

Glossary of research terms

Abstract: A brief summary of the study and its results. It should tell you what the study tried to show, how the researchers went about it, and what they found.

Adverse event: An adverse outcome that occurs during or after the use of a drug or other intervention but is not necessarily caused by it.

Arm: Refers to a group of participants allocated a particular treatment. In a randomised controlled trial, allocation to different arms is determined by the randomisation procedure. Many controlled trials have two arms, a group of participants assigned to an experimental intervention (sometimes called the treatment arm) and a group of participants assigned to a control (the control arm). Trials may have more than two arms.

Attrition: The loss of participants during the course of a study. (Also called loss to follow up.)

Bias: A systematic error or deviation in results or inferences from the truth. In studies of the effects of health care, the main types of bias arise from systematic differences in the groups that are compared (selection bias), the care that is provided, exposure to other factors apart from the intervention of interest (performance bias), withdrawals or exclusions of people entered into a study (attrition bias) or how outcomes are assessed (detection bias). Reviews of studies may also be particularly affected by reporting bias, where a biased subset of all the relevant data is available.

Blinding: The process of preventing those involved in a trial from knowing to which comparison group a particular participant belongs. The risk of bias is minimised when as few people as possible know who is receiving the experimental intervention and who the control intervention. Participants, caregivers, outcome assessors, and analysts are all candidates for being blinded. Blinding of certain groups is not always possible, for example surgeons in surgical trials.

Clinical guideline: A systematically developed statement for practitioners and participants about appropriate health care for specific clinical circumstances.

Clinical trial: An experiment to compare the effects of two or more healthcare interventions. Clinical trial is an umbrella term for a variety of designs of healthcare trials.

Cluster randomised trial: A trial in which clusters of individuals (e.g. clinics, families, geographical areas), rather than individuals themselves, are randomised to different arms.

Cohort study: An observational study in which a defined group of people (the cohort) is followed over time. The outcomes of people in subsets of this cohort are compared, to examine people who were exposed or not exposed (or exposed at different levels) to a particular intervention or other factor of interest. A prospective cohort study assembles participants and follows them into the future. A retrospective (or historical) cohort study identifies subjects from past records and follows them from the time of those records to the present.

Confidence interval: A measure of the uncertainty around the main finding of a statistical analysis. Wider intervals indicate lower precision; narrow intervals, greater precision.

Confounder: A factor that is associated with both an intervention and the outcome of interest. For example, if people in the experimental group of a controlled trial are younger than those in the control group, it will be difficult to decide whether a lower risk of death in one group is due to the intervention or the difference in ages. Age is then said to be a confounder, or a confounding variable. Randomisation is used to minimise imbalances in confounding variables between experimental and control groups. Confounding is a major concern in non-randomised

Contamination: The inadvertent application of the intervention being evaluated to people in the control group; or inadvertent failure to apply the intervention to people assigned to the intervention group.

Control: A participant in the arm that acts as a comparator for one or more experimental interventions. Controls may receive placebo, no treatment, standard treatment, or an active intervention, such as a standard drug.

Cost-effectiveness analysis: An economic analysis that views effects in terms of overall health specific to the problem, and describes the costs for some additional health gain (e.g. cost per additional stroke prevented).

Economic analysis (economic evaluation): Comparison of the relationship between costs and outcomes of alternative healthcare interventions

Effect size: A generic term for the estimate of effect of treatment for a study.

Efficacy: The extent to which an intervention produces a beneficial result under ideal conditions. Clinical trials that assess efficacy are sometimes called explanatory trials.

Epidemiology: The study of the health of populations and communities, not just particular individuals.

Equipoise: A state of uncertainty where a person believes it is equally likely that either of two treatment options is better.

Factorial design: A trial design used to assess the individual contribution of treatments given in combination, as well as any interactive effect they may have. In a trial using a 2x2 factorial design, participants are allocated to one of four possible combinations. This type of study is usually carried out in circumstances where no interaction is likely.

Follow-up: The observation over a period of time of study/trial participants to measure outcomes under investigation.

Gold standard: The method, procedure, or measurement that is widely accepted as being the best available, against which new developments should be compared.

Interaction: The situation in which the effect of one independent variable on the outcome is affected by the value of a second independent variable.

Interim analysis: Analysis comparing intervention groups at any time before the formal completion of a trial, usually before recruitment is complete. Often used with stopping rules so that a trial can be stopped if participants are being put at risk unnecessarily. Timing and frequency of interim analyses should be specified in the protocol.

Intervention: The process of intervening on people, groups, entities or objects in an experimental study. In controlled trials, the word is sometimes used to describe the regimens in all comparison groups, including placebo and no-treatment arms.

Intervention group: A group of participants in a study receiving a particular health care intervention. Parallel group trials include at least two intervention groups.

Meta-analysis: The use of statistical techniques in a systematic review to integrate the results of included studies. Sometimes misused as a synonym for systematic reviews, where the review includes a meta-analysis.

Morbidity: Illness or harm.

Mortality: Death.

Multicentre trial: A trial conducted at several geographical sites. Trials are sometimes conducted among several collaborating institutions, rather than at a single institution - particularly when very large numbers of participants are needed.

Non-inferiority trial: A trial designed to determine whether the effect of a new treatment is not worse than a standard treatment by more than a pre-specified amount.

Observational study: A study in which the investigators do not seek to intervene, and simply observe the course of events. There is a greater risk of selection bias than in experimental studies.

Outcome: A component of a participant's clinical and functional status after an intervention has been applied, that is used to assess the effectiveness of an intervention.

Participant: An individual who is studied in a trial, often but not necessarily a patient.

Peer review: A refereeing process for checking the quality and importance of reports of research. An article submitted for publication in a peer-reviewed journal is reviewed by other experts in the area.

Placebo: An inactive substance or procedure administered to a participant, usually to compare its effects with those of a real drug or other intervention, but sometimes for the psychological benefit to the participant through a belief that they are receiving treatment. Placebos are used in clinical trials to blind people to their treatment allocation. Placebos should be indistinguishable from the active intervention to ensure adequate blinding.

Power: The probability of rejecting the null hypothesis when a specific alternative hypothesis is true. In clinical trials, power is the probability that a trial will detect, as statistically significant, an intervention effect of a specified size. Ideally we want a test to have high power.

Pragmatic trial: A trial that aims to test a treatment policy in a 'real life' situation, when many people may not receive all of the treatment, and may use other treatments as well.

Primary outcome: The outcome of greatest importance.

Primary research: 'Original research' in which data is collected.

Probability: The chance or risk of something happening

Protocol: The plan or set of steps to be followed in a study.

Randomisation: The process of randomly allocating participants into one of the arms of a controlled trial. There are two components to randomisation: the generation of a random sequence, and its implementation, ideally in a way so that those entering participants into a study are not aware of the sequence (concealment of allocation).

Randomised controlled trial (RCT): An experiment in which two or more interventions, possibly including a control intervention or no intervention, are compared by being randomly allocated to participants.

Reporting/publication bias: A bias caused by only a subset of all the relevant data being available. The publication of research can depend on the nature and direction of the study results. Studies in which an intervention is not found to be effective are sometimes not published. Because of this, systematic reviews that fail to include unpublished studies may overestimate the true effect of an intervention. In addition, a published report might present a biased set of results.

Retrospective study: A study in which the outcomes have occurred to the participants before the study commenced. Case-control studies are usually retrospective, cohort studies sometimes are, randomised controlled trials never are.

Secondary outcome: An outcome used to evaluate additional effects of the intervention deemed a priori as being less important than the primary outcomes.

Secondary research: A study of studies: a review of individual studies (each of which is called a primary study). A systematic review is a secondary study.

Specificity: In screening/diagnostic tests this is a measure of a test's ability to correctly identify people who do not have the disease.

Statistically significant: A result that is unlikely to have happened by chance.

Sub-group analysis: An analysis in which the intervention effect is evaluated in a defined subset of the participants in a trial, or in complementary subsets, such as by sex or in age categories.

Systematic review: A review of a clearly formulated question that uses systematic and explicit methods to identify, select, and critically appraise relevant research, and to collect and analyse data from the studies that are included in the review. Statistical methods (meta-analysis) may or may not be used to analyse and summarise the results of the included studies.

Toxicity: The degree to which a medicine is poisonous. How much of a medicine can be taken before it has a toxic effect.

Treatment: The process of intervening on people with the aim of enhancing health or life expectancy. Sometimes, and particularly in statistical texts, the word is used to cover all comparison groups, including placebo and no treatment arms of a controlled trial and even interventions designed to prevent bad outcomes in healthy people, rather than cure ill people.

Trialist: Used to refer to a person conducting or publishing a controlled trial.

References

Cochrane Collaboration glossary. Accessed on August 23, 2011. Available at:
<http://www.cochrane.org/glossary/5>