Research Design

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Research design

• = the process in which the investigators determine how they can best answer their research questions

• Research problem
  Research design
  Data analysis
Methods of obtaining knowledge

Research Paradigms

Quantitative Paradigm:
Study of groups whose treatment is manipulated

Qualitative Paradigm:
Broad description of a phenomenon without manipulation

Single-system Paradigm:
Individual responses to manipulation
Is the left center circle bigger?
Do you see the three faces?
Study Designs

- Observational
- Experimental
Cohort

Case-series

Case-control

Cross-sectional
Case-series studies

• Simple description of interesting observations in a small number of subjects

• Generally not planned before

• Do not involve hypothesis

• Do not include control subjects
Case-series studies
Example

Case-series studies

• Advantage:
  - easy to write
  - useful in new observations or disease

• Disadvantage:
  - subject to bias related to subject selection
"We can’t find anything wrong with you, so we’re going to treat you for Symptom Deficit Disorder."
Case-control studies

- Start with the presence or absence of an outcome, and look back into the past to detect possible causes or risk factors.

**Cases** = individuals with disease or outcome

**Controls** = individuals without disease or outcome
Case-control studies

Example


**Cases** = 250 individuals with Bell’s palsy

- 27% vaccinated

**Controls** = 722 individuals without Bell’s palsy

- 1% vaccinated
Case-control studies

- Advantages:
  - can be easily performed (cheap & quick)
  - useful for rare diseases
  - allow the investigation of multiple risk factors

- Disadvantages:
  - recall bias
  - cannot establish cause-effect relationship
Cross-sectional studies

- Observational studies in which all the measurements are performed on a single occasion (no follow-up period)

- **Prevalence**: the proportion of the population who has the disease at one period of time
Cross-sectional studies
Example

Cross-sectional studies

• Advantages:
  ➢ can be easily performed (cheap & quick)
  ➢ no follow-up loss

• Disadvantages:
  ➢ not useful for rare disease
  ➢ cannot establish cause-effect relationship
Cohort studies

• Cohort = group of subjects that have something in common and are followed over time

• Prospective vs. Retrospective
Prospective cohort studies

• The researcher defines a sample of subjects and identifies certain risk factors (e.g., hypertension, diabetes) that may predict the subsequent outcome.
Prospective cohort studies
Example

• Purpose:

to examine factors associated with the development of cardiovascular disease
Prospective cohort studies

Example

1. **Assemble the cohort:** 6000 subjects from Framingham, Massachusetts in 1948

2. **Measure potential risk factors:** diabetes, hypertension, smoking, hypercholesterolemia

3. **Follow-up and measure outcomes:** the subjects were followed for 20 years to determine the occurrence of coronary artery disease
Prospective cohort studies

• Advantages:
  ➢ useful when experimental study cannot be conducted for ethical or practical reasons
  ➢ information on incidence
  ➢ variables are measured accurately

• Disadvantages:
  ➢ expensive and time consuming
  ➢ impractical for rare diseases
Retrospective cohort studies

- Starts with identifying a cohort, then collect data about predictor variables (which occurred in the past), then follow the subjects to determine the occurrence of the outcome

- Direction of inquiry is still forward in time
“Do I get partial credit for simply having the courage to get out of bed and face the world again today?”
Experimental Studies

Clinical Trials
Experimental group

Pre-test (baseline)

Control group

Post-test

No intervention

Sham
Randomization

- the way participants are allocated to the experimental or control groups
- To create groups that are as similar as possible
Randomization

• To ensure that the results are attributable to the intervention rather than to some other variable
  (e.g., age, socioeconomic status, disease duration)
Randomization

- Computer-generated numbers
- Stratification
Control

• Five types of control are common:

1. Control of the implementation of the independent variable:
   ➢ The investigator must have a rational to govern the implementation of the variable and a mechanism to monitor the implementation
1. Control of the implementation of the independent variable

• Problem: effect of heat on R.O.M of the low back The use of heat must be standardized:
  - Does heat mean hot pack, ultrasound, or other modality?
  - If hot pack, should all hot packs be the same size, or adjusted to the size of the patient?
  - If ultrasound, what is the duration and frequency? Area of application?
2. Control of subject selection

• **Inclusion / exclusion criteria**: for admission of subjects to the study
  – Example: age, gender, pain (chronic or acute)

• **Homogeneous sample**: tight selection criteria reducing the variability between subjects

• **Heterogeneous sample**: broad selection criteria increasing the variability between subjects
3. Control of extraneous variables

• **Extraneous** or *confounding* variables = factors that may influence the dependent variable (other than the independent variable)
  ➢ Example: temperature, time of the day for testing, lighting, learning effect

• You must rule out the effect of the confounding variables (related to the setting & subjects)
4. Control of information given to subjects & researchers

- **Incomplete information**: about the purpose of the study to control the effect of expectations (BUT be aware of ethics)

- **Subject blinding**: to withhold information about which of several treatments the patient is receiving

- **Researcher blinding**: to the treatment received by the patients, to control the effect of the researcher expectations
4. Control of information given to subjects & researchers

- **Single-blind study**: either the subject OR the researcher is blind to the treatment or group assignment

- **Double-blind study**: both subject and researcher are blind
5. Control of measurement

- Reliability
- Validity
All Evidence is not created equal!!
Hierarchy of Evidence

Meta-analysis of RCTs
Systematic review of RCTs

Individual RCT

Observational studies

Basic research

Clinical experience
THINK BIG!

start small

ACT NOW