# 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?
- What are the results?
- Will the results help locally?
- (Section B) (Section C)

(Section A)

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.

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

©CASP This work is licensed under the Creative Commons Attribution - NonCommercial-ShareAlike 3.0 Unported License. To view a copy of this license, visit <u>http://creativecommons.org/licenses/by-nc-sa/3.0/.</u> www.casp-uk.net

# (A) Are the results of the review valid?

### **Screening Questions**

Yes Can't tell No 1. Did the trial address a clearly focused issue? HINT: An issue can be 'focused' In terms of The population studied • The intervention given ۲ • The comparator given The outcomes considered • Yes Can't tell No 2. Was the assignment of patients to treatments randomised? HINT: Consider How was this carried out? • • Was the allocation sequence concealed from researchers and patients?

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

HINT: Consider

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



# 4. Were patients, health workers and study personnel 'blind' to treatment? HINT: Think about Patients? Health workers? Study personnel? 5. Were the groups similar at the start of the trial? Yes Can't tell No

• Other factors that might affect the outcome such as age, sex, social class

Is it worth continuing?

**Detailed questions** 

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





# (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? Yes Can't tell No 9. Can the results be applied in your context? (or to the local population?) 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? Yes Can't tell No 10. Were all clinically important outcomes considered? **HINT: Consider** Is there other information you would like to have seen? • If not, does this affect the decision? • Yes Can't tell No 11. Are the benefits worth the harms and costs? HINT: Consider Even if this is not addressed by the review, • what do you think?