**Meeting title**: RoB 2 Pilot Web Clinic

**Location**: GoTo Meeting

**Date and time**: 19 December 2019, 12:00-13:00 (GMT)

**Recorded**: Yes (access recording [here](https://www.dropbox.com/sh/boc6gh44jh4q3fb/AAAGiNSZHXNf_t8KVo0rhLRxa?dl=0))

**Chair:** Kerry Dwan, Methods Support Unit Lead and Statistical Editor

**Other organisers:** Ella Flemyng (Methods Implementation Coordinator), Rebecka Hall (RevMan Product Owner), Tess Moore (Systematic Review Methodology Editor)

**Notes**: Tess Moore (Systematic Review Methodology Editor)

# **Minutes**

**Discussion points that relate to reporting:**

1. Showcase of the designs for interactive, outcome-level RoB 2 tables for inclusion in published Cochrane Reviews, including requests for feedback from you all on some design features (led by **Ella Flemyng**).

Feedback from attendees included:

* Concerns about the use of question marks for ‘Some concerns’: A question mark is more associated with the old terminology of ‘Unclear’ – could cause confusion for review teams to emphasis a change has been made between the previous tool and this version. Proposed an alternative of '≈'.
* Concerns with the upwards and downward arrows: People said the arrows suggested direction of change/effect instead of low and high. The arrows also suggest upgrading/ downgrading (terminology used for GRADEing).
* Feedback that the tables give a great overview of RoB assessments for an outcome.
* Some preferred the table version without text in the cell with a legend (especially for reviews with >40 studies), some preferred the tables with text in the cells. Especially as users become used to the icons, the wording in the cells might be less needed.
* If you do have text in the cells, requested that it says ‘High risk’ and ‘Low risk’, not ‘High’ and ‘Low’ as this could be confused with high and low quality (users can confuse bias and quality so need to be clear).
* Requested that the icons used for the different assessments (high risk, low risk and some concerns) are kept consistent across forest plots, tables and figures, etc (in Cochrane Reviews and RevMan).
* Need to ensure we consider the readability of the Review more generally as having seven of these large tables (for your seven outcomes) within a Review could take the emphasis away from the effect of the intervention and make RoB assessments seem more dominant.

***Please share any further feedback or comments with Ella Flemyng.***

1. Guidance on writing up RoB 2 in the Results section (led by **Kerry Dwan**).

RoB 2 Pilot Team (Kerry Dwan, Ella Flemyng and Tess Moore) are developing guidance on how to write up of RoB2 results section.

Ella Flemyng is working with the other MECIR authors to update the Protocol, Reporting and Updating standards to reflect RoB 2 (currently only the Conduct standards are RoB 2 compliant).

Discussed some considerations for the results section:

* Include all the interesting points relating to RoB2 (rather than re-summarising, especially with the outcome-level table summary discussed in Agenda Point 1 above).
* Need to consider what should be discussed in the ‘Effects of interventions’ section.
* Need to consider what should be discussed in the ‘GRADE’ section and how it is reflected in the SoF table.

**Discussion points that relate to Domain 2:**

1. Review with the effect of interest as adherence with a selected outcome of (specific) adverse effects – which deviations from the intended interventions should be specified in this case (led by **Tess Moore**)?
   1. occurrence of non-protocol interventions
   2. failures in implementing the intervention that could have affected the outcome
   3. non-adherence to their assigned intervention by trial participants

Further comments: *Could option 3 be the most appropriate, though in the majority of the studies it is not reported whether AEs and SAEs had any impact on the adherence to treatment protocol, a part of discontinuation due to AEs, which is a separate outcome in our review and assessed at the level of assignment on the randomised participants (ITT)*

If you are interested in adverse/serious adverse events, then please select all three of the types of deviation, this is because all have the capacity to affect the outcome.

The guidance was meant to be read to i) explain the different types of deviations that COULD appear in an RCT and ii) allow review authors to drop one of them if there was some reason it didn't apply to a specific set/ type of RCTs. Or you weren't interested in it. For adverse events/ serious adverse effects, you would want to look at all three of these.  The simplest way forward is to include all three types. Information on this for “Effect of adherence to intervention can be found in Section 5.2, Section 5.3.1 and Box 7 and Table 7 of the RoB\_2.0\_guidance\_parallel\_trial 20190822. Examples of deviations are also included in Box 5 of the RoB\_2.0\_guidance\_parallel\_trial 20190822.

The guidance states:

 "When assessing the effect of adhering to the intervention review authors should specify what types of deviations from intended intervention will be examined  which will be one or more of of (i) occurrence of non-protocol interventions; (ii) failures in implementing the intervention that could affect the outcome; and (iii) non-adherence by trial participants to their assigned intervention (see section 5.3). We have summarised briefly below but please read the detailed guidance for the specifics.

"i) occurrence of non-protocol interventions…" This refers to interventions the trial participants might get that aren't in the trial protocol - BUT are related to the trial i.e. it is an 'intervention'' that is not expected.

"ii) failures in implementing the intervention that could affect the outcome..." This refers to the outcome not being delivered as it should be. E.g. For a psychological therapy that follows a manual - and in the trial -  therapists who  do not follow the manual  for example participants will not get the  intervention as it was meant to be delivered in the trial protocol.   For drugs - this could be medicines not stored correctly - e.g. vaccines. Or a  lower dose of drugs was given out by a pharmacy - because that was all that was available. It is the sort of thing trialists might report if things go wrong with their RCT. It might be rare - but if you saw it reported - you would want to record it and make a judgement on bias.

“iii) adherence to the intervention…” This could cover for example people in the protocol arm seeking out the intervention – even though they were not randomised to it, switches from one arm to another IF this was not allowed for in the Trial protocol,

re Deviations

1. Request for more examples for “Deviations from interventions” domain that are specific to the “Effect of adherence to intervention” and for adverse event outcomes (if these are different to how one would consider other outcomes).

RoB 2 Pilot Team (Kerry Dwan, Ella Flemyng and Tess Moore) will raise this with the RoB 2 researchers and Bias Methods Group.

**Discussion points that relate to Domain 5:**

1. Selection of the reported results - Domain 5 specific signalling question 5.1, 5.2, and 5.3 ask reviewers to compare to the pre-specified analysis plan, or the protocol. When the study protocol is not available, is it correct to use the information reported in the published article (Methods section) to answer the signalling questions (led by **Kerry Dwan**)?

Please use all documentation available for each RCT (its ok if this varies across RCTs in a review). If you haven’t got any prespecified information then be transparent in how you make your decisions and be consistent. If there is no information then use the no information option. Authors have the option to us “Probably yes” and “Probably no” as they are making decisions. Please document how you do this.

**Discussion points that relate to conducting RoB 2 assessments:**

1. Call for feedback on the RoB 2 Excel tool and contact details for user queries (led by **Tess Moore**).

Excel tool: ROB 2\_IRPG\_2018\_beta\_v6\_25Jun2019 is not very use friendly with minimal instructions to use. If a RoB 2 domain has the same assessment for multiple outcomes, it’s not clear how to copy this across so you don’t have to manually re-enter it in another Excel file.

You can email [risk-of-bias@bristol.ac.uk](mailto:risk-of-bias@bristol.ac.uk) to feedback any issues with the Excel tool.

This guidance has also now been added to the Starter Pack in the FAQs:

***When using the RoB 2 Excel tool, if I have assessed risk of bias for one outcome from a study and have a second outcome that will have (some of) the same domain outcomes and responses to signalling questions, how can I copy these across to the second outcome?***

*Use the following process:*

1. *Complete the RoB Assessment Form for the first outcome (e.g. Unique ID “outcome1” and Study ID “study1”) and close the interactive window*
2. *Go to the Excel worksheet tab “Results”*
3. *Copy the complete row for outcome1 (should be row 3 if it’s the first assessment)*
4. *Paste it into the following row (e.g. row 4)*
5. *Edit the Unique ID for the new row (e.g. cell B4) to a new ID, e.g. “outcome2”*
6. *Go back to the first Excel worksheet tab (“Intro”) and open up the RoB 2 Assessment Form.*
7. *In the drop-down box for Unique ID you should now have two identical assessments, but with different Unique IDs. You can amend the second one to match the second outcome in the study.*

**Any other business:**

Next clinic is on 30 Jan 2020 at 4pm GMT.

Updates to the RoB 2 starter pack:

* [risk-of-bias@bristol.ac.uk](mailto:risk-of-bias@bristol.ac.uk) email address added in case you have any issues with the Excel tool

***Request to all pilot review groups to drop us a brief email with the status of your review for our records.***