Revised Cochrane risk-of-bias tool for randomized trials (RoB 2.0)

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the ROB2 Development Group

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| **Study details**

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| **Reference** |  |

**Study design**

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| □ | Individually-randomized parallel-group trial |
| □ | Cluster-randomized parallel-group trial |
| □ | Individually randomized cross-over (or other matched) trial |

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| **Specify which outcome is being assessed for risk of bias** |  |

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| **Specify the numerical result being assessed.** In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed. |  |

**Is the review team’s aim for this result…?**

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| □ | to assess the effect of *assignment to intervention* (the ‘intention-to-treat’ effect) |
| □ | to assess the effect of *adhering to intervention* (the ‘per-protocol’ effect) |

**Which of the following sources were obtained to help inform the risk-of-bias assessment? (tick as many as apply)**□ Journal article(s) with results of the trial□ Trial protocol□ Statistical analysis plan (SAP)□ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)□ Company-owned trial registry record (e.g. GSK Clinical Study Register record)□ “Grey literature” (e.g. unpublished thesis)□ Conference abstract(s) about the trial□ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)□ Research ethics application□ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)□ Personal communication with trialist□ Personal communication with the sponsor |

**Domain 1: Risk of bias arising from the randomization process**

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| **Signalling questions** | **Description** | **Response options** |
| **1.1 Was the allocation sequence random?** |  | Y / PY / PN / N / NI |
| **1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?** | Y / PY / PN / N / NI |
| **1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?**  |  | Y / PY / PN / N / NI |
| **Risk-of-bias judgement** |  | Low / High / Some concerns |
| Optional: What is the predicted direction of bias arising from the randomization process? |  | Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable |

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

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| **Signalling questions** | **Description** | **Response options** |
| **2.1. Were participants aware of their assigned intervention during the trial?** |  | Y / PY / PN / N / NI |
| **2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?** | Y / PY / PN / N / NI |
| **2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context?** |  | NA / Y / PY / PN / N / NI |
| **2.4. If Y/PY to 2.3: Were these deviations from intended intervention balanced between groups?** |  | NA / Y / PY / PN / N / NI |
| **2.5 If N/PN/NI to 2.4: Were these deviations likely to have affected the outcome?** |  | NA / Y / PY / PN / N / NI |
| **2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?** |  | Y / PY / PN / N / NI |
| **2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?** |  | NA / Y / PY / PN / N / NI |
| **Risk-of-bias judgement** |  | Low / High / Some concerns |
| Optional: What is the predicted direction of bias due to deviations from intended interventions? |  | Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable |

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of adhering to intervention*)

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| **Signalling questions** | **Description** | **Response options** |
| **2.1. Were participants aware of their assigned intervention during the trial?** |  | Y / PY / PN / N / NI |
| **2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?** | Y / PY / PN / N / NI |
| **2.3. If Y/PY/NI to 2.1 or 2.2: Were important co-interventions balanced across intervention groups?** |  | NA / Y / PY / PN / N / NI |
| **2.4. Could failures in implementing the intervention have affected the outcome?** |  | Y / PY / PN / N / NI |
| **2.5. Did study participants adhere to the assigned intervention regimen?** |  | Y / PY / PN / N / NI |
| **2.6. If N/PN/NI to 2.3 or 2.5 or Y/PY/NI to 2.4: Was an appropriate analysis used to estimate the effect of adhering to the intervention?** |  | NA / Y / PY / PN / N / NI |
| **Risk-of-bias judgement** |  | Low / High / Some concerns |
| Optional: What is the predicted direction of bias due to deviations from intended interventions? |  | Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable |

Domain 3: Missing outcome data

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| **Signalling questions** | **Description** | **Response options** |
| **3.1 Were data for this outcome available for all, or nearly all, participants randomized?** |   | Y / PY / PN / N / NI |
| **3.2 If N/PN/NI to 3.1: Is there evidence that result was not biased by missing outcome data?** |  | NA / Y / PY / PN / N |
| **3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?** |  | NA / Y / PY / PN / N / NI |
| **3.4 If Y/PY/NI to 3.3: Do the proportions of missing outcome data differ between intervention groups?**  |  | NA / Y / PY / PN / N / NI |
| **3.5 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?** |  | NA / Y / PY / PN / N / NI |
| **Risk-of-bias judgement** |  | Low / High / Some concerns |
| Optional: What is the predicted direction of bias due to missing outcome data? |  | Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable |

Domain 4: Risk of bias in measurement of the outcome

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| **Signalling questions** | **Description** | **Response options** |
| **4.1 Was the method of measuring the outcome inappropriate?** |  | Y / PY / PN / N / NI |
| **4.2 Could measurement or ascertainment of the outcome have differed between intervention groups ?** |  | Y / PY / PN / N / NI |
| **4.3 Were outcome assessors aware of the intervention received by study participants?** |  | Y / PY / PN / N / NI |
| **4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?** |  | NA / Y / PY / PN / N / NI |
| **4.5 If Y/PY/NI to 4.4:** **Is it likely that assessment of the outcome was influenced by knowledge of intervention received?** |  | NA / Y / PY / PN / N / NI |
| **Risk-of-bias judgement** |  | Low / High / Some concerns |
| Optional: What is the predicted direction of bias in measurement of the outcome? |  | Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable |

Domain 5: Risk of bias in selection of the reported result

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| **Signalling questions** | **Description** | **Response options** |
| **5.1**  **Was the trial analysed in accordance with a pre-specified plan that was finalized before unblinded outcome data were available for analysis ?** |  | Y / PY / PN / N |
| **Is the numerical result being assessed likely to have been selected, on the basis of the results, from...** |  |  |
| **5.2. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?** |  | Y / PY / PN / N / NI |
| **5.3 ... multiple analyses of the data?** |  | Y / PY / PN / N / NI |
| **Risk-of-bias judgement** |  | Low / High / Some concerns |
| Optional: What is the predicted direction of bias due to selection of the reported result? |  | Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable |

Overall risk of bias

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| **Risk-of-bias judgement** |  | Low / High / Some concerns |
| Optional: What is the predicted direction of bias due to selection of the reported result? |  | Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable |