



GUIDE TO SCIENTIFIC RESEARCH PAPERS

During the last three decades, the growth in the number of published scientific papers of relevance to health has been enormous. This brief guide highlights the types of studies published in the scientific and medical literature and is intended to help in their interpretation.

In many cases, abstracts (summaries) of or press releases about published scientific papers are the easiest to access. However, reliance on an abstract or press release significantly limits the scope for an accurate and balanced review of the totality of the paper. Anyone reviewing scientific papers should ensure that they have access to the full text.

TYPES OF RESEARCH STUDIES

The main types of research studies are shown in the pyramid. Studies which are generally of most clinical relevance in human health are at the top of the pyramid while those of less

clinical relevance appear towards the bottom.

The four layers above case series involve clinical research in human beings, while the five bottom layers do not. However, all evidence is useful and it is the totality of evidence that should be taken into account.

When the results of a new study are published, they should be assessed in the context of previous research. If a new study reports negative findings while previous research has been largely positive, find out why. Getting the opinion of an expert can be useful to help put new research into context.

WHAT IS A META-ANALYSIS?

A meta-analysis is where all the information from a number of published studies is pooled together. It does not include new data.

In theory, a meta-analysis should be a better guide to a health issue than a single study, but, as with any research, there are good

and bad examples. Meta-analyses are not infallible and are subject to many pitfalls:

- A meta-analysis is only as good as the trials included within it.
- Studies included may support a particular agenda. Studies that do not support that agenda may be omitted.
- Relevant studies may be missed or different inclusion and exclusion criteria may be used. If relevant trials are missed out, the meta-analysis will come up with a conclusion that is simply wrong.
- A major concern with meta-analyses is the way in which they mix different types of studies. They do not always compare like with like. For example:
 - The subjects or patients in the included studies may be different (eg, healthy, diseased, different ages) and different groups of people respond to healthcare interventions very differently. Trials looking at healthy people (primary prevention trials) often show different outcomes than trials in people with disease (secondary prevention trials)
 - Healthcare interventions in the included studies may differ (eg, different doses of vitamins may be used over different periods of time).
 - Outcomes examined may differ between studies (eg, the effect of calcium on the risk of fracture, or the effect of calcium on bone density).
 - The study settings may vary (eg, different countries, hospital or community).
- Meta-analyses should include high quality trials of similar design. Combining poor quality trials is like combining small piles of rubbish to create a big pile of rubbish (ie, the principle of 'garbage in, garbage out' (GOBI)).
- Meta-analyses should be studied very carefully. If a meta-analysis is flawed, its conclusion will simply be wrong.

TYPES OF STUDIES: THE EVIDENCE PYRAMID



WHAT IS A SYSTEMATIC REVIEW?

A systematic review is the collection of relevant primary trials in human populations that deal with a focused question, and includes a summary of the evidence from these primary sources. A meta-analysis is a particular type of systematic review that uses quantitative methods to combine the results from a number of studies. It is a statistical analysis of combined results of these studies.

WHAT IS A RANDOMISED CONTROLLED TRIAL?

Randomised controlled trials (RCTs) are used to establish the average benefit of a treatment such as a drug, a food supplement or type of diet.

In a randomised controlled trial, subjects are randomised into two groups (treatment and control groups). The treatment group receives the treatment under investigation (eg, drug, diet or dietary supplement) and the control group receives either no active treatment (a placebo) or a standard treatment. For example, in a trial in people with osteoarthritis, glucosamine could be compared with a placebo or with a drug treatment such as ibuprofen.

Subjects are randomly assigned to all groups in the study. Randomisation is done by computer, and works like tossing a coin. If the coin lands heads, the subject is assigned to the treatment group while if it lands tails, the subject is assigned to the control group.

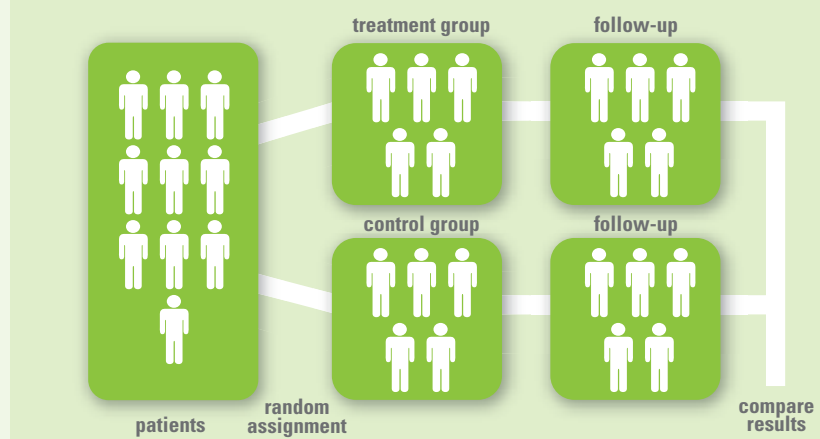
The point about randomization is that it reduces the chance of selection bias and increases the probability that any differences seen in the outcomes of the study groups can be attributed to the treatment.

The test that randomization has been achieved in a study is that the subjects in the different groups have the same characteristics at the start of the study (eg, same number of men and women, same degree of disease severity, same age range, same body weight etc).

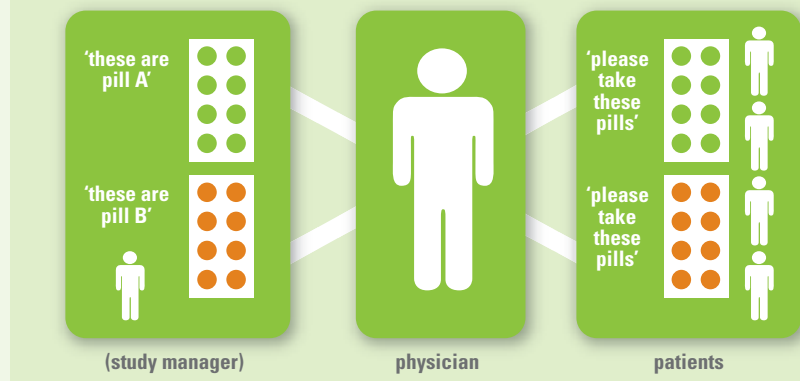
RCTs may be open or blinded. In an open trial, the researcher knows full details of the treatment and so does the patient. Such trials are open to bias and do nothing to reduce the placebo effect.

Blinded trials can be either single blind or double blind. In a single blind trial the researcher knows the details of the treatment while the patient does not. This reduces the placebo effect but is still open to bias because the researcher knows who is getting the 'active' treatment may treat the patients differently. In the double blind trial, neither

RANDOMISED CONTROLLED TRIAL (RCT)



DOUBLE-BLIND, RANDOMISED TRIAL



the researcher giving the treatment nor the patient knows which group they have been allocated to. This reduces the risk of the placebo effect and the researcher treating the

patients differently. Therefore double blind randomised trials are preferred over open trials as they tend to give the most accurate results.

THINGS TO LOOK FOR IN A RANDOMISED CONTROLLED TRIAL

- What sort of people were included in the study? A trial investigating one population group may not be applicable to the whole population. For example, the results of a trial of a supplement in people with angina may not be transferable to people without angina.
- Where was the trial conducted? Which country? Community or hospital? In a clinical unit or among free living people at home? A trial conducted in China may not be relevant for the UK.
- Were full details of the trial provided in the paper? Was the randomisation procedure reported? Was the trial blinded?
- Were all the subjects in the study accounted for? Were there any drop-outs? If so, why? Was this explained and reported?
- Were the statistical methods reported?
- Did the authors discuss their results logically in the context of previous studies?
- Were their conclusions justified from their results?
- Who funded the trial?

A report of a clinical trial should be sufficiently detailed for another researcher to conduct the same trial again. Vague descriptions of methods, subjects, interventions, statistics and results should ring alarm bells. The conclusions of such a trial may be wrong. Again, this is where an expert is useful – to help to distinguish between good and bad trials and whether the trial's conclusions are justified.