



Critical Appraisal Toolkit

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# Critical Appraisal Toolkit for Randomised Controlled Trials

## How to use this toolkit?

Three broad issues need to be considered when appraising the report of a systematic review:

- Is the study 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.

### 1. Did the review ask a clearly-focused question?

Consider if the question is "focused", in terms of the population studied, the intervention given, or exposure, and the outcomes considered. Is this the case?

Yes  Can't Tell  No

### 2. Was this an RCT and was it appropriately so?

Consider if this study was carried out as an RCT and if this was the right research approach for the question being asked.

Yes  Can't Tell  No

**If you have answered "Yes" to both questions, it is worth continuing with the appraisal**

### 3. Were participants appropriately allocated to intervention and control groups?

Consider how participants were allocated to intervention and control groups. Was it truly random? Is the method of allocation described? Was a method used to balance the randomization (e.g. stratification). How was the randomization schedule generated and how were participants allocated to study groups? Were the groups well balanced? Are any differences between groups at entry to the trial reported? Were there differences reported that might have explained any outcome(s) (confounding)?

Yes  Can't Tell  No

### 4. Were participants, staff and study personnel 'blind' to participant' study group studies?

Consider the fact that blinding is not always possible, if every effort was made to achieve blinding and if you think it matters in this study and the fact that we are looking for observer bias.

Yes  Can't Tell  No

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**5. Were all of the participants who entered the trial accounted for at its conclusion?**

Consider if any intervention group participants got a control-group option and vice-versa, if all the participants were followed up in each study group (was there loss to follow up?), if all participants' outcomes were analysed by the groups to which they were originally allocated (intention-to-treat analysis) and what additional information you would like to have seen to make you feel better about this.

Yes  Can't Tell  No

**6. Were the participants in all groups followed up and data collected in the same way?**

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.

Yes  Can't Tell  No

**7. Did the study have enough participants to minimise the play of chance minimise the play of chance?**

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).

Yes  Can't Tell  No

**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 the results?**

Consider if the result is precise enough to make a decision, if a confidence interval were reported, whether your decision about whether or not to use this intervention be the same at the upper confidence limit as at the lower confidence limit and if a p-value is reported where confidence intervals are unavailable

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

Consider whether your local setting differs much from that of the trial: are your patients different from those included in the trial; can you provide the same treatment. Consider outcomes from the point of view of the individual, policy maker, professionals, family/carers and wider community Does any benefit reported outweighs any harm and/or cost. Should policy or practice change as a result of the evidence contained in this trial?

Yes  Can't Tell  No

For more information or assistance in using this toolkit, please contact the Knowledge and Informatics Trainer for the Knowledge and Information Service:  
01522 57(3478) or [Library.Informatics@ulh.nhs.uk](mailto:Library.Informatics@ulh.nhs.uk).