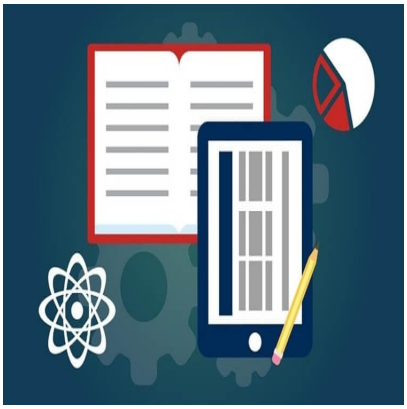

Description

Study designs are of utmost importance in research. Right from ideation to testing the hypothesis, researchers need to plan and develop a strategy that aptly fits their experimental goals. Although scheming a study is an exciting process, it is often challenging as well. Many factors such as financial constraints, timelines and ethical issues need to be considered while choosing the right protocol and suitable participants.

Study design is a blueprint or a set of methods and procedures, used for gathering, measuring and analyzing the data. A common error made by investigators is to begin research way too soon! Foremost, it is important to critically evaluate the kind of data required to address the research problem. Without proper analysis of the study designs, the information gathered might become invalid or incomplete. Decision on the type of study design depends on three factors. These include, nature of research question, goal of the research and the availability of resources.

Before delving into understanding the different types of study designs, let's get familiarized with the commonly used terminologies that are used when choosing the right design.

Variable

It is the measurable attribute that varies across study units. It can be specific for individual participants in the study. Additionally, it may also represent attributes measured for an individual over a period of time. Examples include height, weight, age, health status – diseased or healthy / treated or untreated, smoking status – yes/no.

Exposure and Outcome Variables

These terminologies help in assessing the relationship between two variables. This includes identifying whether one variable (exposure) is responsible for change in other variable (outcome). Suppose that an investigator is interested in determining ' Does consumption of folic acid during early pregnancy reduces nervous system defects in the developing fetus?' Here, supplementation (yes/no) of folic acid to the participant forms the exposure variable. The presence or absence of nervous system defects in the participating groups forms the outcome variable.

Clinical Trial Arm

The cluster or group of participants (specifically patients) receiving a specific intervention/ treatment (or no treatment), based on the trial's protocol, is known as an 'arm' of clinical trial. There are five major types of arms. These include experimental arm, sham comparator arm, placebo comparator arm, active comparator arm, and no intervention arm.

1. Experimental arm – An arm type where a group of participants receive the treatment or intervention that is the prime focus of the clinical trial.
2. Sham comparator arm – An arm type where a group of participants receive a procedure that apparently is similar to the actual procedure, but does not include the active components.
3. Placebo comparator arm – An arm type in which a group of participants receive a placebo during a clinical trial.
4. Active comparator arm – An arm type in which a group of participants receive a potentially effective treatment or an intervention.
5. No intervention arm – An arm type where a group of participant does not receive any treatment or intervention.

Baseline Characteristics

It includes all the relevant data such as age, gender and ethnicity. It also includes study-specific measures such as prior drug exposure or systolic blood pressure.

Eligibility Criteria

Eligibility criteria refers to the key prerequisites and characteristics that must be present in individuals who want to participate in a clinical study. The inclusion criteria defines the requirements that permits the person to participate in a study. Similarly, the exclusion criteria defines the conditions which do not allow the participant to be a part of the clinical trials.

Informed Consent

Informed consent is the protocol used by investigators to communicate the probable risks and benefits to potential participants who wish to get enrolled for the clinical trials.

Treatment Allocation

Allocation refers to the protocol followed to assign participants to an arm of clinical study. Ideally, the participants and recruitment team must not be aware of the treatment allocation prior to entering the trial.

Masking

A clinical design strategy in which one or more groups (participants or investigators) involved in the clinical trial, do not know which participants have been allocated which interventions. Types of masking include: open label (non-blinded), single blind and double blind masking.

1. Open label – A clinical trial in which there is no masking. All the parties are aware of the treatment or interventions.
2. Single blind – Only the patient is unaware of the treatment.
3. Double blind – Neither the patient, nor the team conducting the clinical trials knows what treatment plan the patient is receiving.

Observational Vs Experimental / Interventional studies

Studies in which researchers observe and document the effect of a prior treatment, intervention, risk factors or a diagnostic test without attempting to perform any active intervention are known as observational studies. An example of observational studies may include documenting the incidence of respiratory disorders in smokers vs non-smokers. Another example can be comparing the prenatal nutritional habits of mothers with birth weight of babies. In these cases, the researcher plays no role in influencing smoking or nutritional habits in individuals. These include ecological designs, case-control studies, cross sectional studies and cohort studies.

Interventional studies are the ones in which the investigator introduces a treatment or intervention and studies its effects on the participants. Examples include administration of a vaccine/drug, conducting of a therapeutic or diagnostic procedure and assessing the outcome after the intervention. These include diagnostic designs and randomized controlled trials.

Retrospective Studies Vs Prospective Studies

The terminologies 'Retrospective' and 'Prospective' refer to the timing of research pertaining to the development of outcome. In retrospective studies, during the time of enrollment, there are two possibilities. Either the outcome has already occurred (as in patients), or not occurred (as in controls). Data collection methods include questioning participants, scanning through previous records and asking participants to recall exposures.

On the contrary, prospective studies include enrolling participants and then studying the occurrence of outcomes over a period of time. This known as a follow-up exercise. For example, prospective studies may include grouping participants on the basis of their BMI. Then further comparing subsequent development of cardiovascular diseases over a period of time.

Once there is a thorough understanding of the terminologies that describe study designs, one can easily evaluate different study designs. Moreover, this helps researchers to correctly identify and adapt a study design that best aligns with their research goals.

Category

1. Publishing Research
2. Understanding Ethics

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