

## The 3-Question Approach: A Simplified Framework for Selecting Study Designs

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Conventional algorithms for selecting study designs are difficult to use for a novice researcher, especially the postgraduate students. An inherent limitation of using the existing algorithms is the requirement of *a priori* knowledge of the characteristics of various study designs. We propose a simple and novel 3-question approach to select study designs. The questions are asked in a stepwise manner with answers in 'yes' or 'no'. The responses to each of these questions lead the researcher towards choosing the appropriate study design. We believe that this 3-question approach would be useful for unexperienced researchers in selecting study designs, besides serving as a tool to teach-learn selection of study designs.

**Keywords:** Algorithm, Case-control study, Cross-sectional study, Research methods.

Several algorithms are available in the literature for selecting the appropriate study designs [1,2]. Conventional algorithms focus more on what the various study designs are, rather than facilitating how to approach a research question and arrive at the appropriate design. To be able to use these algorithms, the user should have *a priori* knowledge about the various study designs [3]. Most of these approaches try to fit in all the types of study designs in a single algorithm that makes it confusing for a novice researcher, especially a postgraduate student [4].

A traditional study design algorithm lacks two key elements; (a) the presence or absence of a comparative group, and (b) the timeframe over which the data is to be collected. Without explicitly stating the number of groups, single arm trials or one group cohort studies may be missed [5]. The dimension of time is also important in medical research for follow-up or repeated measurements. For example, a study to determine the change in blood pressure will require at least two readings at different time points. We propose a simplified '3-Question (3Q) Approach' that overcomes these limitations, and is primarily targeted at the novice medical researcher.

The 3Q approach should be applied after the researcher has framed the research question or the primary objective of the study. A well-framed Research question (RQ) is an essential pre-requisite for arriving at an appropriate study design. As the name suggests, three questions are to be answered in a cascading manner; in yes or no responses (**Fig. 1**).

### THE FIRST QUESTION

This aims to differentiate between an observational and an interventional study.

Question 1: Are we trying to modify/ change the outcome of interest, in the study?

Responses: No → Observational study;  
Yes → Interventional study

The answer to the first question results in the formation of two broad categories of study designs. An observational study is defined as "a type of study in which individuals are observed or certain outcomes are measured" [6]. The study does not intend to change the patient outcome. The researcher may use certain tools for observation such as microscopy for malaria parasite detection in a malaria prevalence study. Carrying out procedures like microscopy or endoscopy to find out the burden of disease or risk factors does not make it an interventional study. Diagnostic studies to find out sensitivity and/or specificity are also considered as observational studies.

In the context of study design, intervention means that the researcher is experimenting by changing or modifying some existing variable and evaluating how it affects the outcome(s). This may be a 'novel drug' for an existing condition, an 'existing drug' for a 'novel indication,' or a 'novel diagnostic technique' to be evaluated for outcome [7]. The term interventional study is synonymous with experimental study or trial [8].

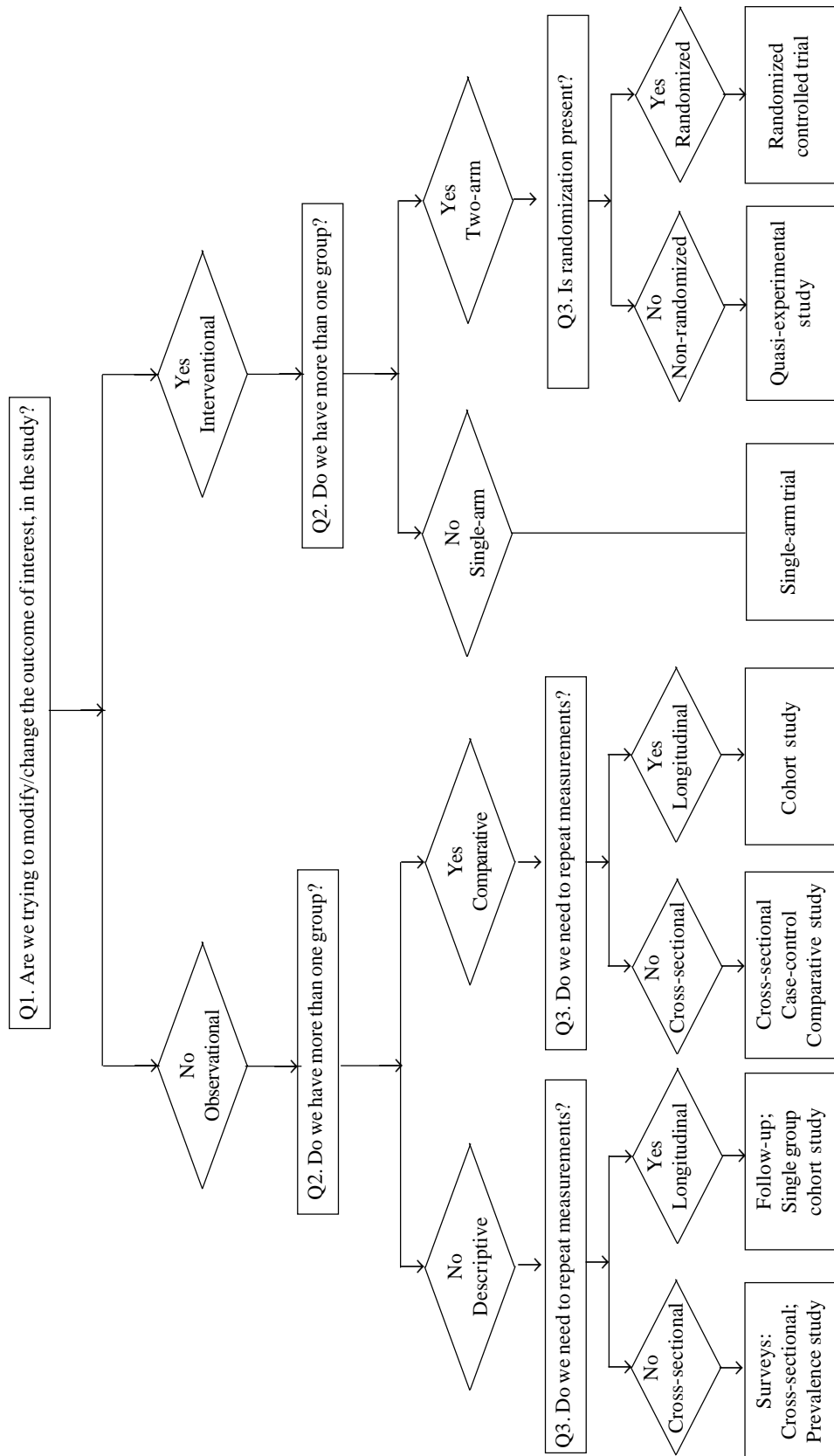


FIG. 1 The 3-question approach algorithm for selecting study designs in medical research.

**THE SECOND QUESTION**

The second question differs for an observational study and for an interventional study, based on the response to the first question.

For an observational study, its aim is to identify the purpose of the study.

Question 2a: Do we have more than one group?

*Responses:* No → Descriptive study;  
Yes → Comparative study

When the purpose of a study is to describe a single population group, it is a descriptive study. These include studies that compare population parameters such as rates, proportions, or means. Summary statistics (such as mean, standard deviation, proportion) will be applicable to descriptive studies. The statistical tests of significance are applicable on comparative studies and not on descriptive studies [9]. Studies of diagnostic accuracy wherein the objective is to assess sensitivity, specificity *etc.* are also technically descriptive studies as the focus is on single group, *i.e.* the ‘diseased.’ Traditional algorithms keep diagnostic accuracy studies as a separate category. In the 3Q approach, these types of studies are integrated within the whole framework.

In a case-control study, the diseased and non-diseased groups are compared with respect to the presence or absence of the risk factor. For a cohort study, a group with a risk factor under evaluation and another without the risk factor are compared with respect to the development of the disease.

For an interventional study, the aim is to identify whether there is an intent to compare.

Question 2b: Do we have more than one group?

*Responses:* No → Single arm trial;  
Yes → Two-arm trial

The possible responses to the second question lead to two situations: if there is no comparison arm, it is called a single arm trial or a before-after study [10, 11]; in two arm trials, there is a treatment arm and a comparison arm.

**THE THIRD QUESTION**

This also differs according to whether it is an observational or an interventional study.

For an observational study, the aim of this question is to ascertain the time factor.

Question 3a: Do we have repeated measurements?

*Responses:* No → Cross-sectional study;  
Yes → Longitudinal study

Cross-sectional studies are those where measurement is done only at one point of time. This measurement is either for the risk factor or the outcome, or for both together. When repeated measurements are done on the same individual, it is known as a longitudinal study. Since interventional studies are always longitudinal, this question is irrelevant for these studies.

For an interventional study, the aim of this question is to determine the status of randomization in a two-arm trial.

Question 3b: Is randomization present?

*Responses:* No → Non-Randomized study;  
Yes → Randomized study

For a two-arm trial, it is important to mention the randomization status. It is well known that the process of ‘randomization’ increases the validity of the study. Randomized clinical trials are true experimental studies. In a non-randomized trial, the difference in the outcomes or the endpoint values in both the groups may be due to the differences in baseline values. These are also known as quasi-experimental studies.

**LIMITATIONS OF THE 3 Q APPROACH**

Validation studies have not been conducted for this approach yet. However, the authors have used the 3Q approach in more than 30 workshops for faculty and medical students on ‘selecting study designs in medical research’ in different parts of the country till now, and have found from the participants’ feedback that this approach facilitated their understanding of study designs. We suggest that studies to assess the validity of this approach be conducted.

To conclude, the 3Q approach is an easy-to-use framework to decide study designs. However, it requires a well-framed research objective. It gives the researcher insight into how the study should be conducted, based on the responses that are obtained from these three questions. It is easy to apply and can also be used to teach how to choose study designs to novice researchers, including medical students and younger faculty.

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