Assessing The Quality Of An RCT

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What is a Randomised Controlled Trial (RCT)?

A prospective study that measures the effectiveness of a new intervention (prospective = looking forward into the future)

What's the purpose of an RCT?

- The process of randomisation reduces the risk of bias
- Shows if there is a true cause-effect relationship between an intervention & outcome
- Understand how an intervention causes a desired outcome, if present

What are the key areas of a RCT I need to assess?

Below are the most significant aspects of an RCT that may indicate the overall quality of a trial. Each aspect can be used as a 'checklist' to form the basis of your research appraisal:

1. **Randomisation** - Was there evidence of concealed allocation to the randomisation sequence eg. use of an independent service to randomly allocate study participants to receive an intervention
2. **Blinding** - Was there blinding of the outcome assessment? eg. ensuring the researchers that will assess the outcome do not know the intervention a participant received
3. **Intention-to-treat analysis** - Did they conduct an Intention-to-treat analysis? This means that all participants that have been randomised to receive an intervention at the start of the study will be included in the final analysis, even if they decide to drop out of the study
4. **Inclusion / Exclusion criteria** - Did the authors define an appropriate inclusion and exclusion criteria? This is important as the criteria will impact the external validity of the study results
5. **Baseline comparability** - Did the authors include a table/description of the demographic and baseline data for both the intervention and control groups? This is important as participants may have a characteristic hat may have the potential to influence the outcome eg. overweight participants are more likely to develop moderate-severe osteoarthritis
6. **Defined primary outcome** - Did the authors describe a single pre-determined, measurable outcome that will determine if the intervention is effective or not? Eg. Researchers may look for a change in quality of life, pain score or death, for example. A good primary outcome should be important to patients, clinicians and/or healthcare organisations
7. **Participant retention at follow-up** - Did the authors report how many participants were involved in the follow-up analyses after the trial ended? This is important as a significantly low number of participants at follow-up may over- or underestimate the true effectiveness of the intervention
8. **Follow-up length** - Was the trial follow-up of adequate length? This is important in long-term studies or in trials where the primary outcome may take considerable time to develop after recruitment
9. **Sample size calculation** - Did the authors report a sample size calculation or power analysis to recruit a sufficient number of participants? This is important to reduce risk of random error in the results eg. detecting an effect that is not actually present (Type 1 error) or neglecting an effect that is actually present (Type 2 error)

Takeaway Messages

It is possible that 'better designed studies' such as a RCT may still be of poor quality after you critique the study.

Why should we not assume that all RCTs are high quality?

- May have poor randomisation technique
- The intervention may be poorly reproducible
- May have a biased outcome measurement
- Results may be analysed poorly
- Results may be poorly generalisable (low external validity) to the wider population