

Supplemental Table 4. The risk of bias assessment tool for randomized controlled studies

Supplemental Table 4.1 The risk of bias table

Item	Judgement	Support for judgement
Random sequence generation (selection bias)		
Allocation concealment (selection bias)		
Blinding of participants and personnel (performance bias)		
Blinding of outcome assessment (detection bias)		
Incomplete outcome data addressed (attrition bias)		
Selective reporting (reporting bias)		
Other bias		

Supplemental Table 4.2 The recommended list of items in the risk of bias tool

Bias domain	Source of bias	Support for judgment	Review authors' judgment (assess as low, unclear or high risk of bias)
Selection bias	Random sequence generation	Describes the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups	Selection bias (biased allocation to interventions) due to the inadequate generation of a randomised sequence
	Allocation concealment	Describes the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen before or during enrolment	Selection bias (biased allocation to interventions) due to inadequate concealment of allocations before assignment
Performance bias	Blinding of participants and personnel*	Describes all measures used, if any, to blind trial participants and researchers from knowledge of which intervention a participant received. Provides any information related to	Performance bias due to knowledge of the allocated interventions by participants and personnel during the study

		whether the intended blinding was effective.	
Detection bias	Blinding of outcome assessment*	Describes all measures used, if any, to blind outcome assessments from knowledge of which intervention a participant received. Provides any information related to whether the intended blinding was effective.	Detection bias due to knowledge of the allocated interventions by outcome assessment
Attrition bias	Incomplete outcome data*	Describes the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. States whether attrition and exclusions were reported, the numbers in each intervention group (compared with the total number of randomised	Attrition bias due to the amount, nature, or handling of incomplete outcome data

		participants), reasons for attrition or exclusions where reported, and any reinclusions in analyses for the review.	
Reporting bias	Selective reporting	States how selective outcome reporting was examined and what was found.	Reporting bias due to selective outcome reporting
Other bias	Anything else, ideally prespecified	States any important concerns about bias not covered in the other domains of the tool.	Bias due to problems not covered elsewhere

*Assessments of each main outcome or class of outcomes should be performed.

Supplemental Table 4.3 Approach to formulating summary assessments of the risk of bias for each important outcome (across domains) within and across trials

Risk of bias	Interpretation	Within a trial	Across trials
Low risk of bias	Bias, if present, is unlikely to alter the results seriously	A low risk of bias for all key domains	Most information is obtained from trials at low risk of bias
Unclear risk of bias	A risk of bias that raises some doubt about the results	A low or unclear risk of bias for all key domains	Most information is obtained from trials at low or unclear risk of bias
High risk of bias	Bias may substantially alter the results	A high risk of bias for one or more key domains	The proportion of information from trials at high risk of bias is sufficient to affect the interpretation of results