Cochrane Training

Cochrane Learning live webinar: May 7th 2020: Introduction to RoB2

Introduction to RoB 2

Julian Higgins, Jonathan Sterne and Tess Moore
Population Health Sciences
Bristol Medical School

With special thanks to Jelena Savović, Matthew Page, Roy Elbers, Barney Reeves, Asbjørn Hróbjartsson, Isabelle Boutron, Luke McGuinness, Vincent Cheng and all RoB 2 collaborators

Trusted evidence.
Informed decisions.
Better health.

RoB 2: contributors

Core group:

- Julian Higgins, Jonathan Sterne, Jelena Savović, Matthew Page, Asbjørn Hróbjartsson, Isabelle Boutron, Barney Reeves, Roy Elbers

Contributors:

- Natalie Blencowe, Marion Campbell, Mike Campbell, Christopher Cates, Vincent Cheng, Rachel Churchill, Mark Corbett, Nicky Cullum, Francois Curtin, Amy Drahota, Sandra Eldridge, Jonathan Emberson, Bruno Giraudeau, Jeremy Grimshaw, Miguel Hernán, Sally Hopewell, Daniela Junqueira, Peter Jüni, Jamie Kirkham, Toby Lasserson, Tianjing Li, Alexandra McAleenan, Stephen Senn, Sasha Shepperd, Ian Shrier, Nandi Siegfried, Lesley Stewart, Kate Tilling, Ian White, Penny Whiting

Further acknowledgements:

- Doug Altman, Henning Keinke Andersen, Mike Clarke, Jon Deeks, Sharea Ijaz, Geraldine MacDonald, Richard Morris, Mona Nasser, Nishith Patel, Jani Ruotsalainen, Holger Schünemann, Jayne Tierney

Funding

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- The original tool was developed with support from a **Cochrane Quality Improvement Project** grant and its evaluation and early revisions by the **Cochrane Methods Innovation Fund**

Session outline

- From the original Cochrane risk of bias tool to RoB 2
  - Introductory and historical remarks
  - Why RoB 2?
- An overview of RoB 2
  - Domains of bias covered
  - Specifying the effect of interest
  - Signalling questions and risk of bias judgements
  - Resources available
- Using RoB 2 in a Cochrane Review
- What to write about in a protocol
- Questions

What is bias?

Systematic error or deviation from the truth

- a study may systematically overestimate or underestimate the effect of intervention
  - beyond random error (sampling variation)

- our focus is on **internal validity**
  - whether the result reflects what the study aims to estimate
  - distinct from **external validity** (generalizability): the relevance of the study to external situations

Bias is not the same as…

Low quality

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

Poor reporting

- good methods may have been used but not well reported
- inappropriate methods may have been used but not clearly described

Imprecision

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

Quality scales and checklists

- many scales and checklists are available
  - but many include criteria not related to bias
- different scales lead to different conclusions
- **numerical scales are not justified**
  - There is no empirical basis for weighting different items

Quality scales should not be used in Cochrane

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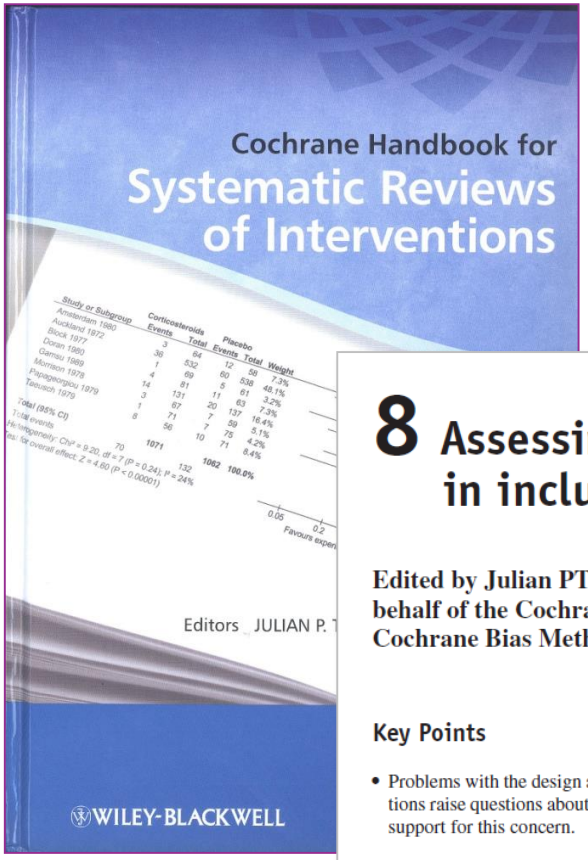

8 Assessing risk of bias in included studies

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.

BMJ 2011; 343: d5928

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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Poll

Have you used the original (2008 or 2011) version of the Cochrane risk of bias tool?

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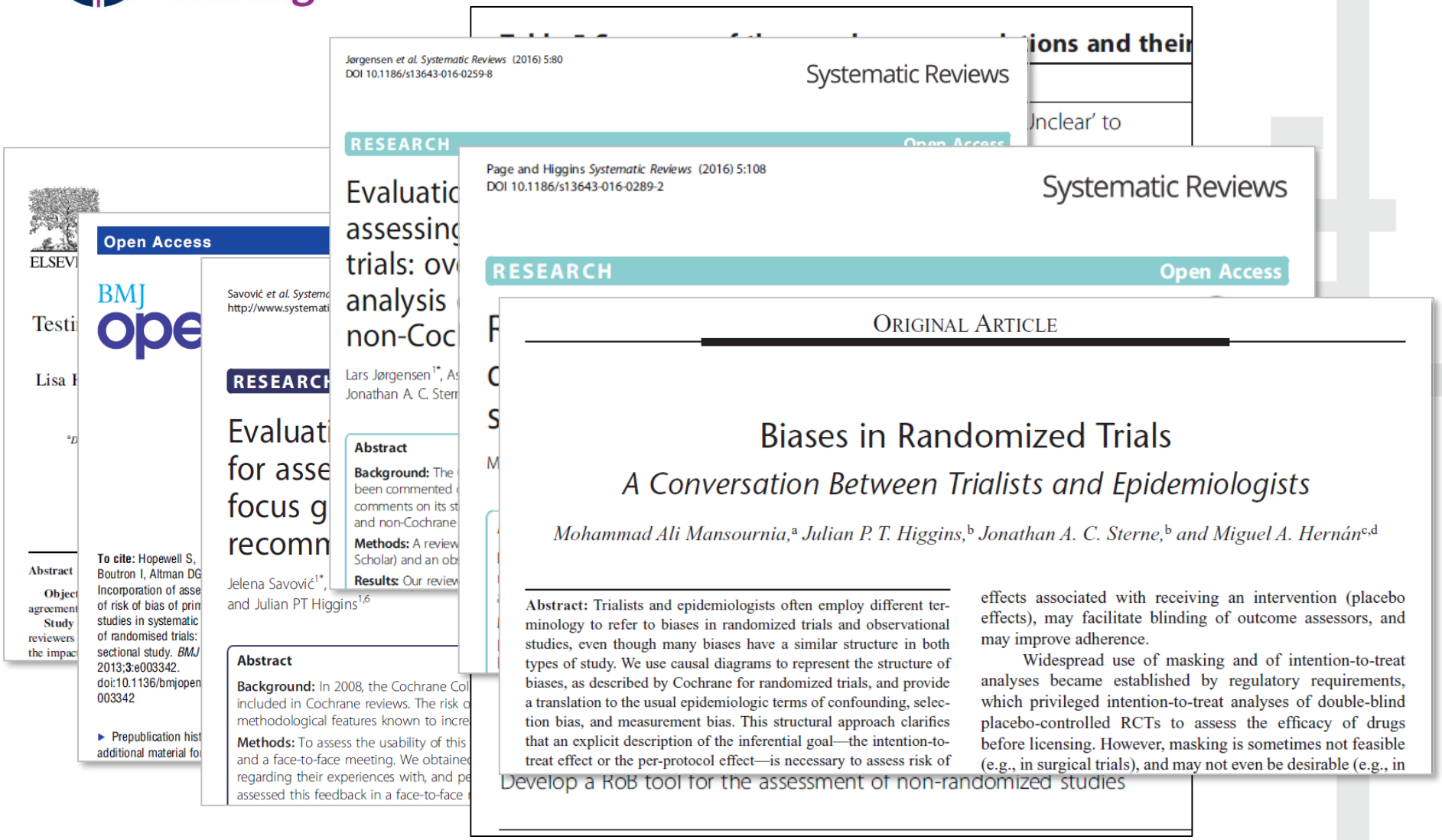

Some issues raised with existing tool

- Used simplistically: guidance not followed
- Used inconsistently: domains added or removed
- Modest agreement rates
- Overuse of “unclear” judgement, itself ambiguous
- Some domains too complex, particularly incomplete outcome data and selective reporting
- Challenges with unblinded trials
- Not well suited to cross-over trials or cluster-randomized trials
- No overall risk of bias judgement

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Why a new version?

More appropriate

- more comprehensive
- versions appropriate to cluster-randomized trials, cross-over trials

More usable and (we hope) reliable

- more structure to improve consistency
- 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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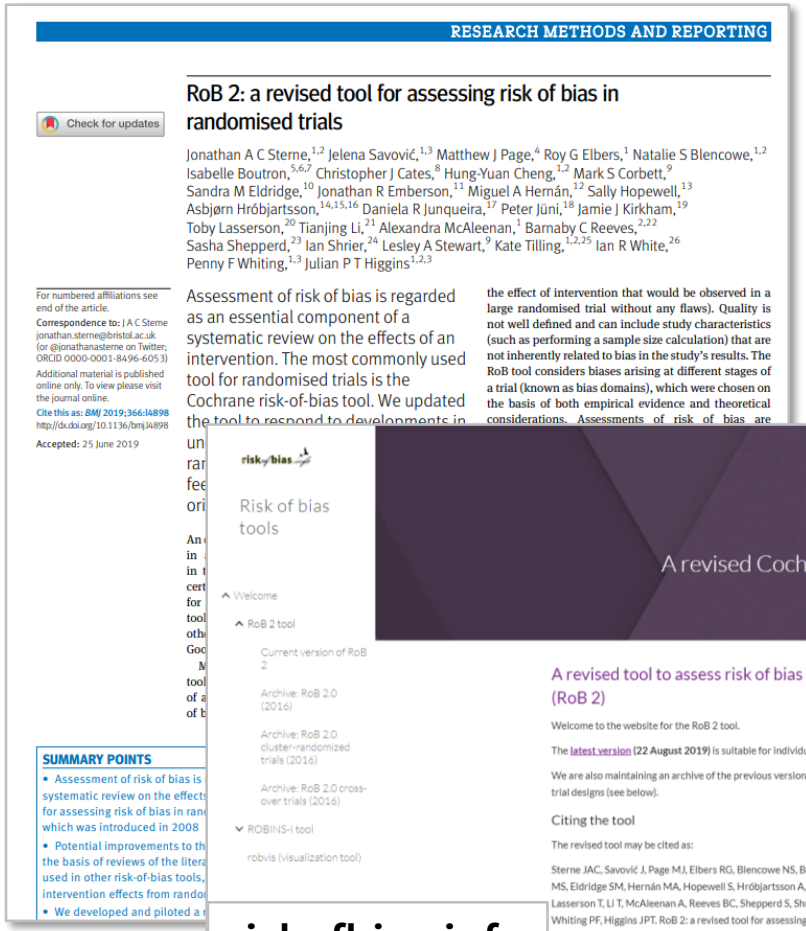


RESEARCH METHODS AND REPORTING

RoB 2: a revised tool for assessing risk of bias in randomised trials

Check for updates

Jonathan A C Sterne,[1,2] Jelena Savović,[1,3] Matthew J Page,[4] Roy G Elbers,[1] Natalie S Blencowe,[1,2] Isabelle Boutron,[5,6,7] Christopher J Cates,[8] Hung-Yuan Cheng,[1,2] Mark S Corbett,[9] Sandra M Eldridge,[10] Jonathan R Emberson,[11] Miguel A Hernán,[12] Sally Hopewell,[13] Asbjørn Hróbjartsson,[14,15,16] Daniela R Junqueira,[17] Peter Jüni,[18] Jamie J Kirkham,[19] Toby Lasserson,[20] Tianjing Li,[21] Alexandra McAleenan,[1] Barnaby C Reeves,[2,22] Sasha Shepperd,[23] Ian Shrier,[24] Lesley A Stewart,[9] Kate Tilling,[1,2,25] Ian R White,[26] Penny F Whiting,[1,3] Julian P T Higgins[1,2,3]

For numbered affiliations see end of the article.

Correspondence to: J A C Sterne jonathan.sterne@bristol.ac.uk (or @jonathanasterne on Twitter; ORCID 0000-0001-8496-6053)

Additional material is published online only. To view please visit the journal online.

Cite this as: *BMJ* 2019;366:l4898 http://dx.doi.org/10.1136/bmj.l4898

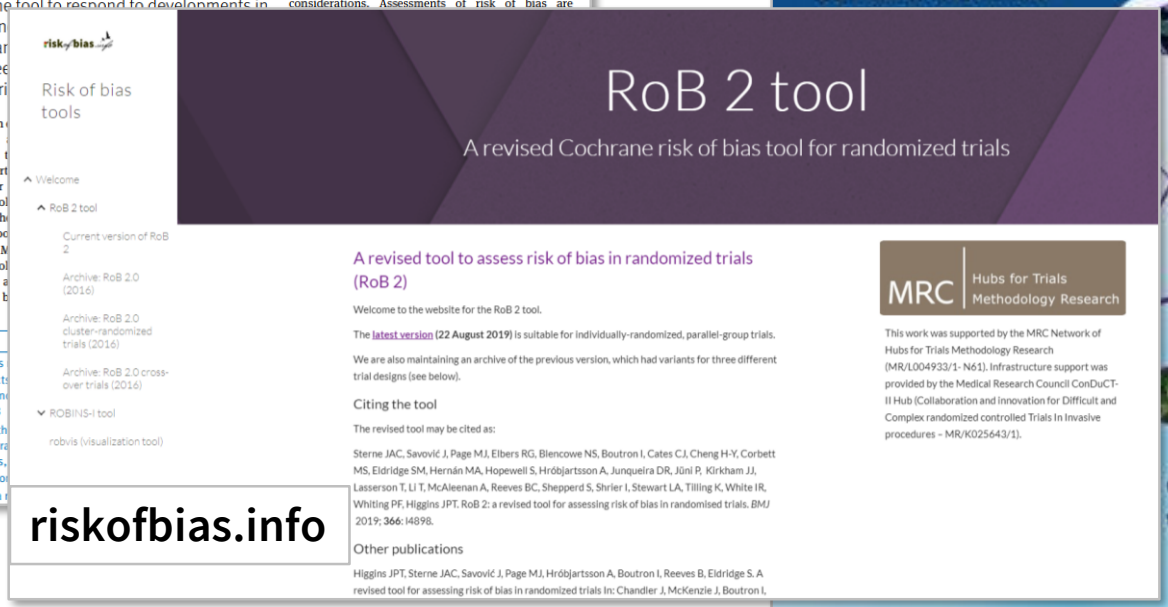
Accepted: 25 June 2019

Assessment of risk of bias is regarded as an essential component of a systematic review on the effects of an intervention. The most commonly used tool for randomised trials is the Cochrane risk-of-bias tool. We updated the tool to respond to developments in

the effect of intervention that would be observed in a large randomised trial without any flaws). Quality is not well defined and can include study characteristics (such as performing a sample size calculation) that are not inherently related to bias in the study's results. The RoB tool considers biases arising at different stages of a trial (known as bias domains), which were chosen on the basis of both empirical evidence and theoretical considerations. Assessments of risk of bias are

SUMMARY POINTS

- Assessment of risk of bias is
- systematic review on the effects
- for assessing risk of bias in ran
- which was introduced in 2008
- Potential improvements to th
- the basis of reviews of the litera
- used in other risk-of-bias tools,
- intervention effects from rando
- We developed and piloted a r



risk of bias

Risk of bias tools

- Welcome
- RoB 2 tool
  - Current version of RoB 2
  - Archive: RoB 2.0 (2016)
  - Archive: RoB 2.0 cluster-randomized trials (2016)
  - Archive: RoB 2.0 cross-over trials (2016)
- ROBINS-I tool
- robvis (visualization tool)

RoB 2 tool

A revised Cochrane risk of bias tool for randomized trials

A revised tool to assess risk of bias in randomized trials (RoB 2)

Welcome to the website for the RoB 2 tool.

The latest version (22 August 2019) is suitable for individually-randomized, parallel-group trials.

We are also maintaining an archive of the previous version, which had variants for three different trial designs (see below).

Citing the tool

The revised tool may be cited as:

Sterne JAC, Savović J, Page MJ, Elbers RG, Blencowe NS, Boutron I, Cates CJ, Cheng H-Y, Corbett MS, Eldridge SM, Hernán MA, Hopewell S, Hróbjartsson A, Junqueira DR, Jüni P, Kirkham JJ, Lasserson T, Li T, McAleenan A, Reeves BC, Shepperd S, Shrier I, Stewart LA, Tilling K, White IR, Whiting PF, Higgins JPT. RoB 2: a revised tool for assessing risk of bias in randomised trials. *BMJ* 2019; **366**: l4898.

Other publications

Higgins JPT, Sterne JAC, Savović J, Page MJ, Hróbjartsson A, Boutron I, Reeves B, Eldridge S. A revised tool for assessing risk of bias in randomized trials In: Chandler J, McKenzie J, Boutron I,

MRC Hubs for Trials Methodology Research

This work was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/1- N61). Infrastructure support was provided by the Medical Research Council ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomized controlled Trials In Invasive procedures – MR/K025643/1).

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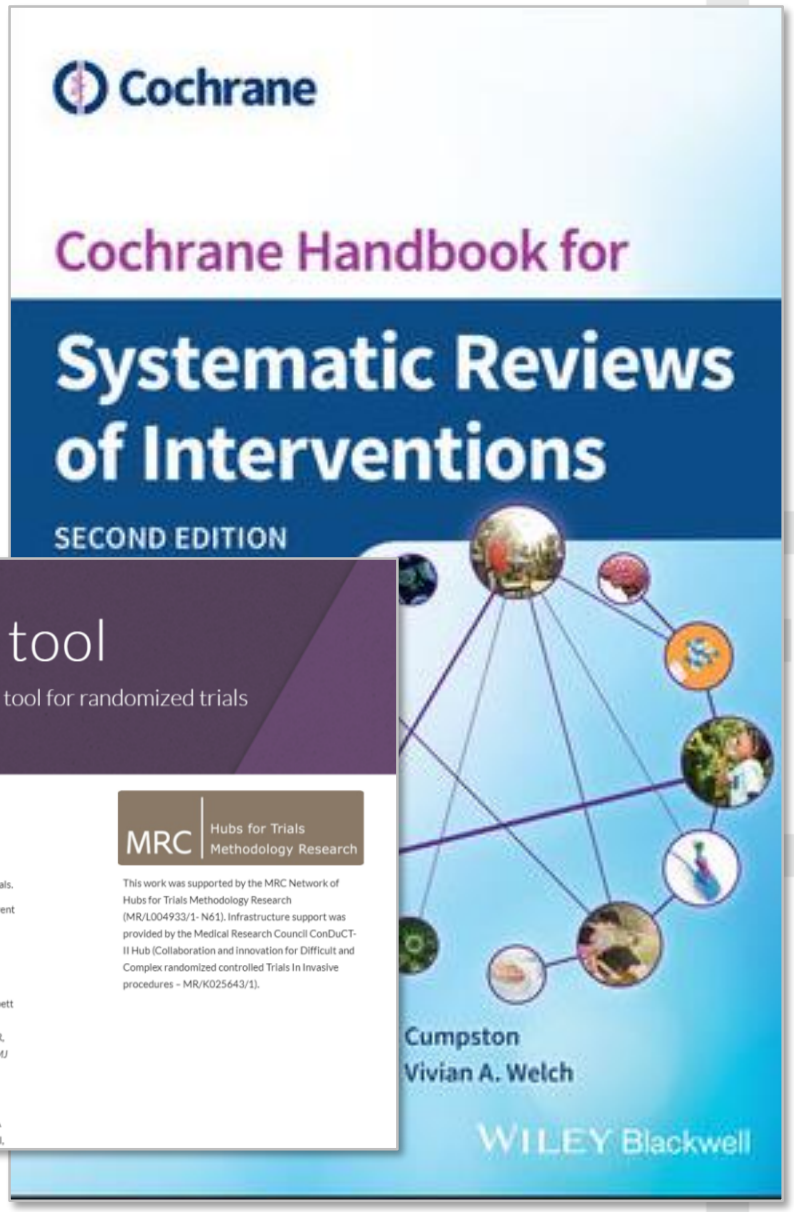


Cochrane

Cochrane Handbook for

Systematic Reviews of Interventions

SECOND EDITION

Cumpston

Vivian A. Welch

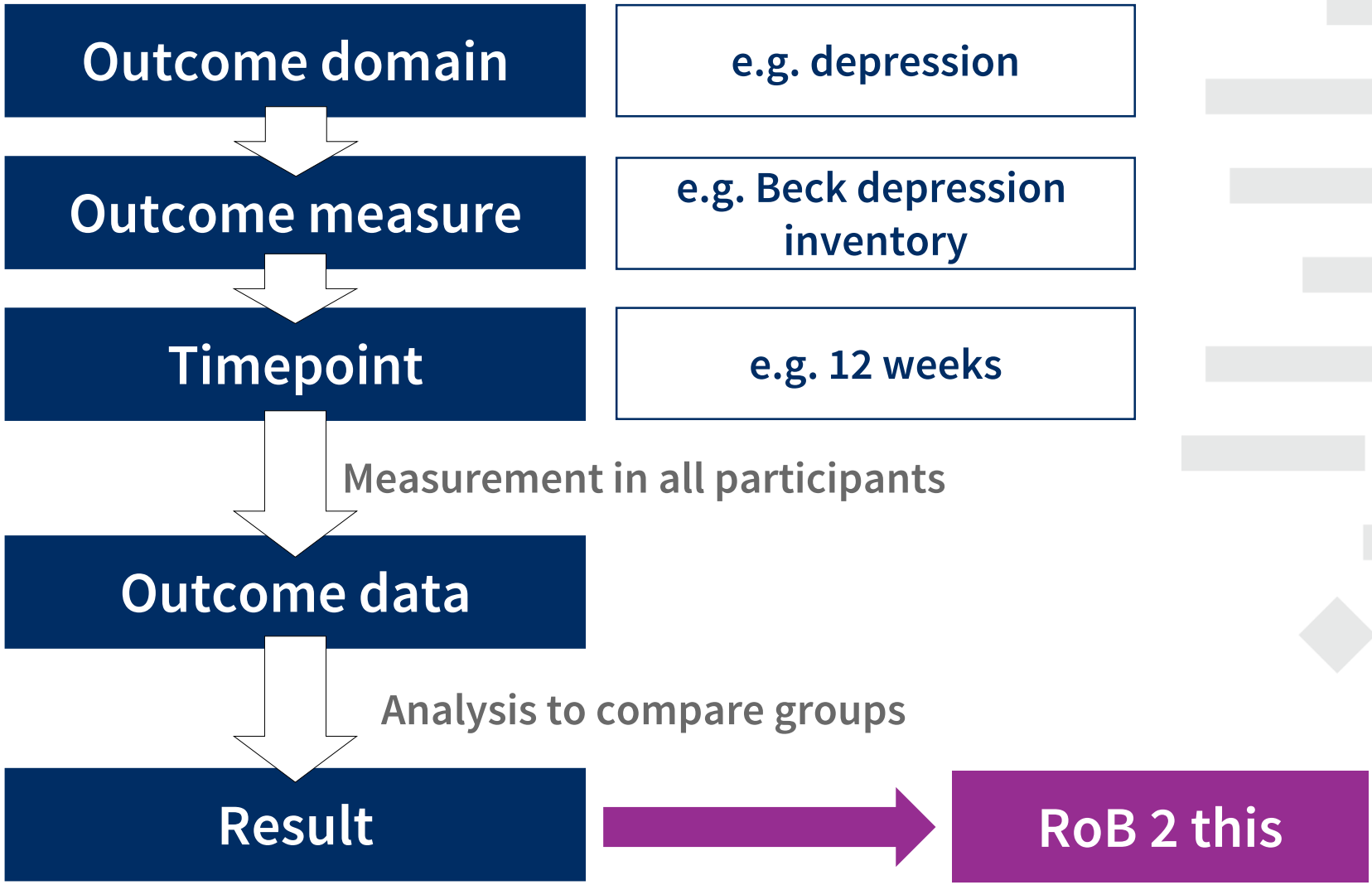
WILEY Blackwell

Risk of bias

- assess key results from each included study for **risk of bias**
  - can't measure the presence of bias
  - look for methods shown to minimize risk
  - … and evidence that the study ran successfully

- risk of bias is a property of a result
  - rather than of a study, or an outcome
  - if there is no result from a study, the result of the synthesis (meta-analysis) may be at risk of bias because of **M**issing **E**vidence
    - see **reporting bias; RoB ME** tool

Result-based tool



Overview of RoB 2

- fixed set of five **bias domains**
  - all are mandatory, and none can be added
  - (there is an additional domain in versions for cross-over trials and cluster-randomized trials)
- includes an **overall risk of bias**
  - used to guide analysis and interpretation
- important distinction between **effects of interest**
- funding and vested interests should be examined separately, and used to inform RoB 2 assessments
  - see **TACIT** (Tool for Addressing Conflicts of Interest in Trials)

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RoB 2 process

For each outcome (each key synthesis in the review)

For each study

Risk of bias assessment for a specific result

1. Specify result being assessed	2. Specify effect of interest	3. List sources of information used to inform assessment
4. Answer signalling questions	5. Judge risk of bias for each domain	6. Judge overall risk of bias for the result

For the synthesis

Integrate judgement(s) into results and conclusions

e.g. stratify meta-analysis by overall risk of bias judgement

Risk of bias in randomized trials

Bias arising from the randomization process

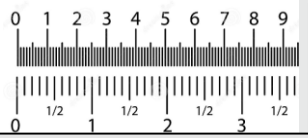
Bias due to deviations from intended intervention

Bias due to missing outcome data

Bias in measurement of the outcome

Experimental

Comparator



Outcome

Outcome

1.02 3.87
2.20 4.32
1.38 5.44

Bias in selection of the reported result

The effect of interest

Scenario: trial of screening for colorectal cancer

- people individually randomized to receive invitation to attend screening
- 55% of patients in the intervention arm attend screening
- all patients followed up for 10 years

We could be interested in either or both of:

- the **effect of assignment to intervention**
  - of most interest to a policymaker considering whether to introduce a screening programme
  - the 'intention-to-treat' (ITT) effect
- the **effect of adhering to intervention**
  - of most interest to a patient deciding whether to be screened
  - the 'per-protocol' effect

Signalling questions and judgements

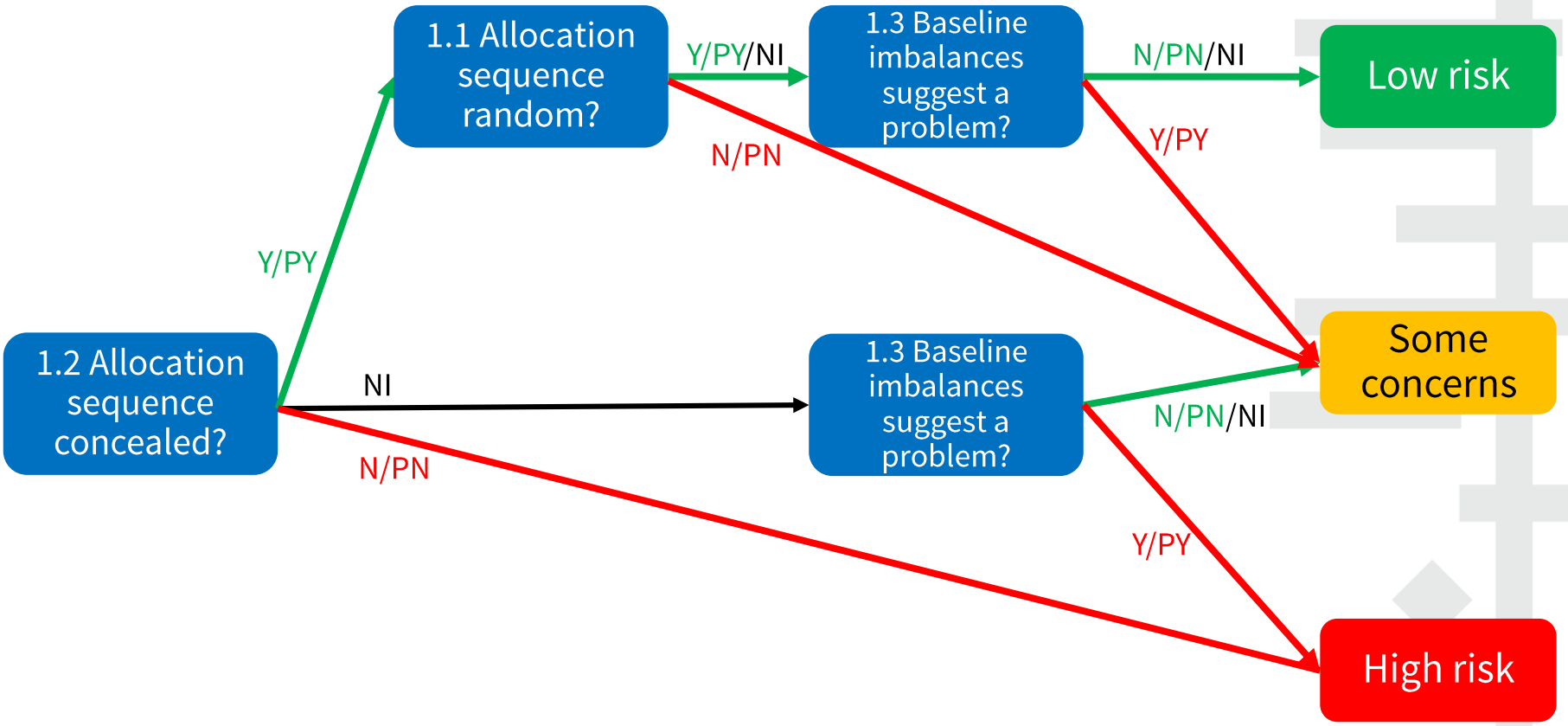
- **signalling questions** increase transparency
  - 'Yes', 'Probably yes', 'Probably no', 'No', 'No information'
  - support each one with evidence/quotes/explanation
- algorithms map answers to signalling questions onto **risk of bias judgements**
  - '**Low risk of bias**', '**Some concerns**', '**High risk of bias**'
  - "Probably yes" = "Yes", and "Probably no" = "No"
  - algorithms can be overridden
- a 'High risk of bias' judgement in any one domain puts the result at high risk of bias

Illustration of signalling questions: Domain 1

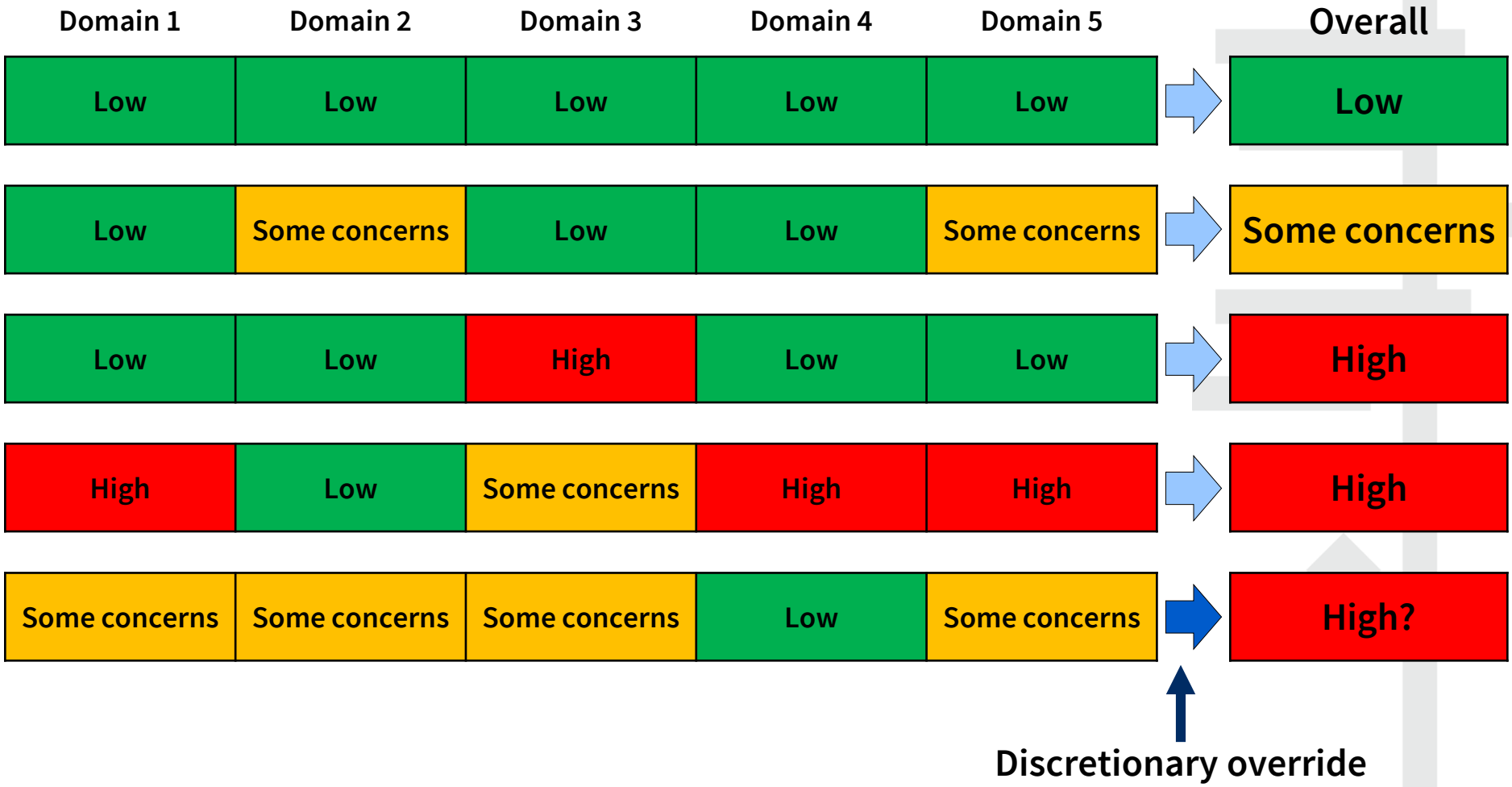
Bias arising from the randomization process

- 1.1 Was the allocation sequence random?
  - Yes / Probably yes / Probably no / No / No information
- 1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?
  - Yes / Probably yes / Probably no / No / No information
- 1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?
  - Yes / Probably yes / Probably no / No / No information

Illustration of algorithm: Domain 1



Suggested overall risk of bias judgement



Cluster-randomized trials

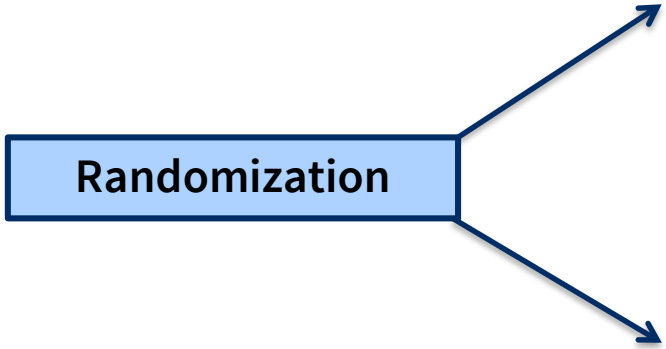
Adapted tool addresses issues that differ compared with individually-randomized trials, e.g.:

- Bias arising from the timing of identification and recruitment of participants (additional domain)
- Outcome data may be missing for cluster or individuals within clusters
- Outcome assessors may not be aware that a trial is taking place

Crossover trials

(with thanks to Tianjing Li)

Parallel-groups design



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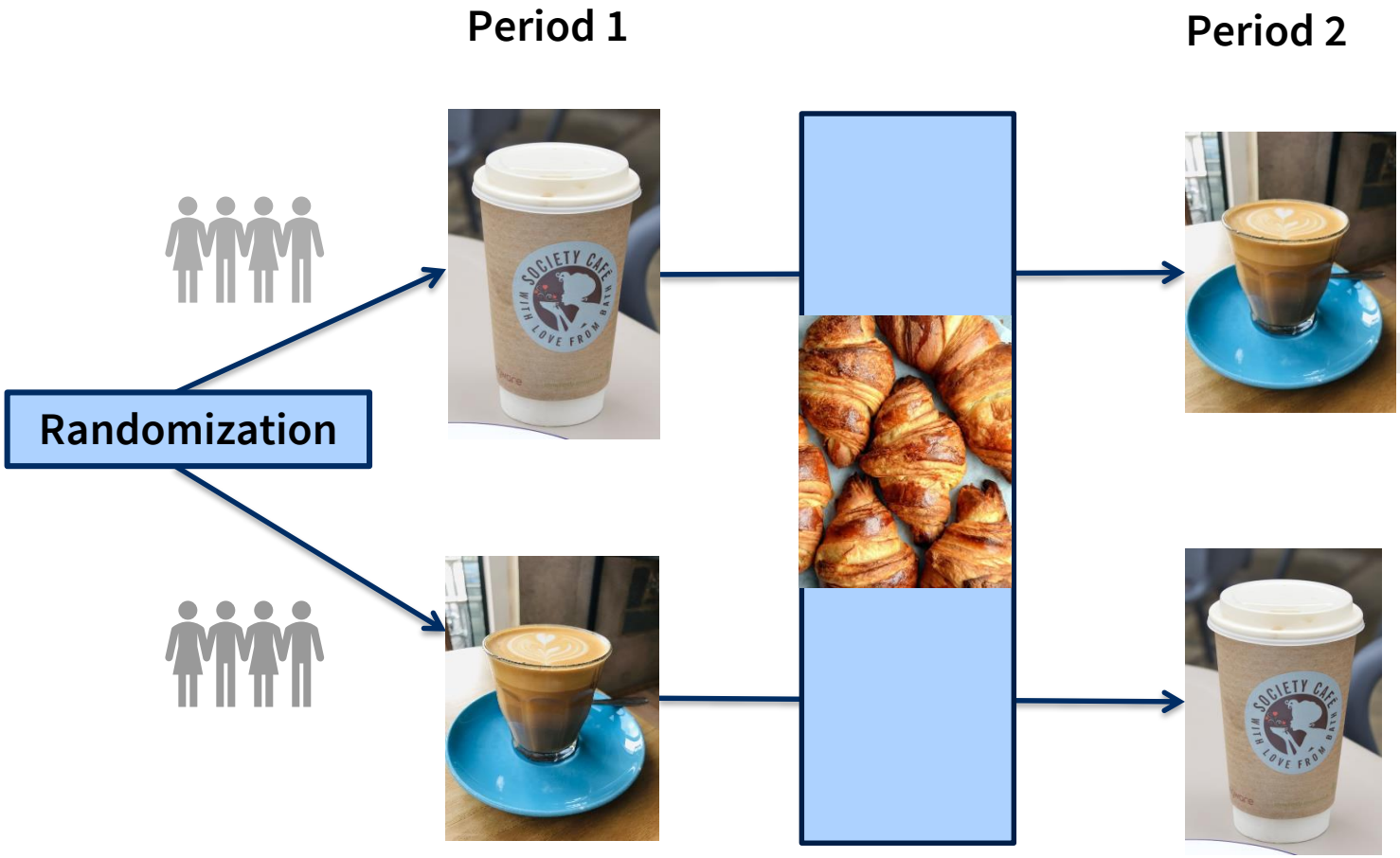
Crossover trials

(with thanks to Tianjing Li)

Crossover design

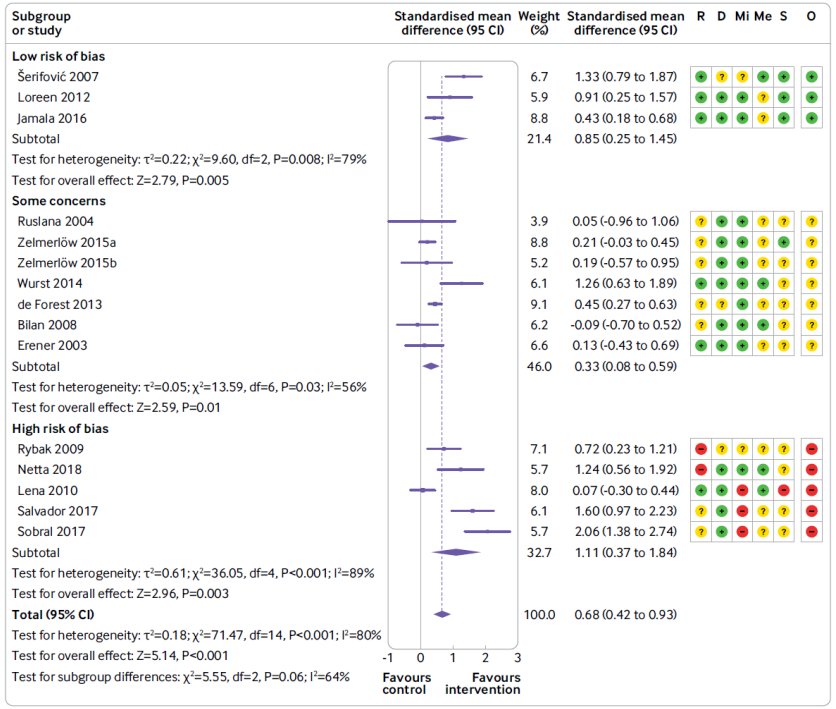


Issues addressed in adapted tool for crossover trials

- Bias due to period effects
- Bias due to carryover effects
- Selective reporting of first period data

Incorporating findings into a review

- Options include
  - narrative only
  - stratified analysis
  - restrict primary analysis to studies at low risk (or 'low risk' and 'some concerns')
  - explore the impact further



- More about this in webinar 7

Address risk of bias outcome by outcome

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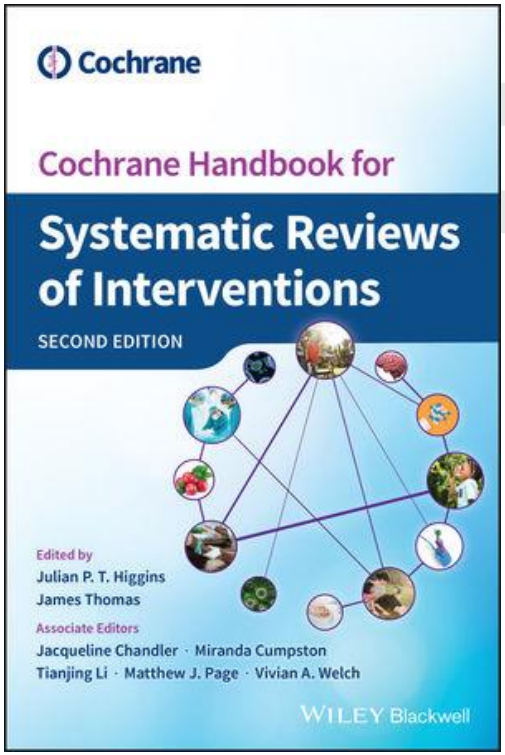
Resources available

Cochrane Handbook (v 6)

- **Chapter 7** explains risk of bias issues in general
- **Chapter 8** provides a brief overview of the RoB 2 tool
- **MECIR** items summarize *Handbook* guidance



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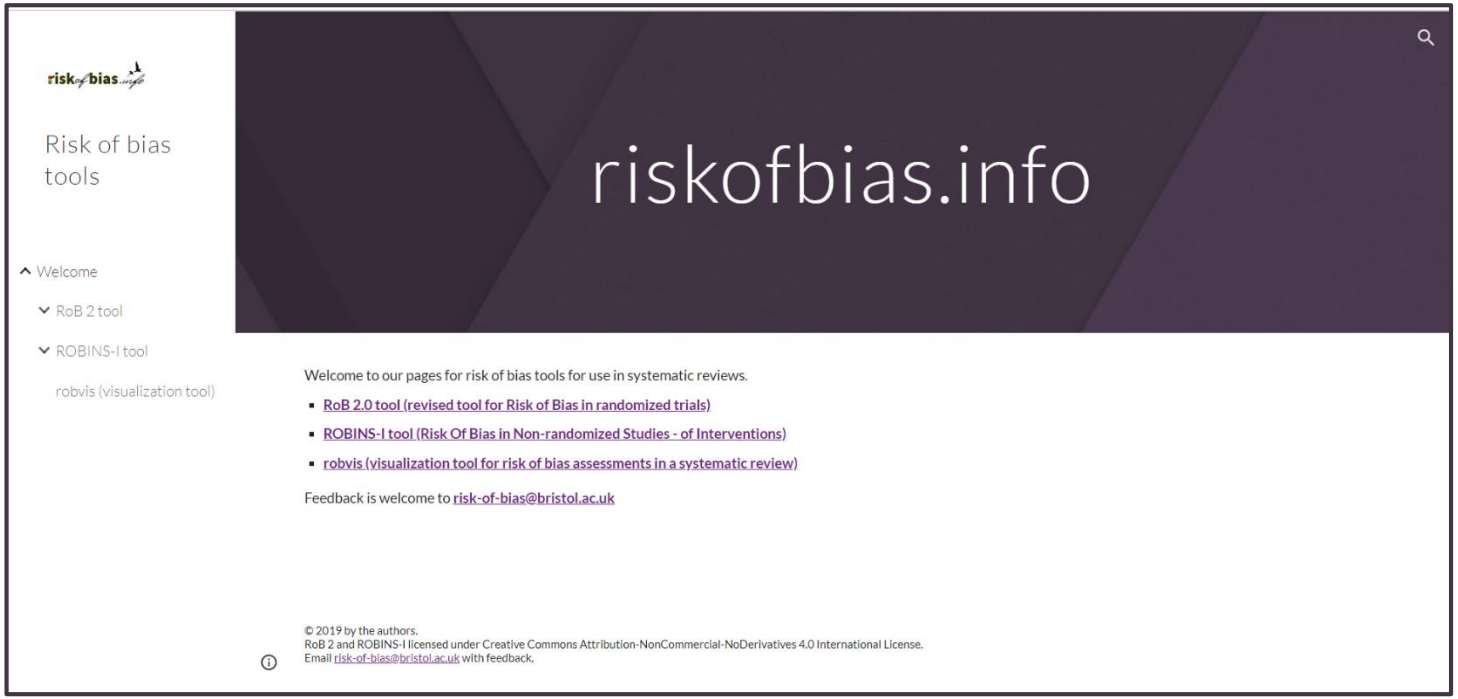

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Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the RoB2 Development Group

22 August 2019

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

Contents

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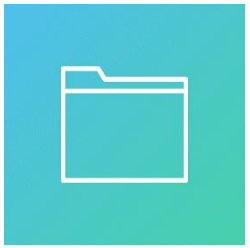
In development!



Archived: Cluster randomized trials (parallel groups)

Available:

- Background information and detailed guidance for using the RoB 2.0 tool for cluster-randomized trials

Additional Domain: Bias arising from the timing of identification and recruitment of participants

Archived: Cross-over trials (individually randomized)

Available:

- Background information and detailed guidance for using the RoB 2.0 tool for cross-over trials

Add issues related to carry over and period effects

Cochrane Handbook Chapter 23: Including variants on randomized trials

- **Interim guidance is available via the RoB 2 pilot**

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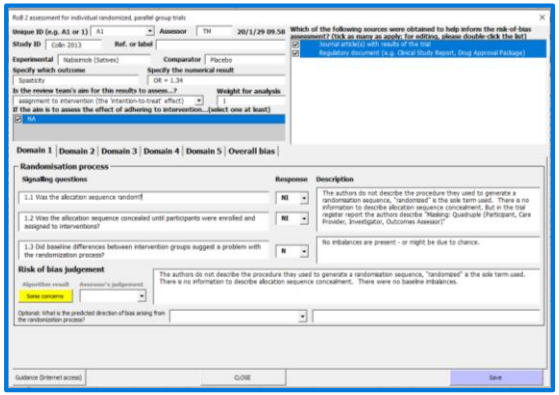
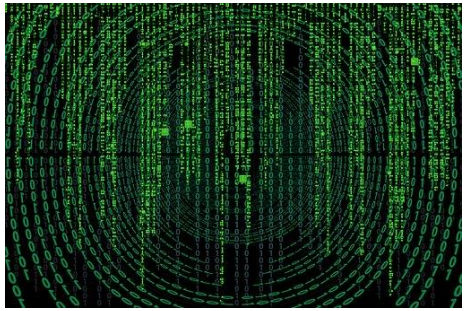
Excel tool

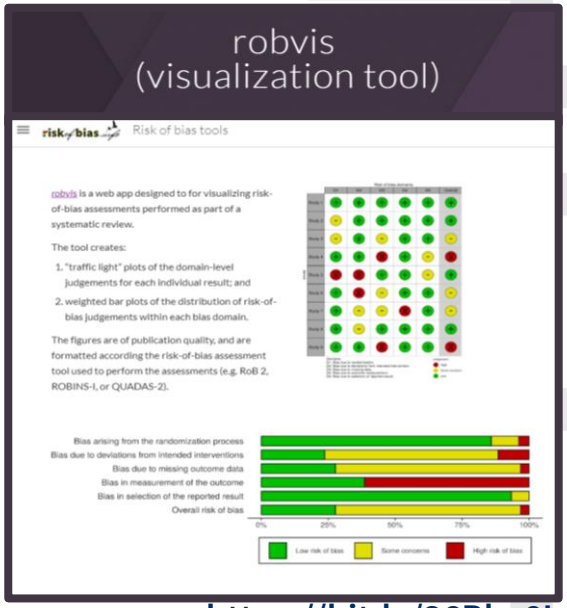


The recommended way to do RoB 2 assessments at the moment

Online platform (later in 2020)



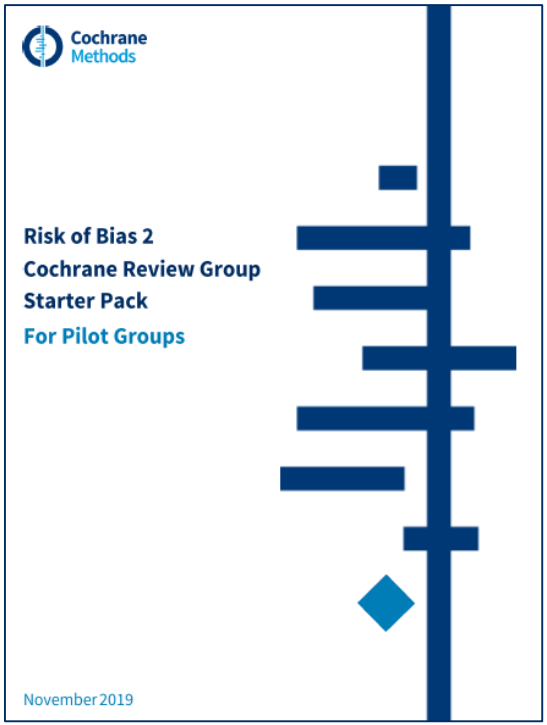
robvis



https://bit.ly/36Bku8L

Other Cochrane resources

- Interactive learning module
- Standard author training materials currently being updated
- RoB 2 Pilot Starter Pack



RoB 2 in Cochrane reviews

RoB 2 Implementation

- Pilot
- RevMan Web

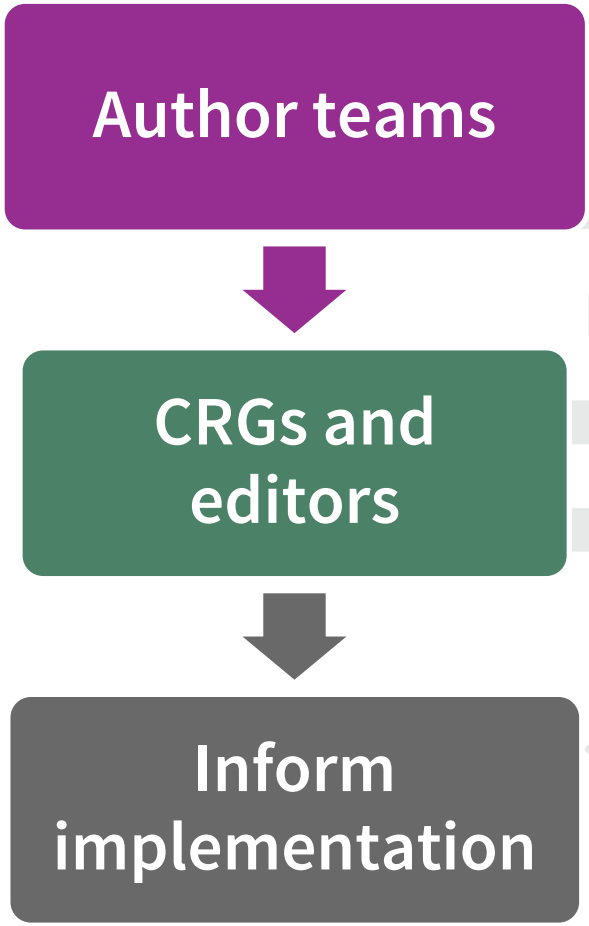
Protocol considerations

Implementation

- Gradual, supported rollout across 2019/2020

- RoB2 pilot
  - **Review teams**
  - **CRGs**

- Publication
  - **RevMan 5**
  - **RevMan Web**



RoB 2 pilot

CRG / Author team join the Pilot

Protocol assessment

Kick off call

Monthly web clinics

Methods Support Unit

CRG
MSU
Authors
Implementation team
RevMan Web developers

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RoB 2 pilot

Editorial comments on RoB 2

CRG

Review teams

Methods Support Unit

RoB 2 pilot

Progress

Pilot	Joining the pilot	Total
• 18 reviews • 16 CRGs	• 22 reviews • 8 CRGS	• 40 reviews • 23 CRGs

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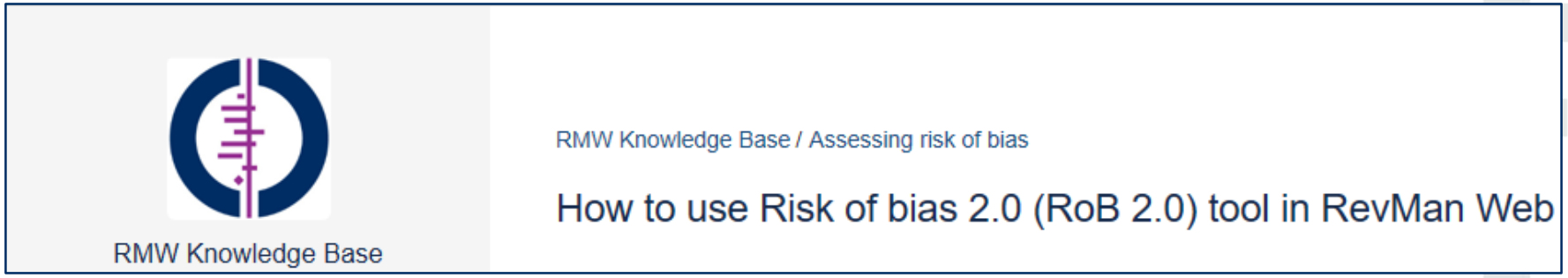
RevMan Web

RevMan 5

RevMan Web



RMW knowledgebase:

\https://documentation.cochrane.org/revman-kb

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RevMan Web

Investigate sensitivity - 1.1 Headache

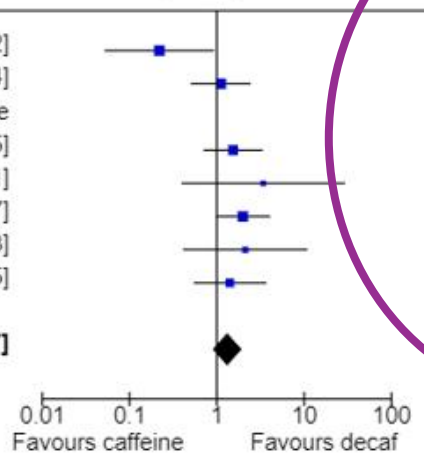
Odds ratio | **Risk ratio** | Risk difference | **Fixed effect** | Random effects | Scale 100 | Save image

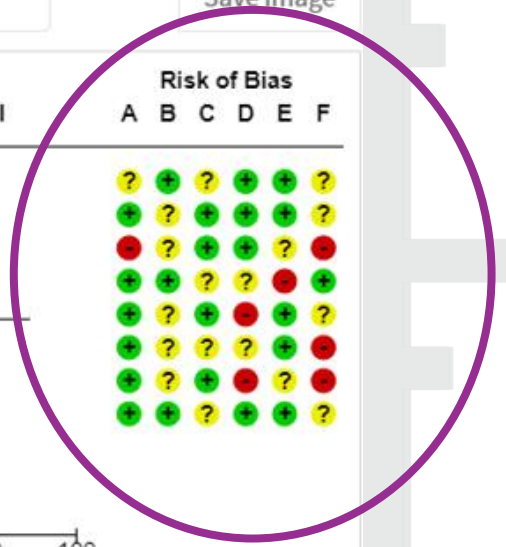
Study or Subgroup	Caffeine Events	Caffeine Total	Decaf Events	Decaf Total	Weight	Risk ratio M-H, Fixed, 95% CI
✓ Amore-Coffea 2000	2	31	10	34	21.2%	0.22 [0.05 , 0.92]
✓ Deliciozza 2004	10	40	9	40	20.0%	1.11 [0.51 , 2.44]
✓ Kahve-Paradiso 2002	0	0	0	0		Not estimable
✓ Mama-Kaffa 1999	12	53	9	61	18.6%	1.53 [0.70 , 3.35]
✓ Morrocona 1998	3	15	1	17	2.1%	3.40 [0.39 , 29.31]
✓ Norscafe 1998	19	68	9	64	20.7%	1.99 [0.97 , 4.07]
✓ Oohlahlazza 1998	4	35	2	37	4.3%	2.11 [0.41 , 10.83]
✓ Piazza-Allerta 2003	8	35	6	37	13.0%	1.41 [0.54 , 3.65]
Total (95% CI)		**277**		**290**	**100.0%**	**1.31 [0.92 , 1.87]**
Total events:	58		46			

Heterogeneity: Chi² = 8.66, df = 6 (P = 0.19); I² = 31%

Test for overall effect: Z = 1.51 (P = 0.13)

Test for subgroup differences: Not applicable





Risk of bias legend

(A) Bias arising from the randomization process
(B) Bias due to deviations from intended interventions: Headache
(C) Bias due to missing outcome data: Headache
(D) Bias in measurement of the outcome: Headache
(E) Bias in selection of the reported result: Headache
(F) Overall bias: Headache

https://documentation.cochrane.org/revman-kb/assessing-risk-of-bias/how-to-use-risk-of-bias-2-0-rob-2-0-tool-in-revman-web

\https://documentation.cochrane.org/revman-kb

How to join the RoB 2 pilot

Author teams

Contact your:

- CRG

CRG teams

Contact your:

- Network Associate Editor
- Method Support Unit

https://bit.ly/2YGGBtY

Protocol – Methods

- **Criteria for considering studies for this review**
  - Types of studies
  - Types of participants
  - Types of interventions
  - Types of outcomes
- **Search methods for identification of studies**
  - Electronic
  - Other
- **Data collection and analysis**
  - Selection of studies
  - Data extraction and management
  - Assessment of risk of bias in included studies
  - Measures of treatment effect
  - Unit of analysis issues
  - Dealing with missing data
  - Assessment of heterogeneity
  - Assessment of reporting biases
  - Data synthesis
  - Subgroup analysis and investigation of heterogeneity
  - Sensitivity analysis
  - Summary of findings and assessment of the certainty of the evidence

Protocol – Methods

- **Criteria for considering studies for this review**
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Implications for RoB 2

- **Data collection and analysis**
  - Selection of studies
  - Data extraction and management
  - **Assessment of risk of bias in included studies**
  - Measures of treatment effect
  - Unit of analysis issues
  - Dealing with missing data
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RoB 2 has implications

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Types of studies

Randomized trials	Cluster-randomized trials	Crossover trials
		

Rationale: Implications for which variants of the RoB 2 tool you will use

Assessment of risk of bias in included studies

For all users of RoB 2:

1. State RoB 2 will be used and provide a reference to it
2. State which results will be assessed ← *Usually those in SoF table*
3. State effect of interest ← *Your choice*
4. State plans for design variants (cluster-rand., crossover) if needed
5. Detail assessors (how many? who? independently? consensus?)
6. List the domains in the tool (these can't be modified)
7. List the judgement options : High, Low, Some concerns; overall RoB
8. Storage and presentation of assessments (inc. consensus decisions)

Data synthesis; Heterogeneity; Certainty

Primary analysis

- all ‘at Low risk of bias overall’?
- stratified analyses?

Does RoB 2 explain heterogeneity?

- subgroup analyses
- meta-regression

Secondary analysis

- sensitivity analyses?
- advanced: bias adjustment?

Certainty of the evidence

- RoB 2 will feed directly into GRADE

Rationale: All methods in Cochrane systematic reviews are pre-specified to minimize bias

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- **Froeks Kamminga**
- **Andrew Anglemeyer**
- **Kayleigh Kew**
- **Rebecka Hall** — RevMan Web team

More information:

https://methods.cochrane.org/our-team

Methods Support Unit https://bit.ly/2YGGBtY

RevMan Web \https://documentation.cochrane.org/revman-kb

Cochrane online RevMan training https://bit.ly/2SFKZWa

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Questions

Trusted evidence.
Informed decisions.
Better health.