



11 questions to help you make sense of a trial

How to use this appraisal tool

Three broad issues need to be considered when appraising the report of a randomised controlled trial:

- **Are the results of the trial valid?** (Section A)
- **What are the results?** (Section B)
- **Will the results help locally?** (Section C)

The 11 questions on the following pages are designed to help you think about these issues systematically.

The first two questions are screening questions and can be answered quickly. If the answer to both is **yes**, it is worth proceeding with the remaining questions.

There is some degree of overlap between the questions, you are asked to record a **yes**, **no** or **can't tell** to most of the questions. A number of prompts are given after each question. These are designed to remind you why the question is important. Record your reasons for your answers in the spaces provided.

There will not be time in the small groups to answer them all in detail!

These checklists were designed to be used as educational tools as part of a workshop

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(A) Are the results of the trial valid?

Screening Questions

1. Did the trial address a clearly focused issue?

Yes

Can't tell

No

Consider: An issue can be 'focused' In terms of

- The population studied
- The intervention given
- The comparator given
- The outcomes considered

2. Was the assignment of patients to treatments randomised?

Yes

Can't tell

No

Consider:

- How was this carried out, some methods may produce broken allocation concealment
- Was the allocation concealed from researchers?

Is it worth continuing?



Detailed questions

3. Were patients, health workers and study personnel blinded?

Yes

Can't tell

No

Consider:

- Health workers could be; clinicians, nurses etc
- Study personnel – especially outcome assessors

4. Were the groups similar at the start of the trial?

Yes

Can't tell

No

Consider: Look at

- Other factors that might affect the outcome such as age, sex, social class, these may be called baseline characteristics

5. Aside from the experimental intervention, were the groups treated equally?

Yes

Can't tell

No

6. Were all of the patients who entered the trial properly accounted for at its conclusion?

Yes

Can't tell

No

Consider:

- Was the trial stopped early?
- Were patients analysed in the groups to which they were randomised?

(B) What are the results?

7. How large was the treatment effect?

Consider:

- What outcomes were measured?
- Is the primary outcome clearly specified?
- What results were found for each outcome?
- Is there evidence of selective reporting of outcomes?

8. How precise was the estimate of the treatment effect?

Consider:

- What are the confidence limits?
- Were they statistically significant?

(C) Will the results help locally?

**9. Can the results be applied in your context?
(or to the local population?)**

Yes Can't tell No

Consider:

- Do you have reason to believe that your population of interest is different to that in the trial
 - If so, in what way?
-

10. Were all clinically important outcomes considered?

Yes Can't tell No

Consider:

- Is there other information you would like to have seen?
 - Was the need for this trial clearly described?
-

11. Are the benefits worth the harms and costs?

Yes Can't tell No

Consider:

- Even if this is not addressed by the trial, what do you think?

