

# Quality Assessment Template

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## Item Settings

## Editor

[I want to start from scratch](#)

+

⬆

Use only for RCTs

1. –

Enter a judgement

+

⬆

Sequence generation

1. –
- High
2. –
- Low
3. –
- Unsure

+

⬆

Allocation concealment

1. –
- High
2. –
- Low
3. –
- Unsure

+

⬆

## Blinding of participants and personnel

1. –  
High
2. –  
Low
3. –  
Unsure



## Blinding of outcome assessment

1. –  
High
2. –  
Low
3. –  
Unsure



## Incomplete outcome data

1. –  
High
2. –  
Low
3. –  
Unsure



## Selective reporting

1. –  
High
2. –  
Low
3. –  
Unsure



## Other sources of bias

1. –

High

2. –

Low

3. –

Unsure



Use for all other study types

1. –

Enter a judgement



Was the hypothesis/aim/objective of the study clearly stated?

1. –

Yes

2. –

Partial

3. –

No



Was the study conducted prospectively?

1. –

Yes

2. –

Unclear

3. –

No



Were the cases collected in more than one center?

1. –

Yes

2. –

Unclear

3. –

No



Were patients recruited consecutively?

1. –

Yes

2. –

Unclear

3. –

No



Were the characteristics of the patients included in the study described?

1. –

Yes

2. –

Partial

3. –

No



Were the eligibility criteria (i.e. inclusion and exclusion criteria) for entry into the study clearly stated?

1. –

Yes

2. –

Partial

3. –

No



Did patients enter the study at a similar point in the disease?

1. –

Yes

2. –

Unclear

3. –

No



Was the intervention of interest clearly described?

1. –

Yes

2. –

Partial

3. –

No



Were additional interventions (co-interventions) clearly described?

1. –

Yes

2. –

Partial

3. –

No



Were relevant outcome measures established a priori?

1. –

Yes

2. –

Partial

3. –

No



Were outcome assessors blinded to the intervention that patients received?

1. –

Yes

2. –

Unclear

3. –

No





Were the relevant outcomes measured using appropriate objective/subjective methods?

1. –

Yes

2. –

Partial

3. –

No



Were the relevant outcome measures made before and after the intervention?

1. –

Yes

2. –

Unclear

3. –

No



Were the statistical tests used to assess the relevant outcomes appropriate?

1. –

Yes

2. –

Unclear

3. –

No



Was follow-up long enough for important events and outcomes to occur?

1. –

Yes

2. –

Unclear

3. –

No



Were losses to follow-up reported?

1. –

Yes

2. –

Unclear

3. –

No



Did the study provide estimates of random variability in the data analysis of relevant outcomes?

1. –

Yes

2. –

Partial

3. –

No



Were the adverse events reported?

1. –

Yes

2. –

Partial

3. –

No



Were the conclusions of the study supported by results?

1. –

Yes

2. –

Unclear

3. –

No



Were both competing interests and sources of support for the study reported?

1. –

Yes

2. –

Partial

3. –

No

## Preview

Use only for RCTs

Extractors will also be able to add supporting text to justify their judgements

Sequence generation

Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.

1. ☐ High

2. ☐ Low

3. ☐ Unsure

Extractors will also be able to add supporting text to justify their judgements

Allocation concealment

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.

1. ☐ High

2. ☐ Low

3. ☐ Unsure

Extractors will also be able to add supporting text to justify their judgements

Blinding of participants and personnel

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.

1. ☐ High

2. ☐ Low

3. ☐ Unsure

Extractors will also be able to add supporting text to justify their judgements

Blinding of outcome assessment

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.

1. ☐ High

2. ☐ Low

3. ☐ Unsure



Extractors will also be able to add supporting text to justify their judgements  
Incomplete outcome data

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.

1. ☐ High
2. ☐ Low
3. ☐ Unsure

Extractors will also be able to add supporting text to justify their judgements  
Selective reporting

State how the possibility of selective outcome reporting was examined by the review authors, and what was found.

1. ☐ High
2. ☐ Low
3. ☐ Unsure

Extractors will also be able to add supporting text to justify their judgements  
Other sources of bias

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.

1. ☐ High
2. ☐ Low
3. ☐ Unsure

Extractors will also be able to add supporting text to justify their judgements  
Use for all other study types

Extractors will also be able to add supporting text to justify their judgements  
Was the hypothesis/aim/objective of the study clearly stated?

1. ☐ Yes
2. ☐ Partial
3. ☐ No

Extractors will also be able to add supporting text to justify their judgements  
Was the study conducted prospectively?

1. ☐ Yes
2. ☐ Unclear
3. ☐ No

Extractors will also be able to add supporting text to justify their judgements  
Were the cases collected in more than one center?

1. ☐ Yes
2. ☐ Unclear
3. ☐ No

Extractors will also be able to add supporting text to justify their judgements  
Were patients recruited consecutively?

1. ☐ Yes
2. ☐ Unclear
3. ☐ No

Extractors will also be able to add supporting text to justify their judgements  
Were the characteristics of the patients included in the study described?

1. ☐ Yes
2. ☐ Partial
3. ☐ No

Extractors will also be able to add supporting text to justify their judgements  
Were the eligibility criteria (i.e. inclusion and exclusion criteria) for entry into the study clearly stated?

1. ☐ Yes
2. ☐ Partial
3. ☐ No

Extractors will also be able to add supporting text to justify their judgements  
Did patients enter the study at a similar point in the disease?

1. ☐ Yes
2. ☐ Unclear
3. ☐ No

Extractors will also be able to add supporting text to justify their judgements  
Was the intervention of interest clearly described?

1. ☐ Yes
2. ☐ Partial
3. ☐ No

Extractors will also be able to add supporting text to justify their judgements  
Were additional interventions (co-interventions) clearly described?

1. ☐ Yes
2. ☐ Partial
3. ☐ No

Extractors will also be able to add supporting text to justify their judgements  
Were relevant outcome measures established a priori?

1. ☐ Yes
2. ☐ Partial
3. ☐ No

Extractors will also be able to add supporting text to justify their judgements  
Were outcome assessors blinded to the intervention that patients received?

1. ☐ Yes

2. ☐ Unclear
3. ☐ No

Extractors will also be able to add supporting text to justify their judgements

Were the relevant outcomes measured using appropriate objective/subjective methods?

1. ☐ Yes
2. ☐ Partial
3. ☐ No

Extractors will also be able to add supporting text to justify their judgements

Were the relevant outcome measures made before and after the intervention?

1. ☐ Yes
2. ☐ Unclear
3. ☐ No

Extractors will also be able to add supporting text to justify their judgements

Were the statistical tests used to assess the relevant outcomes appropriate?

1. ☐ Yes
2. ☐ Unclear
3. ☐ No

Extractors will also be able to add supporting text to justify their judgements

Was follow-up long enough for important events and outcomes to occur?

1. ☐ Yes
2. ☐ Unclear
3. ☐ No

Extractors will also be able to add supporting text to justify their judgements

Were losses to follow-up reported?

1. ☐ Yes
2. ☐ Unclear
3. ☐ No

Extractors will also be able to add supporting text to justify their judgements

Did the study provide estimates of random variability in the data analysis of relevant outcomes?

1. ☐ Yes
2. ☐ Partial
3. ☐ No

Extractors will also be able to add supporting text to justify their judgements

Were the adverse events reported?

1. ☐ Yes
2. ☐ Partial
3. ☐ No

Extractors will also be able to add supporting text to justify their judgements

Were the conclusions of the study supported by results?

1. ☐ Yes
2. ☐ Unclear
3. ☐ No

Extractors will also be able to add supporting text to justify their judgements

Were both competing interests and sources of support for the study reported?

1. ☐ Yes
2. ☐ Partial
3. ☐ No

Extractors will also be able to add supporting text to justify their judgements

## Feedback & Support

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