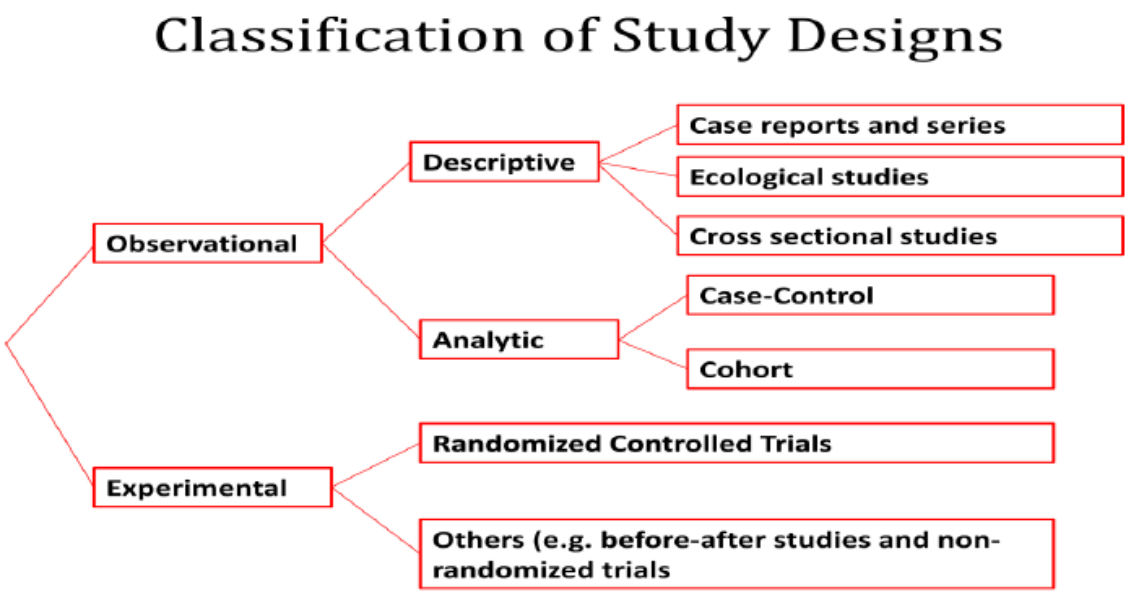
Clinical/Epidemiological Study Design

There are three general classifications of study designs: observational, experimental and meta-analysis. I will describe observational and experimental study designs in this tutorial.

Observational studies can be descriptive or analytic. Descriptive studies are exploratory, addressing "who", "where", "when" and "what" questions and evaluating relationships among variables. On the other hand, the analytic study design is appropriate for testing a research hypothesis that follows from a research question. Analytic study designs are used to address "how" and "why" questions.

Experimental designs, including clinical trials, enable us to overcome some of the inherent deficiencies in observational designs. The use of experimentation to derive knowledge about the causes of disease has instinctive appeal. In a controlled clinical trial, by exercising control over who will receive the exposure as well as the level of the exposure, the investigator more confidently may attribute cause and effect to associations than in non-experimental designs.

The figure below exhibits the classification of study design.



Ref:
Epidemiology, by Leon Gordis
Epidemiology for public health practice, by Robert Friis and Thomas A. Sellers

Here is a brief summary of strength and weaknesses of the different study designs:

Study Name	Description	Strength	Weaknesses
Cross-sectional	Variables measured at a point in time. No distinction between potential risk factors and outcomes	• Control over study population • Control over measurements • Several association between variables can be studied at the same time • Short time period required • Complete data collection • Produces prevalence	• No data on the time relationship between exposure and injury/disease development • Not feasible with rate exposures or outcomes • Does not yield incidence or relative risk • No causal relationship can be made
Case-Control	Presence of risk factor(s) for people with a condition is compared with similar people without a condition. Start with a disease, look for an exposure.	• Effective for rare outcomes • Compared with cohort study, it requires less time and money • Yields the odds ratio	• Limited to one outcome condition • Does not provide incidence, relative risk, or natural history • Less effective than a cohort study at establishing time sequence of events • Potential recall and interviewer bias
Cohort	People are followed over time (prospectively or retrospectively) to describe the incidence or natural history of a disease. Assessment can also be made of risk factors for various conditions. Start with exposures and look for diseases	• Establishes time sequence of events • Several outcomes can be assessed • Allows assessment of incidence and natural history of disease • Yield incidence, relative risk, attributable risk	• Large samples often required • May not be feasible in terms of time and money • Not feasible with rare outcomes • Potential bias caused by loss to follow-up
Clinical Trial	Are generally regarded as the most scientifically rigorous method of hypothesis testing available. It evaluates therapeutic and preventive aspects of medical practice	• Provides most reliable evidence from clinical research • Randomization offers ability to control confounders • Can conclude causal relationships	• Costly and time-consuming • May be limited in generalizability

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