

STUDY DESIGN

1. How do we begin to answer the question?

- Start with the building blocks of any design
 - Participants of investigation
 - Outcomes of investigation
 - Direction of inquiry (prospective or retrospective)
 - Other considerations (e.g. possibility and resources)

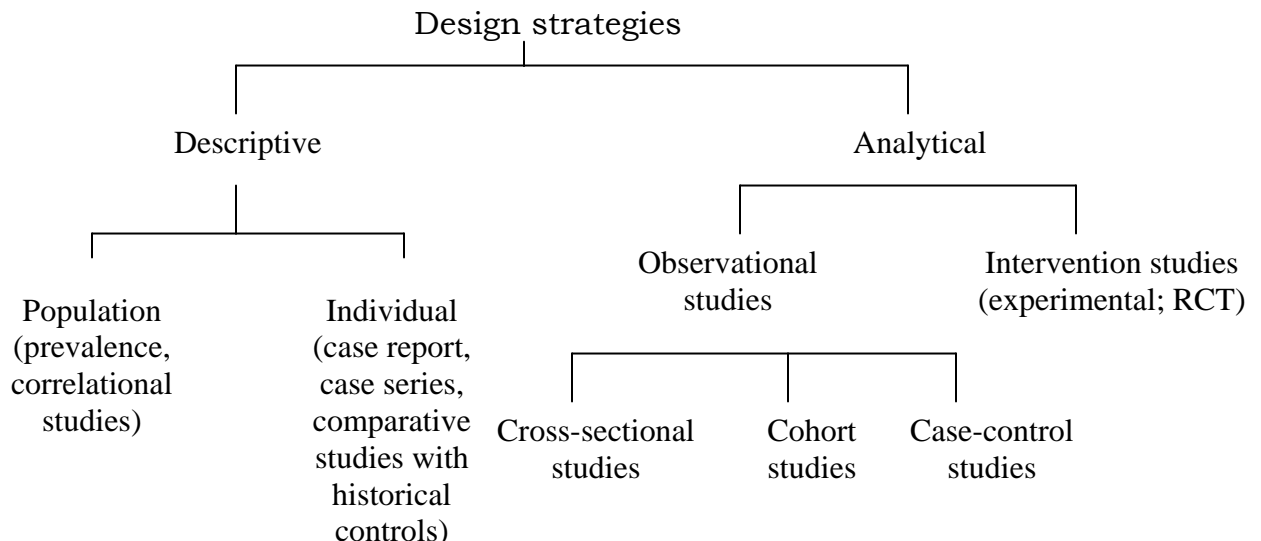
2. Think about our research question?

- Identify the participants of interest
- What are the outcomes of interest

3. About the investigation

- Presence of a comparison group
 - Dependent on the objective of the study
 - Generally increases the validity of an observed association
- Exposure (risk) (or intervention) and outcome
 - Must be measured with as little error as possible

4. Overview of epidemiologic studies:



5. Case report

- Strength
 - Hypothesis (question) generation
 - Clinical observation
- Weaknesses
 - May be one off
 - Nothing to compare

6. Case series

- Strengths
 - Strengthens the hypothesis
 - Able to establish temporal relationship
- Weakness
 - Nothing to compare

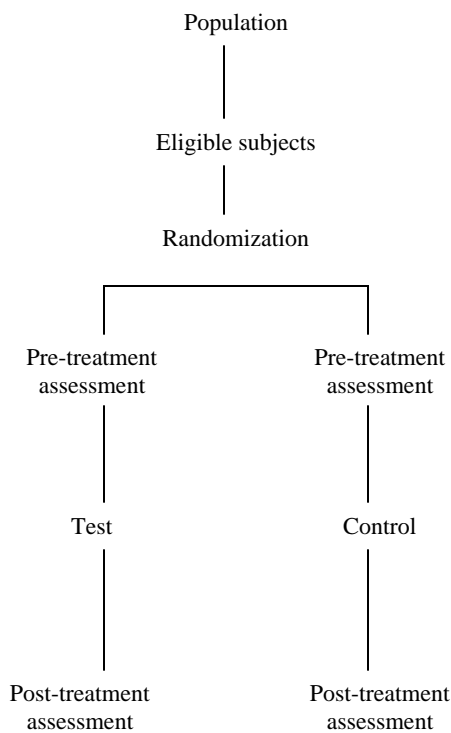
7. Comparative studies with historical controls

- Strength
 - Like two case series
 - Have something to compare to
- Weaknesses
 - May be other differences between groups
 - Relies on recoding information being accurate

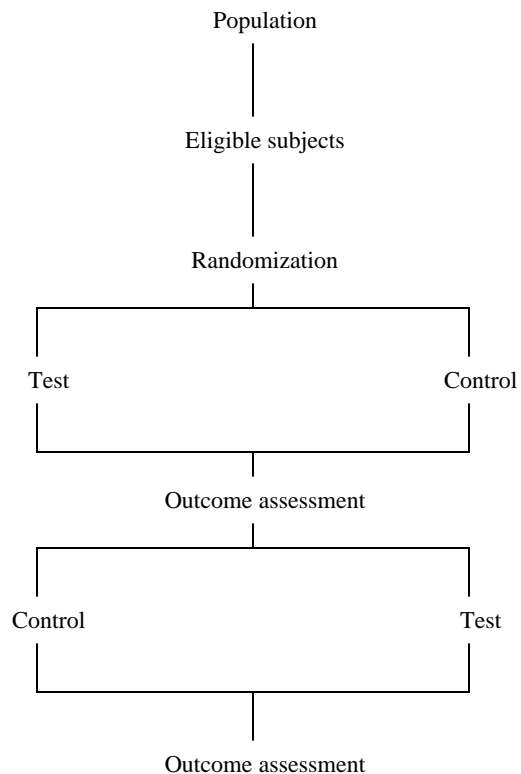
8. Randomized Controlled Trial

- 'Goal standard' test of treatment
- Selection of groups entirely random
- Control group identical to treatment group at start except for intervention
- Participants/investigators commonly 'blind' to group allocation to reduce bias

- May evaluate good and bad outcomes
- End point blinding → e.g. the pathologist are not given any information about the study sample slide so the pathologist didn't know whose slide it is and he/she will decide based on his/her independent interpretation about the slide.
- There are few of RCT
 - Single blind
 - Double blind
 - Triple blind
 - Multiple blind
 - End point blinding
- There are 2 design of RCT
 - Parallel RCT
 - Cross-over RCT



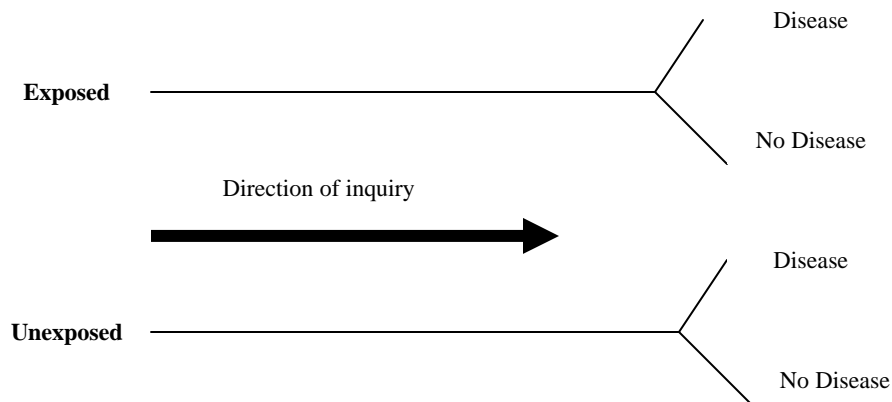
Parallel RCT



Cross-over RCT

9. Prospective cohort:

- A group of people (cohort) is assembled, none of whom has experienced the outcome interest
- On entry, people are classified according to characteristics that might be related to outcome
- Other names: longitudinal, prospective, incidence studies.

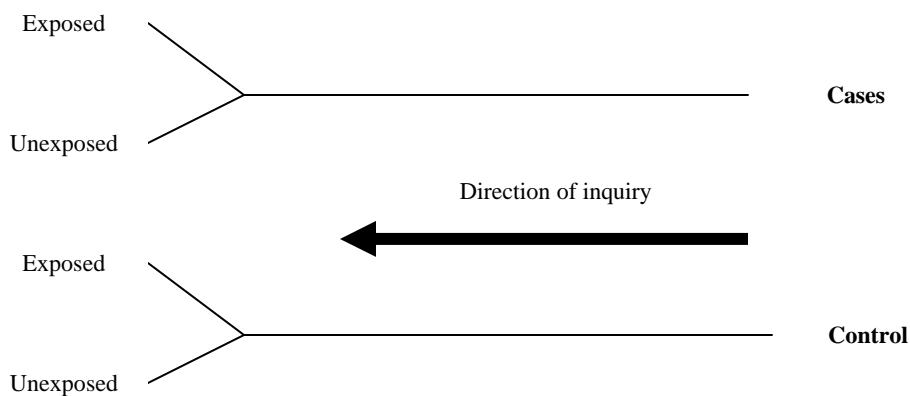


- Advantages of cohort studies
 - The only way of establishing incidence directly
 - Follow the same logic as clinical question: if person exposed, do they get the disease?
 - Exposure can be elicited without the bias
 - Can assess if the relationship between exposure and many diseases
 - Calculate risk directly: relative risk (RR)
- Strengths
 - Powerful design for defining incidence and investigating potential causes (aetiology questions)
 - Establishes temporal sequences
 - Appropriate for interventions where can't randomize
 - Investigator has opportunity to measure important variables completely (not relying on record information)

- Weaknesses
 - Expensive and inefficient for rare outcomes – needs more patients
 - May be other differences between group

10. Case control studies

- Analytic study design
 - Looking back in nature
 - We were not there to measure risk directly
 - Associate outcome (disease) with prior exposure
- Calculate indirect estimate of risk: odds ratio (OR)
- Compare the frequency of a risk factor in a group of cases and a group of controls
- There must be a comparison group that does not have the disease
- There must be enough people in the study so that chance does not play a large part in the observed results
- Groups must be comparable except for the factor of interest

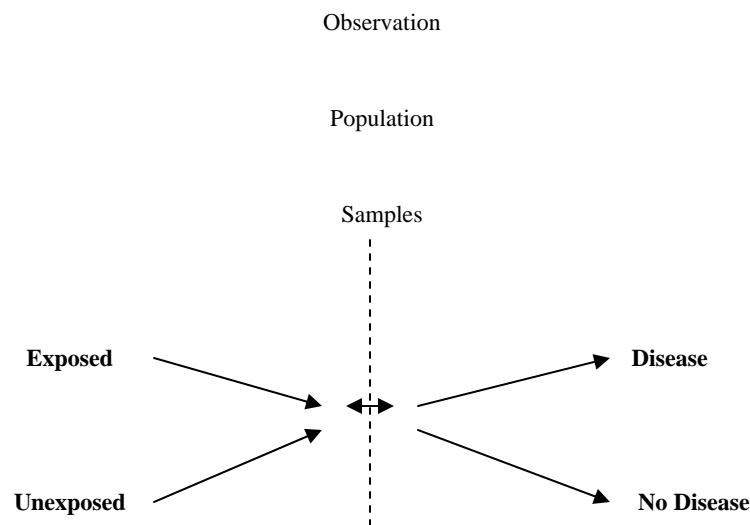


- Advantages of case-control studies
 - No need to wait for a long time for disease to occur (causal or prognostic factors)

- Most important methods used to study rare disease
- Best design for disease with long latent period
- Can evaluate multiple possible potential exposure
- Strengths
 - Very efficient design for rare outcomes
- Weaknesses
 - Does not allow for the examination of incidence or risk
 - Cannot directly calculate incidence: OR; and indirect estimate of risk.
 - Increased susceptible to bias in measurement of exposure
 - Exposure & disease occurred “prior to” the study
 - More potential for biases

11. Cross-sectional study

- Distinguish features
 - Observe at on particular time or over a period
 - Exposure and outcomes measured at the same time
 - Information obtained from the subjects only once



- Categories of cross-sectional study

- Descriptive
 - Prevalence studies
 - A point prevalence
 - Disease occurrence at the particular time
 - E.g. the point prevalence of upper respiratory tract infection on 1st of July 2005
 - A period prevalence
 - Disease occurrence at the particular period of time
 - E.g. the ten-year year period prevalence (1996-2005) of the cancer of breast in Malaysia.
- Analytical
 - Analytical studies is valid only when the current values of the exposure are extremely stable over time
 - Two types
 - Classical cross-sectional
 - Comparative cross-sectional study
 - A comparative way of conducting a cross-sectional study
 - Samples are drawn from two or more defined different populations
 - Measure exposure and outcome factors
 - Investigate the association between exposure and outcome
- Strengths of cross sectional studies
 - Very quick and inexpensive to implement
 - Useful for determining prevalence
 - Appropriate for diagnostic test validity
- Weaknesses
 - Difficulty in establishing links of causal effect (temporal relationship)

- Impractical for rare outcomes