Critical Appraisal Skills Programme (CASP)

making sense of evidence

10 questions to help you make sense of randomised controlled trials

How to use this appraisal tool

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

- **Is the trial valid?**
- **What are the results?**
- **Will the results help locally?**

The 10 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.

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.

The 10 questions are adapted from Guyatt GH, Sackett DL, and Cook DJ, Users' guides to the medical literature. II. How to use an article about therapy or prevention. *JAMA* 1993; 270 (21): 2598-2601 and *JAMA* 1994; 271(1): 59-63

Screening Questions

1. Did the study ask a clearly-focused question? ❑ Yes ❑ Can't tell ❑ No

Consider if the question is 'focused' in terms of:

– the population studied

– the intervention given

– the outcomes considered

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2. Was this a randomised controlled trial (RCT) and was it appropriately so? ❑ Yes ❑ Can't tell ❑ No

Consider:

– why this study was carried out as an RCT

– if this was the right research approach for the question being asked

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Is it worth continuing?

Detailed Questions

3. Were participants appropriately allocated to intervention and control groups? ❑ Yes ❑ Can't tell ❑ No

Consider:

– how participants were allocated to intervention and control groups. Was the process truly random?

– whether the method of allocation was described. Was a method used to balance the randomization, e.g. stratification?

– how the randomization schedule was generated and how a participant was allocated to a study group

– if the groups were well balanced. Are any differences between the groups at entry to the trial reported?

– if there were differences reported that might have explained any outcome(s) (confounding)

4. Were participants, staff and study personnel 'blind' to participants' study group? ❑ Yes ❑ Can't tell ❑ No

Consider:

– the fact that blinding is not always possible

– if every effort was made to achieve blinding

– if you think it matters in this study

– the fact that we are looking for 'observer bias'

5. Were all of the participants who entered the trial accounted for at its conclusion? ❑ Yes ❑ Can't tell ❑ No

Consider:

– if any intervention-group participants got a control-group option or vice versa

– if all participants were followed up in each study group (was there loss-to-follow-up?)

– if all the participants' outcomes were analysed by the groups to which they were originally allocated (intention-to-treat analysis)

– what additional information would you liked to have seen to make you feel better about this

6. Were the participants in all groups followed up and data collected in the same way? ❑ Yes ❑ Can't tell ❑ No

Consider:

– if, for example, they were reviewed at the same time intervals and if they received the same amount of attention from researchers and health workers. Any differences may introduce performance bias.

7. Did the study have enough participants to minimise the play of chance? ❑ Yes ❑ Can't tell ❑ No

Consider:

– if there is a power calculation. This will estimate how many participants are needed to be reasonably sure of finding something important (if it really exists and for a given level of uncertainty about the final result).

8. How are the results presented and what is the main result?

Consider:

– if, for example, the results are presented as a proportion of people experiencing an outcome, such as risks, or as a measurement, such as mean or median differences, or as survival curves and hazards

– how large this size of result is and how meaningful it is

– how you would sum up the bottom-line result of the trial in one sentence

9. How precise are these results?

Consider:

– if the result is precise enough to make a decision

– if a confidence interval were reported. Would your decision about whether or not to use this intervention be the same at the upper confidence limit as at the lower confidence limit?

– if a p-value is reported where confidence intervals are unavailable

10. Were all important outcomes considered so the results can be applied?

❑ Yes ❑ Can't tell ❑ No

Consider whether:

– the people included in the trail could be different from your population in ways that would produce different results

– your local setting differs much from that of the trial

– you can provide the same treatment in your setting

Consider outcomes from the point of view of the:

– individual

– policy maker and professionals

– family/carers

– wider community

Consider whether:

– any benefit reported outweighs any harm and/or cost. If this information is not reported can it be filled in from elsewhere?

– policy or practice should change as a result of the evidence contained in this trial