

Suggested risk of bias criteria for EPOC reviews

1. Risk of bias for studies with a separate control group

- **Randomised trials**
- **Non-randomised trials**
- **Controlled before-after studies**

Nine standard criteria are suggested for all randomised trials, non-randomised trials and controlled before-after studies. Further information can be obtained from the [Cochrane handbook](#): Chapter 8, Risk of bias in randomized trials and Chapter 25, Risk of bias in non-randomized studies.

Random sequence generation

Score “Low risk” if a random component in the sequence generation process is described (e.g. Referring to a random number table). Score “High risk” when a nonrandom method is used (e.g. performed by date of admission). Non-randomised trials and controlled before-after studies should be scored “High risk”. Score “Unclear risk” if not specified in the paper.

Allocation concealment

Score “Low risk” if the unit of allocation was by institution, team or professional and allocation was performed on all units at the start of the study; or if the unit of allocation was by patient or episode of care and there was some form of centralised randomisation scheme, an on-site computer system or sealed opaque envelopes were used. Controlled before-after studies should be scored “High risk”. Score “Unclear risk” if not specified in the paper.

Baseline outcome measurements similar^{1,2}

Score “Low risk” if performance or patient outcomes were measured prior to the intervention, and no important differences were present across study groups. In randomised trials, score “Low risk” if imbalanced but appropriate adjusted analysis was performed (e.g. Analysis of covariance). Score “High risk” if important differences were present and not adjusted for in analysis. If randomised trials have no baseline measure of outcome, score “Unclear risk”.

¹ If some primary outcomes were imbalanced at baseline, assessed blindly or affected by missing data and others were not, each primary outcome can be scored separately.

² If “Unclear risk” or “High risk”, but there is sufficient data in the paper to do an adjusted analysis (e.g. Baseline adjustment analysis or Intention to treat analysis) the criteria should be re scored as “Low risk”.

Suggested citation: Cochrane Effective Practice and Organisation of Care (EPOC). [Title]. EPOC Resources for review authors, 2017. epoc.cochrane.org/resources/epoc-resources-review-authors (accessed DD Month YYYY)

Baseline characteristics similar

Score “Low risk” if baseline characteristics of the study and control providers are reported and similar. Score “Unclear risk” if it is not clear in the paper (e.g. characteristics are mentioned in text but no data were presented). Score “High risk” if there is no report of characteristics in text or tables or if there are differences between control and intervention providers. Note that in some cases imbalance in patient characteristics may be due to recruitment bias whereby the provider was responsible for recruiting patients into the trial.

Incomplete outcome data¹

Score “Low risk” if missing outcome measures were unlikely to bias the results (e.g. the proportion of missing data was similar in the intervention and control groups or the proportion of missing data was less than the effect size i.e. unlikely to overturn the study result). Score “High risk” if missing outcome data was likely to bias the results. Score “Unclear risk” if not specified in the paper (Do not assume 100% follow up unless stated explicitly).

Knowledge of the allocated interventions adequately prevented during the study^{1,3}

Score “Low risk” if the authors state explicitly that the primary outcome variables were assessed blindly, or the outcomes are objective, e.g. length of hospital stay. Primary outcomes are those variables that correspond to the primary hypothesis or question as defined by the authors. Score “High risk” if the outcomes were not assessed blindly. Score “Unclear risk” if not specified in the paper.

Protection against contamination

Score “Low risk” if allocation was by community, institution or practice and it is unlikely that the control group received the intervention. Score “High risk” if it is likely that the control group received the intervention (e.g. if patients rather than professionals were randomised). Score “Unclear risk” if professionals were allocated within a clinic or practice and it is possible that communication between intervention and control professionals could have occurred (e.g. physicians within practices were allocated to intervention or control)

Selective outcome reporting

Score “Low risk” if there is no evidence that outcomes were selectively reported (e.g. all relevant outcomes in the methods section are reported in the results section). Score “High risk” if some important outcomes are subsequently omitted from the results. Score “Unclear risk” if not specified in the paper. For further information see Chapter 13 of the [Cochrane handbook](#): Assessing risk of bias due to missing results in a synthesis.

³ This refers to blinding of participants and personnel and blinding of outcome assessment.

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Other risks of bias

Score “Low risk” if there is no evidence of other risk of biases.

2. Risk of bias for interrupted time series studies

Seven standard criteria are used for all interrupted time series studies. Further information can be obtained from Chapter 25: Risk of bias in non-randomized studies of the [Cochrane handbook](#).

Note: If the interrupted time series study has ignored secular (trend) changes and performed a simple *t-test* of the pre versus post intervention periods without further justification, the study should not be included in the review unless reanalysis is possible.

Intervention independent of other changes

Score “Low risk” if there are compelling arguments that the intervention occurred independently of other changes over time and the outcome was not influenced by other confounding variables/historic events during study period. *If Events/variables identified, note what they are.*
Score “High risk” if reported that intervention was not independent of other changes in time.

Shape of the intervention effect pre-specified

Score “Low risk” if point of analysis is the point of intervention OR a rational explanation for the shape of intervention effect was given by the author(s). Where appropriate, this should include an explanation if the point of analysis is NOT the point of intervention. Score “High risk” if it is clear that the condition above is not met.

Intervention unlikely to affect data collection

Score “Low risk” if reported that intervention itself was unlikely to affect data collection (for example, sources and methods of data collection were the same before and after the intervention);
Score “High risk” if the intervention itself was likely to affect data collection (for example, any change in source or method of data collection reported).

Knowledge of the allocated interventions adequately prevented during the study^{3,4}

Score “Low risk” if the authors state explicitly that the primary outcome variables were assessed blindly, or the outcomes are objective, e.g. length of hospital stay. Primary outcomes are those variables that correspond to the primary hypothesis or question as defined by the authors. Score “High risk” if the outcomes were not assessed blindly. Score “Unclear risk” if not specified in the paper.

⁴ If some primary outcomes were assessed blindly or affected by missing data and others were not, each primary outcome can be scored separately.

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Incomplete outcome data adequately⁴

Score “Low risk” if missing outcome measures were unlikely to bias the results (e.g. the proportion of missing data was similar in the pre- and post-intervention periods or the proportion of missing data was less than the effect size i.e. unlikely to overturn the study result). Score “High risk” if missing outcome data was likely to bias the results. Score “Unclear risk” if not specified in the paper (Do not assume 100% follow up unless stated explicitly).

Selective outcome reporting

Score “Low risk” if there is no evidence that outcomes were selectively reported (e.g. all relevant outcomes in the methods section are reported in the results section). Score “High risk” if some important outcomes are subsequently omitted from the results. Score “Unclear risk” if not specified in the paper.

Other risks of bias

Score “Low risk” if there is no evidence of other risk of biases. E.g. should consider if seasonality is an issue (i.e. if January to June comprises the pre-intervention period and July to December the post, could the “seasons’ have caused a spurious effect).

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