Randomised control trials

Lesson 7.2.1 | A Level issues, debates and methods

Core ideas

A randomised control trial compares an intervention group with a control or comparison group to judge whether the intervention changes an outcome.

Random allocation means participants are assigned to groups by chance, helping reduce selection bias and participant differences between conditions.

A control group may receive no treatment, usual treatment, a waiting-list condition, a placebo or an alternative intervention.

Outcome measures should be chosen before the trial and should match the aim, such as symptom scores, relapse rates, behaviour records or quality-of-life ratings.

Blinding can reduce expectation bias when participants or researchers might change behaviour or judgements if they know the condition.

Key terms

Randomised control trial: A study comparing groups assigned by chance to test an intervention.

Random allocation: Assigning participants to groups by chance.

Intervention group: The group that receives the treatment, programme or change being tested.

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Continued

Control group: A comparison group used to judge the effect of the intervention.

Placebo: An inactive treatment used to compare against an active treatment.

Blinding: Keeping participants or researchers unaware of group allocation to reduce bias.

Outcome measure: The score, behaviour or result used to judge whether the intervention worked.

Attrition: Loss of participants before the trial is completed.

Further detail and evidence

An RCT randomly allocates participants to intervention/comparison groups. It aims to distribute known and unknown participant differences on average. Random allocation is different from randomly sampling a population and does not guarantee a representative sample.

Comparisons can use placebo, usual care, a waiting list or another active treatment, depending on the question and ethical needs. Blinding participants, providers and assessors are separate possibilities. Psychological therapies often cannot blind therapists/clients, but outcome assessors may be blinded.

Specify baseline, standardised treatment delivery, outcome measures, follow-up, adherence and dropout handling. Intention-to-treat analysis retains people in assigned groups where appropriate, protecting the comparison from some selective adherence effects. It cannot magically recover every missing outcome.

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Applying the ideas

Lovell compares delivery formats of active CBT/ERP using random allocation and blind assessors. Grant's original medication trials included placebo/blinding. The later pooled predictor analysis is different from a new randomised test of family-history causation.

Worked example: A clinic tests a new anxiety programme by randomly assigning 80 clients to the programme or to usual support, then comparing symptom scores after eight weeks. What features make this an RCT? This is an RCT because clients are allocated by chance to two groups, one receiving the new programme and one acting as a comparison group with usual support. The symptom score after eight weeks is the outcome measure. The design helps judge whether the programme adds benefit beyond usual support, although the clinic should also monitor consent, withdrawal, attrition and whether the groups were treated fairly.

Worked example: In a trial for a sleep intervention, 12 of 60 participants leave before the follow-up. The remaining participants improve more than the control group. How should the result be interpreted? The improvement suggests the intervention may be effective because it is compared with a control group. However, attrition is 20 percent because 12 out of 60 participants left, so the result should be interpreted carefully. If the people who left differed from those who stayed, the final comparison may overestimate or underestimate the intervention's effect.

Evaluation and connections

RCTs can give strong evidence for effectiveness, but they may raise ethical issues and may not reflect every real treatment setting.

RCTs strengthen causal inference when allocation, implementation and follow-up are sound. Attrition, crossover, expectancy and selected eligibility can still bias interpretation. Non-inferiority needs a justified margin and precision; no significant difference alone does not demonstrate equality. Evaluate real-world feasibility and appropriate ethical care.