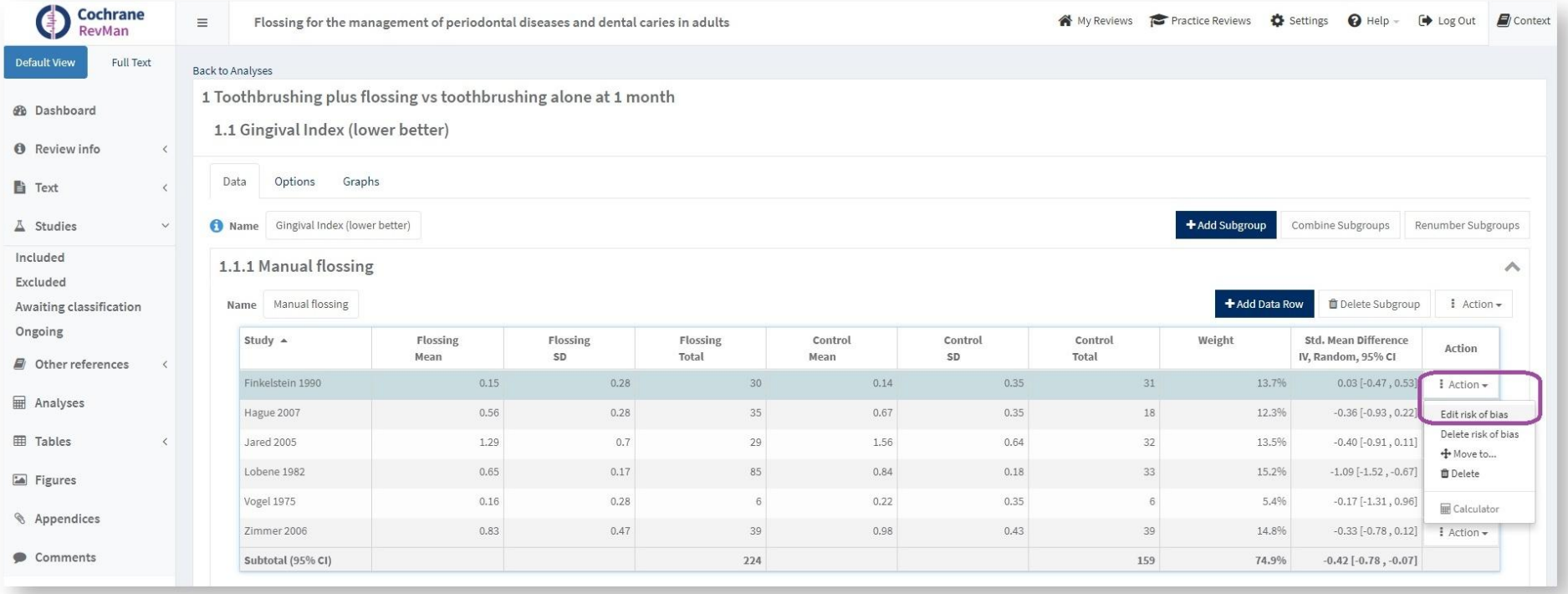
Risk of Bias 2.0 in RevMan Web



Study	Flossing Mean	Flossing SD	Flossing Total	Control Mean	Control SD	Control Total	Weight	Std. Mean Difference IV, Random, 95% CI	Action
Finkelstein 1990	0.15	0.28	30	0.14	0.35	31	13.7%	0.03 [-0.47 , 0.53]	Action
Hague 2007	0.56	0.28	35	0.67	0.35	18	12.3%	-0.36 [-0.93 , 0.22]	
Jared 2005	1.29	0.7	29	1.56	0.64	32	13.5%	-0.40 [-0.91 , 0.11]	
Lobene 1982	0.65	0.17	85	0.84	0.18	33	15.2%	-1.09 [-1.52 , -0.67]	
Vogel 1975	0.16	0.28	6	0.22	0.35	6	5.4%	-0.17 [-1.31 , 0.96]	
Zimmer 2006	0.83	0.47	39	0.98	0.43	39	14.8%	-0.33 [-0.78 , 0.12]	Action
Subtotal (95% CI)			**224**			**159**	**74.9%**	**-0.42 [-0.78 , -0.07]**	

Back to Analyses 1.1 Trainee Mental Health: Up to 6 months

Risk of Bias: Suzuki 2014

Results being assessed

1.1 Trainee Mental Health: Up to 6 months

Caffeine Events	Caffeine Total	Decaf Events	Decaf Total	Risk Ratio M-H, Fixed, 95% CI
2	31	10	34	0.22 [0.05 , 0.92]

Bias arising from the randomization process

This is a study-level judgement, changes made here apply to all results within the study

Judgement

Low risk of bias | **Some concerns** | High risk of bias

Support for judgement

The authors report that 'random numbers were produced by a computer program and four clusters were randomly assigned to the intervention or control group (two clusters each group)'. It appears as if there was some pair-matching of clusters, as in each of the 5 institutions two clusters were created and then allocated randomly to intervention or control. It also appears that the clusters were combined to ensure clusters contained 9-18 participants. The number of participants in the intervention group (65) was considerably higher than the number in the control group (49).

Bias due to deviations from intended interventions

Judgement

Low risk of bias | **Some concerns** | High risk of bias

Support for judgement

Participants and teachers aware of group allocation. There is no information about attrition from training, or fidelity to training model.

Training materials in the Knowledge base to support the pilot

How to use Risk of bias 2.0 (RoB 2.0) tool in RevMan Web

Created by Dario Sambunjak, last modified on Feb 07, 2019

1. Switch to RoB 2.0

For the piloting of RoB 2.0 integration in RevMan Web (RMW), your review in RMW will be switched to RoB 2.0 tool by the RMW developers. (Eventually, users themselves will be able to select between RoB 1.0 and RoB 2.0)

To check that your review is set up for using RoB 2.0, go to Included studies, then click on the 'Risk of Bias Setup' button.

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Feedback so far

Different ways of simplifying input of judgments

- Automatic transfer of data
- Re-using judgments from another result
- Improved navigation between assessments for different results within the same analysis

Supporting results where meta-analysis is not possible

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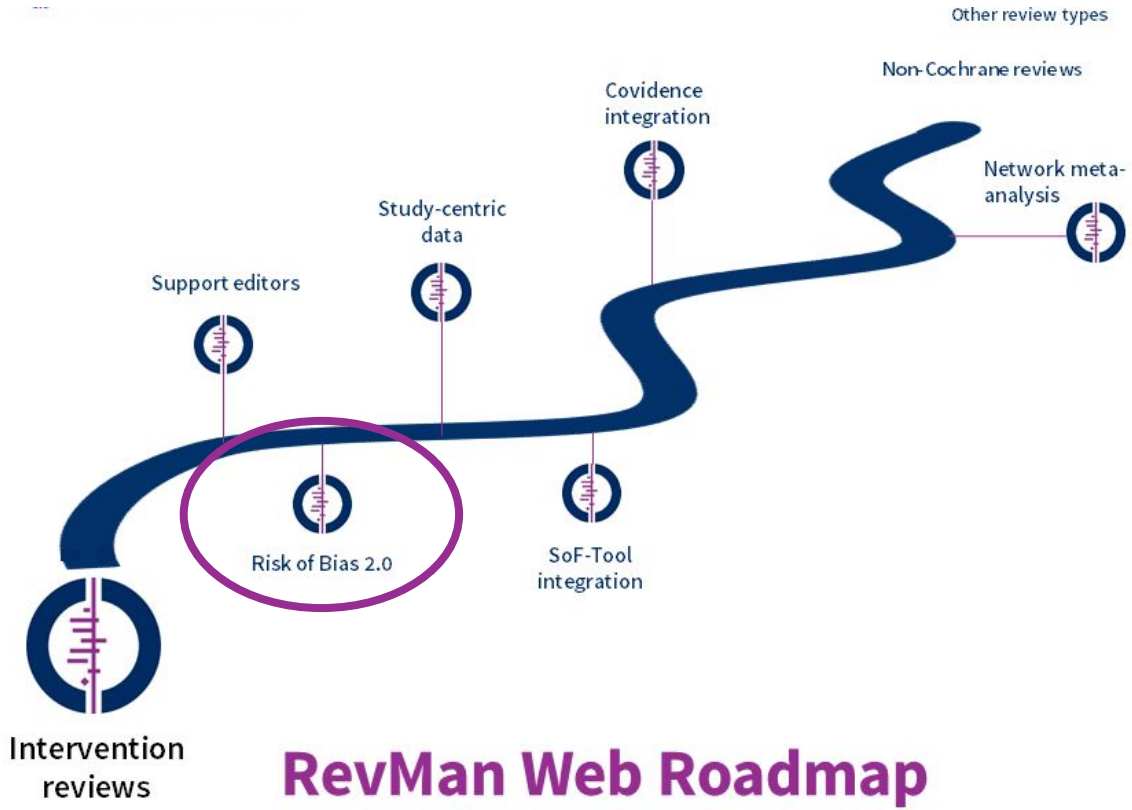

RevMan Web Roadmap

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Roll-out RevMan Web

Stage	Timing
Compatible with RevMan 5 for all features and reviews	Until basic functionality is reached
Break RevMan 5 compatibility for certain features. E.g. Risk of Bias 2.0	Basic functionality is in place for both authors and editors
Features that break RevMan 5 compatibility are default for new reviews	Joint decision with CRGs, EMD and ITS
Remove RevMan 5 check-out and retire RevMan 5	

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Save your ideas for the group exercise!

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Implementation in the Cochrane Library

Presented by Toby Lasserson
Senior Editor (Methods)
Editorial and Methods Department

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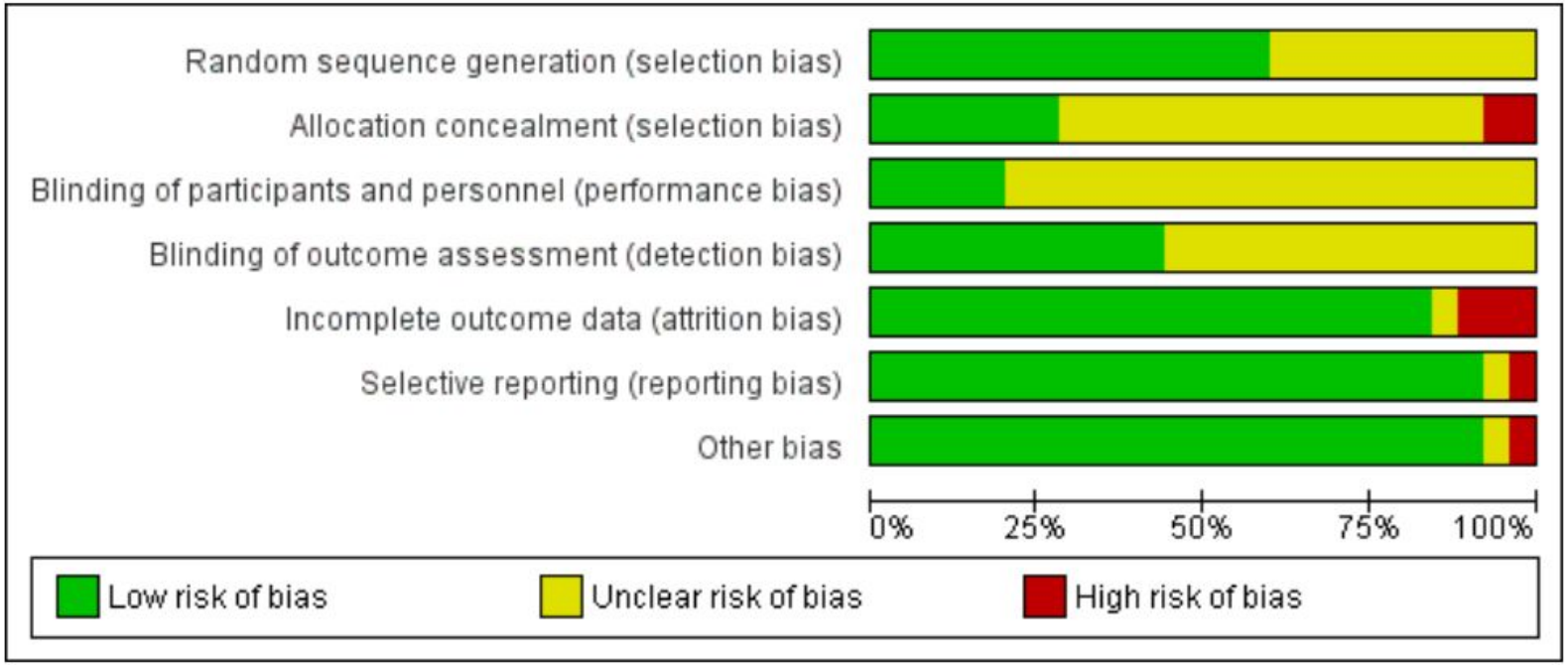
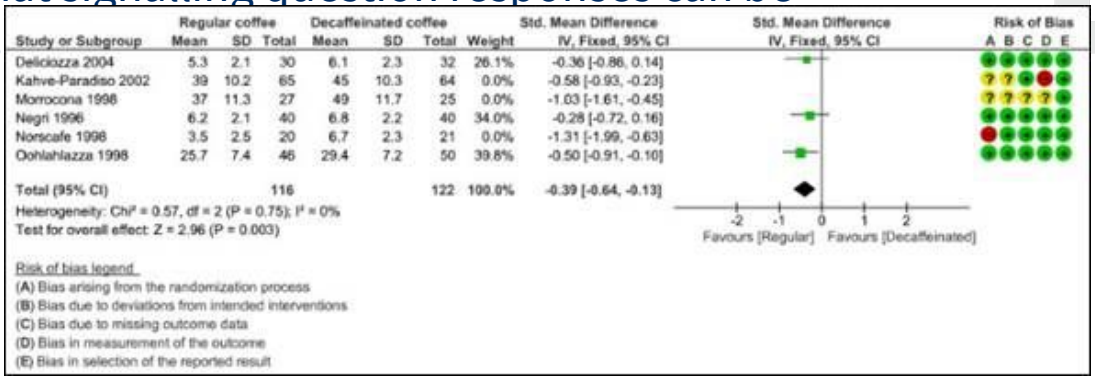
Current view



bias)

Proposals for how it will look

- ‘Risk of bias’ new home
  - No longer within the Characteristics of studies table
  - Forest plots and traffic lights default
  - Supplementary files mean that signalling question responses can be published alongside reviews



Potential changes under discussion

Click on bais header to see the **Support for Judgement** for that bias

Reset table

Study	Bias arising from the randomisation process	Bias due to deviations from intended interventions	Bias due to missing outcome data	Bias in measurement of the outcome Knowledge related outcomes	Bias in measurement of the outcome Other outcomes	Bias in selection of the reported result	Overall bias Knowledge related outcomes	Overall bias Other outcomes
Lasserson, 2019	Some concerns	Some concerns	Some concerns	Some concerns	Some concerns	Some concerns	Some concerns	Some concerns
	Not all of the outcomes reported in the paper were pre-specified in the Trial Registry entry. The outcome of the types of help offered to students is listed in the Trial Registry, but not in the paper.							
Lasserson, 2019	Some concerns	Some concerns	Some concerns	Some concerns	Some concerns	Some concerns	Some concerns	Some concerns
	Not all of the outcomes reported in the paper were pre-specified in the Trial Registry entry. The outcome of the types of help offered to students is listed in the Trial Registry, but not in the paper.							

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Tools, guidance, training and support: breakout discussions

Presented by Ella Flemyng
Methods Implementation Coordinator
Editorial and Methods Department

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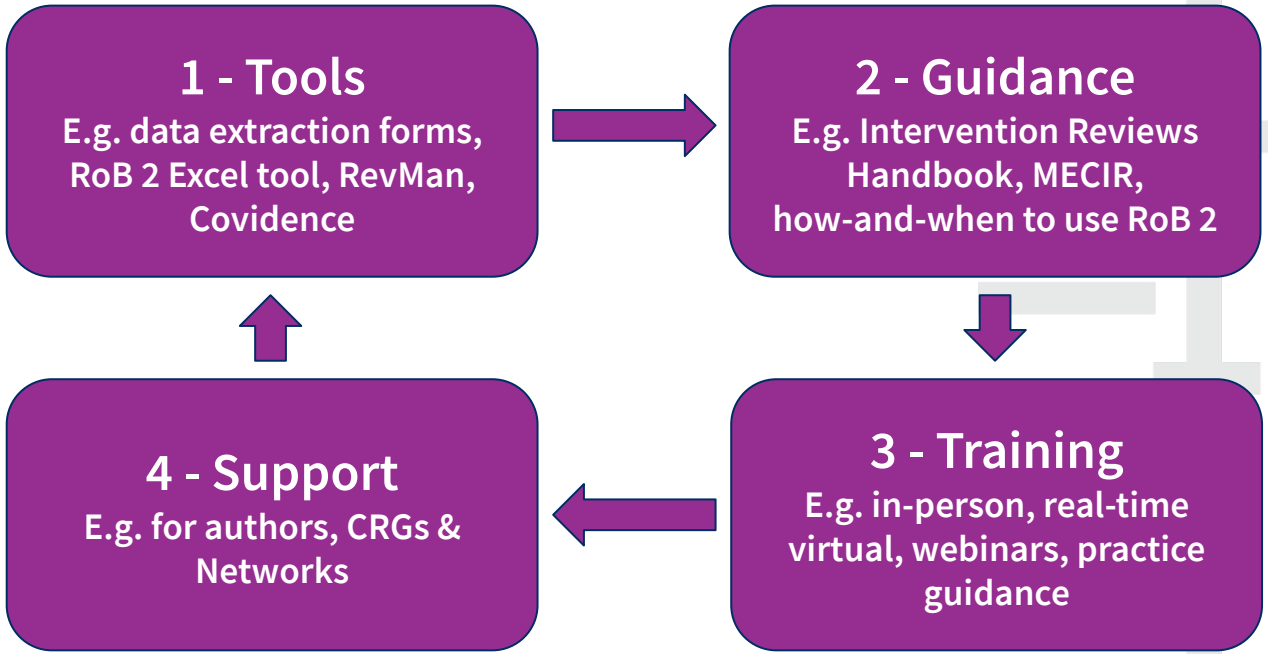
What do you need to be able to use RoB 2?

Discuss all four categories on your tables.

One piece of paper per category and add all ideas.

Select one priority idea per category.



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Addressing RoB 2 implementation

Thank you!

Presenters: Kerry Dwan, Ella Flemyng, Rebecka Hall, Julian Higgins, Toby Lasserson, Rachel Richardson.

Any additional questions or feedback, email methods@cochrane.org