Study Designs

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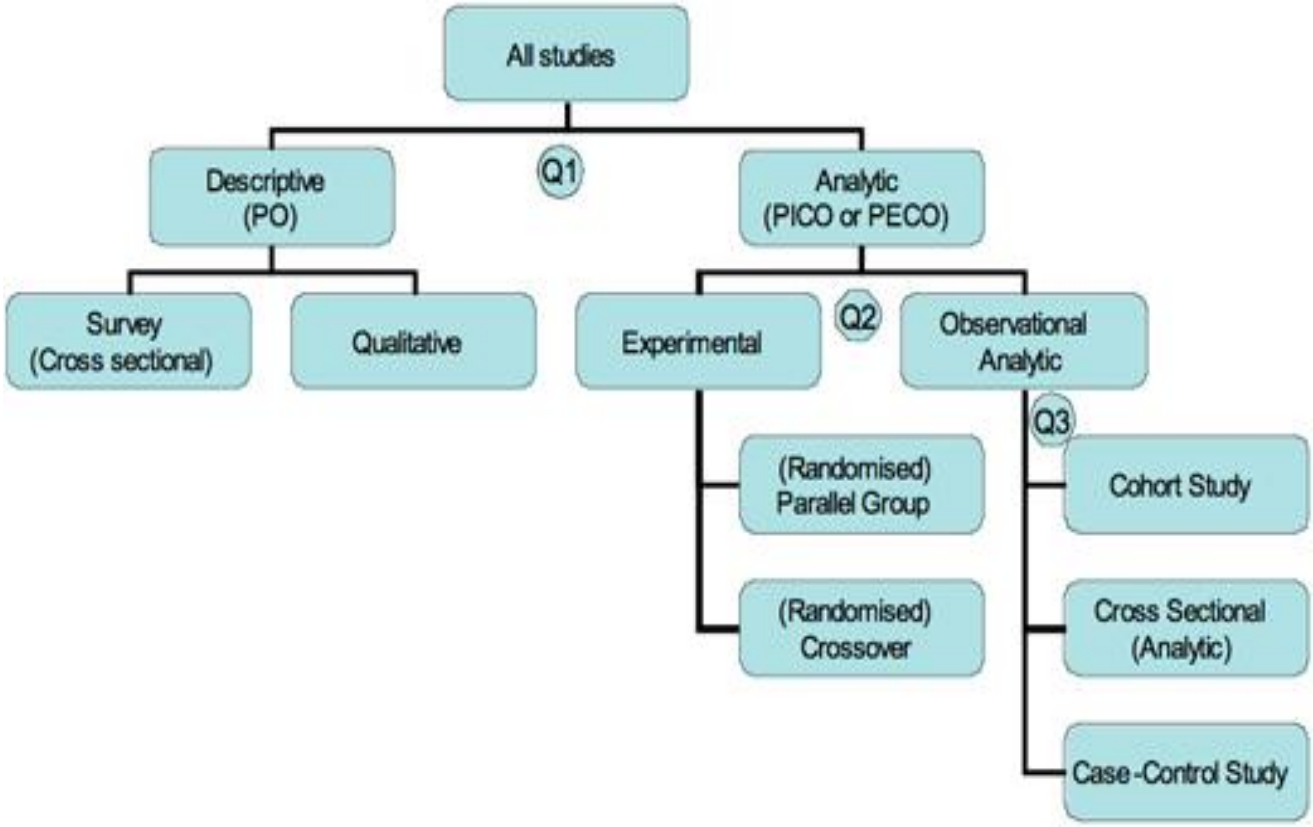
Study Designs

- **Definition:**

✓ Study design is an organized process used to evaluate a hypothesis to test wither its accepted to rejected or not.

Overview of the design tree



- The Study design can be divided into **two main types** :
- Descriptive study and Analytical study , with their subtypes.

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❖ **Descriptive study:**

- ✓ We are trying to **describe** the **outcome** of something among a specific **sample** or group of **people** (only describing what is happening) – like describing its number or other things by time ,place and person.
- ✓ Establish **the prevalence.**
- ✓ No control group.

* (**PO**) = (P : the population or the group sample) , (O : the outcome)

❖ **Example** : The prevalence of insomnia among medical student

P= Medical student , O = insomnia

***So we are trying just to Describe how is common (prevalent) is insomnia among medical student**

* **We are just Observing the outcome !**

❖ **Analytical study (PECO) :**

- ✓ We are trying to **Analyze** or **study** the **relationship** between an **Exposure** and an **Outcome**.

So, there must be **an exposure or intervention and an outcome** that we are looking to see if the study sample is exposing to it.

* (**PECO**) = (P : population or group sample), (E: Exposure or intervention), (C: comparison group), (O: outcome)

Example : The prevalence of insomnia among medical student and its effect on academic performance Or The effect of insomnia on academic performance among medical student

P = medical student, E= insomnia, C= group with no insomnia, O= academic performance

So here we are trying to **analyze the relationship between insomnia and academic performance** , is there an effect or no ? is it a harmful effect or protective effect ?

****** Note : The exposure can be a drug , risk factor, education or other things that we can study its effect on something (outcome).**

- ➢ **Types of Descriptive study (PO)** :
  - ✓ Case study
  - ✓ Case series
  - ✓ Cross-sectional study
  - ✓ Incidence and prevalence
- ➢ **Types Of Analytical study (PECO) :**
  It can be divided into two types :-

1. **Observational analytical study** : here we observe the relation between exposure and outcome , just observation without changing the amount of exposure or its dose.
   It include : Cross-sectional study , Case-Control, Cohort study
2. **Experimental analytical study** : here we manipulate exposure, that mean we can change the exposure dose or amount to all the study groups not just observing.
   It include : Randomized control trials

Example for analytical study : (The effect of caffeine consumption on blood sugar)

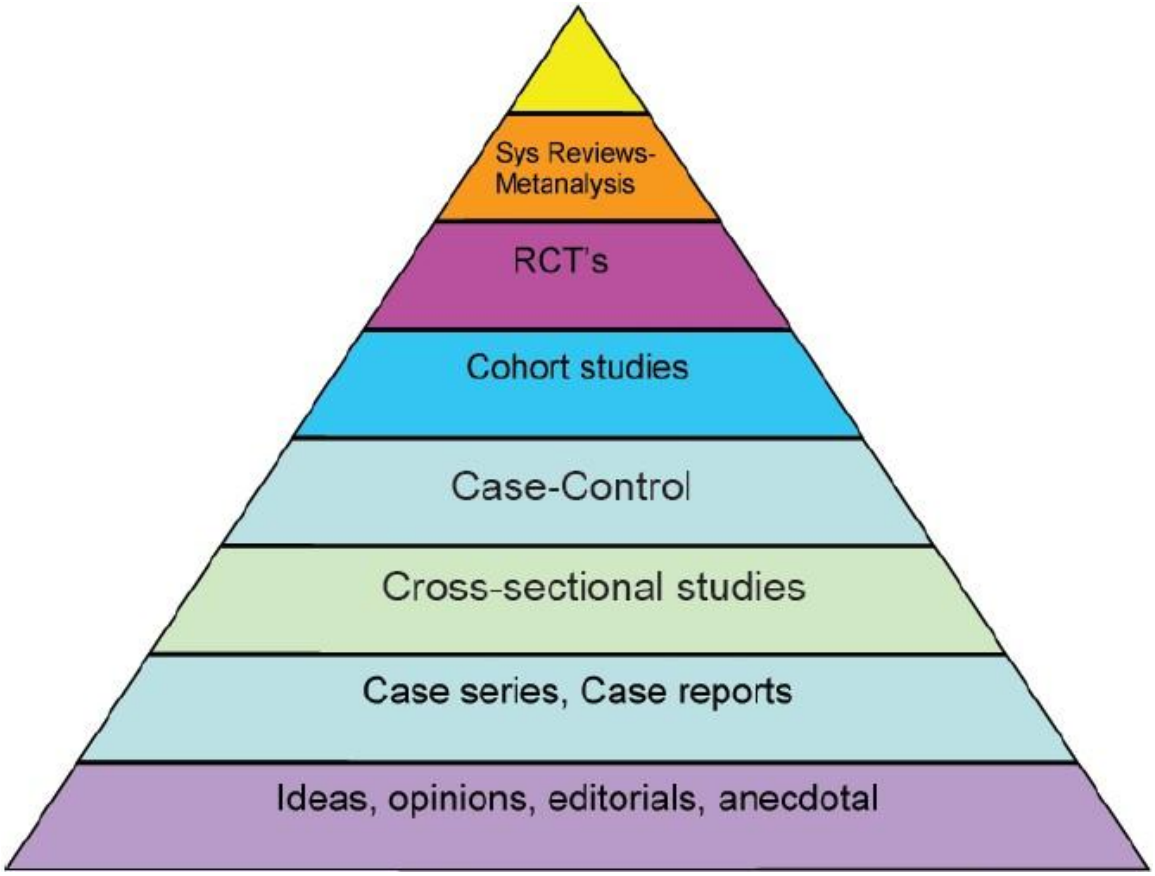
** If we want to conduct an observational analytical study : we will choose a groups of people who consume Caffeine(E) regard its amount and another group who do not take caffeine and we will see the blood sugar level(O) in both group does caffeine increase or decrease blood sugar ??

** if we want to conduct an experimental analytical study : we will choose 2 groups of people , the study group will be given caffeine of 50mg daily (same amount of exposure in all individual), and the control group (with no exposure) will be given another drink which has no caffeine , and we will see the blood sugar in both group.

****Note : cross-sectional study can be descriptive or analytical , it depend on your research :**

- **The prevalence of insomnia among medical student using cross-sectional method** (here we detect the number of student having insomnia only)-(PO)

- **The prevalence of insomnia among medical student and its effect on academic performance** (here we detect the number of insomniac student and we have a relation that we would like to study which is the insomnia(E) and academic performance(O)-(PECO)



- This Graph represent the **hierarchy of study design** , which one is stronger and more evident .
- **The RCT (randomized control trial)** is **the gold stander study** and the most evident one .

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Case-Control Study

❖ **Type of study :**

✓ Observational analytical study (PECO).

✓ In this study we are trying to see a **relation** between an exposure and an outcome in which the outcome is already present and we try to see the past history of the individual, did he expose to our exposure or no ?

✓ **Based on the outcome** (Study begin from the outcome).

✓ **Exposure is a RISK, not a cause** (If the exposure associated with outcome, we can say that the exposure X is risk for the disease Y " NOT a cause of disease Y ")

✓ It is **retrospective study** , which mean it goes back in time of the already present outcome .

✓ There are **two groups** , **one with outcome and the other without outcome (control).**

✓ No randomization. No intervention.

❖ **How is it conducted** ?

1st : **Select 2 group of people : A case group and A control group**

- The case group is the study group which has the outcome
- The control group is the group without the outcome
- Note : control group must be equivalent in most aspect of case group (like age and other factor) but they don't have the disease of course !
- Note : the case group must have the best confirmative test to say that they have the outcome

2nd : **Collect data :**

- The data can be collected by using a standardized question used in both groups , you have to ask both groups whether they exposed to the desired exposure in the past or no , You should ask the same questions in both with no bias to one group , you can use also other method then equations like detecting the exposure level in blood (biomarker) .

3rd: Measure the association between exposure and outcome and interpret the result.

- The used measure in Case-Control study is **Odds ratio**

$$\text{Odds Ratio(OR)} = \frac{\text{Chance of event hapening}}{\text{Chance of non event hapening}}$$

- **Interpretation** of the Odds Ratio :
  - ✓ **OR = 1 → Exposure NOT related to disease(outcome)**
  - ✓ **OR >1 → Exposure POSITIVELY related to disease(outcome)**
  - ✓ **OR <1 → Exposure NEGATIVELY related to disease(outcome)**

*** Note : as odds ratio increase , as the strength of relation between E+O is more .**

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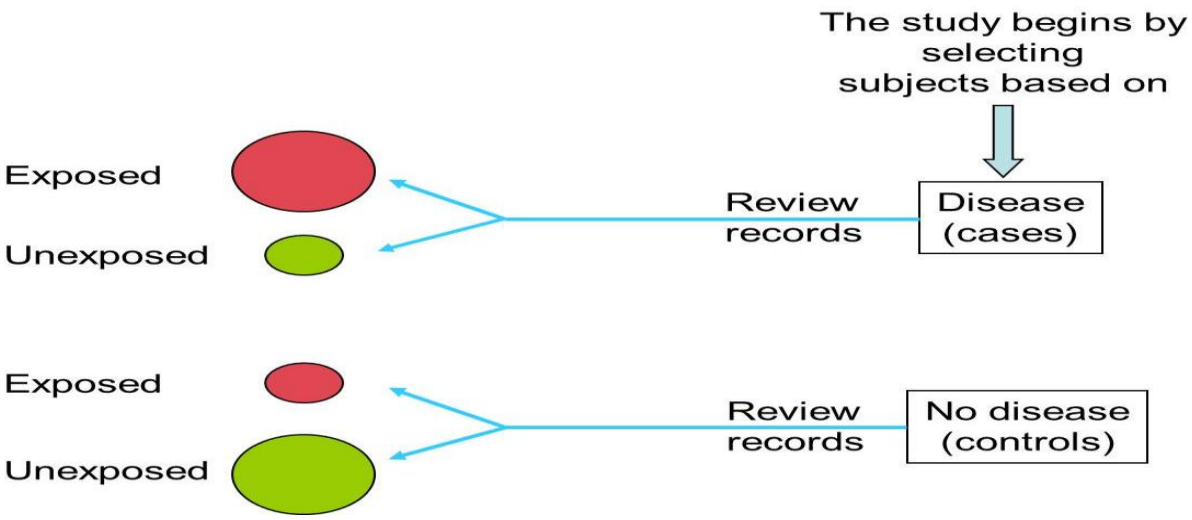

- **Example:**
  - **The effect of caffeine(E) on insomnia(O) :**
    - **Case Group(a+b): Group with insomnia**
    - **Control Group(c+d) : Group with normal sleep pattern**
  - We will ask both groups , did you consume caffeine before ? how much and for how long?
  - Collect data from both group , and calculate odds ratio
  - If result were as follow :

	Diseased(Case)	Non-diseased (Control)
Exposure	1200 (a)	100 (c)
Non-exposure	300 (b)	1400 (d)
Total	1500 (a+b)	1500 (c+d)

- Odds Ratio(OR) $= \frac{\text{Chance of event hapening}}{\text{Chance of non event hapening}}$ **(of both Groups)**

- **Case group:** $\frac{a}{b} = \frac{1200}{300} = 4$, **Control Group:** $\frac{c}{d} = \frac{100}{1400} = 0.07$

- Then we divide the case group ratio by control group ratio to calculate odds ratio :

- $\mathbf{OR} = \frac{4}{0.07} = 57.1$, so there is a true relation between caffeine consumption and insomnia , caffeine is a risk factor for insomnia

  - ✓ **Interpret** : People who consume caffeine are 57 times more likely to develop insomnia than non-caffeine consumer.

Advantage	Disadvantage
Easy and quick	Cannot generate incident data
Cheap and has good rank	Bias (specially recall) is common
Good for rare disease	Control selection can be difficult

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Cohort Study

❖ **Type of the study:**

✓ Observational analytical study

✓ Aim to see **the relation** between the exposure and outcome among two groups without previous outcome.

✓ There are **two groups completely healthy or without outcome**, **one is exposed and the other not exposed (control) , then follow the two groups in the future to see the outcome.**

✓ **Based on exposure** (Study begin from the exposure).

✓ No randomization. No intervention

✓ **Time of the study depends on the feature of the outcome** (How long does the outcome take to appear ?).

✓ **Exposure is a RISK, not a cause** (If the exposure associated with outcome, we can say that the exposure X is risk for the disease Y " NOT a cause of disease Y ").

❖ **Two designs:**

1. **Prospective cohort design.**
2. **Retrospective cohort design.**

1) Prospective cohort design:

- **Exposure & non-exposure occur during the beginning of the study**, then followed up into the future to see the outcome.
- Requiring **the collection of new data**
- Can measure **the incidence.**
- Less liable for confounding or bias.

❖ **How is it conducted** ?

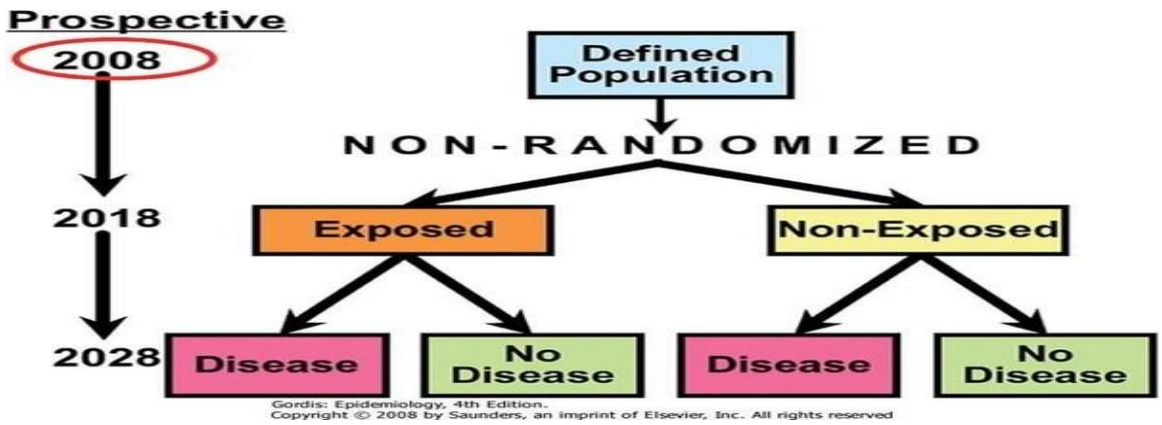
1st : Select 2 group of people completely free of outcomes :

- (A) Exposed group.
- (B) Control group without exposure.

2nd :Follow the two groups in the future then collect data about the outcome.

3rd: Measure the association between exposure and outcome and interpret the result:

- The used measure in Cohort study is **Relative Risk (RR).**



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2) Retrospective cohort design:

- **Exposure(including zero exposure or no exposure) established from past records, and outcome determined at the beginning of the study.**
- Looking back in time, thus **using existing data** such as medical records or claims database
- Used to minimize the time spend in the study and decrease the cost of the study.
- More liable for confounding or bias.

❖ **How is it conducted** ?

1st : Select 2 large groups of exposed and not exposed from a point in the past.
2nd : See the records and determine the incidence of outcome among both.
3th: Measure the association between exposure and outcome and interpret the result:

- The used measure in Cohort study is **Relative Risk (RR).**

3) Retro-Prospective cohort study:

- Combine between the two designs.

$$\text{Relative Risk(RR)} = \frac{\text{incidence of of outcome in exposed}}{\text{incidence of outcome in non} - \text{exposed}}$$

- **Interpretation** of the Relative Risk :
- ✓ **RR = 1 → Exposure NOT related to disease(outcome)**
- ✓ **RR >1 → Exposure POSITIVELY related to disease(outcome)**
- ✓ **RR <1 → Exposure NEGATIVELY related to disease(outcome)**

*** Note : as relative risk increase , as the strength of relation between E+O is more .**

- **Example:**
- **The effect of caffeine(E) on insomnia(O):**
  - **Exposed group(b+d): Group drinking caffeine .**
  - **Non-exposed (Control) group(a+c) : Group not drinking caffeine.**
- Then follow them in the future to see insomnia development in both groups
- If result were as follow :

	Non-exposed (Control)	Exposed
Healthy	1200 (a)	100 (b)
Diseased	300 (c)	1400 (d)
Total	1500 (a+c)	1500 (b+d)

- $\text{RR} = \frac{\text{incidence of of outcome in exposed}}{\text{incidence of outcome in non}-\text{exposed}}$

- $\text{RR} = \frac{d/(b+d)}{c/(a+c)}$

- $\text{RR} = \frac{1400/(1500)}{300/(1500)} = \frac{0.93}{0.12} = 4.66$, so there is a positive relation between caffeine consumption and insomnia , caffeine is a risk factor for insomnia.

- ✓ **Interpret** : The people who consume caffeine are 4.66 times more likely to develop insomnia than non-caffeine consumer.

Advantage	Disadvantage
Easy to understand	Cannot determine the causal conclusion
Can estimate both incidence rate & incidence rate ratio	Costly
Suitable for addressing risk factors	Require long time

Experimental Study

❖ **Type of the study:**

✓ Analytic study

✓ Aim to establish **the causal** relationship between exposure and outcome.

✓ It is a **prospective study**.

✓ **Exposure is a CAUSE**, (If the exposure X associated with outcome Y, we can say that the exposure X is a cause for the outcome Y).

❖ **Two types:**

1. **Randomized Controlled Trials**
2. **Quasi-experimental**

1) Randomized Controlled Trials (RCTs):

- Characters:

✓ **Manipulation (Trial) :** Researcher does something (Intervention).

✓ **Control group :** Researcher introduces one or more control groups to compare with

✓ **Randomization (everyone has an equal chance to be selected) :** The researcher takes care to randomly assign subjects to the control and experimental groups

- Use **Blinding process** to **avoid bias**:

The process by which the researcher tries to make sure that as few as much people know about which one belongs to which group , treatment or placebo, including: The patients, the nurses and the doctors.

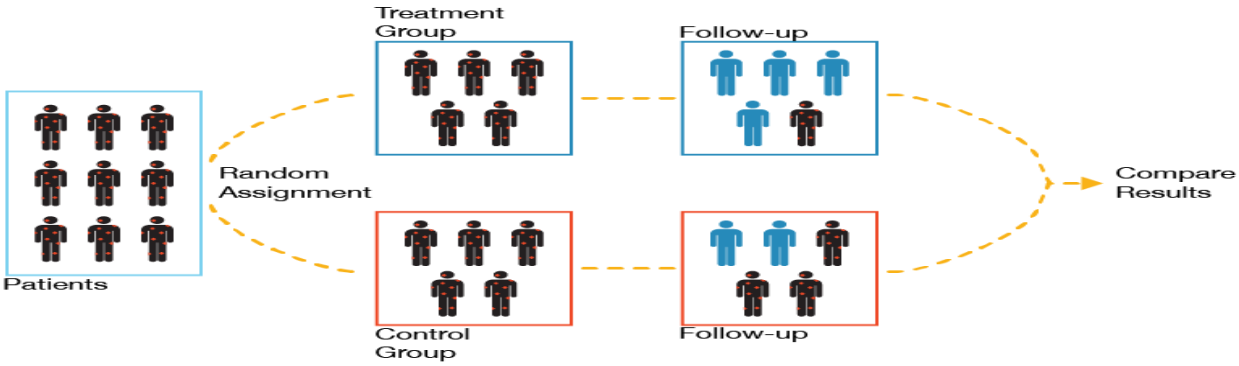
❖ **How is it conducted** ?

1st : From a pool of study, subjects/participants randomly select into two groups:

- (A) Group exposed to intervention.
- (B) Control group without intervention, or with placebo, or standard treatment.

2nd : Give the first group the intervention (as drug) , and leave the control group without intervention or with placebo, or standard treatment.

3rd : Follow them in the future to see the outcome.



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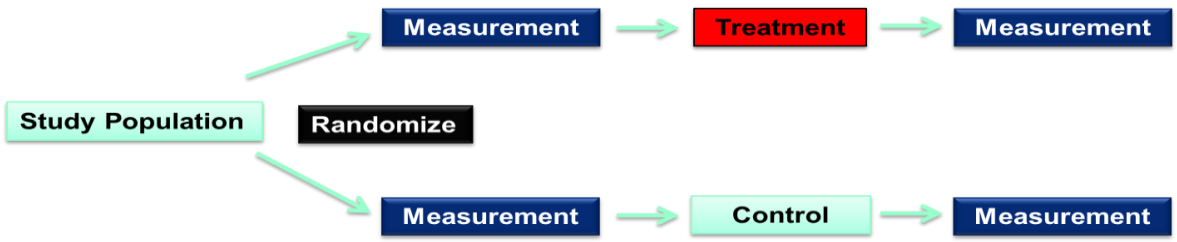
❖ **Phases of RCT:**

- **Phase I:**
  - Healthy volunteers, answers the question whether the intervention is compatible with life.
- **Phase II:**
  - Uncomplicated cases ,
  - Does the intervention have an effect on the outcome?
- **Phase III:**
  - The Proper RCT
- **Phase IV:**
  - Post-marketing. In case of drug intervention, you can ask in hospitals or clinics.

❖ **Example:**

- **The effect of caffeine(E) on insomnia(O):**
  - **Exposed group(b+d): Group drinking caffeine (Intervention) .**
  - **Control group(a+c) : Group not drinking caffeine (Non intervention).**
  - **(Both group are selected randomly).**
- Then follow them in the future to see insomnia development in both groups

☒ **Pre-test/Post-test Control Group:**



2) Quasi-Experimental Study:

- One characteristic of a true experiment is missing, either **randomization or the use of separate control group.**
- Always includes the manipulation of an independent variable which serves as the intervention.

❖ **Example:**

- **The effect of caffeine(E) on insomnia(O):**
  - **Exposed group(b+d): Group drinking caffeine (Intervention) .**
  - **(No control group)**

  Then follow them in the future to see insomnia development.

  Or
  - **Exposed group(b+d): Group drinking caffeine (Intervention) .**
  - **Control group(a+c) : Group not drinking caffeine (Non intervention).**
  - **(Both group are not selected randomly).**
  - Then follow them in the future to see insomnia development in both groups

☒ **One-shot Case Study :**

☒ **One-group Pre-test/Post-test :**

Advantage	Disadvantage
Perfect design	Unethical if exposure is harmful
Unbiased if blinded	Unethical if sure that treatment works
Can study all aspects of the relation risk-exposure	Expensive
Shows causality	Difficult if outcome is rare