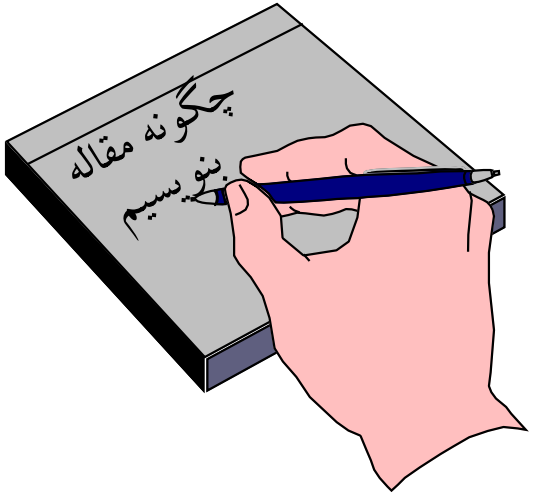
معاونت تحقیقات و فناوری
مرکز توسعه و هماهنگی پژوهش

دانشگاه علوم پزشکی و خدمات بهداشتی درمانی تبریز

چگونه مقاله بنویسیم؟



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Study Types

Aim of a studies

- To determine distribution of disease/condition

Descriptive Studies

- To test a hypothesis

Analytical Studies

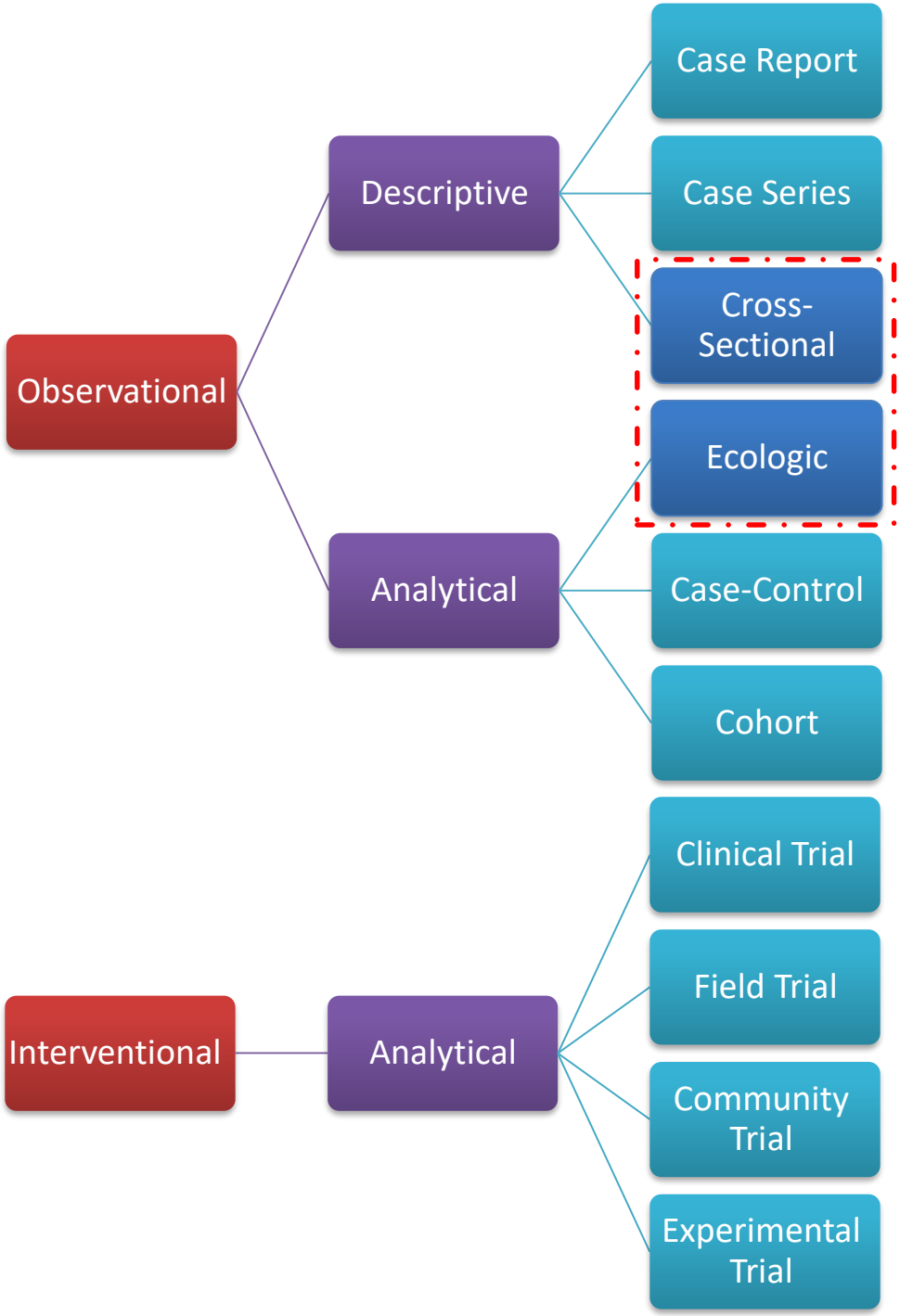
Descriptive studies

- Focus on person, place and time.
- Create Hypothesis

- Case reports and case series are examples of descriptive studies.

Analytical studies

- Test a hypothesis which has already been suggested
- Observational or interventional
- Case-control, Cohort and Clinical Trials are examples of analytical studies.


Observational
Descriptive
Case Report
Case Series
Cross-Sectional
Ecologic
Analytical
Case-Control
Cohort
Interventional
Analytical
Clinical Trial
Field Trial
Community Trial
Experimental Trial

The Hierarchy of Evidence

1. Systematic reviews & meta-analyses
2. Randomised controlled trials
3. Cohort studies
4. Case-control studies
5. Cross sectional surveys
6. Case reports
7. Expert opinion
8. Anecdotal

Case Reports and Case Series

- Describe the occurrence of new disease entities.
- Describe the outcome of patients with specific diseases.
- Allows for the description of outcomes associated with rare diseases.
- Formulate hypotheses

Limitations of Case Report & Case Series

- Impossible to determine disease frequency.

- Cannot establish causality between exposures or risk factors and disease or outcome.

Case reports

- Documentation:

In 1961, a published case report of a 40 year-old woman who developed pulmonary embolism after beginning use of oral contraceptive

Case Series

- Create hypothesis

In Los Angeles, five young homosexuals men, previously healthy, were diagnosed with pneumocyst cariini pneumonia in a 6-month period (80-81)

Cross-sectional studies

Cross-sectional studies

- Cross-Sectional Studies measure existing disease and current exposure levels.
- They provide some indication of the relationship between the disease and exposure or non-exposure
- Mostly prevalence studies/surveys

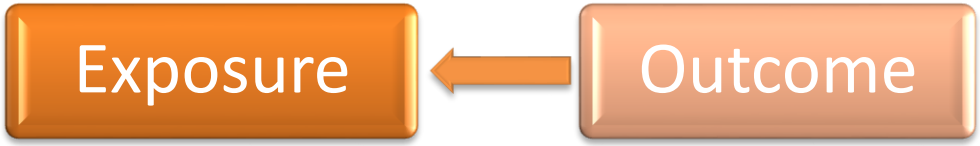
Cross Sectional Studies

- Good design for hypothesis generation
- Can estimate exposure proportions in the population
- Can study multiple exposures or multiple outcomes
- Relatively easy, quick and inexpensive
- Best suited to study permanent factors (breed, sex, blood-type)
- Often good first step for new study issue

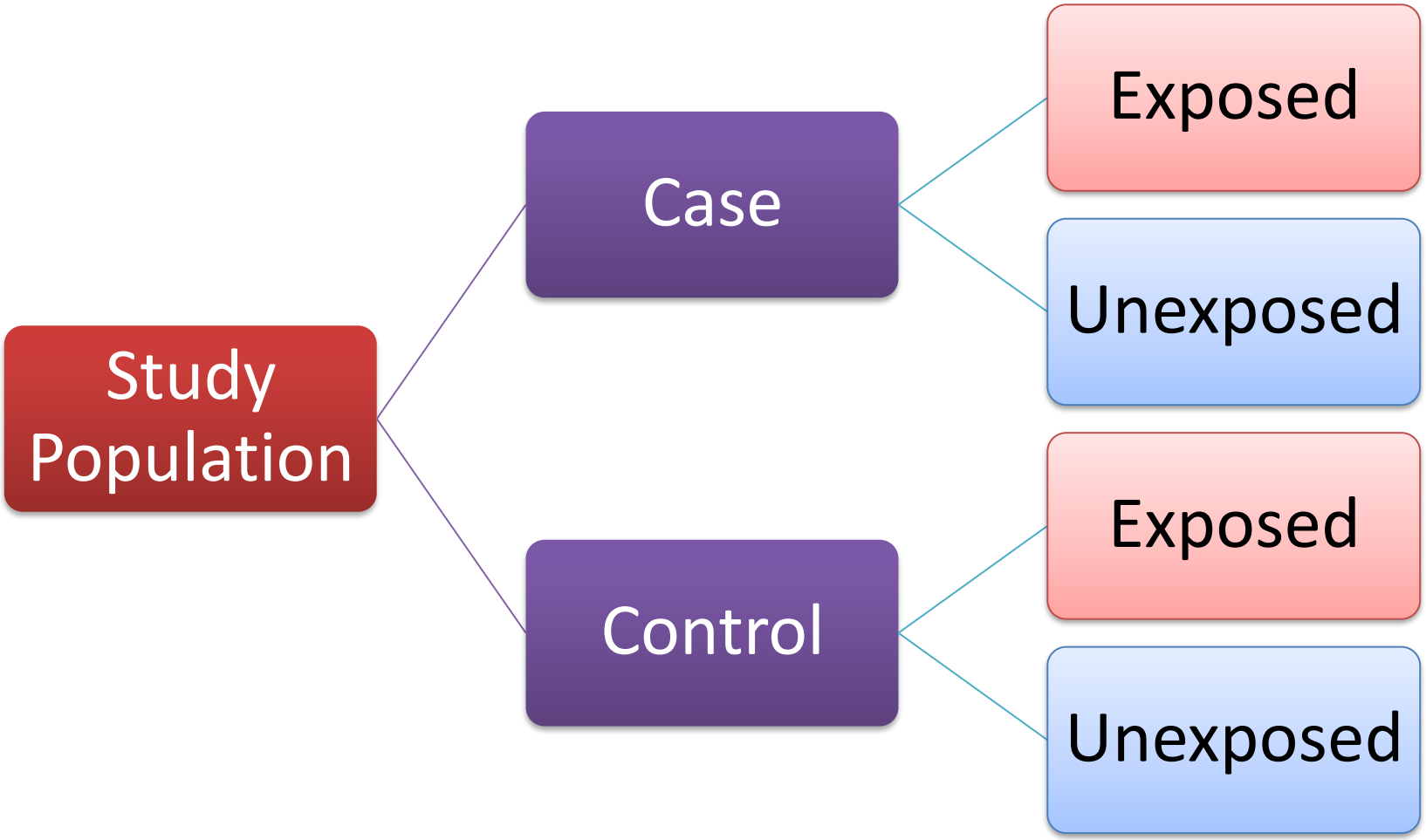
Cross Sectional Studies

- Impractical for rare diseases
- Problems with temporal sequence of data
- Not a useful type of study for establishing causal relationships
- Confounding is difficult to control
- hard to decide when disease was actually acquired
- miss diseases still in latent period
- recall of previous exposure may be faulty

Case-control studies


Exposure
Outcome

Case-Control



Steps

- Hypothesis definition
- Selection of cases and controls
- Exposure measurement
- Analysis & interpretation

Special features of case control study

- Studying diseases with long latency
- Efficient in time and cost
- Suitable for rare diseases
- Wide range of potential exposure

Selection of cases

- Sources of cases
  - Population
  - Hospital
  - Registry

- Are the cases representative of total population or a fraction of it?

case definition

- Strict diagnostic criteria
- Homogenous or heterogeneous?
- Where, when and whom?
- Hospital versus population
- Incident versus prevalent (survival factors)

Types of controls

- Sources of controls

  Population case → Population control

  Hospital case → Hospital control

- Hospital controls: Patients with mixture of diagnosis are usually used as controls
- Dead controls
- Similar disease as controls
- Friend or neighbor controls
- Population controls

Selection of matched controls

- Increased power efficiency
- Matching variable can not be investigated as a possible risk factor
- Overmatching (Many variables, wrong variable)
- Difficult to find suitable matches

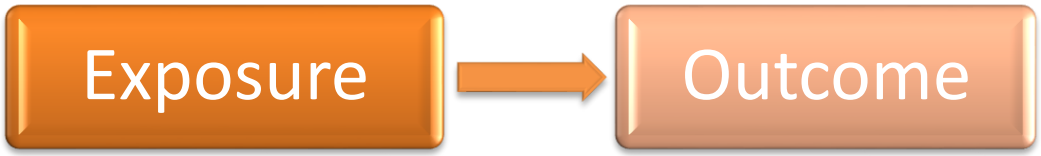
➢ Frequency and individual matching

Matched design ⟶ Matched analysis

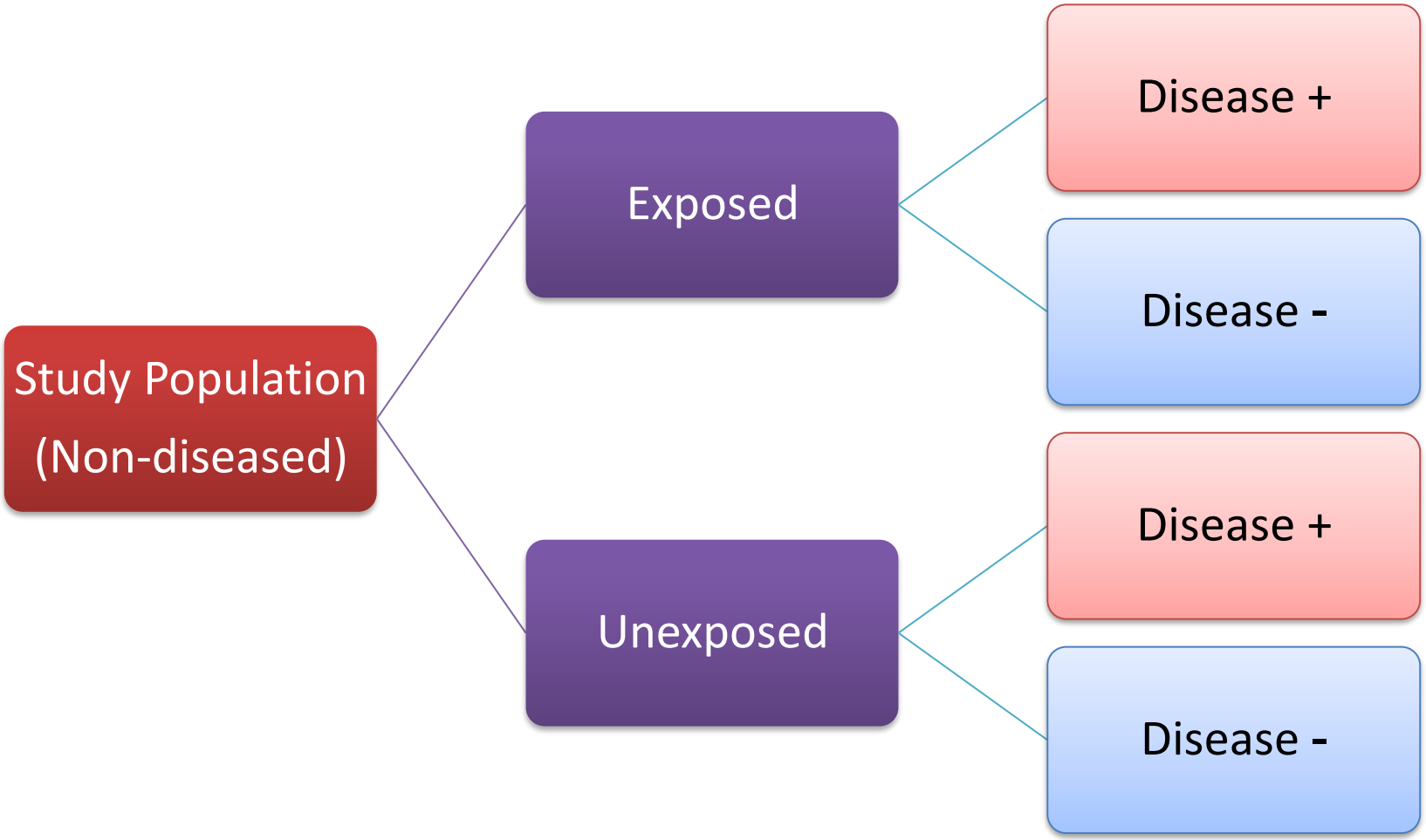
Measures of exposure

- Intensity (level or frequency)
- Duration
- Dose
- Average exposure
- Time since first
- Time since last

Cohort studies


Exposure
Outcome

Cohort


Study Population
(Non-diseased)
Exposed
Unexposed
Disease +
Disease -
Disease +
Disease -

Steps

- Hypothesis definition
- Selection of exposed and unexposed
- Follow-up and outcome measurement
- Analysis & interpretation

Selection of the Exposed Population

- Sample of the general population:
  - Geographically area, special age groups, birth cohorts
- A group that is easy to identify:
  - Nurses health study
- Special population (often occupational epidemiology):
  - Rare and special exposure

Selection of the Comparison Population

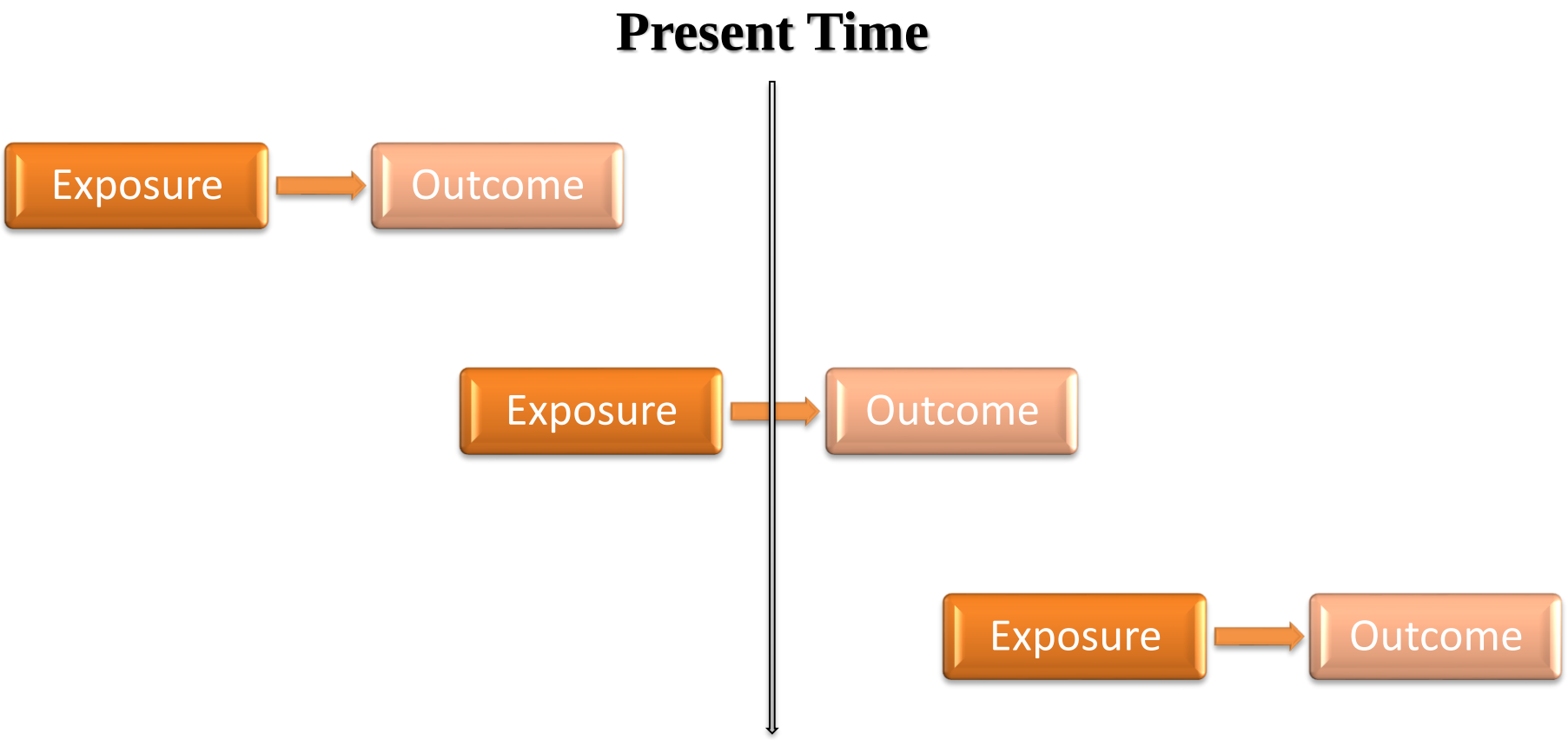
- **Internal Control Group**
  - Exposed and non-exposed in the same Study population (Framingham study, Nurses health study)
    - Minimise the differences between exposed and non-exposed
- **External Control Group**
  - Chosen in another group, another cohort (Occupational epidemiology: Asbestosis vs. cotton workers)
- **The General Population**

You follow the participants to define:

- The occurrence of outcome
- Loss to Follow-up

- Define the outcome
- Define “loss”

Cohort


Present Time
Exposure
Outcome
Exposure
Outcome
Exposure
Outcome

Prospective vs. retrospective Cohort Studies

Prospective Cohort Studies

- Time consuming, expensive
- More valid information on exposure
- Measurements on potential confounders

Retrospective Cohort Studies

- Quick, cheap
- Appropriate to examine outcome with long latency periods
- Difficult to obtain information of exposure
- Risk of confounding

Ecological studies

Ecological Studies

- Use populations as units of analysis
- Correlation (multiple populations)
- Comparison (two populations)

- *Populations can be countries, provinces, counties, schools, etc.*

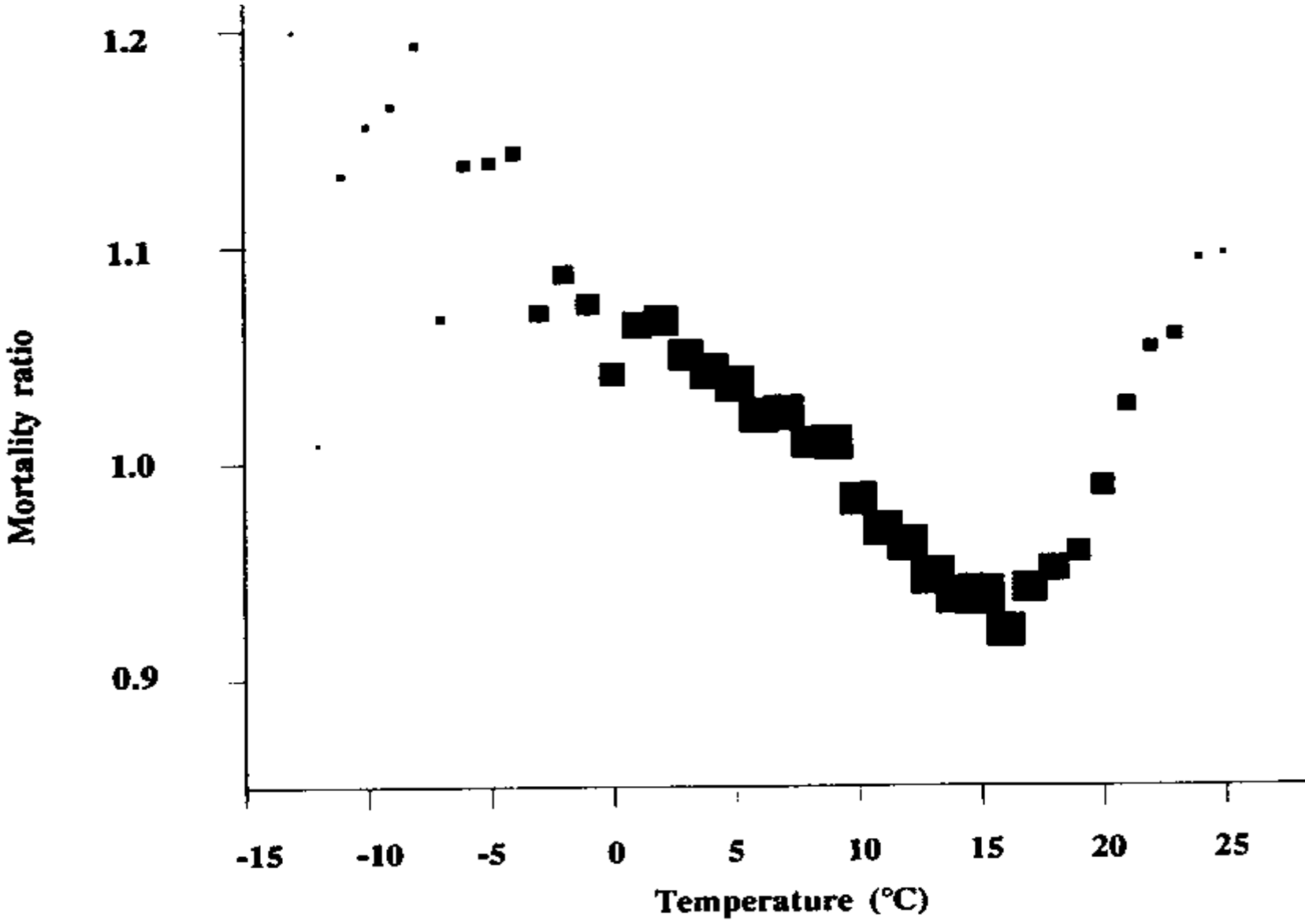
- Ecological study– focus on
  - characteristics of population groups
  - rather than their individual members.

- The unit of analysis
  - not an individual
  - but a group: defined by
    - time (calendar period, birth cohort)
    - geography (country, province, or city)
    - social-demographic characteristics (e.g. ethnicity, religion, or socio-economic status)
- Provide the first look of relations for hypothesis generation

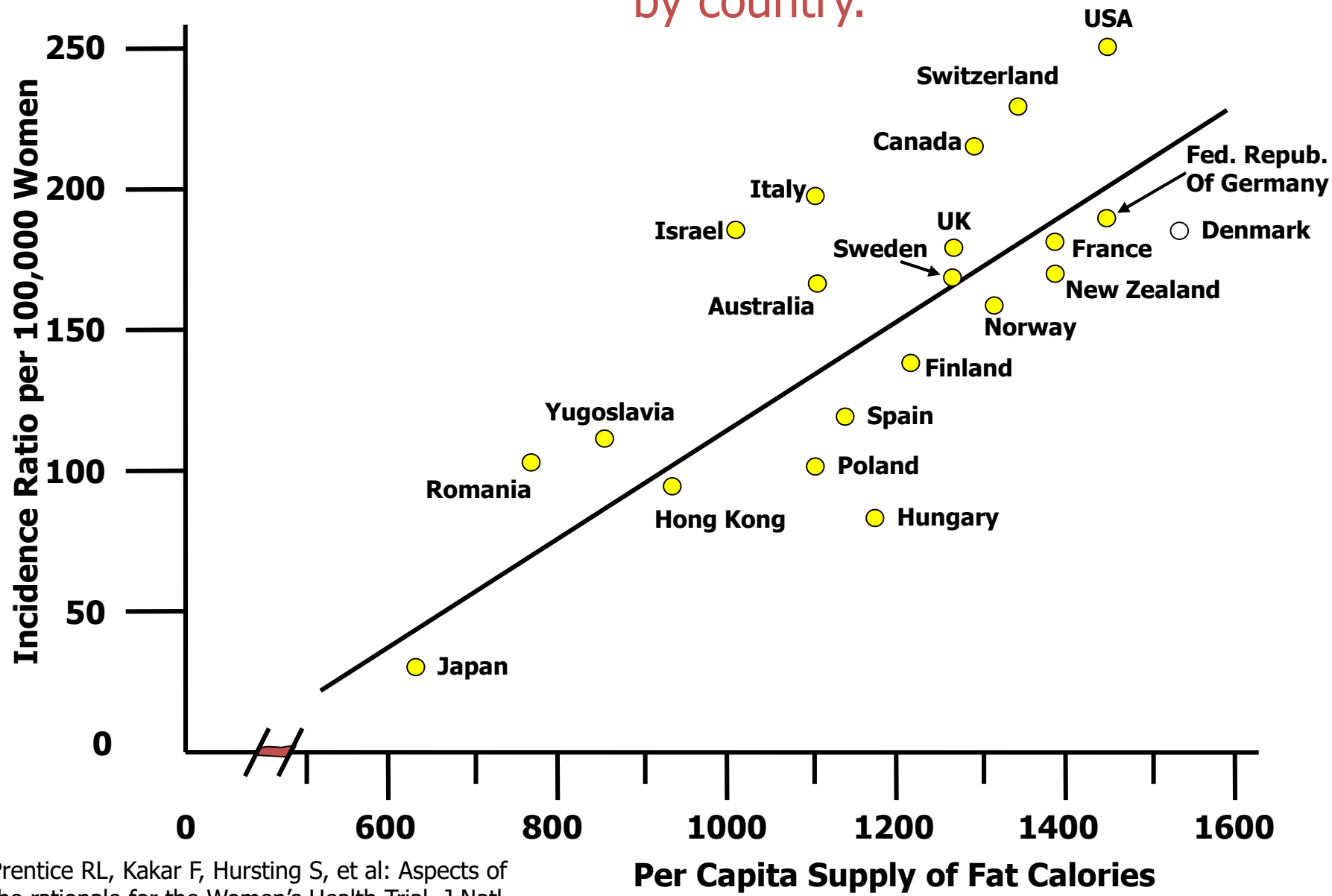
Ecologic studies

- Cannot link factor and a disease at the level of the individual
- Other factors may account for differences in disease rates
- Relationships which occur when groups used as units of analysis may not exist when individuals are used as units of analysis

Daily mortality vs. outside temperature



Correlation between dietary fat intake and breast cancer by country.



Prentice RL, Kakar F, Hursting S, et al: Aspects of the rationale for the Women's Health Trial. J Natl Cancer Inst 80:802-814, 1988.)

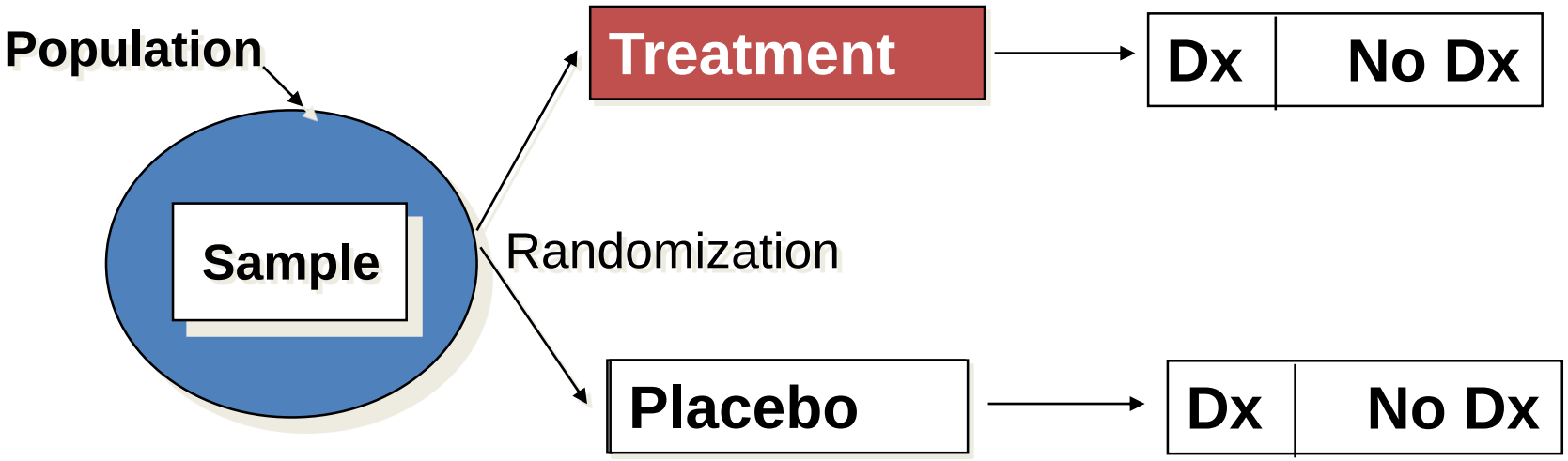
ECOLOGICAL FALLACY

- “Ecological fallacy”, “ecological bias”, “cross-level bias”

- “Failure of ecological level associations to properly reflect individual level associations”

Randomized Clinical Trials

Basic Trial Design



Steps in a randomized controlled trial

1. Select participants
2. Measure baseline variables
3. Randomize
   - Eliminates baseline confounding
   - Types (simple, stratified, block)

Steps in a randomized controlled trial

4. Blinding the intervention
   - As important as randomization
5. Follow subjects
6. Measure outcome
   - Clinically important measures
   - Adverse events

Samples

- Randomization is the key
- Allocation is at random, not sampling
- Simple versus systematic Randomization

considerations

- Strict inclusion and exclusion criteria (impact on generalisability)
- Ethical considerations
- Technical considerations

Title and Abstract

- How participants were allocated to interventions (eg, “random allocation,” “randomized,” or “randomly assigned”).

Methods

- Eligibility criteria for participants
- settings and locations
- Precise details of the interventions
- Specific objectives and hypotheses
- Clearly defined primary and secondary outcome measures
- methods used to enhance the quality of measurements
- How sample size was determined

Also …

- Method of Randomization
- Method of Concealment
- Method of Implementation
- Level of blinding
- Participant flow

Select study design to match the research goals

Objective	Design
Description of disease	Case series or report
	Cross-Sectional study
Evaluate a new diagnostic test	Cross-Sectional study
Describe prognosis	Cohort study
Determine cause-effect	Cohort study
	Case-Control study
Compare new interventions	Randomized Clinical Trial
Summarize literature	Systematic review