Final Report N61: Refinement of and extension to the Cochrane Risk of Bias tool for Randomised trials

Applicants: Jelena Savović, Julian Higgins, Vincent Cheng, Jamie Kirkham, Matthew Page, Rebecca Turner, Jonathan Sterne

Summary of original objectives

- We aimed to facilitate use of our new RoB 2 tool by producing an easy-to-use, online interactive implementation of the tool.

What was achieved

- During the course of the project, the RoB 2 tool itself was further piloted, refined, and eventually published on 28 August 2019 (BMJ 2019; 366: l4898; doi: https://doi.org/10.1136/bmj.l4898).
- We developed the online system, which implements the latest (published) version of the tool. It includes features such as:
    - user registration and log in;
    - set-up of a systematic review, of studies within the review, and of results within the study;
    - storage of documents relevant to a study within the system;
    - implementation of the full RoB 2 tool;
    - full implementation of the conditionality in the tool, such that signalling questions are greyed out if there is no need to answer them (on the basis of the answer to a previous signalling question);
    - interactive implementation of the basic guidance for completing the tool: elaborations for each signalling question and judgement appear in pop-up boxes when hovering over the section;
    - implementation of algorithms within each bias domain, so that the system automatically displays a suggested risk-of-bias judgement for the domain once the signalling questions within the domain have been answered;
    - separation of free text information to support each signalling question in the forms of (i) quotes from reports and (ii) assessor's comments (the former to facilitate machine learning at a later date);
    - implementation of the algorithm across domains, so that the system automatically displays a suggested overall risk of bias judgement once the domain-level judgements have been confirmed;
    - an embedded tool to compare and consolidate assessments from two or more assessors of the same result, with the ability to copy one of these assessments into a 'consensus' assessment, and edit this to refine and finalize it;
    - export routines to produce publishable tables and figures.
- The tool has been tested by members of our RoB 2 team here in Bristol.
- We are still awaiting a successful outcome to our application for a public server on which to host the tool (lodged on 11 October 2019). We have no reason to fear that the application will be denied, and just have to wait for the outcome. Although we are therefore unable to provide access to the tool at the time of writing, we include a series of screenshots below for illustration.
- We worked closely with Cochrane, following their decision to embrace the tool and roll it out across the organization. We are currently working with the Cochrane RevMan Web team and Cochrane Methods team to explore integration of our tool with Cochrane software and processes.
- We delivered several dissemination events about RoB 2, including:
    - Cochrane 2019 Methods Training Event commissioned by Cochrane Methods with a view to rolling out the RoB 2 across the organization: *Assessing Bias in Randomized and Non-Randomized Studies: Cochrane Risk-of-Bias*, (Bristol, 10-12 July 2019; 47 participants);

- Invited workshop at Cochrane Croatia: *Assessing Risk of Bias in Randomized Trials (RoB 2)*. (Split, 27 Jun 2019; 15 participants);
- Guest Lecture, London School of Hygiene and Tropical Medicine MSc course: *Assessing risk of bias in randomized and non-randomized studies* (April 2019);
- Training workshop at Cochrane UK & Cochrane Ireland Symposium: *Assessing risk of bias in randomized trials (RoB 2)*, (Oxford, 21-22 March 2019; ~50-60 participants);
- Short courses at the Swiss Epidemiology Winter School: *Assessing Bias in Randomized and Non-Randomized Studies: New Approaches, New Tools* (Wengen, 21-23 Jan 2019 and 20-22 Jan 2020; 25 participants each).

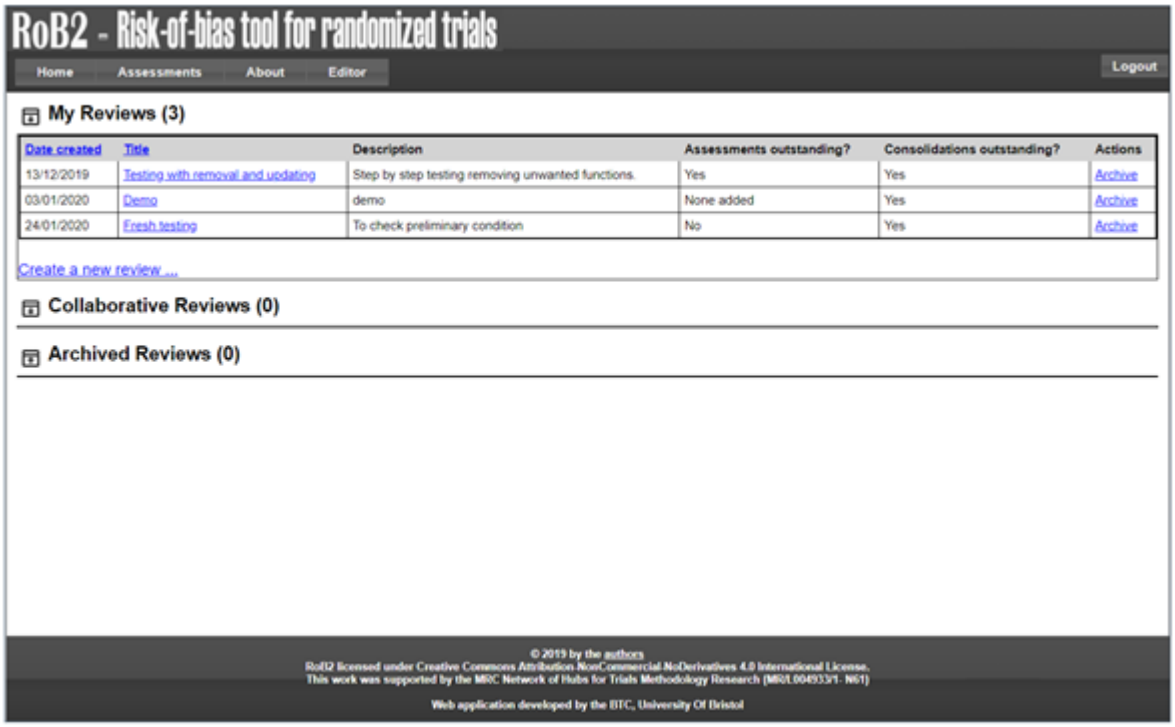
Next steps over coming 12 months

- We will upload the tool to a public server once we are given access to one.
- We will invite a larger group of testers to try out the tool.
- We will improve the appearance and operability of the tool in response to feedback from users.
- We will disseminate information about the tool, particularly through Cochrane (including the Cochrane Colloquium to be held in Toronto in October 2020).

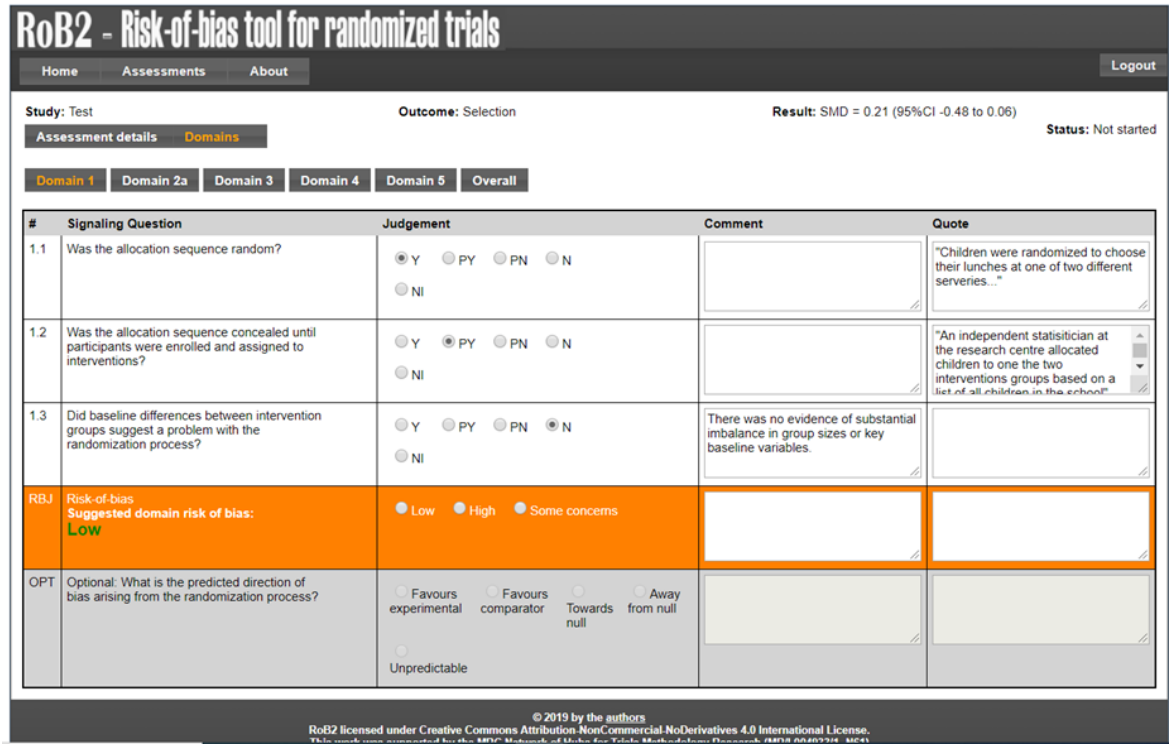
Appendix: Screenshot illustrations

1. Log in screen.

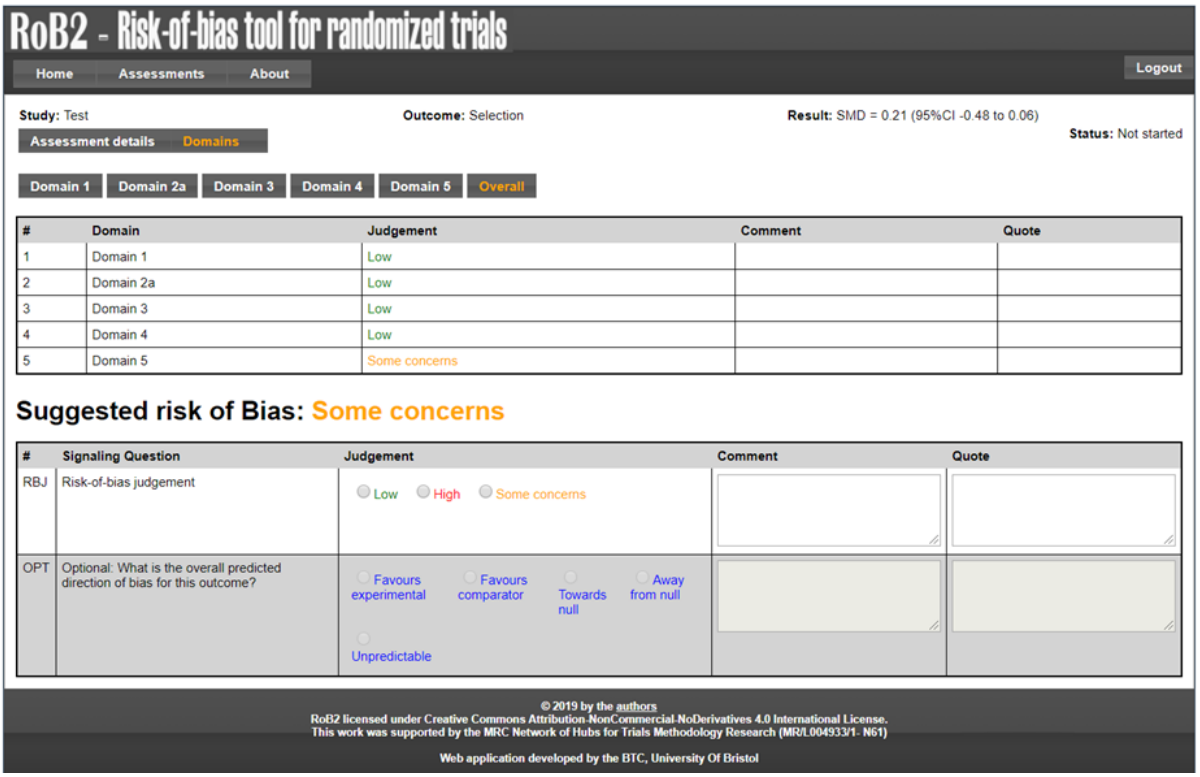
2. List of reviews (My Reviews are those owned by the user; Collaborative Reviews are those on which the user has been invited to make assessments of risk of bias).



3. Assessment of the domain “Bias arising from the randomization process”, illustrating how the suggested risk-of-bias judgement based on the in-built algorithm (“Low”) is displayed to the assessor.



4. Overall risk of bias assessment, illustrating how the suggested overall risk-of-bias judgement based on the in-built algorithm (“Some concerns”) is displayed to the assessor.



5. The assessment consolidation screen in which the assessments of two assessors (AA and BB) of the same result and displayed side-by-side, with the ability to copy over one or the other, and enter a consensus assessment. This facility is enabled once both of the initial assessments have been 'locked'.