

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 a randomised controlled trial study:

Are the results of the study 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 italicised 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.

These checklists were designed to be used as educational pedagogic tools, as part of a workshop setting, therefore we do not suggest a scoring system. The core CASP checklists (randomised controlled trial & systematic review) were based on JAMA 'Users' guides to the medical literature 1994 (adapted from Guyatt GH, Sackett DL, and Cook DJ), and piloted with health care practitioners.

For each new checklist a group of experts were assembled to develop and pilot the checklist and the workshop format with which it would be used. Over the years overall adjustments have been made to the format, but a recent survey of checklist users reiterated that the basic format continues to be useful and appropriate.

Referencing: we recommend using the Harvard style citation, i.e.:

Critical Appraisal Skills Programme (2017). CASP (insert name of checklist i.e. Randomised Controlled Trial) Checklist. [online] Available at: *URL*. Accessed: *Date Accessed*.

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| (A) Are the results of the trial va | ilid? | | |
|--|-------|---------------|--|
| Screening Questions | | | |
| 1. Did the trial address a clearly focused issue? | Yes | Can't tell No | |
| HINT: 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 | |
| HINT: Consider • How was this carried out? • Was the allocation sequence concealed from researchers and patients? | | | |
| 3. Were all of the patients who entered | Yes | Can't tell No | |
| the trial properly accounted for at its conclusion? | | | |
| Was the trial stopped early? Were patients analysed in the groups to which they were randomised? | | | |
| Is it worth continuing? | | | |

| Detailed questions 4. Were patients, health workers and study personnel 'blind' to treatment? HINT: Think about Patients? Health workers? | Yes | Can't tell | No |
|---|-----|------------|----|
| • Study personnel? 5. Were the groups similar at the start of the trial? HINT: Look at | Yes | Can't tell | No |
| Other factors that might affect the outcome such as age, sex, social class | | | |
| 6. Aside from the experimental intervention, were the groups treated equally? | Yes | Can't tell | No |

(B) What are the results?

7. How large was the treatment effect?

HINT: Consider

- What outcomes were measured?
- Is the primary outcome clearly specified?
- What results were found for each outcome?

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

HINT: Consider

What are the confidence limits?

(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

HINT: Consider whether

Do you think that the patients covered by the trial are similar enough to the patients to whom you will apply this?, if not how to they differ?

| 10. Were all clinically important outcomes | Yes | Can't tell | No |
|---|-----|------------|----|
| considered? | | | |
| HINT: Consider | | | |
| Is there other information you would like to have seen? If not, does this affect the decision? | | | |
| | | | |
| | | | _ |
| 11. Are the benefits worth the harms and costs? | Yes | Can't tell | No |
| HINT: Consider | | | |
| Even if this is not addressed by the trial, what do you think? | | | |