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Scientific study designs for research: an overview

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Abstract

Research is a scientific, well planned methodical attempt to answer questions with valid data. "The rules that govern the process of collecting and arranging the data for analysis are called research designs". They are broadly classified into "Observational" and "Experimental" study designs. In observational study design, the researcher simply observes and does not intervene in any way whereas in the latter, some kind of intervention/manipulation is done. Descriptive, observational study designs are useful for only generating hypothesis whereas, analytical, observational study designs are helpful for both generating and testing hypothesis. Randomised controlled trials are the "Gold Standard" for determining the strongest evidence for concluding causation. However, no study design is perfect. Each has its own inherent advantages and disadvantages. Depending on the type of research question, practicability, and resources in terms of manpower, money and time, the investigator has to choose the appropriate study design which will answer the research question in the most scientific manner. This article gives a brief overview of the various study designs commonly used in research.

Key words: Research design; cross-sectional; case-control; cohort; randomised controlled trial.

Research is derived from "re-search". Search refers to "seek", "investigate" or "explore" and in typical Hindi parlance it means "khoj". Research may be a new search or an old thing being again investigated (re-search).

Once a research question is in place, what kind of study should be planned is important and this is primarily the focus of this article.

A study design is a specific plan or protocol for conducting the study, which allows the investigator to translate the conceptual hypothesis into an operational one. In other words ***"The rules that govern the process of collecting and arranging the data for analysis are called research designs"*** [1] which we shall be discussing in brief along with their advantages and dis-advantages.

It is very important to realise that **"a poor design cannot be salvaged by good statistics"**. A good study design should be sound and scientific and planned very methodically. Therefore, an epidemiologist and statistician should be on board from the start of the study.

The epidemiologic study designs are broadly classified into **"Observational"** and **"Experimental"** study designs. Further classifications of various types of studies is outlined in Table 1.

A. OBSERVATIONAL STUDY DESIGNS

In an observational study design, the researcher or the investigator simply observes the individuals in the study and does not intervene in any way. They are further classified into "Descriptive" and "Analytical" studies.

DESCRIPTIVE STUDIES- These describe certain observations and could be in form of case reports or case series. Descriptive studies can be used

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Table 1- Types of scientific study designs

A) OBSERVATIONAL

- DESCRIPTIVE

- o Case Reports
- o Case Series

- ANALYTICAL

- o Ecological studies
- o Cross-sectional
- o Case-control
- o Cohort

B) EXPERIMENTAL

- o Randomised controlled clinical trial (RCCT)
- o Randomised controlled field trial (RCFT)

C) META ANALYSIS/SYSTEMATIC REVIEWS

for hypothesis generation and can also suggest associations. However, they cannot be used for testing the hypothesis.

ANALYTICAL STUDIES

Ecological studies- are usually undertaken to study the prevalence or incidence of diseases in populations or groups wherein the unit of study is population group rather than the individual [2]. For example, if we study the frequency of a characteristic (e.g. Alcohol intake) and some outcome of interest (e.g. Cirrhosis of Liver) occurring in the same geographic location (e.g. a city, state or a country). These studies can be used for generating hypotheses but not to draw causal conclusions because we do not have information as to whether people who consumed alcohol are the same people who developed cirrhosis of liver.

Cross-sectional study- In a cross-sectional study, data is collected at a single point in time or in a time frame. It is helpful to describe associations and determine prevalence. An example of a cross-sectional study is "Prevalence of Hypertension in Adults in a community" as shown in Figure 1.

The strengths of cross-sectional studies are that they can be performed quickly, are relatively inexpensive, provide the prevalence of a disease/ risk factor and are useful to formulate a hypothesis. In spite of these salutary advantages, it has its

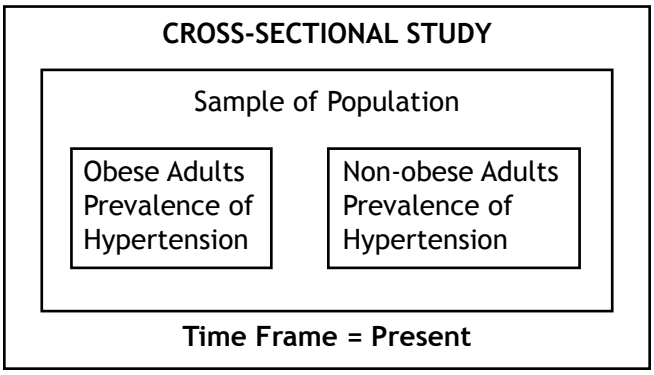

Figure 1- Depiction of a cross-sectional study

inherent weaknesses viz. cross-sectional studies cannot establish cause-effect relationship and cannot be used to test a hypothesis.

Case-Control Study- In a case-control study, one starts with people who have disease (cases) and then matches them with controls that do not have the disease. Then the researcher looks back and assesses the exposures in both the groups (cases as well as controls). A diagrammatic representation of a case control study is depicted in Figure 2.

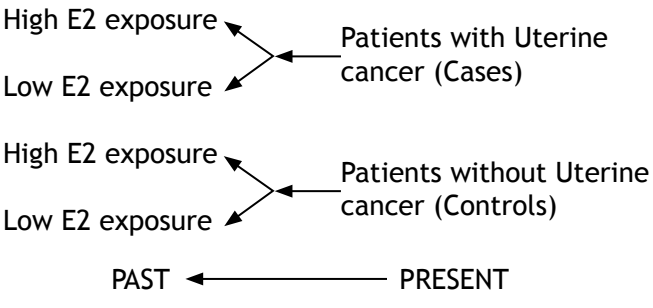

Figure 2- Example of a Case-Control Study- Are those with uterine cancer more likely to have consumed Estrogen (E2)?

The strengths of case-control studies are that they can be done in a short-period of time, are relatively inexpensive, are good for rare outcomes like cancer and can examine many exposures. Besides, they are useful to generate hypothesis and also are helpful in providing the odds ratio. The weak points include, that they cannot be used to determine the incidence, prevalence or the relative risk. Besides, they can only study one outcome and have a high susceptibility to bias.

The third type of analytical observational studies commonly planned are the Cohort studies. Cohort studies are the most difficult ones; they begin with disease-free patients/subjects and classify them as exposed/unexposed. After, this the outcomes are recorded in both the groups and the outcomes are compared using relative risk.

Example of a Cohort Study is- "To determine the effects of smoking on lung Cancer mortality in a population".

In a prospective cohort study, exposure may or may not have occurred at study entry, but outcome definitely has not occurred at time of study entry. The subjects are followed up for a fixed period of time or till the disease occurs. In a retrospective (historical) cohort study, both the disease and exposure have already occurred at the time of study.

The advantages of cohort studies are that they provide incidence data, help in establishing time sequence for causality, eliminate recall bias, can study rare exposures and allow for accurate measurement of exposure variables.

Cohort studies can measure multiple outcomes and can adjust for confounding variables and can also calculate relative risk. Despite the several advantages, there are weaknesses as well and these include- cohort studies are expensive, time-consuming, cannot study rare outcomes and require a relatively large sample size. Besides, exposure may change over a period of time, there is attrition of study population over time and diseases which have a long pre-clinical phase can be problematic to study as well.

B. EXPERIMENTAL STUDIES

Analytical experimental/interventional studies are studies in which an intervention is performed and hence, also are referred to as "clinical trials". Clinical trials provide the "gold standard" for determining the strongest evidence for concluding causation. Various instruments which are employed during clinical trials include-

- Randomisation
- Blinding
    - o Placebo-controlled or
    - o Standard treatment

Randomisation literally means to toss a coin to decide the assignment of the patient to a study group. The most critical element in randomisation is the unpredictability of the next assignment which essentially ensures elimination of selection bias [3].

Blinding or masking involves many components. The subjects should not know to which group they are assigned to. This can be either done by using a "placebo" or where standard treatments are available they should be given. For example, to study a new drug against HIV/AIDS in a study group, standard treatment should be provided to the control group as it would be unethical to give a placebo to the control group.

When the study subjects are only blinded, it is termed as "Single Blind study" whereas when both the study subjects as well as data collectors are blinded, it is a "Double-blind" study.

There are two types of randomised trials: (1) Randomised Controlled Clinical Trial (RCCT) (2) Randomised Controlled Field Trial (RCFT)

Example of a Randomised Controlled Clinical Trial (RCCT) is depicted in Figure 3- To study the association between garlic consumption and cardiovascular disease prevention in a city.

Randomised Controlled Field Trial (RCFT): It is similar to an RCCT except that the intervention is preventive and not therapeutic. These are usually preventive trials in which the efficacy of a preventive

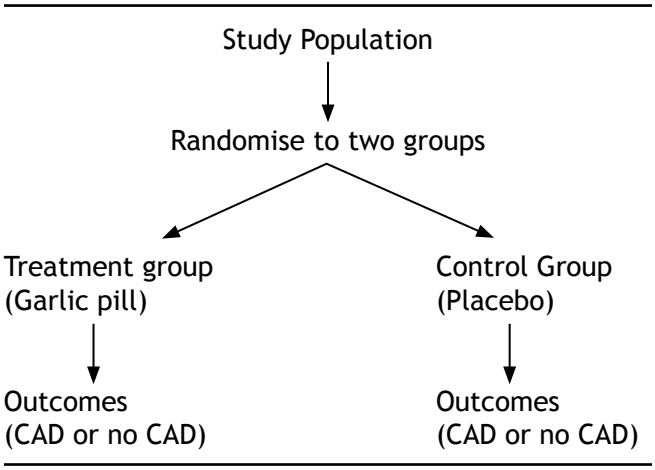

Figure 3- Example of a Randomised Controlled Clinical Trial

intervention such as a new vaccine is tested in one study group and the other group receives a placebo or standard. As they are usually conducted in the community, the term used is Randomised Controlled Field Trial (RCFT).

The advantages and disadvantages of a RCCT and RCFT are similar. The strengths are that they are the best measure of a causal relationship, are the best design for controlling bias and can measure multiple outcomes. The weaknesses include the high cost, compliance issues and at times, ethical issues may be a problem. Sometimes, it may take a long time to obtain results. Another disadvantage of both is "External Validity" which is the ability to generalise the findings to other groups of population [1].

C. META ANALYSIS/SYSTEMATIC REVIEWS

It is analysis of multiple studies including statistical techniques for merging and contrasting results across studies [4]. The need for a meta-analysis or a systematic review arises when there are conflicting evidences available from different studies addressing the same research question. However a number of biases can occur like publication bias, aggregation bias, and bias in exclusion of studies. Detailed description is beyond the purview of this article.

Table 2 provides a tabulated summary of the characteristics of various study designs.

	Cross-sectional	Case-control	Cohort	RCT
Cost	+	++	+++	++++
Duration	+	++	+++	+++
Sample Size	Varies	Small	Large	Varies
Incidence/ Prevalence	Prevalence	None	Incidence	Incidence
Multiple Outcomes	Yes	No	Yes	Yes
Bias prone	Yes	Yes	No	No
Causality	No	No	No	Yes

Table 2- Salient features of various study designs.

The above treatise should help clarify the doubts of scientific personnel and help them in planning what study design they require to achieve their respective research questions.

Key Points

- Choosing an appropriate study design to address a research question is very critical to obtain valid results.
- For hypothesis generation, observational, descriptive studies are generally used whereas for generation as well as hypothesis testing, observational, analytic studies like case-control, cohort studies are commonly employed.
- Randomised controlled trials are the "Gold Standard" for determining the strongest evidence for concluding causation.

References

1. Jekel JF, Katz DL, Elmore JG, Wild DMG. Epidemiology, Bio-statistics and Preventive Medicine. Saunders Elsevier, Philadelphia, 2007 3rd edn; pp. 77-89.
2. Das R, Das PN. Biomedical Research Methodology including Biostatistical Applications, Jaypee Brothers Medical Publishers, 2011 1st edn; pp. 19.
3. Leon G. Epidemiology. Saunders Elsevier, Philadelphia, 2009 4th edn; pp. 135.
4. Greenland S, O'Rourke K. Meta-analysis. In: Rothman KJ, Greenland S, Lash TL (eds). Modern Epidemiology. Lippincott Williams & Wilkins, Philadelphia, 2008 3rd edn; pp.652-82.