# RoB 2 Excel Marco Form Manual (Beta Version 7)

Date: 15 Oct 2020

## Table of Contents

# 1. General notes

- Enable Macros before you start
- Each workbook can take a maximum of 300 assessments
- Although this tool can manage different outcomes and different effects of interest (i.e. 'intention-to-treat' and 'per-protocol' effects) in the same review, we recommend that different files are created for different outcomes and effects of interest, so that separate summary tables and figures are produced for these.
- A YouTube channel contains short clips to illustrate each of the steps described below (see 'Demo clip' sign)

<Back to Table of Contents>

# 2. Getting started with your first RoB 2 assessment
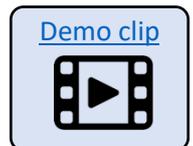
❶ Click the 'RoB 2 Assessment Form' button to initialise the user form (note: the form will look slightly different in Microsoft Excel for Mac, but functionality is not affected).

❷ Give each assessment a 'Assessment ID', and enter this in the relevant space on the form. The ID can be letters, numbers, or a combination of both, and is used to identify a specific risk of bias assessment. As RoB 2 is an outcome-based assessment, we recommend you to have a naming system incorporating the outcome. This will be used to match assessments done by another reviewer in the '*Discrepancy check*' function.

❸ Complete the assessment by filling-in all boxes on the form. Each bias domain of RoB 2 is on a separate tab in the form. Answers to the signalling questions should be selected from the drop-down menu, and there is space for justification for your answers.

❹ Give a final judgement and justification for each domain after reviewing your answers to the signalling questions and the suggested algorithm results. Click the 'Save' button.

❺ Enter a different 'Assessment ID' to create a new assessment.

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**Note**

- Double-clicking on the signalling question causes guidance on answering the signalling question to appear.

- Double-clicking the justification column in each domain will populate all the notes from the signalling questions. This is made to facilitate the Revman outputs.

- RoB 2 incorporates an algorithm to produce risk of bias judgements for each domain, based on the answers to the signalling questions. Clicking the 'Algorithm' button will cause such suggested judgements to appear. These can be used to inform the '*Assessor's judgement*' in the adjacent box.

- There is a box that enables you to input a weight for each result. This is set to 1.00 by default (each result has equal weight), but can be edited to reflect the weight given to the result has in the meta-analysis. This is only relevant for the plots created by clicking the 'Summary' button on the 'Intro' sheet (explained below). *Note that weights should be entered in the same format for all studies (e.g. decimal or percentage)*

**RoB 2 assessment for individual randomized, parallel group trials** ✕

| | |
|---|---|
| **Assessment ID** [ ▼ ] | **Assessor** [ ] 20/2/17 10.10 |
| **Study ID** [ ] **Ref. or label** [ ] | |
| **Experimental** [ ] **Comparator** [ ] | |
| **Specify which outcome** [ ] **Specify the numerical result** [ ] | |

**Which of the following sources were obtained to help inform the risk-of-bias assessment? (tick as many as apply)**
- ☐ Journal article(s)
- ☐ 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, Research Councils UK Gateway to R
- ☐ Personal communication with trialist

**Is the review team's aim for this result to assess...?** [ ▼ ] **Weight for analysis** [ ]

**If the aim is to assess the effect of adhering to intervention...(select one at least)**
- ☐ occurance of non-protocol interventions
- ☐ failures in implementing the intervention that could have affected the outcome
- ☐ non-adherence to their assigned intervention by trial participants

**Domain 1** | Domain 2 | Domain 3 | Domain 4 | Domain 5 | Overall bias

**Randomisation process**

| Signalling questions | Response | Description |
|---|---|---|
| 1.1 Was the allocation sequence random? | [ ▼ ] | [ ] |
| 1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions? | [ ▼ ] | [ ] |
| 1.3 Did baseline differences between intervention groups suggest a problem with the randomization process? | [ ▼ ] | [ ] |

**Risk of bias judgement**

Algorithm result  Assessor's judgement
[ Algorithm ]  [ ▼ ]  [ ]

Optional: What is the predicted direction of bias arising from the randomization process? [ ▼ ] [ ]

[ Guidance (Internet access) ]          [ CLOSE ]          [ SAVE ]

<Back to Table of Contents>

# 3. Editing existing assessments



Demo clip

There are two ways to edit an existing entry: a) by using the interactive form; or b) by directly editing the excel sheet containing the results:
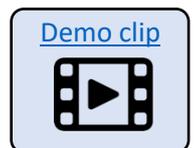
### a. Using the interactive form

❶ Find or type the 'Assessment ID' on the user form. The saved version of the assessment will be loaded.

❷ Make the necessary edits.

❸ Click the 'Save' button.

### b. Edit the Results sheet directly

❶ Find the sheet 'Results'.

❷ Make the necessary edits.

❸ Save the excel file.

**Note**

- The suggested risk of bias judgement for the domain will not update automatically. If you have made edits to your answers to your signalling questions you may wish to click on the 'Algorithm' button again.

<Back to Table of Contents>

# 4. Deleting an existing assessment

You will need to delete an existing assessment in the 'Results' sheet:

❶ Find the row corresponding to the assessment you wish to delete in the 'Results' sheet.

❷ Delete the whole row.

❸ Save the excel file.

<Back to Table of Contents>
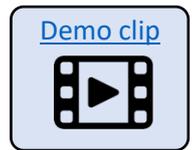
# 5. Creating a summary table and risk of bias graph

This outputs details of each assessment (Assessment ID, Study ID, Reference, Outcome, Result, Weight) plus domain level and overall risk of bias judgements. It also outputs risk of bias graphs that illustrate the proportions of results or information at low risk, some concerns or high risk of bias for each domain (example risk of bias graph shown below).

❶ Click the 'Summary' button on the 'Intro' sheet.

❷ All assessments should appear in the 'Summary' sheet.

❸ A plot of the percentage of risk of bias assessments at each level of risk of bias per domain will be displayed on the right-hand side of the sheet. The default setting results in equal weighting for each study (and the plot can be interpreted as showing the proportion of results at each level of risk of bias). If weights have been entered, the plot is weighted by this (and can be interpreted as the proportion of information at each level of risk of bias).

> **Note**
>
> • Change the order of studies by sorting results in the 'Results' sheet.

❹ Cross-check the results if necessary.



<Back to Table of Contents>
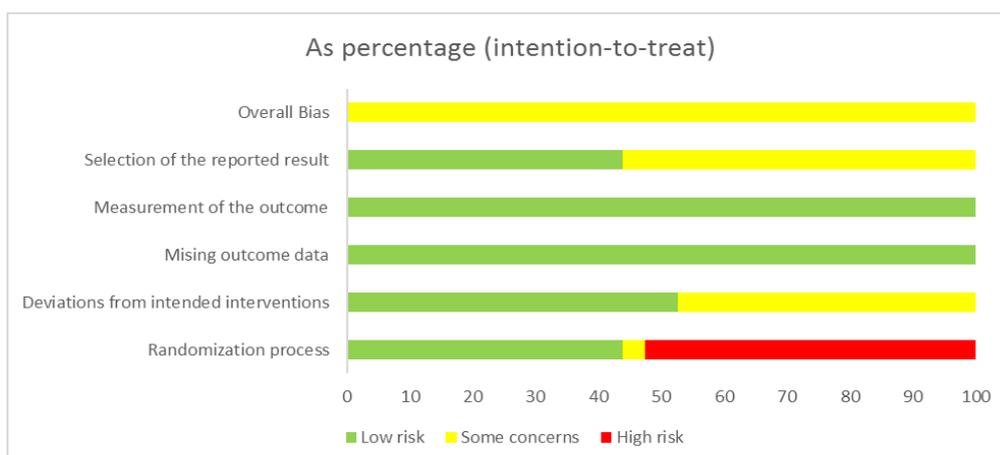
# 6. Risk of bias figures

This outputs Cochrane-style risk of bias figures ("traffic light plots"), which display the domain and overall judgements study-by-study, as shown below. Figures are displayed separately according to effect of interest ('assignment to intervention ' or 'adhering to intervention')

❶ Click the 'Figures' button on the 'Intro' sheet.

❷ Figures will be produced in the 'Figures (ITT)' or 'Figure (PP)' sheet depending on results.

❸ Figures can be further edited, for example by adding borders and lines using normal excel functionality, before being copied and pasted into manuscripts (we suggest pasting as 'picture' to avoid distortion in format).

❹ A separate button in each Figure sheet can print figures and saved as PDFs.

**Note**

• Change the order of studies by sorting results in the 'Results' sheet.

| Intention-to-treat | Unique ID | Study ID | Experimental | Comparator | Outcome | Weight | D1 | D2 | D3 | D4 | D5 | Overall | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | ID1 | Study1 | Experimental | Comparator | Effectiveness | 1 | + | ! | ! | ! | ! | - | + | Low risk |
| | ID2 | Study2 | Experimental | Comparator | Effectiveness | 1 | + | ! | ! | ! | ! | - | ! | Some concerns |
| | ID3 | Study3 | Experimental | Comparator | Effectiveness | 1 | - | ! | ! | ! | ! | - | - | High risk |
| | ID6 | Study6 | Experimental | Comparator | Effectiveness | 1 | ! | ! | ! | ! | ! | - | | |
| | ID7 | Study7 | Experimental | Comparator | Effectiveness | 1 | + | ! | ! | ! | ! | - | D1 | Randomisation process |
| | ID8 | Study8 | Experimental | Comparator | Effectiveness | 1 | + | ! | ! | ! | ! | - | D2 | Deviations from the intended interventions |
| | ID9 | Study9 | Experimental | Comparator | Effectiveness | 1 | + | ! | ! | ! | ! | - | D3 | Missing outcome data |
| | ID10 | Study10 | Experimental | Comparator | Effectiveness | 1 | + | ! | ! | ! | ! | - | D4 | Measurement of the outcome |
| | | | | | | | | | | | | | D5 | Selection of the reported result |

<Back to Table of Contents>

# 7. Populating results for printing

This outputs the full results for each study assessment, including the answers to signalling questions and the justifications given for answers, into a template. This may facilitate double-checking or allow the creation of supplementary materials for publications.

❶ Click 'Populate printing' on the 'Intro' sheet.

❷ Results will be copied and pasted in the 'Print (ITT)' or 'Print (PP)' sheets.

❸ You may need to adjust the height and width of columns and rows to accommodate text used for justification of answers.

❹ Change page breaks for printing if necessary.

**Note**

• Change the order of studies by sorting results in the 'Results' sheet.

• To ensure that the width of the template prints on one A4 sheet, we suggest selecting the option of scaling so that all columns fit on one page when printing.

<Back to Table of Contents>

# 8. Discrepancy check

This facilitates the discrepancy check between two reviewers' answers and allows the output of agreed (final) judgements. The two reviewers should enter their assessments into different Excel files. IT IS IMPORTANT BACK UP YOUR RESULTS (first reviewer's results) BEFORE USING THIS FUNCTION as the first reviewer's results will be replaced with the agreed judgements!
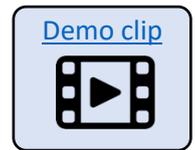
**[Setup]**

❶ Copy and paste *ALL* Reviewer 2's results (from their sheet called '*Results'*) into the 'Check' sheet.

❷ Ensure that the same 'Assessment ID's have been used for the assessments of the same results in BOTH reviewers' results.

**[Use]**

❶ Click the 'Discrepancy Check' button on the 'Intro' sheet.

❷ A user form should appear.

> **Note**
>
> • *Reviewer 2's results cannot be edited in this form*.

❸ Both reviewers' answers should be displayed side-by-side. Judgements will be coloured in red if the judgements reached by the two reviewers are different.

❹ Edit Consensus with final decisions and save. Results can then be produced using the 'Summary', 'Figures' and 'Print' functions as described previously.

<Back to Table of Contents>

# 9. System and software requirements

Microsoft Excel 2016 in Windows 10/7. The tool appearance looks different and might function differently in the Macintosh operating system. Please make sure you update your Excel to date.

The compatibility with older versions of Microsoft Excel has not yet been tested.

<Back to Table of Contents>

# 10. Contact

This is a beta version based on the RoB 2 version dated 22 Aug 2019 If you have any problems while using this form or any suggestions, please contact:

Vincent Cheng via risk-of-bias@bristol.ac.uk

<Back to Table of Contents>

# 11. Update

Key updates from V6:

- Updated the instructions with latest changes in the form and added YouTube videos to illustrate the use of the form
- Adjusted form size to resolve display problems in devices with low screen resolutions
- Added double-click to populate comments from signalling questions
- De-bugged 'Discrepancy Check' function for matching studies from the second reviewer
- De-bugged 'Summary' function for 'pre-protocol' assessments
- Separated 'Figures' into two tabs to simplify the figure production
- Added a new function to print Figures
- Revised the wording and aligned the signalling questions and elaboration with RoB 2 cribsheet dated 22 Aug 2019
- Set 'intention-to-treat' assessments as default after creating a new study
- Removed 'Double-click' for editing lists of resources and 'pre-protocol' questions to simplify the editing process
- Highlighted certain essential columns in the form

<Back to Table of Contents>