Ibrahim Card Med J 2012; 2(2): 41-44

Study Design in Medical Research

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ABSTRACT

An appropriate study design is key to answer the research question or to test the hypothesis of a study. A study design is, in fact, how a study can be conducted in a given situation. A study design is more important than analysis of data, for a faulty study design can never be retrieved once it is applied, whereas a poorly analysed study can be retrieved and reanalyzed if needed. Therefore, appropriate study design is an effective way to draw a meaningful conclusion from the research data. Here we highlight the key concept of study design, their types and formulating a study design based on research question and hypothesis.

Key words: Study design, medical research, research question or hypothesis.

INTRODUCTION

During research works, different types of research questions may arise. To address these questions, appropriate study design is required. Study design is in fact, how a research study can be conducted in a given situation. In many ways, study designs are more important than analysis of data. A faulty study design can never be retrieved once it is applied. On the other hand, a poorly analysed study can be retrieved and reanalyzed if required.[1] Therefore, appropriate study design is mandatory to get the effective and meaningful conclusion derived from the research. Moreover, proper study design governs the research investigators how the data obtained from a particular research can be analyzed.

What is a study design?

A study design is a specific plan or protocol for conducting the study, which allows the research investigators to translate the conceptual hypothesis into an operational one.[2,3]

What are the types study designs?

There are several types of study designs and each type shall answer specific research questions related to that research problem. As for example, randomized controlled clinical trial (RCCT) shall answer which intervention or therapeutic option is more effective in that situation where the research has been conducted, whereas, prospective and cohort studies investigate the etiology of a disease/condition of interest. Thus, a research can generate accurate data according to study design contemplated. Broadly, the study design can be divided into following two types:

1. Non-interventional or non-experimental

2. Interventional or experimental

1. Non-interventional or non-experimental: Here the researcher just shall describe and analyse objects or situation but does not intervene. This is again subdivided into the following sub-types:

I. Exploratory
II. Descriptive
III. Analytical

I. Exploratory types: This type of design is usually carried-out when there is little or no information available regarding a problem or disease or its risk factors. This type of study is usually of small-scale with relatively short duration. In this design, working hypothesis is neither generated nor tested. It is the first research method generally used to study a

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particular disease or its risk factors and thus, it is called exploratory. For example, National HIV/AIDS survey.

II. Descriptive types: This type of design is aimed to describe the occurrence and distribution of a disease or its risk factors. But it dose not offer any explanation or situation to test a hypothesis (theoretical assumption). It merely generates a description of a disease or an event of interest or its risk factors in terms of people, place and time involved, such as 'who', 'where' and 'when'. Such studies are often based upon records of hospitals, health complexes or health facilities or community clinics etc. However, a working hypothesis can be formulated from the study result. For example, an initial survey of HIV/AIDS revealed that male homosexual, drug abusers and hemophilics are at risks. But subsequent study findings should find the actual cause or etiology of the HIV/AIDS and thus, generates useful hypothesis.

III. Analytical types: This type of study is carried-out when there is limited, vague or conflicting knowledge/information about a disease or its risk factors available. Furthermore, this design attempts to establish the association of risk factors with the disease outcome. However, the analytical study is designed to test a hypothesis and to show whether a casual association exists between two categories of events or things i.e. to what strength the risk factors are associated with the extent of the disease and how strong is this assumption. Analytical study is also called 'comparative study'. This study is again subdivided into following sub-types:

- ***Cross-sectional study***
- ***Case-control study***
- ***Cohort study***
- ***Case series study***

Cross-sectional study: This type of study is being carried-out just at one point in time and is completed at another point in time over a short period. This type of study design collects data once from a group of subjects or patients at one point of time rather than over a prolonged period of time and analyze them. Cross-sectional studies are designated to learn or to know what is happening to the subjects right now. This type of study is usually conducted in epidemiological study to measure disease prevalence not the incidence. Cross-sectional studies can also be carried-out in clinical research where data can be collected on a group of subjects or patients for a particular disease condition at one time rather than over a period of time. Thus, this study design is also called 'short-term study'.

Case-control study: The case-control study is a backward-looking study and proceeds from effect to cause. The study begins with an outcome or event (disease or condition) which has already had occurred and compares one group in whom a problem or a disease is present called the 'case' with another group in whom the problem or the disease is absent called the 'control' (i.e. apparently healthy person). The case group might be exposed to a particular risk factor or factors over a prolonged period of time and the control group remains unexposed to the same risk factor or factors for the same period of time. The subjects in both the groups are then followed retrospectively (i.e. in backward direction) for the history of such exposure. It is to be remembered that baseline characteristics of the subjects in both the groups such as age, sex, socio-demographic status etc. must be identical. The classical example of case-control study is 'smoking and lung cancer'. Here the risk factor is 'smoking' and the outcome is the lung cancer. The case-control study is also called 'retrospective longitudinal study'. The study answers the question 'what has happened to the subjects following exposure to risk factor i.e. smoking for long time'.

Cohort study: The cohort study focuses or provides information on risk factor related to the outcome (i.e. development of a disease). The term 'cohort' refers to a group of subjects/people who have something in common or common characteristics like age, sex, occupation, level of education, marital status, dietary habits etc. In this study design following exposure to a particular risk factor, the subjects are followed prospectively (in forward direction). Like case–

control study, here also two groups of subjects are enrolled. One group will have the exposure to any risk factor (cases) and the other group shall remain unexposed to the same risk factor (control) for a certain period of time as in the case group. The cohort study shall answer the question 'what will happen to the subject following exposure to a risk factor'. This study is also called 'forward-looking study'.

Case series study: The case series study describes the clinical presentation of a disease in a number of patients at a particular time. The patients are followed prospectively. The best example of a case series study is 'writing a case report'. In this type of study patients are followed relatively for a short period of time. By definition, a case series study does not include control subjects/persons who are free from the disease or clinical condition being described. Furthermore, case-series study are generally not planned study and this, do not involve any research hypothesis.

2. Interventional or experimental study: In contrast to observational studies, experimental study designs allow the researchers to exercise high degree of control over the study subjects and conditions. As a result, three important features distinguish experimental studies from non-experimental studies. The features are as follows:

(a) Subjects are randomly assigned to comparison groups. In contrast, subjects in observational studies 'self-select' their group status.

(b) The researcher compares the subjects with an appropriate control group.

(c) The researcher manipulates the treatment under investigation, also known as independent variable.

It is to be remembered that in the interventional studies, the researcher manipulates as mentioned above a situation by his/her own design and measures the effects of manipulation. It usually, but not always compares two groups as already mentioned above. The study may be comprised of one group only in which an intervention (a new drug) is given (case or experimental group). The interventional studies can be of two types:

I. Randomized controlled clinical trial (RCCT)

II. Quasi Experimental phase II clinical trial

I. Randomized controlled clinical trial (RCCT): In this design, trial subjects are randomly assigned/allocated in the treatment (experimental) or placebo (control) group as desired. One group of subjects is given an intervention, for example, a new drug, while the other group is not given intervention but receive a placebo or standard treatment (control or comparator group). The results of both groups are then compared to evaluate the effect of intervention by new drug. From statistical point of view, RCCT is a strong and efficient clinical study that provides evidenced based data.[4] Thus, findings of the study are really the findings or effects of the new drug or intervention or innovation.

RCCT is regarded as the 'gold standard' research design, for it provides more strong and the most convincing evidence-based relationship between exposure or intervention and the outcome or the effect as compared to observational designs. This is due to the fact that in this design, variation is less and bias is controlled. For example, clinical trials of hormone replacement therapy in menopausal women found no protection for heart diseases, thus contrasting findings of previous observational studies.[5]

II. Quasi experimental study or non-randomized trial: Unlike RCCT, this study is done without any control. This is also called Quasi Experimental phase II clinical trial. In this trial, at least one characteristic of true experiment is missing, which is randomization or use of a separate control group. Thus, from statistical point of view, this is not efficient and the findings of the study may not reflect the true effect of the study and do not represent the population. A phase II trial however, always includes manipulation of an independent variable that serves as the intervention.

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