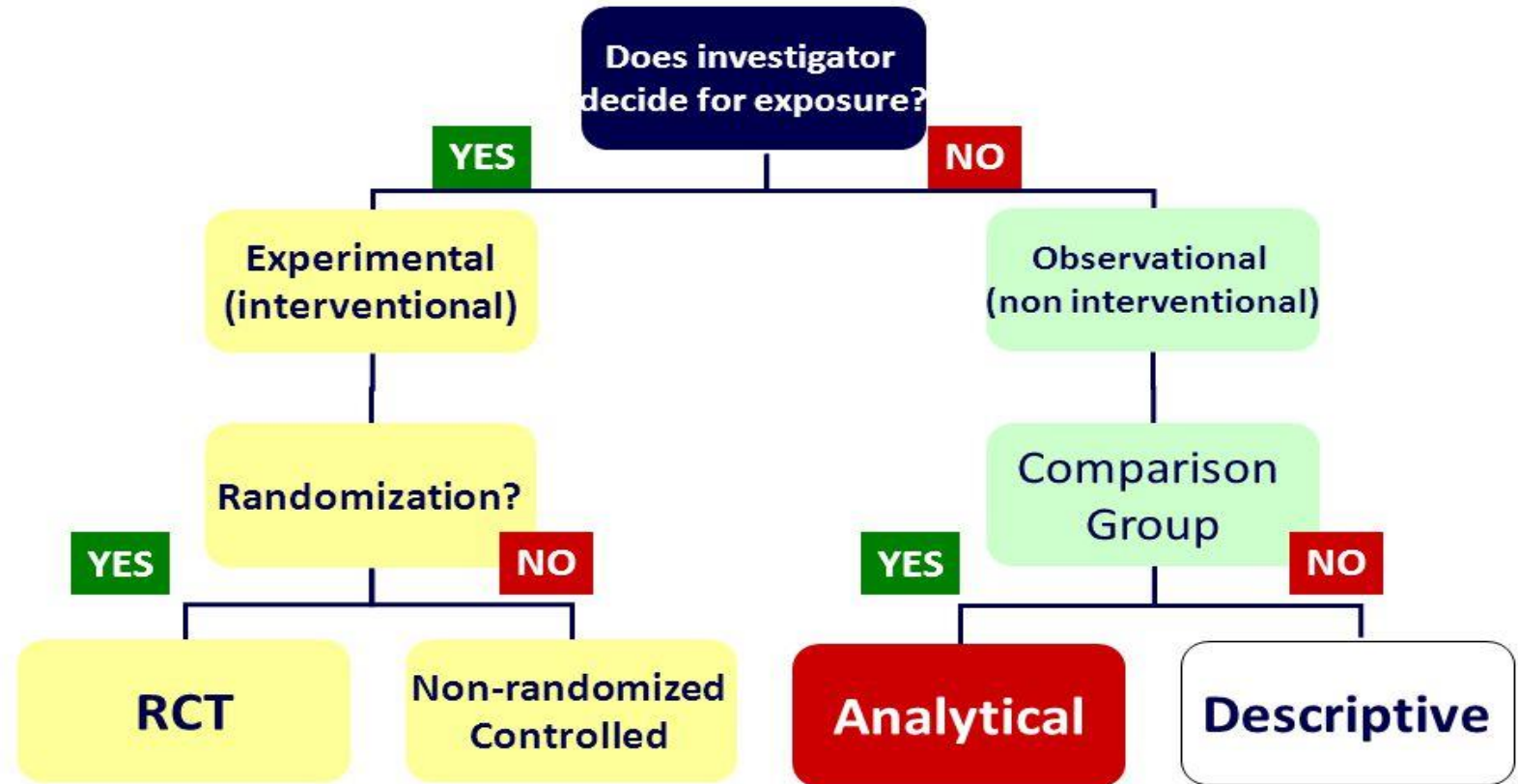


# Study design

study design is a specific plan or protocol for conducting the study, which allows the to translate the conceptual Hypothesis into an **operational** one.

## Study Designs



# Observational studies

## Types of primary studies

- **Descriptive studies**
  - describe occurrence of outcome
- **Analytic studies**
  - describe **association** between exposure and outcome

Descriptive studies examine the frequency to which diseases occur. Analytic studies evaluate the relationship of disease to different exposures

**(Describe the occurrence of outcome).**

## **Descriptive Studies**

Characterize who, where, or when in relation to what (outcome)

- **Person:** characteristics (age, sex, occupation) of the individuals affected by the outcome
- **Place:** geography (residence, work, hospital) of the affected individuals
- **Time:** when events (diagnosis, reporting; testing) occurred

### **a- Popular (correlation studies).**

Measure of association in correlation study is (correlation coefficient) ( $r$ ), which ranges from (-1) to(+1), if  $r = -ve$  means inverse association (maybe preventive).

If  $r = +ve$  means positive association (maybe causal ). If  $r = 0$  means no association.

**b-Individual:- Divided into: 1-Case-Series.**

2-Case-Report.

3-Cross-Section

# Cross-sectional

## Cross-sectional Study

### Example:-

- Using a national US database, rates of lung cancer were determined among New Yorkers, Texans, and Californians. Lung cancer prevalence was 25% in New York, 30% in Texas, and 20% in California. The researchers concluded that living in Texas is associated with higher rates of lung cancer.

### Key points:

- Presence of different groups could make you think of other study types
- However, note lack of time frame
- Study is just a fancy description of disease prevalence

- لاحظ أن هذا المثال أيضا لا يوجد فيه تتبع المجموعة عبر الزمن و أيضا الهدف من هذه الدراسة هو تحديد نسبة سرطان الرئة في المناطق المختلفة.

## Cross-sectional Studies



- Often used to study conditions that are relatively frequent with long duration of expression (nonfatal, chronic conditions)
- It measures prevalence, not incidence of disease
- Example: community surveys
- Not suitable for studying rare or highly fatal diseases or a disease with short duration of expression

Cross-sectional studies involve point prevalence, not incidence. For very infrequent diseases they are of limited utility

## **Case-series:**

### **Clinical case series**

- A case series is, effectively, a register of cases.
- Analyse cases together to learn about the disease.
- Clinical case series are of value for studying symptoms and signs and creating case definitions.

To make sense of case-series data the key requirements are:

- The diagnosis (case definition) or, for mortality, the cause of death.
- The date of disease or death occurred (**time**), the place where the person lived or worked (**place**), the characteristics of the person (**person**), and the characteristics of the **population at risk**.
- Collect data from medical records (possibly by electronic data linkage) or the person directly

# Analytic studies

Describe the association between the exposure and outcome, divided into.

a- observational studies.

1- Case-Control Study.

2- **Cohort Studies.**

b-Interventional study. (Clinical Trial) .

## Analytic Studies Definition

Analytic studies test hypotheses about exposure-outcome relationships

- Measure the association between exposure and outcome
- Include a comparison group

## C C S

- Controls reveal the ‘normal’ or ‘expected’ level of exposure in the population that gave rise to the cases.
- Issue of *comparability* to cases – the concept of the “*study base*”
  - Controls should be from the same underlying population or study base that gave rise to the cases.
- Controls should have the same eligibility criteria as the cases

Population-based Controls: Ideal represents exposure distribution in the general healthy population, but it is difficult, costly, and not routinely done.

### Hospital-based Controls

Hospital-based case-control studies are used when population-based studies are not feasible

# CCS

- **Analysis of CCS**

- **The OR as a measure of association**

- OR = Odds of exposure among cases (disease) a/c

Odds of exposure among controls (non-dis) b/d

- Odds of exposure among cases =
- Odds of exposure among controls =
- Odds ratio =  $\frac{a/c}{b/d} = \frac{a.d}{b.c}$  [= cross-product ratio]

- OR=1 implies no association.

- Assuming statistical significance:

- OR = 2 suggests cases were twice as likely as controls to be exposed.
- OR < 1 suggests a protective factor.



- The table below shows the results of a case control study conducted to find out the relationship of pelvic inflammatory disease to use and duration of use of intrauterine device (IUD):

C C pills	Cases	Control
Long term	12	10
Short term	15	47
Non used	77	340
Total	99	397

- Characteristics: follow-up period (prospective; retrospective)
- advantages: no temporal ambiguity; several outcomes could be studied at the same time; suitable for incidence estimation
- Limitations (of prospective type): expensive; time-consuming; inefficient for rare diseases; may not be feasible
- **Effect measure:** Risk Ratio (Relative Risk)
- **RR= incidence rate among exposed ( $a/a+b$ ) /incidence rate among non-exposed ( $c/c+d$ ).**
- **If RR=1 ( Mean no association between exposure and risk of disease).**
- **If RR> 1 ( Positive association, mean increase risk among exposed). risk factor**
- **If RR<1 (Negative association, mean decrease risk among exposed). protective factor**
- **Chi-square test suitable statistical analysis for cohort study.**

# Clinical trial

Participants are assigned to an *experimental* treatment and followed for events of interest

Clinical trials may:

- a) ...be randomized or non-randomized
- b) ...include a control group or have no control group
- c) ...compare current treatment to historical control

## Therapeutic or secondary prevention trials.

- The study groups are (diseased), it is conducted on patients to evaluate the effect of certain drugs or procedures in minimizing disease.

## 2- Preventive or( primary preventive trial ).

- Conducted on healthy people who are at risk or excess risk to develop outcome
- Statistical analysis for clinical trial ,
- Chi square for qualitative data . 2x2 table
- T-test and ANOVA for quantitative data, with mean and standard deviation .