Glossary of Terms in The Cochrane Collaboration
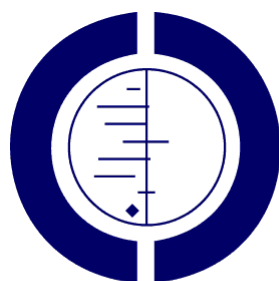
Version 4.2.5

Updated May 2005

**THE COCHRANE
COLLABORATION®**

A

A priori analyses	See **planned analyses**.
Absolute risk difference	See **risk difference**.
Absolute risk reduction	See **risk difference**.
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.
Additive model	A statistical model in which the combined effect of several factors is the sum of the effects produced by each of the factors in the absence of the others. For example, if one factor increases risk by a% and a second factor by b%, the additive combined effect of the two factors is (a + b)%. See also **multiplicative model**.
Adjusted analysis	An analysis that controls (adjusts) for baseline imbalances in important patient characteristics. See also **confounder**, **regression analysis.**
Administrator (of a Collaborative Review Group)	See **Review Group Co-ordinator**.
Adminors	The name of the e-mail discussion list for **Review Group Co-ordinators**.
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.
Adverse effect	An **adverse event** for which the causal relation between the drug/intervention and the event is at least a reasonable possibility. The term 'adverse effect' applies to all interventions, while 'adverse drug reaction' (ADR) is used only with drugs. In the case of drugs an adverse effect tends to be seen from the point of view of the drug and an adverse reaction is seen from the point of view of the patient.
Adverse reaction	See **adverse effect**
Aggregate data	Data summarised by groups, for example summary outcome data for **treatment** and **control groups** in a **controlled trial**.
Allocation concealment	See **concealment of allocation**.
Alpha	See **Type I error**.
Anecdote	See **case study**.
Applicability	See **external validity**.
Arbiter, Funding	See **Funding Arbiter**.
Arbiter, Publication	See **Publication Arbiter**.
Arithmetic mean	See **mean**.

Arm	[In a **controlled trial**.] 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, with more than one experimental arm and/or more than one control arm.
Ascertainment bias	See **detection bias**.
Association	A relationship between two characteristics, such that as one changes, the other changes in a predictable way. For example, statistics demonstrate that there is an association between smoking and lung cancer. In a **positive association**, one quantity increases as the other one increases (as with smoking and lung cancer). In a **negative association**, an increase in one quantity corresponds to a decrease in the other. Association does not necessarily imply a **causal effect**. (Also called **correlation**.)
Attrition	The loss of **participants** during the course of a study. (Also called **loss to follow up**.) Participants that are lost during the study are often call **dropouts**.
Attrition bias	Systematic differences between **comparison groups** in withdrawals or exclusions of **participants** from the results of a study. For example, participants may drop out of a study because of side effects of an **intervention**, and excluding these participants from the analysis could result in an overestimate of the effectiveness of the intervention, especially when the proportion dropping out varies by treatment group.
Author/Reviewer	See **Reviewer/Author**.

B

Baseline characteristics	Values of demographic, clinical and other variables collected for each **participant** at the beginning of a trial, before the **intervention** is administered.
Bayes' theorem	A probability theorem used to update the probability of an event in the light of a piece of new evidence. A common application is in diagnosis, where the prior probability of disease, obtained from **population** data, is updated to a posterior probability in the light of a positive or negative result from a diagnostic test.

Bayesian statistics	An approach to statistics based on application of **Bayes' theorem** that can be used in single studies or **meta-analysis**. A Bayesian analysis uses Bayes' theorem to transform a prior **distribution** for an unknown quantity (e.g. an **odds ratio**) into a posterior distribution for the same quantity, in light of the results of a study or studies. The prior distribution may be based on external evidence, common sense or subjective opinion. Statistical inferences are made by extracting information from the posterior distribution, and may be presented as **point estimates**, and credible intervals (the Bayesian equivalent of **confidence intervals**).
Beta	See **Type II error**.
Bias	[In statistics.] 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.
Bias prevention	Aspects of the design or conduct of a study designed to prevent **bias**. For **controlled trials**, such aspects include **randomisation**, **blinding** and **concealment of allocation**.
Binary data	See **dichotomous data**.
Binomial distribution	A statistical distribution with known properties describing the number of occurrences of an event in a series of observations. Thus, the number of deaths in the **control** arm of a **controlled trial** follows a binomial distribution. The distribution forms the basis for analyses of **dichotomous data**.
Blinding	[In a **controlled trial**:] 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. The terms **single blind**, **double blind** and **triple blind** are in common use, but are not used consistently and so are ambiguous unless the specific people who are blinded are listed. (Also called **masking**.)
Block randomisation	See **random permuted blocks**.

Brochure, Collaboration	Document describing **The Cochrane Collaboration**. Removed from the web site for updating; contact the **Secretariat** for more information.

C

Carry over	[In a **cross-over trial**:] The persistence, into a later period of **treatment**, of some of the effects of a treatment applied in an earlier period.
Case history	See **case study**.
Case series	A study reporting observations on a series of individuals, usually all receiving the same **intervention**, with no **control group**.
Case study	A study reporting observations on a single individual. (Also called **anecdote**, **case history**, or **single case report**.)
Case-control study	A study that compares people with a specific disease or **outcome** of interest (cases) to people from the same **population** without that disease or outcome (**controls**), and which seeks to find associations between the outcome and prior exposure to particular risk factors. This design is particularly useful where the outcome is rare and past exposure can be reliably measured. Case-control studies are usually **retrospective**, but not always.
Categorical data	Data that are classified into two or more non-overlapping categories. Race and type of drug (aspirin, paracetamol, etc.) are examples of categorical variables. If there is a natural order to the categories, for example, non-smokers, ex-smokers, light smokers and heavy smokers, the data are known as **ordinal data**. If there are only two categories, the data are **dichotomous data**. See also **continuous data**.
Causal effect	An **association** between two characteristics that can be demonstrated to be due to cause and effect, i.e. a change in one causes the change in the other. Causality can be demonstrated by experimental studies such as **controlled trials** (for example, that an experimental **intervention** causes a reduction in mortality). However, causality can often not be determined from an **observational study**.
CCAG	See **Cochrane CENTRAL Advisory Group**.
CCN	See **Cochrane Consumer Network**.
CCRCT	See the **Cochrane Central Register of Controlled Trials (CENTRAL)**.
CCSG	See **Cochrane Collaboration Steering Group**.
CDSR	See **Cochrane Database of Systematic Reviews**.

Censored	[In **survival analysis**:] A term used in studies where the **outcome** is the time to a particular event, to describe data from patients where the outcome is unknown. A patient might be known not to have had the event only up to a particular point in time, so 'survival time' is censored at this point.
CENTRAL (Cochrane Central Register of Controlled Trials [CCRCT])	**The Cochrane Collaboration's** register of reports of studies that may be relevant for inclusion in **Cochrane Reviews**. CENTRAL aims to include all relevant reports that have been identified through the work of The Cochrane Collaboration, through the transfer of this information to the US Cochrane Center. It is published in **The Cochrane Library**.
Centre	Cochrane Centres have responsibility for helping to co-ordinate and support the Collaboration. Each Centre is responsible for providing support within its geographic and linguistic area. Details of Centre responsibilities and a list of the Centres responsible for any given country are available in **The Cochrane Library**.
Centre for Reviews and Dissemination (CRD)	CRD, based in York, UK, produces the **Database of Abstracts of Reviews of Effects (DARE)**.
Chi-squared test	A statistical test based on comparison of a test statistic to a chi-squared distribution. Used in **RevMan** analyses to test the statistical significance of the **heterogeneity** statistic.
CI	See **confidence interval**.
CINAHL (Cumulative Index to Nursing and Allied Health Literature)	Electronic database covering the major journals in nursing and allied health.
CLIB	See **The Cochrane Library**.
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, including **uncontrolled trials**, **controlled trials**, and **randomised controlled trials**. (Also called **intervention study**.)

Clinically significant	A result (e.g. a **treatment effect**) that is large enough to be of practical importance to patients and healthcare providers. This is not the same thing as **statistically significant**. Assessing clinical significance takes into account factors such as the size of a treatment effect, the severity of the condition being treated, the side effects of the treatment, and the cost. For instance, if the estimated effect of a treatment for acne was small but statistically significant, but the treatment was very expensive, and caused many of the treated patients to feel nauseous, this would not be a clinically significant result. Showing that a drug lowered the heart rate by an average of 1 beat per minute would also not be clinically significant.
CLUG	See **Cochrane Library Users' Group**.
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**. In such studies, care should be taken to avoid **unit of analysis errors**.
CMAG	See **Criticism Management Advisory Group**.
Cochrane, Archie	**The Cochrane Collaboration** is named in honour of Archie Cochrane, a British medical researcher who contributed greatly to the development of epidemiology as a science.
Cochrane CENTRAL Advisory Group (CCAG)	An advisory group to the **CCSG**. It is responsible for ensuring that **Collaborative Review Groups** are helped to develop and maintain specialised **registers of controlled trials** falling within their respective scopes. The CCAG is also responsible for maintaining the Management Plan for the **Cochrane Central Register of Controlled Trials (CENTRAL)**.
Cochrane Central Register of Controlled Trials (CCRCT)	See **CENTRAL**.
Cochrane Collaboration, The	An international organisation that aims to help people make well-informed decisions about health care by preparing, maintaining, and ensuring the accessibility of **systematic reviews** of the effects of healthcare interventions.
Cochrane Collaboration Steering Group (CCSG)	It has overall responsibility for overseeing the development and implementation of policy affecting The Cochrane Collaboration. The **CCSG** also has legal responsibility as the Board of Directors for The Cochrane Collaboration as a registered charity.
Cochrane Consumer Network (CCN)	A registered entity in **The Cochrane Collaboration**, responsible for co-ordinating and facilitating **consumer** involvement.

Cochrane Database of Systematic Reviews (CDSR)	One of the databases in **The Cochrane Library**. It brings together all the currently available **Cochrane Reviews** and **Protocols** for Cochrane Reviews. It is updated quarterly, and is available via the Internet and CD-ROM. See **The Cochrane Library**.
Cochrane Groups	See **entities**.
Cochrane Library (CLIB)	A collection of databases, published on CD-ROM and the Internet and updated quarterly, containing the **Cochrane Database of Systematic Reviews**, the **Cochrane Central Register of Controlled Trials**, the **Database of Abstracts of Reviews of Effects**, the **Cochrane Methodology Register**, the **HTA Database**, **NHSEED**, and information about **The Cochrane Collaboration**.
Cochrane Library Users' Group (CLUG)	An advisory group to the **CCSG**. Its remit is to advise on the content, functionality, and design of **The Cochrane Library**.
Cochrane Manual	Document describing the policies and operating procedures of **The Cochrane Collaboration**. Accessible via the Collaboration web site.
Cochrane Methodology Register (CMR, formerly the Cochrane Review Methodology Database [CRMD])	A bibliography (with **abstracts**) of articles and books about methodological issues relevant to summarising evidence of the effects of healthcare. It is published in **The Cochrane Library**.
Cochrane Review	Cochrane Reviews are systematic summaries of evidence of the effects of healthcare interventions. They are intended to help people make practical decisions. For a review to be called a 'Cochrane Review' it must be in **CDSR** or **CMR**. The specific methods used in a Review are described in the text of the review. Cochrane Reviews are prepared using **Review Manager (RevMan)** software provided by the Collaboration, and adhere to a structured format that is described in the **Cochrane Handbook for Systematic Reviews of Interventions**.
Cochrane Handbook for Systematic Reviews of Interventions (Previously called Cochrane Reviewers' Handbook)	Document containing guidance and advice on how to prepare and maintain Cochrane reviews. Accessible on the Collaboration web site and in the **RevMan** software. Updated regularly.
Cochrane Review Methodology Database (CRMD)	See the **Cochrane Methodology Register**.

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. Because subjects are not allocated by the investigator to different interventions or other exposures, **adjusted analysis** is usually required to minimise the influence of other factors (**confounders**).

Co-intervention

The application of additional diagnostic or therapeutic procedures to people receiving a particular programme of **treatment**. In a **controlled trial**, members of either or both the **experimental** and the **control groups** might receive co-interventions.

Collaborative Review Group (CRG)

CRGs are made up of individuals sharing an interest in a particular healthcare problem or type of problem. The main purpose of a CRG is to prepare and maintain **systematic reviews** of the effects of healthcare interventions within the scope of the CRG. Members participate in the CRG not only by preparing **Cochrane Reviews** but also by handsearching journals and other activities that help the CRG to fulfil its aim. Each CRG is coordinated by an **editorial team**, responsible for regularly updating and submitting an edited **module** of Cochrane Reviews and information about the CRG, for publication in **The Cochrane Library**.

Collaborative Trialists' Group

Investigators who conduct similar **randomised controlled trials** and agree to contribute individual patient data from their trials to a **meta-analysis**.

Colloquia/Colloquium

The annual conferences of **The Cochrane Collaboration**, which usually take place in October. They last for five or six days, and have between 600 and 1200 participants. Colloquia take place in countries where there is a **Cochrane Centre**, which volunteers to host a Colloquium, and is responsible for organising it.

Colloquium Policy Advisory Group (CPAG)

The CPAG is an advisory group to the **CCSG**. Its remit is to maintain a record of policy decisions about Cochrane **Colloquia**, to move forward new policies after appropriate consultation, and to help ensure that hosts of future Colloquia know about and adhere to such policies.

Co-morbidity	The presence of one or more diseases or conditions other than those of primary interest. In a study looking at **treatment** for one disease or condition, some of the individuals may have other diseases or conditions that could affect their **outcomes**. (A co-morbidity may be a **confounder**.)
Comparison group	See **control group**.
Concealment of allocation	The process used to ensure that the person deciding to enter a **participant** into a **randomised controlled trial** does not know the **comparison group** into which that individual will be allocated. This is distinct from blinding, and is aimed at preventing **selection bias**. Some attempts at concealing allocation are more prone to manipulation than others, and the method of allocation concealment is used as an assessment of the quality of a trial. See also **bias prevention**. (Also called **allocation concealment**.)
Conference abstracts/proceedings	Short summaries of presentations at conferences, which may be published as proceedings. Abstracts from Cochrane **Colloquia** are available on the Collaboration web site.
Confidence interval	A measure of the uncertainty around the main finding of a statistical analysis. Estimates of unknown quantities, such as the odds ratio comparing an **experimental intervention** with a **control**, are usually presented as a point estimate and a 95% confidence interval. This means that if someone were to keep repeating a study in other samples from the same **population**, 95% of the confidence intervals from those studies would contain the true value of the unknown quantity. Alternatives to 95%, such as 90% and 99% confidence intervals, are sometimes used. Wider intervals indicate lower precision; narrow intervals, greater precision. (Also called **CI**.)
Confidence limits	The upper and lower boundaries of a **confidence interval**.
Conflict of interest declaration (or Competing interests declaration)	A statement by a contributor to a report or review of personal, financial, or other interests that could have influenced someone.
Confounded comparison	A **comparison** between two treatment groups that will give a biased estimate of the effect of treatment due to the study design. For a comparison to be unconfounded, the two treatment groups must be treated identically apart from the randomised treatment. For instance, to estimate the effect of heparin in acute stroke, a trial of heparin alone versus **placebo** would provide an **unconfounded comparison**. However, a trial of heparin alone versus aspirin alone provides a confounded comparison of the effect of heparin. (See also **unconfounded comparison**.)

also **unconfounded comparison**.)

Confounder	A factor that is associated with both an **intervention** (or exposure) 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 studies**. See also **adjusted analyses**.
Consumer (healthcare consumer)	Someone who uses, is affected by, or who is entitled to use a health related service.
Consumer advocate or representative	Consumer who is actively involved with other consumers and able to represent the perspectives and concerns of that broader group of people. Consumer representatives work in Cochrane **entities** to ensure that consumers' views are taken account of when **review** questions are being decided and results presented.
Contamination	[In a **controlled trial**:] 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**. Fear of contamination is one motivation for performing a **cluster randomised trial**.
Context	The conditions and circumstances that are relevant to the application of an **intervention**, for example the setting (in hospital, at home, in the air); the time (working day, holiday, night-time); type of practice (primary, secondary, tertiary care; private practice, insurance practice, charity); whether routine or emergency.

Contingency table	A table of frequencies or counts. In a two-way contingency table, sub-categories of one characteristic are indicated horizontally (in rows) and subcategories of another characteristic are indicated vertically (in columns). Tests of association between the characteristics can be readily applied. The simplest two-way contingency table is the **2x2 table**, which is used in **clinical trials** to compare **dichotomous outcomes**, such as death, for an **experimental intervention** and **control group**.
Continuous data	Data with a potentially infinite number of possible values within a given range. Height, weight and blood pressure are examples of continuous variables. See also **categorical data**.
Control	1. [In a **controlled trial**:] 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.
	2. [In a **case-control study**:] A person in the group without the disease or **outcome** of interest.
	3. [In statistics:] To adjust for, or take into account, extraneous influences or observations.
Control event rate	See **risk**.
Control group	1. [In a **controlled trial**:] The **arm** that acts as a comparator for one or more experimental **interventions**. See also **control**. (Also called **comparison group**.)
	2. [In a **case-control study**:] The group without the disease or **outcome** of interest. (Also called **comparison group**.)
Control group risk	See **risk**.
Control program	[In communicable (infectious) diseases:] Programs aimed at reducing or eliminating the disease.
Controlled before and after study	A **non-randomised study** design where a control **population** of similar characteristics and performance as the **intervention group** is identified. Data are collected before and after the **intervention** in both the **control** and intervention groups.
Controlled (clinical) trial (CCT)	See **clinical trial**. This is an indexing term used in **MEDLINE** and **CENTRAL**. Within CENTRAL it refers to trials using quasi-randomisation, or trials where double blinding was used but **randomisation** was not mentioned.
Controlled trial	A **clinical trial** that has a **control group**. Such trials are not necessarily randomised.

Convenience sample	A group of individuals being studied because they are conveniently accessible in some way. This could make them particularly unrepresentative, as they are not a **random sample** of the whole population. A convenience sample, for example, might be all the people at a certain hospital, or attending a particular support group. They could differ in important ways from the people who haven't been brought together in that way: they could be more or less sick, for example.
Conventional treatment	Whatever the standard or usual treatment is for a particular condition at that time.
Co-ordinating Editor (of a Collaborative Review Group)	This member of the **CRG's** editorial team has the primary responsibility for ensuring that the CRG is productive and efficient, and operates according to the principles of **The Cochrane Collaboration**.
Correlation	1. See **association**. (Positive correlation is the same as positive association, and negative correlation is the same as negative association.)
	2. [In statistics:] Linear association between two variables, measured by a correlation coefficient. A correlation coefficient can range from -1 for perfect negative correlation, to +1 for perfect positive correlation (with perfect meaning that all the points lie on a straight line). A correlation coefficient of 0 means that there is no linear relationship between the variables.
Cost-benefit analysis	An economic analysis that converts effects into the same monetary terms as costs and compares them.
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).
Cost-utility analysis	An economic analysis that expresses effects as overall health improvement and describes how much it costs for some additional **utility** gain (e.g. cost per additional quality-adjusted life-year).
Cox model	See **proportional hazards model**.
CPAG	See **Colloquium Policy Advisory Group**.
CRD	See the **Centre for Reviews and Dissemination**.
CRG	See **Collaborative Review Group**.
CRG module	See **module**.
Critical appraisal	The process of assessing and interpreting evidence by systematically considering its **validity**, results, and relevance.
Criticism Management Advisory Group (CMAG)	An advisory group to the **CCSG**. CMAG's remit is to advise on policies and procedures for managing comments and criticisms of **Cochrane Reviews**.

CRMD	See the **Cochrane Methodology Register**.
Cross-over trial	A type of **clinical trial** comparing two or more **interventions** in which the **participants**, upon completion of the course of one treatment, are switched to another. For example, for a comparison of treatments A and B, the participants are randomly allocated to receive them in either the order A, B or the order B, A. Particularly appropriate for study of treatment options for relatively stable health problems. The time during which the firs **interventions** is taken is known as the first period, with the second intervention being taken during the second period. See also **carry over**, and **period effect**.
Cross-sectional study	A study measuring the distribution of some characteristic(s) in a population at a particular point in time. (Also called **survey**.)
Cumulative meta-analysis	A **meta-analysis** in which studies are added one at a time in a specified order (e.g. according to date of publication or quality) and the results are summarised as each new study is added. In a graph of a cumulative meta-analysis, each horizontal line represents the summary of the results as each study is added, rather than the results of a single study.
Current Contents	Electronic database that provides access to the tables of contents and bibliographic data from current issues of the world's leading scholarly research journals in the sciences, social sciences, arts, and humanities.

D

DARE	See **Database of Abstracts of Reviews of Effects**.
Data derived analyses	See **unplanned analyses.**
Data dredging	Performing many analyses on the data from a study, for example looking for associations among many variables. Particularly used to refer to **unplanned analyses**, where there is no apparent hypothesis, and only statistically significant results are reported.
Data monitoring committee	An expert committee set up to monitor the results of a continuing trial periodically, and assess whether or not the trial should continue or stop on ethical grounds, that is, if a treatment appears to be dramatically effective or harmful, and providing it or denying it to half the participants has become unethical. See also **equipoise**.
Database of Abstracts of Reviews of Effects (DARE)	A collection of structured abstracts and bibliographic references of systematic reviews of the effects of healthcare interventions produced by the NHS **Centre for Reviews and Dissemination** in York, UK. One of the databases in **The Cochrane Library**.

Decision analysis
A technique that formally identifies the options in a decision-making process, quantifies the probable outcomes (and costs) of each (and the uncertainty around them), determines the option that best meets the objectives of the decision-maker and assesses the robustness of this conclusion.

Degrees of freedom
A concept that refers to the number of independent contributions to a sampling distribution (such as **chi-squared distribution**). In a **contingency table**, it is one less than the number of row categories multiplied by one less than the number of column categories; e.g. a 2 x 2 table comparing two groups for a **dichotomous outcome**, such as death, has one degree of freedom.

Dependent variable
The **outcome** or response that results from changes to an **independent variable**. In a **clinical trial**, the outcome (over which the investigator has no direct control) is the dependent variable, and the treatment arm is the independent variable. The dependent variable is traditionally plotted on the vertical axis on graphs. (Also called **outcome variable**.)

Descriptive study
A study that describes characteristics of a sample of individuals. Unlike an **experimental study**, the investigators do not actively intervene to test a hypothesis, but merely describe the health status or characteristics of a sample from a defined population.

Design effect
A number that describes how much larger a sample is needed in designs such as **cluster randomised trials** to achieve the same **precision** as a simple random sample. It is the ratio of the true variance of a statistic (taking the sampling design into account) to the variance of the statistic for a simple random sample with the same number of cases.

Detection bias
Systematic difference between **comparison groups** in how **outcomes** are ascertained, diagnosed or verified. (Also called **ascertainment bias**.)

Detection rate
See **sensitivity**.

Dichotomous data
Data that can take one of two possible values, such as dead/alive, smoker/non-smoker, present/not present. (Also called **binary data**.) Sometimes **continuous data** or **ordinal data** are simplified into dichotomous data (e.g. age in years could become <75 years or ≥75 years).

Distribution
The collection of values of a **variable** in the **population** or the sample, sometimes called an empirical distribution. See also **probability distribution**.

Dose dependent
A response to a drug which may be related to the amount received (i.e. the dose). Sometimes trials are done to test the effect of different dosages of the same drug. This may be true for both benefits and harms.

Dose response relationship	The relationship between the quantity of treatment given and its effect on **outcome**. In **meta-analysis**, dose-response relationships can be investigated using **meta-regression**.
Double blind	See **blinding**.
Dropouts	See **attrition**.

E

Economic analysis (economic evaluation)	Comparison of the relationship between costs and outcomes of alternative healthcare interventions. See **cost-benefit analysis**, **cost-effectiveness analysis**, and **cost-utility analysis**.
Editor (of a Collaborative Review Group)	A member of the **CRG's editorial team**, often not located at the **editorial base**, who not only prepares and maintains one or more **Cochrane Reviews** as a member of a CRG, but also has responsibilities to support the **Co-ordinating Editor** in editing Cochrane Reviews prepared by others, and in fostering the smooth running of the CRG.
Editorial base	**Collaborative Review Groups** have an editorial base at which their work is co-ordinated. Usually the **Co-ordinating Editor**, the **Review Group Co-ordinator,** the **Trials Search Co-ordinator**, secretarial support, and the **CRG's** trials register are located there. Reviewers/Authors are encouraged to come there to work on their **Cochrane Reviews**.
Editorial Management Advisory Group (EMAG)	Formerly called the **ModMan Advisory Group (MAG)**. Advises on the development of software that supports the **editorial process** of **Collaborative Review Groups**.
Editorial process	The process by which each individual **CRG** decides on the criteria for editing and including **Cochrane Reviews** in its edited **module** for inclusion in the **Cochrane Database of Systematic Reviews**. See also **referee process**.
Editorial team (of a Collaborative Review Group)	Normally consists of a **Co-ordinating Editor**, **Review Group Co-ordinator**, several **editors**, in most cases a **Trials Search Co-ordinator**, and in some cases a secretary.
Effect size	1. A generic term for the **estimate of effect** of **treatment** for a study. 2. A dimensionless measure of effect that is typically used for **continuous data** when different scales (e.g. for measuring pain) are used to measure an **outcome** and is usually defined as the difference in means between the **intervention** and **control groups** divided by the **standard deviation** of the control or both groups. See also **standardised mean difference**.

Effectiveness	The extent to which a specific **intervention**, when used under ordinary circumstances, does what it is intended to do. **Clinical trials** that assess effectiveness are sometimes called pragmatic or management trials. See also **intention-to-treat.**
Efficacy	The extent to which an **intervention** produces a beneficial result under ideal conditions. **Clinical trials** that assess efficacy are sometimes called explanatory trials and are restricted to participants who fully co-operate.
EMAG	See **Editorial Management Advisory Group**.
EMBASE	Excerpta Medica database. A major European database of medical and health research.
Empirical	Empirical results are based on observation rather than on reasoning alone.
Endpoint	See **outcome**.
Entities	The term used for registered groups in **The Cochrane Collaboration** (**Collaborative Review Groups**, **Centres**, **Fields**, **Methods Groups**, and **The Cochrane Consumer Network**).
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.
Equivalence trial	A trial designed to determine whether the response to two or more **treatments** differs by an amount that is clinically unimportant. This is usually demonstrated by showing that the true treatment difference is likely to lie between a lower and an upper equivalence level of clinically acceptable differences. See also **non-inferiority trial**.
Estimate of effect	The observed relationship between an **intervention** and an **outcome** expressed as, for example, a **number needed to treat to benefit, odds ratio**, **risk difference**, **risk ratio**, **standardised mean difference**, or **weighted mean difference**. (Also called **treatment effect**.)
Event rate	See **risk**.
Executive	A sub-group of the **CCSG**, responsible for making interim decisions on behalf of the full Steering Group between its bi-annual meetings on issues other than monitoring, registration, and publishing policy. The Executive is also responsible for co-ordinating and ensuring good communication among groups responsible for core functions and CCSG.

Expected date (of a Cochrane Review)
The date by which a user of the **Cochrane Database of Systematic Reviews (CDSR)** can expect to have access to a completed review. This date appears on **Protocols** in **CDSR**.

Experimental intervention
An **intervention** under evaluation. In a **controlled trial**, an experimental intervention arm is compared with one or more control arms, and possibly with additional experimental intervention arms.

Experimental study
A study in which the investigators actively intervene to test a **hypothesis**. In a **controlled trial**, one type of experiment, the people receiving the **treatment** being tested are said to be in the experimental group or **arm** of the trial.

Explanatory trial
A trial that aims to test a **treatment** policy in an ideal situation where patients receive the full course of therapy as prescribed, and use of other treatments may be controlled or restricted. See also **pragmatic trial**.

Explanatory variable
See **independent variable**.

External peer reviewer (of a Cochrane Review)
A person with relevant content, **methodological**, or user expertise who critically examines **Cochrane Reviews** in her/his area of expertise.

External validity
The extent to which results provide a correct basis for generalisations to other circumstances. For instance, a **meta-analysis** of trials of elderly patients may not be generalisable to children. (Also called **generalisability** or **applicability**.)

Extramural
Outside (the walls or boundaries of) a community or institution. Refers to 'external' sources of support (such as funding) as opposed to 'internal' (intramural) support.

F

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. Most trials only consider a single factor, where an **intervention** is compared with one or more alternatives, or a **placebo**. In a trial using a 2x2 factorial design, **participants** are allocated to one of four possible combinations. For example in a 2x2 factorial RCT of nicotine replacement and counselling, participants would be allocated to: nicotine replacement alone, counselling alone, both, or neither. In this way it is possible to test the independent effect of each intervention on smoking cessation and the combined effect of (interaction between) the two interventions. This type of study is usually carried out in circumstances where no **interaction** is likely.

False negative	A falsely drawn negative conclusion.
	[In diagnostic tests:] A conclusion that a person does not have the disease or condition being tested, when they actually do.
	[In clinical trials:] See **Type II error**.
False positive	A falsely drawn positive conclusion.
	[In diagnostic tests:] A conclusion that a person does have the disease or condition being tested, when they actually do not.
	[In clinical trials:] See **Type I error**.
Field	Fields (which can also be called **Networks**) are Cochrane **entities** that focus on dimensions of health care other than health problems, such as the setting of care (e.g. primary care), the type of consumer (e.g. older people), the type of provider (e.g. nursing), the type of intervention (e.g. complementary medicine), or a broad area of health care (e.g. cancer). Among their tasks, people working in Fields **handsearch** specialist journals, help to ensure that priorities and perspectives in their field of interest are reflected in the work of **Collaborative Review Groups**, compile specialist databases, co-ordinate activities with relevant agencies outside the Collaboration, and comment on **Cochrane Reviews** relating to their particular area.
Fixed-effect model	[In **meta-analysis**:] A model that calculates a pooled effect estimate using the assumption that all observed variation between studies is caused by the play of chance. Studies are assumed to be measuring the same overall effect. An alternative model is the **random-effects model**.
Follow-up	The observation over a period of time of study/trial **participants** to measure **outcomes** under investigation.
Forest plot	A graphical representation of the individual results of each study included in a **meta-analysis** together with the combined meta-analysis result. The plot also allows readers to see the **heterogeneity** among the results of the studies. The results of individual studies are shown as squares centred on each study's point estimate. A horizontal line runs through each square to show each study's **confidence interval** - usually, but not always, a 95% confidence interval. The overall estimate from the meta-analysis and its confidence interval are shown at the bottom, represented as a diamond. The centre of the diamond represents the pooled point estimate, and its horizontal tips represent the confidence interval.

FTP (File Transfer Protocol) Server	Enables users to open a connection to a host computer and transfer files between the host computer and a remote computer.
Funders' Forum	A group of people with an interest in establishing infrastructure funding for the work of **The Cochrane Collaboration**. This initiative is led by the Department of Health in England; the group usually meets during Cochrane **Colloquia**.
Funding Arbiter	In forming a commercial sponsorship policy for **The Cochrane Collaboration**, the **CCSG** established the position of Funding Arbiter in March 2004, analogous to the **Publication Arbiter**. The Funding Arbiter is a CCSG member and convenes a standing panel of three to give guidance on difficult cases of potential sponsorship.
Funnel plot	A graphical display of some measure of study **precision** plotted against **effect size** that can be used to investigate whether there is a link between study size and **treatment effect**. One possible cause of an observed **association** is **reporting bias**.

G

Generalisability (also: applicability, external validity)	See **external validity**.
Gold standard	The method, procedure, or measurement that is widely accepted as being the best available, against which new developments should be compared.
Grey literature	Grey literature is the kind of material that is not published in easily accessible journals or databases. It includes things like conference proceedings that include the **abstracts** of the research presented at conferences, unpublished theses, and so on.

H

HAG	See **Handbook Advisory Group**.
Handbook	See the **Cochrane Handbook for Systematic Reviews of Interventions** (previously called the Cochrane Reviewers' Handbook.)
Handbook Advisory Group (HAG)	The Handbook Advisory Group is an advisory group to the **CCSG**. It is responsible for the **Cochrane Handbook for Systematic Reviews of Interventions** (previously called the Cochrane Reviewers' Handbook.

Handsearching, Handsearcher	Handsearching within **The Cochrane Collaboration** refers to the planned searching of a journal page by page (i.e. by hand), including editorials, letters, etc., to identify all reports of **randomised controlled trials** and **controlled clinical trials**. All the identified trials, regardless of the topic, are sent to the United States Cochrane Center, for inclusion in **CENTRAL**, and forwarding to the US National Library of Medicine (NLM) for re-tagging in **MEDLINE**. Trials that are within the scope of a **Collaborative Review Group** or **Field** go into their **specialised register of trials**. A handsearching manual is available through the US Cochrane Center. A journal handsearch registration form must be completed for each journal title and sent to the US Cochrane Center to avoid duplication of effort.
Hazard rate	The probability of an event occurring given that it hasn't occurred up to the current point in time.
Hazard ratio	A measure of effect produced by a **survival analysis**. This represents the increased **risk** with which one group is likely to experience the **outcome** of interest. For example, if the hazard ratio for death for a treatment is 0.5, then we can say that treated patients are likely to die at half the rate of untreated patients.
Heterogeneity	1. Used in a general sense to describe the variation in, or diversity of, **participants**, **interventions**, and measurement of outcomes across a set of studies, or the variation in internal **validity** of those studies.

2. Used specifically, as statistical heterogeneity, to describe the degree of variation in the **effect estimates** from a set of studies. Also used to indicate the presence of variability among studies beyond the amount expected due solely to the play of chance.

See also **homogeneous**, **I2**. |
| **Heterogeneous** | Used to describe a set of studies or **participants** with sizeable **heterogeneity**. The opposite of **homogeneous**. |
| **Historical control** | A **control** person or group for whom data were collected earlier than for the group being studied. There is a large risk of **bias** in studies that use historical controls due to systematic differences between the **comparison groups**, due to changes over time in **risks**, prognosis, health care, etc. |

Homogeneous	1. Used in a general sense to mean that the **participants**, **interventions**, and measurement of **outcomes** are similar across a set of studies.
	2. Used specifically to describe the **effect estimates** from a set of studies where they do not vary more than would be expected by chance.
	See also **homogeneous**, **heterogeneity**.
HTA Database	A database within *The Cochrane Library*, containing structured records describing health technology assessment projects. Compiled by the NHS Centre for Reviews and Dissemination.
Hypothesis	An unproved theory that can be tested through research. To properly test a hypothesis, it should be pre-specified and clearly articulated, and the study to test it should be designed appropriately. See also **null hypothesis**.
Hypothesis test	A statistical procedure to determine whether to reject a null hypothesis on the basis of the observed data.

I

I^2	A measure used to quantify **heterogeneity**. It describes the percentage of the variability in **effect estimates** that is due to **heterogeneity** rather than sampling error (chance). A value greater than 50% may be considered to represent substantial heterogeneity.
IMSG	See **Information Management System Group**.
Incidence	The number of new occurrences of something in a **population** over a particular period of time, e.g. the number of cases of a disease in a country over one year.
Independent	A description of two events, where knowing the **outcome** or value of one does not inform us about the outcome or value of the other. Formally, two events 'A and B' are independent if the probability that A and B occur together is equal to the probability of A occurring multiplied by the probability of B occurring.
Independent group design	See **parallel group trial**.
Independent variable	An exposure, **risk factor**, or other characteristic that is hypothesized to influence the **dependent variable**. In a **clinical trial**, the **outcome** (over which the investigator has no direct control) is the dependent variable, and the **treatment arm** is the independent variable. In an **adjusted analysis**, patient characteristics are included as additional independent variables. (Also called **explanatory variable**.)

Index Medicus	Catalogue of the United States National Library of Medicine (NLM), and a periodical index to the medical literature. Available in printed form, or electronically as **MEDLINE**.
Individual patient data	[In **meta-analysis**:] The availability of raw data for each study participant in each included study, as opposed to **aggregate data** (summary data for the **comparison groups** in each study). **Reviews** using individual patient data require collaboration of the investigators who conducted the original studies, who must provide the necessary data.
Information Management System Group (IMSG)	The Information Management System Group (**IMSG**) is an advisory group to the **CCSG**. It is responsible for overseeing the development of any software within the Collaboration that is mandatory to use (for instance, by the **editorial bases** of all **Collaborative Review Groups**), and for advising on Collaboration-wide use of other software.
Intention to treat analysis	A strategy for analysing data from a **randomised controlled trial**. All **participants** are included in the **arm** to which they were allocated, whether or not they received (or completed) the **intervention** given to that arm. Intention-to-treat analysis prevents **bias** caused by the loss of participants, which may disrupt the **baseline** equivalence established by randomisation and which may reflect non-adherence to the **protocol**. The term is often misused in trial publications when some participants were excluded.
Interaction	The situation in which the effect of one independent variable on the **outcome** is affected by the value of a second independent variable. In a trial, a test of interaction examines whether the **treatment effect** varies across sub-groups of **participants**. See also **factorial trial**, **sub-group analysis**.
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**.
Intermediary outcomes	See **surrogate endpoints**.
Internal validity	The extent to which the design and conduct of a study are likely to have prevented **bias**. Variation in **quality** can explain variation in the results of studies included in a **systematic review**. More rigorously designed (better quality) trials are more likely to yield results that are closer to the truth. (Also called **methodological quality** but better thought of as relating to **bias prevention**.) See also **external validity**, **validity**, **bias prevention**.

Inter-rater reliability	The degree of stability exhibited when a measurement is repeated under identical conditions by different raters. Reliability refers to the degree to which the results obtained by a measurement procedure can be replicated. Lack of inter-rater reliability may arise from divergences between observers or instability of the attribute being measured. See also **intra-rater reliability**.
Interrupted time series	A research design that collects observations at multiple time points before and after an **intervention** (interruption). The design attempts to detect whether the intervention has had an effect significantly greater than the underlying trend.
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**. See also **treatment**, **experimental intervention** and **control**.
Intervention group	A group of **participants** in a study receiving a particular health care **intervention**. **Parallel group trials** include at least two intervention groups.
Intervention study	See **Clinical trial**.
Intramural	Within (the walls or boundaries of) a community or institution (e.g. a university). Used to distinguish from 'external' (extramural) sources of support (such as funding).
Intra-rater reliability	The degree of stability exhibited when a measurement is repeated under identical conditions by the same rater. Reliability refers to the degree to which the results obtained by a measurement procedure can be replicated. Lack of intra-rater reliability may arise from divergences between instruments of measurement, or instability of the attribute being measured.

K

Key words	A string of words attached to an article to be used to index or code the article in a database. See also **MeSH** and **MEDLINE**.

L

L'Abbé plot	A scatter plot of the **risk** in the **experimental group** against the risk in the **control group**. Ideally the size of the plotting symbols should be proportional to the size of the trials. Trials in which the experimental **treatment** had a higher risk than the control will be in the upper left of the plot, between the *y* axis and the line of equality. If experimental is no better than control then the point will fall on the line of equality, and if the control treatment has a higher risk than the experimental treatment then the point will be in the lower right of the plot, between the *x* axis and the line of equality.
Leaflet, Collaboration	A concise overview of **The Cochrane Collaboration's** aims and activities. It can be downloaded from the Collaboration web site.
LILACS (Latin American and Caribbean Health Sciences Literature)	An electronic database based on a regional database of medical and science literature. It is compiled by the Latin American and Caribbean Centre for Health Science Information, a unit of the Pan American Health Organisation.
Linear scale	A scale that increases in equal steps. In a linear scale on a **RevMan forest plot**, the distance between 0 and 5 is the same as the distance between 5 and 10, or between 10 and 15. A linear scale may be used when the range of numbers being represented is not large, or to represent differences. See also **logarithmic scale**.
Logarithmic scale	A scale in which the logarithm of a value is used instead of the value. In a logarithmic scale on a **RevMan forest plot**, the distance between 1 and 10 is the same as the distance between 10 and 100, or between 100 and 1000. A logarithmic scale may be used when the range of numbers being represented is large, or to represent ratios. See also **linear scale.**
Logistic regression	A form of **regression analysis** that models an individual's **odds** of disease or some other outcome as a function of a **risk** factor or **intervention**. It is widely used for **dichotomous** outcomes, in particular to carry out **adjusted analysis**. See also **meta-regression**.
Logo, Cochrane	See **Confidence interval**.
Log-odds ratio	The (natural) log of the **odds ratio**. It is used in statistical calculations and in graphical displays of odds ratios in **systematic reviews**.
Loss to follow up	See **attrition**.

M

MAG	See **EMAG**.
Masking	See **blinding**.

Matching	[In a **case-control study**:] Choosing one or more **controls** with particular matching attributes for each case. Researchers match cases and controls according to particular **variables** that are thought to be important, such as age and sex.
Mean	An average value, calculated by adding all the observations and dividing by the number of observations. (Also called **arithmetic mean**.)
Mean difference	[In **meta-analysis**:] A method used to combine measures on continuous scales (such as weight), where the **mean**, **standard deviation** and sample size in each group are known. The weight given to the difference in means from each study (e.g. how much influence each study has on the overall results of the meta-analysis) is determined by the precision of its estimate of effect and, in the statistical software in **RevMan** and the **Cochrane Database of Systematic Reviews**, is equal to the inverse of the **variance**. This method assumes that all of the trials have measured the outcome on the same scale. See also **standardised mean difference**. (Also called **WMD**, **weighted mean difference**.)
Median	The value of the observation that comes half way when the observations are ranked in order.
MEDLINE	An electronic database produced by the United States National Library of Medicine (NLM). It indexes millions of articles in selected journals, available through most medical libraries, and can be accessed on the Internet.
MeerKat	An Access-based database system (written for **The Cochrane Collaboration**) that can be used to manage a study-based **register of trials**.
MeSH headings (Medical Subject Headings)	Terms used by the United States National Library of Medicine to index articles in **Index Medicus** and **MEDLINE**. The MeSH system has a tree structure in which broad subject terms branch into a series of progressively narrower subject terms.
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.
Meta-regression	[In **meta-analysis**:] A technique used to explore the relationship between study characteristics (e.g. **concealment of allocation**, baseline risk, timing of the **intervention**) and study results (the magnitude of effect observed in each study) in a **systematic review**. See also **logistic regression**.
Methodological quality	See **internal validity**, **bias prevention**.

Methodology expert	A person who assists **reviewers** in conducting **systematic reviews** by using their statistical or other methodological expertise.
Methods Group (MG) (formerly known as Methods Working Group [MWG])	Develop methodology and advise **The Cochrane Collaboration** on how the validity of **Cochrane Reviews** can be improved. In addition to conducting methodological research, they provide policy advice, training, and support. They help to monitor the quality of systematic reviews prepared within the Collaboration, and serve as a forum for discussion.
Minimisation	A method of allocation used to provide **comparison groups** that are closely similar for several **variables**. The next **participant** is assessed with regard to several characteristics, and assigned to the treatment group that has so far had fewer such people assigned to it. It can be done with a component of **randomisation**, where the chance of allocation to the group with fewer similar participants is less than one. Minimisation is best performed centrally with the aid of a computer program to ensure **concealment of allocation**.
Mission Statement	"**The Cochrane Collaboration** is an international organisation that aims to help people make well-informed decisions about health care by preparing, maintaining, and promoting the accessibility of systematic reviews of the effects of healthcare interventions. It is a not-for-profit organisation, established as a company, limited by guarantee, and registered as a charity in the UK (number 1045921)."
Module Manager (ModMan)	Software developed by **The Cochrane Collaboration** to allow **Collaborative Review Groups** to assemble and manage their edited **Protocols** and **Cochrane Reviews**. ModMan also contains information about the Collaborative Review Group. ModMan is used by **Review Group Co-ordinators** to edit and update modules that are submitted, at quarterly intervals, for publication in **The Cochrane Library**.
ModMan Advisory Group	See **EMAG**.
Module	Edited **Protocols** and **Cochrane Reviews**, and information about a **Collaborative Review Group**, are referred to as the **CRG's** module. Other Cochrane **entities** also produce modules for inclusion in **The Cochrane Library**.
Monitoring and Registration Group (MRG)	The Monitoring and Registration Group (MRG) is a sub-group of the **CCSG**. It is responsible for establishing and implementing processes for monitoring and registering **entities**, and for making recommendations to the full Steering Group about de-registration of an entity.
Morbidity	Illness or harm. See also **co-morbidity**.

Mortality	Death.
MRG	See **Monitoring and Registration Group**.
Multi-arm trial	A trial with more than two **arms**.
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.
Multiple comparisons	The performance of multiple analyses on the same data. Multiple statistical comparisons increase the probability of making a **Type I error**, i.e. attributing a difference to an **intervention** when chance is a reasonable explanation.
Multiplicative model	A statistical model in which the combined effect of several factors is the product of the effects produced by each in the absence of the others. For example, if one factor multiplies **risk** by a% and a second factor by b%, the combined effect of the two factors is a multiplication by (a x b)%. See also **additive model**.
Multivariate analysis	Measuring the impact of more than one **variable** at a time while analysing a set of data, e.g. looking at the impact of age, sex, and occupation on a particular outcome. Performed using **regression analysis**.

N

N of 1 randomised trial	A randomised trial in an individual to determine the optimum treatment for that individual. The individual is given repeated administrations of experimental and **control** interventions (or of two or more experimental treatments), with the order of the treatments being randomised.
Negative association	See **association**.
Negative predictive value	[In screening/diagnostic tests:] A measure of the usefulness of a screening/diagnostic test. It is the proportion of those with a negative test result who do not have the disease, and can be interpreted as the probability that a negative test result is correct. It is calculated as follows: NPV = Number with a negative test who do not have disease/Number with a negative test.
Negative study	A term often used to refer to a study with results that either do not indicate a beneficial effect of **treatment** or that have not reached **statistical significance**. The term can generate confusion because it can refer to either statistical significance or the direction of effect. Studies often have multiple **outcomes**, the criteria for classifying studies as 'negative' are not always clear and, in the case of studies of **risk** or undesirable effects, 'negative' studies are ones that do not show a harmful effect.

Networks	See **Fields**.
NHSEED	A database within *The Cochrane Library*, the NHS Economic Evaluation Database containing structured abstracts of articles describing the economic evaluation of healthcare interventions. Compiled by the NHS Centre for Reviews and Dissemination.
NNH	See **number needed to treat to harm**.
NNT	See **number needed to treat to benefit**.
NNTb	See **number needed to treat to benefit**.
NNTh	See **number needed to treat to harm**.
Non-experimental study	See **observational study**.
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. A one-sided version of an **equivalence trial.**
Non-randomised study	Any quantitative study estimating the **effectiveness** of an **intervention** (harm or benefit) that does not use **randomisation** to allocate units to comparison groups (including studies where 'allocation' occurs in the course of usual treatment decisions or peoples' choices, i.e. studies usually called 'observational'). To avoid ambiguity, the term should be substantiated using a description of the type of question being addressed. For example, a 'non-randomised intervention study' is typically a comparative study of an experimental intervention against some control intervention (or no intervention) that is not a **randomised controlled trial**. There are many possible types of non-randomised intervention study, including **cohort studies**, **case-control studies**, **controlled before-and-after studies**, **interrupted-time-series studies** and controlled trials that do not use appropriate randomisation strategies (sometimes called quasi-randomised studies).
Normal distribution	A statistical distribution with known properties commonly used as the basis of models to analyse **continuous data**. Key assumptions in such analyses are that the data are symmetrically distributed about a **mean** value, and the shape of the distribution can be described using the **mean** and **standard deviation**.
Null hypothesis	The statistical hypothesis that one **variable** (e.g. which **treatment** a study **participant** was allocated to receive) has no association with another variable or set of variables (e.g. whether or not a study participant died), or that two or more **population** distributions do not differ from one another. In simplest terms, the null hypothesis states that the factor of interest (e.g. treatment) has no impact on **outcome** (e.g. risk of death).

Number needed to harm	See **number needed to treat to harm**.
Number needed to treat	See **number needed to treat to benefit**.
Number needed to treat to benefit	An estimate of how many people need to receive a **treatment** before one person would experience a beneficial **outcome**. For example, if you need to give a stroke prevention drug to 20 people before one stroke is prevented, then the number needed to treat to benefit for that stroke prevention drug is 20. The NNTb is estimated as the reciprocal of the absolute **risk difference**. (Also called **NNT**, **NNTB**, **number needed to treat**.)
Number needed to treat to harm	A **number needed to treat to benefit** associated with a harmful effect. It is an estimate of how many people need to receive a treatment before one more person would experience a harmful **outcome** or one fewer person would experience a beneficial outcome. (Also called **NNH**, **NNTH**, **number needed to harm**.) See also **number needed to treat to benefit**.

O

Observational study	A study in which the investigators do not seek to intervene, and simply observe the course of events. Changes or differences in one characteristic (e.g. whether or not people received the **intervention** of interest) are studied in relation to changes or differences in other characteristic(s) (e.g. whether or not they died), without action by the investigator. There is a greater risk of **selection bias** than in **experimental studies**. See also **randomised controlled trial**. (Also called **non-experimental study**.)
Odds	A way of expressing the chance of an event, calculated by dividing the number of individuals in a sample who experienced the event by the number for whom it did not occur. For example, if in a sample of 100, 20 people died and 80 people survived the odds of death are 20/80 = ¼, 0.25 or 1:4.
Odds ratio	The ratio of the **odds** of an event in one group to the odds of an event in another group. In studies of **treatment effect**, the odds in the treatment group are usually divided by the odds in the **control group**. An odds ratio of one indicates no difference between **comparison groups**. For undesirable **outcomes** an OR that is less than one indicates that the **intervention** was effective in reducing the **risk** of that outcome. When the risk is small, odds ratios are very similar to **risk ratios**. (Also called **OR**.)

Ombudsman	The role of the two Ombudsmen is to help resolve areas of conflict that arise between people or entities within **The Cochrane Collaboration**, for which the usual process of involving the Directors of the reference Cochrane **Centre**(s) has not been sufficient. The Ombudsmen are appointed by the **CCSG** (and must not be current members of the CCSG). They report to the CCSG every six months giving details of their activity during the period, but not identifying specific details if, in the opinion of the Ombudsmen, there is a need for these details to remain confidential. If the Ombudsmen are unable to resolve an issue, it can be referred to the CCSG.
One-sided test	See **one-tailed test**.
One-tailed test	A **hypothesis test** in which the values for which we can reject the **null hypothesis** are located entirely in one tail of the probability distribution. Testing whether one **treatment** is better than another (rather than testing whether one treatment is either better or worse than another) would be a one-tailed test. (Also called **one-sided test**.) See also **two-tailed test**.
Open clinical trial	There are at least three possible meanings for this term: 1. A clinical trial in which the investigator and **participant** are aware which **intervention** is being used for which participant (i.e. not **blinded**). **Random allocation** may or may not be used in such trials. Sometimes called an 'open label' design. 2. A clinical trial in which the investigator decides which intervention is to be used (non-random allocation). This is sometimes called an open label design (but some trials which are said to be 'open label', are randomised). 3. A clinical trial that uses an **open sequential design**.
Open sequential design	A **sequential trial** where the decision to stop the trial rests on the size of effect in those studies, and there is no finite maximum number of **participants** in the study.
OR	See **odds ratio**.
Ordinal data	Data that are classified into more than two categories which have a natural order; for example, non-smokers, ex-smokers, light smokers and heavy smokers. Ordinal data are often reduced to two categories to simplify analysis and presentation, which may result in a considerable loss of information.
Original study	See **primary study**.

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**. See also **primary outcome**, **secondary outcome**.
Outcome variable	See **dependent variable**.
Overview, systematic	See **systematic review**.

P

Paired design	A study in which **participants** or groups of participants are matched (e.g. based on prognostic factors). One member of each pair is then allocated to the **experimental (intervention) group** and the other to the **control group**.
Parallel group trial	A trial that compares two groups of people concurrently, one of which receives the **intervention** of interest and one of which is a **control group**. Some parallel trials have more than two **comparison groups** and some compare different interventions without including a non-intervention control group. (Also called **independent group design**.)
Parameter	A quantity defining a theoretical model. Unlike **variables**, parameters do not relate to actual measurements or attributes of patients.
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. See also **external peer reviewer** (of a **Cochrane Review**).
Per protocol analysis	An analysis of the subset of **participants** from a **randomised controlled trial** who complied with the protocol sufficiently to ensure that their data would be likely to exhibit the effect of **treatment**. This subset may be defined after considering exposure to treatment, availability of measurements and absence of major protocol violations. The per protocol analysis strategy may be subject to **bias** as the reasons for non-compliance may be related to treatment. See also **intention to treat analysis**.
Performance bias	Systematic differences between **intervention groups** in care provided apart from the intervention being evaluated. For example, if **participants** know they are in the **control group**, they may be more likely to use other forms of care. If care providers are aware of the group a particular participant is in, they might act differently. **Blinding** of study participants (both the recipients and providers of care) is used to protect against performance **bias**.

Period effect
[In a **cross-over trial**:] A difference in the measured **outcomes** from one **treatment** period to another. This could be caused, for instance, by all patients in a trial naturally healing over time.

Person-years
The average number of years that each **participant** is followed up for, multiplied by the number of participants.

Peto method
A way of combining **odds ratios** that has become widely used in **meta-analysis**. It is especially used to analyse trials with **time to event** outcomes. The calculations are straightforward and understandable, but this method produces biased results in some circumstances. It is a **fixed-effect model.**

Phase I, II, III, IV trials
A series of levels of trials required of drugs before (and after) they are routinely used in clinical practice: Phase I trials assess toxic effects on humans (not many people participate in them, and usually without **controls**); Phase II trials assess therapeutic benefit (usually involving a few hundred people, usually with controls, but not always); Phase III trials compare the new treatment against standard (or placebo) treatment (usually a full **randomised controlled trial**). At this point, a drug can be approved for community use. Phase IV monitors a new treatment in the community, often to evaluate long-term safety and effectiveness.

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 s/he is 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**.

Planned analyses
Statistical analyses specified in the trial **protocol**; that is, planned in advance of data collection. In contrast to **unplanned analyses**. (Also called **a priori analyses**, **pre-specified analyses**.)

Point estimate
The results (e.g. **mean**, **weighted mean difference**, **odds ratio**, **risk ratio** or **risk difference**) obtained in a sample (a study or a **meta-analysis**) which are used as the best estimate of what is true for the relevant **population** from which the sample is taken.

Poisson distribution
A statistical distribution with known properties used as the basis of analysing the number of occurrences of relatively rare events occurring over time.

Population
[In research:] The group of people being studied, usually by taking samples from that population. Populations may be defined by any characteristics e.g. geography, age group, certain diseases.

Positive association
See **association**.

Positive predictive value	[In screening/diagnostic tests:] A measure of the usefulness of a screening/diagnostic test. It is the proportion of those with a positive test result who have the disease, and can be interpreted as the probability that a positive test result is correct. It is calculated as follows: PPV = Number with a positive test who have disease/Number with a positive test.
	[In trial searching:] See **precision**.
Positive study	A study with results indicating a beneficial effect of the **intervention** being studied. The term can generate confusion because it can refer to both **statistical significance** and the direction of effect; studies often have multiple outcomes; the criteria for classifying studies as negative or positive are not always clear; and, in the case of studies of risk or undesirable effects, 'positive' studies are ones that show a harmful effect.
Post hoc analyses	See **unplanned analyses.**
Posterior distribution	The outcome of Bayesian statistical analysis. A **probability** distribution describing how likely different values of an **outcome** (e.g. **treatment effect**) are. It takes into account the belief before the study (the prior distribution) and the observed data from the study.
Power	[In statistics:] The **probability** of rejecting the null hypothesis when a specific alternative hypothesis is true. The power of a hypothesis test is one minus the probability of **Type II error**. In **clinical trials**, power is the probability that a trial will detect, as **statistically significant**, an **intervention** effect of a specified size. If a clinical trial had a power of 0.80 (or 80%), and assuming that the pre-specified **treatment effect** truly existed, then if the trial was repeated 100 times, it would find a statistically significant treatment effect in 80 of them. Ideally we want a test to have high power, close to maximum of one (or 100%). For a given size of effect, studies with more **participants** have greater power. Studies with a given number of participants have more power to detect large effects than small effect. (Also called **statistical power**.)
PPG	See **Publishing Policy Group**.
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. This is as opposed to an **explanatory trial**, which is done under ideal conditions and is trying to determine whether a therapy has the ability to make a difference at all (i.e. testing its **efficacy**).

Precision	1. [In statistics:] A measure of the likelihood of **random errors** in the results of a study, **meta-analysis** or measurement. The greater the precision, the less random error. **Confidence intervals** around the estimate of effect from each study are one way of expressing precision, with a narrower confidence interval meaning more precision. 2. [In trial searching:] The proportion of relevant articles identified by a **search strategy** expressed as a percentage of all articles (relevant and irrelevant) identified by that strategy. Highly sensitive strategies tend to have low levels of precision. It is calculated as follows: Precision = Number of relevant articles/Number of articles identified. Also called **positive predictive value**. See also **sensitivity**.
Pre-specified analyses	See **planned analyses**.
Prevalence	The proportion of a **population** having a particular condition or characteristic: e.g. the percentage of people in a city with a particular disease, or who smoke.
Prevalence study	A type of **cross-sectional study** that measures the prevalence of a characteristic.
Primary outcome	The **outcome** of greatest importance.
Primary study	'Original research' in which data are collected. The term primary study is sometimes used to distinguish it from a **secondary study** (re-analysis of previously collected data), **meta-analysis**, and other ways of combining studies (such as economic analysis and decision analysis). (Also called **original study**.)
Probability	The chance or risk of something happening.
Probability distribution	The function that gives the probabilities that a variable equals each of a sequence of possible values. Examples include the **binomial distribution**, **normal distribution** and **Poisson distribution**. See also **distribution**.
ProCite	A software package designed to manage bibliographic references.
Proportional hazards model	[In **survival analysis**:] A statistical model that asserts that the effect of the study factors (e.g. the **intervention** of interest) on the hazard rate (the risk of occurrence of an event, such as death, at a point in time) in the study **population** is multiplicative and does not change over time. (Also called **Cox model**.)

Prospective study
In evaluations of the effects of healthcare **interventions**, a study in which people are identified according to current **risk** status or exposure, and followed forwards through time to observe **outcome**. **Randomised controlled trials** are always prospective studies. **Cohort studies** are commonly either prospective or **retrospective**, whereas **case-control studies** are usually retrospective. In **Epidemiology**, 'prospective study' is sometimes misused as a synonym for cohort study. See also **retrospective study**.

Protocol
The plan or set of steps to be followed in a study. A Protocol for a **systematic review** should describe the rationale for the review, the objectives, and the methods that will be used to locate, select, and critically appraise studies, and to collect and analyse data from the included studies.

Publication Arbiter
The role of the Publication Arbiter relates specifically to the publication of **Cochrane Reviews**, and was established to help people to reach agreement in areas of dispute between the **editorial teams** of **Collaborative Review Groups** (i.e. of the appropriate home for a specific Cochrane Review), and between reviewers and their editorial team (e.g. when reviewers are unwilling to make changes suggested by the **editors**). The Publication Arbiter does not replace **The Cochrane Collaboration's Ombudsman**, whose role is to help with disputes and conflict more generally.

Publication bias
See **reporting bias**.

Publishing Policy Group (PPG)
The Publishing Policy Group (PPG) is a sub-group of the **CCSG**. It is responsible for providing advice on the contents of the Collaboration's products and setting the principles for the pricing, distribution, and marketing arrangements for Cochrane products. Where principles have been established, day-to-day management of these issues may be delegated to The Cochrane Collaboration's Chief Executive Officer (CEO).

PubMed
A free access Internet version of **MEDLINE** also including records from before 1966 (old MEDLINE), some very recent records and some other life science journals.

P-value
The probability (ranging from zero to one) that the results observed in a study (or results more extreme) could have occurred by chance if in reality the **null hypothesis** was true. In a **meta-analysis**, the P-value for the overall effect assesses the overall **statistical significance** of the difference between the **intervention groups**, whilst the P-value for the **heterogeneity** statistic assesses the statistical significance of differences between the effects observed in each study.

Q

QAG See **Quality Advisory Group**.

Quality A vague notion of the methodological strength of a study, usually indicating the extent of **bias prevention**.

Quality Advisory Group (QAG) The Quality Advisory Group is an advisory group to the **CCSG**. Its remit is to co-ordinate activities aimed at improving the quality of **Cochrane Reviews**; to identify and follow up issues of quality relevant to Cochrane Reviews; to provide advice on the development of standards and tools for assessing the quality of Cochrane Reviews; to suggest priorities for quality activities relevant to Cochrane Reviews; and to help facilitate quality activities.

Quality score A value assigned to represent the **validity** of a study either for a specific criterion, such as **concealment of allocation**, or overall. Quality scores can use letters (A, B, C) or numbers. See also **bias prevention**.

Quasi-random allocation Methods of allocating people to a trial that are not **random**, but were intended to produce similar groups when used to allocate **participants**. Quasi-random methods include: allocation by the person's date of birth, by the day of the week or month of the year, by a person's medical record number, or just allocating every alternate person. In practice, these methods of allocation are relatively easy to manipulate, introducing **selection bias**. See also **random allocation**, **randomisation**.

R

RAG See **RevMan Advisory Group**.

Random Governed by chance. See also **randomisation**.

Random allocation A method that uses the play of chance to assign **participants** to **comparison groups** in a trial, e.g. by using a random numbers table or a computer-generated random sequence. Random allocation implies that each individual or unit being entered into a trial has the same chance of receiving each of the possible **interventions**. It also implies that the **probability** that an individual will receive a particular intervention is independent of the probability that any other individual will receive the same **intervention**. See also **quasi-random allocation**, **randomisation**.

Random error Error due to the play of chance. **Confidence intervals** and **P-values** allow for the existence of random error, but not systematic errors (**bias**).

Random permuted blocks

A method of **randomisation** that ensures that, at any point in a trial, roughly equal numbers of **participants** have been allocated to all the **comparison groups**. Permuted blocks should be used in trials using **stratified randomisation**. (Also called **block randomisation**.)

Random sample

A group of people selected for a study that is representative of the **population** of interest. This means that everyone in the population has an equal chance of being approached to participate in the **survey**, and the process is meant to ensure that a sample is as representative of the population as possible. It has less **bias** than a **convenience sample**: that is, a group that the researchers have more convenient access to. Randomised trials are rarely carried out on random samples.

Random-effects model

[In **meta-analysis**:] A statistical model in which both within-study sampling error (**variance**) and between-studies variation are included in the assessment of the uncertainty (**confidence interval**) of the results of a meta-analysis. See also **fixed-effect model**. When there is **heterogeneity** among the results of the included studies beyond chance, random-effects models will give wider confidence intervals than fixed-effect models.

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**). (Also called **randomisation**.)

Randomisation blinding

See **concealment of allocation**.

Randomised clinical trial

See **randomised controlled trial**.

Randomised controlled trial

An experiment in which two or more interventions, possibly including a control intervention or no intervention, are compared by being randomly allocated to participants. In most trials one intervention is assigned to each individual but sometimes assignment is to defined groups of individuals (for example, in a household) or interventions are assigned within individuals (for example, in different orders or to different parts of the body).

Rate

The speed or frequency of occurrence of an event, usually expressed with respect to time. For instance, a mortality rate might be the number of deaths per year, per 100,000 people.

RCT

See **randomised controlled trial**..

Recall

[In trial searching:] See **sensitivity**.

Recall bias

A **bias** arising from mistakes in recollecting events, both because of failures of memory, and looking at things 'with hindsight' and possibly changed views. People's reports of what is happening to them currently, therefore, can be more accurate than their recall of what happened two years ago and how they felt about it at the time. This bias is a threat to the **validity** of **retrospective studies**.

Referee

Referees provide feedback to **reviewers** on the content and design of their **Protocols** and **reviews**. They are provided with checklists to guide and assist them in this.

Referee process

System by which a **review** goes out to **editors** and external parties with content, methodological, or user expertise. These people are sometimes called **external peer reviewers** or **referees**. See also **editorial process**.

Reference Manager

A software package designed to manage bibliographic references. Sometimes confusingly referred to as RefMan (see **RevMan**). Examples of other similar packages are Papyrus and **ProCite**.

Reference population

The **population** that the results of a study can be generalised to. See also **external validity**.

Register of controlled trials

See **trials register**.

Regression analysis

A statistical modelling technique used to estimate or predict the influence of one or more **independent variables** on a **dependent variable**, e.g. the effect of age, sex, and educational level on the **prevalence** of a disease. **Logistic regression** and **meta-regression** are types of regression analysis.

Relative risk

See **risk ratio**.

Relative risk reduction

The proportional reduction in risk in one treatment group compared to another. It is one minus the **risk ratio**. If the risk ratio is 0.25, then the relative risk reduction is 1-0.25=0.75, or 75%.

Reliability

The degree to which results obtained by a measurement procedure can be replicated. Lack of reliability can arise from divergences between observers or measurement instruments, measurement error, or instability in the attribute being measured.

Replicate/reproduce

Do the same thing to other people in order to achieve the same outcomes that occurred in a study. Also, repeating the circumstances of a study to test whether the results and outcomes are similar in another sample or population.

Reporting 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 (e.g. only **outcomes** or sub-groups where a **statistically significant** difference was found. (Also called **publication bias**.)
Reproducible	Able to be done the same way elsewhere. See **replicate/ reproduce**.
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. See also **prospective study.**
Review	1. A **systematic review**.

2. A review article in the medical literature which summarises a number of different studies and may draw conclusions about a particular intervention. Review articles are often not systematic. Review articles are also sometimes called overviews.

3. To referee a paper. See **referee**, **referee process**, **external peer reviewer**. |
Review Group Co-ordinator (RGC) of a Collaborative Review Group (previously known as Administrator)	The key person in managing and supporting a **Collaborative Review Group** (**CRG**) on a day-to-day basis. Most CRGs have a full-time RGC working in an editorial base. Responsibilities of an RGC include: co-ordinating the activities of the CRG; fostering liaison and communication between **editors** and **reviewers**; setting up and maintaining a **trials register**; producing newsletters; providing reviewers with the relevant software (**RevMan**), manuals, and support to do their reviews; submitting reviews via the **ModMan** software, for inclusion in the **Cochrane Database of Systematic Reviews**.
Review Manager	See **RevMan**.
Review Protocol	See **Protocol**.
Reviewer/Author	Somebody responsible for preparing and, in the case of **Cochrane Reviews**, keeping up-to-date a **systematic review**. The term 'reviewer' is also sometimes used to refer to an **external peer reviewer**, or **referee**. Between 2004 and 2006, a phased approach will be used to move from using the word 'reviewer' (of a Cochrane Review) to 'author'.

RevMan (Review Manager)	Software developed for **The Cochrane Collaboration** to assist **reviewers** in preparing **Cochrane Reviews**. Reviewers enter their **Protocols** and **reviews** into RevMan, from which they are exported and sent to a Review Group Co-ordinator to be considered for inclusion in the **Cochrane Database of Systematic Reviews**. (Also called **Review Manager**.)
RevMan Advisory Group (RAG)	A sub-group of the **Information Management System Group (IMSG)**, which advises on development of **RevMan**.
RGC	See **Review Group Co-ordinator**.
Risk	The proportion of **participants** experiencing the event of interest. Thus, if out of 100 participants the event (e.g. a stroke) is observed in 32, the risk is 0.32. The **control group** risk is the risk amongst the **control** group. The risk is sometimes referred to as the **event rate**, and the control group risk as the control event rate. However, these latter terms confuse risk with **rate**. Statistical texts in particular are happy to discuss risk of beneficial effects as well as adverse events.
Risk difference	The difference in size of risk between two groups. For example, if one group has a 15% risk of contracting a particular disease, and the other has a 10% risk of getting the disease, the risk difference is five percentage points. (Also called **absolute risk difference**, **absolute risk reduction**.)
Risk factor	An aspect of a person's condition, lifestyle or environment that affects the **probability** of occurrence of a disease. For example, cigarette smoking is a risk factor for lung cancer.
Risk ratio	The ratio of **risks** in two groups. In **intervention studies**, it is the ratio of the risk in the **intervention group** to the risk in the **control group**. A risk ratio of one indicates no difference between **comparison groups**. For undesirable **outcomes**, a risk ratio that is less than one indicates that the **intervention** was effective in reducing the risk of that outcome. (Also called **relative risk**, **RR**.)
RR	See **risk ratio**.

Run-in period	A period before **randomisation** when **participants** are monitored but receive no **treatment** (or they sometimes all receive one of the study treatments, possibly in a blind fashion). The data from this stage of a trial are only occasionally of value but can serve a valuable role in screening out ineligible or non-compliant participants, in ensuring that participants are in a stable condition, and in providing baseline observations. A run-in period is sometimes called a **washout period** if treatments that participants were using before entering the trial are discontinued.

S

Safety	[of an intervention:] Refers to serious **adverse effects**, such as those that threaten life, require or prolong hospitalization, result in permanent disability, or cause birth defects. Indirect adverse effects, such as traffic accidents, violence, and damaging consequences of mood change, can also be serious.
Science Citation Index	A database of reports of studies that also enables the user to identify which reports have cited a specific report of a study. Often used to identify most recent research in a field.
SE	See **standard error**.
Search strategy	1. The methods used by a **Collaborative Review Group** (**CRG**) to identify trials within the CRG's scope. This includes **handsearching** relevant journals, searching electronic databases, contacting drug companies, other forms of personal contact and checking reference lists. CRGs must describe their search strategy in detail in the CRG's **module**. Authors can refer to the CRG's search strategy when preparing a **Cochrane Review**, and if necessary supplement this with a description of their own additional searches. 2. The methods used by a **reviewer** to locate relevant studies, including the use of a CRG's **trials register**. 3. The combination of terms used to identify studies in an electronic database such as **MEDLINE**.
Secondary outcome	An **outcome** used to evaluate additional effects of the **intervention** deemed a priori as being less important than the **primary outcomes**.
Secondary study	A study of studies: a review of individual studies (each of which is called a **primary study**). A **systematic review** is a secondary study.

Secretariat

The administrative office of **The Cochrane Collaboration**, based in Oxford, England, which supports the **CCSG** and is responsible for the organisation's internal communications.

Selection bias

1. Systematic differences between **comparison groups** in prognosis or responsiveness to treatment. **Random allocation** with adequate **concealment of allocation** protects against selection bias. Other means of selecting who receives the **intervention** are more prone to bias because decisions may be related to prognosis or responsiveness to treatment.

2. A systematic error in **reviews** due to how studies are selected for inclusion. **Reporting bias** is an example of this.

3. A systematic difference in characteristics between those who are selected for study and those who are not. This affects **external validity** but not **internal validity**.

Sensitivity

1. [In screening/diagnostic tests:] A measure of a test's ability to correctly detect people with the disease. It is the proportion of diseased cases that are correctly identified by the test. It is calculated as follows: Sensitivity = Number with disease who have a positive test/Number with disease. (Also called **true positive rate**, **detection rate**.)

2. [In trial searching:] A measure of a search's ability to correctly identify relevant articles. It is the proportion of all relevant articles from all searches that were identified by the particular search of interest. It is calculated as follows: Sensitivity = Number of relevant articles identified by the search/Total number of relevant articles from all searches. (Also called **recall**.)

Sensitivity analysis

An analysis used to determine how sensitive the results of a study or **systematic review** are to changes in how it was done. Sensitivity analyses are used to assess how robust the results are to uncertain decisions or assumptions about the data and the methods that were used.

Sequential trial	A randomised trial in which the data are analysed after each **participant's** results become available, and the trial continues until a clear benefit is seen in favour of one of the **comparison groups**, or it is unlikely that any difference will emerge. The main advantage of sequential trials is that they are usually shorter than fixed size trials when there is a large difference in the effectiveness of the interventions being compared. Their use is restricted to conditions where the outcome of interest is known relatively quickly. In a group sequential trial, a limited number of **interim analyses** of the data are carried out at pre-specified times during recruitment and follow up, say 3-6 times in all.
Side effect	Any unintended effect of an intervention. Side effects are most commonly associated with pharmaceutical products, in which case they are related to the pharmacological properties of the drug at doses normally used for therapeutic purposes in humans. See also **adverse effect**
Single blind	(Also called single masked.) See **blinding**.
Single case report	See **case study**.
SMD	See **standardised mean difference**.
Specialised register	In **The Cochrane Collaboration** this is a database of bibliographic references to studies relevant to a **Collaborative Review Group** or **Field**, that is maintained at the **editorial base**. Software such as **ProCite**, or **Reference Manager** is used to manage the database. Once a relevant report of a study is identified, it is coded and entered onto the register. Wherever possible, relevant study reports are downloaded directly into the register from an electronic database such as MEDLINE. Information about unpublished and ongoing studies is also included in these registers. When specialised registers only contain reports of controlled trials (such as **randomised controlled trials**, or **controlled clinical trials**), they are sometimes referred to as **trials registers**.
Specificity	1. [In screening/diagnostic tests:] A measure of a test's ability to correctly identify people who do not have the disease. It is the proportion of people without the target disease who are correctly identified by the test. It is the complement of the **false positive** rate (FPR=1-specificity). It is calculated as follows: Specificity = Number without disease who have a negative test/Number without disease. 2. [In trial searching:] There is no equivalent concept in trial searching, as we do not know the total number of irrelevant articles in existence. The concept of **precision** is usually used instead.

Standard deviation	A measure of the spread or dispersion of a set of observations, calculated as the average difference from the mean value in the sample.
Standard error	The **standard deviation** of the sampling distribution of a statistic. Measurements taken from a sample of the **population** will vary from sample to sample. The standard error is a measure of the variation in the sample statistic over all possible samples of the same size. The standard error decreases as the sample size increases. (Also called **SE**.)
Standard treatment	See **conventional treatment**.
Standardised mean difference	The difference between two estimated means divided by an estimate of the **standard deviation**. It is used to combine results from studies using different ways of measuring the same concept, e.g. mental health. By expressing the effects as a standardised value, the results can be combined since they have no units. Standardised mean differences are sometimes referred to as a d index. (Also called **SMD**.)
Statistical power	See **power**.
Statistically significant	A result that is unlikely to have happened by chance. The usual threshold for this judgement is that the results, or more extreme results, would occur by chance with a probability of less than 0.05 if the **null hypothesis** was true. Statistical tests produce a p-value used to assess this.
Steering Group	The board of trustees of **The Cochrane Collaboration**. See **Cochrane Collaboration Steering Group** (**CCSG**).
Stopping rule	A procedure that allows **interim analyses** in **clinical trials** at predefined times, whilst preserving the **Type I error** at some pre-specified level. See also **sequential trial**.
Strategic Plan	The **The Cochrane Collaboration's** elected **Steering Group** (**CCSG**) developed a strategic plan to guide The Cochrane Collaboration's evolution. The initial plan was updated in May 2003: see the Collaboration web site.
Stratification	The process by which groups are separated into mutually exclusive sub-groups of the **population** that share a characteristic: e.g. age group, sex, or socioeconomic status. It is possible to compare these different strata to try and see if the effects of a treatment differ between the sub-groups. See also **sub-group analysis**.

Stratified randomisation	A method used to ensure that equal numbers of **participants** with a characteristic thought to affect prognosis or response to the **intervention** will be allocated to each **comparison group**. For example, in a trial of women with breast cancer, it may be important to have similar numbers of pre-menopausal and post-menopausal women in each comparison group. Stratified randomisation could be used to allocate equal numbers of pre- and post-menopausal women to each treatment group. Stratified randomisation is performed by performing separate randomisation (often using **random permuted blocks**) for each strata. See also **minimisation**.
Student's t-test	See **t test**.
Style Guide, Cochrane	A guide to issues of style arising in the preparation of **Cochrane Reviews**.
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. Trial sizes are generally too small for sub-group analyses to have adequate statistical **power**. Comparison of sub-groups should be by test of **interaction** rather than by comparison of **p-values**. Sub-group analyses are also subject to the multiple comparisons problem. See also **multiple comparisons.**
Surrogate endpoints	**Outcome** measures that are not of direct practical importance but are believed to reflect outcomes that are important; for example, blood pressure is not directly important to patients but it is often used as an outcome in **clinical trials** because it is a **risk factor** for stroke and heart attacks. Surrogate endpoints are often physiological or biochemical markers that can be relatively quickly and easily measured, and that are taken as being predictive of important clinical outcomes. They are often used when observation of clinical outcomes requires long follow-up. (Also called **intermediary outcomes**, **surrogate outcomes**.)
Surrogate outcomes	See **surrogate endpoints**.
Survey	See **cross-sectional study**.
Survival analysis	The analysis of data that measure the time to an event e.g. death, next episode of disease. See also **time to event**.
Systematic review (synonym: systematic overview)	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. See also **Cochrane Review**.

T

t distribution	A statistical distribution describing the distribution of the means of samples taken from a **population** with unknown variance.
t test	A statistical **hypothesis test** derived from the **t distribution**. It is used to compare **continuous data** in two groups. (Also called **Student's t-test**.)
Technical Implementation Advisory Group (TIAG)	A sub-group of the **Information Management System Group** (**IMSG**), the TIAG advises the Information Management System Group on technical issues.
Temporal sequence	The sequence of events in time, used as one of the criteria in evaluating causation – the exposure or **intervention** must have occurred before the **outcome** to be a plausible cause of the outcome.
Test of association	A statistical test to assess whether the value of one **variable** is associated (i.e. varies with) the value of another variable, or whether the presence or absence of a factor is more likely when a particular outcome is present. See also **correlation**.
The Collaboration Trading Company, Limited	A wholly owned subsidiary of **The Cochrane Collaboration**, the registered charity.
Time to event	A description of the data in studies where the analysis relates not just to whether an event occurs but also when. Such data are analysed using **survival analysis**. (Also called survival data.)
Tolerability	[of an intervention:] usually refers to medically less important (that is, without serious or permanent sequelae), but unpleasant **adverse effects** of drugs. These include symptoms such as dry mouth, tiredness, etc, that can affect a person's quality of life and willingness to continue the treatment. As these adverse effects usually develop early on and are relatively frequent, randomised controlled trials may yield reliable data on their incidence.
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. See also intervention, **experimental intervention** and **control**.
Treatment effect	See **estimate of effect**.

Trend	1. A consistent movement across ordered categories, e.g. a change in the effect observed in studies grouped according to, for instance, intensity of **treatment**.
	2. Used loosely to refer to an association or possible effect that is not statistically significant. This usage should be avoided.
Trialist	Used to refer to a person conducting or publishing a **controlled trial**.
Trials register	See **specialised register**.
Trials Search Co-ordinator (TSC)	Member of the editorial team of a **Collaborative Review Group** (**CRG**), or member of a Cochrane **Centre** or **Field**. Their role is to co-ordinate trial identification by **handsearching** and electronic means and to make reports of trials they identify accessible through the **Cochrane Central Register of Controlled Trials** (**CENTRAL**). TSCs of CRGs and Fields establish a **specialised register** of studies falling within the scope of their entity and submit this to CENTRAL. TSCs of CRGs also provide listings of studies to Cochrane **reviewers/authors** to conduct and update their **reviews**. In some CRGs, the **Review Group Co-ordinator** also fulfils the responsibilities of the TSC, but most CRGs have a dedicated TSC.
Triple blind	(Also called triple masked). See **blinding**.
True positive rate	See **sensitivity**.
2x2 table	A contingency table with two rows and two columns. It arises in **clinical trials** that compare **dichotomous** outcomes, such as death, for an **intervention** and **control group** or two intervention groups.
Two sided	See **two-tailed test**.
Two-tailed	A **hypothesis test** in which the values for which we can reject the **null hypothesis** are located entirely in both tails of the **probability** distribution. Testing whether one **treatment** is either better or worse than another (rather than testing whether one treatment is only better than another) would be a two-tailed test. (Also called **two-sided test**.) See also **one-tailed test.**
Type I error	A conclusion that a **treatment** works, when it actually does not work. The risk of a Type I error is often called **alpha**. In a statistical test, it describes the chance of rejecting the **null hypothesis** when it is in fact true. (Also called **false positive**.)

Type II error	A conclusion that there is no evidence that a **treatment** works, when it actually does work. The risk of a Type II error is often called **beta**. In a statistical test, it describes the chance of not rejecting the **null hypothesis** when it is in fact false. The risk of a Type II error decreases as the number of **participants** in a study increases. (Also called **false negative**.)

U

Unconfounded comparison	A comparison between two **treatment** groups that will give an unbiased estimate of the effect of treatment due to the study design. For a comparison to be unconfounded, the two treatment groups must be treated identically, apart from the randomised treatment. For instance, to estimate the effect of heparin in acute stroke, a trial of heparin alone versus **placebo** would provide an unconfounded comparison. However, a trial of heparin alone versus aspirin alone provides a confounded comparison of the effect of heparin.
Uncontrolled trial	A **clinical trial** that has no **control group**.
Unit of allocation	The unit that is assigned to the alternative **interventions** being investigated in a trial. Most commonly, the unit will be an individual person but, in a **cluster randomised trial**, groups of people will be assigned together to one or the other of the interventions. In some other trials, different parts of a person (such as the left or right eye) might be assigned to receive different interventions. See also **unit of analysis error**.
Unit of analysis error	An error made in statistical analysis when the analysis does not take account of the **unit of allocation**. In some studies, the **unit of allocation** is not a person, but is instead a group of people, or parts of a person, such as eyes or teeth. Sometimes the data from these studies are analysed as if people had been allocated individually. Using individuals as the unit of analysis when groups of people are allocated can result in overly narrow **confidence intervals**. In **meta-analysis,** it can result in studies receiving more weight than is appropriate.
Unplanned analyses	Statistical analyses that are not specified in the trial **protocol**, and are generally suggested by the data. In contrast to **planned analyses**. (Also called **data derived analyses**, **post hoc analyses**.)
Update Software	The **Cochrane Collaboration's** publishers from 1994 to 2003.
Users of reviews	People using a **review** to make practical decisions about health care, and researchers conducting or considering further research.

Utility
In economic and decision analysis, the value given to an outcome, usually expressed as being between zero and one (e.g. death typically has a utility value of zero and a full healthy life has a value of one).

V

Validity
The degree to which a result (of a measurement or study) is likely to be true and free of **bias** (systematic errors). Validity has several other meanings, usually accompanied by a qualifying word or phrase; for example, in the context of measurement, expressions such as 'construct validity', 'content validity' and 'criterion validity' are used. See also **external validity**, **internal validity**.

Variable
A factor that differs among and between groups of people. Variables include patient characteristics such as age, sex, and smoking, or measurements such as blood pressure or depression score. There can also be **treatment** or condition variables, e.g. in a childbirth study, the length of time someone was in labour, and outcome variables. The set of values of a variable in a **population** or sample is known as a **distribution**.

Variance
A measure of the variation shown by a set of observations, equal to the square of the **standard deviation**. It is defined as the sum of the squares of deviations from the **mean**, divided by the number of observations minus one.

Vision statement
Healthcare decision-making throughout the world will be informed by high quality, timely research evidence. **The Cochrane Collaboration** will play a pivotal role in the production and dissemination of this evidence across all areas of health care.

W

Washout period/phase
[In a **cross-over trial**:] The stage after the first **treatment** is withdrawn, but before the second treatment is started. The washout period aims to allow time for any active effects of the first treatment to wear off before the new one gets started.

Weighted least squares regression
[In **meta-analysis**:] A **meta-regression** technique for estimating the parameters of a regression model, wherein each study's contribution to the sum of products of the measured variables (study characteristics) is weighted by the precision of that study's **estimate of effect**.

Weighted mean difference
See **mean difference**.

Wiley, John & Sons Ltd
The Cochrane Collaboration's publishers since 2003.

WMD
See **mean difference**.

X

Y

Z

z   [On a forest plot in **RevMan**:] The value of the test for the overall effect of **treatment** , from which a **p-value** is derived.

Those amending the glossary have made use of the following publications:

Altman DG. *Practical Statistics for Medical Research*. London: Chapman & Hall, 1991.

Altman DG, Schulz KF, Moher D, Egger M, Davidoff F, Elbourne D, Gøtzsche PC, Lang T. The revised CONSORT statement for reporting randomized trials: explanation and elaboration. Annals of Internal Medicine 2001;134(8):663-694.

Australian Government. Department of Health and Ageing. Glossary to Accompany the Guidelines for the Pharmaceutical Industries or Preparation of Submissions to the Pharmaceutical Benefits Advisory Committee (PBAC). Canberra, Australia: Department of Health and Ageing. www.health.gov.au/pbs/pharm/pubs/pharmpac/glossary/glossary.htm (accessed 9 November 2004).

Bandolier. EBM Glossary. www.jr2.ox.ac.uk/bandolier/glossary.html (accessed 9 November 2004).

Clinical Trials Research Unit. Medical Glossary. Auckland, New Zealand: Clinical Trials Research Unit, Faculty of Medical and Health Sciences, The University of Auckland. www.ctru.auckland.ac.nz/medglossary/a.html (accessed 9 November 2004)

Cooper H, Hedges LV. *The Handbook of Research Synthesis*. New York: Russell Sage Foundation, 1993.

Easton VJ, McColl JH. The STEPS Statistics Glossary v1.1. www.cas.lancs.ac.uk/glossary_v1.1/Alphabet.html (accessed 9 November 2004).

Goodman C. *Literature searching and evidence interpretation for assessing health care practices*. Stockholm: SBU, 1993.

Last JM (ed). *A Dictionary of Epidemiology*. 2nd ed. New York: Oxford University Press, 1988.

National Center for Education Statistics. Statistical Standards Glossary. Washington DC, USA: National Center for Education Statistics, Institute of Education Sciences, U.S. Department of Education. http://nces.ed.gov/statprog/2002/glossary.asp (accessed 9 November 2004)

NHS Centre for Reviews and Dissemination. *Undertaking Systematic Reviews of Research on Effectiveness* (CRD Report 4). York: The University of York, 1996.

Senn S. Statistical Issues in Drug Development. Chichester: John Wiley & Sons, Ltd., 1997.

Errors in, or omissions from this Glossary should be notified, please, to:

The Cochrane Collaboration Secretariat (secretariat@cochrane.org).