



# Choosing the study participants

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# Outline

- Study participants.
- Priorities in participants selection.
- Recruitment of study participants.
- Inclusion criteria.
- Exclusion criteria.



# Objectives

At the end of this session, the student should be able to:

- Define the study participants.
- Define inclusion criteria.
- Identify reasons to exclude participants from the study.



# Priorities in participant selection

1. Participants must be representative of the study population.
2. Participants must have the biological, social, or behavioral attributes that will enable the researcher to achieve aim and objectives of the research.
3. The participants selected should be least vulnerable to harm from the research interventions or procedures.



# Recruitment

## Aim of recruitment

1. To recruit a sample that adequately represents the target population. Consider non-response (not more than 20-25%).
2. To recruit enough participants to meet the sample size requirements of the study.
3. Method of recruitment must be selected based on its potential to reach potential participants in sufficient numbers and its appropriateness to the study population.



# **Inclusion & exclusion criteria**

- Inclusion/Exclusion criteria should have clear scientific or clinical rationale and may differ depending on the study design.
- Specifying Inclusion/Exclusion Criteria will enhance the quality of participant selection.



# Inclusion & exclusion criteria ( Cont.)

- Effective inclusion and exclusion criteria create the ideal pool of participants to get the most beneficial data for the study.
- There are several challenges when determining the inclusion and exclusion criteria:
  - Too narrow of a criterion can lead to a sample size that produces insignificant amounts of data.
  - Too broad of a criterion can lead to data that is clouded by external factors.



# Inclusion criteria

- Are characteristics that the participants must have if they are to be included in the study.
- Defined as the key features of the target population that the investigators will use to answer the research question.
- It will explain the different requirements someone must meet in order to participate in your study.





## **Inclusion criteria ( Cont.)**

- Typical inclusion criteria include demographic, clinical, and geographic characteristics.
- It is the researcher responsibility to determine which criteria are crucial for the participants to meet in order to help the study collect the most significant results.



# Inclusion criteria ( Cont.)

**It may include factors such as:**

- Age
- Sex
- Ethnicity.
- Type and stage of disease.
- The participant's previous treatment history.
- The presence or absence of other medical, psychosocial, or emotional conditions.



# Exclusion criteria

- Exclusion criteria are those characteristics that disqualify prospective participants from inclusion in the study.
- Describe subset of population that won't be studied.
- Characteristics that make it unethical to withhold treatment.
- Participants at high risk of side effects high likelihood of lost to follow-up.
- Characteristics that might interfere with the quality of the data.



## Exclusion criteria ( Cont.)

- The exclusion criteria list features of a person that, if met, immediately deems that person ineligible to participate in the study.
- It is consist of qualities about a person or the external factors around them that would go against the aim of the study or interfere with it.



## Exclusion criteria ( Cont.)

This may include:

- ✓ Medication use.
- ✓ Participation in another study with similar study interventions or procedures at the same time.
- ✓ Diagnosis of a condition that might interfere with the finding of the study.



# Enrollment criteria in any clinical research study

## Inclusion Criteria

Characteristics that are relevant to the research question.

- Demographic characteristics (e.g., age).
- Clinical characteristics (e.g., diagnosis).
- Geographic characteristics (e.g., clinic patients).
- Vulnerable populations (if applicable).



# Establishing Inclusion Criteria

- The inclusion criteria specify the main characteristics that define populations that are relevant to the research question and efficient for study.

E.g. a 5 year trial of calcium supplementation for preventing osteoporosis.



# Establishing Inclusion criteria(Cont.)

## ❖ Considerations

- Demographic characteristics

e.g. Females 50-60 years old

- Clinical characteristics

e.g. In good general health





# Establishing Inclusion criteria ( Cont.)

## ❖ Considerations

- Geographic (administrative) characteristics.

## ❖ Example

- Patients attending clinic at the investigator hospital.



# Establishing exclusion criteria

- Exclusion criteria specify subset of the population that will not be studied because of many factors.
- This may improve the feasibility of a study at the cost of generalizability.



# Establishing Exclusion criteria(Cont.)

## □ Considerations

- A high likelihood of being lost to follow-up.  
e.g. plan to move out of state.
- An inability to provide good data.  
e.g. Disoriented or have a language barrier.



# Establishing Exclusion criteria ( Cont.)

## □ Considerations

- Being at high risk of side effects.

e.g. Sarcoidosis due to propensity for hypocalcaemia.

- Characteristics that make it unethical to withhold study treatment.

e.g. Taking corticosteroids.



# Clinical versus community populations

- Clinic or hospital-based patients are inexpensive and easy to recruit.
- They are good for research questions concerned with diagnosis, and treatment.
- Patients usually got serious forms of disease, so give wrong impression about prognosis and other disease features.



# Population based samples

- Useful for guiding public health and clinical practice in the community.
- But they are difficult and expensive to recruit.



# How to increase sample size and diversity

- Collecting data by mail or telephone.
- Collaborating with colleagues in other cities.
- Using preexisting data sets.
- Collecting data by e mail.



# Non-response

How to minimize refusal to participate:

- Repeat contact attempts.
- Use alternative methods like mail, telephone, and home visits.
- Avoid invasive and uncomfortable tests.





## Non-response(Cont.)

How to minimize refusal to participate:

- Use brochures and individual discussions to decrease anxiety and discomfort.
- Provide incentives (provide test results and transportation costs).
- For language barriers: use bilingual staff and translated questionnaires.



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