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

**Location**: GoTo Meeting

**Date and time**: 24 September 2020, 16:00-17:00 (BST)

**Recorded**: Yes (all past recordings are available [here](https://www.dropbox.com/sh/boc6gh44jh4q3fb/AAAGiNSZHXNf_t8KVo0rhLRxa?dl=0))

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

**Other organisers:** Tess Moore (Systematic Review Methodology Editor), Ella Flemyng (Methods Implementation Coordinator), Bias Methods Group

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

**Agenda:**

1. Updates from last Web Clinic:
   1. Update on numbers of Reviews in the Pilot.

72 using RoB 2, with another 15 that have expressed an interest

5 reviews have been submitted

The first has moved to copyedit today

1. Questions to be discussed:
   1. **Is there an easy way for 2 reviewers to use the spreadsheet, blinded to the others judgements until the discrepancy check? (Neil O’Connell):**

You can use a separate spreadsheet each as long as you agree on the unique code for each study and outcome. Then you can follow the steps for the discrepancy check.

* 1. **How do we do a discrepancy check for the judgements? (Sarah Hetrick):**

You can do this within the excel tool and this is described on the first tab of the excel tool. How to do the discrepancy check was demonstrated. It was highlighted that the two assessors should save their independent spreadsheets and then create a third consensus spreadsheet as when you do the discrepancy check it will change the first assessors decisions to the consensus decision.

* 1. **On the spreadsheet we’ve noticed that the “sources of info” options disappear after the first selection -  it would be handy if they didn’t. (Neil O’Connell):**

Have you tried double clicking in the space to make it appear? (if they have it might be worth reporting this issue to Vincent?)

* 1. **Is there an easy way to carry over judgements and comments from judgements from the same trial to different ROB2 assessments or do we need to cut and paste by hand? (Neil O’Connell):**

If you go into the Results tab in excel you can copy and paste an assessment into a new row. You should then edit the Unique ID (and optionally any other fields, such as the outcome). When you return to the data entry box, the new assessment will appear, and you can edit the entries as appropriate for the new assessment. (Note that you can actually do all the editing in the Results tab; it’s just less convenient.)

* 1. **When comparing judgements and agreement do we necessarily need to resolve “Y vs PY” or “N vs PN” judgements given that they both result in the same outcome in terms of bias judgement? (Neil O’Connell):**

This is necessary if the authors will present the answers to the signalling questions, which is a recommendation (but probably not mandatory). I suggest that generally it would be safe to resolve in the direction Y to PY.

* 1. **When assessing risk of bias are we assessing for the primary outcome of the review, and not the trial. But, if, for example, if our primary outcome is repetition of self-harm at post-intervention, but the trial’s is at 18 months, and no data is reported on self-harm at post-intervention in the trial, is it fair to assess the trial at “some concerns” on the basis of selective outcome reporting if this never was the time point that the trial nominated as its primary end point? (Katrina Witt):**

It depends what is specified in the review protocol – this is what you are assessing. It also depends how specific you have been in your protocol. In the example you give, you have no data at post intervention so you would not assess this trial for RoB 2 as there is no result to assess at the timepoint you have specified and therefore nothing to include in the meta-analysis.

* 1. **Domain 1. We have an instance (and will likely have many more) of a small trial (n=24, split into 4 conditions) that randomised, concealed allocation but presents no baseline date for each condition. It is quite common for these trials to have sizeable baseline differences (at random). I have seen instances in the past where the final post-intervention between group difference is smaller than the baseline difference but hailed as a positive result. So for signalling question 1.3 we might say NI and the algorithm takes us to low, but the issues above raise concerns. As the imbalance likely occurred at random should we keep it “low” or judge “some concerns” as it might still be a substantial issue. (Neil O’Connell):**

I’m not quite sure here if they mean it is randomised into 4 or stratified into 4 and then randomised to 2 interventions? The author clarified this was randomised to 4 groups. Baseline imbalances will occur by chance and likely more apparent in a trial with such small numbers. The majority of the time the answer to this question is N/ PN/ NI and not as Y/ PY unless you have strong concerns about an important prognostic factor. You can always override the judgement for the domain but you would need to provide justification for this. Even if the post-intervention differences are smaller than the baseline differences, if these are all due to chance then wide confidence intervals should reflect this.

* 1. **Domain 2 and 4. Issues of participant blinding seem to be well addressed in signalling questions 2.1. However many of our outcomes are self-reported (pain intensity) with the participant the assessor and so the same issues can be picked up in Domain for and SQ 4.3. This was always an issue with ROB1 too. In the instance of unblinded participants where that might influence their experience with and engagement with an intervention (Domain 2) and their perception of the outcome and subsequent assessment of it (Domain 4) would we double-dip and reflect that ROB in both domains? (Neil O’Connell):**

Domain 2 covers deviations from intended interventions whereas Domain 4 is covering measurement of the outcome. These domains cover different aspects, so a trial should not be penalised twice for the same issue. Domain 2 addresses things that the participant does, or trial personnel do, that would change the true value of the outcome (e.g. the amount of pain present), and Domain 4 addresses how the participant portrays the outcome (e.g. whether they misreport the pain they experience). It may be that both are a problem, or one or the other, or neither.

* 1. **Adverse events have posed an issue for us so far. They are generally poorly reported and often presented only descriptively and without adequate information to include in an analysis. So as ROB2 is based on the results of our pooling studies to generate an estimate of effect we might not need to do ROB2 for those papers as the best we will manage it to describe what they reported. However that raises a wider issue for us about analysing ROB where we do not pool data, or have a rather messy narrative synthesis, as we will still want to be able to make robust comments around the certainty of that data. (Neil O’Connell):**

Even if you are not pooling data and you have a numerical result whether you are presenting this narratively or using SWIM methodology you can still undertake RoB 2 assessments. However, if you do not have a numerical result, or only a partially reported result i.e. a p-value you would not use RoB2. There is another tool in development but it is not yet finalised or approved by the scientific committee. You can still use GRADE to assess the certainty of the evidence.

* 1. **My understanding is that once the analysis is done, that is the point at which we start to use the web based ROB2 tool? May I just check this understanding and that I am to ignore the risk of assessment functionality in Covidence? (Lorna O’Doherty):**

Please do not use the risk of bias assessment functionality in Covidence (it’s not RoB 2 compliant). Instead we advise that you use the Excel tool hosted on the [riskofbias.info website](https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsites.google.com%2Fsite%2Friskofbiastool%2Fwelcome%2Frob-2-0-tool%2Fcurrent-version-of-rob-2%3Fauthuser%3D0&data=02%7C01%7Ckdwan%40cochrane.org%7Ce7c61b245bde4c39f6d908d859877387%7Cb6c2e21e4db74533916398c1451c1caa%7C0%7C0%7C637357785940656619&sdata=VcV1zWNUmqw%2BTUpyjjekuAp3BPq1TKrkdNSTy8U%2BRIE%3D&reserved=0). We are developing a screencast to introduce this tool to review teams and will be able to share it as soon as it’s ready. However, there is an informative overview on how to use the tool on the first sheet in the Excel file too.

Please ensure you import your data from Covidence into the desktop RevMan5 before you switch on RoB 2 in RevMan Web as switching on RoB 2 breaks compatibility with RevMan5. You don’t need to switch on RoB 2 in RevMan Web until you have input all of your results data.

1. Any other questions or feedback from pilot teams on using RoB 2 - anything to share from reviews in the pilot, such as tricks, tips or challenges.
2. Recent updates to the RoB 2 Pilot Starter Pack.

Added a RoB 1 vs Rob 2 table at the beginning to showcase some of the differences between the tools.

General rewording throughout to bring the text up-to-date.

Protocol checklist now includes an example published protocol to look at.

In the reporting of the full review checklist, the point about stating whether the bias of bias assessments have implications on the reviews objective or conclusions in the Effects of Intervention section has been moved to the GRADE consideration section in the Discussion following feedback from MEs.

Show where to find the most up-to-date version <https://methods.cochrane.org/risk-bias-2>

Highlight the introduction pack and the short videos.

1. Next web clinic – Thursday 29 October, 09:00-10:00 (GMT).
2. Request from Ella Flemyng to all pilot review groups to drop us a brief email with the status of your review for our records.