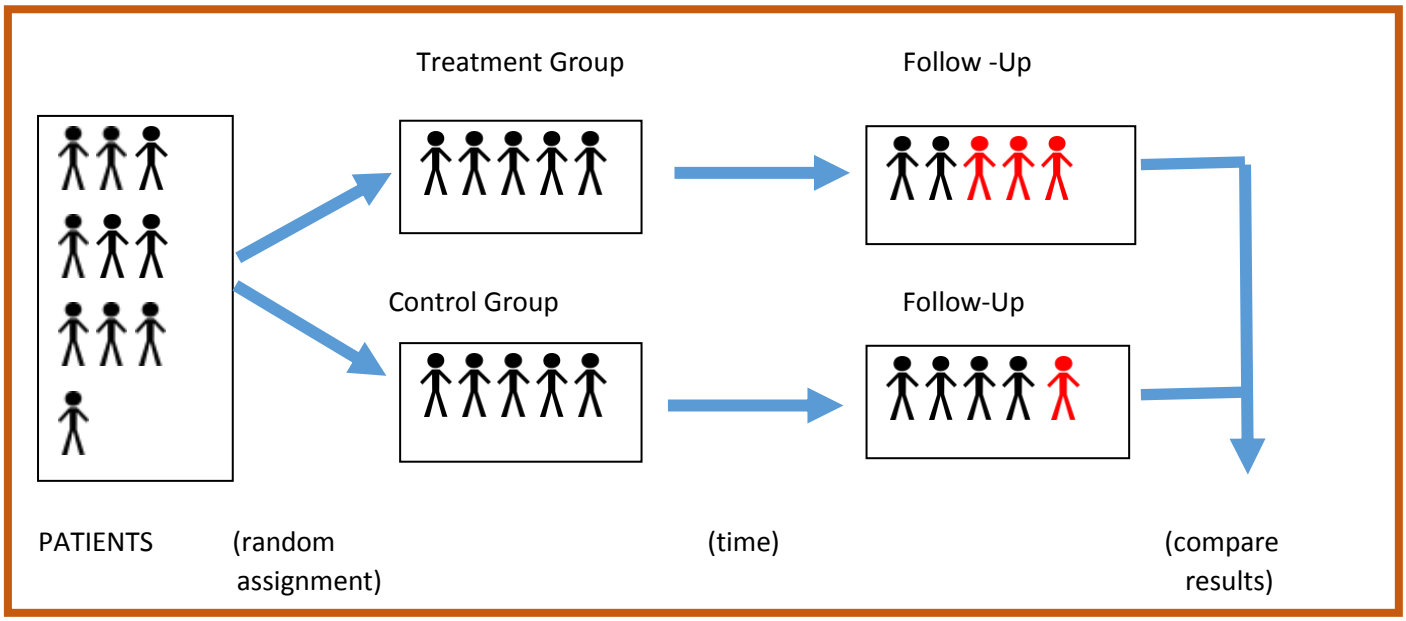
All you need to know about: Randomised Controlled Trials



Definition:

A study in which a number of similar people are randomly assigned to 2 (or more) groups to test a specific drug, treatment or other intervention. One group (the experimental group) has the intervention being tested, the other (the comparison or control group) has an alternative intervention, a dummy intervention (placebo) or no intervention at all. The groups are followed up to see how effective the experimental intervention was. Outcomes are measured at specific times and any difference in response between the groups is assessed statistically. This method is also used to reduce bias.

(NICE: https://www.nice.org.uk/glossary?letter=r)

Key Features:

* Used when two or more interventions are compared
* Is a Primary and Experimental research design
* Is the only design that can show a cause and effect association
* Participants randomly allocated to balanced groups
* Groups followed up in exactly the same way except for the intervention
* Starts in the present and goes forward over time

Strengths:

If correct methodologies used-

* Unbiased distribution of confounders due to randomisation)
* Ability to show cause and effect association
* Gold standard for effectiveness of interventions

Weaknesses:

* Expensive
* Volunteer bias
* Ethical issues/constraints
* Large number of participants often required

Examples:

"Total hip replacement versus open reduction and internal fixation of displaced femoral neck fractures"

"The effectiveness of the Australian Medical Sheepskin for the prevention of pressure ulcers in somatic nursing home patients"

"Is oral versus intravenous ibuprofen more effective for patient ductus artirosus closure?"

"Effectiveness of nurse-led clinics for patients with coronary heart disease"

Associated Terminology:

You may come across the following terms while reading a RCT

- ***Randomisation:*** *The trial subjects are randomly allocated to one of the study groups so that their allocation is based on chance and not on choice.*
- **Control Group:** *The control group receives an alternative intervention to the one being tested. Instead they may receive the current standard intervention ('usual care') or a dummy intervention ('placebo').*
- ***Blinding***: *is when procedures are used that prevent study participants, caregivers or outcome assessors from knowing which intervention was received.*
- ***Allocation Concealment:*** *protects the randomisation process so that it is not known which group will receive which therapy until after the patients have entered the study.*
- ***Intention to Treat Analysis (ITT):*** *Is an assessment of the people taking part in a trial based on the group they were initially allocated to. This is done regardless of whether they dropped out, adhered swapped to an alternative treatment. ITT analyses are often used to assess clinical effectiveness because they mirror actual practice, when not everyone adheres to the treatment, and the treatment people have may be changed according to how their condition responds to it.*
- ***Power Calculation:*** Is an analysis used to calculate the minimum sample size required to provide a reasonable likelihood of detecting an effect.
- ***P-value:*** *Is the statistical measure that indicates whether an effect is statistically significant (the effect is unlikely to have been due to chance) By convention, if the p value is below 0.05 (that is, there is less than a 5% probability that the results occurred by chance), it is considered that there probably is a real difference between treatments. If the p value is 0.001 or less (less than a 1% probability that the results occurred by chance), the result is seen as highly significant.*

Further resources:

- **CASP Checklist for Critically Appraising RCTs :** http://media.wix.com/ugd/dded87_40b9ff0bf53840478331915a8ed8b2fb.pdf
- ***"How to Read a paper: The Basics of Evidence-Based Medicine"*** by Patricia Greenhalgh. 4th Edition, 2010 published by Wiley-Blackwell. ISBN: 9781444334364
- ***"Epidemiology, evidence-based medicine and public health: lecture notes"*** by Y. Ben-Shlomo et al. 6th Edition, 2013 published by Wiley-Blackwell. ISBN: 9781444334784
- **NICE Glossary:** https://www.nice.org.uk/Glossary?letter=A
- **Centre for Evidence Based medicine:** www.cebm.net

Further training and assistance:

If you would like to learn more about Critical Appraisal, please contact the Library and Knowledge service. We can arrange training sessions tailored to your needs at a time and location that is convenient to you.

website: http://www.knowledge-nw.nhs.uk

email: library@sthk.nhs.uk

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