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An Overview of Research Study Designs in Quantitative Research Methodology

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ABSTRACT

The paucity of knowledge of research study design poses challenges to the approach to current research methodologies. This study aims to highlight the various types of research study designs and their suitability for quantitative research studies. This was an exploratory essay on research designs in quantitative research methodology. The study was conducted by the literature review of similar articles on research study designs using Google Scholar, African Journal Online (AJOL), PubMed, MEDLINE and CINAHL as databases. A pair of medical subject headings (Research Design and Quantitative Research Methodology) were used as a search strategy to explore the research question in the above database. There are two arms of research designs in quantitative research study namely the experimental and non-experimental study designs. The experimental arm includes prospective (i.e., clinical trial) and diagnostic studies. In contrast, the nonexperimental arm which is predominantly an observational study is subdivided into descriptive (i.e., case series, case-control) and analytical (i.e., case-control, retrospective, cross-sectional) studies. In conclusion, the research design in quantitative research methodology is broadly classified into experimental and nonexperimental study designs. It plays a significant role in the decision-making of the data collection mechanism. It is a vital tool for the verification of the credibility of a quantitative research methodology.

Keywords: Research, Study Design, Quantitative Research Methodology, Experimental study design, Nonexperimental study design.

Introduction

The research process is the systematic procedure (also known as steps) a researcher will undergo to make a discovery. These systematic procedures must be followed in logical sequential fashions linked with each other (Coughlan et al., 2007). The strong terms that define a successful research process such as credibility, integrity, validity, reliability, reproducibility and generalizability depend on strict adherence to these procedural steps. The process of researching is born out of critical analysis of the results of previous studies relevant to the research area of interest (Polit and Beck, 2006).

Research design is a framework or procedural technique used for data collection and analysis of a research problem (Ranganathan & Aggarwal, 2018). It is the methodological approach to the research question. There are several study designs, each with its scope, peculiarities, merits and flaws. From the research perspective, a research project study design is designed to address research questions (hypothesis), its goal and its objective. It is the main determinant of the validity and reliability of the research findings of a research project. As a result of the importance of study design to the overall outcome of a research process, it is important to identify the various types of research study designs, their strengths, limitations and similarities.

To effectively understand the concept of research study design, some terms are frequently used while describing it. These include variable, exposure and outcome variables. A variable is a term used to describe any measurable attribute which can vary across a study unit. Examples of variables include individual participants in a study, and personal characteristics of individual participants in a research study such as age, sex, weight, height, body mass index, health status and educational status just to mention a few. The exposure (or intervention) variable is used to define the risk factor whose effect is being studied. It is also known as the independent variable, the causative variable or the predictor variable, while the outcome (also known as predicted or dependent) variable is the consequence of the exposure (or intervention). There is a subtle difference between the terms ‘‘exposure’’ and ‘‘intervention’’ independent variables. The term ‘‘exposure’’ variable is a naturally determined causative variable. It is used if the ‘‘causative’’ variable is naturally determined as commonly used in observational studies (i.e., age, sex, smoking, educational status). The term ‘‘intervention’’ variable is an artificially determined causative variable. It is used if the ‘‘causative’’ variable is artificially determined as commonly used in experimental studies such as clinical trials of a new drug or vaccine.

Classification of Research Designs

There are about four major different ways of categorizing research study design from the quantitative research methodological perspective. These include:

1. Based on naturally and artificially determined causative (i.e., Predictor) variables as in Observational versus Interventional (experimental) study.
2. Based on analytical status the variable Descriptive (non-analytical) versus Analytical (inferential) study.

3. Based on the directionality of methodological approach to the exposure-outcome variables as Case-control versus Cohort study.
4. Based on the timing of the exposure-outcome variables as Retrospective versus Prospective study.

Observational versus Experimental studies: These are two arms of research study designs. An observational study is a study where the researcher takes a record of a naturally occurring relationship between an exposure and its outcome. In this study, the observer who in this context is the investigator or researcher does not assign any intervention to the participants of the study. He observes and records outcomes over time. An example of an observatory study is the incidence of diabetes mellitus (outcome variable) in obese versus non-obese population; the sociodemographic characteristics of haematological malignancy patients. An exposure must precede the outcome to predict the outcome. When exposure proceeds an outcome, it is no longer considered an ‘‘exposure.’’ Observatory study is subdivided into descriptive (non-analytical) and analytical (inferential) study designs.

The interventional study is otherwise known as an experimental study. In this study, the researcher assigns active intervention to the participants (i.e., subjects) and records the relationship between the intervention and the outcome. The ‘‘intervention’’ in this context could be a clinical trial using a new drug or vaccine, diagnostic/screening test for disease detection, or introduction of a new educational tool. Any innovation that can change the outcome of participants or target population (i.e., health indices, behaviour) is an interventional study design. Other examples include randomly assigning aspirin and placebo for a duration and assessing the outcome of the target population to cerebrovascular accident (stroke); and incidence of obesity in the regular versus no exercise target population.

Descriptive versus inferential study design- A descriptive or non-analytical observational study is a study design where the researcher describes a variable without drawing inferences or establishing any relationship between two variables. Examples are case studies, case reports, case series and some cross-sectional studies.

Inferential (analytical) study attempts to test a hypothesis and establish a causal relationship with the outcome variable (causal-inference relationship). In this study, the researcher assesses the relationship between the exposure and outcome variables. An inferential study can be observational (if the cause of the study is naturally driven) or experimental when the researcher actively administers the cause of the study.

Case-control versus Cohort study design: This classification is based on the direction the researcher determines to study the relationship between the exposure and outcome variables in a research project. There are two possible directions in this context namely the forward (follow-up) and backward (follow-down or retrospective) directions.

The cohort study is a prototype of a forward (follow-up) directional study design. Here, the researcher determines the exposure (risk factor) to be studied in the subjects and follow-up the participants to assess whether an outcome occurred at a future time point. In this study, the investigation

starts from the exposure (risk) variable point to the outcome variable point. Cohort studies are usually analytical studies that can be observational or experimental in classification. A typical research study design example is a prospective study. An example of a cohort study is the follow-up of a group of smokers and non-smokers over a timeframe to determine the incidence of lung cancer among them.

The case-control study is a prototype of a backward (follow-down) directional study design. Here, the outcome (i.e., disease) has taken place and so the researcher uses the outcome to trace back the possible causative variables. This study starts from the outcome variable point and ends at the exposure variable point. Case-control studies are usually analytical observational studies. A typical example is a retrospective study design. An experimental study design cannot be designed in a follow-down direction so it cannot be a type of case-control study. Examples include ‘‘the sedentary lifestyle of hypertensive sub-population.’’ In this study, the outcome variable is hypertension and this can be used to trace the sedentary lifestyle of the subjects. There is usually a control group for case-control studies. The control group in this context is the sedentary lifestyle of a group of age-sex matched population who have normal blood pressure.

Prospective versus Retrospective study:

The prospective and retrospective studies are time-dimension research study designs. In both studies, the researcher will consider the timing of the exposure to the development of the outcome.

In a retrospective study, both the exposure and the outcome have already taken place and so the researcher will collect the data in retrospect. It is a prototype of a case-control longitudinal study that follows a backward (follow-down) directionality in studying the relationship between the exposure and outcome variables. It is an analytical observational study. However, it does not fit into the experimental classification of the cohort. In this study, the data are collected from records (i.e., the use of medical records abstraction forms) to collect data on the study population. The ethical clearance in this study does not require obtaining informed consent from the participants unlike in prospective or experimental studies where this is necessary.

A prospective study is an analytical observatory or experimental cohort study. It is a study in which either or both the exposure and outcome have not taken place. This is a follow-up study design in direction. Here the researcher follows up on the effect of the exposure on the participants until an outcome is confirmed. A typical example is the effect of vaccines in a study population over a timeframe.

The new classification of research design in quantitative research methodology is tending towards experimental and nonexperimental quantitative research designs. The nonexperimental is further divided into the primary ‘‘research objective’’ study design (descriptive, prediction, and explanatory study) and ‘‘time’’ dimension research designs such as cross-sectional, longitudinal and retrospective studies (Johnson 2001). The summary of research designs can be demonstrated using a flow chart in Figure 1 below.

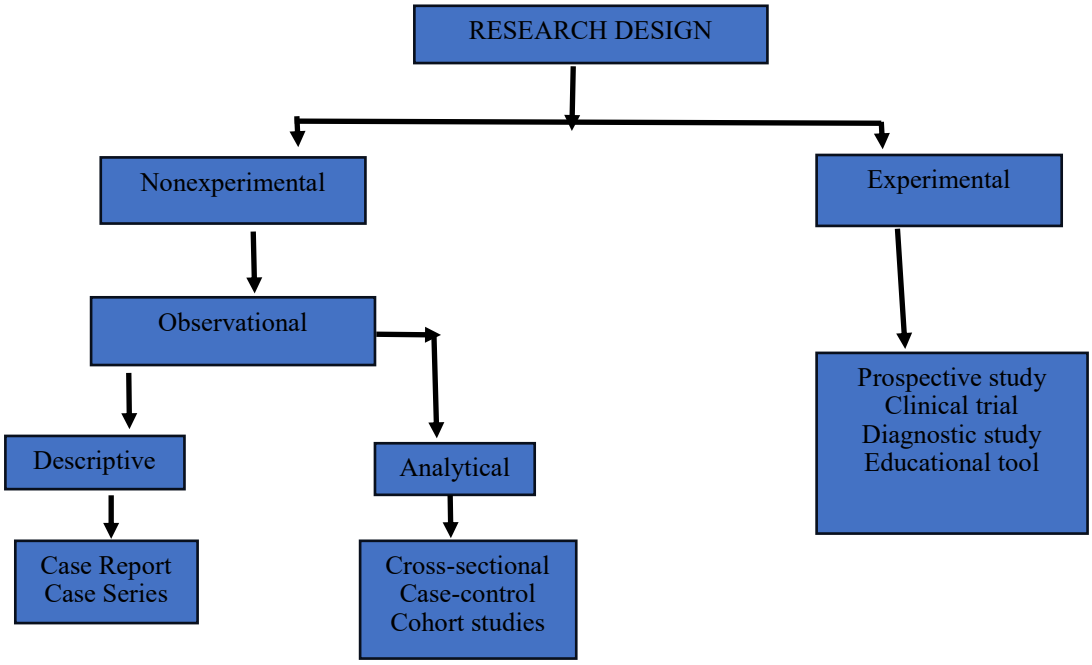

Figure 1. A flow chart of research study designs

Table 1. Comparison of Observational and Experimental Study Design

Serial Number	**Social Dimension**	**Observational**	**Interventional (Experimental)**
1.	Exposure-outcome determinants	Naturally-determined causative variable.	Artificially-determined causative variable.
2.	Mode of administration of intervention by researcher	The researcher administers no intervention.	The researcher administers an intervention to some of the participants.
3.	Role of the Researcher	Observer	Interventionist
4.	Sub-division	Descriptive (non-analytical) and analytical (inferential)	Analytical
5.	Directionality of study to exposure-outcome pathway	Bidirectional: Case-control or Cohort study	Unidirectional: Cohort study
6.	Other research study designs that fall under the category	Descriptive Analytical Retrospective Prospective	Analytical Prospective
7.	Examples	1. Incidence of diabetes mellitus in obesity versus normal BMI sub-population. 2. Incidence of cancer of the lung in smokers versus non-smokers. 3. A retrospective study of adult haematological malignancies in a tertiary health institution.	1. A clinical trial of COVID-19 vaccine in a newly diagnosed COVID-19 sub-population. 2. The screening test for multiple myeloma. 3. The knowledge-attitude and practices of healthcare providers towards haematological malignancies pre- and post-educational tool introduction.

Table 2: Relationship between Descriptive and Inferential (Analytic) Variables

Serial number	Social Dimension	Descriptive	Inferential
	Analysis	Non-analytical- descriptive.	Analytical.
	Category	Observational only.	Observational and experimental.
	Hypothesis	Does not test a hypothesis.	Attempts to test a hypothesis.
	Causal relationship	Does not assess the relationship with variables.	Assess the relationship between exposure and outcome variables.

Table 3. Comparison between Retrospective and Prospective Studies

Serial Number	Social Dimensions	Retrospective	Prospective
	Category	Observational only	Observational or Experimental
	Analysis	Both are Analytical Research Study Designs	
	Study directionality	Case-control study (Follow-down)	Cohort study (Follow-up)
	Source of exposure	Natural predominantly	Natural or interventional
	Exposure-Outcome knowledge before study	Already known	Either the exposure or both are unknown
	Data collection method	Already established records (i.e., *MRAF) are not necessarily documented by the researcher.	Observed records or results of investigations by the researcher.
	Ethical Clearance	No informed consent is required. Ethical approval is required from the Institutional Review Board (IRB).	Informed consent from participants is required. Ethical approval from IRB is required.

*MRAF= Medical Record Abstraction Form

Conclusion

Research study design is a framework on how to approach research methodology. It can be classified into experimental and nonexperimental, observational and interventional (experimental), non-analytical (descriptive) and analytical, case-control and cohort study designs based on standard criteria for classification. A research design plays a vital role in the validity, reproducibility and accuracy of a research study.

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