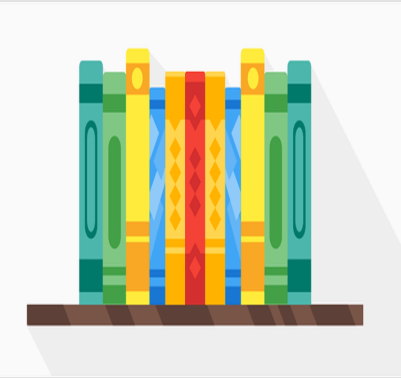

Description

In Part I of this series, the concept of ‘study designs’ was introduced and the important terminologies were discussed. In this article, we look at the strategy to choose the appropriate study design.

A good research study design ensures there is quality, logical execution and meaningful interpretation of research.

Steps for Choosing the Study Design

The three simple questions put forth by the Centre for Evidence-based Medicine greatly facilitate in determining the appropriate study design.

1. Is the aim of your study to simply observe a population and assess the relationship between two variables, without trying to change or modify the outcome?

If the answer is yes, it is a descriptive study, and if no, it is an analytical study.

2. In case, it is an analytical study, did the investigator control the exposure?

If yes, it is an observational study, and if no, it is an experimental study.

3. Further, if it is an observational study, what was the timing of measurement of outcome?
    1. A case control study – If the outcomes are measured at the start of the study (before the exposures are determined).
    2. A cohort study – If the outcomes are measured at the end of a period of follow-up (small period after the exposure/intervention).
    3. A cross-sectional study – If the outcomes are measured simultaneously (at the same time as the exposure or intervention).

Ever study design has its own set of inherent strengths and weaknesses. Studies having interventions, experiments or clinical trials provide stronger evidence than observational studies.

Let us have a closer look at the different types of study designs.

Study Design Classification

Descriptive Study Designs

A descriptive study describes the desired characteristics of the population under investigation. It includes a single sample population without any comparison or control group. It helps in generalizing the findings from a 'representative sample' and extrapolating them to the population at large. Therefore, when choosing descriptive study designs for research, it is important that the sample must be representative of the population and the sample size must be adequate.

The different types of descriptive studies include case reports and case series, cross sectional studies and ecological studies.

Case Reports and Case Series

Case reports pertain to a specific description of an individual demonstrating an atypical disease condition. The abnormal findings in the case report may imply an association between a risk factor and the disease. Case series is a collection of cases belonging to a set of patients with the same outcome or finding.

Cross Sectional Study design

These studies provide a snapshot of the prevalence of a disease in a population at a given point of time. An example of cross sectional studies would be enrolling participants who are either current smokers or non-smokers and assessing whether or not they have respiratory disorders. Cross sectional studies are relatively less expensive and allow to assess multiple outcomes simultaneously. However, one can only assess the prevalence but not the incidence of a disease.

Ecological Study Design

This study design compares groups of people, clustered on the basis of their geographical location. It helps in determining association between an exposure (risk factor) and an outcome across different populations rather than individuals. For example, of ecological study is the comparison of the prevalence of lung cancer in Russia and Germany. Ecological studies are cost-effective and often serve as the initiation point for generation of hypothesis.

Analytical Study Designs

Descriptive studies can only identify existing patterns among cases, within and across populations with respect to time and place. Researchers can use these studies to generate a hypothesis. However, they rarely have the power to test the hypothesis. For achieving this, researchers need analytical study designs.

Analytical study designs focus on finding causes and effects and quantifying associations between exposures and outcomes and finding evidence. This facilitates identification of control and prevention measures.

Analytical studies include experimental and observational designs. The following sections discuss the different types of analytical study designs.

Case-Control Study Design

This study involves a comparison between a group of participants having the disease (cases) and another group of participants without the disease (control). The study is retrospective in nature as it begins with an outcome and then traces back to compare the frequency of exposure to risk factors. The advantages of this design include, simultaneous assessment of multiple risk factors and feasibility to study rare conditions or disease.

Cohort Study Design

The study plan involves following a group of participants over a pre-determined time period to assess the effect of exposure on the incidence of outcome. These studies can be either prospective or retrospective. A retrospective cohort study involves detailed assessment of all the previously collected data. This also includes information prior to development of the outcome. Whereas, in a prospective study, the participants are tested over a period of time to determine which participants develop the proposed outcome(s). While designing cohort studies it is very important to conduct regular and timely follow-ups.

Randomized Control Trials

It is one of the most rigorous study design. The participants are randomly allocated to receive different interventions (no intervention, placebo, existing treatment, new treatment). This allows the investigators to exclude confounding factors such as selection bias and environmental exposure. A control group ensures and allows the researcher to conclude that any improvement in the outcome is due to the treatment rather than any other factor. The main limitation with this type of study design is that it requires a large sample size.

Cross-Over Trials

These study designs are similar to randomized trials as they involve allocating treatments to participants randomly. The difference, however is that, instead of staying on same treatment throughout the trial (as in randomized control trials) the participants receive two or more treatments one after the other. Every participant receives multiple treatments in this study. Moreover, each participant also serves as the control. This means there is no requirement of a large sample size. There are some limitations to this study as well. There could be a ‘carry-over’ effect (carrying the improvement from the first treatment to the second phase) for the participants.

Keeping all the factors in mind, researchers can make informed decision about the study design that best suits their purpose. Subsequently, they can successfully integrate and execute all the different

elements of the study in a coherent and logical manner.

Category

1. Reporting Research
2. Understanding Ethics

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