انتخاب روش تحقیق

محسن ویژه
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Research methods

- ✓ Independent variables are presumed to be the cause of changing in dependent variables (salt on blood pressure).
- ✓ We are doing research to find it!
- ✓ randomized (anyone of population can be included) sampling permit the use of inferential statistics, while non-randomized sampling just use for descriptive statistics.
- ✓ Random sampling trend to be representative
- ✓ Bias: consistently errs in a particular direction (unrepresentative)

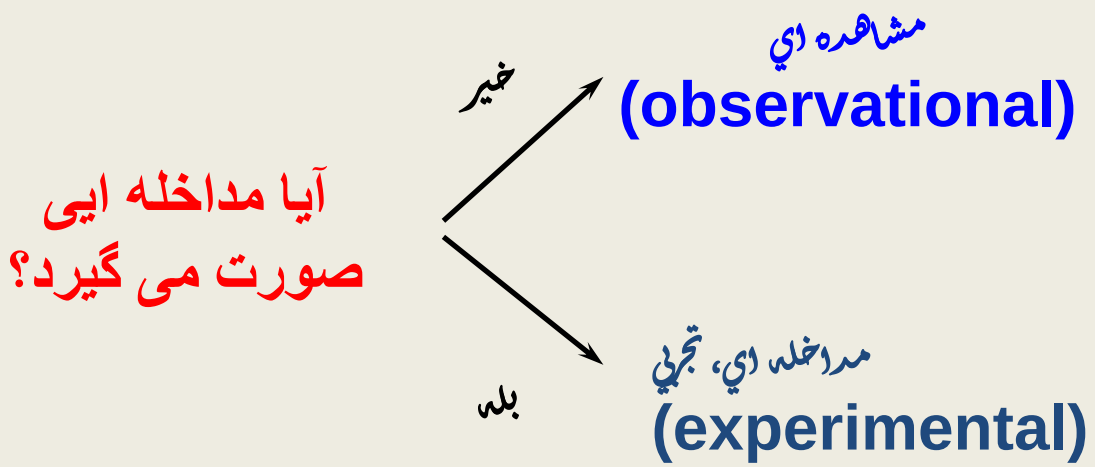
قدم اول

- ✓ جمعیت هدف
  - مثال: تمام جامعه،گروه سنی، جنسی، و یا نژادی خاص
- ✓ مطالعه در چه محدوده جغرافیایی انجام می شود؟
  - مثال: بیمارستان، شهر، روستا، تمام کشور
- ✓ زمان انجام مطالعه
  - آیا در این زمینه مطالعه ای در ۱۰ سال قبل انجام شده؟
  - اگر مدت مطالعه طولانی شود، نتیجه مطالعه چگونه تفسیر خواهد شد؟
- ✓ با انجام این مطالعه، چه شاخصی بدست می آید؟
  - مثال: اثر بخشی، شیوع یا بروز؟
- ✓ تا کنون چه روش مطالعه ایی در این زمینه بکار گرفته شده است؟
  - مثال: مورد-شاهد، مقطعی

The Most valuable evidence

1. Evidence syntheses:
   A) Systemic reviewer
   B) Meta-analysis
2. Experimental data
   A) Randomized controlled trials
   B) Non-randomized controlled trials
3. Non-experimental data
   A) Cohort
   B) Case-control
   C) Cross-sectional
   D) Case series
   E) Case report
   F) Expert opinion

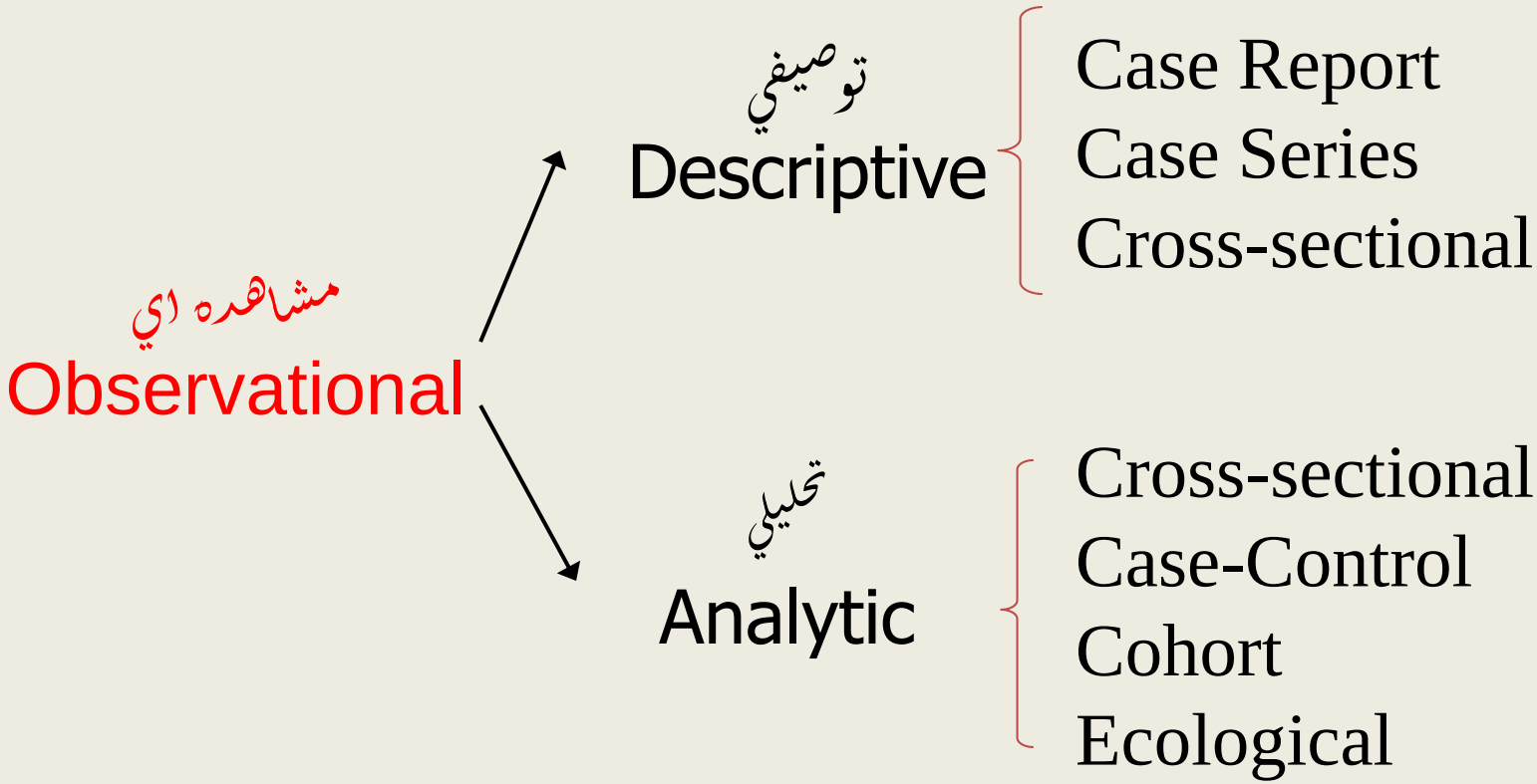
کلیات انواع مطالعات



- case series
- cross-sectional
- case-control
- cohort

- RCT & NRCT
- basic science

مطالعات مشاهده اي



Observational study

- ✓ Descriptive studies (exploratory studies):
  - Place, time, and people
  - Increase our knowledge about present situation
  - Low cost and short time needed
  - Case report: single clinical subject
  - Case series: group clinical subject
- ✓ Analytic studies: aim to test a hypothesis or provide explanation about a disease
  - Cross-sectional (prevalence study): particular point of time
  - Case-control: disease vs non-disease, retrospective
  - Cohort: group follow over time, prospective

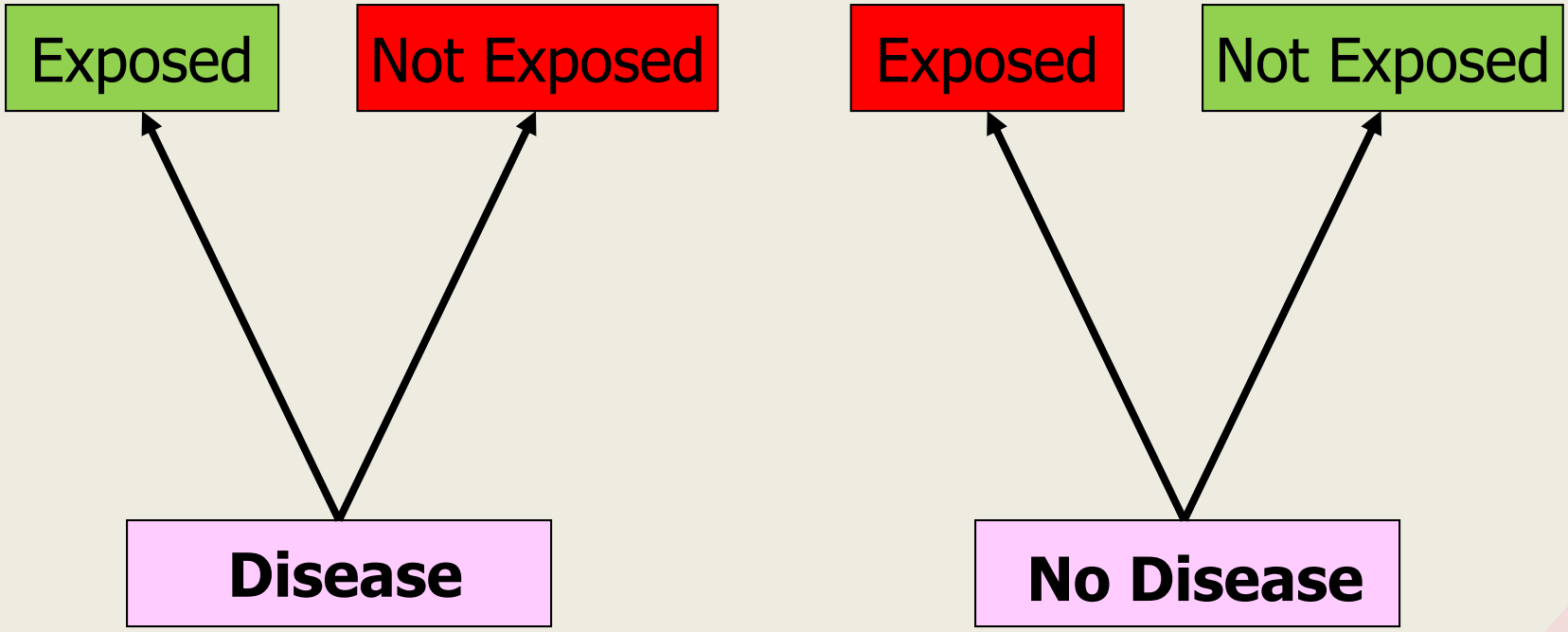
Cross-sectional study

- ✓ Scanning the current situation
- ✓ May show **correlation**, not causality
- ✓ **Over represent** chronic diseases
- ✓ **Underestimate** acute diseases
  - Unusable for acute conditions
- ✓ Some patient may not available for survey
- ✓ **Prevalence**

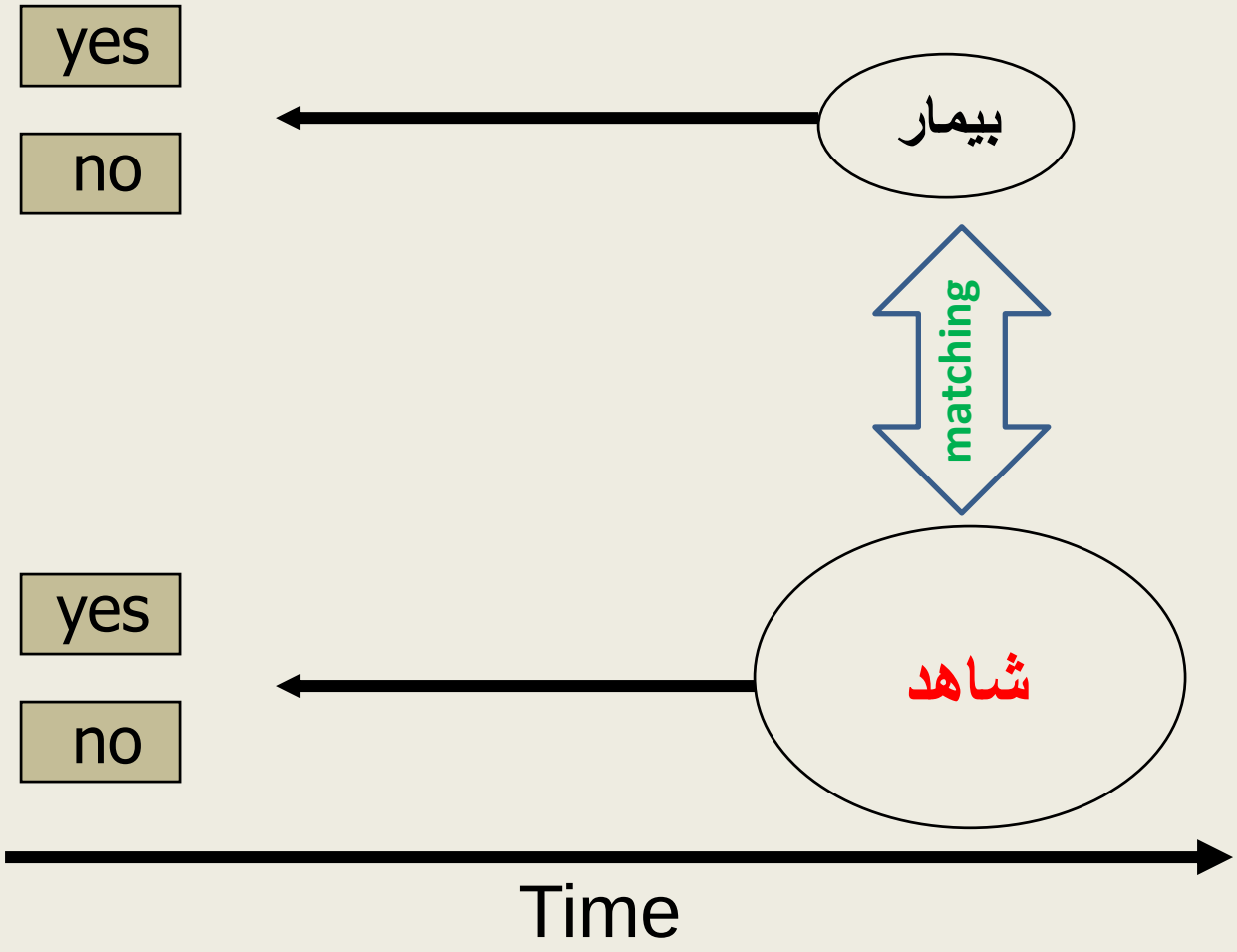
Case-control study

- ✓ People who have vs who have not a particular disease
- ✓ For rare diseases
- ✓ Like historical cohort but start with outcome (disease)
- ✓ Undiagnosed or asymptomatic case are missed

مطالعه مورد-شاهدي (Case-Control)



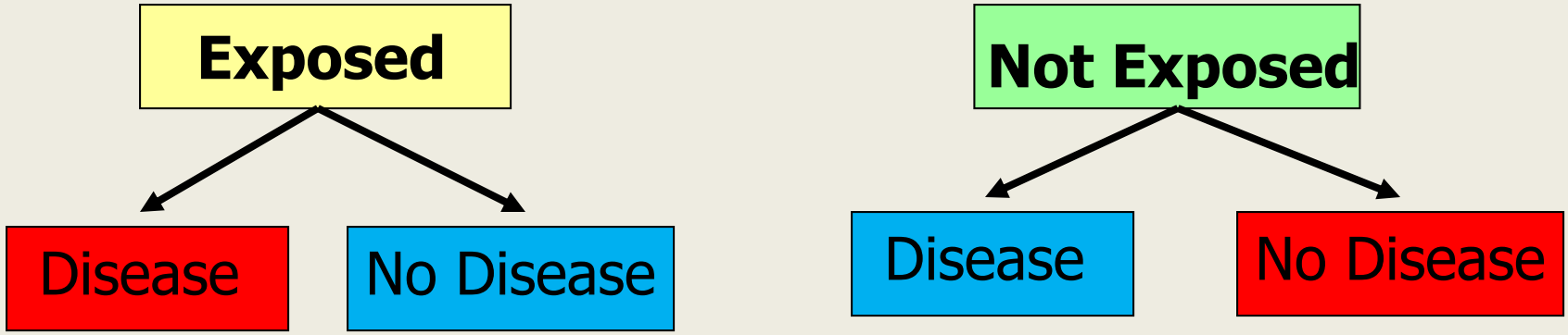
مطالعه مورد - شاهدي (Case-Control)



Cohort (longitudinal) study

- ✓ Natural history of a disease
- ✓ From exposure to disease (allocation)
- ✓ Good for high incidence diseases (or high risk groups)
- ✓ Calculate:
  - Incidence
  - relative risk (I_e/I_u): how much more likely?
  - attributable risk (I_e-I_u): how many more cases?
- ✓ Unbiased by outcomes
- ✓ Disadvantage
  - loss follow-up
  - take a long time to appear diseases
  - expensive
- ✓ Histological or retrospective cohort

مطالعه هم گروهي



جمع بندی مطالعات همگروهی

- مطالعه همگروهی از **مطالعات قوی** مشاهده ای تحلیلی است
- صرف **وقت و هزینه زیادی** دارند
- این نوع مطالعه برای بررسی **چندین پیامد ناشی از یک مواجهه** مناسب است
- **همسان سازی** در مطالعات همگروهی قابل انجام است ولی به اندازه ای مطالعات مورد شاهدی ضرورت ندارد
- مطالعات همگروهی برای بررسی **مواجهات** نادر مناسب هستند.

Comparison among observational study

Characteristics	Cross-sectional	Case-control	Cohort
Time	One simple point	Retrospective	Prospective
Incidence	No	No	Yes
Prevalence	Yes	No	No
Causality	No	Yes	Yes
Associations	Risk factor of disease	Begin with disease	End with disease
Data analysis	Chi-square	Odds ratios	Relative risk

Case-control vs cohort study

Case-control study	Cohort study
Small number of subjects	Large number of subjects
Lower cost	Higher cost
Short time period	Long time period
One disease Multiple past exposure	One exposure Multiple outcomes
For low prevalence disease	For high prevalence diseases
Major source of bias: recall	Major source of bias: selection

Randomization for RTC

- ✓ Simple
- ✓ Systemic
- ✓ Matching
  - Each patient in the experimental group is paired with a person in the control group
  - Not matched variable can be a confounder!
- ✓ Stratified randomization:
  - Combination of randomization and matching
  - Divided to subgroups
  - Internally homogeneous
  - Randomly allocated to experimental and control groups

Restriction

- ✓ Participants form certain characteristics (i.,e. gender, race)
- ✓ Enrollment ➪ Allocation ➪ Follow-up ➪ Analysis
- ✓ Loss of sample ➪ loss of statistical power
- ✓ Lost cases may have worse outcomes

Control groups

1. No-treatment group: nonspecific placebo effect
2. A placebo control group (should be double-blind, prevent detection bias)
3. Partially controlled: no-treatment control group that receive other source of helps!

- ✓ Control group should exactly match (as much as possible!) with the experimental group, except, they do not receive the treatment
- ✓ Eliminate alternative explanations for a study's results
- ✓ Confounder: factors other than the experimental treatment and not constant across the two groups. Decreased by randomization, matching, stratification, and restriction

Clinical trial phases

- ✓ Phase I: small number (n=100) of healthy volunteers (investigate; safety, side effects, and bio-kinetic)
- ✓ Phase II: lager number (n=1000) patients, control group, clinical effects on the conditions and the treatment's short-term side effects and safety
- ✓ Phase III: controlled trial with larger numbers of patients (multicenter studies), efficacy and safety
- ✓ Phase IV or Post-marketing survey: gathering data about a particular medication that is already in market

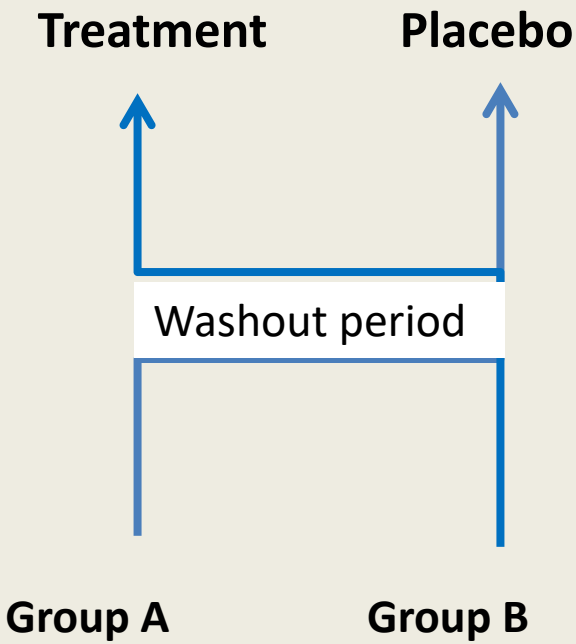
جمع بندی مطالعات مداخله ای

- ✓ تخصیص در هر گروه **تصادفی** است
- ✓ درصورتیکه تخصیص تصادفی بدستی انجام شده باشد و حجم نمونه نیز باندازه کافی بزرگ باشد، دو گروه مورد مطالعه تقریبا از بابت عوامل مخدوش کننده شناخته شده و ناشناس همسان خواهند بود
- ✓ **قویترین** مطالعات جهت بررسی رابطه علت و معلولی

Research ethics & safety

- ✓ Participants' autonomy
- ✓ Protect vulnerable people
- ✓ Benefits are maximized
- ✓ Potential harms minimized
- ✓ Informed consent: give sufficient and understandable information
- ✓ Waiting list control: receive treatment after cases

Crossover study (within-subjects)



- ✓ Ecological study: data is collected about whole population and is analyzed at that level.