Glossary of research terms for the NIHR Evaluation, Trials and Studies Coordinating Centre

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.

Academics: Senior staff employed by universities and/or health trusts who have specific responsibility for research.

Acceptability: Whether the research is likely to be acceptable to potential participants, e.g. in terms of what is being done and how.

Action research: Action research is used to bring about improvement or practical change. A group of people who know about a problem work together to develop an idea about how it might be resolved. They then go and test this idea. The people who take part in the testing provide feedback on their experiences. They may also identify further actions that need to be researched and tested. This cycle of developing solutions and testing them is repeated until the problem has been solved.

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.

Applicant: A member of the project team who is part of an application for funding. An applicant would always be listed in the application form.

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.

Blind: This term applies to trials where a new treatment is compared against another treatment or a placebo (usually phase III trials). A trial is ‘single-blind’ if either the participants or the researchers do not know which option the participants are receiving, and ‘double-blind’ if both the participants and the researchers do not know which option the participants are receiving. This makes the results of the trial more objective and therefore more reliable.

Blinding: see blind.
**Carer:** A carer is a relative, friend or partner who provides (or intends to provide, or used to provide) a substantial amount of care to another person on a regular basis, but not necessarily through living with them.

**Case study:** In depth analysis and systematic description of one patient or group of similar patients to promote a detailed understanding of their circumstances.

**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 effect of two or more interventions. ‘Clinical trial’ is a term used for a variety of designs of studies.

**Clinicians:** A health professional (such as a doctor, dentist, nurse, pharmacist or physiotherapist) whose purpose is to provide and/or manage the care of a sick person.

**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.

**Comparator:** An alternative, or control, that researchers use to compare with the test or treatment that is the subject of the study. For example, it may be an alternative test or drug for a condition, or it may be a placebo or simply no treatment at all.

**Conclusive:** Research which gives a clear answer.

**Conduct:** The way in which the trial protocol is implemented and the study is carried out.

**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.

**Control group:** In a controlled trial this would be the group (see arm) which were assigned to either receive placebo or standard care (see control).
**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).

**Crossover trial:** A trial that involves patients receiving one treatment for a certain amount of time then swapping to an alternative treatment for a certain amount of time.

**Deliverable:** If a research project is deliverable then the project team is able to do what they set out to do within the costings and timeframe which were set out in the application.

**Dissemination:** making sure that the research and information produced is spread widely and is readily available to a large audience. This is done through our website, printed leaflets, newsletters, news articles, conferences, presentations and through our own research journal(s), as well as getting articles into other research journals.

**Double-blind:** see **blind**.

**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.

**Eligibility criteria:** Descriptions of people that can (inclusion criteria) or cannot (exclusion criteria) take part in a trial.

**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.

**Ethics:** A set of principles that guide researchers who are carrying out research with people. Ethical principles are designed to protect the safety, dignity, rights and well-being of the people taking part. They include the requirement to ask each individual to give their informed consent to take part in a research project.

**Evaluative research:** Evaluative research seeks to assess or judge in some way, providing useful information about something other than might be gleaned in mere observation or investigation of relationships.

**Evidence Synthesis:** Systematically combining evidence from multiple studies.

**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.
Funding board: Meeting where applications are discussed and assessed by a group of appropriate experts and public members. The board makes funding recommendations regarding the applications they assess.

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

Governance: Clinical governance is a process designed to ensure that standards of care are maintained and improved.

Grey literature: Material that is less formal than an article in a peer review journal or a chapter in a book – so it’s not easily tracked down. It includes internal reports, committee minutes, conference papers, factsheets, newsletters and campaigning material. However, ‘grey literature’ may be made available on request and is increasingly available on the Internet.

Health economics: Comparison of the relationship between costs and outcomes of alternative healthcare interventions.

Honorary contract: Required by anyone who wants to carry out research or observe people in an NHS setting, but who does not already have an employment contract or a volunteer contract with the relevant NHS Trust. The contract ensures that they are covered by NHS liability insurance, and that they are contractually bound to take proper account of the NHS duty of care.

Impact: The contribution, effect on, or benefit that excellent research makes to knowledge, health, the NHS, health services, society or the economy.

Importance: Whether the research is of value to stakeholders, including decision makers, patients and members of the public and clinicians.

Informed consent: The process of learning what is involved in a clinical trial and then agreeing to take part.

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.

Knowledge mobilisation: Getting the right information to the right people in the right format at the right time, so as to influence decision-making. Knowledge Mobilization includes dissemination, knowledge transfer and knowledge translation.

Lay (lay person): The term ‘lay’ means non-professional, or that they will be contributing from a non-professional perspective. In research, it refers to the people who are neither academic researchers nor health or social care professionals. NETSCC would refer to them as public contributors.
**Longitudinal study**: A study that follows a group of patients over a period of time.

**Meta-analysis**: The use of statistical techniques in a systematic review to review the results of a large number of trials on a similar subject. Sometimes misused as a synonym for systematic reviews, where the review includes a meta-analysis.

**Methodology**: Procedures by which a research study is conducted. A description of the methodology will usually include statistics, study design and health economics (see health economics).

**Morbidity**: Illness or harm.

**Mortality**: Death.

**Multi-centre trial**: A trial being carried out at more than one location

**Natural experiment**: Occur by chance when all variables for a population are constant except one, which is different for one large part of the population compared with the other, e.g. when half of a flock comes from one climate and the other half is a local resident in another climate.

**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.

**Outputs**: This includes the final report, journal articles and other documents/web content for dissemination.

**Overlap**: Where two projects are either the same or have elements which are the same.

**Participant**: A patient or appropriate person who is part of a study, e.g. being a participant in a clinical trial or part of a population which is being looked at as part of a study.

**Palliative care**: Care for the terminally ill and their families, esp. that provided by an organized health service.

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

**Performance bias**: See bias.

**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**: A ‘dummy’ treatment that resembles a medical treatment but is intended to have no physical effect on a participant. A new treatment is often compared against a placebo to get more reliable evidence about its effectiveness.

**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.

**Preclinical study:** Research using animals to find out if a drug, procedure, or treatment is likely to be useful. Preclinical studies take place before any testing in humans is done.

**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.

**Public contributors:** Refers to the members of the public who contribute to the research management process in our programmes and the studies that they fund. Public contributors would include patients, potential patients, carers and people who use health and social care services.

**Qualitative research:** Qualitative research is the type of research people use to gain insight into a problem, issue or theory and is interested in the lived experiences of individuals. Qualitative researchers study things in their natural settings, attempting to make sense of, or to interpret, phenomena in terms of the meanings people bring to them.

**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.

**Recruitment:** The people who agree to be participants in a trial would be ‘recruited’ to a trial.

**Remit:** The area of authority or responsibility of an individual, group, or organisation.

**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.

**Research methods:** The approach which a project takes to their research design.

**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.
Selection bias: See bias.

Setting: The research setting is the environment in which research is carried out. This could be a laboratory or a 'real' setting, such as the subject's working environment if you are conducting research into people's working lives.

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.

Study design: The formulation of trials and experiments in research.

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

