Cochrane Public Health Project 1. Characteristics of Preferred/Acceptable Risk of Bias Tools for Non-Randomised Studies of Interventions

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the study is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. This study has been approved by the GSBS Ethics Committee, Glasgow Caledonian University (United Kingdom).

Why is this study being carried out?

This project will produce guidelines that will be used by Cochrane review authors and editors to help them choose the optimal way to assess risk of bias when conducting a systematic review that includes non-randomised studies of interventions, when ROBINS-I cannot be used to assess the included studies. The aim of this survey is to collect views on the relative importance of different characteristics of risk of bias tools. The results will be used to inform recommendations of preferred and acceptable tools, and guidance on how to select a tool for use in a review.

Why have I been invited to take part?

The members of the following interest groups have been approached to take part in this study: Cochrane Public Health and Health Systems Network; Cochrane Bias Methods Group; Cochrane Non-Randomised Study Methods Group; GRADE NRS Project Group. You have been approached because you are a member of one or more of these groups, or an author of a recent COVID-19 related review. If you have received multiple invitations, please complete the survey only once.

Do I have to take part?

You can decide whether or not you want to take part. If you do decide to take part, you will be asked to indicate your consent by selecting 'Yes - Start Survey' below. If you do decide to take part, you are still free to withdraw at any time and without giving a reason by closing this browser window. A decision to withdraw at any time, or a decision not to take part, will not affect your role or relationships in the interest groups or in Cochrane; participation is anonymous. If you would like further information or to discuss the study before or after taking part, you can contact the lead researcher, Dr Michele Hilton Boon, at mbo5@gcu.ac.uk.

What will happen if I take part?

You will be asked in the survey to indicate your opinion of the relative importance of different characteristics of risk of bias tools. The lead researcher will analyse the survey results. All participation is anonymous and IP addresses of participants will not be collected. All individual responses are confidential. Any details of responses that could constitute identifiable data will be removed before responses are quoted or summarised in the study results. No personal data will be requested or collected from you.

How long will it take?

It may take 20 minutes of your time.

What will happen to the information that I give?

The data will be securely stored on the GCU REDCap platform server and access will be password protected. Only aggregate data will be reported. The project will be completed by 31 March 2022 and the data will be deleted on 30 June 2022.

Will I benefit directly from this research study?

This research will be used to inform guidance that in turn will produce improvements in the quality and consistency of Cochrane reviews. The guidance may help Cochrane authors and editors to make decisions when a risk of bias tool other than ROBINS-I is needed to assess non-randomised studies. However, these outcomes cannot be guaranteed. The information we get from this study may also point to further research and guidance that could help to improve the quality of Cochrane reviews in future.

What to do now

If you would like more information before you decide about taking part, please contact the lead researcher, Michele Hilton Boon (mbo5@gcu.ac.uk).

If you would like to take part, please select ‘Yes - Start Survey’ below.

Thank you for taking time to read this information.

I confirm that I have read and understood the above information; that my participation is voluntary and I can withdraw at any time; and that I agree to take part in the above study.	◯ Yes - Start Survey

Structure and presentation of tool (9 items). Rate the importance of each criterion in deciding whether to use a particular risk of bias tool for non-randomised studies of interventions.

		essential	desirable	unimportant	not sure
1	User guidance is provided	○	○	○	○
2	The user guidance explains the interpretation of each criterion/item/signalling question	○	○	○	○
3	Training materials are available to support new users	○	○	○	○
4	The tool supports outcome-based or result-level-based assessment	○	○	○	○
5	The tool supports documentation of the processes followed in arriving at a judgment	○	○	○	○
6	The tool supports documentation of evidence from the study used to arrive at a judgment	○	○	○	○
7	Responses to signalling questions are suitable for traffic-light presentation consistent with other Cochrane ROB tools, i.e. yes/no/some concerns	○	○	○	○
8	The overall judgment is consistent with other Cochrane ROB tools, i.e. high/some concerns/low risk of bias	○	○	○	○
9	The formatting and output of the tool enable comparison of risk of bias across studies	○	○	○	○

Any comments on the structure and format of preferred/acceptable risk of bias tools for non-randomised studies?

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Development methods of tool (9 items). Rate the importance of each criterion in deciding whether to use a particular risk of bias tool for non-randomised studies of interventions.

	essential	desirable	unimportant	not sure
The methods used to develop the tool have been documented and reported	○	○	○	○
The tool was developed using standard psychometric techniques (Streiner & Norman, 1991)	○	○	○	○
The reported methods of development included a comprehensive literature search	○	○	○	○
The reported methods of development included a critical review of existing tools	○	○	○	○
The reported methods of development included consultation with experts	○	○	○	○
The reported methods of development included user testing/pilot testing	○	○	○	○
The development process was based on a pre-specified protocol	○	○	○	○
The tool has been published in a peer-reviewed journal	○	○	○	○
The developers have disclosed any conflicts of interest	○	○	○	○

Any comments on the development methods of preferred/acceptable risk of bias tools for non-randomised studies?

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Content of tool (9 items). Rate the importance of each criterion in deciding whether to use a particular risk of bias tool for non-randomised studies of interventions.

	essential	desirable	unimportant	not sure
The tool's explicit purpose is for risk of bias assessment in systematic reviews	○	○	○	○
Domains and signalling questions are based on empirical evidence of risk of bias where possible	○	○	○	○
The tool assesses confounding	○	○	○	○
The tool assesses selection bias	○	○	○	○
The tool assesses information bias	○	○	○	○
The tool assesses reporting bias	○	○	○	○
The tool includes a method for arriving at a summary (overall) risk of bias judgment	○	○	○	○
The tool DOES use a quantitative summary score	○	○	○	○
The tool DOES NOT use a quantitative summary score	○	○	○	○

Any comments on the content (signalling questions, scoring) of preferred/acceptable risk of bias tools for non-randomised studies? _____

Performance of tool (2 items). Rate the importance of each criterion in deciding whether to use a particular risk of bias tool for non-randomised studies of interventions.

	essential	desirable	unimportant	not sure
The tool's validity has been formally assessed	○	○	○	○
The tool's reliability has been formally assessed	○	○	○	○

Any comments on the performance (validity, reliability) of preferred/acceptable risk of bias tools for non-randomised studies? _____

User perceptions (7 items). Rate the importance of each criterion in deciding whether to use a particular risk of bias tool for non-randomised studies of interventions.

	essential	desirable	unimportant	not sure
Signalling questions/criteria are easy to interpret	○	○	○	○
The tool is comprehensive in addressing all elements of risk of bias	○	○	○	○
The tool has good validity	○	○	○	○
The tool has good reliability	○	○	○	○
The tool is easy to use	○	○	○	○
The time required to complete assessments is feasible within the context of the review	○	○	○	○
The methodological expertise required to complete assessments is feasible within the context of the review	○	○	○	○

Any comments on the user perceptions of preferred/acceptable risk of bias tools for non-randomised studies? _____

Any other considerations

Are there any considerations in selecting a risk of bias tool that you consider important that have not been addressed in the above questions?

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