

## Definitions for the Cochrane COVID-19 Study Register's Study Characteristics

*Please note: the working definitions below are used by the study register's team when classifying studies. Definitions are derived with minor modifications from sources including the retired Cochrane glossary, MeSH and Wikipedia. These are provided to assist users of the Cochrane COVID-19 Study Register and are not intended as authoritative definitions.*

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### STUDY TYPE

**Observational:** Observational studies are studies where the researchers observed rather than intervened. Subjects are not randomised to the exposed or unexposed groups but observed to determine both their exposure and their outcome status.

**Interventional:** Interventional studies are studies where the researchers deliberately intervened as part of the study design, for example, allocating some patient to a particular treatment to assess its effects.

**Modelling:** Modelling studies are studies that use data from existing sources such as primary studies, and then model the data to estimate the effects of interventions on health outcomes and costs.

**Qualitative:** Qualitative studies are studies that often seek to gather opinions and perspectives to gain insight into problems. Qualitative research involves any research that uses data that do not indicate ordinal values; it involves collecting or working with text, images or sounds.

**Adaptive/Platform:** Clinical studies in which a prospectively planned opportunity is included to modify trial designs and hypotheses based on analysis of data from subjects in the study. Note: PICO annotations for adaptive/platform trials require monitoring and regular updating. See also the MeSH publication type for "Adaptive Clinical Trial" - <https://www.ncbi.nlm.nih.gov/mesh/2023545>

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### STUDY AIM

**Diagnosis/prognosis:** where the study aims to understand the signs and symptoms of a condition or disease, to assess the accuracy of a test in diagnosing a condition/disease, or to predict a certain outcome (prognosis).

**Epidemiology:** where the study aims to look at the incidence, distribution, and possible control of the virus at a population level.

**Health services research:** where the study aims to evaluate the delivery, processes, management, organization, or financing of healthcare. Note: hospital case reports should be classified with this study aim.

**Mechanism:** where the study aims to examine the possible underlying causes of the COVID-19 infection, the pathophysiology of COVID-19, or the mechanism of action of drugs being trialed for the prevention or treatment of COVID-19

**Other:** where the study aims don't meet any of the other aims. One example might be a study looking at the mental health effects of students not able to take their exams during the pandemic, or another example is a study looking at the treatment and management of health conditions other than COVID-19 during the pandemic.

**Prevention:** where the study aims to assess one or more interventions for preventing the development of a specific disease or health condition.

**Transmission:** where the study aims to estimate or calculate the spread of the virus as well as those that look at specific characteristics and cases of transmission (passing on of the virus) between people.

**Treatment and management:** where the study aims to evaluate treatment or management intervention for a specific health condition to treat, maximize comfort, or alleviate symptoms or side effects. It could be a drug or surgery or a non-pharmacological (non-drug) therapy like light or music therapy.

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## STUDY DESIGN

**Case Series/Case Control/Cohort:** The Cochrane COVID-19 Study Register uses a single descriptor to classify these three study designs.

**Case series:** A study reporting observations on a series of individuals, usually all receiving the same intervention, with no control group.

**Case control:** An observational study in which two existing groups with different outcomes are compared based on a causal attribute.

**Cohort study:** An observational study in which a defined group of people 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.

**Cross-Sectional:** An observational study that measures the distribution of some characteristic in a population at a particular point in time.

**Case Report:** A study reporting observations on a single individual. For the Cochrane COVID-19 Study Register, we classify reports that describe five or fewer patients or a family cluster as a case report. We also classify case studies of hospitals or hospital departments as case reports.

**Parallel/Crossover:** The Cochrane COVID-19 Study Register uses a single descriptor to classify these two study designs.

**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.)

**Crossover 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.

**Time Series:** A method of statistical analysis involving tracking a long-term period before and after a point of intervention to assess the intervention's effects. An interrupted time series 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.

**Single Arm/Controlled Before After:** The Cochrane COVID-19 Study Register uses a single descriptor to classify these two study designs.

**Single arm trial:** A non-randomised study in which everyone enrolled in the trial receives the same intervention.

**Controlled Before 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.

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## INTERVENTION ASSIGNMENT

**Randomised:** An experiment in which two or more interventions, possibly including a control intervention or no intervention, are compared by being randomly allocated to participants

**Non-Randomised:** 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').

**Quasi-Randomised:** 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.

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**Unclear:** Used for the Cochrane COVID-19 Study Register to describe references with contradictory study design information (e.g., a study labelled both randomised and single arm).