Research Design

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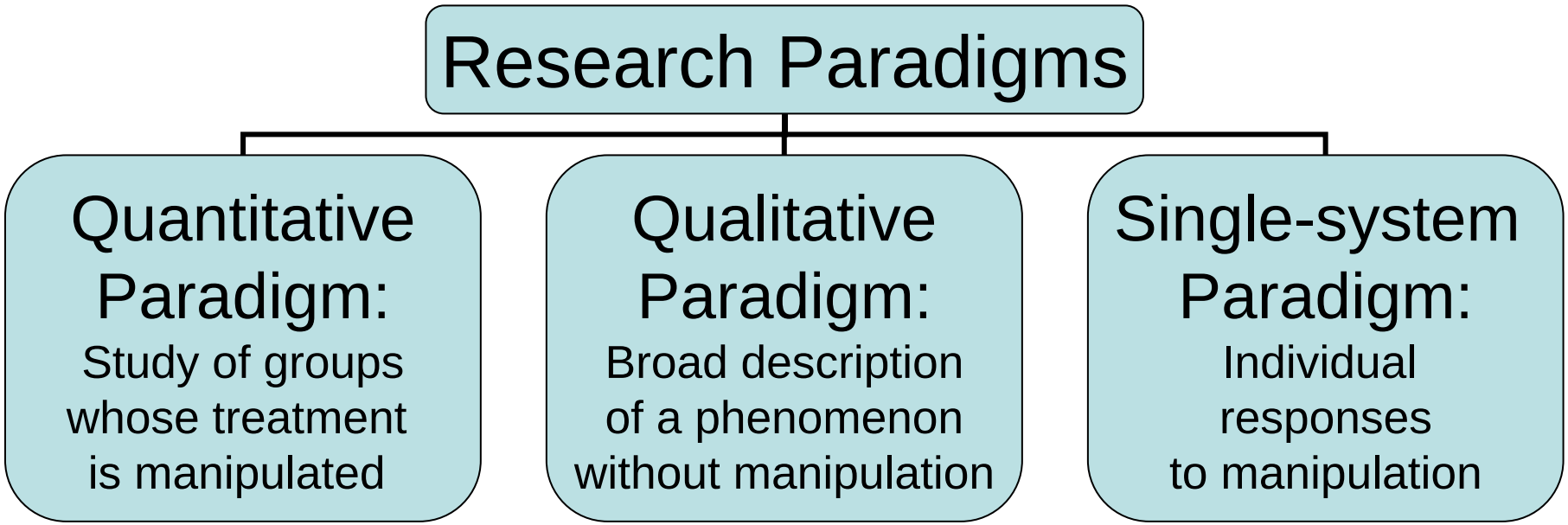
Research design

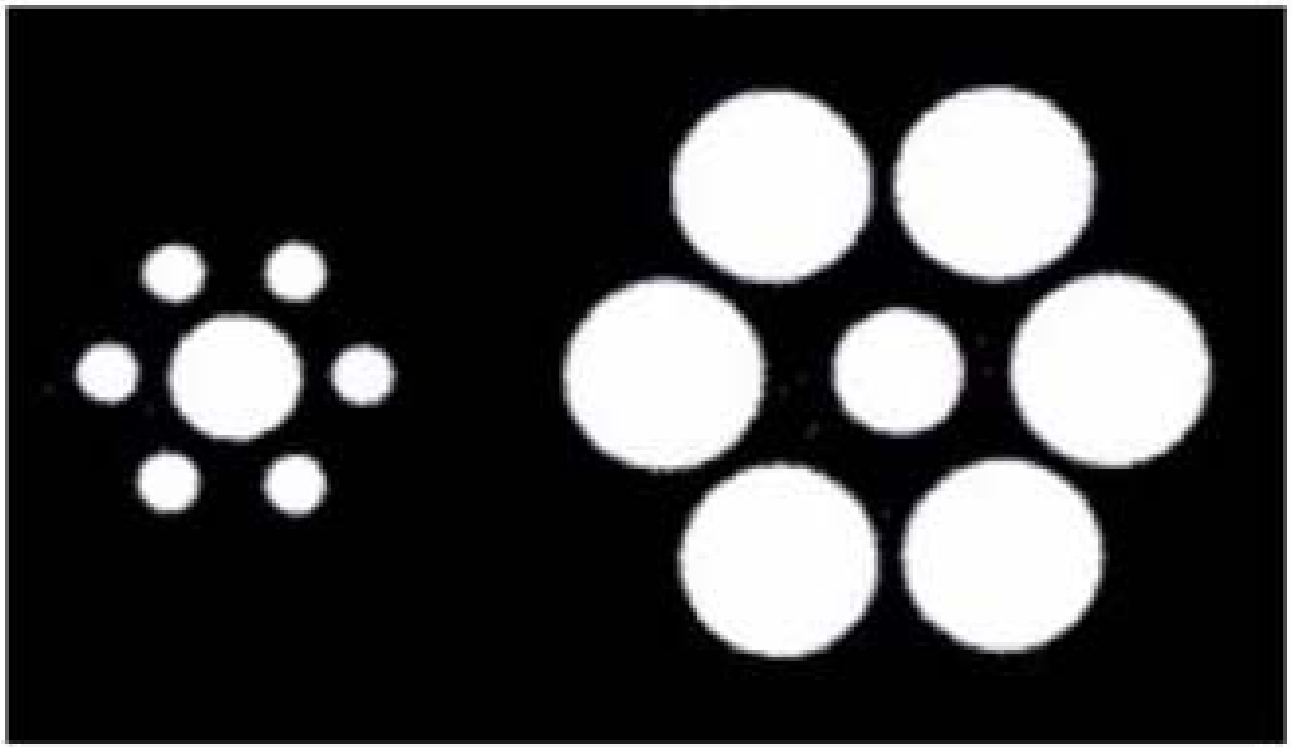
- = the process in which the investigators determine how they can best answer their research questions

- Research problem ⟶
  Research design ⟶
  Data analysis

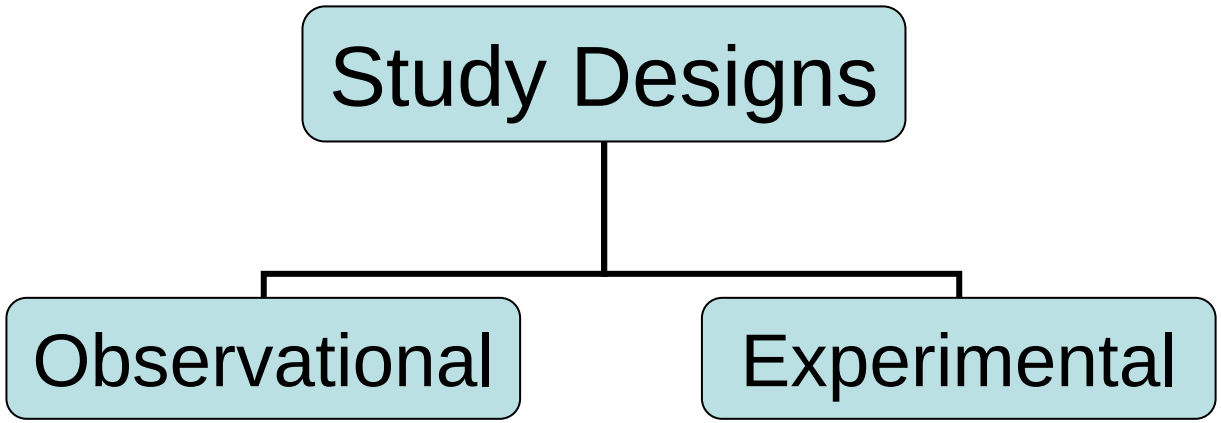
Methods of obtaining knowledge

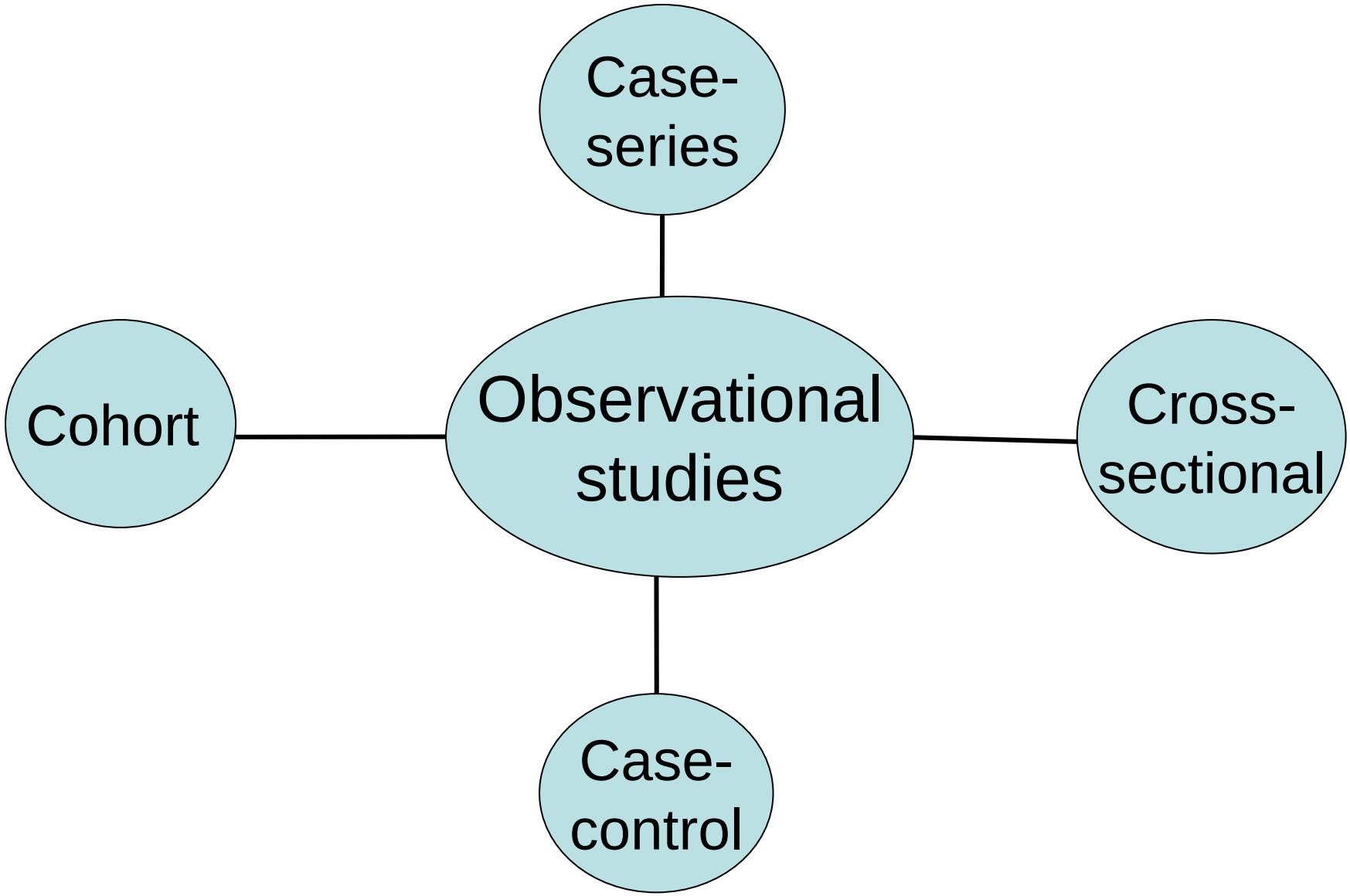


Is the left center circle bigger?



Do you see the three faces?


Study Designs
Observational
Experimental


Case-series
Cohort
Observational studies
Cross-sectional
Case-control

Case-series studies

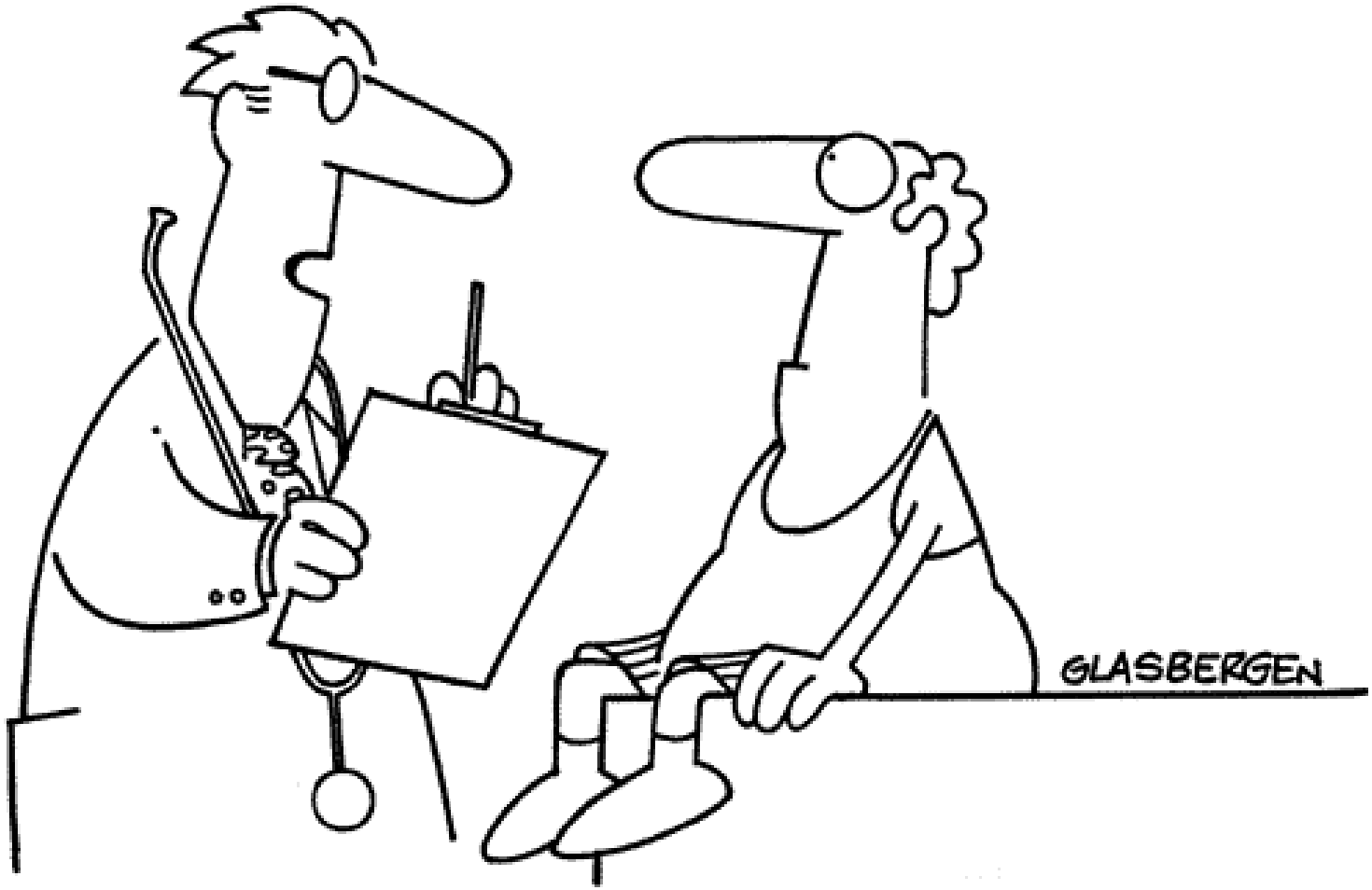
- Simple description of interesting observations in a small number of subjects
- Generally not planned before
- Do not involve hypothesis
- Do not include control subjects

Case-series studies
Example

Wong et al. (2003). Clinical presentation and outcome of severe acute respiratory syndrome in dialysis patients. **Am J Kidney Dis** ;42:1075-1081.

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

Mutsch et al. (2004). Use of the inactivated intranasal influenza vaccine and the risk of Bell's palsy in Switzerland. **N Engl J Med**; 350:896-903.

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
  - can not 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

Al-Eisa E, Egan D, & Wassersug R (2004). Fluctuating asymmetry and low back pain.

Evolution and Human Behavior; 25: 31-37.

Cross-sectional studies

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

- Disadvantages:
  - ➢ not useful for rare disease
  - ➢ can not 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, hypercholestremia

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

Prospective cohort studies

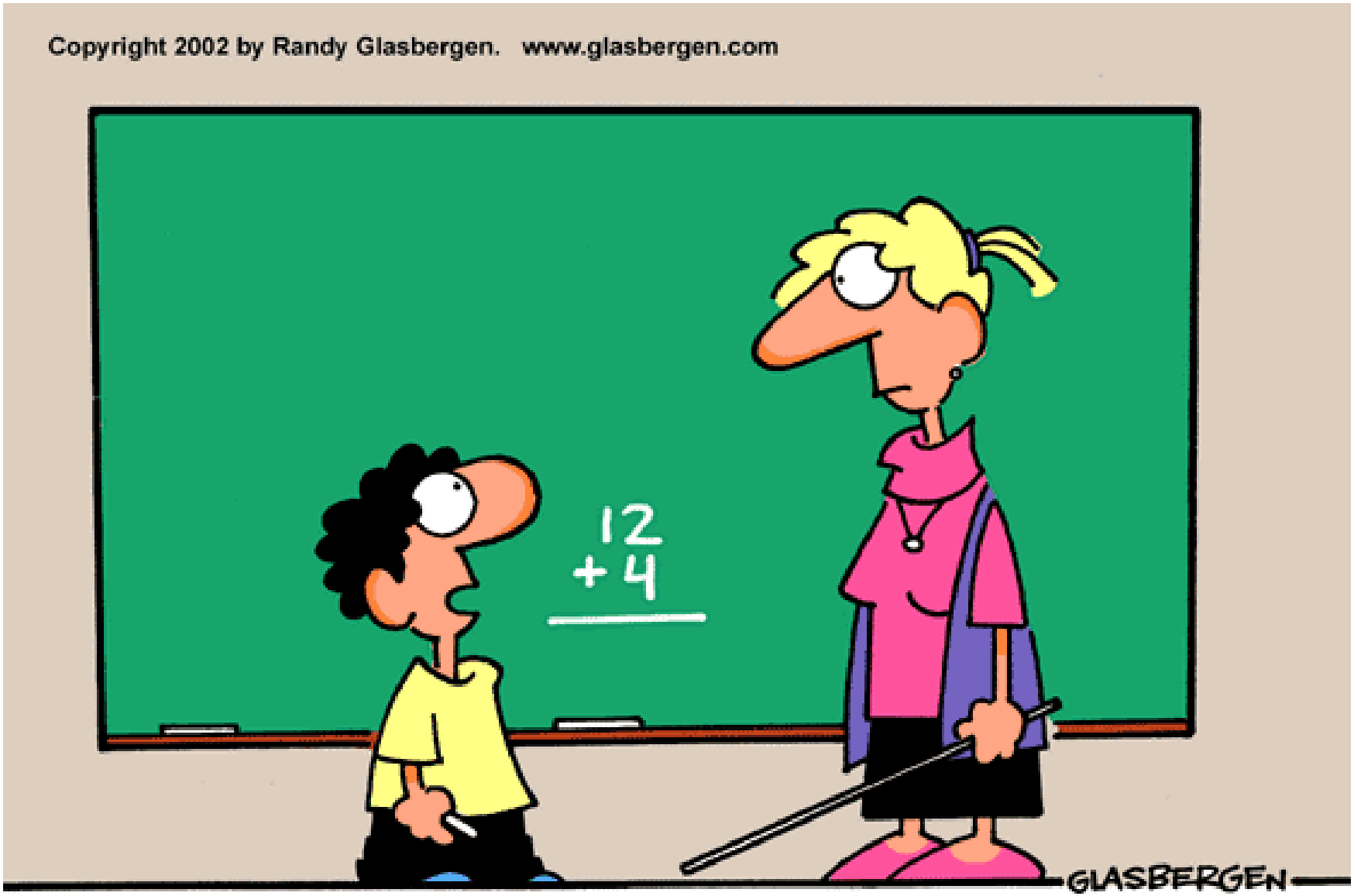
- Advantages:
  - useful when experimental study cannot be conducted for ethical or practical reasons
  - information on incidence
  - variables are measured accurately

- 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

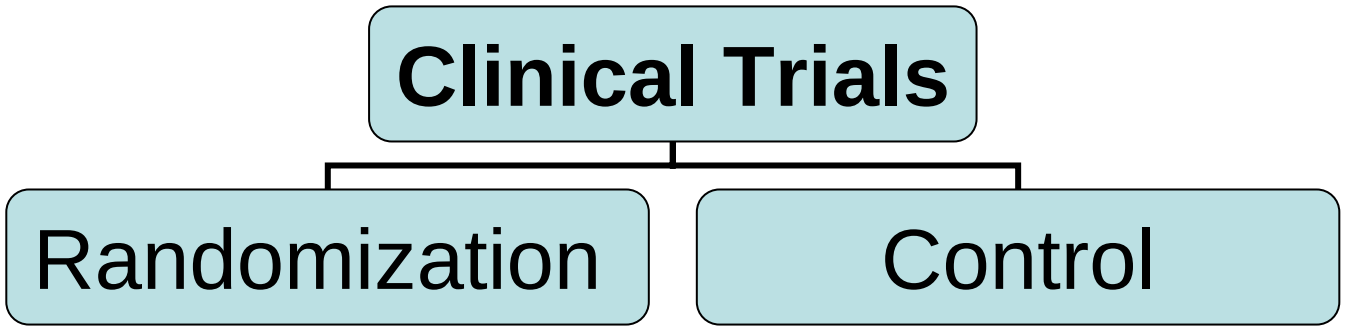
Pre-test
(baseline)

Experimental group

Control group

No intervention
Sham

Post-test


Clinical Trials
Randomization
Control

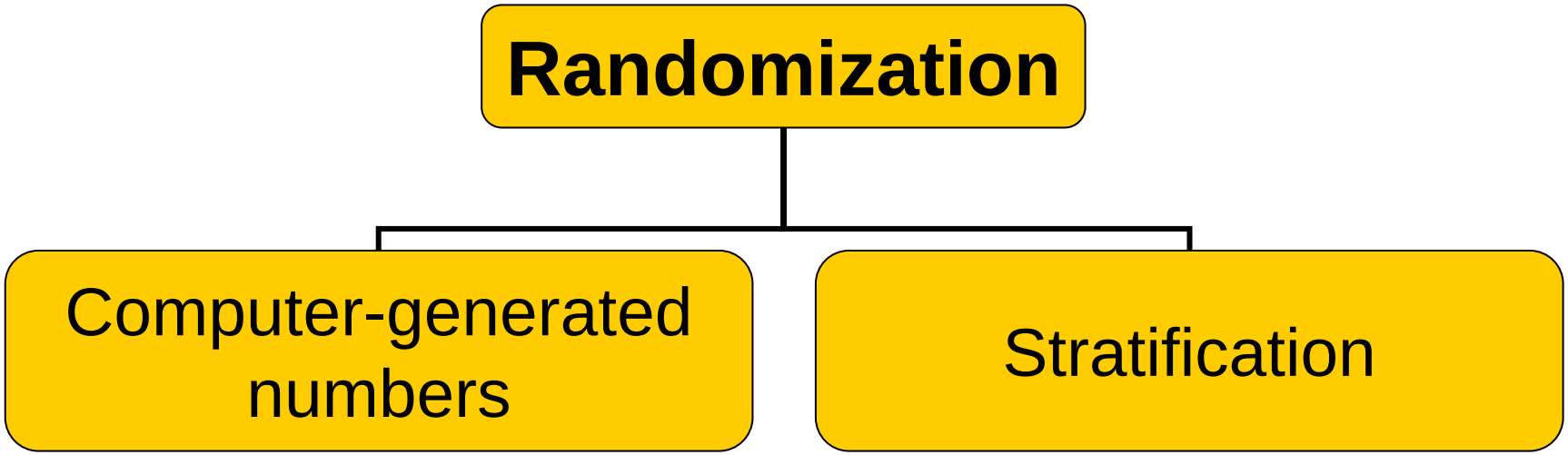
Randomization

- = 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

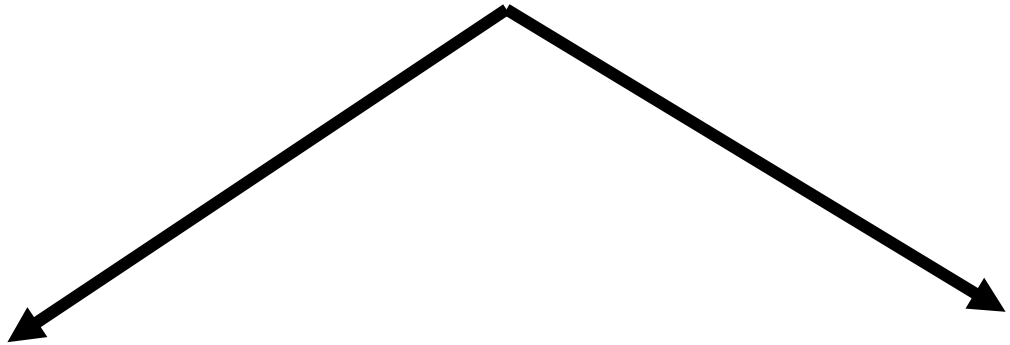
- **Researcher blinding**: to the treatment received by the patients, to control the effect of the researcher expectations

4. Control of information given to subjects & researchers

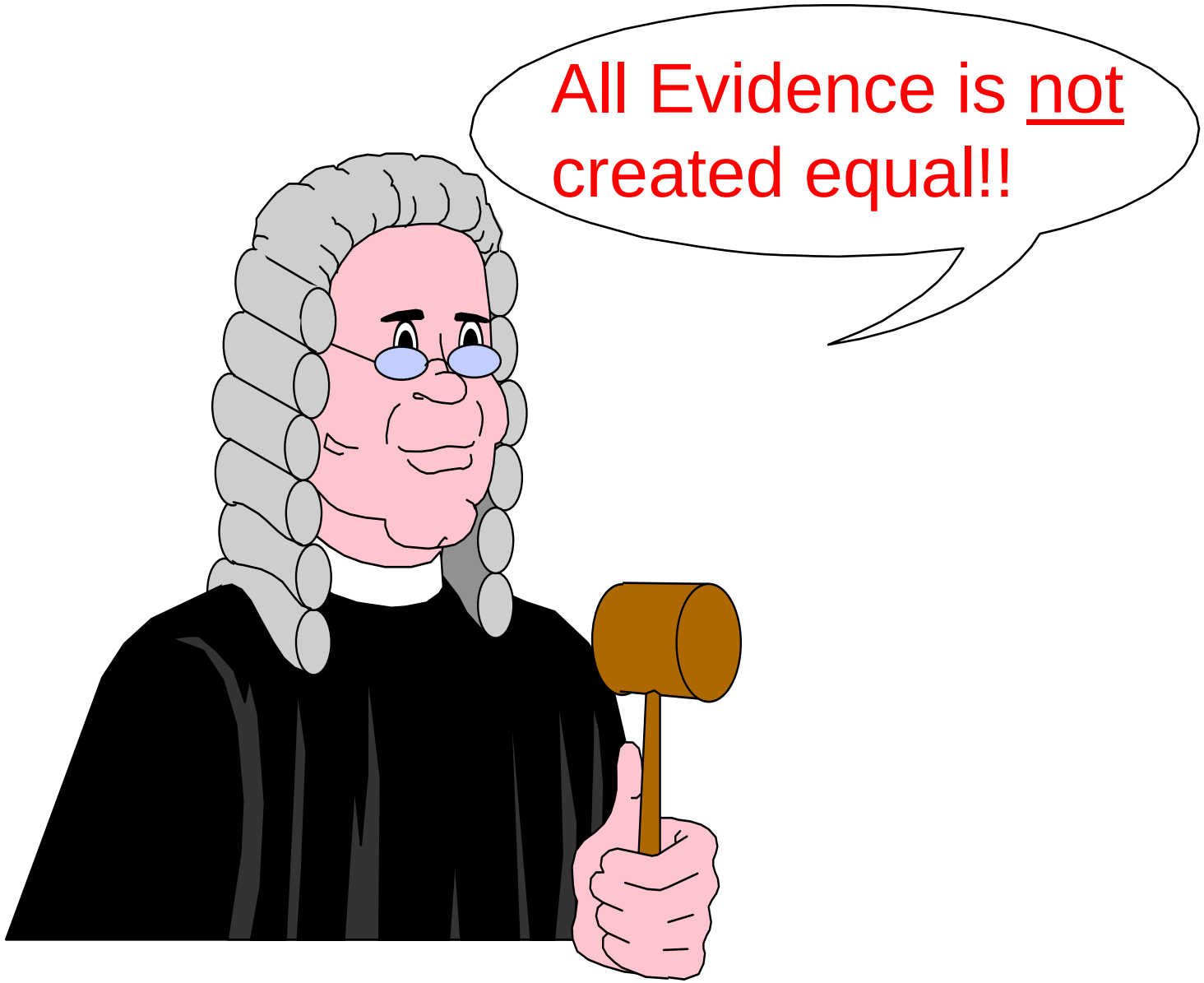
- **Single-blind study**: either the subject OR the researcher is blind to the treatment or group assignment

- **Double-blind study**: both subject and researcher are blind

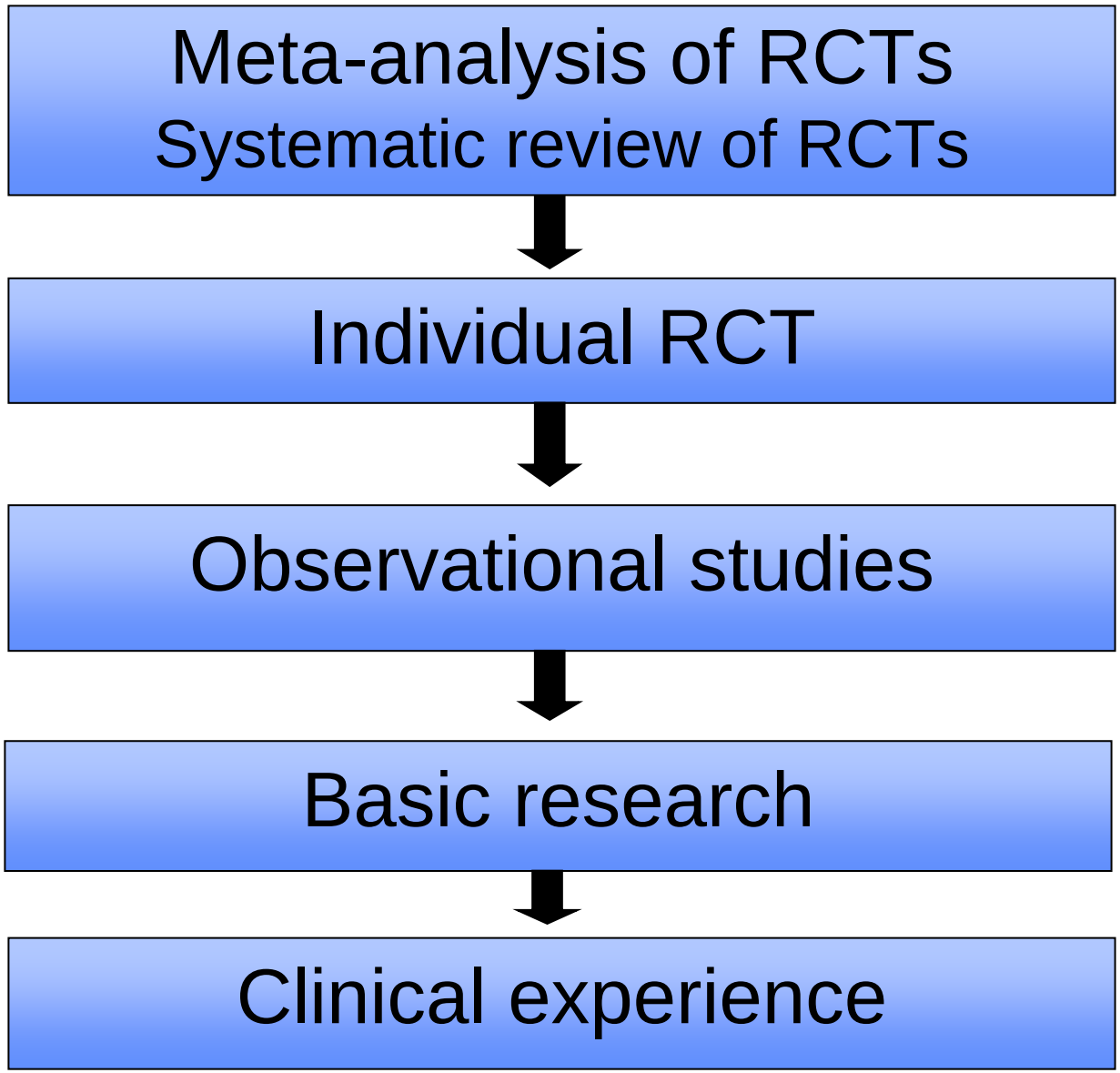
5. Control of measurement



Reliability **Validity**


All Evidence is not created equal!!

Hierarchy of Evidence



THINK BIG !

start small

ACT NOW