

Essential concepts and terminologies relevant to the design of observational clinical research:

Here is an overview of essential terms and concepts that form the foundation for understanding and designing observational clinical research:

Terminology	Explanation
Retrospective	It refers to the medical events from past to present means researchers study medical events that happened in the past, up to the present moment
Prospective	It refers to the studies carried out from present time to future means researchers gather information over time to see how different factors affect health without changing how patients are treated
Exposure	Something a person naturally experiences or has, which researchers study to see if it's linked to certain health results. So it's the factor being studied Example: Studying whether smoking is linked to lung cancer in a population. Here smoking is an "exposure"
Outcome	The result or condition being measured Example: Studying whether smoking is linked to lung cancer in a population. Here lung cancer is an "outcome"
Prevalence	The total number of people who already have a condition at a specific time Example: In a study of 1,000 people, if 100 already have diabetes, the prevalence is 10%
Incidence	The number of new cases of a condition that develop during a certain time period Example: In an observational study of 500 people without high blood pressure, if 50 develop it over one year, the incidence is 10%
Cohort	A set of people who have something in common and are tracked over time to see what happens to them

	Example: A group of smokers followed for 10 years to see how many develop lung disease
Cohort Study	Follows exposed and unexposed groups over time to assess the incidence of outcomes Example: Following smokers and non-smokers over years to compare lung cancer rates
Case-Control Study	This design starts with people who already have a certain outcome, referred to as cases and compares them to people without that outcome, referred to as controls, retrospectively to assess exposure or risk factors Example: Comparing people with lung cancer to those without to assess past smoking exposure
Cross-Sectional Study	This is a design where data is collected from a group of people at a single point in time. It provides a “snapshot” of the population by measuring both exposures such as risk factors and outcomes such as diseases simultaneously. Example: Surveying a population for current vitamin D levels and presence of osteoporosis
Longitudinal Study	In this type of study, researchers observe the same group of people multiple times over a period of time. The goal is to track and understand how their health or certain conditions change or develop naturally, without intervention Example: Tracking cognitive function in elderly individuals every year for a decade to study aging effects
Essential concepts and terminologies relevant to the design of Interventional or Experimental Clinical Trial: This overview covers the basic terms and concepts needed to understand and design interventional clinical trials:	
Terminology	Explanation
Non-Randomized Controlled Trials	A non-randomized controlled trial tests an intervention such as a new drug or treatment by placing participants into treatment and control groups without randomization,

	using non-random methods like researcher choice or patient preference etc.
Randomized Controlled Trials	A randomized controlled trial is a study that tests how well an intervention such as a new drug or treatment works by randomly putting participants into groups. One gets the treatment and the other gets a standard treatment, placebo, or no treatment
Open Label Trial	An open label trial is a type of clinical study in which both the participants and the researchers know exactly which treatment or intervention is being given. The term open-label applies to both randomized and nonrandomized controlled trials
The following terms and concepts are usually associated with randomized controlled trials:	
Blinded Trials	A blinded trial is a type of clinical study where information about the treatment given is kept hidden from one or more parties involved in the trial to prevent bias
Single Blind	Researchers know about the treatment but participant does not know
Double Blind	Researcher and Participant, both doesn't know about the treatment
Active Control	An active control trial is a study where a new drug is compared to an existing treatment that is already known to work to see if the new drug is just as effective or better
Placebo Control	A placebo-controlled study is a test of a medical treatment where one group gets the real treatment and another group gets a fake treatment that is placebo which has no actual effect. This helps compare the results and see if the treatment really works
Superiority	It is a trial which aims to show that a new treatment works better than the current standard treatment or a placebo

Equivalence	It is a trial that tests whether a new treatment works as well as an existing one, showing it is not much better or worse than the standard treatment, within an acceptable range called the equivalence margin
Non-Inferiority	It is a trial that shows that a new treatment is not significantly worse than an existing one. Essentially, it seeks to show the new treatment is "good enough" compared to the current standard of care
Dose Response Relationship	It is a correlation between the amount of a drug given that is a "dose" and the effect it produces that means a "response". It helps to determine how different doses impact the effectiveness and safety of the treatment. This relationship guides finding the best dose that works well with minimal side effects