

WHAT'S SPECIAL ABOUT A RANDOMISED CONTROLLED TRIAL? (CNIN FEB 2009)

Over the last twenty years there has been increasing interest in one type of research study design – randomised controlled trials (or RCTs). Some researchers and policy makers see RCTs as being the gold standard for developing research evidence as to whether an intervention such as a new drug or surgical technique is effective. When people talk about levels of evidence, systematic reviews and randomised controlled trials are generally regarded as the highest levels of evidence.



Basically an RCT is an experimental design that randomly allocates subjects in a study to an intervention or control group to take into account other variables. Subjects and clinicians normally don't know to which group they are allocated. Randomisation of allocation is an important way of reducing potential bias.

Good quality randomised controlled trials try to eliminate or balance between groups potential or actual confounders that could affect the outcome other than the intervention. Researchers will plan for and then report on aspects such as:

- Characteristics of the patients they were studying so that people can check that research question was relevant to the study group.
- Ensuring that control groups and the intervention groups have a similar composition at the start of the trial.
- Checking that the intervention is the only thing different between the care of the two groups
- Putting an appropriate control in place. Often usual care is used as the control. Or in drug trials, it may be a placebo.
- Describing what happened to all those who started the trial. This includes checking how many dropped out or had adverse events and which groups they were from.
- Choosing and outlining a process for allocating subjects to the intervention or control group.
- Making sure, as far as is realistic, that the researchers, clinicians and patients don't know which group they are in.
- Making sure the trial is an appropriate length to determine any effects.
- Ensuring there are sufficient numbers in the trial.

RCTs are not the only way of creating research evidence but they are a powerful method for determining the effect of a particular intervention.

Finding out more

- [Randomised Controlled Trials – Why and When \(PHCRED Workshop 2003\)](#)

CareSearch is an online resource funded by the Department of Health and Ageing to help clinicians find relevant evidence about palliative care. Available now at www.caresearch.com.au