# Cochrane Collaboration Modified Tool for Assessing Risk of Bias in RCTs

| Domain | Description | High risk of bias | Low risk of bias | Unclear risk of bias | Reviewer Assessment |
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| **REF ID:** | | | | **Reviewer:** | |
| *Selection bias* <br><br> ***Random sequence generation*** | Described the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups. <br><br> **Reviewer Comments:** | Selection bias (biased allocation to interventions) due to inadequate generation of a randomized sequence. | Random sequence generation method should produce comparable groups | Not described in sufficient detail | **Judgment: Random Sequence generation** <br><br> ☐ **High** <br> ☐ **Low** <br> ☐ **Unclear** |
| *Selection bias* <br><br> ***Allocation concealment*** | Described 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, enrollment. <br><br> **Reviewer Comments:** | Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment. | Intervention allocations likely could not have been foreseen in advance of, or during, enrollment | Not described in sufficient detail | **Judgment: Allocation concealment** <br><br> ☐ **High** <br> ☐ **Low** <br> ☐ **Unclear** |
| *Reporting Bias* <br><br> ***Selective reporting*** | State how the possibility of selective outcome reporting was examined by the authors and what was found. <br><br> **Reviewer Comments:** | Reporting bias due to selective outcome reporting. | Selective outcome reporting bias not detected | Insufficient information to permit judgment of 'Low risk' or 'High risk'. <br><br> (*It is likely that the majority of studies will fall into this category.*) | **Judgment: Selective reporting** <br><br> ☐ **High** <br> ☐ **Low** <br> ☐ **Unclear** |
| *Other bias* <br><br> ***Other sources of bias*** | Any important concerns about bias not addressed above. If particular questions/entries were pre-specified in the study's protocol, responses should be provided for each question/entry. <br><br> **Reviewer** | Bias due to problems not covered elsewhere in the table. | No other bias detected | There may be a risk of bias, but there is either: Insufficient information to assess whether an important risk of bias exists; or Insufficient rationale or evidence that an identified problem will introduce bias. | **Judgment: Other sources of bias** <br><br> ☐ **High** <br> ☐ **Low** <br> ☐ **Unclear** |

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**Outcome(s):**

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| *Performance bias*<br><br>***Blinding (participants and personnel)*** | Described all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provided any information relating to whether the intended blinding was effective.<br>**Reviewer Comments:** | Performance bias due to knowledge of the allocated interventions by participants and personnel during the study. | Blinding was likely effective. | Not described in sufficient detail | **Judgment: Blinding (participants and personnel)**<br><br> ☐ **High**<br> ☐ **Low**<br> ☐ **Unclear** |
| *Detection bias*<br><br>***Blinding (outcome assessment)*** | Described all measures used, if any, to blind outcome assessors from knowledge of which intervention a participant received. Provided any information relating to whether the intended blinding was effective.<br>**Reviewer Comments:** | Detection bias due to knowledge of the allocated interventions by outcome assessors. | Blinding was likely effective. | Not described in sufficient detail | **Judgment: Blinding (outcome assessment)**<br><br> ☐ **High**<br> ☐ **Low**<br> ☐ **Unclear** |
| *Attrition bias*<br><br>***Incomplete outcome data*** | Described the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. Stated whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported.<br>**Reviewer** | Attrition bias due to amount, nature or handling of incomplete outcome data. | Handling of incomplete outcome data was complete and unlikely to have produced bias | Insufficient reporting of attrition/exclusions to permit judgment of 'Low risk' or 'High risk' (e.g. number randomized not stated, no reasons for missing data provided) | **Judgment: Incomplete outcome data**<br><br> ☐ **High**<br> ☐ **Low**<br> ☐ **Unclear** |

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