



# Research CoP - **Study Design**

26 September 2023



until  
**No Leprosy Remains**

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# Today's topics



Introduction to study designs

Determinants & outcomes

Confounding and bias

Research methods: qualitative - quantitative

Different types of study designs

- Descriptive studies
- Analytical studies

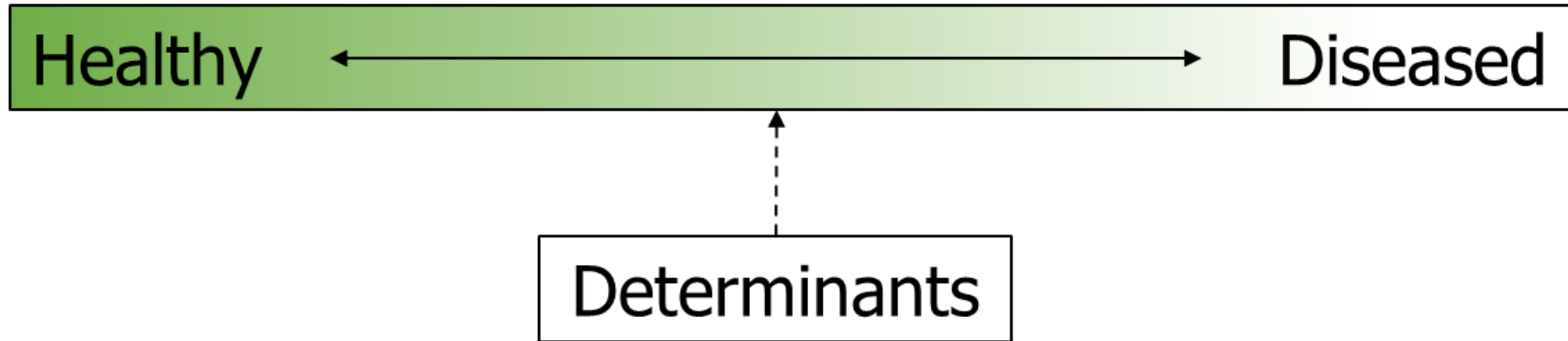
# Study design



- A **study design** is a strategy for answering your research question using empirical data.
- A well-planned research design helps to ensure that your methods match your research objectives and that you use the right kind of analysis for your data.



# Determinants & outcomes

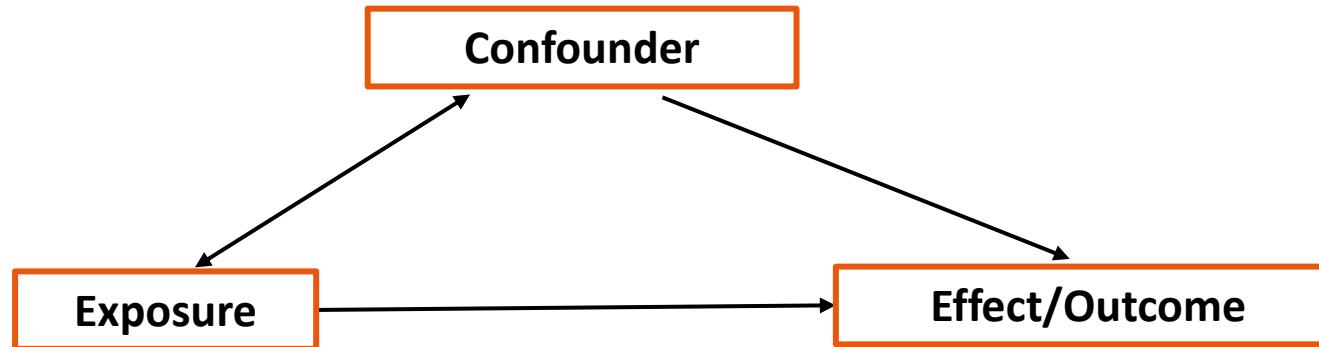


Determinants may be:

- Social and economic environment
- Physical environment
- Genetical factors
- Person's individual characteristics and behaviours.

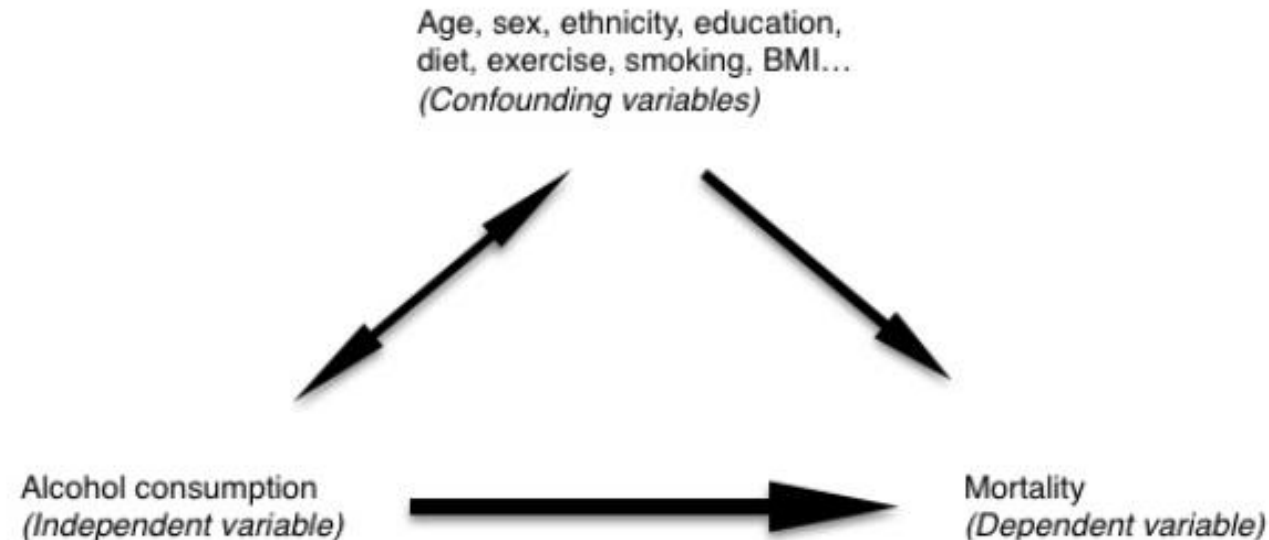
# Confounder

- Is a risk factor for the disease (**outcome**)
- Is associated with the independent variable (**exposure**)
- Is not on the causal pathway between exposure and disease



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# How to avoid confounding

## 1. Study design

- Randomization
- Restrictions
- Matching (case-control studies)
- Collect data on the confounding variable

## 2. Analysis

- Take the confounding variable into account in your data analysis ('stratified analysis')

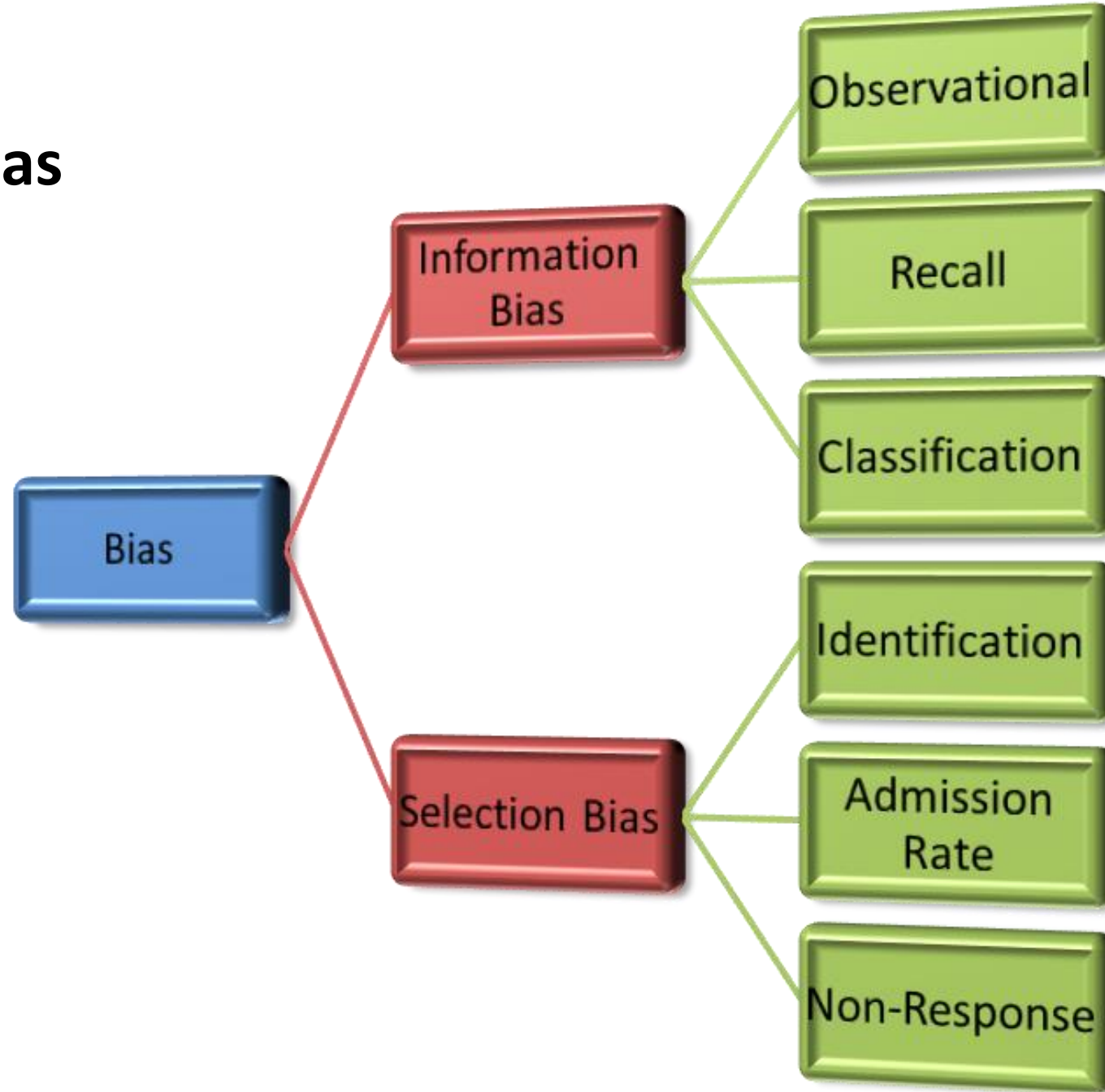
# Bias

- Systematic error
- Leads to results that are consistently wrong in one direction
- Bias can occur at any phase of a study, e.g., planning, data collection, analysis, and publication phases.
- Bias impacts the validity and reliability of your findings, leading to misinterpretation of data

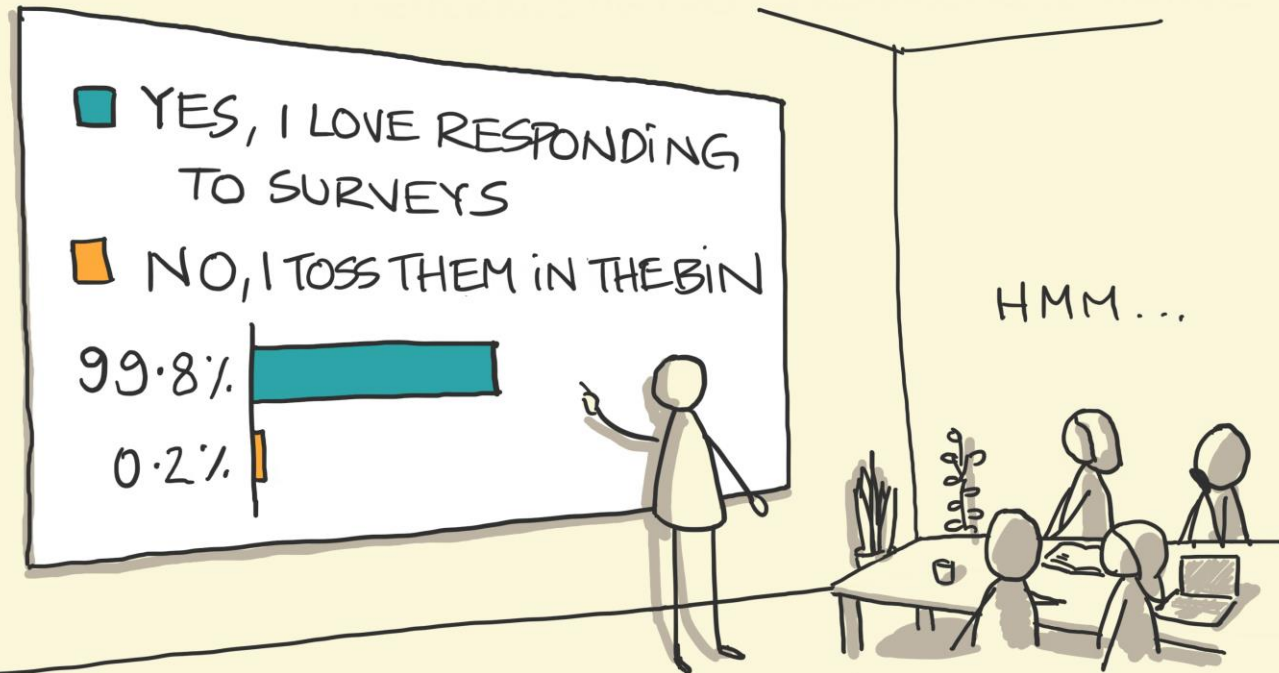
Once there is bias in your study – you can no longer control for it during the analysis phase (unlike confounding).



# Types of bias



# SAMPLING BIAS



" WE RECEIVED 500 RESPONSES AND  
FOUND THAT PEOPLE LOVE RESPONDING  
TO SURVEYS "

sketchplanations

# Research methods



## Qualitative methods



Exploring ideas, formulating hypotheses/theories



In-depth information about the 'why' and 'how' - expressed in **words**



Small sample size

## Quantitative methods



Testing hypotheses or theories



Expressed in **numbers**



Large sample size

# Research methods

## Quantitative Methods

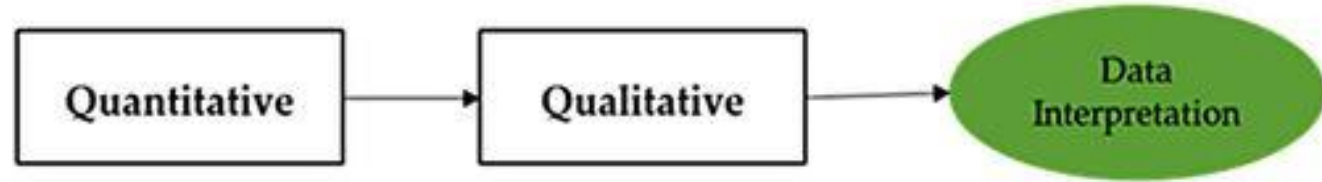


## Qualitative Methods

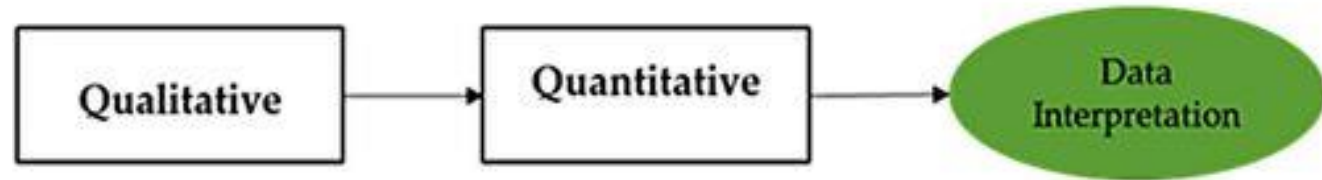


# Mixed-methods

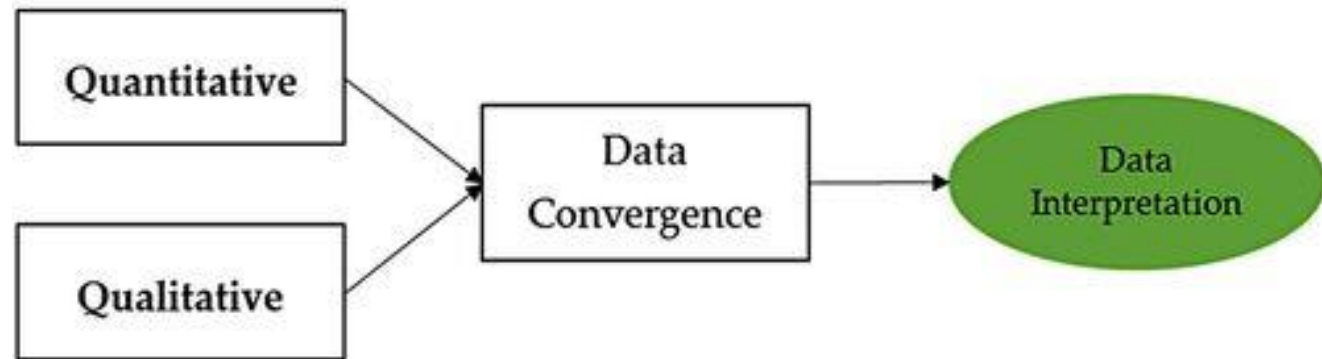
A. Sequential Explanatory Design



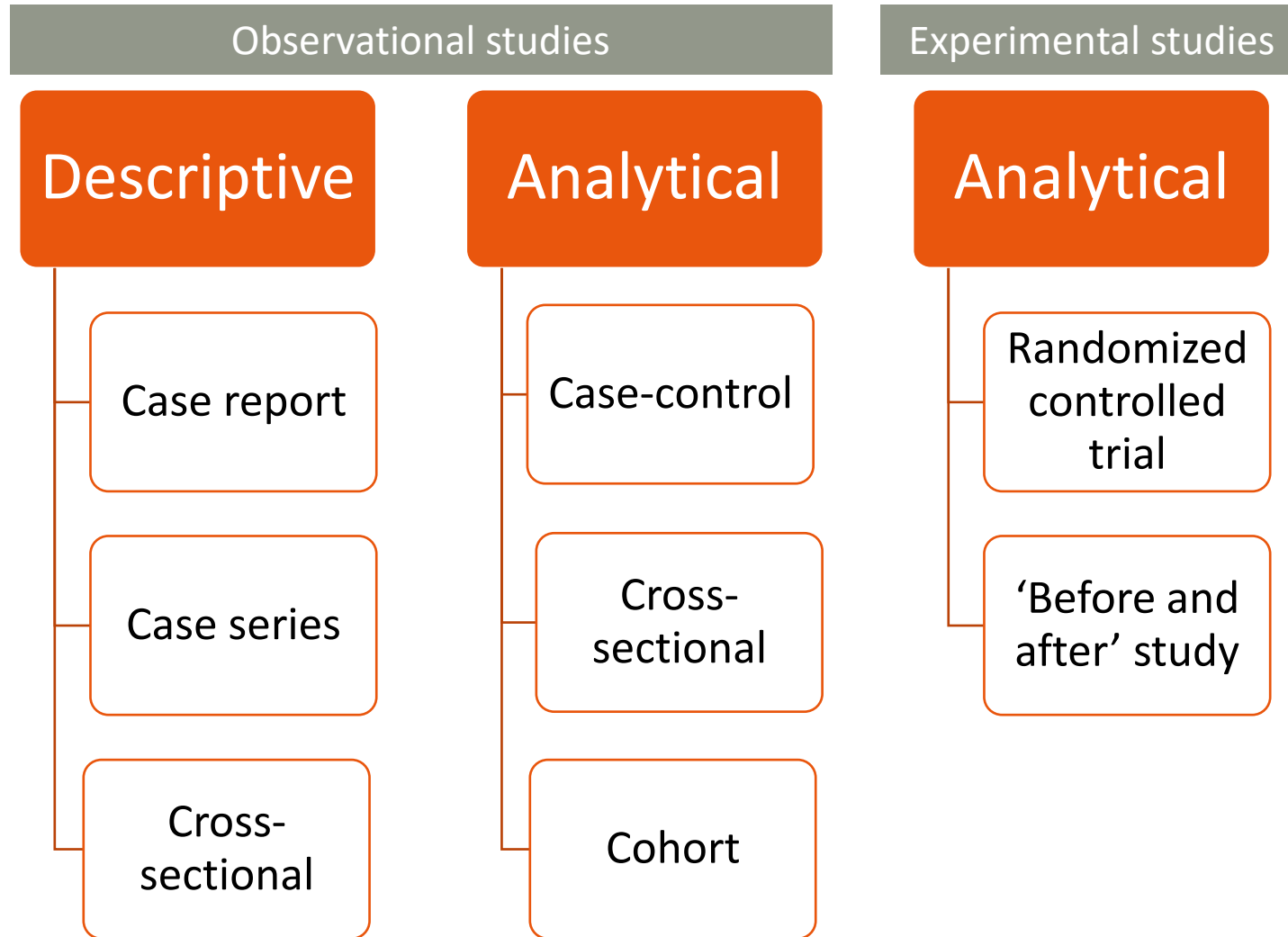
B. Sequential Exploratory Design

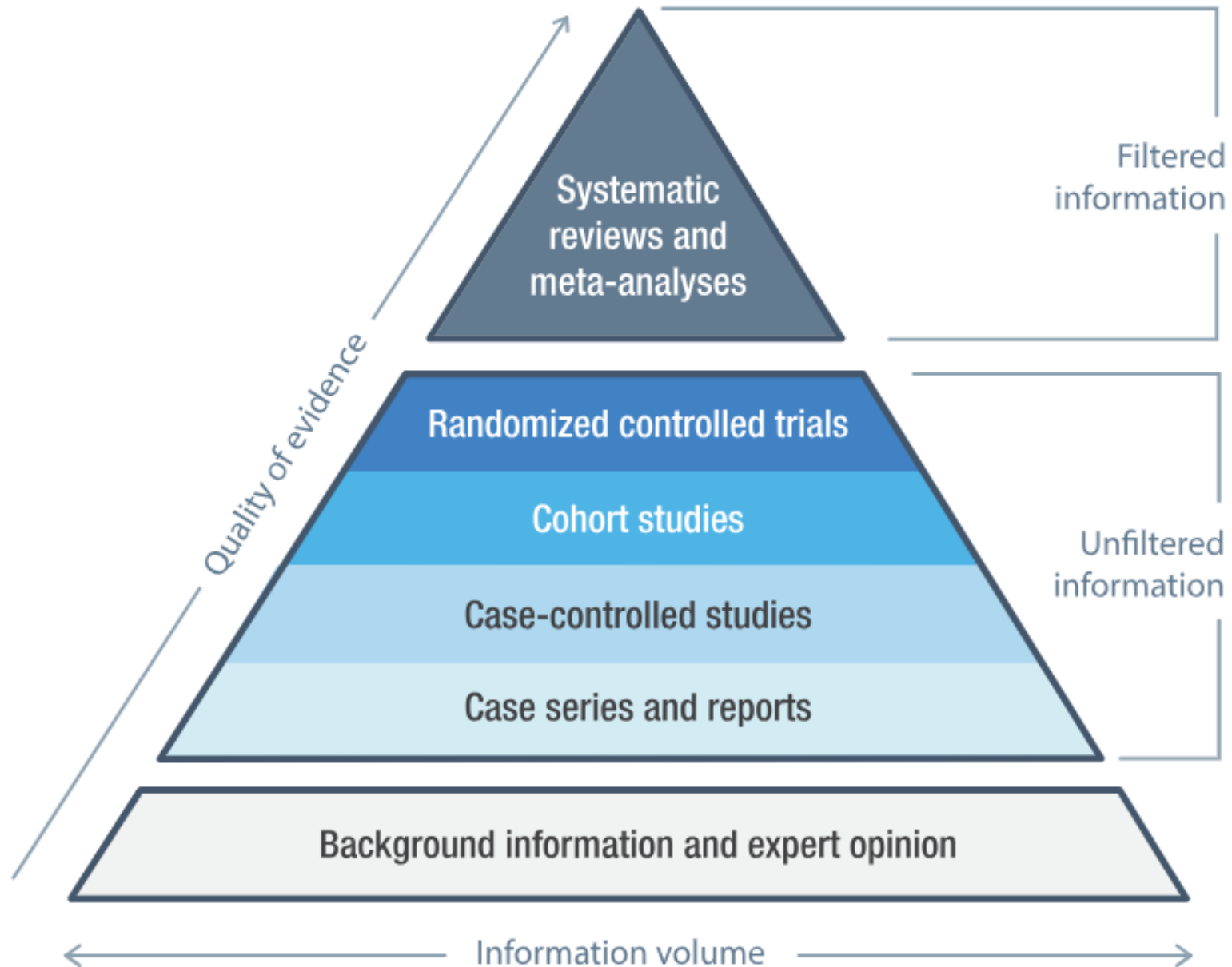


C. Concurrent Triangulation Design



# Types of study designs

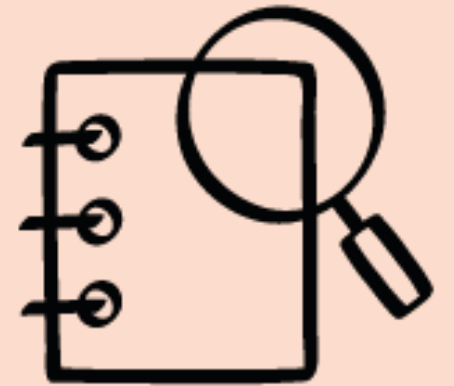




# Descriptive studies



Aim to determine, describe or identify **what is** [the situation]





# Case study / case report

Detailed study of a specific subject, such as a person, group, event, organization, or phenomenon.

## Advantages

- Useful for hypothesis generation
- Informative for rare (manifestations of) diseases
- Relatively easy and inexpensive

## Disadvantages



- Cases may not be representative for the broader population
- May include researcher bias
- Difficult to replicate



### Single patch, mononeuritic multibacillary leprosy: A case report

Arshdeep Arshdeep <sup>a</sup>, Rama Kumari Badyal <sup>b</sup>, Pranab Dey <sup>b</sup>, Tarun Narang <sup>a,\*</sup>, Sunil Dogra <sup>a</sup>

### Erythema Nodosum Leprosum (ENL) treated with additional Clofazimine – A case series

 Vivek Vasudev Pai <sup>a,\*</sup>,  Anju Vilas Wakade <sup>b</sup>,  C. Ruth Butlin <sup>c</sup>

# Cross-sectional study

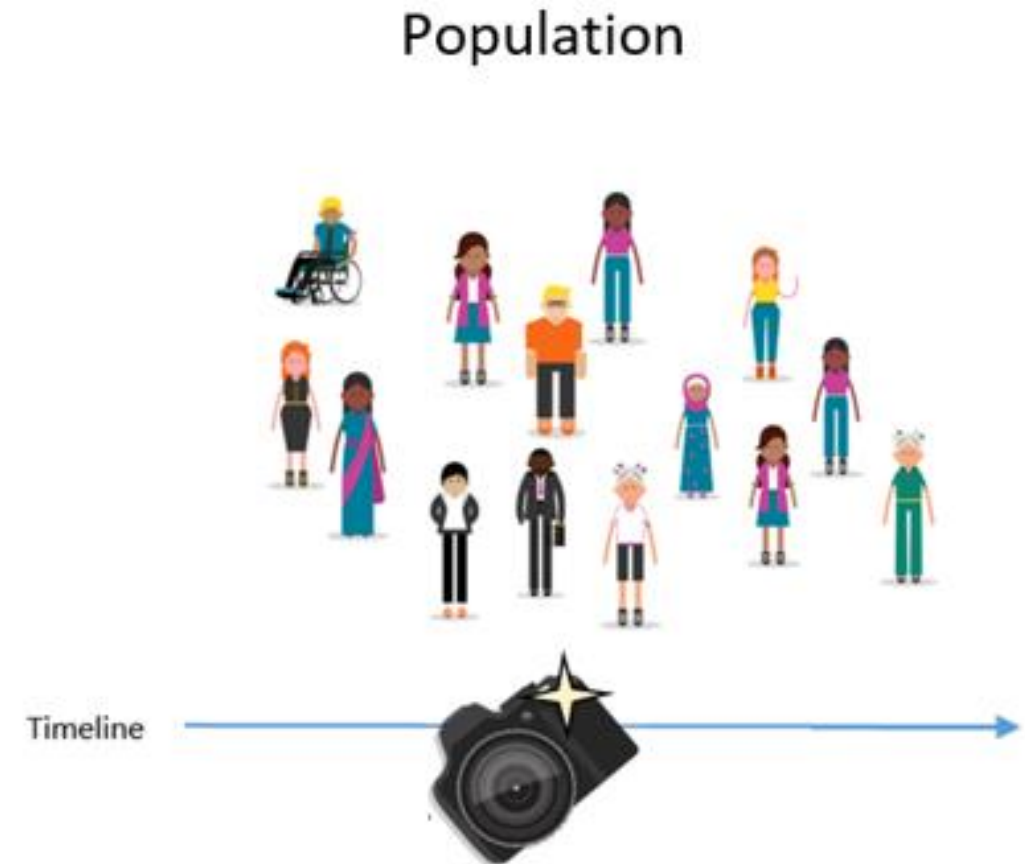
Aims to describe and quantify the distribution (frequency of occurring) of certain factors in a population **at a single point in time**.

## Advantages

- No loss to follow-up
- Relatively short study duration
- Relatively inexpensive
- Can measure the prevalence of disease
- Multiple variables can be studied

## Disadvantages

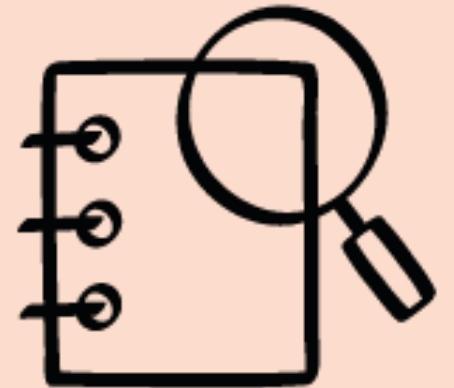
- Cannot measure the incidence of disease
- Cannot assess direct causation or temporal relationships



# Analytical studies



Aim to establish *why* it is that way  
or *how* it came to be.



# Case-control study



Compares patients who have a disease/outcome of interest (**cases**) with those who do not have the disease/outcome (**controls**).

Exposure to risk factors is then compared between the cases and controls.

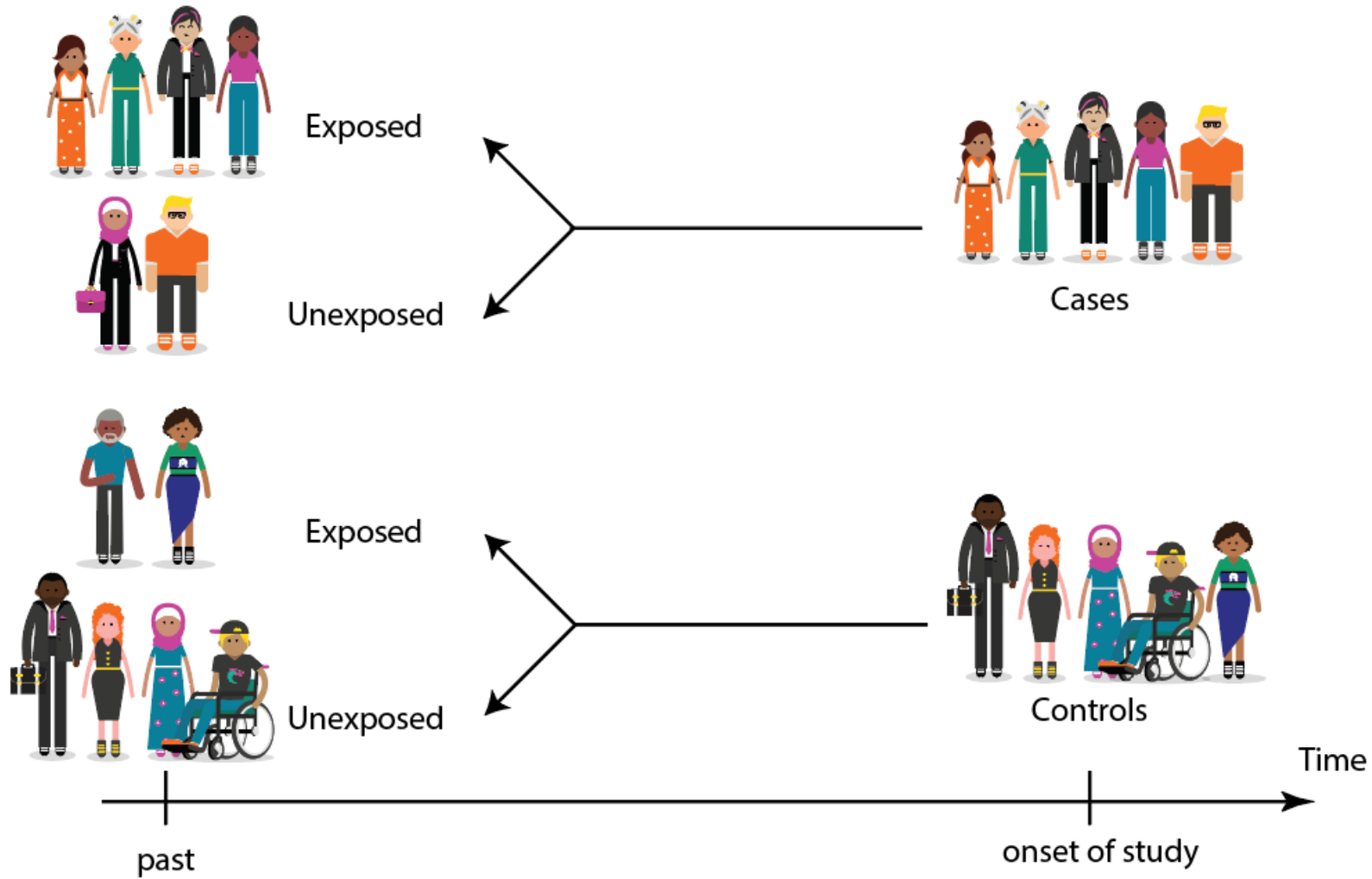
## Advantages

- Good for studying rare diseases / diseases with long latency between exposure and outcome
- Relatively inexpensive and quick
- Examine multiple exposure variables at once

## Disadvantages

- Exposure data collected retrospectively: incomplete
- Susceptible to 'bias' (recall bias)
- Only one outcome can be studied
- It can be difficult to find a suitable control group

# Case-Control Study



# Cohort study



Cohort studies are longitudinal, observational studies, which investigate **predictive risk factors and health outcomes**. They differ from clinical trials, in that no intervention, treatment, or exposure is administered to the participants. The factors of interest to researchers already exist in the study group under investigation.

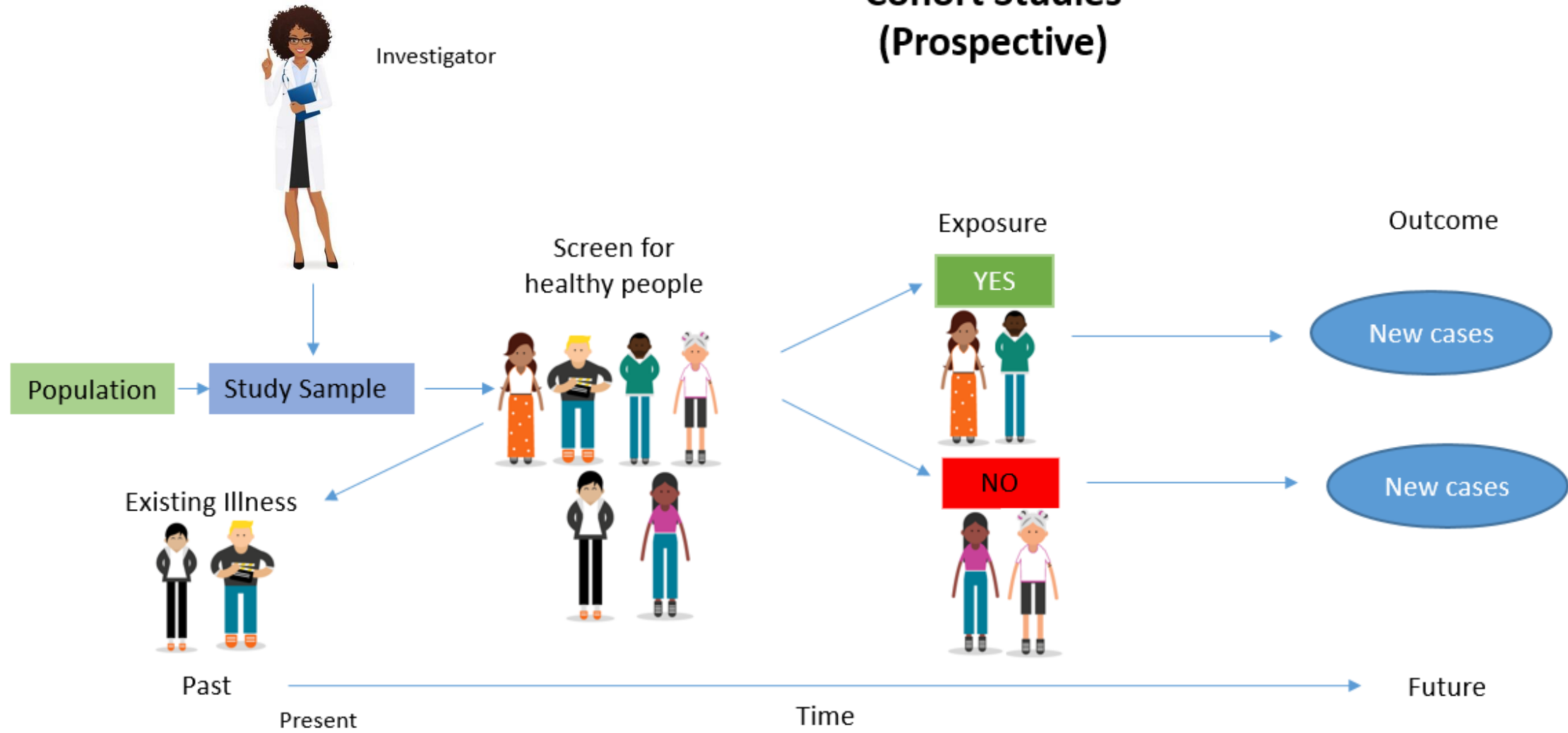
## Advantages

- The only observational study design that directly investigates risk of disease and the factors contributing to it.
- Can measure incidence.
- Multiple outcomes can be measured.
- Can establish temporal relationships.

## Disadvantages

- Not appropriate for rare diseases or those that take a long time to develop.
- Not appropriate for studying multiple exposures.
- Can be costly and time consuming.

# Cohort Studies (Prospective)



# Randomized controlled trial (RCT)

Study participants are **randomly** assigned to the intervention and control group. Ideally, the study team and participants are **blinded** to which arm they are allocated.

## Advantages

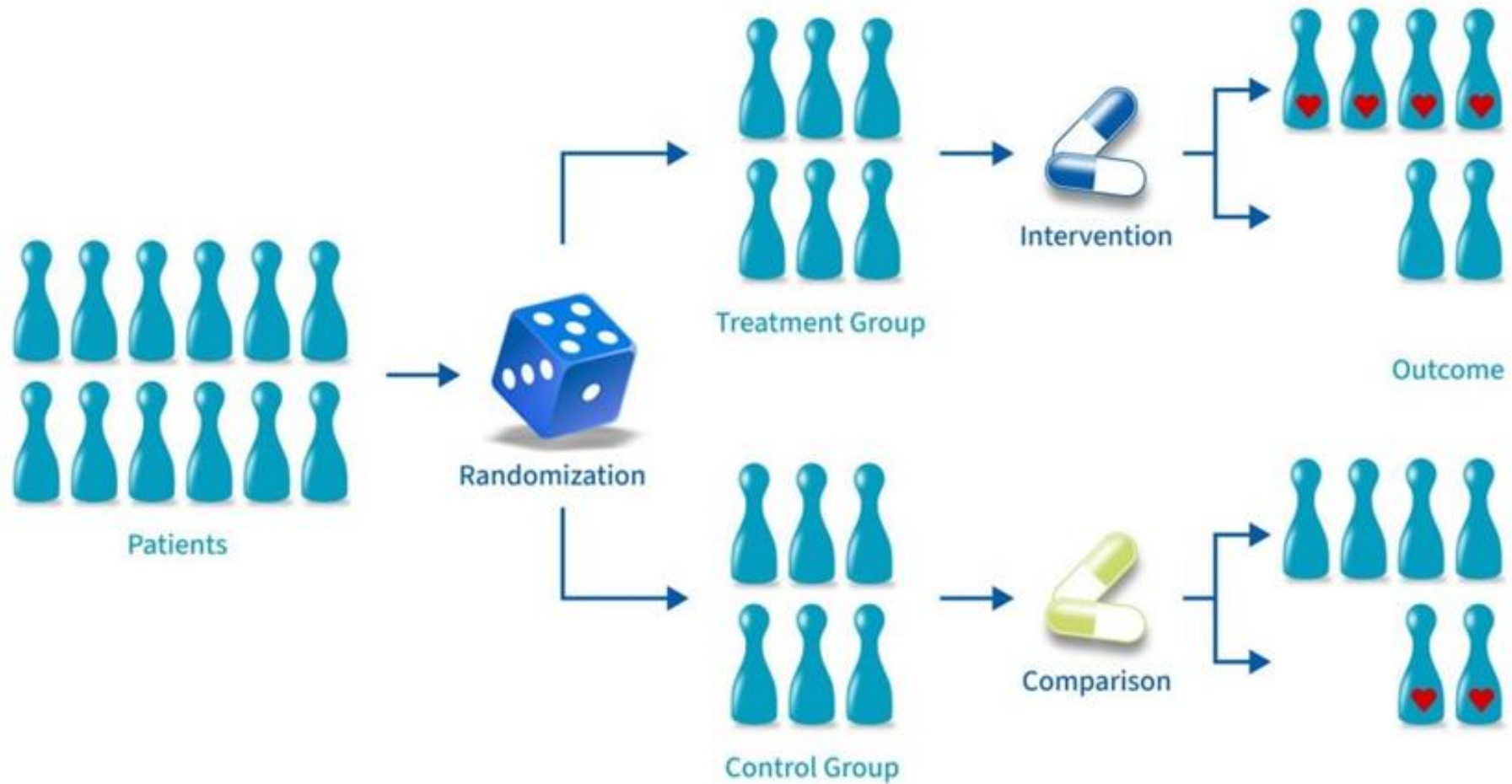
- Randomisation and blinding reduce bias and impact of confounders.
- Researchers have greater control over the study's circumstances.
- Can lead to strong conclusions about a causal relationship between exposure and feature(s) of interest.

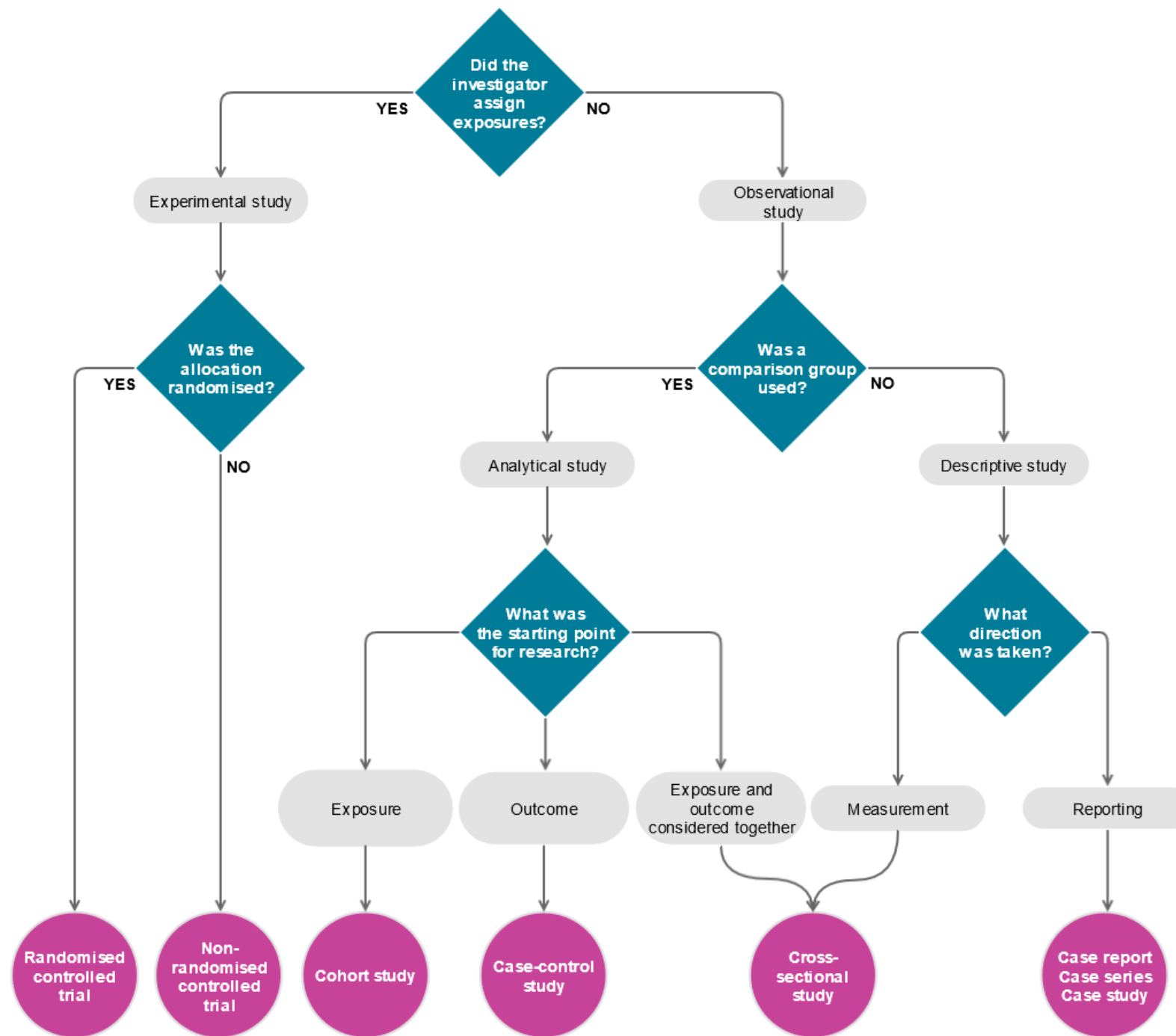
## Disadvantages

- Design, execution and evaluation can be complex, costly and lengthy.
- Recruitment of participants can be difficult for some research.
- May not be appropriate for some research due to ethical concerns.
- Loss to follow-up.



# Randomized controlled trial (RCT)



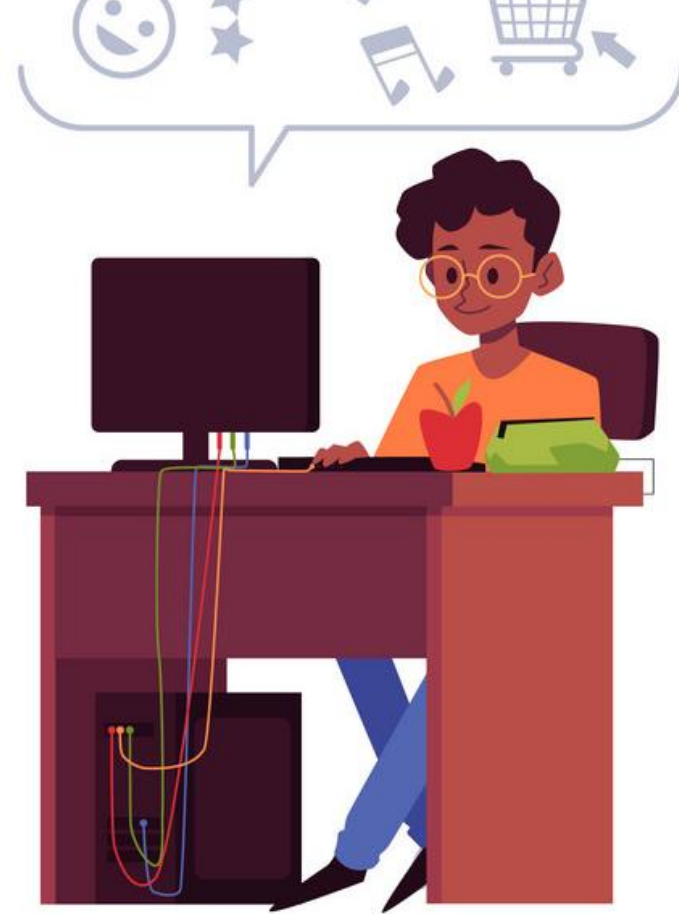


# Conclusion

The study design depends on the:

- Type of the problem
- The available knowledge
- The available resources

When choosing a study design – you should also consider the role of confounding and bias and how you avoid them when planning your study.





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# Useful resources

- <https://www.cebm.ox.ac.uk/resources/ebm-tools/study-designs>
- <https://www.cebm.ox.ac.uk/files/testing/cebm-study-design-april-20131.pdf>
- <https://himmelfarb.gwu.edu/tutorials/studydesign101/>
- <https://deakin.libguides.com/quantitative-study-designs/about>
- <https://www.scribbr.com/methodology/research-design/>
- <https://www.scribbr.com/methodology/confounding-variables/>
- <https://www.scribbr.com/category/research-bias/>

## Videos:

- [Research Design: Choosing a Type of Research Design](#)
- [How to Create a Strong Research Design: 2-minute Summary](#)
- [Research Design: Defining Your Research Aims and Approach](#)
- [Quantitative vs. Qualitative Research: The Differences Explained](#)