Contents
About Risk of Bias 2 2
What guidance is available? 3
What training is available? 3
What tools are available? 4
RoB 2 considerations for protocol development 4
RoB 2 considerations for reporting the review 6
What support is available? 9
Other RoB 2 tips from review teams 10
Providing feedback on using RoB 2 in Cochrane 11

About Risk of Bias 2
Up-to-date information from the developers on Risk of Bias 2 (RoB 2) is available via the Risk of Bias tools website: https://www.riskofbias.info/

Up-to-date information on the piloting and implementation of RoB 2 can be found via the Cochrane Methods Website: https://methods.cochrane.org/risk-bias-2

Watch the six-minute video on RoB 2 guidance, training and tools here

The table below gives an overview of how RoB 2 differs from the original Risk of Bias tool (RoB 1).

<table>
<thead>
<tr>
<th>Focus of assessment</th>
<th>RoB1</th>
<th>RoB2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study (all studies in the review)</td>
<td>Outcome data with a numerical result– if there is no numerical result for an outcome from a specific study, then you do not need to complete a risk of bias assessment as it will not be contributing to the review</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Structure</th>
<th>7 standard domains</th>
<th>Preliminary considerations Signalling questions 5 domains plus overall risk of bias</th>
</tr>
</thead>
<tbody>
<tr>
<td>Domains</td>
<td>-Random sequence generation -Allocation concealment -Blinding of participants and personnel -Blinding of outcome assessment -Incomplete outcome data (attrition bias) -Selective reporting (reporting bias)* -Other bias</td>
<td>-Bias arising from the randomization process -Bias due to deviations from intended interventions -Bias due to missing outcome data -Bias in measurement of the outcome -Bias in selection of the reported result Plus ‘Overall risk of bias’</td>
</tr>
<tr>
<td>Basis of judgement</td>
<td>Author defined</td>
<td>Signalling questions answered Yes; Probably yes; Probably no; No; No information with suggested algorithm for reaching judgement</td>
</tr>
<tr>
<td>Judgement options</td>
<td>Low risk – Unclear – Highrisk</td>
<td>Low risk – Some concerns – High risk (plus optional direction of bias)</td>
</tr>
</tbody>
</table>

*Authors should note that, as a result of the move to outcome-based assessment, selective reporting bias is not part of the revised tool.
What guidance is available?

Core Cochrane resources for RoB 2 in Cochrane Reviews
An introductory leaflet on RoB 2, the most-up-to-date version of this Starter Pack and the RoB 2 FAQs for Cochrane Reviews can be found via the Cochrane Methods website.

Full guidance on the Cochrane Risk of Bias tool for randomised trials (RoB 2)
Detailed and comprehensive guidance on RoB 2 can be found via the Risk of Bias tools website. Review teams can use this to help answer any question they have about the tool.

RoB 2 cribsheet
This document summarises the RoB 2 tool, providing the fields that need to be completed, brief explanations for help answer the signalling questions within each bias domain, and the key considerations for how to come to risk of bias judgements for each domain and overall. The document can be found via the Risk of Bias tools website here. It is intended to be used regularly as a reference document while completing the tool – particularly to help answer the signalling questions.

Handbook
The Cochrane Handbook for Systematic Reviews of Interventions (Version 6) relevant chapter is Chapter 8, titled ‘Assessing risk of bias in a randomized trial’. Review teams should ensure they are familiar with contents of this chapter.

MECIR
The Methodological Expectations for Cochrane Intervention Reviews (MECIR) includes nine standards for assessing risk of bias in included studies here (C52-60). Review teams are expected to follow the MECIR standards.

Using RevMan Web
RoB 2 is only available in RevMan Web and is not supported by RevMan 5 (desktop version). The key resource for RevMan Web is the Knowledge Base here. This includes details on getting started and introductory webinars, as well as step by step guides, the ability to search and how to use the RevMan Web Practice Platform.

How-to guides for RoB 2 data input in RevMan Web
Guidance on how to enter RoB 2 assessments in RevMan Web can be accessed here.

What training is available?

Cochrane Learning Live webinars
A Cochrane Learning Live webinar series from May 2020 to January 2021, presented by leading experts, covers an introduction of RoB 2, detailed sessions on the five Risk of Bias 2 (RoB 2) domains, reaching overall RoB judgements, RoB 2 bias in other types of studies (crossover and cluster trials) and editorial considerations. Full details and sign-up here.

The Cochrane Interactive Learning (CIL) Module 5 on ‘Introduction to study quality and risk of bias’ is RoB 2 compliant. Full CIL course can be accessed here.
What tools are available?

Data collection form
A sample data collection form is available. The previous version from the Editorial Resources Committee has been revised in light of the development of RoB 2. It should be seen as a starting point for developing bespoke data collection forms for reviews, and it should be modified accordingly. The form can be found here.

Tools for managing your RoB 2 assessments
The developers have created two templates for completing the RoB 2 assessment. It is advised that review groups use one, and both are available via the Risk of Bias tools website here:

1. RoB 2 Excel tool (recommended) – this tool has a manual embedded within it, with short videos on how to use it - can email risk-of-bias@bristol.ac.uk to feedback any issues.
3. A browser-based online tool is under development.

Watch the RoB 2 Excel tool demo videos for managing your risk of bias assessments here

As a service to Cochrane authors, submit your completed risk of bias assessments to your Cochrane Review Group to check before you finish your review write-up, e.g. the completed RoB 2 Excel tool – this will facilitate peer review.

Other tools
We advise that Cochrane authors use RevMan Web to create forest plots with traffic lights to visually represent RoB 2 data. If authors want to showcase the RoB 2 assessments in other ways, robvis is a tool for creating other risk of bias figures and can be found via the Risk of Bias tools website. These figures can be uploaded into RevMan Web as an additional figure. If you use robvis, please ensure you cite it in your review: https://www.riskofbias.info/welcome/robvis-visualization-tool.

RoB 2 considerations for protocol development

Watch the five-minute video about RoB 2 protocol considerations here

There are ten key items to consider when using the RoB 2 tool:

<table>
<thead>
<tr>
<th>What to report</th>
<th>Further details</th>
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<tbody>
<tr>
<td>1. State that RoB 2 tool will be used and reference it</td>
<td></td>
</tr>
<tr>
<td>2. State your effect of interest - effect of assignment or effect of adherence</td>
<td>Guidance: Section 1.3 Detailed guidance (Riskofbias.info); Section 8.2.2 Cochrane Handbook.</td>
</tr>
<tr>
<td>3. List or refer to the results that will be assessed using RoB 2, inc.</td>
<td>Guidance: Section 1.3 Detailed guidance (Riskofbias.info); Section 7.3.2, Section 8.2.1 and Section 8.7 Cochrane Handbook.</td>
</tr>
</tbody>
</table>
| Outcome(s), Outcome measure(s) and timepoint(s) | Reference the RoB variant for crossover trials and/ or the RoB 2 variant for cluster trials. **Guidance:** [RoB for for crossover trials via riskofbias.info](https://riskofbias.info) and [RoB 2 for cluster trials via riskofbias.info](https://riskofbias.info)  
**NB:** Please note, as of December 2020, the cluster and cross trial variants for RoB 2 have not been developed in RevMan Web yet so there is interim guidance on how to display these results.  
**NB:** Please note, if you have intended from the OUTSET to ONLY use data from the first period of the crossover, then you can use the standard version of RoB 2 as it is. However, please be alert to the potential impact of selective reporting of first period of data only when carry over is detected by trialists. Omission of trials which do not report first period data may lead to bias at the meta-analysis level. For details are in Section 23.2 Cochrane Handbook. |
<table>
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<tbody>
<tr>
<td>5. State who will assess RoB2 (initials), how many and whether independently and duplicate</td>
<td><strong>Guidance:</strong> <a href="https://riskofbias.info">MECIR C53; Section 7.3.2 Cochrane Handbook</a></td>
</tr>
<tr>
<td>6. List the domains of the tool</td>
<td><strong>Guidance:</strong> <a href="https://riskofbias.info">Section 1.3 Detailed guidance (Riskofbias.info); Section 8.2.3 Cochrane Handbook</a></td>
</tr>
<tr>
<td>7. List the judgment options (High, Some Concerns, Low) and how overall risk of bias is reached, e.g. using the signalling questions/tool algorithms</td>
<td><strong>Guidance:</strong> <a href="https://riskofbias.info">Section 1.1, Section 1.2.1 and Section 1.2.3 Detailed guidance (Riskofbias.info); Section 8.2.3 and Section 8.2.4 Cochrane Handbook</a></td>
</tr>
<tr>
<td>8. State if you plan to use any tools to manage the assessment of bias using RoB 2</td>
<td>For example, the RoB2 Excel tool to implement RoB 2 (available on the riskofbias.info website)</td>
</tr>
</tbody>
</table>

**Methods section - 'Data synthesis'**

| 9. State whether the primary analysis will include all eligible studies or only those which have low risk of bias, or low risk and some concerns | This may depend on the number of studies with each risk of bias rating as you'll need sufficient numbers for the analyses. It could also be appropriate to pool data from studies at high risk of bias and use a sensitivity analysis to assess the effects of restricting the analysis to RCTs overall ‘low’ or ‘low/some concerns’. | **Guidance:** [MECIR C21; Section 7.6.2 Cochrane Handbook](https://riskofbias.info) |

**Methods section - 'Subgroup analysis and investigation of heterogeneity'**

| (If applicable) Specify if subgroup analysis is planned based on risk of bias | Consider whether overall risk of bias should be used as the basis for any subgroup analysis.  
Subgroup analyses may be done as a means of investigating heterogeneous results, or to answer specific questions about particular patientgroups, types of intervention or types of study (as well as clinical heterogeneity there is methodological heterogeneity). If you would like to perform subgroup analyses using risk of bias, please discuss with your CRG Managing Editor during protocol development. | **Guidance:** [MECIR C22; Section 10.11.2 and Section 7.6.2 Cochrane Handbook](https://riskofbias.info) |

**Methods section - 'Sensitivity analysis'**

| (If applicable) Specify if sensitivity analysis is planned based on risk of bias | Consider whether overall risk of bias should be used as the basis for any sensitivity analysis.  
A sensitivity analysis is a repeat of the primary analysis or meta-analysis in which alternative decisions or ranges of values are substituted for decisions that were arbitrary or unclear. In respect to risk of bias, review authors may perform sensitivity analyses to show how conclusions might be affected if studies at a high risk of bias, or high risk bias and some concerns, were included. | **Guidance:** [MECIR C71; Section 10.14 and Section 7.6.2 Cochrane Handbook](https://riskofbias.info) |

**Methods section - 'Summary of findings and assessment of the certainty of the evidence'**
10. State how the RoB 2 assessment will be used to assess the certainty of the evidence/GRADE/SoF

State that the overall RoB judgement will be used to feed into the GRADE assessment.

**Guidance:** MECIR C54; Section 7.3.2 Cochrane Handbook.

**Other considerations**

Authors should not adapt the RoB 2 tool.

State how you will store and present your detailed RoB2 data - the RoB2 tool may generate a large amount of data. We recommend that the consensus decisions for the signalling questions are available to your readers in the full review so your rational for judgements is transparent. This can be stored as supplemental data or files (see the Editorial and Publishing Policy for full details).

**Guidance:** MECIR C54; Section 7.3.2 Cochrane Handbook.

See this published protocol as an example:

- **Contraception decision aids to improve care and effective method use** (missing Point 8 – whether they have plans to use any tools to manage the assessment of bias using RoB 2)

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**RoB 2 considerations for reporting the review**

Watch the seven-minute video about RoB 2 review reporting considerations [here](#)

There are seven key items to consider when reporting RoB 2 in the full review:

**Please note, this checklist ONLY highlights RoB 2 considerations for review reporting**

<table>
<thead>
<tr>
<th>What to report</th>
<th>Further details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methods - ‘Assessment of risk of bias in included studies’</strong></td>
<td></td>
</tr>
<tr>
<td>1. Include all the RoB 2 considerations from the Protocol.</td>
<td>Compare the Review to the Protocol to ensure they are consistent (it may be useful to assess the reporting against the protocol checklist for RoB 2 to ensure everything was included originally). If there were any deviations from the Protocol, these should be detailed in the ‘Differences between protocol and review’ section (see below).</td>
</tr>
<tr>
<td>2. State the version of the RoB 2 tool that was used.</td>
<td>The riskofbias.info website lists the current version and archived versions of the RoB 2 tool. Ensure you state which version of the tool you used, e.g. when this guidance was created the 2019 version was the current version with the full guidance was published on 22 August 2019.</td>
</tr>
<tr>
<td><strong>Results - ‘Risk of bias in included studies’</strong></td>
<td></td>
</tr>
<tr>
<td>3. Refer to the results-level RoB 2 tables, which includes the support for judgement for each domain assessment.</td>
<td>The results-level RoB 2 tables are located in the ‘Risk of bias’ section after the characteristics of studies section. Each outcome prespecified for risk of bias assessments (likely to be the reviews’ critical and important outcomes included in the SoF table) should have a table that includes the risk of bias judgements (high, low or some concerns) and the support each judgement. <strong>Guidance:</strong> How to create and view the Risk of bias tables is detailed in the RevMan Web Knowledge Base (see RoB 2 in RevMan Web).</td>
</tr>
</tbody>
</table>
In certain circumstances, authors may wish to use other figures that best present the risk of bias data, e.g. weighted risk of bias bar plots can provide a succinct summary when there are lots of studies in a synthesis.

4. State how to access detailed risk of bias assessments data (with consensus responses to the signalling questions).

These may be cited in the main text as supplemental data or files (they should not be included within the Review itself).


5. Provide a brief overview of the risk of bias assessments.

Consider **overall comments on key aspects** of the risk of bias assessments, e.g. the quality of randomization and extent to which blinding was implemented.

Consider whether there are **important differences** in risk of bias by outcome.

**If risk of bias assessments are very similar** (or identical) for all outcomes in the review, a summary of the assessments across studies should be presented here.

**If risk of bias assessments are very different** for different outcomes, this section should be very brief, and summaries of the assessments across results should be discussed with other GRADE considerations in the Discussion (see point 7 below).

**Results - ‘Effects of intervention’**

6. Refer to visual representations of the risk of bias assessments in relation to each result.

Using forest plots with traffic lights is highly recommended (reference this from the Analyses section – you do not need to add additional Figures).

**Guidance:** How to create and view forest plots with traffic lights in Analyses is detailed in the RevMan Web Knowledge Base (see RoB 2 in RevMan Web).

It may be very helpful to stratify forest plots according to overall risk of bias.
For synthesis without meta-analysis, we recommend that a column is added to any visual representation of the data that highlights the overall risk of bias associated with each of the results in the table/figure, e.g.:
**Risk of Bias 2 CRG Starter Pack**

<table>
<thead>
<tr>
<th>of bias judgments.</th>
<th></th>
</tr>
</thead>
</table>

**Results - ‘Sensitivity analysis’**

(If applicable) Discuss any sensitivity analysis conducted that relates to the risk of bias judgments.

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**Discussion - ‘Certainty of the evidence’** (previously the ‘Quality of the evidence’ section)

7. Discuss any risk of bias judgements that affect the certainty of the evidence along with all other GRADE considerations.

Along with the other GRADE considerations, highlight any important implications from the risk of bias assessments for each of the outcomes prespecified for risk of bias assessments (likely to be the reviews’ critical and important outcomes included in the SoF table), such as whether the risk of bias assessments results in downgrading the certainty of the evidence for a specific outcome and whether the effects of the intervention may need to be interpreted with caution.

**Guidance:** Section 7.5 and Section 14.2.2 Cochrane Handbook

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**History - ‘Differences between protocol and review’**

(If applicable) State if there were any deviations from the Protocol.

**Guidance:** MECIR R107 and R108.

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**Other considerations**

See this published review as an example:

- Physical activity interventions for people with congenital heart disease

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**What support is available?**

**RoB 2 Introductory Leaflet**

This includes key information for review teams to read/watch before they initiate a Review using RoB 2, including short screencasts that highlight guidance, training and tools, as well as considerations for writing your protocol and review. It can be accessed here.

**Protocol and Review development support from the Methods Support Unit**

The Methods Support Unit are available to support Cochrane Review Groups (CRG) with Reviews using RoB 2. CRGs who have not participated in the Pilot will receive hands-on support for the first protocol and review using RoB 2 that goes through their group and training to manage subsequent reviews. The MSU will provide advice and guidance on an ongoing basis but will not routinely review the application of RoB 2, unless additional support is needed (e.g. for large network meta-analyses or reviews including a range of study designs).
Support available for Cochrane Reviews using RoB 2

Key resources

- Online training
- Tips and timesavers
- RoB 2 Starter Pack
  - Tools for using RoB 2
  - Example reviews
- Protocol checklist
- Review checklist

*MSU Web Clinic webform: methods.cochrane.org/methods-support-unit-web-clinic

FAQs

- Introductory leaflet
  With pre-recorded videos

Protocol development

Authors

- Propose review using RoB 2 (added to proposed form)
- Use RoB 2
- Incorporate RoB 2 considerations and submit protocol

CRG

- CRG agrees with the use of RoB 2 and prepares the review in RevMan Web
- Use RoB 2 checklist to assess RoB 2 methods during usual QA
- Available for advice via email thereafter

MSU

- Share RoB 2 resources with authors
- RoB 2 resources sent and replaced by MSU for first review going through CRG
- RoB 2 checks completed by MSU, for first review going through CRG
- Collate and send feedback to authors with CRG/peer review comments
- Revisions required

When ready, email support@cochrane.org to ask for RoB 2 functionality to be switched on in RevMan Web

Review development

Authors

- Authors conduct RoB 2 assessments
- Authors submit RoB 2 assessments before write-up for checks
- Authors submit RoB 2 assessments to CRG
- Authors submit RoB 2 assessments before write-up for CRG
- CRG checks the RoB 2 ‘support for judgement’ statements
- MSU available for RoB 2 ‘support for judgement’ checks
- MSU available for RoB 2 ‘support for judgement’ checks

CRG

- Submit RoB 2 issues and queries via the webform for discussion with MSU
- Use RoB 2 checklist provided by MSU for first review going through CRG
- Use RoB 2 checklist during usual QA
- Available for advice via email thereafter

MSU

- Monthly Web Clinics hosted by MSU
- MSU available for RoB 2 ‘support for judgement’ checks

As a service to Cochrane authors, submit your completed risk of bias assessments to your Cochrane Review Group to check before you finish your review write-up, e.g. the completed RoB 2 Excel tool – this will facilitate peer review.

Cochrane authors and Cochrane Review Group staff can submit RoB 2 questions to the monthly Methods Support Unit Web Clinic for discussion – read more and submit questions here.

Questions via email

Questions about RevMan Web functionality can be sent to support@cochrane.org and questions about RoB 2 assessments, guidance, tools, or other miscellaneous questions can be directed to Kerry Dwan (kdwan@cochrane.org) or Tess Moore (tmoore@cochrane.org).

Other RoB 2 tips from review teams

To facilitate the move into a phased implementation, we have brought together some of the key takeaways from the pilot and encourage all members of the community to send additional tips and feedback to methods@cochrane.org:

Worked examples are key. Training courses and webinars are most helpful when they include or reference high-quality examples illustrating how to carry RoB 2 through the text, figures and tables of a review. Example protocols and reviews using RoB 2 will be added to the protocol and reviews consideration sections above, respectively, as they become available.
Disagreements are no bad thing. Practicing a couple of assessments will always highlight differences that can be ironed out, but inter-rater discrepancies beyond that should be expected and may even improve the review. The signalling questions in RoB 2 provide a clearer framework for discussing differences in judgements and justifications than the old tool, and the process of doing so is a key part of gaining understanding and interrogating the evidence.

Early investment goes a long way. While RoB 2 is an outcome-based assessment, considering which domains are expected to be consistent across results within a study and designing the data-collection form accordingly can save a lot of time, e.g., issues in randomization will be common to all outcomes, issues of missing data may differ for outcomes at different time points, and issues of outcome assessment may be different between patient-reported outcomes and outcomes derived from routine data sources. The first few assessments may take some time to get right but, once done, subsequent assessments naturally become much easier and faster.

Back to bias assessment as it was always intended. Shifting from assessing studies to assessing results may initially feel like a daunting task but, once a rhythm is found, it can refocus the mind on why bias assessment is so important in Cochrane reviews. RoB 2 provides a framework for building meaningful bias considerations through reviews, from protocol planning to writing up results.

The authors are not expected to assess risk of bias for all results from all included studies: The risk of bias assessment should focus on results of studies that contribute information to outcomes that users of the review will find most useful. This will generally correspond to the results that are used to populate outcomes in 'Summary of Findings' (SoF) tables; however, this will depend on your review question and protocol, which may have specified other outcomes for risk of bias assessment. If there is no explicit link described here between the risk of bias and the SoF outcomes then editorial teams should ask for clarification in any feedback provided to the author teams. Also consider whether the number of outcomes intended for the SoF table is manageable.

Providing feedback on using RoB 2 in Cochrane
Cochrane is seeking feedback of your experience of using RoB2. All feedback is useful as we build the infrastructure and support for Cochrane Review groups (CRGs) to use RoB 2. Below are some questions to help us frame your feedback to use to make improvements. We suggest that you make notes on the questions as you proceed through the different stages of the review.

We may ask review teams if these questions can be used to develop Q&A community posts as a resource for future review groups, subject to approval by the review team.

Assessing risk of bias:
1. How did you find the process of selecting outcomes for RoB 2 assessment and did you face any issues with this?
2. How did you find the general process of using RoB 2?
3. How did you store the answers to the signalling questions and do you think it was fit for purpose? If not, what would you advise?

Tools and guidance:
4. Did you use any of the other listed guidance documents and if so, how did you find the usability, and do you have any recommendations for developing the guidance?
5. Did you make use of the updated data collection form on Cochrane.org? What were the main benefits and/or limitations of using the form, and do you have any recommendations for their development?
6. Did you use either the RoB 2 Excel tool or Word template? What were the main benefits and/or limitations of using the tool(s), and do you have any recommendations for its development?

**RevMan Web and Cochrane Library:**
7. How was the process of transferring RoB2 information into RevMan Web? What could facilitate this process?
8. Within the Results section, was the new ‘Risk of bias in included studies’ section fit for purpose? Did the pre-populated subheadings within that section facilitate reporting? Do you have any recommendations that could help facilitate RoB 2 reporting within the review?
9. Please provide feedback on the RoB 2 table in the RevMan Web. What sort of changes do you think are needed or advice would you give to others about using it?
10. Please provide feedback on the RoB 2 table in the Cochrane Library (in the published review). Do you think it is fit for purpose? If not, what do you advise?

**Other questions:**
11. How did you find this RoB 2 CRG Starter Pack and do you think there is any important guidance or information missing?
12. Were there any issues with any software, tools or guidance that haven’t been captured above? If so, please provide details.
13. What do you think should be our key priority to help CRGS use RoB 2 in the future (tools, software, guidance, training etc.)?
14. On reflection, was there anything you would have done differently at the protocol stage to facilitate the RoB 2 assessments?
15. What do you think the key benefit was in using RoB 2 for your review?
16. Any final comments to prospective review groups?