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EVIDENCE-BASED PRACTICE

INTRODUCTION TO EVIDENCE-BASED PRACTICE

By:

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Introduction

***Healthcare is filled with uncertainty in situations such as:**

-Which treatment is most effective to produce the best patient outcome?

-How are patients experiencing their illness?

-What will be the outcome of a diagnosis if left untreated?

As PHYSIOTHERAPISTS, How do we know?

-Each clinical decision made or action taken is based on **knowledge**.

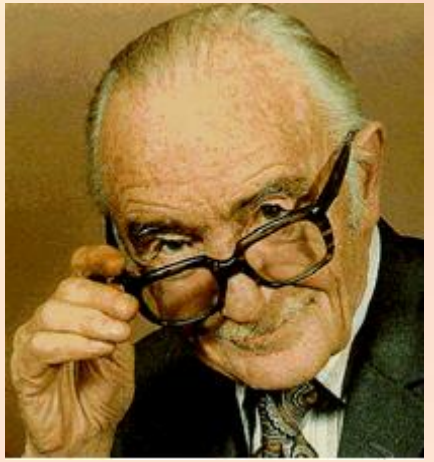
-This **knowledge** derives from a variety of sources, such as research, theories, experience, tradition, trial and error, authority, or logical reasoning.

III. Key Steps Of Evidence-based Practice

Evidence-Based Practice

- Founded by **Dr. Archie Cochrane**, a British epidemiologist, Who struggled with the efficacy of healthcare and challenged the public to pay only for care that had been empirically supported as effective **(Enkin, 1992)**.

- **Cochrane** was a strong proponent of using evidence from randomized Clinical trials because he believed that this was the strongest evidence on which to base clinical decisions.



Evidence-Based Practice

- In an exemplar case, **Cochrane** noted that thousands of low birth-weight premature infants **died needlessly**.

- He emphasized that the results of several randomized clinical trials supporting the effectiveness of corticosteroids therapy halt premature labor in high-risk women.

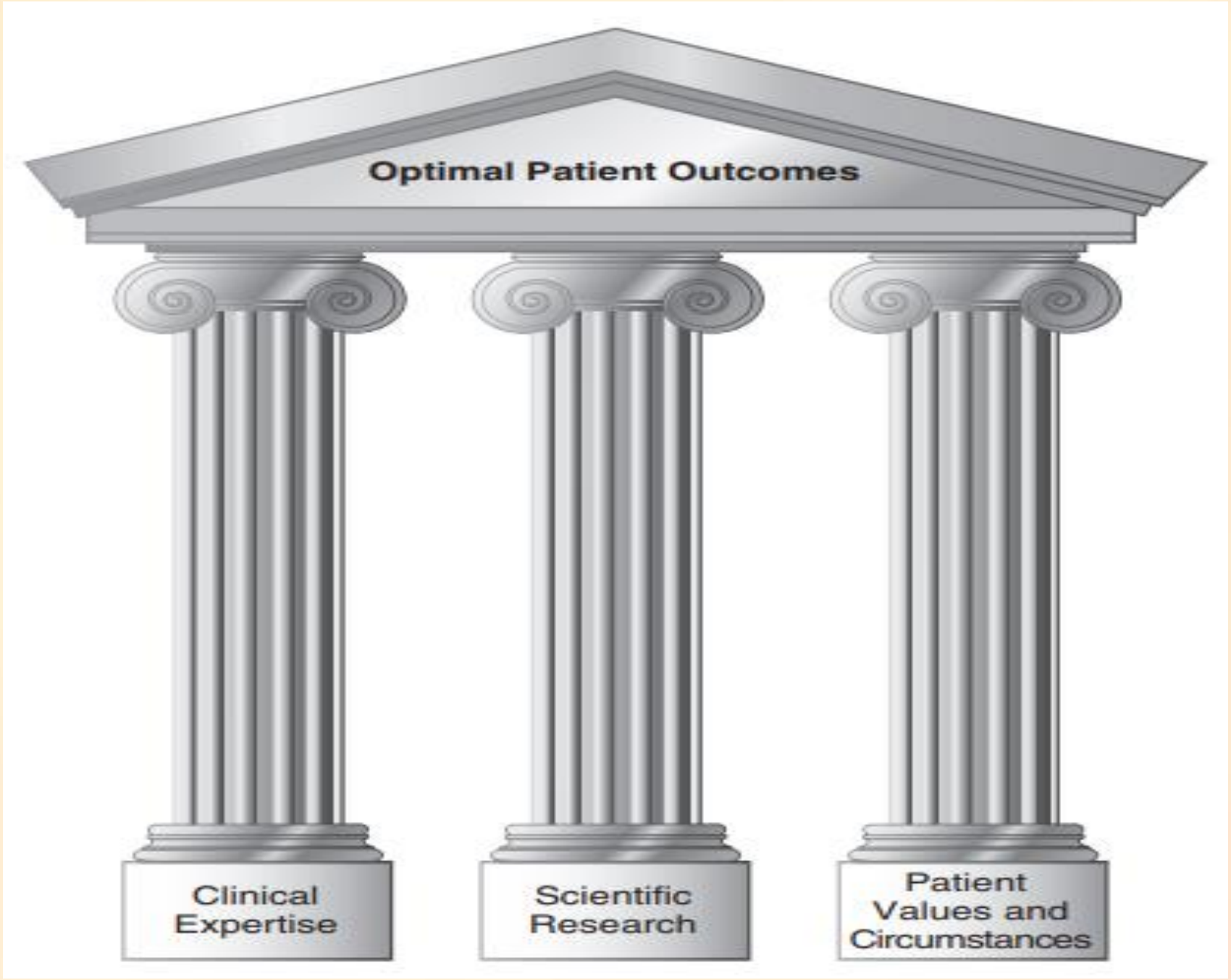
- A **systematic review** showed that **corticosteroid** therapy reduced the odds of premature infant death from **50%** to **30%** **(Cochrane collaboration, 2001)**.

Evidence-Based Practice

*Definition of EBP:

-It is the conscientious use of **Current Best Evidence** in making decisions about patient care.

-The integration of best research evidence with **best available scientific research, clinical expertise,** and **patient values** which when applied by practitioners will ultimately lead to improved patient outcome.


Optimal Patient Outcomes
Clinical Expertise
Scientific Research
Patient Values and Circumstances

***In the original model there are three fundamental components of evidence-based practice:**

1) Best evidence which is usually found in **clinically relevant research** that has been conducted using sound methodology.

2) Clinical expertise refers to the clinician's cumulated education, experience and clinical skills.

3) Patient values include the beliefs, preferences, expectations, and cultural identification that the patient and caregivers brings to the therapy environment.

TERMINOLOGY

- **Evidence-based Practice (EBP)**
- **Evidence-based Physical Therapy (EBPT)**
- **Evidence-based Health Care (EBHC)**
- **Evidence-based Medicine (EBM)**

*As an **evidence-based therapists**, **PTs** will provide care that is grounded in scientific research, guided by **clinical expertise**, and directed by **patients' individual values** and **circumstances**.

Evidence-Based Practice

- These **three types of evidence**: scientific research, clinical expertise, and patient values and circumstances form the basis on which the Physical Therapist and patients will decide on **the best physical therapy treatment plan** in any given situation.

- The **aim of evidence-based** is to make Physical Therapists sure that patient care is informed by the greatest available research in order to maximize the benefits that patients receive from therapy.

*Third-party payers, patients, and the general health-care community have an expectation that the practice of physical therapists is evidence based.

*The most efficient way to search for the best research evidence is to start by searching for evidence summaries.

*Then, if necessary (as is frequently the case), proceed down the levels of the pyramid to individual studies.

*Learning to search in research databases, such as PubMed, to find the best research evidence takes practice and persistence.

Challenges Of EBP

- New, unfamiliar
- Need to develop good search strategies
- Must identify **best** databases
- Need to do critical appraisals

- Much of relevant research is qualitative; need more systematic reviews of **quantitative** research

- **Practice on evidence** can decrease the uncertainty that patients and clinicians experience in a complex healthcare system.

- **Evidence** indicates that patients who receive care based on the best and latest evidence from well designed studies **experience 28% better outcomes (Heater, Becker, & Olson, 1988)**.

Benefits of EBP

-Effective, and optimum care for a specific patient.
-Bridging and closing clinicians' knowledge gaps efficiently.
-Enhanced provider-patient relationships including improved patient participation, adherence to instructions.
-Supports professional competency through efficient continuing education, managing the need to "keep up" and the increasing volume of medical information.
-More efficient reimbursement of costs based on effective diagnoses and treatments, answering challenges to clinical decisions with strong research evidence.
-Supports patients with well-researched health care questions and the desire to participate in their own health management.

Key Steps of Evidence-Based Practice

- **Step 1:** Identify the Need for Information, and Develop a Focused and Searchable Clinical Question.
- **Step 2:** Conduct a Search to Find the Best Possible Research Evidence to Answer Your Question.
- **Step 3:** Critically Appraise the Research Evidence for Applicability and Quality.
- **Step 4:** Integrate the Critically Appraised Research Evidence With Clinical Expertise and the Patient' s Values and Circumstances.
- **Step 5:** Evaluate the Effectiveness and Efficacy of Your Efforts in Steps 1–4, and Identify Ways to Improve Them in the Future.

• STEP 1: Formulate The Clinical Question

*Clinical questions should be asked in the format that will yield the most relevant and best evidence using the **PICO** format (i.e., Patient or population, intervention of interest, comparison intervention or status, and outcome).

-Remember, **PICO** is a model, **NOT** a rigid structure.

“P” for the **patient** or **problem**

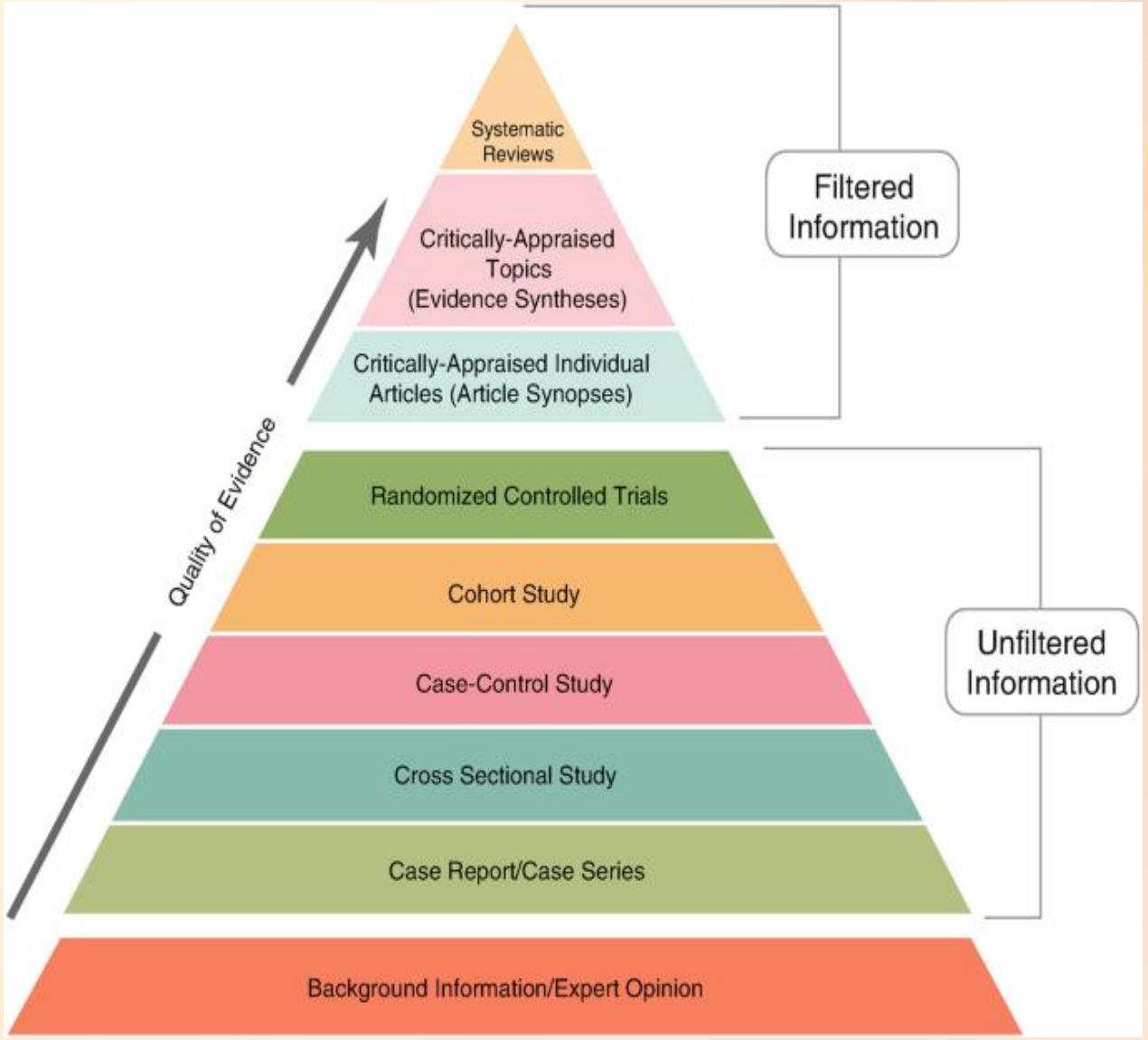
“I” for the **intervention** of interest

“C” for **comparison**, and

“O” for **outcome**

• STEP 2: Search For Best Evidence

*First begin with, systematic reviews or meta-analyses (summaries) and evidence-based clinical practice guidelines, which are regarded as **the strongest level of evidence** on which to base practice decisions **(Guyatt & Rennie, 2002)**.



• STEP 3: Appraise the evidence

*It is important to **be skilled** in **critical appraisal** so that you can further filter out studies that may seem interesting but are weak.

*Use a simple critical appraisal method that will answer these questions:

-what question did the study address?

-Were the methods valid?

-What are the results?

-How do the results apply to practice?

• STEP 4: Implement The Evidence

*Individual clinical decisions can then be made by **combining the best available evidence** with **clinical expertise and patients' values.**

*These clinical decisions should then **be implemented into PT practice** which can then be justified as **Evidence Based Physical Therapy**. The final step in the process is to evaluate the effectiveness

• STEP 5: Evaluate The Outcome

*The **final step** in the process is to **evaluate** the effectiveness and efficacy of the clinical decision in direct relation to the patient.

-Was the application of the new information effective?

-Should this new information continue to be applied to practice?

-Can the clinical decision lead to a more effective, safe, and rewarding quality of life?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ASKING A CLINICAL QUESTION
AND
SEARCHING FOR RESEARCH EVIDENCE

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How Do I Know If I Need Information?

*During your physical therapy education, you are flooded with information about how to care for patients. As an evidence based therapist and lifelong learner, you will constantly add to your knowledge.

*Every patient is different, and many present in ways that push you to find new information to optimize their care. Also, scientific evidence rapidly changes. There are now over 3,500 new clinical trials published every year related to physical therapy. You cannot know the answer to every clinical question that arises.

*The key is to identify important knowledge gaps and know how to fill them with the best available evidence.

*Identification of your information needs may occur before you see a patient and throughout a patient's course of care.

The six components of the APTA definition regarding patient management

***Examination:** "Physical therapists conduct a history, perform a systems review, and use tests and measures in order to describe and/or quantify an individual's need for services.

***Evaluation:** A dynamic process in which the physical therapist makes clinical judgments based on data gathered during the examination. This process also may identify possible problems that require consultation with or referral to another provider.

***Diagnosis:** A process of "integrating and evaluating the data that are obtained during the examination to describe the individual condition in terms that will guide the physical therapist in determining the prognosis and developing a plan of care.

*__Prognosis:__ Determination of the level of optimal improvement that may be attained through intervention and the amount of time required to reach that level. The plan of care specifies the interventions to be used and their timing and frequency.

*__Intervention:__ “Physical therapists purposefully interact with the individual and, when appropriate, with other people involved in his or her care, using various” procedures or techniques “to produce changes in the condition.

*__Outcomes:__ Results of patient/client management, which include the impact of physical therapy interventions in the following domains: pathology/pathophysiology (disease, disorder, or condition); impairments, functional limitations, and disabilities; risk reduction/prevention; health, wellness, and fitness; societal resources; and patient/client satisfaction

*The **American Physical Therapy Association** (**APTA**) defines patient management as having the following six components:

1. Examination
2. Evaluation
3. Diagnosis
4. Prognosis
5. Intervention
6. Outcomes measurement

*Questions may pertain to:

(1) the anatomic, physiologic, or pathophysiologic nature of the problem or issue.

(2) the medical and surgical management options.

(3) the usefulness of diagnostic tests and clinical measures to identify, classify, and/or quantify the problem.

(4) which factors will predict the patient or client's future health status.

(5) the benefits and risks of potential interventions.

(6) the utility of clinical prediction rules.

(7) the nature of the outcomes themselves and how to measure them.

(8) the perspectives and experiences of others with similar problems or issues.

*The 1st and 2nd forms are referred to as "**background questions**". While the forms from 3 to 8 are referred to as "**foreground questions**".

Background Questions

*Background questions reflect a desire to understand the nature of an individual's problem or need.

*Often these questions focus on the natural evolution of a condition and its medical or surgical management rather than on the physical therapy component.

*Here are some examples:

- "What are the side effects of steroid treatment for asthma?"
- "How long will it take for a total knee arthroplasty incision to heal?"
- "What are the signs and symptoms of an exacerbation of multiple sclerosis?"
- "Will it be possible to play baseball again after elbow surgery?

TABLE 3-1 Examples of Potential Sources of Answers to Background Questions

Name	Type of Source	Helpful Links
Centers for Disease Control and Prevention	Government	www.cdc.gov/DiseasesConditions/ www.cdc.gov/HealthyLiving/ www.cdc.gov/DataStatistics/
National Institutes of Health	Government	http://health.nih.gov/
American Heart Association	Professional Society	www.heart.org/HEARTORG/Conditions/Conditions_UCM_001087_SubHomePage.jsp
American Physical Therapy Association	Professional Society	www.moveforwardpt.com/Default.aspx
National Coalition for Cancer Survivorship	Patient Advocacy	https://www.canceradvocacy.org
National Down Syndrome Society	Patient Advocacy	www.ndss.org/Resources/Health-Care/

Foreground Questions

*Foreground questions are the heart of EBPT practice. These questions help clinicians, and their patients or clients make decisions about the specific physical therapist management of their problem or concern.

*Foreground questions contain four key elements originally referred to with the acronym “PICO” (population, intervention, comparison, outcome).

TABLE 3-2 Foreground Questions Physical Therapists Might Ask About Diagnostic Tests, Clinical Measures, Prognostic Factors, Interventions, Clinical Prediction Rules, Outcomes, Self-Report Outcomes Measures and Patient or Client Perspectives

	Foreground Questions: Simple	**Foreground Questions: Comparative**
Diagnostic Test	Will the Neer's test (I) help me to detect rotator cuff impingement (O) in a 35-year-old male tennis player with shoulder pain (P)?	Is the Neer's test (I) more accurate than the lift-off test (C) for detecting rotator cuff impingement (O) in a 35-year-old male tennis player with shoulder pain (P)?
Clinical Measure	Is a manual muscle test (I) a reliable and valid measure of quadriceps strength (O) in a 42-year-old woman with multiple sclerosis (P)?	Is a manual muscle test (I) as reliable and valid as a handheld dynamometer (C) for measuring quadriceps strength (O) in a 42-year-old woman with multiple sclerosis (P)?

Prognostic Factor	Is lower extremity muscle strength (I) a predictor of fall risk (O) in a 76-year-old woman with diabetes (P)?	Which is a more accurate predictor of fall risk (O), lower extremity muscle strength (I) or proprioception (C), in a 76-year-old woman with diabetes (P)?
Intervention	Is proprioceptive neuromuscular facilitation (PNF) (I) an effective treatment technique for restoring core trunk stability (O) in a 7-year-old child with right hemiparesis due to stroke (P)?	Is PNF (I) more effective than the neurodevelopmental technique (NDT) (C) for restoring core trunk stability (O) in a 7-year-old child with right hemiparesis due to stroke (P)?
Clinical Prediction Rule	Are the Ottawa Ankle Rules (I) a valid clinical prediction rule to determine the need for a radiograph (O) in an 11-year-old child with ankle pain after a fall on an icy surface (P)?	Which is a more valid clinical prediction rule to determine the need for a radiograph (O) in an 11-year-old child with ankle pain after a fall on an icy surface (P): the Ottawa Ankle Rules (I) or the Malleolar Zone Algorithm (C)?

Outcomes	Does participation in a cardiac rehabilitation program (I) increase the chance that a 58-year-old man who has had a myocardial infarction (P) will return to work (O)?	Does participation in a cardiac rehabilitation program (I) increase the chance of returning to work (O) more than a home walking program (C) for a 58-year-old man following a myocardial infarction (P)?
Self-Report Outcomes Measure	Will the Minnesota Living with Heart Failure Questionnaire (MLHFQ) (I) detect change following rehabilitation (O) in an 82-year-old woman with chronic heart failure (P)?	Which instrument is more sensitive to change following rehabilitation (O) for an 82-year-old woman with chronic heart failure (P): the MLHFQ (I) or the Chronic Heart Failure Questionnaire (CHFQ) (C)?
Patient or Client Perspective	Will a 66-year-old homeless man (P) perceive as helpful (O) the implementation of a physical activity program at a local shelter (I)?	When considering homeless individuals (P), do perceptions about the helpfulness (O) of a physical activity program (I) differ between males and females (C)?

*Questions About Diagnostic Tests:

Foreground questions about diagnostic tests usually focus on which tests will provide the most accurate and persuasive information (e.g., the likelihood that an individual has the condition of interest) in a timely manner with the least amount of risk, cost, or both.

*Questions About Clinical Measures:

Foreground questions about clinical measures usually focus on assessments of measurement reliability and measurement validity.

*Questions About Prognostic Factors:

Foreground questions about prognostic factors arise because therapists and patients or clients want to know which indicators, predictors, or factors are most important to consider when predicting the outcomes of preventive activities, interventions, or inaction.

*Questions About Outcomes and Self-Report Outcomes Measures:

Outcomes are likely to have the most relevance for an individual when they pertain to activities and participation in the context of their daily life. Foreground questions about these instruments focus on their ability to capture relevant information, their responsiveness to changes in a patient or client's status, and their ease of administration and processing.

Searching for Evidence:

Once a person-centered clinical question is formulated, it is important to plan a general search strategy before diving into the various sources of evidence available.

***The following five steps are recommended as a starting point:**

1) Determine Which Database Will Be Most Useful:

(e.g., Medline/PubMed, Physiotherapy Evidence Database [PEDro], Google Scholar, and Cochrane Library.

2) Identify Search Terms to Enter into the Database:

All electronic databases and search engines require input from the user to start the search. The most common form of input is a keyword, or search term that will be used to identify relevant information.

*__Keyword(s):__ The word(s) or term(s) that is/are entered into an electronic database search function to locate evidence pertaining to a clinical question.

3) Use Search Configuration Options to Streamline the Process:

Words such as “and,” “or,” “not,” and “near” are used universally to create search term combinations. Configuration options also include methods to limit or expand the search.

*Search filters may include the language in which the evidence was written, publication date, type of research design, and search basis, such as keyword, author, or journal name.

4) Be Prepared to Reformulate the Question:

A common problem during an evidence search is either an excessive number of citations (or hits) or none at all. When this situation happens, the first thing to do is go back to the database features and determine if there are additional options to narrow or expand the search.

*There are several options for revising the question to be more precise:

A. Using a more specific diagnostic label such as “degenerative joint disease” or “rheumatoid arthritis” instead of the general phrase “joint pain”;

B. Adding more specific details about the individual, such as his age; and/or

C. Using a more specific outcome, such as “pain relief” instead of “symptom management.”

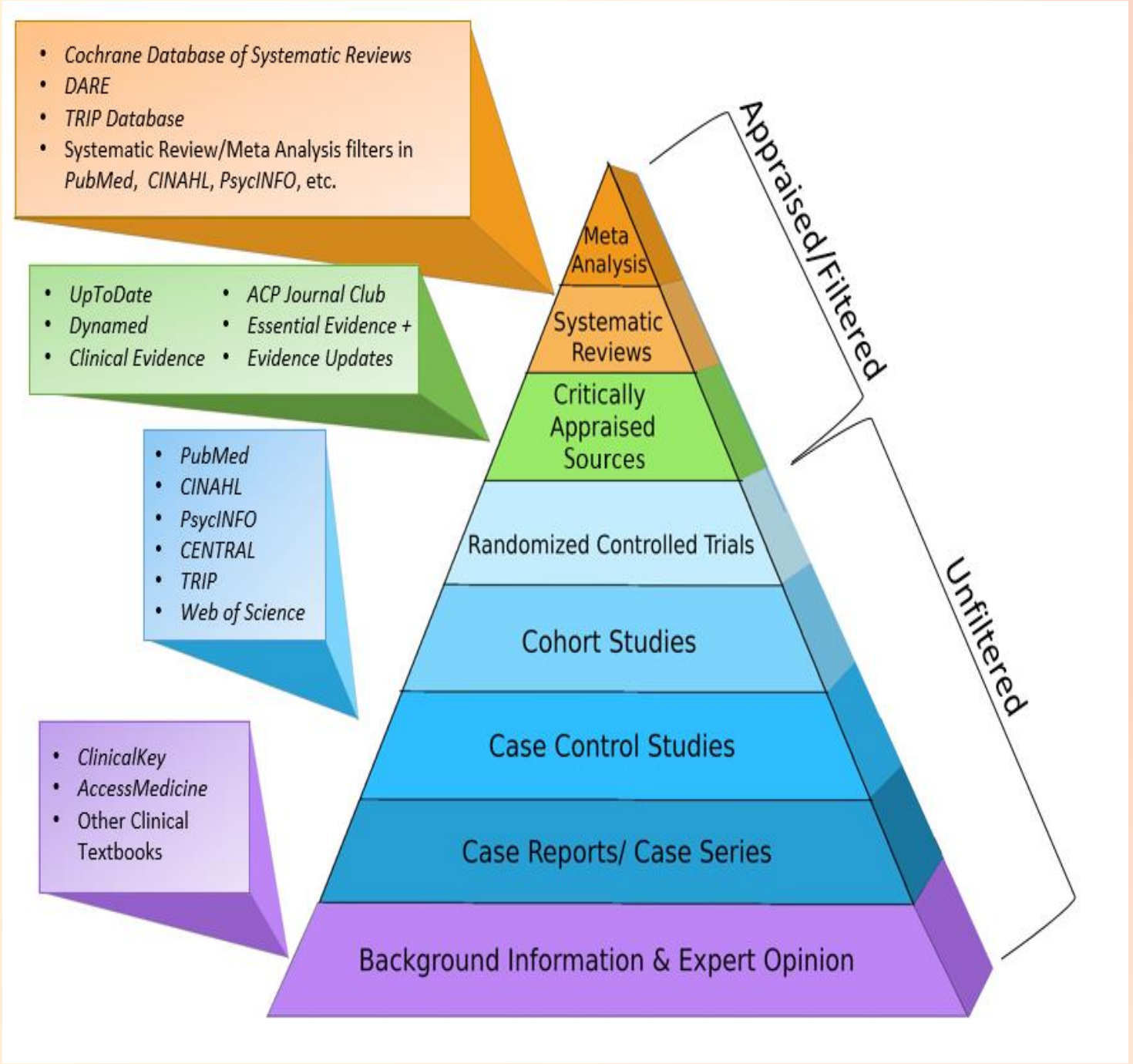
5) Aim for the Highest Quality Evidence Available:

The two general sources of evidence are described as primary and secondary.

-**Primary sources** provide individual original research reports via peer-reviewed journals and websites, theses, and proceedings from professional meetings.

-**Secondary sources**, such as textbooks, summaries on websites, and review papers, contain information based on primary sources.

*Evidence hierarchies have been developed to speed up identifying high-quality evidence from primary and secondary sources.

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EVIDENCE-BASED PRACTICE

RESEARCH DESIGNS

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General Features of Research Designs

The following general features of research designs are important to recognize and understand when reviewing evidence:

- The investigator’s research paradigm.
- The overall implemented design format is consistent with the research paradigm.
- The number of groups studied.
- The type(s) of data collected.
- The role of time in the study.
- The type and degree of control imposed, if any.

Research Paradigms:

Research designs usually reflect one of two paradigms about how the world is understood that is, either a quantitative or a qualitative perspective.

-A **quantitative research paradigm** is based on a positivist philosophy that is used to describe an approach to the study of society that relies specifically on empirical scientific evidence, such as controlled experiments and statistics.

-A **qualitative research paradigm**, in contrast, assumes that knowledge and understanding are contextual and relative to everyone studied.

Design Format: Quantitative Research:

*Quantitative research designs are characterized by whether the investigators actively intervene with the research subjects.

***Experimental designs** are those in which the researchers purposefully manipulate some of the subjects and then measure their resulting behavior.

*These designs use at least two groups of subjects for comparison purposes and include a process for randomly allocating individuals into each of these groups.
*The comparison allows investigators to determine whether there are differences in outcomes between the group(s) that is (are) manipulated and the group(s) that is (are) not.
*Random assignment to these groups is the method best suited to distributing individuals equally among them.

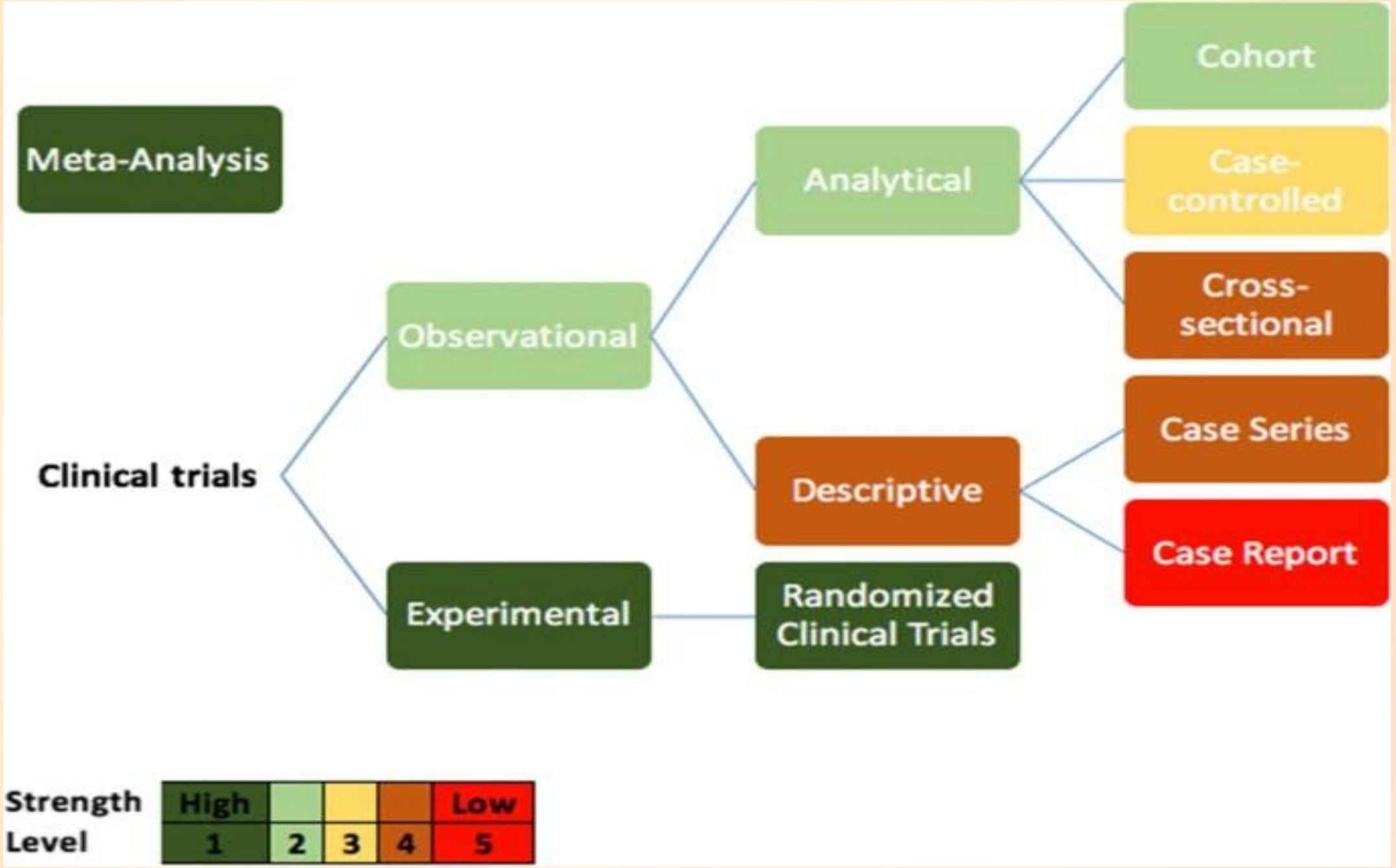
*__Quasi-experimental designs__ also involve purposeful manipulation of the subjects by the investigators, but they lack either a second group for comparison purposes or a random assignment process, or both.

*Finally, __nonexperimental designs__ are those in which the investigators are simply observers who collect information about the phenomenon of interest; there is no purposeful manipulation of subjects by the researchers to produce a change in behavior or status. These designs also are referred to as “observational studies.

Design Format: Qualitative Research:

*Qualitative studies investigate subjects’ thoughts, perceptions, opinions, beliefs, attitudes, and/or experiences.

*The analyses focus on the identification of patterns or themes in the data (i.e., words or descriptive observations) that may be used for further exploration in a subsequent round of data collection.


Meta-Analysis
Clinical trials
Observational
Experimental
Analytical
Descriptive
Randomized Clinical Trials
Cohort
Case-controlled
Cross-sectional
Case Series
Case Report
Strength
Level
High
Low
1
2
3
4
5

Number of Groups:

*Research designs may be characterized by the number of groups of subjects used in the analysis.

*In quantitative approaches, the number of groups commonly is of most interest when comparisons between or among data points are intended to answer the research question. A study in which repeated measures of an outcome are compared for a single group of subjects is referred to as a within-subjects design.

*In these designs, everyone's baseline measure is compared to any of their own subsequent measures to determine if a change has occurred. Alternatively, a design in which outcomes are compared between two or more independent groups of subjects is referred to as a between-subjects design.

*Typically, the average outcome score for each group is used in these analyses. The number of groups studied also is relevant to investigations in which associations between variables and predictions about outcomes are evaluated.

*In qualitative approaches, the number of groups included depends on the extent to which knowledge and experience are distributed across the population of interest as well as the influence of logistical considerations related to access and/or time.

Type of Data:

*Quantitative designs most commonly use numeric data that may be analyzed by mathematical techniques. However, non-numeric data also may be used, as is often the case with survey responses or classifications into descriptive categories such as gender, race/ethnicity, or religious affiliation.

*Qualitative designs, in contrast, focus on the collection of subjects' words or the researchers' descriptions of subject behaviors in order to identify themes that provide insight into the meaning of a phenomenon.

Time Elements:

*All quantitative and qualitative research designs incorporate a time element that has both duration and direction. With regard to the duration, investigators must decide whether they want data collected once during a single point in time or a limited time interval (a cross-sectional study) or whether they will take repeated measures over an extended period of time (a longitudinal study).

*The time "direction" is determined by whether the investigators want to use historical information for data (a **retrospective design**) or they want to collect their own data in real-time (a **prospective design**).

Degree of Control:

*Another design feature is the degree to which controls can be imposed on the behavior of all participants in the study, as well as the conditions under which the project is conducted.

*The issue of control relates to the need to minimize bias in a study. Bias refers to results that systematically deviate from the truth.

***Degree of control** is provided in procedures related to:

- Recruitment, assignment, communication with, and management of subjects.
- Calibration and use of necessary equipment.
- Maintenance of the environmental conditions during study activities.
- Administration of testing and/or training activities.
- Collection and recording of data.
- Communication among investigators and others involved in the project.

*__Experimental designs__ are the most restrictive in terms of the amount of control imposed on study participants and conditions. At a minimum, this effort starts with the randomization of subjects into two or more groups for comparison.

*This **control is necessary** to improve the believability of a study whose aim is to demonstrate a cause-and-effect relationship between the variable that is manipulated (e.g., a new treatment technique) and the change in subject behavior (e.g., improvement in function).

*__Quasi-experimental designs__ lack either the control achieved by the random placement of subjects into groups, or the use of a comparison group, or both; however, they may still include procedures that manage participant behavior and environmental conditions pertinent to the study.

*Finally, the extent of control in **nonexperimental studies** is limited to protocols for measurement and collection of data.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ADVANTAGES AND DISADVANTAGES OF RESEARCH DESIGNS

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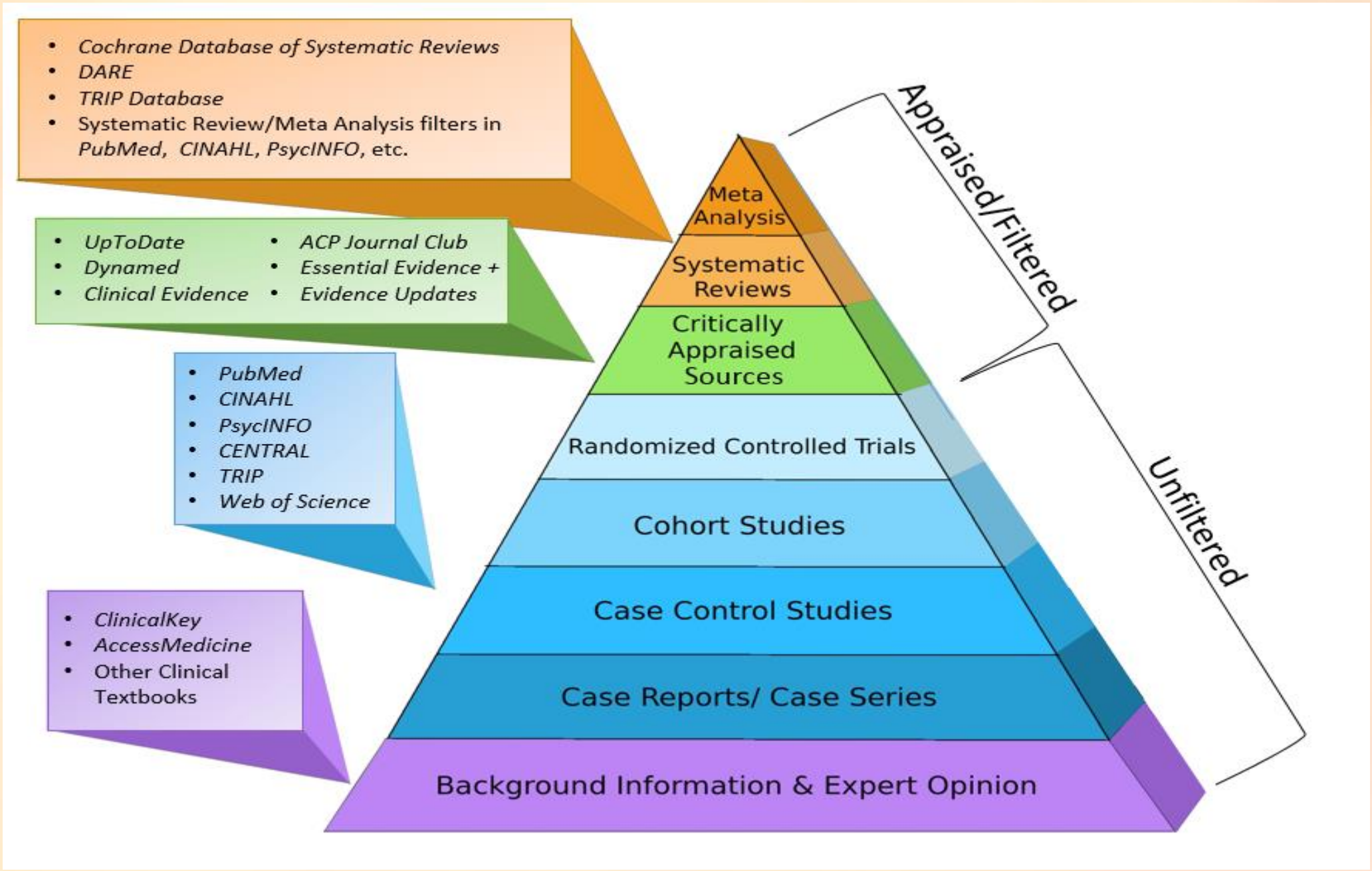
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DARE
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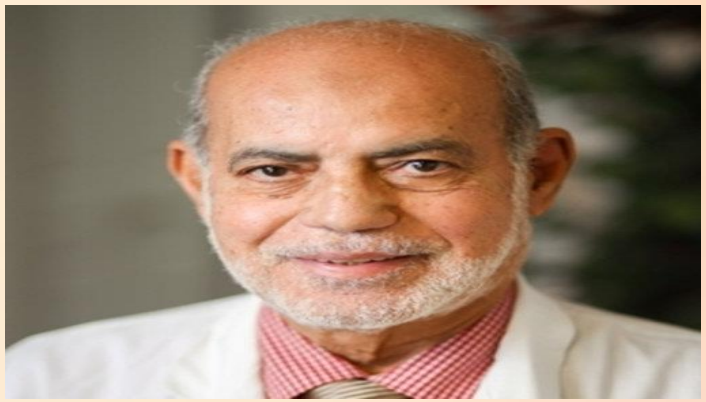
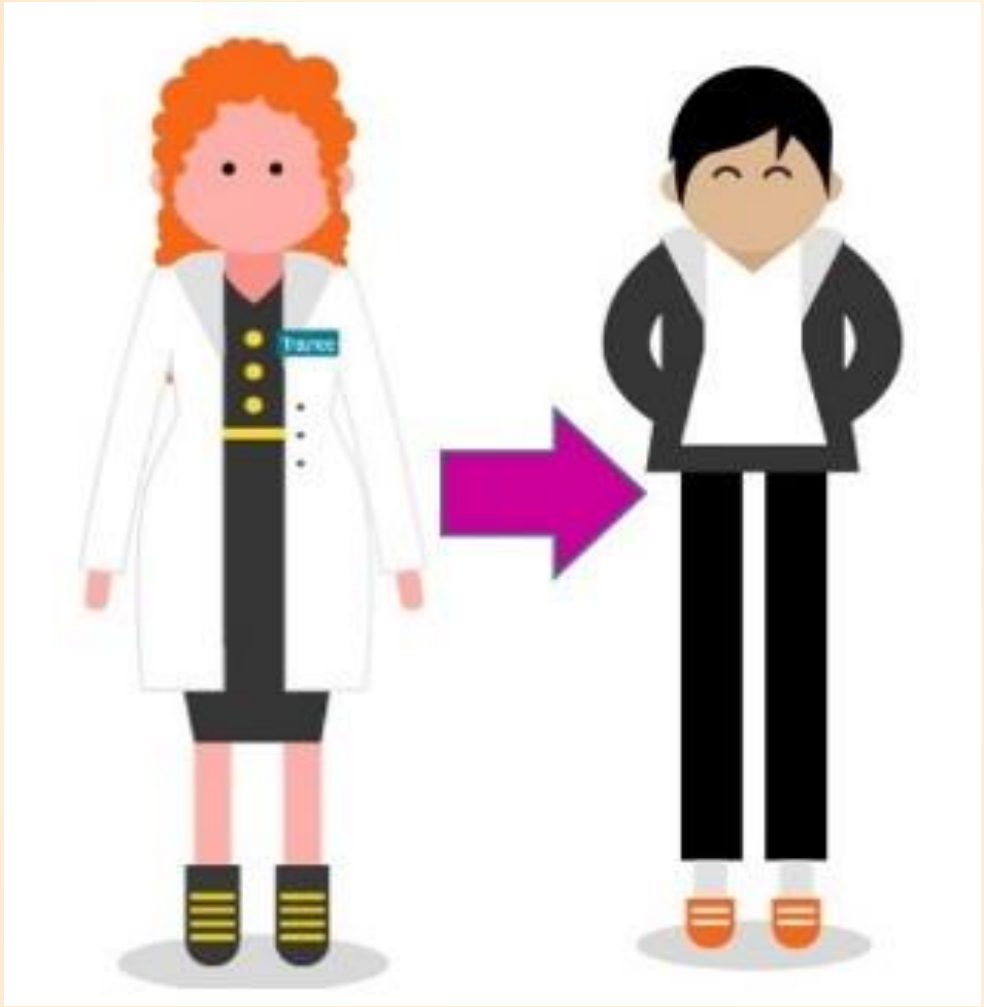
UpToDate
Dynamed
Clinical Evidence
ACP Journal Club
Essential Evidence +
Evidence Updates
PubMed
CINAHL
PsycINFO
CENTRAL
TRIP
Web of Science
ClinicalKey
AccessMedicine
Other Clinical Textbooks
Meta Analysis
Systematic Reviews
Critically Appraised Sources
Randomized Controlled Trials
Cohort Studies
Case Control Studies
Case Reports/ Case Series
Background Information & Expert Opinion
Appraised/Filtered
Unfiltered

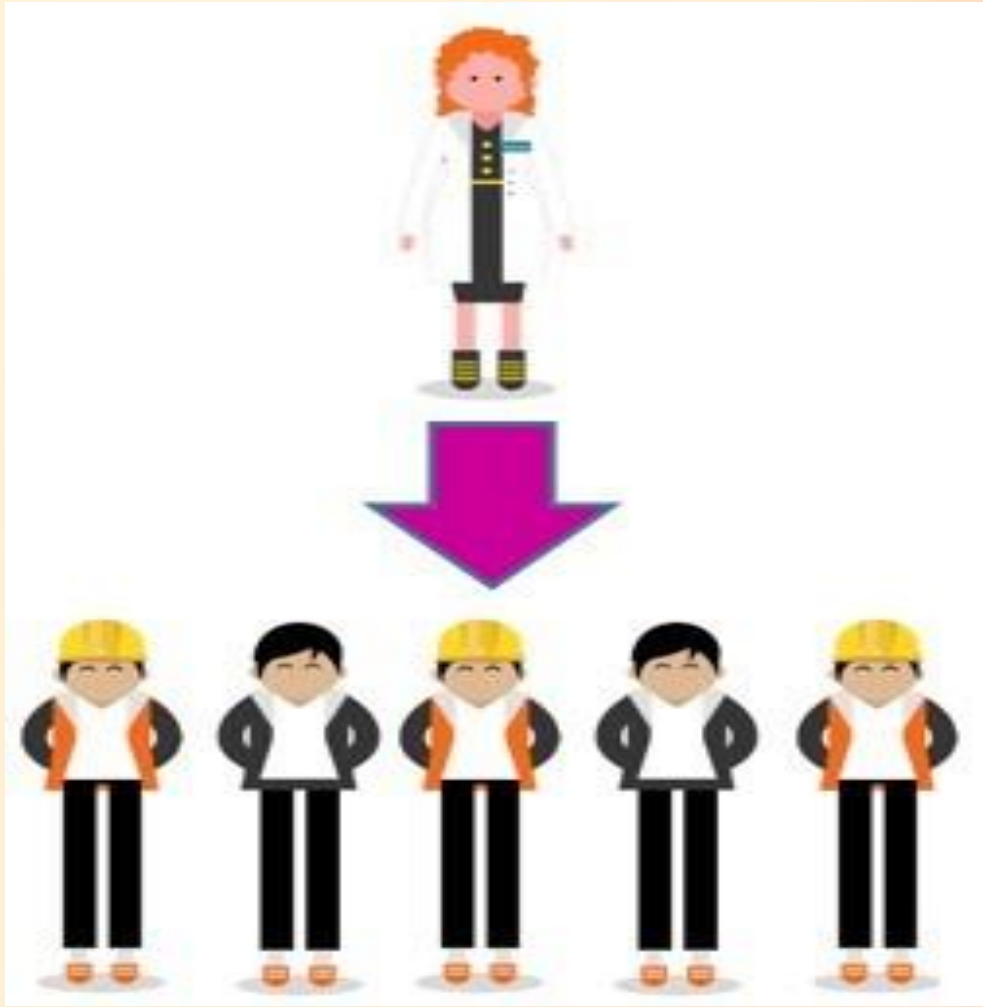
Features of Research Designs

In-Vitro Research, Animal Research, and Expert Opinion



Case Reports, Case Series study





*Description of the Case Reports, and Case Series study designs:

-Case Reports (Case study) is an observation for an event that occurred in a single patient or maximally in 5 patients.

-Case Series is description of characteristics of group of patients (maximally 10 patients) with the same disease or treatment.

*Advantages of the Case Reports, and Case Series study designs:

-Can be published quickly

-Provides very detailed information

-It has the ability to detect the novelties.

-Feasible (Less time and finance)

*Disadvantages of the Case Reports, and Case Series study designs:

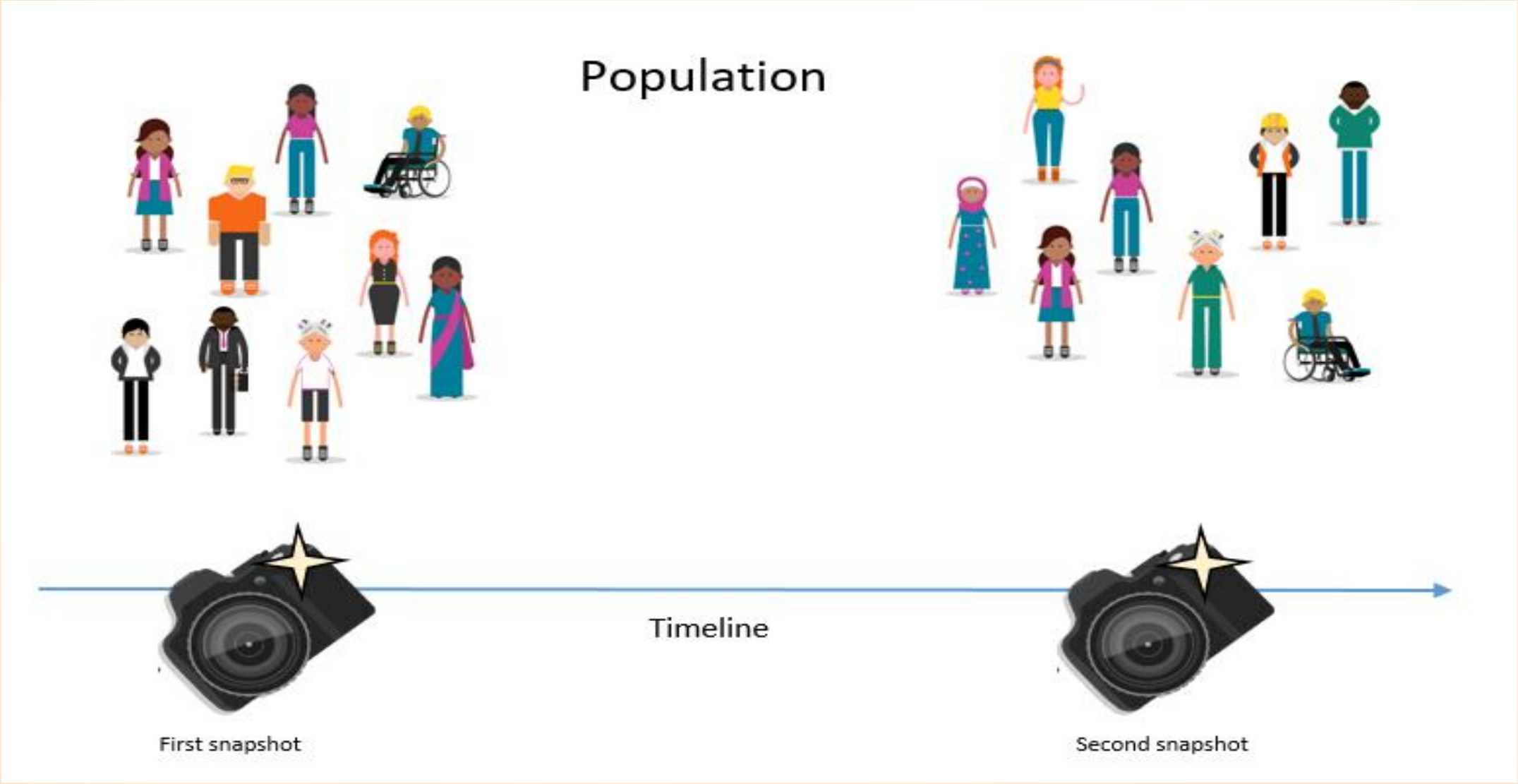
-May include researcher bias

-Can't always be generalized to the broader population

-No control (uncontrolled)

-The lack of causal-effect relationship

Cross-sectional study



*Description of the Cross-sectional study design:

Measures prevalence of risk factors (e.g., interventions, exposures) and outcomes at **one time point**.

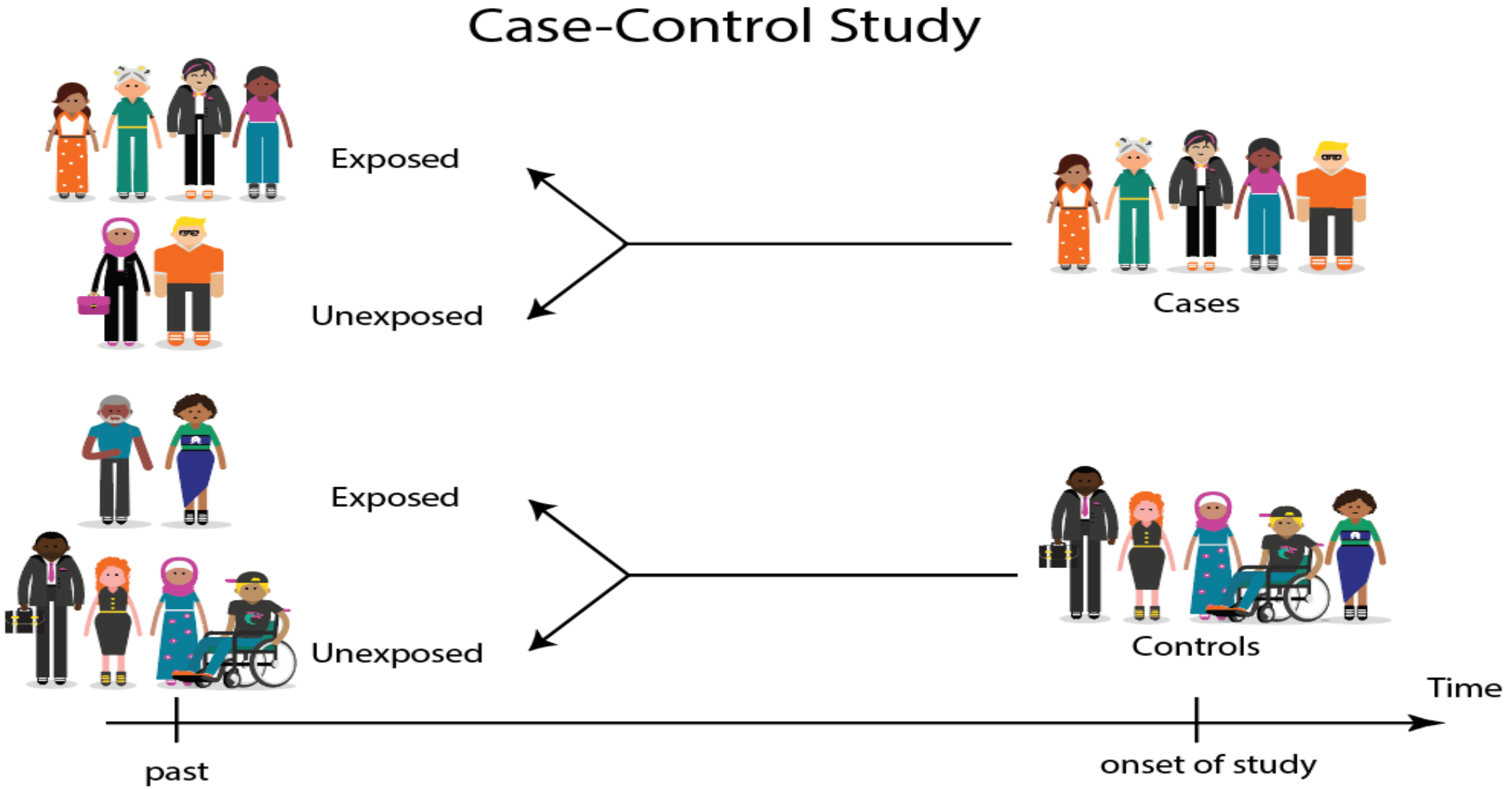
*Advantages of the Cross-sectional study design:

-Relatively inexpensive, easy, and quick
-Often generalizable
-Provides valid estimates of prevalence for risk factors and outcomes.

*Disadvantages of the Cross-sectional study design:

-Lack of generalizability
-Inability to show cause and effect
-The danger of over interpretation of a single case
-The lack of relevance on the rare

Case-Control study



*Description of the Case-Control study design:

A study that compares two groups of people: those with the disease or condition under study (cases) and a very similar group of people who do not have the disease or condition (controls).

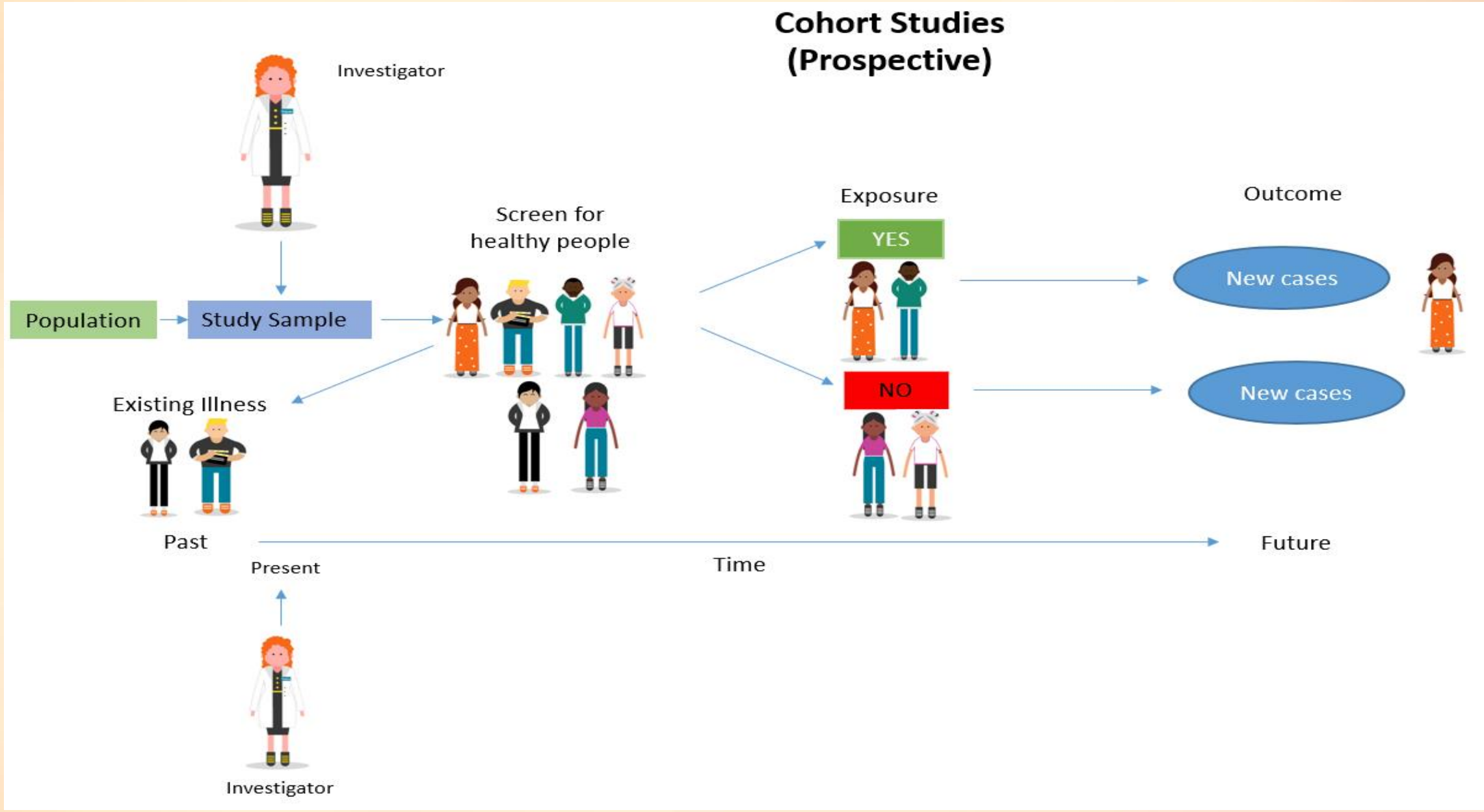
*Advantages of the Case-Control study design:

-Require less time and less expensive
-Require smaller sample size
-Can evaluate multiple exposures
-Good for uncommon diseases

*Disadvantages of the Case-Control study design:

-Cannot determine incidence or prevalence
-Cannot determine causality
-Recall bias and Selection bias

Prospective Cohort study



*Description of the Prospective Cohort study design:

A study that follows over time groups of individuals who are alike in many ways but differ by a certain characteristic (e.g., male doctors who smoke and those who do not smoke) and compares them for a particular outcome (such as lung cancer).

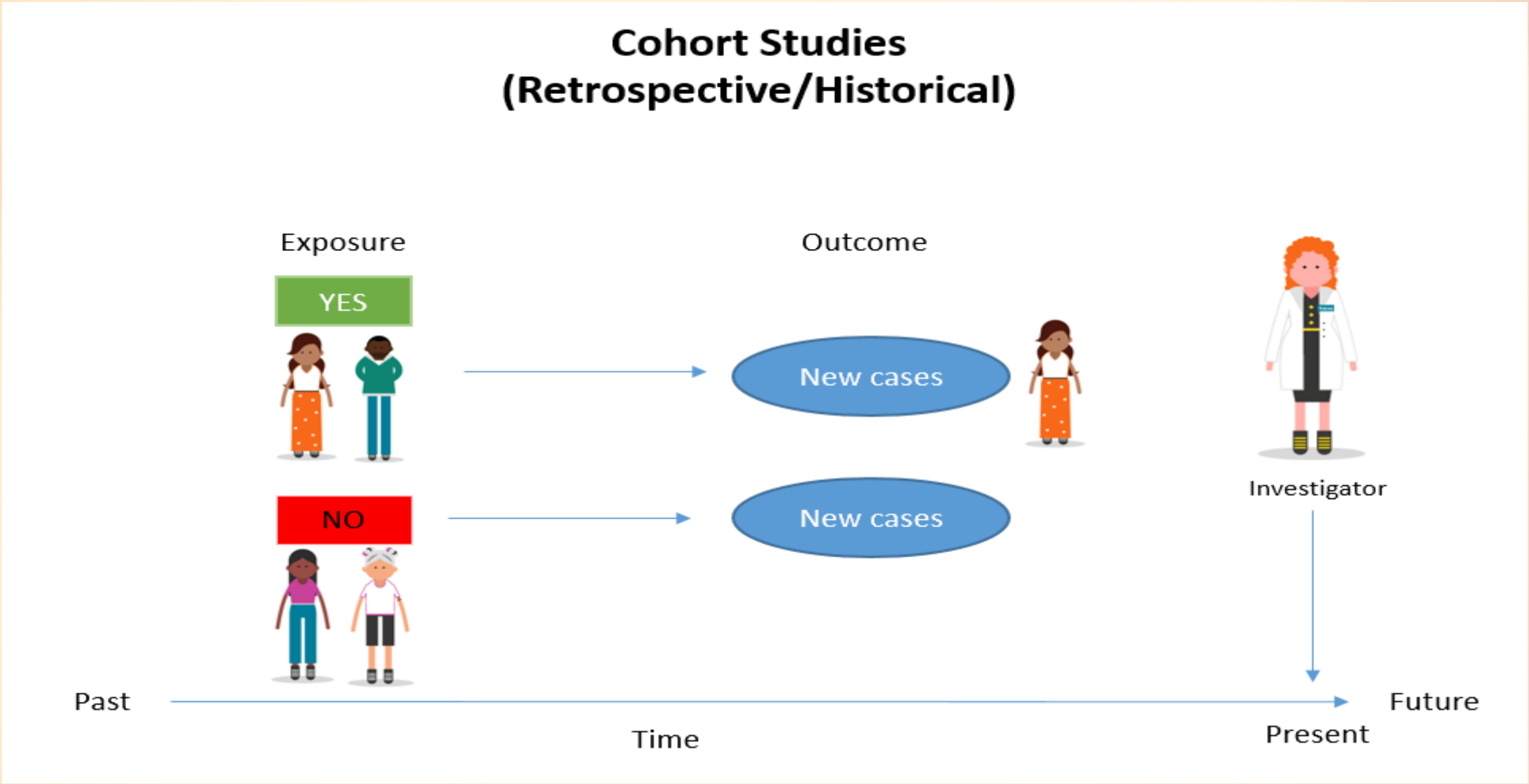
*Advantages of the Prospective Cohort study design:

-Can determine incidence
-Can determine causality of exposure
-Can evaluate multiple outcomes and risk factors

*Disadvantages of the Prospective Cohort study design:

-High cost
-Not suitable for rare diseases
-Longer duration of follow up
-Subjects lost over time (Dropouts)

Retrospective Cohort study



*Description of the Retrospective Cohort study design:

A type of observational study, also called a historic cohort study. The data are collected from records. Both the exposure and outcome of interest have already occurred in the past. It is often used in fields related to medicine to study the effect of exposures on health outcomes.

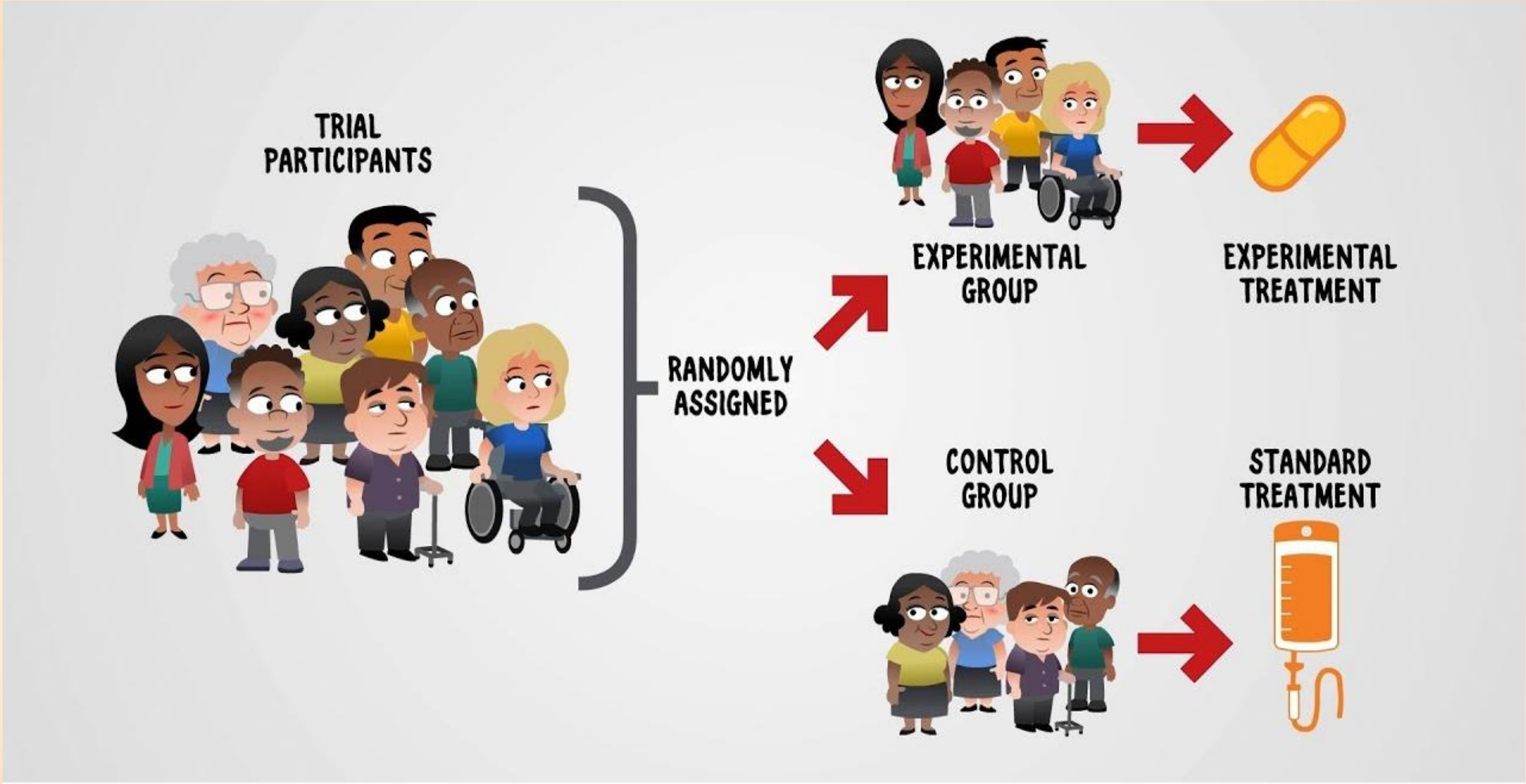
*Advantages of the Retrospective Cohort study design:

-A great choice if there are any ethical considerations
-Quick and inexpensive
-Can be useful when studying rare exposures

*Disadvantages of the Retrospective Cohort study design:

-Recall bias and Observer bias
-Can never establish causality. This leads to low internal and external validity.
-Difficulty in controlling of confounders

Randomized Controlled study



*Description of the Randomized Controlled study design:

It measures the effectiveness of a new intervention or treatment. Randomization reduces bias and provides a rigorous tool to examine cause-effect relationships between an intervention and outcome.

*Advantages of the Randomized Controlled study design:

-Demonstrates Causality
-Randomization eliminates the influence of confounding variables
-Blinding decreases bias

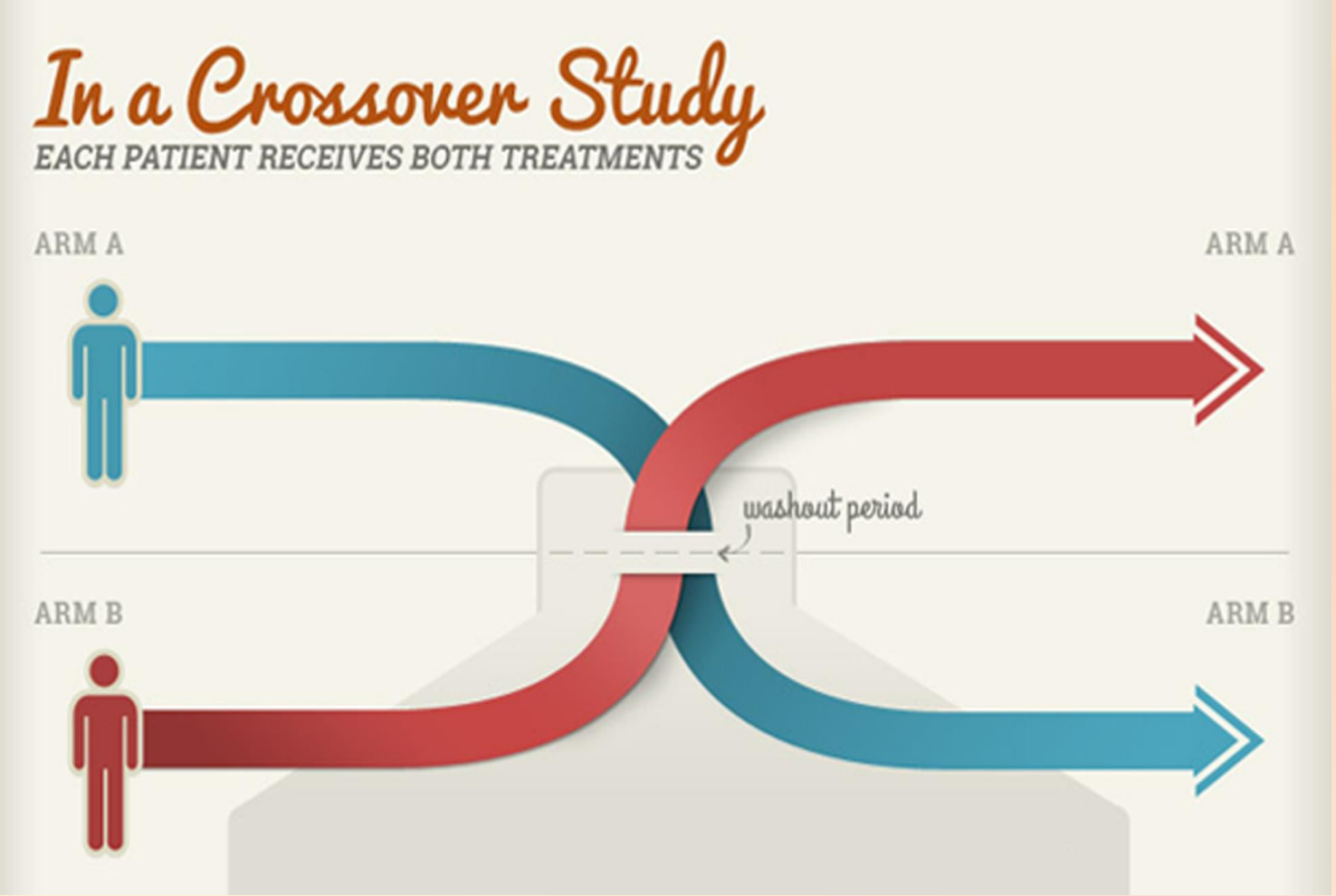
*Disadvantages of the Randomized Controlled study design:

-Expensive and time consuming
-Ethical considerations
-Usually requires a large number of participants
-Inclusion and exclusion criteria my limit generalizability

Crossover Study Design

*Description of the Crossover Study Design:

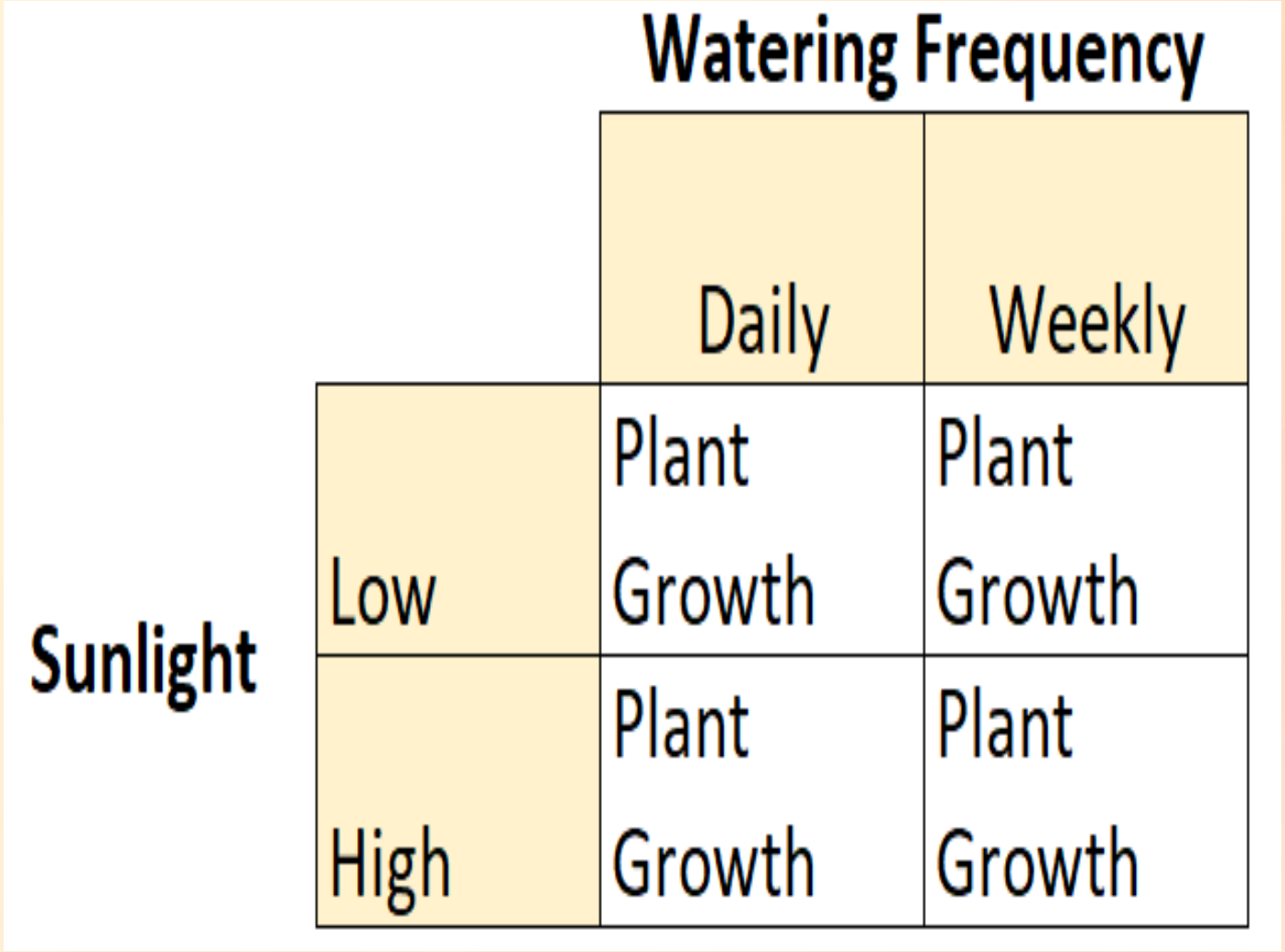
-A type of clinical trial in which all participants receive the same two or more treatments, but the order in which they receive them depends on the group to which they are randomly assigned. For example, one group is randomly assigned to receive drug A followed by drug B.



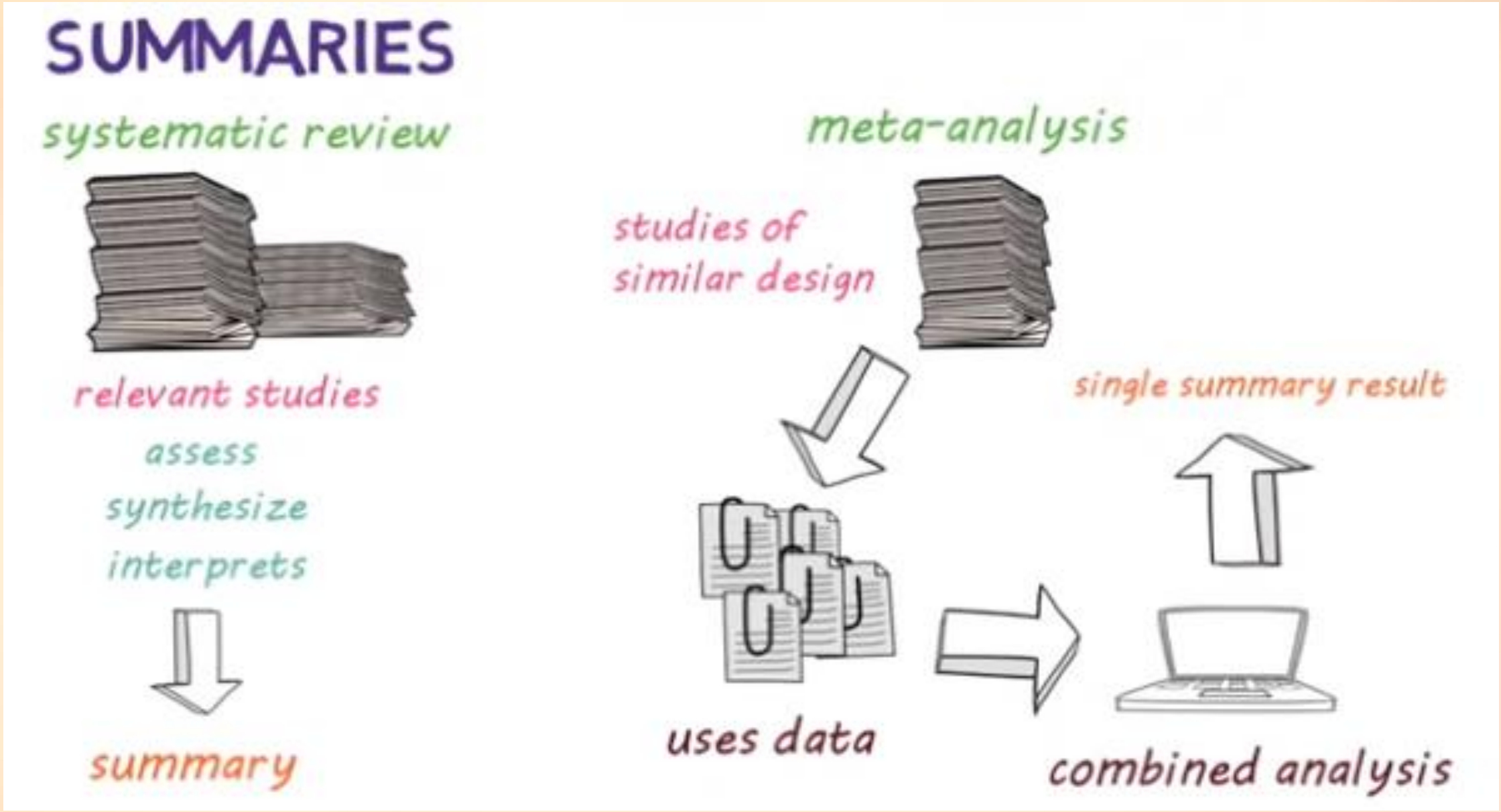
Factorial Study Design

*Description of the Factorial Design:

-A design consists of two or more variables (Independent), each with discrete possible "levels“.



Systematic Reviews and Meta-Analysis



*Description of Summaries (Systematic Review & Meta-Analysis):

-A systematic review is a comprehensive summary of all available evidence that meets predefined rigorous eligibility criteria to address a specific clinical question.

-A meta-analysis is a statistical analysis used to judge between studies that examine the effect of same treatment on a specific outcome yielding different conclusions.

*Advantages of Summaries (Systematic Review & Meta-Analysis):

-Summaries evidence, keep people up to date without reading all published research

-Reduce bias – removes reviewers personal opinions, and preferences

-More reliable conclusions because of the used methods

-Allow large amounts of data to be assimilated by busy clinicians, and policy makers

*Disadvantages of Summaries (Systematic Review & Meta-Analysis):

-Selection bias and publication bias

-Heterogeneity of the studies as in Systematic reviews

-A specialized Expertise is required to do it


Thank
you!


سُبْحانك
اللّهُمّ وبحمدك
أشهدُ أنْ لا إله إلاّ أنت
أستغفرُك وأتوبُ إليك


قال ﷺ: "من سلك طريقاً يلتمسُ فيه علماً،
سهل اللّه له به طريقاً إلى الجنة"


وَقُل رَّبِّ زِدْنِي عِلْمًا
طه ١١٤
Islamiyatsb

EVIDENCE-BASED PRACTICE

VARIABLES AND LEVEL OF MEASUREMENTS

By:

Dr. Mohamed Gamal AbouElYazeed Ali

Lecturer of Physical Therapy

South Valley University

Variables

***Variables** are characteristics of individuals, objects, or environmental conditions that may have more than one value.

-**Attributes of individuals** commonly used in clinical research on individuals include but are not limited to, age, gender, race/ethnicity, type of pathology, the degree of impairment in body functions and structures, activity limitations, and participation restrictions. Performance characteristics, such as strength, flexibility, endurance, balance, and task-specific skill level.

-**Characteristics of objects** often refer to the nature of diagnostic tests and interventions

-**Characteristics of environmental conditions** describe the study's context.

1) Independent Variables:

*An **independent variable** traditionally is defined as a variable that is purposefully manipulated by investigators in an effort to produce a change in an outcome.

*In **clinical research**, **independent variables** are the interventions that are evaluated through the use of experimental and quasi-experimental designs.

*For example**, Seynnes et al.** examined the impact of an exercise program on strength and function in frail elders. The **independent variable** was a resistance training program that was implemented by the investigators according to a specific protocol under controlled conditions.

*Purposeful manipulation of the variable was achieved through the creation of a high-intensity exercise group, a low-moderate intensity exercise group, and a placebo group.

*These three groups reflect three "**levels**" of the **independent variable**. Investigators define levels when they determine what forms the **independent variable** will take in a study.

*Intervention studies may have **one** or **more independent variables**, a situation that increases the complexity of the research design because of the potential interaction between the **independent variables** at their different levels. Studies in which this interaction is anticipated are referred to as **factorial designs**.

2)Dependent Variables:

*A **dependent variable** is the outcome of interest in a study. Studies about interventions investigate the causal link between an independent variable and a change in the **dependent variable**.

***Seynnes et al.** evaluated the change in the **dependent variables** "strength," "function," and "self-reported disability," which may be caused by different intensities of the independent variable "resistance training.

3)Extraneous Variables:

*An **extraneous variable** is a factor other than the independent variable that is said to influence, or confound, the dependent variable.

*The potential for **extraneous variables** is the principal reason why controls through study design and statistical adjustment are attempted in quantitative research.

*Subjects, investigators, equipment, and environmental conditions are just some of the sources of **confounding influences** in a study. For example, **subject** performance may wax and wane over the course of time due to fatigue or alertness levels. **Investigators** may have varying levels of experience with the outcome measure used. **Equipment** may lose accuracy with repeated use. **Room temperature** and **lighting** may impede a subject's ability to execute a task.

*Any of these problems may influence the outcome of the study resulting in **misleading conclusions** about the impact of, or relationship to, the independent variables.

INDEPENDENT VARIABLE

VARIABLE THAT IS CHANGED

Amount of Water

DEPENDENT VARIABLE

VARIABLE AFFECTED BY THE CHANGE

Size of Plant
Number of Leaves
Living or Dead?

Independent and Dependent Variables: Synonyms

Independent Variable	Dependent Variable
Predictor	Criterion
Presumed cause	Presumed effect
Stimulus	Response
Predicted from…	Predicted to…
Antecedent	Consequence
Manipulated	Measured outcome

Levels of Measurement:

*__Four levels of measurement__ create a continuum from descriptive to numeric value assignment: nominal, ordinal, interval, and ratio.

1)A __nominal level of measurement__ is one in which values are named categories without the mathematical properties of rank and a known equal distance between them. Hair color (i.e., blond, brunette, auburn) and gender (i.e., male, female), as well as survey questions that have "yes–no" response options, are examples of variables captured with nominal measures.

-That is, the categories used for each variable are **assumed to be equal**—one is not greater than or less than the other in value (rank). As a result, any statistical analysis must be performed using the **frequencies** (i.e., numbers or percentages).

2)An **ordinal level of measurement** also classifies characteristics without a known equal distance between them; however, categories have a rank order relative to one another. Ordinal measures are frequently used in questionnaires in which subject opinion or perception is solicited.

-A common clinical example is a survey of patient satisfaction in which the response options are displayed with both word and numerical anchors.

Completely Dissatisfied	Somewhat Dissatisfied	Neutral	Somewhat Satisfied	Completely Satisfied
1	2	3	4	5

-Another example, The variable "weight-bearing status" progresses in value from "none" to "full" of categories in between reflecting increases in the amount of weight bearing allowed. These increases are not measured with numbers but are indicated with modifying words. Traditionally, there is an absence of a known distance between each level of these scales.

3)An **interval level of measurement** is a scale that assigns numeric, rather than descriptive values to variables. These values are numbers that have rank and a known equal distance between them but do not have a known zero point. In other words, the value "0" does not reflect the absence of the characteristic.

-The classic example of an interval scale is the measurement of temperature in Fahrenheit or Celsius. Zero degrees on either scale represents an actual temperature, not the lack of temperature.

-The **lack of a known empirical zero point** means that the quantities identified with an **interval scale** may have positive and negative values.

-In addition, they may be added and subtracted from one another, **but they are not appropriate** for multiplication or division.

4)A **ratio level of measurement** has all of the necessary mathematical properties for manipulation with addition, subtraction, multiplication, and division.

-These quantities have rank order, a known equal distance between them, and a known empirical zero point. The presence of an empirical zero point means that these scales **cannot have negative values**.

-Clinical examples of ratio level measures include Height, weight, blood pressure, speed, and distance are just a few of the many.

*Is VAS considered as an interval or a ratio scale ?

TABLE 7-3 Levels of Measurement

Level	Clinical Examples
Nominal	Sex (male, female)
	Race/ethnicity (Caucasian, African American, Asian, etc.)
	Religious affiliation (Catholic, Jewish, Muslim, Hindu, etc.)
Ordinal	Weight-bearing status (non-weight-bearing, toe touch, weight bearing as tolerated, etc.)
	Level of assistance required (minimum assist, moderate assist, maximum assist, etc.)
	Manual muscle test grades (trace, poor, fair, good, etc.)
	Patient satisfaction (very dissatisfied, somewhat dissatisfied, neutral, somewhat satisfied, very satisfied)
Interval	Temperature (Celsius, Fahrenheit)
	Calendar year (2000, 2001, 2002, 2003, 2004, 2005, etc.)
Ratio	Height (inches)
	Weight (pounds)
	Circumference (centimeters)
	Blood pressure (millimeters of mercury)
	Speed (meters per second)
	Distance (feet)

THE FOUR LEVELS OF MEASUREMENT:

	Nominal	Ordinal	Interval	Ratio
Categorizes and labels variables	✓	✓	✓	✓
Ranks categories in order		✓	✓	✓
Has known, equal intervals			✓	✓
Has a true or meaningful zero				✓


Thank
you!


سُبْحانك
اللّهُمّ وبحمدك
أشهدُ أنْ لا إله إلاّ أنتَ
أستغفرُك وأتوبُ إليك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EVIDENCE-BASED PRACTICE

UNRAVELING STATISTICAL MYSTERIES: DESCRIPTION

By:

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Lecturer of Physical Therapy

South Valley University

Terms In This Lecture:

*__Effect size (ES):__ The magnitude of the difference between two mean values; may be standardized by dividing this difference by the pooled standard deviation to compare effects measured by different scales.

*__Mean:__ The sum of the data points divided by the number of scores (i.e., the average).

*__Median:__ The middle score in a data set.

*__Mode:__ The score that occurs most frequently in the data set.

*__Percentiles:__ Division points in the data, such as quartiles or tertiles, that are used to identify where a certain percentage of the scores lie.

*__Range:__ The spread of data points from the lowest to the highest score.

*__Skew:__ A distortion of the normal bell curve that occurs as the result of extreme scores in the data set.

*__Standard deviation (SD):__ The average absolute distance of scores from the mean score of a data set.

The tools that physical therapists use in the clinic have the following features in common with statistics:

1. A purpose for which they were specifically designed;
2. Indications for their use;
3. A defined method for their use;
4. A specific set of information they provide when used; and
5. Limitations beyond which the instruments cannot perform properly and/or there are important caveats to their use.

For example, a manual goniometer

1. Is designed to measure angles;
2. Is used when a physical therapist needs to quantify joint position and available range of motion during a physical examination;
3. Is applied with the pivot point over the axis of joint motion and the arms aligned with relevant bony landmarks;
4. Provides information in degrees; and
5. Has a standard error of measurement of plus or minus 4°.

Descriptive Statistics

*It describes the data collected by the researchers.

*Researchers describe data for several reasons;

-**First,** they use descriptive statistics when the sole purpose of their study is to summarize numerical details about a phenomenon of interest.

-**Second,** researchers use descriptive statistics in studies about relationships and differences to determine whether their data are ready for statistical testing.

-**Finally,** investigators use descriptive statistics in studies about relationships or differences to provide information about relevant subjects and/or environmental characteristics.

Mean

7, 3, 4, 1, 7, 6

Sum of numbers divided by the total numbers

Mean = (7+3+4+1+7+6)/6
= 28/6 = 4.66

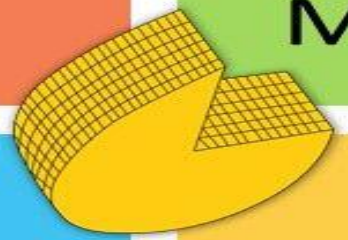
Median

7, 3, 4, 1, 7, 6

Arrange in order and pick the middle value

1, 3, 4, 6, 7, 7

Median = (4+6)/2 = 5



Mode

7, 3, 4, 1, 7, 6

Most common number

7, 3, 4, 1, 7, 6

Mode = 7

Range

7, 3, 4, 1, 7, 6

Difference between highest and lowest

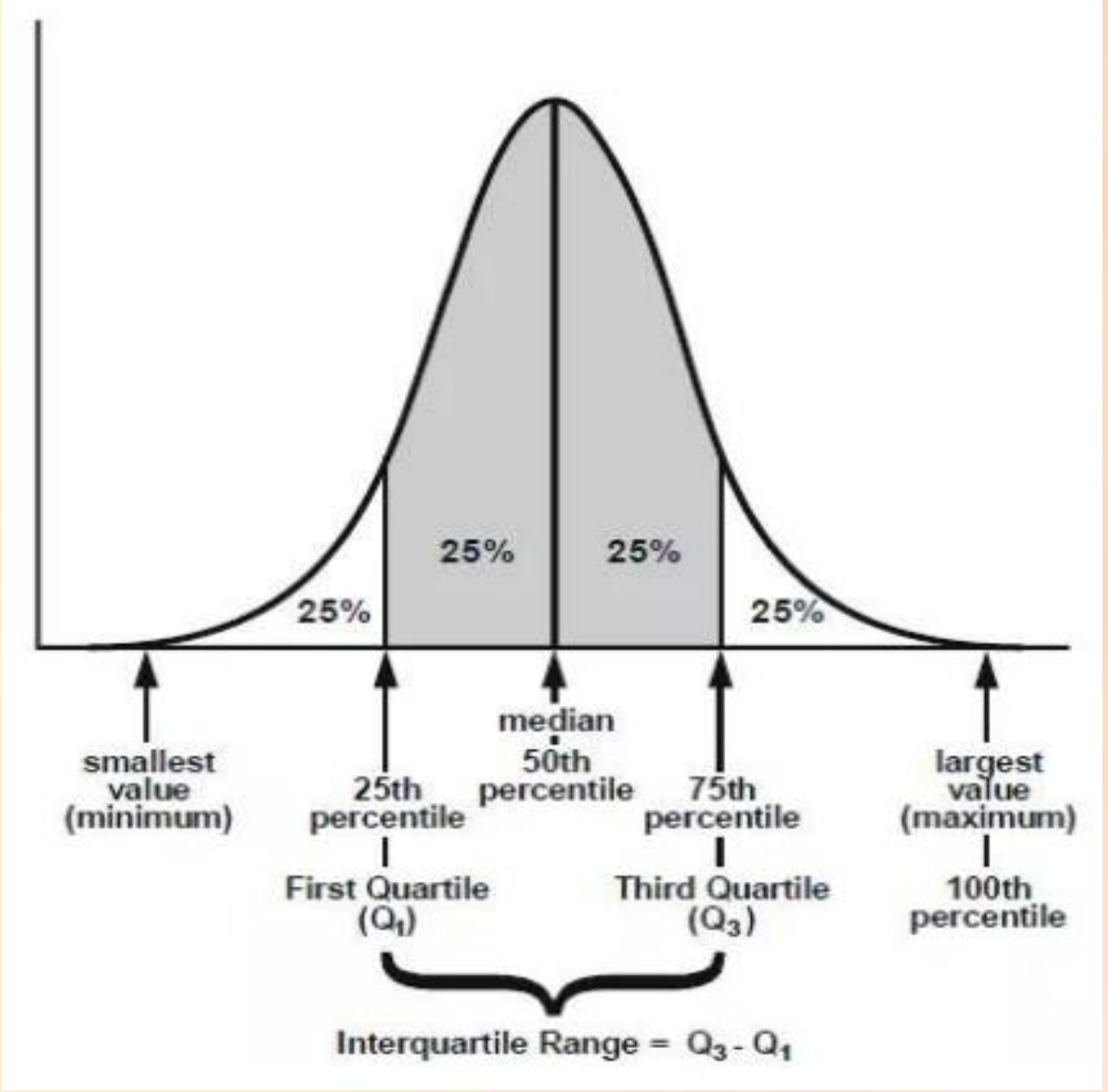
Range = 7 − 1 = 6

*Inter-quartile range [IQR]: Central 50% of data

-Used when a data set has outliers.

What is the Inter-quartile range [IQR] for age in the following data:
Age Median [IQR] 49 [26, 72]
Age Mean (SD) 45 (21)?

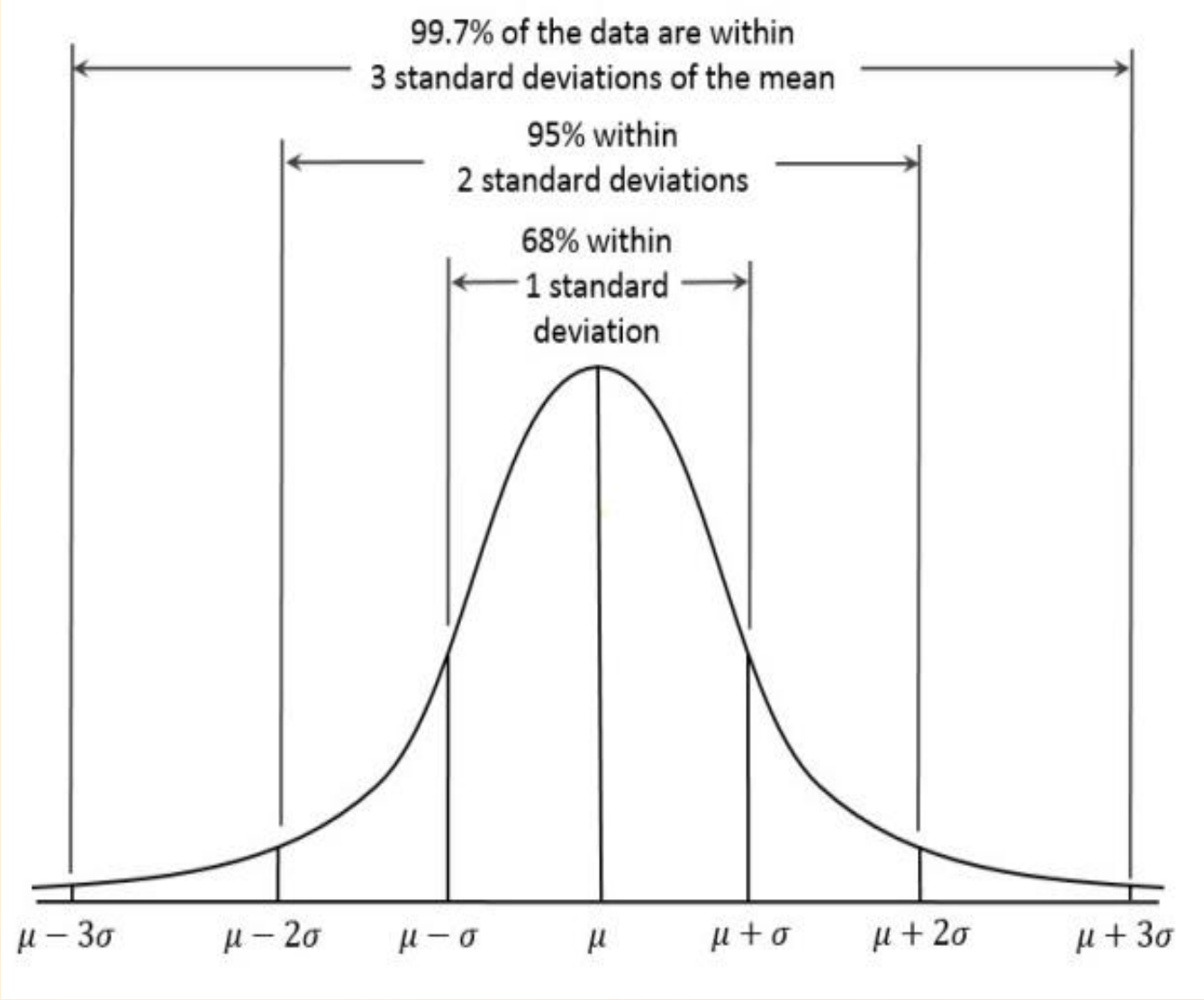
A. 49 years
B. 26 years
C. 21 years
D. 26 to 72 years

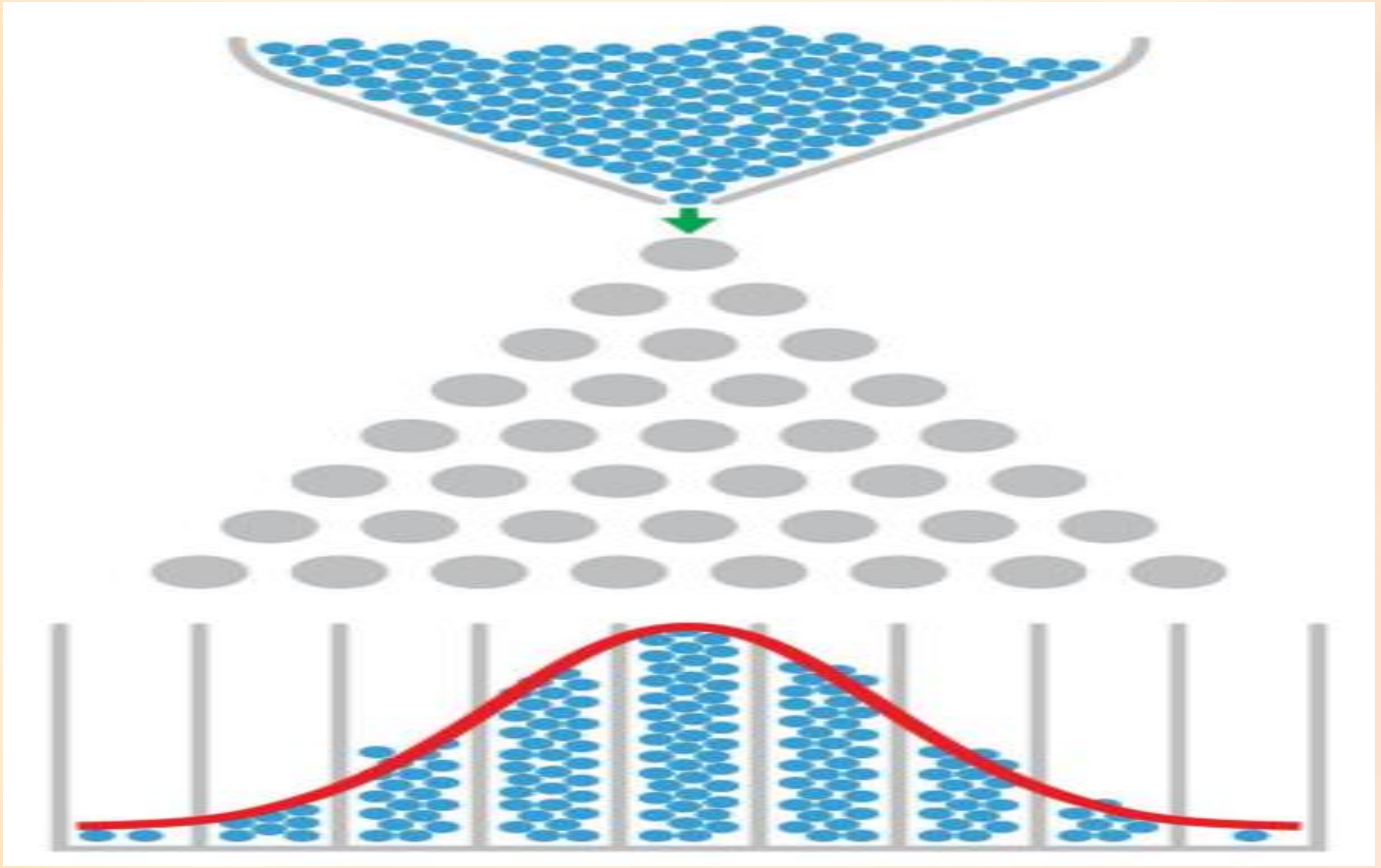


***Standard Deviation (SD):** How tightly the data crowd together around the mean.

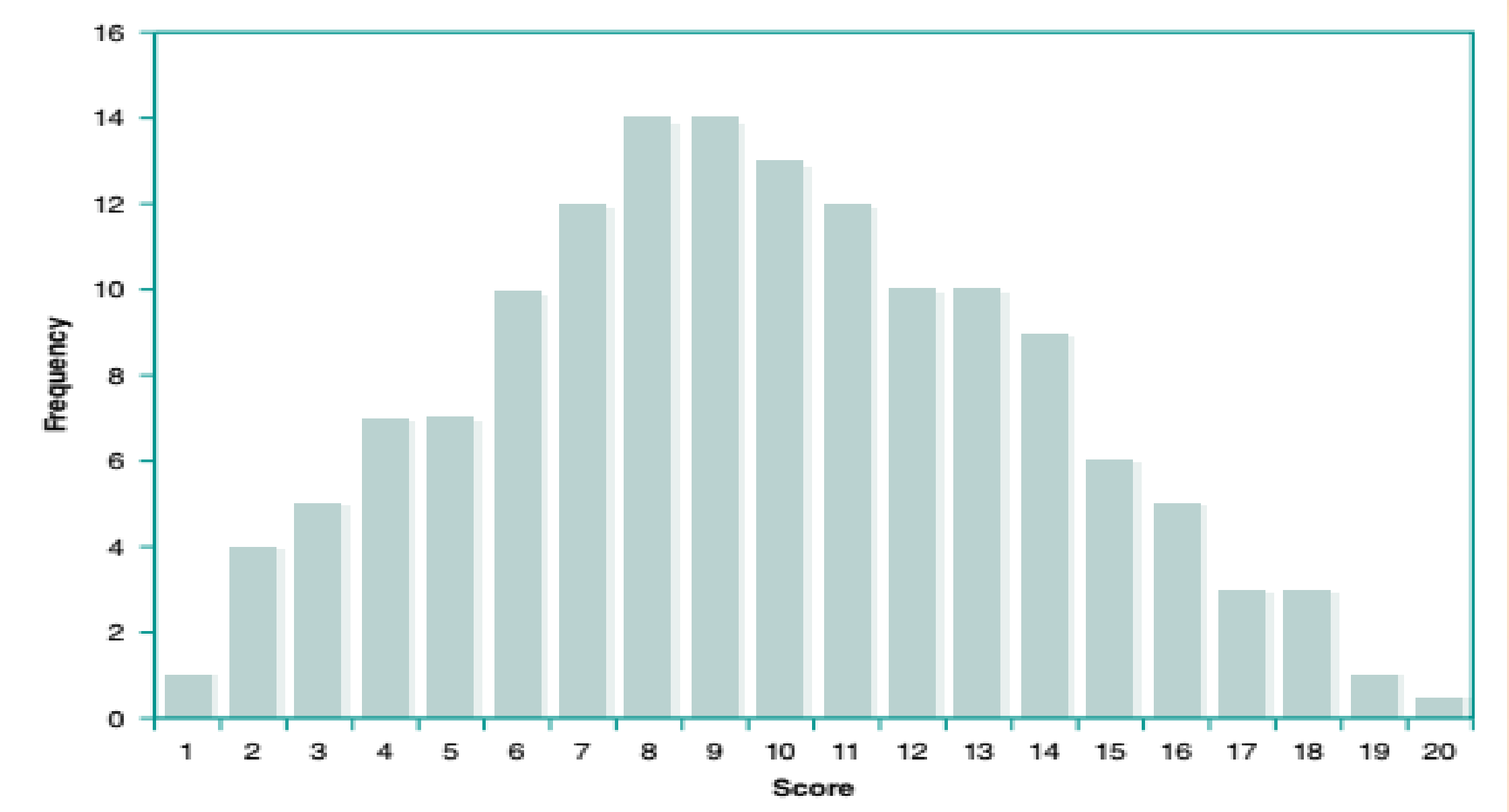
What is the Standard Deviation for age in the following data:
Age Median [IQR] 49 [26, 72]
Age Mean (SD) 45 (21)?

A. 49 years
B. 45 years
C. 21 years
D. 26 to 72 years

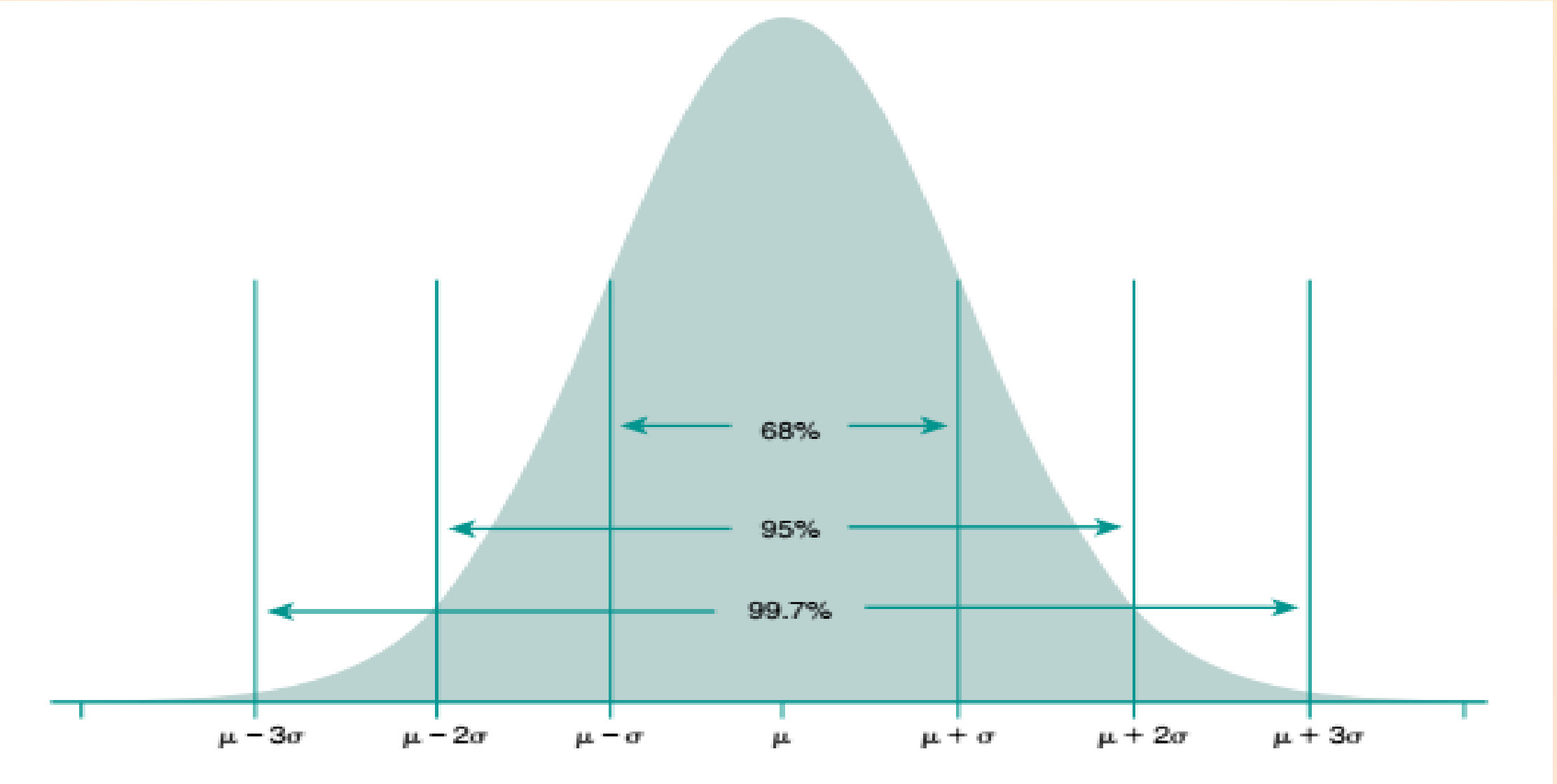




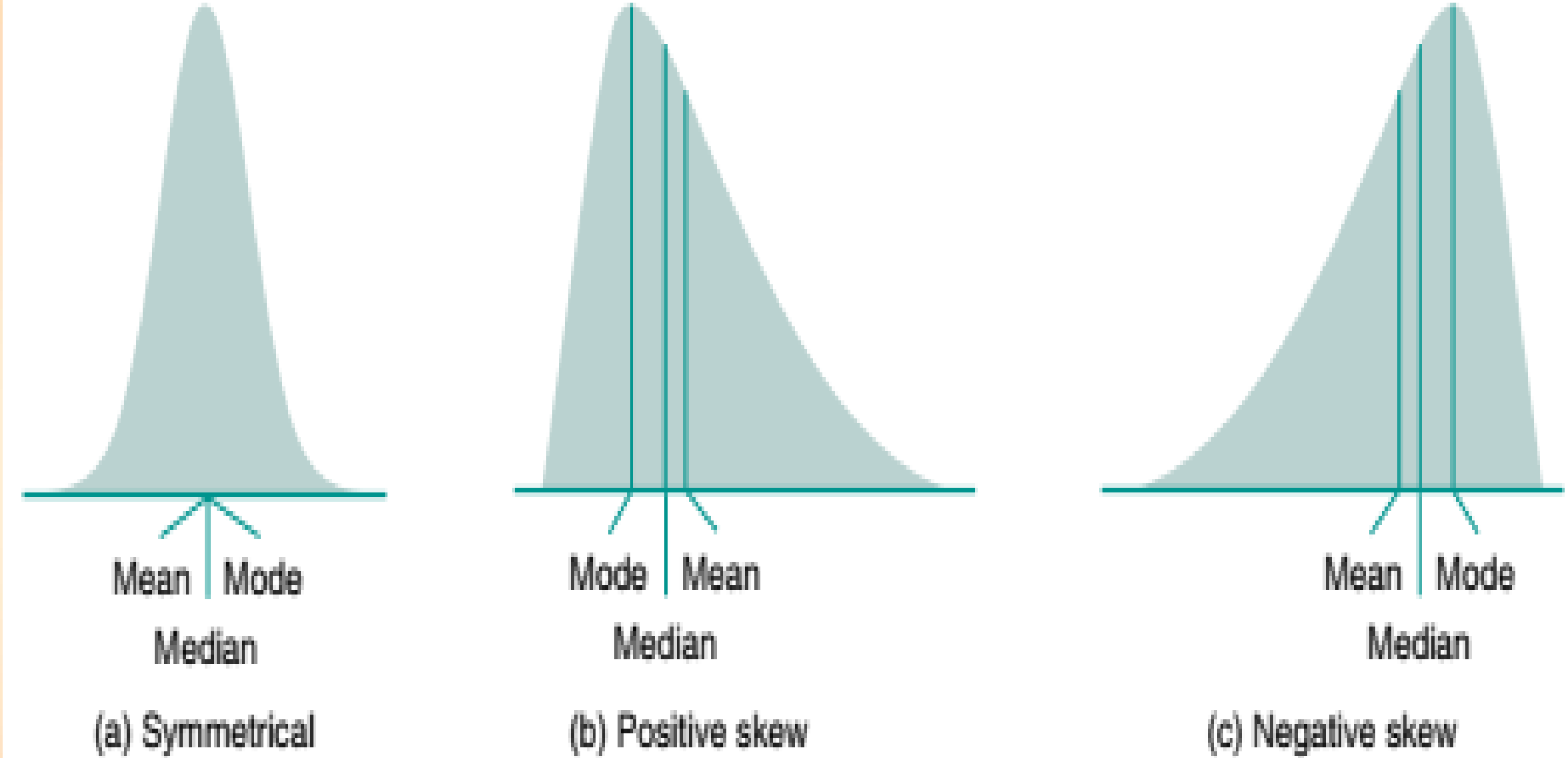
A histogram for a hypothetical set of data



Normal distribution of data (Bell Curve) with 1, 2, and 3 standard deviations



Data distributions: Normal, and Non-Normal distribution (skewed right, and skewed left)



Important Notes

***If a distribution is skewed:**

Mean is usually not in the middle.

The median is a better measure of Central Tendency.

***If Standard Deviation > Mean:**

I will use Median [IQR] for descriptive statistics.

***If data is normally distributed (Bell-shaped):**

I will use Mean (SD) for descriptive statistics.


BREAK
TIME!

Subject Characteristics in Clinical Research:

1. Importance for Evidence-Based Practice:

- Essential for a physical therapist to assess how closely study subjects resemble the patient or client in question.
- Crucial for determining the applicability of study results beyond the research context.

2. Representativeness of the Sample:

- Researchers need to understand how well their sample represents the population it was drawn from.
- Extreme differences between the sample and the population can limit the generalizability of study results.

3. Equitable Distribution for Comparative Studies:

- In studies comparing intervention outcomes among groups, it's vital to ensure that relevant subject characteristics are evenly distributed at the study's outset.

- Unbalanced groups can obscure the true effect of the intervention and compromise research validity

4. Commonly Summarized Subject Characteristics:

Demographic details play a key role in subject characterization:

a. Age
b. Sex
c. Race/ethnicity
d. Education level
e. Socioeconomic status
f. Employment status
g. Marital status
h. Presence and type of insurance coverage

*Clinical information:

a. Height;
b. Weight;
c. Diagnosis(es);
d. Number and/or type of risk factors for disease or adverse event;
e. Number and/or type of comorbidities;
f. Health or functional status;
g. Mental or cognitive status;
h. Type of assistive device required for mobility;
i. Number and/or type of medications;
j. Number and/or type of diagnostic tests;
k. Number and/or type of surgeries; and
l. Type of referring physician.

Summarizing subject characteristics using these demographic factors helps in understanding the sample's representativeness, ensuring balanced groups, and enhancing the applicability of research findings to real-world scenarios in clinical practice.

TABLE 9-1 An Example of Descriptive Statistics in a Hypothetical Study of Risk Factors for Knee Flexion Contracture Development in Elderly Nursing Home Residents

Characteristic	Mean or %	Standard Deviation	Range
Age	84.4	4.5	77–92
Sex (% Female)	72	—	—
Mini Mental State Exam[7] Score	20.7	2.8	16–27
# of Comorbidities	2.75	1.2	1–5
# of Medications	3.75	1.1	2–6
Prior Knee Surgery (% Yes)	31	—	—

Effect Size

Quantitative Evidence Analysis in Clinical Practice:

1.Beyond Descriptive Analysis:

1. Physical therapists require quantitative evidence that goes beyond mere description to answer clinical questions effectively.

2.Analysis of Relationships and Differences:

1. Studies involving the prediction of outcomes or the effectiveness of interventions require analyses of relationships and differences between groups.
2. Statistical significance may not always be sufficient to warrant application to an individual patient or client.

3.Importance of Effect Size (ES):

1. Effect size (ES) is a descriptive statistic used to quantify the magnitude of study findings.
2. ES can be calculated in absolute or relative terms, providing insight into the size of identified relationships or differences.
3. $$ES = \frac{\text{Mean}_{\text{group 1}} - \text{Mean}_{\text{control group}}}{\text{SD}_{\text{control group}}}$$

4. Absolute vs. Relative Magnitude:

- **Absolute magnitude of effect size** measures the actual difference (e.g., a 15-point difference in DASH scores between two intervention groups).
- **Relative magnitude** incorporates data variability, often expressed between 0 and 1, with criteria for evaluation:
  - **0.20: minimal effect**
  - **0.50: moderate effect**
  - **0.80: large effect**
- Effect sizes surpassing 1 are considered even more substantial based on these standards.

What are the fundamental needed data to determine the correct sample size?

1-Determine the Design of the study and the statistical test.

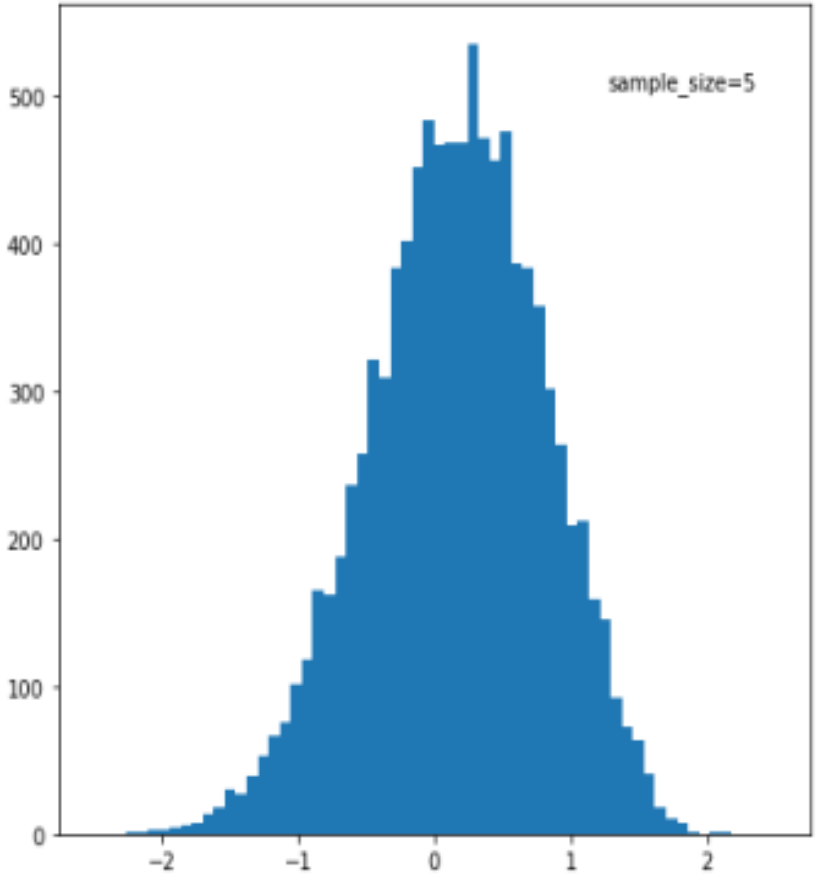
2-Determine the **effect size (ES)** using the formula:

$$ES = \frac{Mean_{group\ 1} - Mean_{control\ group}}{SD_{control\ group}}$$

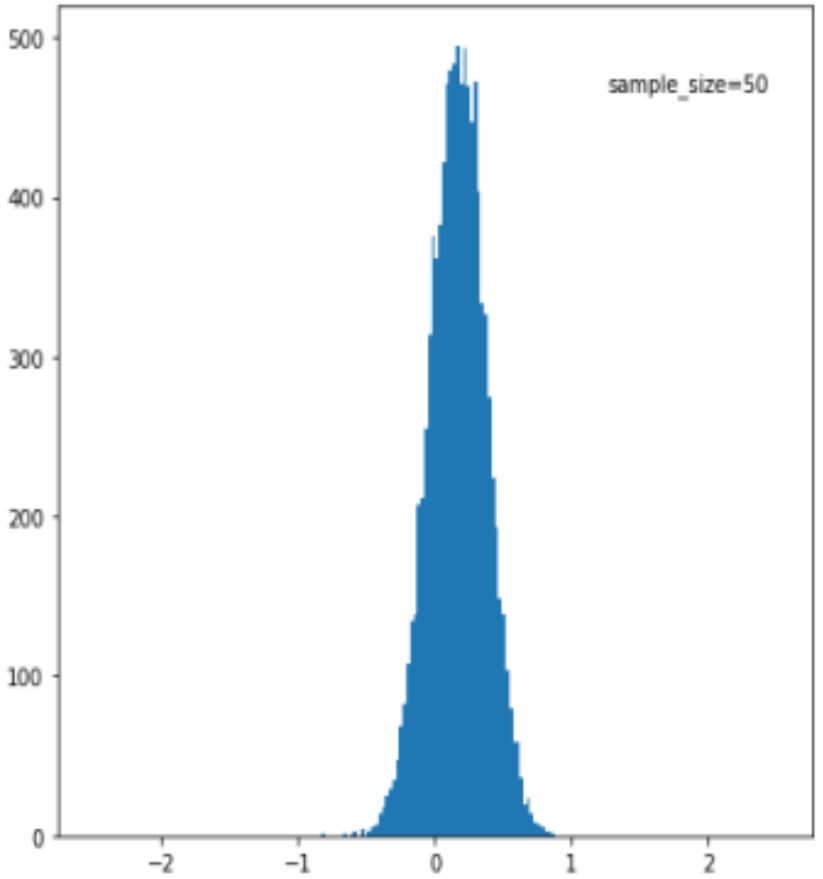
3-Determine **alpha Probability (Type I error: False Positive)** Should be set as **0.05**

4-Determine **Power: 80% up to 95%**: in **Physical Therapy** studies a Power of **80%** is usually used.

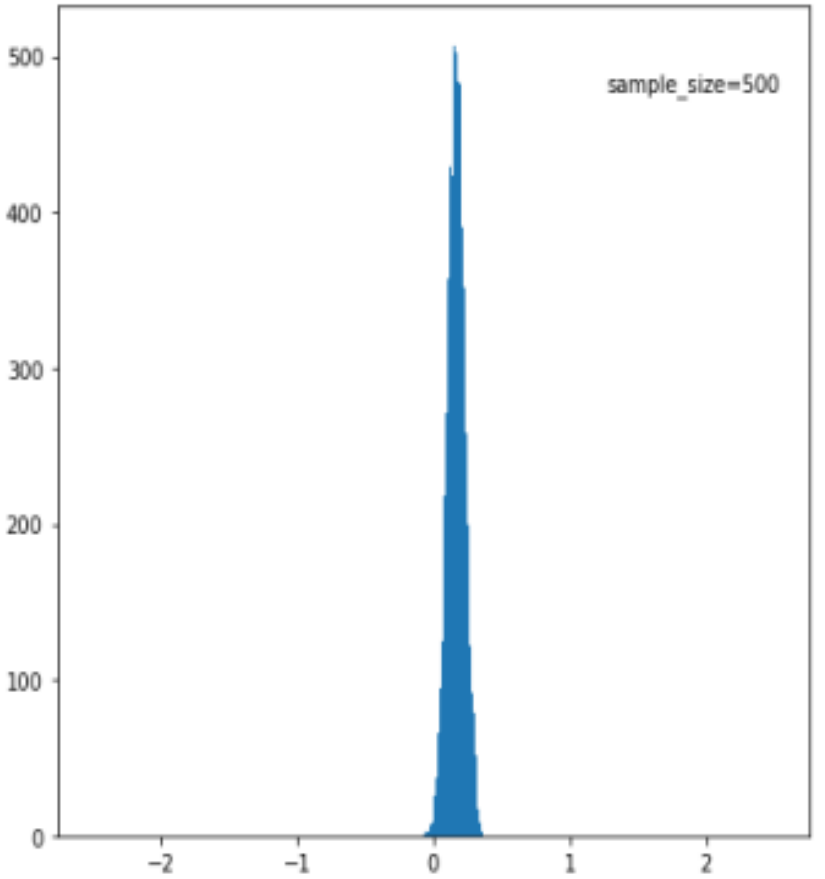
N=5



N=50



N=500



As sample size increases
the Standard Deviation (SD) decreases

*The **p value** is the probability that a study's findings occurred due to chance.

-The **alpha (α) level**, or **significance level**, is the term used to indicate the threshold the investigators selected to detect statistical significance when they designed their study, the **traditional value** of which is **0.05**.

-The Obtained **p values** **lower than** the **0.05** threshold indicate **statistical significant difference**. However **greater than** the **0.05** indicate **statistical NON-significant difference**.

*__Power__ is the probability that a statistical test will detect, if present, a relationship between two or more variables or a difference between two or more groups.

-Failure to achieve adequate **power** will result in a **type II error**, (a **false negative**).

-The threshold for **power** often is set at **0.80 : 0.95**, which translates into a **5 : 20%** chance of committing a **type II error**.

*The **size of the sample** is **very important** for getting **accurate, statistically significant results** and **running the study successfully**.

-If the **sample is too small**, the researcher may include a disproportionate number of individuals who are outliers. These skew the results, and the researcher doesn't get a fair picture of the whole population.

-If the **sample is too big**, the whole study becomes complex, expensive, and time-consuming to run, and although the results are more accurate, the benefits don't outweigh the costs.


Thank
you!


سُبْحانك
اللّهُمّ وبحمدك
أشهدُ أنْ لا إله إلاّ أنت
أستغفرُك وأتوبُ إليك


قال ﷺ: "من سلك طريقاً يلتمسُ فيه علماً،
سهل اللّه له به طريقاً إلى الجنة"


وَقُل رَّبِّ زِدْنِي عِلْمًا
طه ١١٤
Islamiyatsb

EVIDENCE-BASED PRACTICE

CRITICAL APPRAISAL FOR EXPERIMENTAL AND COHORT STUDIES

By:

Dr. Mohamed Gamal AbouElYazeed Ali

Lecturer of Physical Therapy

South Valley University

What does Critical Appraisal mean in clinical practice?

*__Critical appraisal__ is the process of systematically examining research evidence to judge its trustworthiness, its value and relevance in a particular context.

*__Critical appraisal__ allows clinicians to use research evidence reliably and efficiently **(Burls A., 2009)**. __Critical appraisal__ is intended to enhance the healthcare professional's skill to determine whether the research evidence is true (free of bias) and relevant to their patients.

***Three essential questions need to be asked when dealing with an article on therapeutic intervention:**

1) Are the results valid? Do the findings of this study represent the truth? That is, do the results provide an unbiased estimate of the treatment effect?

2) How precise are the results? If the results are unbiased, they need further examination in terms of precision. The precision would be better in larger studies compared with smaller studies.

3) Are the results applicable to my patient? What are the patient populations, disease and treatments and What are the benefits and risks associated with the treatment? Do the benefits outweigh the harms?

Reading an abstract for a scientific paper

*Are the author's issues discussed there?

*What are the main findings of the research?

*Do the Clinician want to know more after reading the abstract?

*Does it address a related question?

*Are there reasons to doubt the findings without reading the whole article?

*The **abstract** should be a concise (**200**, **250 words** or less), standalone summary of the paper, with 1–2 sentences on each of these topics:

-**Background:** What issues led to this work? What is the environment that makes this work interesting or important?
-**Aim:** What were the goals of this work? What gap is being filled?
-**Approach:** What went into trying to achieve the aims (e.g., experimental method, and What was actually done?
-**Results:** What were the main results of the study (including numbers, if appropriate)?
-**Conclusions:** What were the main conclusions? Why are the results important? Where will they lead?

-Unlike the main manuscript, **abstract lacks a discussion section**.

*The **abstract** should be written for the audience of this journal: do not assume too much or too little background with the topic.

*Ensure that **all of the information found in the abstract** also can be found in the body of the paper (main manuscript).

*Ensure that **the important information of the paper** is found in the abstract.

-**Avoid:** using the first paragraph of the introduction as an abstract; citations in the abstract; acronyms (but if used, spell them out); referring to tables from the body of the paper; use of words like “new” or “novel,” or phrases like “in this paper,” “we report,”.


BREAK
TIME!

Reading the Body of the Paper

1) Introduction (Background):

*Indicates the field of the work, why this field is important, and what has already been done (**with proper citations**).

*Indicates a gap, raise a research question, and states the study's hypothesis.

*Outline the purpose and announce the present research, clearly indicating what is novel and why it is significant.

-**Avoid:** repeating the abstract; providing unnecessary background information; exaggerating the importance of the work; claiming novelty without a proper literature search.

2) Methods:

*The **methods** section should describe what was done to answer the research question, describe how it was done, justify the experimental design, and explain how the results were analyzed.

*Describe how the results were generated with sufficient details.

*Has the chosen method like the study design been justified? And from whom the data was collected?

*Are data analysis and statistical approaches justified?

-**Avoid:** **including results in the Method section**; including extraneous details; unneeded references to commercial products.

Study design	Reporting guideline
Randomised controlled trial	CONSORT
Observational study	STROBE
Systematic review and meta-analysis	PRISMA
Case report	CARE
Diagnostic accuracy study	STARD
Meta-analysis of observational studies	MOOSE
Economic evaluation	CHEERS
Experimental animal research	ARRIVE

*Does the study adequately control for differences between the groups being compared?

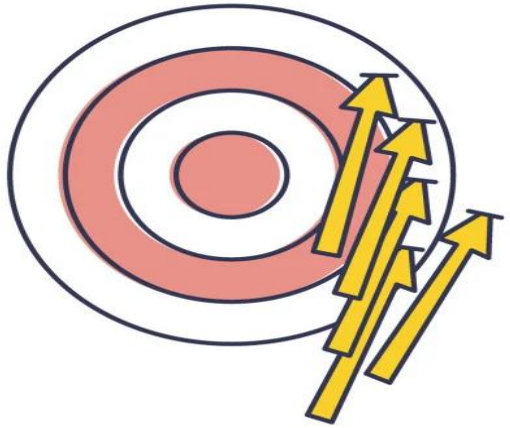
*What about the **inclusion** and **exclusion** criteria?

*Is the **SAMPLE SIZE** large enough to produce significant results?

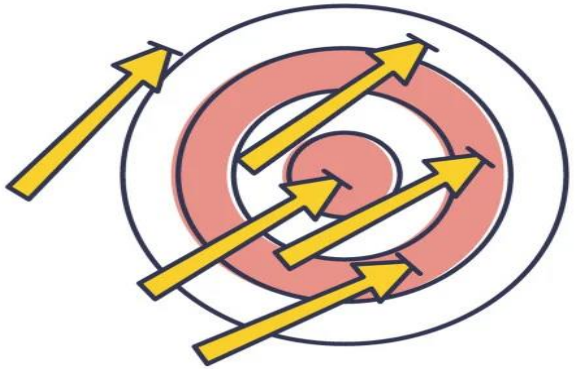
*Do the measures accurately reflect what the researcher was trying to measure (**validity**)?

*Are the used devices **objective**? Are they **valid**, and **reliable** (**Psychometric measures** of the utilized devices)?

RELIABLE
BUT NOT VALID



VALID
BUT NOT RELIABLE



VALID
AND RELIABLE

VALIDITY
VS
RELIABILITY

Validity	Reliability
-**Validity** implies the extent to which the research instrument measures, what it is intended to measure	-**Reliability** refers to the degree to which assessment tool produces consistent results, when repeated measurements are made
-It refers to the ability of the instrument/test to measure what it is supposed to measure	-It refers to the reproducibility of the results when repeated measurements are done
-Answers, 'Is it the right instrument or test for what I need to measure?	-Answers, 'Can the results obtained be replicated if the test is repeated?
-**Validity** looks at accuracy	-**Reliability** looks at repeatability/consistency

3) Results:

*Present the **results** of the paper, in logical order, using tables and graphs as necessary.

*Explain the results and show how they help to answer the research questions posed in the Introduction. The results must be presented and then explained.

***Do not attempt to evaluate the results in this section**. **Report only** what you found; hold all discussion of the significance of results for the Discussion section.

***Tables** generally should report summary-level data, such as **means ± standard deviations**, rather than all your raw data. easy-to-read tables or figures.

-**Avoid:** presenting results that are never discussed; presenting results in chronological order rather than logical order.

4) Discussion:

*The **discussion section** is usually the **hardest section to write**. The authors are trying to bring out the true meaning of their data without being too long.

*Typical stages in the **discussion**: summarizing the results, discussing whether results are expected or unexpected, comparing these results to previous work (studies agree and disagree the work's results), and explaining the results.

*Discuss points of strength and weakness encountered during the work.

*Implication of the research results on the clinical settings.

*Discuss suggestions for future work.

-**Avoid:** repeating the results, this is a discussion.

5) Conclusion:

*The **conclusion** is **the final paragraph of a research paper** and it is intended to help the readers understand why the research should matter to them after they have finished reading the paper.

*Provide a **very brief summary** of the Results and Discussion.

*Explaining how the work is significant and providing the **key message(s)** the author wishes to convey.

*Provide a future perspective on the work.

-**Avoid:** repeating the abstract; repeating background information from the Introduction; introducing new evidence or new arguments not found in the Results and Discussion.


Thank
you!


سُبْحانك
اللّهُمّ وبحمدك
أشهدُ أنْ لا إله إلاّ أنت
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Islamiyatsb

EVIDENCE-BASED PRACTICE

LEVELS OF EVIDENCE

By:

Dr. Mohamed Gamal AbouElYazeed Ali

Lecturer of Physical Therapy

South Valley University

Level	Description	Grade (Strength) of Recommendation
I	-**Ia:** Evidence from high-quality studies: Systematic review (with homogeneity) of multiple RCTs -**Ia:** Randomization of large numbers of patients; multicenter -**Ib:** Individual RCT with a narrow confidence level -**Ic:** All-or-none case series.	**Strong**
II	-**IIa:** Evidence from lesser-quality studies: Systematic review (with homogeneity) of cohort studies -**IIb:** Individual cohort study or low-quality RCT (small N).	**Moderate**
III	-**IIIa:** Systematic review (with homogeneity) of case-control studies. -**IIIb:** Individual case-control study.	**Moderate**
IV	-Case-series and poor-quality cohort and case-control studies. -Largely descriptive studies.	**Weak**
V	-Expert opinion without critical appraisal or based on physiology -Observations not made on patients.	**Theoretical or foundational**

TABLE 2-1 LEVEL OF STRENGTH OF EVIDENCE

Strength of Evidence	Percentage of Studies per Class
Strong	≥50% in class I
Moderate	≥50% in class I + class II
Weak	>50% in class III
Pending	Fewer than 5 studies available

-**A class I** rating was evidence from controlled studies, regardless of randomization and blindness.

-**A class II** rating was evidence from non-controlled studies, also regardless of randomization and blindness.

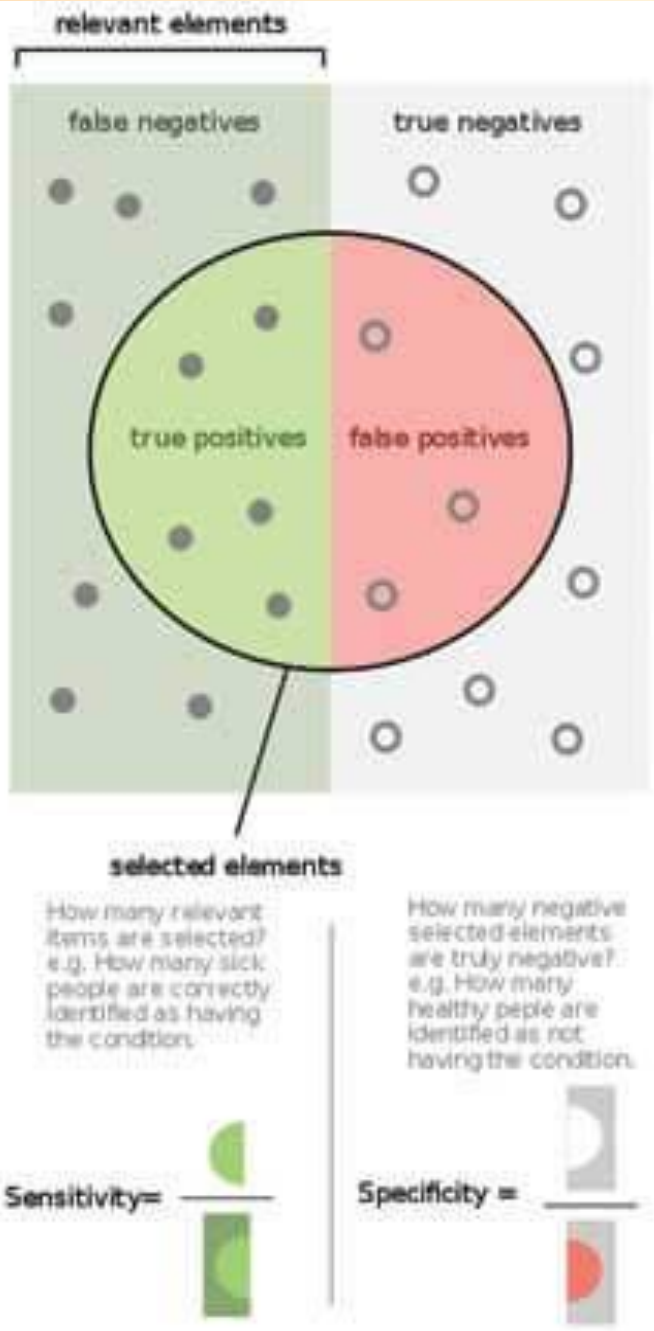
-**A class III** rating was evidence from case reports and case series.

*A **control group** can be defined as an experimental group of patients who receive no treatment, a sham, or a placebo treatment.

TABLE 2-2 LEVEL OF THERAPEUTIC EFFECTIVENESS

Therapeutic Effectiveness	Percentage of Studies Showing Benefit (Yes)
Substantiated	≥60%
Conflicting	≥40% but <60%
Unsupported	<40%
Pending	Fewer than 5 studies available

Parametric Test	Nonparametric Test
Paired t-test	Wilcoxon Signed Rank test
Unpaired t-test	Mann-Whitney U test
One way ANOVA	Kruskal-Wallis H test
Pearson's coefficient	Spearman's coefficient



Sensitivity and Specificity

$$Sensitivity = \frac{Number\ of\ true\ positives}{(Number\ of\ true\ positives\ +\ Number\ of\ false\ negatives)}$$

$$= \frac{Number\ of\ true\ positives}{Total\ number\ of\ individuals\ with\ the\ illness}$$

$$Specificity = \frac{Number\ of\ true\ negatives}{(Number\ of\ true\ negatives\ +\ number\ of\ false\ positives)}$$

$$= \frac{Number\ of\ true\ negatives}{Total\ number\ of\ individuals\ without\ the\ illness}$$

		Patients with bowel cancer (as confirmed on endoscopy)		
		Condition positive	Condition negative	
Fecal occult blood screen test outcome	Test outcome positive	**True positive** (TP) = 20	**False positive** (FP) = 180	Positive predictive value = TP / (TP + FP) = 20 / (20 + 180) = **10%**
	Test outcome negative	**False negative** (FN) = 10	**True negative** (TN) = 1820	Negative predictive value = TN / (FN + TN) = 1820 / (10 + 1820) ≈ **99.5%**
		Sensitivity = TP / (TP + FN) = 20 / (20 + 10) ≈ **67%**	Specificity = TN / (FP + TN) = 1820 / (180 + 1820) = **91%**	


Thank
you!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أستغفرُك وأتوبُ إليك