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Title: Ten Top Tips for using the Risk of Bias 2 (RoB2) tool

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Background

In 2019 Cochrane adopted a new tool (RoB 2) for assessing risk of bias in randomised controlled trials. The tool incorporated new advances in bias research and differed markedly from its predecessor in how it was applied. Cochrane introduced a phased implementation of the RoB 2 tool, with mentored support from the Cochrane Methods support unit (MSU) to assist authors who were new to using it. The MSU team noticed some commonly occurring misconceptions and misapplications by authors. These could potentially lead to inappropriate assessments of bias which could affect certainty in evidence.

Objectives To compile a list of 10 top tips to help authors apply the RoB 2 tool

Methods

From June 2019 to December 2020 the MSU team assessed 144 reviews and protocols and made a record of the most common misapplications and misconceptions in using RoB 2. We made them into a short list of ten useful hints and tips for any review authors, not just Cochrane authors, new to using RoB 2.

Results

The top tips cover all domains of the RoB 2 tool and are as follows. 1) State the effect of interest 2) State the outcome to be assessed 3) Pilot the tool to achieve consistency 4) Apply the tool to a specific numerical result 5) Answer all of the signalling questions 6) Consider whether baseline imbalance reflects problems with the randomisation process rather than chance 7) Don't assume a lack of blinding increases risk of bias 8) Participants changing interventions is not always a cause for concern 9) Avoid arbitrary thresholds for missing data and consider the analysis used 10) A "statistical analysis plan" can be a protocol or a trial register entry - but check the date it was registered.

Conclusions

The list of top tips with their explanations can help authors to answer some of the less familiar concepts covered in the new RoB 2 tool as well as offering practical suggestions. We think this will help authors avoid some of the common pitfalls the MSU saw with authors new to using RoB2 tool.

Relevance and importance to patients: This work is relevant to patients in that it can assist in the more robust evidence production.