

QUALITY CRITERIA

General instructions: Rate each risk of bias item listed below as “Low,” “High,” or “Unclear.”

Rating of individual items for study # _____ :

1. Selection bias

a. Domain: Random sequence generation

(Support for judgement: Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.)

Was the allocation sequence adequately generated?

Low risk High risk Unclear risk

b. Domain: Allocation concealment?

(Support for judgement: Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment)

Was allocation adequately concealed?

Low risk High risk Unclear risk

2. Performance bias

Domain: Blinding of participants and "treating" personnel - i.e. the person(s) delivering the intervention.

(Support for judgement: Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.)

Was knowledge of the allocated intervention adequately prevented during the study?

Low risk High risk Unclear risk Outcome NR

3a. Detection bias (outcome 1 =)

Domain: Blinding of outcome assessment

(Support for judgement: Describe all measures used, if any, to blind outcome assessors from knowledge of which intervention a participant received. Provide any information relating to whether the

intended blinding was effective.)

Was knowledge of the allocated intervention adequately prevented from outcome assessors?

Low risk High risk Unclear risk Outcome NR

3b. Detection bias (outcome 2 =)

Domain: Blinding of outcome assessment

(Support for judgement: Describe all measures used, if any, to blind outcome assessors from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.)

Was knowledge of the allocated intervention adequately prevented from outcome assessors?

Low risk High risk Unclear risk Outcome NR

3c. Detection bias (outcome 3 =)

Domain: Blinding of outcome assessment

(Support for judgement: Describe all measures used, if any, to blind outcome assessors from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.)

Was knowledge of the allocated intervention adequately prevented from outcome assessors?

Low risk High risk Unclear risk Outcome NR

3d. Detection bias (outcome 4 =)

Domain: Blinding of outcome assessment

(Support for judgement: Describe all measures used, if any, to blind outcome assessors from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.)

Was knowledge of the allocated intervention adequately prevented from outcome assessors?

Low risk High risk Unclear risk Outcome NR

4. Attrition bias

Domain: Incomplete outcome data

(Support for judgement: Describe the completeness of outcome data for each main outcome, including

attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by the review authors.)

Were incomplete outcome data adequately addressed?

Low risk High risk Unclear risk

5. Reporting bias

Domain: Selective outcomes reporting

(Support for judgement: State how the possibility of selective outcome reporting was examined by the review authors, and what was found.)

Are reports of the study free of suggestion of selective outcome reporting? (i.e., the author states they will measure an outcome but do not report it)

Low risk High risk Unclear risk

6. Other

Domain: Other sources of bias

(Support for judgement: State any important concerns about bias not addressed in the other domains in the tool. If particular questions/entries were pre-specified in the review's protocol, responses should be provided for each question/entry.)

Are reports of the study free from other bias due to problems not covered above?

Low risk High risk Unclear risk Describe:

Overall risk of bias rating

Low risk
 Unclear risk
 High risk

* Items contained in the Cochrane Risk of Bias Tool