INTRODUCTION

Research study design is a framework, or the set of methods and procedures used to collect and analyze data on variables specified in a particular research problem.

Research study designs are of many types, each with its advantages and limitations. The type of study design used to answer a particular research question is determined by the nature of the question, the goal of research, and the availability of resources. Since the design of a study can affect the validity of its results, it is important to understand the different types of study designs and their strengths and limitations.

There are some terms that are used frequently while classifying study designs which are described in the following sections.

Variable

A variable represents a measurable attribute that varies across study units, for example, individual participants in a study, or at times even when measured in an individual person over time. Some examples of variables include age, sex, weight, height, health status, alive/dead, diseased/healthy, annual income, smoking yes/no, and treated/untreated.

Exposure (or intervention) and outcome variables

A large proportion of research studies assess the relationship between two variables. Here, the question is whether one variable is associated with or responsible for change in the value of the other variable. Exposure (or intervention) refers to the risk factor whose effect is being studied. It is also referred to as the independent or the predictor variable. The outcome (or predicted or dependent) variable develops as a consequence of the exposure (or intervention). Typically, the term “exposure” is used when the “causative” variable is naturally determined (as in observational studies—examples include age, sex, smoking, and educational status), and the term “intervention” is preferred where the researcher assigns some or all participants to receive a particular treatment for the purpose of the study (experimental studies—e.g.,...
administration of a drug). If a drug had been started in some individuals but not in the others, before the study started, this counts as exposure, and not as intervention – since the drug was not started specifically for the study.

Observational versus interventional (or experimental) studies

Observational studies are those where the researcher is documenting a naturally occurring relationship between the exposure and the outcome that he/she is studying. The researcher does not do any active intervention in any individual, and the exposure has already been decided naturally or by some other factor. For example, looking at the incidence of lung cancer in smokers versus nonsmokers, or comparing the antenatal dietary habits of mothers with normal and low-birth babies. In these studies, the investigator did not play any role in determining the smoking or dietary habit in individuals.

For an exposure to determine the outcome, it must precede the latter. Any variable that occurs simultaneously with or following the outcome cannot be causative, and hence is not considered as an “exposure.”

Observational studies can be either descriptive (nonanalytical) or analytical (inferential) – this is discussed later in this article.

Interventional studies are experiments where the researcher actively performs an intervention in some or all members of a group of participants. This intervention could take many forms – for example, administration of a drug or vaccine, performance of a diagnostic or therapeutic procedure, and introduction of an educational tool. For example, a study could randomly assign persons to receive aspirin or placebo for a specific duration and assess the effect on the risk of developing cerebrovascular events.

Descriptive versus analytical studies

Descriptive (or nonanalytical) studies, as the name suggests, merely try to describe the data on one or more characteristics of a group of individuals. These do not try to answer questions or establish relationships between variables. Examples of descriptive studies include case reports, case series, and cross-sectional surveys (please note that cross-sectional surveys may be analytical studies as well – this will be discussed in the next article in this series). Examples of descriptive studies include a survey of dietary habits among pregnant women or a case series of patients with an unusual reaction to a drug.

Analytical studies attempt to test a hypothesis and establish causal relationships between variables. In these studies, the researcher assesses the effect of an exposure (or intervention) on an outcome. As described earlier, analytical studies can be observational (if the exposure is naturally determined) or interventional (if the researcher actively administers the intervention).

Directionality of study designs

Based on the direction of inquiry, study designs may be classified as forward-direction or backward-direction. In forward-direction studies, the researcher starts with determining the exposure to a risk factor and then assesses whether the outcome occurs at a future time point. This design is known as a cohort study. For example, a researcher can follow a group of smokers and a group of nonsmokers to determine the incidence of lung cancer in each. In backward-direction studies, the researcher begins by determining whether the outcome is present (cases vs. noncases [also called controls]) and then traces the presence of prior exposure to a risk factor. These are known as case–control studies. For example, a researcher identifies a group of normal-weight babies and a group of low-birth weight babies and then asks the mothers about their dietary habits during the index pregnancy.

Prospective versus retrospective study designs

The terms “prospective” and “retrospective” refer to the timing of the research in relation to the development of the outcome. In retrospective studies, the outcome of interest has already occurred (or not occurred – e.g., in controls) in each individual by the time s/he is enrolled, and the data are collected either from records or by asking participants to recall exposures. There is no follow-up of participants. By contrast, in prospective studies, the outcome (and sometimes even the exposure or intervention) has not occurred when the study starts and participants are followed up over a period of time to determine the occurrence of outcomes. Typically, most cohort studies are prospective studies (though there may be retrospective cohorts), whereas case–control studies are retrospective studies. An interventional study has to be, by definition, a prospective study since the investigator determines the exposure for each study participant and then follows them to observe outcomes.

The terms “prospective” versus “retrospective” studies can be confusing. Let us think of an investigator who starts a case–control study. To him/her, the process of enrolling cases and controls over a period of several months appears prospective. Hence, the use of these terms is best avoided. Or, at the very least, one must be clear that the terms relate to work flow for each individual study participant, and not to the study as a whole.
Classification of study designs

Figure 1 depicts a simple classification of research study designs. The Centre for Evidence-based Medicine has put forward a useful three-point algorithm which can help determine the design of a research study from its methods section:[1]

1. Does the study describe the characteristics of a sample or does it attempt to analyze (or draw inferences about) the relationship between two variables? – If no, then it is a descriptive study, and if yes, it is an analytical (inferential) study
2. If analytical, did the investigator determine the exposure? – If no, it is an observational study, and if yes, it is an experimental study
3. If observational, when was the outcome determined? – at the start of the study (case–control study), at the end of a period of follow-up (cohort study), or simultaneously (cross sectional).

In the next few pieces in the series, we will discuss various study designs in greater detail.

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Conflicts of interest
There are no conflicts of interest.

REFERENCE

1. Centre for Evidence-Based Medicine. Study Designs; 2016. Available from: https://www.cebm.net/2014/04/study-designs/. [Last accessed on 2018 Sep 04].