

Research Design Algorithm

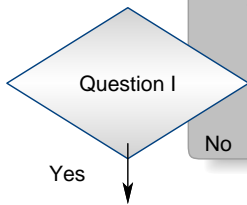
Part 1 of 2



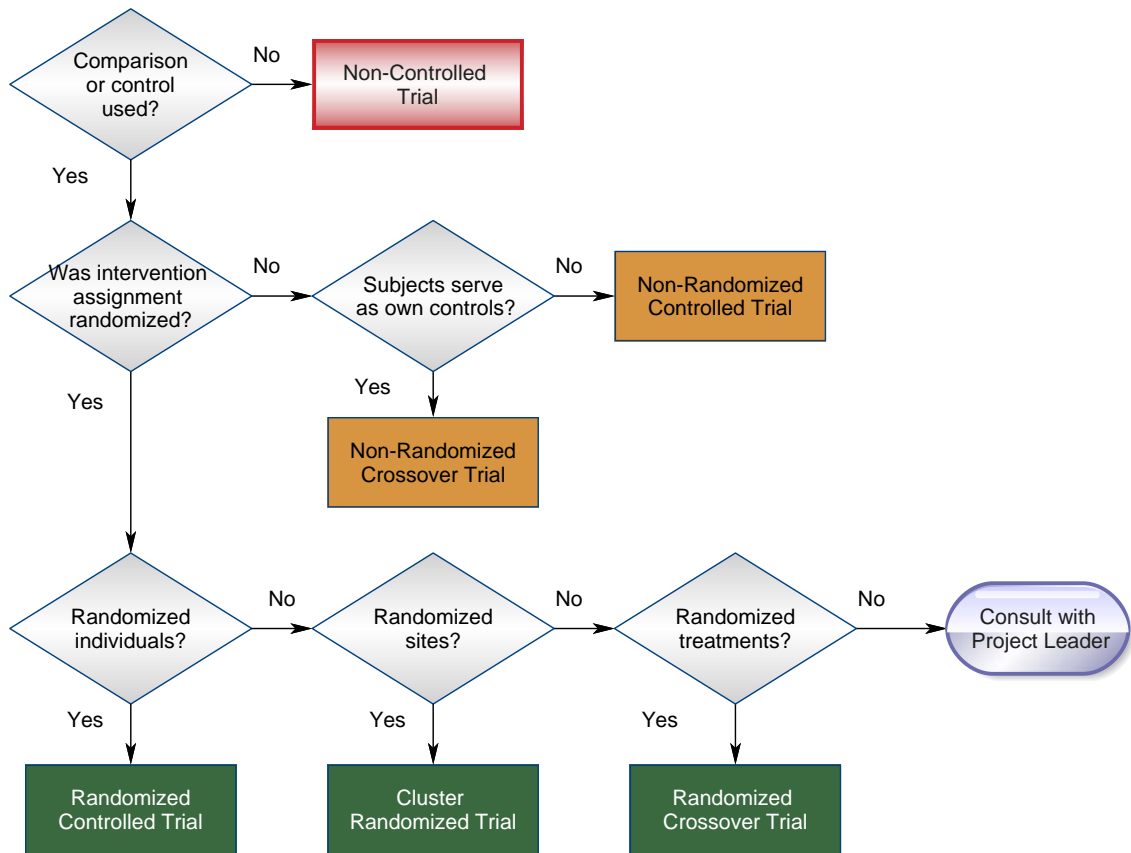
Class Key

I. Is the purpose of the study to determine the effect of a specified intervention (e.g., protocol, method, or treatment) that is managed by the investigator?
Yes: Follow the Experimental Trial Algorithm

No: Proceed to Question II

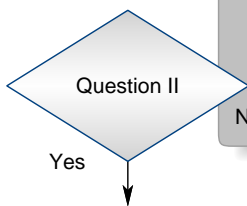


Experimental Trial Algorithm

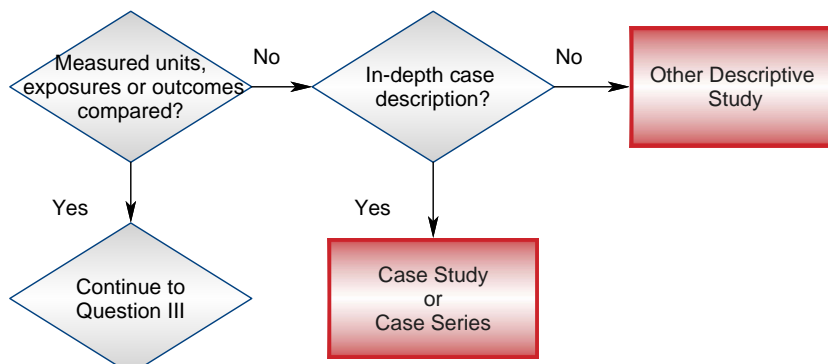


II. Is the purpose of the study to describe and understand some phenomenon in its natural context?
Yes: Follow Descriptive Study Algorithm

No: Proceed to Question III



Descriptive Study Algorithm



Research Design Algorithm

Part 2 of 2

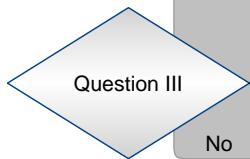


Class Key

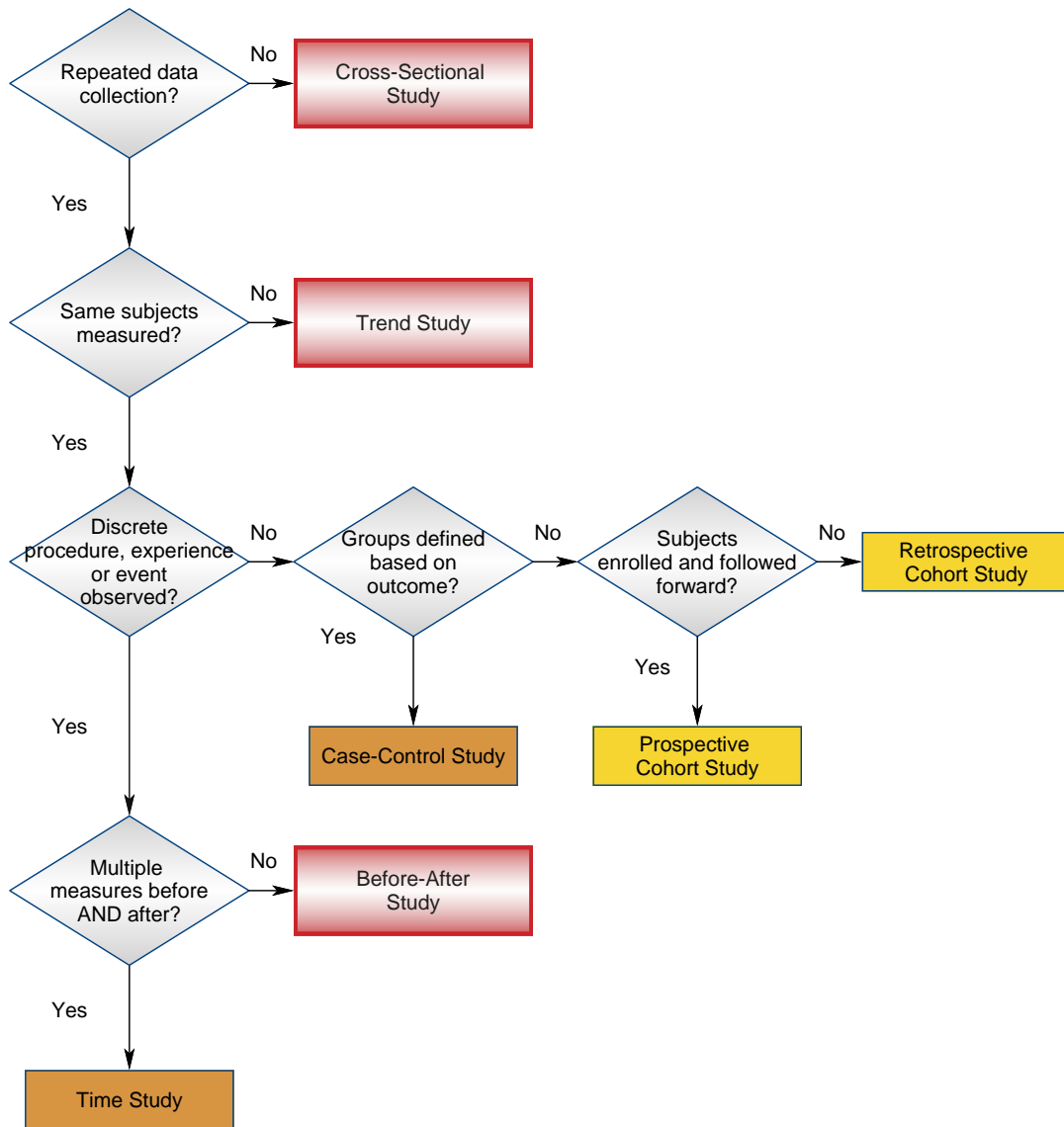
III. Is the purpose of the study to look for an association among variables by studying the situation without managing any intervention?

Yes: Follow the **Observational or Epidemiological Study Algorithm**

No: Proceed to **Question IV**



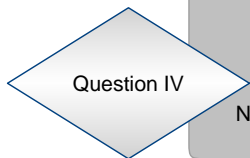
Observational or Epidemiological Study Algorithm



IV. Is the purpose of the study to validate a test, tool or diagnostic method?

Yes: **Diagnostic, Validity or Reliability Study**

No: Consult with project leader or begin again with **Question I.**

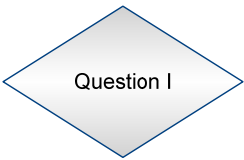

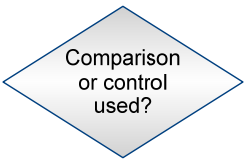
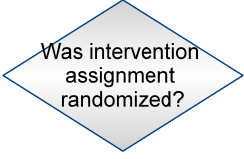
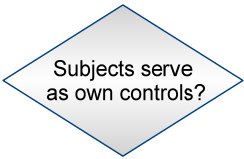



Consult with Project Leader

Diagnostic, Validity or Reliability Study

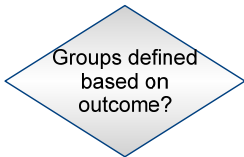
HOW TO USE THE RESEARCH DESIGN ALGORITHM

Below is a diamond by diamond guide for using the Research Design Algorithm developed by the American Dietetic Association, 2010. Included are some “Tips” on what to look for, and some “Watch Out!” instructions that may help you avoid common mistakes.

Decision Diamond	Instructions
Experimental Trial Algorithm	
 <p style="text-align: center;">Question 1</p>	<p>There are two key points here: (1) that there was an intervention (which can be called a treatment or other labels), and (2) the researcher managed or designed the intervention.</p> <p>Watch Out!  Not all studies of the outcomes of an intervention are experimental trials. Sometimes a researcher will examine the outcomes of one or more treatments (for example, different types of bariatric surgery) that occur in usual practice without having any influence on what the treatment is or who the patients are that get it. Studies of this type are not experimental trials. A study can be an experimental trial only if the researcher determines who gets what intervention (or, the order of the treatment) and the specifics of the intervention (and the alternatives).</p> <p>Tips: Look for evidence in the text that the researcher designed the intervention protocol and specified which subjects were eligible for intervention.</p>
 <p style="text-align: center;">Comparison or control used?</p>	<p>Yes: There was at least one alternative to the intervention. This could be a group that received no treatment (referred to as the “control”) or the comparison could a different type of treatment.</p> <p>No: If there was no comparison or control group studied, but there was a researcher managed intervention, the study design is a Non-Controlled Trial.</p>
 <p style="text-align: center;">Was intervention assignment randomized?</p>	<p>Yes: The author mentions that randomization is used. Eligible individuals can be randomized to different intervention groups, or less commonly used, existing clusters of individuals can be randomized to different interventions. Randomization can also be used to determine the order in which the same individuals receive two different interventions.</p> <p>No: Go to next question.</p>
 <p style="text-align: center;">Subjects serve as own controls?</p>	<p>Yes: If individuals are given two (or more) different treatments in the same (or a non random) sequence, then the subjects are their own controls and study design is a Non Randomized Crossover Trial.</p> <p>No: If two or more groups are compared (and subjects are in groups by some method that did not involve randomization), then the study design is a Non Randomized Controlled Trial.</p> <p>Watch Out!  Authors will sometimes have no comparison treatment or control group, but will describe subjects as “their own controls” when they do baseline (before) and after treatment measurements. Just because the same group of subjects is measured at two different time points does not mean that</p>

	<p>they serve as their own controls. Subjects serve as their own controls when the effects of one intervention can be compared to effects of a comparison intervention in a study where both interventions are given to all subjects.</p>
<p style="text-align: center;">Randomized individuals?</p>	<p>Yes: If individual subjects (people) are randomly assigned to different groups, the study design in a Randomized Controlled Trial (RCT)—the classic experimental study design.</p> <p>Watch Out! ⚠️ Just because randomization occurs does not mean that individual people were randomly assigned to groups. Studies can be randomized by sites (e.g., schools, cities), or treatment order (diet A first or diet B first).</p> <p>No: Go to the next question.</p>
<p style="text-align: center;">Randomized sites?</p>	<p>Yes: Rather than randomizing at the individual level, sites with many individuals (e.g., schools, offices, cities) are randomly allocated to intervention alternatives. For instance, imagine a study to test the effectiveness of a school-based physical activity program, ten schools agreed to be in the study. The schools are then randomly assigned to either implement the physical activity program or to an alternative (which could be nothing or a comparison program). This would be a Cluster Randomized Trial.</p> <p>No: If neither individuals nor sites were randomly assigned to treatments or interventions, then the only thing left is that the order of treatments was randomly assigned to the same individuals. The study design would be a Randomized Crossover Trial.</p>
<p>Descriptive Study Algorithm</p>	
<p style="text-align: center;">Question II</p>	<p>The word “phenomena” means any event, circumstance, or experience that is apparent to the senses and that can be scientifically described and appraised. “Natural context” means that the researcher doesn’t change anything. She/he observes “what is”.</p> <p>Tips: Questions II and III are closely related. In both, the researcher is observing the world (e.g., distribution of disease, the way that different therapies are carried out, how patient characteristics relate to each other) without intervening. Descriptive Studies provide an in-depth look at processes, characteristics and patterns.</p>
<p style="text-align: center;">Measured units, exposures or outcomes compared?</p>	<p>Yes: If the study is concerned about measuring and quantifying various factors and looking at the relationship among them it is likely an Observational or Epidemiological Study. Go to Question III.</p> <p>Tips: Sometimes researchers will simply provide information about the incidence or prevalence of diseases or characteristics in a population (e.g., the number of new breast cancer cases in a year, or the average intake of vitamin D among teenagers). These are descriptive studies. Ethnographic studies that apply qualitative methods are also descriptive studies.</p> <p>Watch Out! ⚠️ Just because an author describes prevalence rates (e.g., overweight or obesity) for two groups (men versus women) doesn’t mean that they test for statistical difference! Look carefully at the study purpose and statistical methods and results. If the authors test a hypothesis (whether two groups were statistically different on a certain characteristic, or whether one characteristic is statistically related to or predicts another characteristic), then</p>

	<p>the answer is “yes” and you should move on to Question III.</p> <p>No: Go to the next question.</p>
	<p>Yes: When a researcher provides a detailed description of only one or a handful of clinical cases the study design is a Case Study or a Case Series.</p> <p>No: When the point of the study is to describe a situation, either quantitative or qualitative, but the purpose is not to determine what causes what, or to test hypotheses, the study falls into the Other Descriptive Study category.</p>
Observational or Epidemiological Study Algorithm	
	<p>In this group of study designs the researcher does not manipulate group assignment or provide an intervention, but he/she does have hypotheses about the relationship among variables and may be looking for an association between exposures and outcomes.</p> <p>Tips: Expect to see more details about statistical methods including management of intervening factors and potential confounders, and tests of association or statistical difference.</p>
	<p>Yes: If data are collected at more than one time point, go down to the next question.</p> <p>No: The researchers went to the subjects only once to get data. For instance, if the researcher collected information on the exposure (diet intake) and the outcome (weight) at the same time, then this is a Cross-Sectional Study.</p> <p>Watch Out! Many descriptive studies (under Question II) collect data at only one point in time. What sets a Cross-Sectional study off from an Other Descriptive Study is that the author tests a hypothesis or carries out a statistical test for association or predictive relationships.</p>
	<p>Yes: If there are repeated measures on the same subjects, then go down to the next question.</p> <p>No: If the researcher goes to the population to collect data more than one point in time (say, in different years), but the data are collected on different subjects each time, then the study design is a Trend Study.</p> <p>For example, studies that statistically compare variables from different cycles of NHANES are often Trend Studies.</p> <p>Tips: If you are unsure, determine whether the same subjects or different subjects are measured at each time point.</p>
	<p>Yes: If the emphasis on measuring status before and after a naturally occurring procedure, experience or event, go down to the next question. For example, a “procedure” could be a particular type of surgery or dietary intervention (where the researcher merely observes what surgeons or dietitians do rather than try to influence their practices). An “experience” or “event” is generally a distinct event in time and space (e.g., becoming a college freshman; or the passage of new regulations on food served in school cafeterias).</p> <p>No: Go to the next question.</p>



Yes: If cases (individuals with the outcome) are matched to similar individuals who do not have the outcome (controls) the study design is **Case-Control Study**.

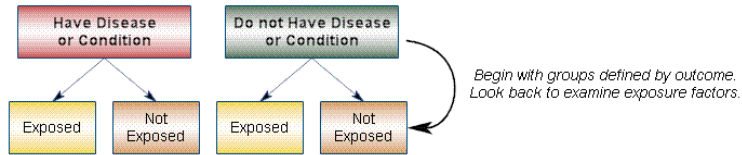
No: Go to next question.

Tips: If comparison groups are defined in terms of an outcome already present (e.g., obese individuals versus non-obese individuals, or persons who developed complications following a surgical procedure versus persons who did not develop complications following the procedure), and then data about pre-existing exposure is examined (e.g., hours of television viewing, or pre-surgery nutrition consult), then the study design is a Case-Control Study.

Watch Out! ⚠️ Case-control studies can be confused with Cohort Studies. The key difference between Case-Control and Cohort Studies depends on whether the comparison groups used in the analysis are based on the outcome or the exposure.

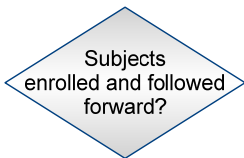
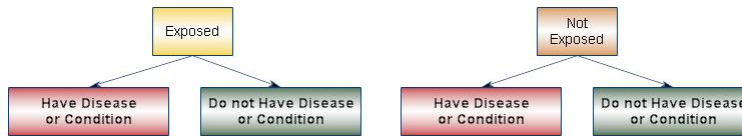
See figures below.

Case Control



Cohort Design

Group subjects based on exposure, then examine association with outcome (may be prospective or retrospective)

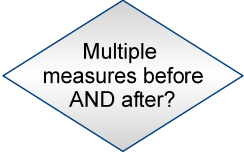


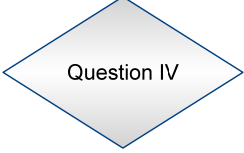


Yes: If subjects are enrolled in the study and followed forward through time with many data collection points (that is, the researchers define the variables to answer a set of research questions and then follow the same subjects and collect data over a long period of time), then the design is a **Prospective Cohort** study.

No: If data for the study are abstracted from existing longitudinal data sets or archival data sources (with many data collection points on the same individuals over time) then it is a **Retrospective Cohort** design.

Tips: A data set that is prospective for one research question may be retrospective for another research question. The difference is how the cohort was created in the beginning. Was it originally set up to answer questions like those in the current study; or is the researcher using an existing data set because it includes variables that allow answering new research questions?

Watch Out! ⚠️ Do not confuse Before-After or Trial designs with follow-up measures as a Cohort design. While there is no hard and fast cut-off for how

	<p>long is “a long period”, in Before-After or Trial designs follow-up measures are taken within months or years (usually less than five years) of the event of interest (the intervention or therapy). Cohort designs generally follow a large number of individuals over the course of many years.</p>
	<p>Yes: If data are collected at several points prior to the procedure, event or experience and again after, the study design is a Time Series Study. An example might be a study of the impact of calorie posting in fast food restaurants on purchases.</p> <p>No: A Before-After Study uses data at baseline or before a program or treatment and after it is completed. One or two follow up measures (e.g. at three months and six months) might be included.</p> <p>Watch Out!  A Before-After Study is an observational study where the researcher does not design the intervention. Before-After Studies can be confused with Non-Controlled Trials where the researcher manages the intervention.</p> <p>Tips: Time Series studies, with multiple measurements prior to the event or treatment, are relatively rare in nutrition research.</p> <p>Watch Out!  Just because a study has multiple follow-up measurements does not make it a Time Series. It must also have more than one measurement before the procedure, event or experience being studied to be a Time Series.</p>
<p>Diagnostic, Validity or Reliability Study</p>	
	<p>Yes: Does the study compare how well two diagnostic, assessment, or screening tools classify individuals in terms of whether or not they have a disease or condition? Does the study assess the validity or reliability of a tool or measurement method (often comparing the results of the tool with a “gold standard”)? These are common examples of a Diagnostic, Validity or Reliability Study.</p>
<p><i>I got to the end, but didn't find an appropriate study design.</i></p>	<p>Tips: Sometimes study designs are very complex and incorporate characteristics of multiple types of designs. Other times, authors will call their study one thing, when in reality it is another. If you get to the end and could not decide, ask your Lead Analyst or Project Leader for help.</p>

Appendix 6: Glossary of Terms Related to Research Design

Before-After Study

A pre-post investigation of a discrete procedure, experience or event that is not managed by the researcher. Data are collected at baseline and one or more times after the procedure, experience or event.

Case Control Study

A study which involves identifying patients who have the outcome of interest (cases) and matching them with individuals who have similar characteristics, but do not have the outcome of interest (controls), and then looking back to see if these two groups differed with regard to the exposure of interest (i.e., the hypothesized causal or contributing factors).

Case Study or Case Series

A descriptive study of one (case study or case report) or a series of patients (case series) defined by eligibility criteria, and where the unfolding course of events (disease progression, therapies, outcomes, etc.) is described in detail. The study researchers do not manipulate interventions. This study design is used to provide a detailed description of an uncommon disease or condition, a unique situation, or the introduction of a new technique.

Cluster Randomized Trial

A special type of a randomized controlled trial (RCT) where groups of individuals (e.g., clinic sites, classrooms, communities), rather than independent individuals, are randomized to the intervention alternatives.

Cohort Study

A study that involves the identification of a group (cohort) of individuals with specific characteristics in common and follows them over time to gather data about exposure to factors and the development of the outcome of interest. Comparison groups can be defined at the beginning or created later using data from the study (e.g., age group, smokers/non-smokers, amount of a specific food group consumed). **Prospective cohort** studies enroll individuals and then collect data at many intervals. **Retrospective cohort** studies use an existing longitudinal data set to look back for a temporal relationship between exposure factors and outcome development. In the medical field, many studies labeled a “population-based clinical study” could be classified as retrospective cohort studies.

Cost Benefit Analysis or Cost Effectiveness Analysis

An analysis that assesses the cost of an intervention in relation to the magnitude of outcome achieved. In cost benefit analysis, the inputs (i.e., intervention alternatives) and the resulting outcomes are quantified and expressed in monetary terms. In cost effectiveness analysis, inputs (i.e., intervention alternatives) are expressed in monetary terms but the outcomes are expressed in a standard unit, such as quality adjusted life years (QALY) or hospitalizations avoided. These are considered a synthesis of primary studies when data from multiple studies are used to derive estimates of inputs and outcomes.

Crossover Study Design

A study where two or more experimental therapies are administered, one after the other, in a specified or a random sequence, to the same group of patients. Usually there is a washout (no treatment) period between therapies. Individuals serve as their own controls. A crossover study is a special type of a randomized or non-randomized trial.

Cross-Sectional study

A study where exposure factors (e.g., individual or environmental risk factor, nutrition education) and outcomes (e.g., disease occurrence, eating behavior) are observed or measured at one point in time in a sample from the population of interest, usually by survey or interview. In this design, a researcher examines the association among factors and outcomes using a statistical test for association, but cannot infer cause and effect.

Descriptive Study

Descriptive studies, as a research category, use a variety of methods to observe existing natural or man-made phenomena without influencing it (no researcher intervention). Data are gathered, organized and analyzed to depict and describe “what is”. Descriptive studies can be quantitative and/or qualitative and provide an in-depth look at processes, characteristics and patterns. Descriptive studies can result in a theory or framework, but they do not try to determine cause and effect.

Diagnostic, Validity or Reliability Study

Types of studies that are designed to determine the sensitivity and specificity of diagnostic and assessment methods and the accuracy and/or consistency of tests or tools used to measure variables and concepts.

Epidemiological Study

Epidemiological studies, as a research category, are analytical studies of the determinants of health and illness in specific populations. Studies are designed to determine the relationship among exposure factors (which can be risk factors or protective factors) and outcomes. Epidemiologic studies are observational; the researcher does not manage any intervention. The most common epidemiological study designs are case-control, cohort, and cross-sectional studies.

Intention to Treat Analysis

A method of analysis for intervention trials in which all patients originally assigned to a treatment group are included in the analysis for that group, regardless of whether or not they completed or received that treatment.

Longitudinal

A general term that indicates data are collected from the same subjects at several points over time. It is not a specific study design.

Magnitude of Effect

Refers to how much change can be attributed to the treatment or intervention in a particular study.

Meta-analysis

A systematic, quantitative method that combines the results of all relevant studies to produce an overall estimate. A meta-analysis can be part of a systematic review, but not all systematic reviews include meta-analysis.

Narrative Review

A summary report of the state of knowledge on a particular topic. Narrative reviews are less rigorous than systematic reviews in that search methods, study inclusion criteria, and quality of the studies are often not reported.

Non-Controlled Trial

A type of intervention trial where only one group is used (there is no comparison group); but the studied intervention is defined and managed by the researcher.

Non-Randomized Controlled Trial

A study where subjects are assigned to intervention (protocol, method or treatment) alternatives by a method that is not random. The researcher does define and manage the alternatives, which could be treatment and control or two or more different interventions.

Observational Study

Observational studies include a wide range of studies in which the course of events is studied as it unfolds. The researcher does not intervene. Changes or differences that occur between groups are used to draw inferences about the association of variables and the relationships between possible causal factors and outcomes.

Phenomena

Any event, circumstance, or experience that is apparent to the senses and that can be scientifically described or appraised.

Prospective Cohort Study

See Cohort Study.

Randomized Controlled Trial (RCT)

Individuals meeting eligibility requirements are randomly assigned into an experimental group or a control group. The experimental intervention (protocol, method or treatment) and its alternative(s) are clearly defined and their implementation is closely managed by the researcher.

Retrospective Cohort Study

See Cohort Study.

Review Article

See Narrative Review or Systematic Review.

Systematic Review

A summary of the scientific literature on a specific topic or question that uses explicit methods to conduct a comprehensive literature search and identify relevant studies, critically appraise the quality of each study, and summarize the body of literature or evidence to answer the question.

Time Series

A study collecting data from the same subjects at a series of points over time during which a discrete preventive or therapeutic procedure, life experience, or event takes place. Data are collected prior to, and after (and sometimes during) the event in order to reach conclusions about its effect. Some studies labeled as “longitudinal” are time series studies.

Trial

An experimental or quasi-experimental study to determine the effect of an intervention.

Trend Study

A study in which the same or similar data about exposures and outcomes are collected from the same population many times, but each time a different sample is used. A trend study is like a series of cross-sectional studies. An example is NHANES.