

Tutorial on Applied Study Designs in Medical Research

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ABSTRACT

Introduction: One of the main pillars of the study is the correct choice of study design. This study aimed to give an overview of different type of study designs in medical research.

Methods: In this tutorial study, all applied research designs in terms of quantitative and qualitative study were reviewed. Accordingly, terms related to "Research Designs" were searched in the online databases such as Google Scholar, PubMed, Web of Science and Scopus.

Results: Based on the findings of the present study, the types of studies are generally divided into two groups: quantitative studies and qualitative studies. Quantitative studies are divided into two categories: primary and secondary studies. Preliminary studies include observational and non-observational studies. Observational studies are divided into two categories: descriptive and analytical studies. Descriptive studies include case reports, cross-sectional studies, cross-sectional correlational studies and ecological studies, and analytical studies include retrospective and group studies. Non-observational studies also include laboratory studies, clinical trials, field trials, and community trials.

Conclusion: With a good understanding of the types of studies, it is easy to decide which type of study is appropriate for the research. Choosing proper study design can reduce the costs of the executive process, increase the accuracy, quality of research and give more reliable results.

Keywords: Study designs, Research methodology, Research Designs, Experimental Designs

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Introduction

Medical science as a life-saving science is constantly progressing, and medical research has been a precursor to all current developments (1). Research in the field of medical sciences is being carried out in all directions, and due to the wide scope of medical science, researchers and those interested in research in medical research have different specialties. One of the complementary specializations along with specialized knowledge is familiarity with research methods (2).

Research methodology includes the basic principles to properly conduct a research. One of the important issues after determining the title of the thesis is how to implement the thesis. In the implementation of the thesis, the first step is to determine the type of study design (3). The type of study is one of the components of study design and should be determined before starting the study because it is not possible to change it during the study (4). Therefore, if a correct understanding of the types of studies is established, it can be easily decided which type of study is suitable for the research. Proper study increases the accuracy of research, reduces the costs of the executive process, observes ethical considerations, increases the quality of research and achieves more reliable results (5, 6) and special attention should be paid to this area.

So far, several books have been written on the topics of research methods and types of studies in

the field of medical sciences, each of which has taught these topics in a way. The authors of the present article have tried to help those interested in the field of research in an easy and practical way, in a concise and useful way, in order to take their first steps in choosing the type of studies correctly and consciously. Therefore, this study was conducted with the aim of reviewing the types of studies in the field of medical sciences.

Methods

This tutorial study was conducted with the aim of reviewing different types of study designs in the field of medical research. Accordingly, terms related to "Research Designs"; were searched in the online databases such as Google Scholar, PubMed, Web of Science and Scopus. Also, in order to obtain the most relevant articles, the main criterion for the inclusion of articles in the present study was that each article that generally examined the types of research and medical studies in the field of health was reviewed. Any study that examined a variety of studies in a specific area of health, such as psychiatry or infectious diseases, was excluded from the present study. It should also be noted that by using the resources used in the obtained articles, every effort was made to complete the search domain.

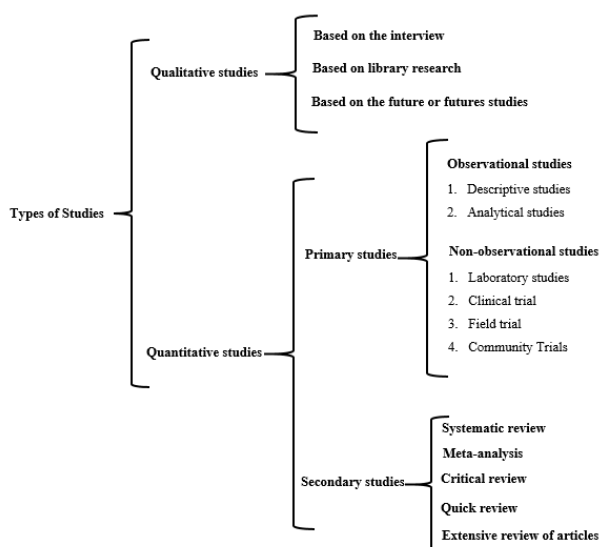


Figure 1. Different types of study designs in medical research

The types of searched studies are mentioned in Figure 1 and their explanations are discussed below.

A research can be divided from different angles and in order to answer the research question and also considering the conditions, administrative costs and ethical issues, the best study method must be determined (7). Types of studies in general and standard are divided into two groups of quantitative studies and qualitative studies:

1. Qualitative research: involves the collection and analysis of non-numerical data to identify different concepts, perspectives and experiences. Non-numeric data refers to items such as text, audio, image or video. Qualitative research relies on first-hand sources to gather information and data. In this type of study, the method of data collection is subjective and the researcher often seeks to identify the qualitative aspect of a phenomenon in the subjects. Qualitative research is performed to understand and describe human experiences, perceptions and feelings of individuals (8). Numerous models have been proposed for qualitative research. The following are the most important of these methods:

1.1. Interview-based quality models:

1.1.1. Content analysis: This model is used to identify, analyze and interpret semantic patterns of qualitative data. Content analysis along with content analysis has been widely used in management and social science studies. This method is one of the simplest and first qualitative research methods that can be used with deductive or inductive approach (9).

1.1.2. Thematic analysis: A method in qualitative research that focuses on identifying, analyzing and interpreting the pattern of meanings of qualitative data. Theme is a key element in this approach (10).

1.1.3. Grounded Theory: This model is used to theorize about the phenomenon under study. This method is used when the research literature on the subject is not rich enough. It also aims to present a new theory that has not yet been proposed in research communities (11).

1.1.4. Phenomenology: Phenomenology is the philosophical study of the structures of experience and awareness of the phenomenon under study from the perspective of first-hand individuals. With the

development of this method, non-philosophical applications have been found and it is also used as a qualitative research model (12).

1.2. Qualitative models based on library research:

1.2.1. Systematic Literature Review: This model is used to study phenomena and identify categories based on research literature. This method is especially useful when the research literature on the phenomenon under study is rich. In such cases, with a systematic method, the underlying categories of the studied phenomenon can be identified, classified and summarized. This method is very similar to meta-study methods such as meta-combination method and meta-analysis method (13).

1.2.2. Meta Study: This study is presented to review, combine, analyze and interpret previous research over the past few years. This type of study is an in-depth analysis of research results in a specific field.

1.3. Qualitative model based on future or futures studies:

Futurism is an intermediate discipline in the social sciences and history. Other names such as futurism, futurism, futurism and future studies have also been used to name this area.

2. Quantitative research: In this type of study, data is collected objectively and the phenomena are examined by accurate and quantitative measurements. The obtained data are then tested or described by statistical techniques. Most of the researches done in medical and health sciences are of small type (14). Quantitative studies are divided into two categories: primary studies and secondary studies:

2.1. Preliminary studies: These are studies that are obtained from direct research.

2.2. Secondary studies: These are studies that are the result of analyzing the results of other studies.

Preliminary studies include the following:

2.1.1. Observational Studies

2.1.2. Non-Observational (Experimental) Studies

2.1.1. Observational studies: The study of events that occur naturally is called observational studies. These studies can be based on a review of the recorded data or on actual observations or a

combination of both. Observational studies are performed without human intervention. In this case, the subjects are slightly harmed. These studies are mostly performed in hospitals (5).

2.1.1.1. Descriptive studies: In descriptive studies, the researcher usually seeks to describe the unknown levels of one or more parameters in different people. These studies show the pattern of disease occurrence in relation to variables of person, place and time. The information obtained from these studies is for health managers (to validate intervention programs on at-risk groups and populations or to implement educational and preventive programs) and for epidemiologists to clarify descriptive features, often referred to as The first step in identifying disease risk factors is useful. In such studies, they use national data on food, medicine or other products from various sources of information such as vital statistics, occupational examinations, clinical files in the public and private sectors. Because these data are pre-prepared, they make descriptive studies cheaper and less time consuming than other studies. Most medical articles are descriptive studies and their main function is to produce hypotheses rather than test hypotheses (15).

2.1.1.1. 1. Case reports of patients:

These studies describe one or more patients with the same diagnosis and often lead to the idea of discovering a new disease or the adverse effects of exposure. These studies make up about 1.3 articles in medical journals. A case report is a case report that looks at an unusual case of an illness and examines how it happened. **For example**, if a young man with angio fibroma goes to a dermatologist with cauliflower lesions, as this is an uncommon case, experts decide to write an article describing the condition. And then report the actions taken to the patient and ultimately his or her fate, which could be recovery, disability, or death. The case report, if instead of one case, several unusual cases that may be related to each other are examined, the case report is done. **For example**, five patients with Pneumocystis carina pneumonia were referred to Hall's Los Angeles Hospital and eventually diagnosed with an AIDS pandemic following similar cases (16).

2.1.1.1.2. Cross-sectional studies

study the frequency and distribution of diseases in a period of time and simultaneously examine the cause of exposure and disease. These studies are known as prevalence studies, which are suitable for estimating the prevalence of health-related outcomes (17). **For example**, the prevalence of esophageal cancer in GORGAN in 2018.

2.1.1.1.3. Correlational cross-sectional studies:

In some cross-sectional studies, in addition to estimating the prevalence, the researcher uses statistical methods and techniques to find possible relationships between the exposure factor and the desired outcome, and thus presents a hypothesis.

2.1.1.1.4. Ecological studies:

Ecological or ecological studies, also called correlation studies, are often the first step in the epidemiological study process, which studies the pattern of disease occurrence in different populations and compares them to produce a hypothesis. These studies are used when the unit of study is a community such as a family, school, tribe, or a population such as a village, city, or country. **For example**, the study of the relationship between cigarette sales and coronary heart disease in different US states during 1960, which compared with different states, it was found that with increasing cigarette sales, the disease rate also increases. In these studies, the correlation coefficient is used, which varies from -1 to +1. Although ecological studies are simple and easy to perform, they are difficult to analyze (18).

2.1.1.2. Analytical studies: An analytical study tries to determine the causes or risk factors in creating a specific problem more accurately than a descriptive study and in general the purpose of research is to test the hypothesis of a specific factor (cause) with a specific disease. (19).

2.1.1.2.1. Retrospective analytical studies or case studies:

The predominant and common method in these studies is the case-control study that people with the disease (case group) with people who do not have the disease (control group) in terms of past case history. Are compared. In this study, referring to the past of the case and control group and the question about the exposure factor, individuals in both groups are

divided into two categories of exposure and no exposure, and then the exposure to the risk factor in the case group and the control group are compared. Are. In case studies, the control group is selected to eliminate the effect of confounding factors in a way that is similar to the patient group in terms of exposure to confounding factors. If in the study, each case is matched with a control, it is called paired or paired matching (**for example**, for a 25-year-old man in the patient group, a similar age and sex control is selected who is not sick). However, if according to the mean or pattern of the effect of the confounding factor, the cases are matched with the controls, it is called group matching, which has less validity than the previous case (**for example**, if obesity is a confounding factor and 35% The people in the case group should be obese, and the people in the control group should be considered obese as well (20).

2.1.1.2.2. Prospective studies:

2.1.1.2.2.1. Prospective cohort studies (prospective cohort):

In these studies, the selection of samples is based on the exposure factor, so that the study begins with the exposure factor and ends with the outcome. In this study, a group of people who are exposed to the factor or have been caused by a group that was not exposed to the cause or cause are followed for a period of time to determine the occurrence of the disease in two groups and then the occurrence of the disease in the two groups are compared with each other. At the beginning of the study, two groups of smokers and non-smokers are selected and followed up for some time to compare the incidence of the disease in the two groups (21).

2.1.1.2.2.2. Retrospective cohort studies (historical cohort):

It is a study in which the cause and effect of both occur in the past, hence it is called retrospective. In this study, the researcher uses historical data related to the past to be able to compress the time frame of the study and obtain the results of the study sooner. In these studies, outcomes occur before the study begins and the researcher goes back over time (sometimes 10 to 30 years) to select the study group from the records and track it over time. Tracing starts from a fixed date in the past and usually continues until the

present. The most important retrospective cohort studies are occupational exposure studies. These studies are generally more economical and provide results sooner than prospective cohort studies, so retrospective cohort studies are more effective in studying diseases with long incubation periods (22).

2.1.1.2.2.3. Case-group or nested case-control study:

This type of study is in fact a combination of case-control and cohort study. The researcher first selects a suitable cohort and at the beginning of the study, collects the desired information from all members of the cohort through a questionnaire, biological samples such as blood, urine, etc. At the end of the follow-up period, all individuals with the outcome were identified and with a random sample from the same group who did not have the desired outcome (as a control group), retrospectively in terms of history of exposure to factors that can be measured and evaluated. They are not possible in group study (23).

2.1.2. Non-observational studies (experimental or interventional study): Experimental study is the strongest type of study to prove a causal relationship. In this study, individuals are randomly divided into at least two groups. One group is affected by the intervention or experience and the other group is maintained as a control. Finally, the results of the intervention are evaluated by comparing the response variables of the two groups. The most important characteristics of an experimental study are intervention, having a control group, random selection of samples and their random division into two groups. If there is no control group or random division between groups, the study is called quasi-experimental. Experimental studies are generally divided into two categories: Laboratory studies and Experimental studies (24, 25).

2.1.2.1. Clinical trial studies:

Clinical trial studies are an experiment or experiment on humans in which the study population is randomly assigned into intervention and control groups and the results are evaluated by comparing the outcome in the study groups. Clinical trials can be designed in a different way, some of which are as follows:

2.1.2.1.1. Parallel clinical trial: In this plan, people who are randomly placed in intervention and control groups remain in their groups until the end of the study and their status is analyzed (26).

2.1.2.1.2. Cross design: This design has two stages. In the first stage, the first group uses treatment A and the second group uses treatment B. After following up and reviewing the outcome, the groups' positions are changed. There should be a period without intervention during this period to eliminate the therapeutic effect of the first stage. This period is called the wash out phase.

2.1.2.1.3. Factorial design: This randomized clinical trial design is a separate evaluation as well as a combination of two or more experimental interventions against the control. This design makes it possible to compare experimental interventions with controls, with each other and their possible interference.

2.1.2.1.4. Non-randomized trial: In this type of trial, for some reason, the researcher can't randomly select patients for the desired treatment methods.

2.1.2.2. Local trial studies (in the field):

In this trial, the study unit is healthy people. Information is often obtained locally and from the public. The aim of this study was to prevent the occurrence of diseases. Adding fluoride to drinking water to prevent tooth decay, prevent coronary heart disease using liquid oil are examples of this type of medical science experiment (27).

2.1.2.3. Community trial:

In this type of study, the community is used as treatment groups instead of individuals. This type of study is especially suitable for diseases that originate from social conditions and can easily intervene in group behavior as well as individual behavior. The limitation of such studies is that only a small number of Rami communities can be included and random allocation of communities is not practical (28).

3.Secondary studies: Secondary studies are one of the types of studies in medical sciences that aim to combine and review the data collected during the primary studies. Other definitions of this type of study are review and re-analysis of existing information that may not have been considered at the time of study design (29-31).

The types of secondary studies are as follows

3.1. Critical review: The purpose of this method is to express the author's concern in the extensive search for initial studies and critical evaluation of their quality. This method will go beyond mere description, which will lead to a degree of conceptual analysis and innovation. Eventually will normally lead to a hypothesis or model.

3.2. Literature review: A general term for published material that describes recent and ongoing articles on the subject matter of the study. This approach can cover a wide range of topics at different levels of completeness and comprehensiveness. This approach may also include research findings.

3.3. Mapping review / systematic map: This method is done with the aim of mapping and categorizing existing studies, which either leads to further reviews or by identifying gaps in existing research to a preliminary research.

3.4. Meta-analysis: A technique that statistically combines the results of quantitative studies to provide a more accurate effect of the results.

3.5. Mixed studies review / mixed methods review: This method refers to a combination of methods in which a significant component is the review of texts (usually structured). Inside the review text, it refers to a combination of browsing approaches. **For example:** combining quantitative research with qualitative research or combining outcomes with process studies (32).

3.6. Overview: A summary of the (medical) literature that attempts to examine the literature under study and ultimately describe its features.

3.7. Qualitative systematic review / qualitative evidence synthesis: This method is a way to combine or compare the findings of qualitative studies. Such studies are examined in search of "subject" or "structure" within each of the initial qualitative studies.

3.8. Rapid review: Evaluating what is currently known about a policy or practical issue using a structured review method and a critical search and evaluation of evidence.

3.9. Scoping review: In this method, a preliminary assessment of the scope and potential

number of available studies is performed to identify the nature and amount of research evidence (usually including ongoing research).

3.10. State-of-the-art review: This approach tends to focus more on current issues than a combination of retrospective and current approaches. This approach may suggest the application of new perspectives on a topic or areas for further research.

3.11. Systematic review: This method seeks to search, evaluate, and combine research evidence in a structured manner. Doing this study often follows the instructions for doing a review study.

3.12. Systematic search and review: This method involves combining the strengths of critical review with a comprehensive search process. It typically addresses a wide range of questions to generate the "best evidence trick."

3.13. Systematized review: This method tries to include elements of the structured review process when it does not decide to do so.

3.14. Umbrella review: This method specifically refers to a review that combines evidence

from multiple reviews into a new, accessible, and usable review study. The focus of this approach is on a wide range of topics on which competitive interventions have been performed and the reviews that have referred to these interventions and their outcomes (33).

Conclusion

With the correct knowledge of the types of studies in the field of medical sciences, the most productivity can be obtained in the research path. In the present study, we have tried to overview different types of studies in the field of medical sciences in an easy and practical way so that researchers can take their first steps in choosing the type of studies correctly and consciously. Obviously, the correct knowledge of different type of study designs can increase the accuracy of research, reduce the costs of the executive process, increase the quality of research and achieve more reliable results, and researchers should pay special attention to this issue.

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