Assessing risk of bias in included studies (C52-C60) 2

Assessing risk of bias in included studies (C52-C60)

Cochrane Training resources: assessing RoB and RoB 2.0 webinar

Cochrane Interactive Learning (CIL): module 5 - introduction to study quality and risk of bias

	Standard	Rationale and elaboration	Resources
C52	*Assessing risk of bias*	***Mandatory***	
	Assess the risk of bias for each study result contributing to an outcome in the 'summary of findings' table. For randomized trials, the RoB 2 tool should be used, involving judgements and support for those judgements across a series of domains of bias, as described in the *Handbook.*	Risk of bias in individual study results for the included studies should be explicitly considered to determine the extent to which findings of the studies can be believed. Risks of bias might vary by result. It may not be feasible to assess the risk of bias in every single result available across the included studies, particularly if a large number of studies and results are available. Review author should therefore assess risk of bias in the results of outcomes included in their 'summary of findings' tables, which present the findings of seven or fewer outcomes that are most important to patients. The RoB 2 tool – as described in the *Handbook*– is the preferred tool for all randomized trials in new reviews. The Cochrane Evidence Production and Methods Directorate is, however, aware that there remain challenges in learning and implementation of the tool, and use of the original Cochrane risk of bias tool is acceptable for the time being.	See *Handbook* Section 7.1.2; Chapter 8
C53	*Assessing risk of bias in duplicate*	***Mandatory***	
	Use (at least) two people working independently to apply the risk-of-bias tool to each included study, and define in advance the process for resolving disagreements.	Duplicating the risk-of-bias assessment reduces both the risk of making mistakes and the possibility that assessments are influenced by a single person's biases.	See *Handbook* Section 7.3.2; Chapter 8
C54	*Supporting judgements of risk of bias*	***Mandatory***	
	Justify judgements of risk of bias (high, low and some concerns) and provide this information in the risk-of-bias tables (as 'Support for judgement').	Providing support for the judgement makes the process transparent.	See *Handbook* Section 7.3.2; Chapter 8
C55	*Providing sources of*	***Mandatory***	

	information for risk of bias assessments		
	Collect the source of information for each risk of bias judgement (e.g. quotation, summary of information from a trial report, correspondence with investigator etc.). Where judgements are based on assumptions made on the basis of information provided outside publicly available documents, this should be stated.	Readers, editors and referees should have the opportunity to see for themselves from where supports for judgements have been obtained.	See *Handbook* Section 7.3.2; Chapter 8
C56	*Summarizing risk-of-bias assessments.*	***Highly desirable***	
	Summarize the risk of bias for each key outcome for each study	This reinforces the link between the characteristics of the study design and their possible impact on the results of the study and is an important prerequisite for the GRADE approach to assessing the certainty of the body of evidence.	See *Handbook* Section 7.5; Chapter 8
C57	*Addressing risk of bias in the synthesis.*	***Highly desirable***	
	Address risk of bias in the synthesis (whether quantitative or non-quantitative). For example, present analyses stratified according to summary risk of bias, or restricted to studies at low risk of bias.	Review authors should consider how study biases affect results. This is useful in determining the strength of conclusions and how future research should be designed and conducted.	See *Handbook* Section 7.6.1; Chapter 8
C58	*Incorporating assessments of risk of bias.*	***Mandatory***	
	If randomized trials have been assessed using one or more tools in addition to the RoB 2 tool, use the RoB 2 tool as the primary assessment of bias for interpreting results, choosing the primary analysis, and drawing conclusions.	For consistency of approach across Cochrane Intervention Reviews, the RoB 2 tool should take precedence when two or more tools are used for assessing risk of bias in randomized trials. The RoB 2 tool also feeds directly into the GRADE approach for assessing the certainty of the body of evidence.	See *Handbook* Section 7.6.1; Chapter 8
C59	*Addressing conflicts of interest in included trials.*	***Highly desirable***	
	Address conflict of interests in included trials, and reflect on possible impact on: a) differences in study design; b) risk of bias in trial result, and c) risk of bias in synthesis result	Review authors should consider assessing whether they judge a trial to be of “notable concern about conflicts of interest”. This assessment is useful for exploration of possible heterogeneity between trials (e.g. in a subgroup analysis), and for reflection on relevant mechanisms for how conflict of interest may have biased trial	See *Handbook* Section 7.8.6; Chapter 8

		results and synthesis results. Concerns about conflicts of interest can be reported in the 'Characteristics of included studies' table.	
C60	*Not applicable*		