Handbook for Health Research

4th Year of Bachelor's Degree in Physiotherapy, San Jorge University

Teaching Innovation Project:

Flipped Health Research: Educational Modules in English

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Introduction and course description: Health Research

This handbook is designed as a self-study resource for 4th-year physiotherapy students at San Jorge University, within the Health Research course. Its main goal is to help students prepare in advance for each class using a flipped classroom methodology, promoting active, reflective, and student-centered learning.

The handbook includes full transcripts of the 15 instructional videos that form the core audiovisual material of the course. Additionally, explanatory diagrams are provided to enhance visual understanding of key concepts. At the end of each unit, a set of theoretical and practical questions is offered to monitor and track students' engagement with the methodology, and to verify their grasp of fundamental content.

Health Research is taught entirely in English during the second semester of the fourth year of the Bachelor's Degree in Physiotherapy and is worth 6 ECTS credits. The course aims to equip future physiotherapists with the essential tools to understand, apply, and share scientific knowledge related to their field, fostering a critical mindset and a professional culture based on evidence.

Developed competencies

During the course, students will work on both general program competencies and specific competencies related to the regulated profession:

General competencies:

— Ability to analyze and synthesize in order to provide effective physiotherapeutic care.
— Creative and efficient resolution of everyday problems.
— Use of ICTs in order to meet needs related to healthcare and to the design/evaluation of treatments.
— Ability to generate new ideas (creativity).
— Incorporation of research and evidence-based practice as part of professional culture.
— Development of lifelong autonomous learning strategies.
— Application of quality criteria and continuous improvement.

Specific competencies:

— Identification of the concept, evolution, and scientific and professional foundations of physiotherapy.

Developed competencies

Competencies specific to the regulated profession:

— Awareness of the need for constant updating of knowledge, skills, and attitudes.

Learning outcomes

Upon completing the course, students will be able to:

— Identify and interpret the main methodological concepts in research.

— Apply previous knowledge of biostatistics and literature search to interpret scientific literature.

— Investigate current scientific evidence regarding the main physiotherapy treatments.

— Communicate research results effectively and understand the procedures for applying for funding.

— Participate actively in work groups, contributing ideas and fostering critical debate.

Main contents

The course is organized into three thematic blocks:

1. Extension of research methodology

— Hypothesis testing, type I and II errors, statistical power.

— Epidemiological study designs: descriptive and analytical studies. Selection of the appropriate design.

— Precision and validity: random errors, sample size estimation, and bias.

2. Major comments

— Clinical applications in different physiotherapy areas: neuromusculoskeletal dysfunctions; cardiorespiratory, paediatric, and neurological conditions.

3. Spread of clinical scientific knowledge

— Preparation and writing of scientific articles.

— Dissemination of research results in academic and professional contexts.

Teaching Innovation Project:
Flipped Health Research: Educational Modules in English

English is the primary language in the global scientific and healthcare community. As a result, students' lack of language skills in English can become a barrier when accessing the most current evidence in their field and may even negatively impact their future professional development (1). Additionally, the terminology used in research is often highly specific and repetitive, so becoming familiar with scientific research vocabulary can be valuable for students, especially in the final stages of their undergraduate studies (2, 3).

The exclusive use of English in this course gives students greater confidence and comfort when independently searching for the best available evidence in their field (for example, when gathering information for their Final Degree Project). Furthermore, adopting English as the sole language of instruction helps promote the internationalization of the Bachelor's Degree in Physiotherapy at San Jorge University and facilitates student exchanges with other universities.

However, using only English can also present a significant barrier for students whose native language is a different one, as it may cause feelings of tension, insecurity, and uncertainty (4). These emotions can sometimes lead to disengagement from the course and the perception that the language makes it harder to achieve learning outcomes, thereby increasing the complexity of the subject.

Given this context, the implementation of a new active learning methodology (flipped classroom) is proposed to facilitate learning. This approach aims to strengthen students' communication skills in a foreign language; increase the amount of classroom time devoted to collaborative and cooperative work and to meaningful interaction between teachers and students; and foster critical thinking through active debates on the projects and problems presented in the course. Additionally, this teaching project gives students the opportunity to take a more active role and greater responsibility in acquiring course competencies, using ICT tools and original audiovisual materials as ongoing learning support.

To ensure the effective implementation of the flipped classroom, audiovisual educational materials will be made available well in advance, focusing on content that does not require highly complex reasoning, and linking key concepts to the interactive tasks to be carried out in class (5). Videos are the most commonly used resource in the flipped classroom, allowing students to watch the material as many times as needed and at their own pace, which is especially helpful when learning in a non-native language (5).

Below is a general outline of how the flipped classroom methodology is implemented in combination with the problem-based and project-based learning approaches already established in the course. The content of the audiovisual materials required for implementing the flipped classroom is detailed is detailed in the following sections.

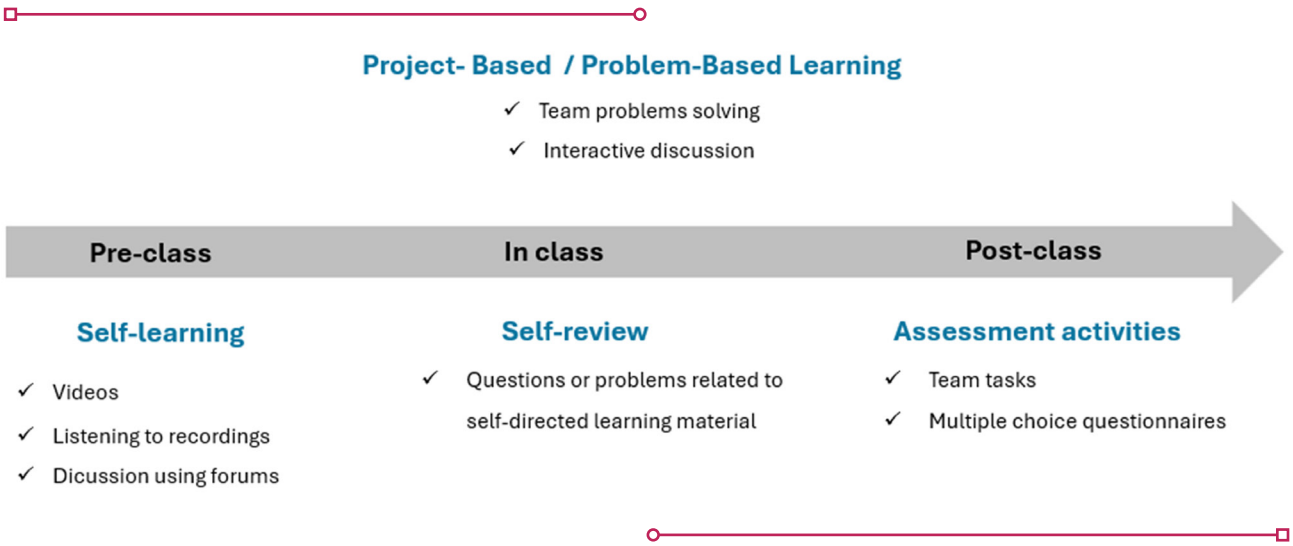

Figure 1. Implementation Framework for the Flipped Classroom Combined with Other Active Learning Methodologies in the "Health Research" Course of the Physiotherapy Degree at San Jorge University

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Video 1: Introductory video to study designs

Welcome to this introductory video to study designs in healthcare research.

Research study designs play a crucial role in answering the questions we encounter in clinical practice: from understanding prevalence to testing the effectiveness of treatments.

In this block, we will cover six key types of study designs:

— **cross-sectional studies**,
— **case-control studies**,
— **cohort studies**,
— **randomized controlled trials (RCTs)**,
— **randomized crossover trials,**
— **systematic reviews with and without meta-analysis**.

But don't worry! We will address each design in individual videos, where we will explore their characteristics, advantages and disadvantages.

Evidence pyramid

These designs are often ordered in the 'evidence pyramid.'

The evidence pyramid is a visual representation of the hierarchy of research study designs based on their **quality of evidence** and **risk of bias**.

— **Risk of bias** refers to the likelihood that the study results are influenced by errors in design, implementation, or analysis. A higher risk of bias reduces the validity of the results and conclusions.

— **Quality of evidence** indicates how confidently we can apply the findings to clinical practice. Higher levels in the pyramid correspond to stronger evidence with lower risk of bias.

Understanding this hierarchy helps us critically evaluate research in physiotherapy.

Key elements to characterize study designs

To choose the right design for your research question, it's important to understand three key characteristics:

Key elements to characterize study designs

1. Descriptive or analytical:

Descriptive studies report on 'what' is happening to a population at a specific moment, such as prevalence, whereas analytical studies report the 'why' or 'how', and involve hypothesis testing such as exploring comparisons between groups or associations between variables.

2. Retrospective or prospective:

Retrospective studies analyze past data or events, while prospective studies follow participants into the future to observe new effects.

3. Observational or experimental:

Observational studies do not involve exposures controlled by the research team, while experimental studies, like RCTs, include the deliberate selection of participant exposures.

And before presenting some examples, don't forget that for each study we can usually define three components:

— **Target population**: Who are we studying?

— **Exposure(s)**: What risk factor or intervention are we examining?

— **Effect(s)**: What outcome or result are we measuring or assessing?

Examples in physiotherapy

Let's bring these concepts to life with examples from different fields of physiotherapy. For contextualization, we will identify the characteristics and explain why. We'll also define the key components presented in the research question.

Example 1: Musculoskeletal pain

The research question is: Does a specific exercise program reduce chronic lower back pain levels compared to standard care?

— First, let's identify **the components** involved in the research question**:**

- **The population is** people with chronic lower back pain.
- **The exposures are** exercise program and standard care.
- **The effect is** reduction in pain levels.

— Second, let's identify **its characteristics**: analytical, prospective, experimental.

But, why should we think that?!

This question involves comparing the effectiveness of two interventions, which requires testing a hypothesis. The study needs to follow participants over time, before and after the interventions, to measure the changes caused by a specific intervention controlled by the research team.

Example 2: Paediatric physiotherapy

The research question is: What is the prevalence of developmental delay in infants born prematurely?

— **The population is** premature infants.

— **There is not exposure presented,** at least with the information provided.

— **The effect is** developmental delay.

Its **characteristics** are: descriptive, retrospective, and observational.

But, again, why should we think that?!

This is a question focused on observing and documenting the prevalence of a condition at a single point in time. There's no hypothesis testing or follow-up involved.

Example 3: Neurological rehabilitation

The research question is: What factors are associated with independent walking ability in chronic stroke survivors?

— **The population is** chronic stroke survivors.

— **The exposures are** age, stroke hemisphere, etc.

— **The effect is** independent walking ability.

Its **characteristics** are: analytical, retrospective, and observational.

Why?

This question aims to identify associations between walking ability and other variables, such as age or stroke hemisphere, without introducing a specific intervention by the research team. There is not any follow-up, and existing data from stroke survivors makes a retrospective design ideal.

Reflection and what's next?

To conclude, consider this question for reflection:

Think of a research question in your area of interest: What components are present and what study design characteristics would you choose and why?

This reflection will help you connect the theory we've discussed to your own interests.

That's all for now! In the upcoming videos, we'll explore each design in detail, including their advantages, disadvantages, and specific applications in physiotherapy research.

See you in class!

Link to video version

https://vimeo.com/1092049175

Follow-up multiple choice questions

1.1. Which element distinguishes an analytical study from a descriptive one?

a) Testing a hypothesis ☐

b) Observing a single population ☐

c) Assessing risk of bias ☐

d) Retrospective data collection ☐

1.2. What is the key characteristic of a prospective study?

a) It involves hypothesis testing ☐

b) It analyzes past data ☐

c) It collects data moving forward in time ☐

d) It tests associations without interventions ☐

Video 2: Cross-sectional studies

Welcome to the second video in our series on research study designs. Today, we'll know more about cross-sectional studies.

By the end of this video, you'll understand what a cross-sectional study is, its key characteristics, how it's conducted, and how it applies to physiotherapy research.

Let's get started!

Contextualization

Why are cross-sectional studies important in healthcare research?

These studies give us a picture of what's happening at a single point in time. For example, in physiotherapy, this type of study can help us understand the prevalence of health conditions and behaviours in different populations.

While cross-sectional studies don't establish causality, which means "a direct relationship between exposure and effect", cross-sectional studies are invaluable for generating new hypotheses that guide further research. They are usually fast, cost-effective, and often the first step in investigating new clinical questions.

Definition and key characteristics

A cross-sectional study is a type of observational research that collects data from a population at a single point in time. They often consist of surveys or a series of questionnaires.

Let's break this down with its key characteristics:

— **Descriptive or analytical:** Cross-sectional studies are descriptive when measuring prevalence, and sometimes have a secondary objective to assess associations between variables. But because of their primary objective, we classify them as descriptive.
— **Retrospective or prospective:** They are retrospective because they analyze existing data or collect information about current states. In other words, there is not a follow-up.
— **Observational or experimental:** These studies are strictly observational. The researcher doesn't intervene or manipulate exposures.

Methodology with a flowchart

Let's explore the methodology of a cross-sectional study. The process is simple, and we can represent it with a flowchart:

1. **Target population:** Define the group of interest, such as patients, athletes, or the general public.
2. **Data collection:** Collect data simultaneously on exposures (e.g., risk factors or behaviours) and effects (e.g., health outcomes) for all participants.
3. **Analysis:** Analyze the data to measure prevalence; in other words, the proportion of a population who have the specific characteristics in that time moment.

For example, imagine we want to study the prevalence of low back pain in office workers.

— Our **target population** is office workers;

— the **exposure** might be, for example, the number of hours sitting per day or if they participate in physical activities in their leisure time; and

— the **effect** would be the presence or absence of low back pain.

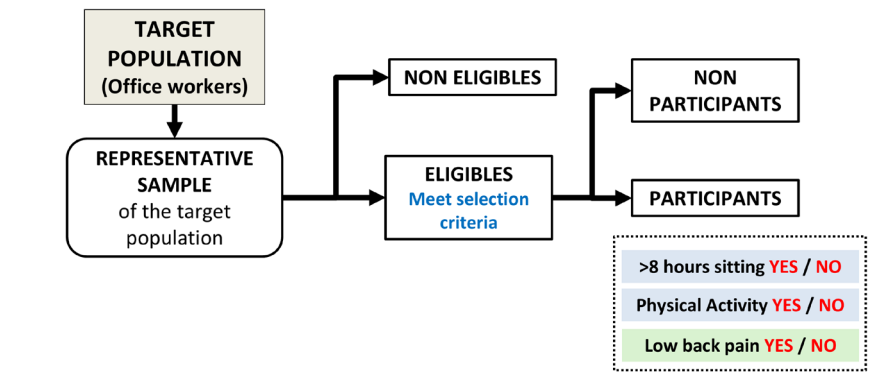

Figure 2. Example number one of a flowchart for a cross-sectional study

Practical examples in physiotherapy

Now, let's look at how cross-sectional studies apply to physiotherapy.

Example: Prevalence of independent walking and exercise habits in stroke survivors

— **Research question:** What is the prevalence of independent walking ability and physical activity habits among stroke survivors?

— **Components:**

- **Population:** Stroke survivors.
- **Exposure:** Physical activity levels (measured in hours per week).
- **Effect:** Functional ambulation (e.g., according to the FAC - *Functional Ambulation Category*).
- **Key design characteristics:** Descriptive, retrospective, and observational.
- **Why?** This study measures the prevalence of independent walking ability and physical activity habits in a specific population at a single point in time. No interventions or longitudinal follow-up are involved.

What would the flowchart look like and what could its results tell us?

Their results could inform us that a percentage of survivors do not engage in sufficient physical activity, which could lead us to investigate barriers and facilitators of physical activity in this population.

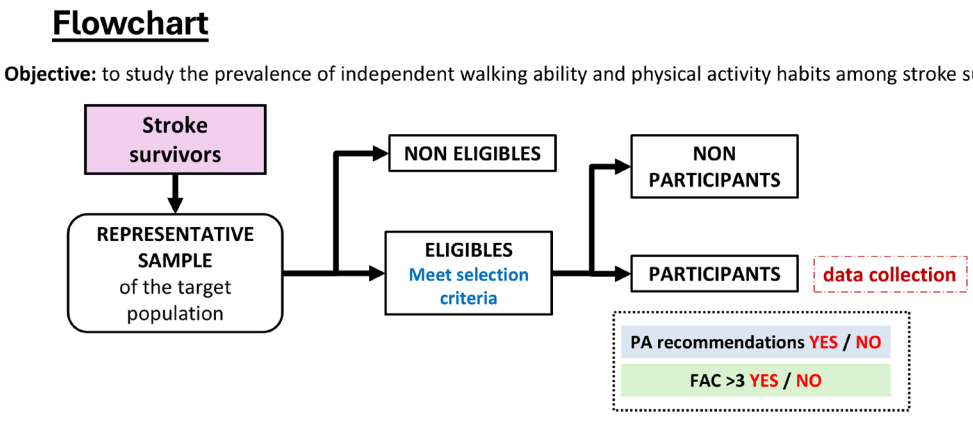

Figure 3. Example number two of a flowchart for a cross-sectional study

Conclusion

To summarize:

— Cross-sectional studies are efficient tools for measuring prevalence.

— They are descriptive, retrospective, and observational by nature.

— While they are not suitable for establishing causality, they provide crucial insights for hypothesis generation and guiding further research.

Reflection

To conclude, think about a clinical question in physiotherapy that a cross-sectional study design could help answer.

What population, exposure and effect would you focus on? What would your flow chart look like?

Write down your thoughts to discuss in class.

Next steps

That's all for now!

In our next video, we'll know more about case-control studies. We'll explore how they differ from cross-sectional designs and their applications in physiotherapy research.

See you in class!

Link to video version

https://vimeo.com/1092105523

Follow-up multiple choice questions

2.1. Which characteristic is inherent in a cross-sectional design?

a) Observational ☐

b) Experimental ☐

c) Prospective ☐

d) All are correct ☐

2.2. What does a cross-sectional study primarily measure?

a) Incidence ☐

b) Prevalence ☐

c) Causal relationship ☐

d) Association between variables ☐

Video 3: Case-control studies

Welcome to the third video in our series on research study designs. Today, we'll know more about case-control studies.

By the end of this video, you'll understand what a case-control study is, its key characteristics, how it's conducted, and how it applies to physiotherapy research.

Let's get started!

Contextualization

Why are case-control studies important in healthcare research?

These studies are essential for investigating relationships between exposures and effects, particularly when studying rare conditions or those with long latency periods.

In physiotherapy, case-control studies help identify risk factors for specific conditions or diseases, providing valuable insights for potential prevention and treatment strategies.

Definition and key characteristics

A case-control study is an observational study design that compares two groups:

1. **Cases:** Individuals with the effect or condition of interest.
2. **Controls:** Similar individuals without the effect or condition.

Researchers then look retrospectively at the exposure history of both groups to determine if certain factors are associated with the condition.

Let's break this down with its key characteristics:

— **Descriptive or analytical:** Case-control studies are designed to explore associations between exposures and effects.

— **Retrospective or prospective:** They are retrospective because they focus on historical data to identify prior exposures with no follow-up.

— **Observational or experimental:** They are observational because the research team don't intervene or manipulate exposures.

A unique characteristic of case-control studies is the "matching": A critical technique where cases and controls are matched on specific characteristics (such age or gender) to minimize bias.

Methodology with a flowchart

Let's break down the methodology of a case-control study using a flowchart:

1. **Define the target population:** Identify a relevant population, such as patients with a specific condition, for example, dysmenorrhea.
2. **Select cases and controls:**
   - **Cases:** Women referring severe dysmenorrhea.
   - **Controls:** Women without severe dysmenorrhea (only mild/moderate dysmenorrhea) but matched with cases based on certain characteristics like age and body mass index.
3. **Collect exposure data:** Examine past exposures, such as premature menarche or presence of facilitated central pain mechanisms (potential risk factors).
4. **Statistical analysis:** Compare the frequency of the exposure in cases versus controls to assess if there is a statistically significant association.

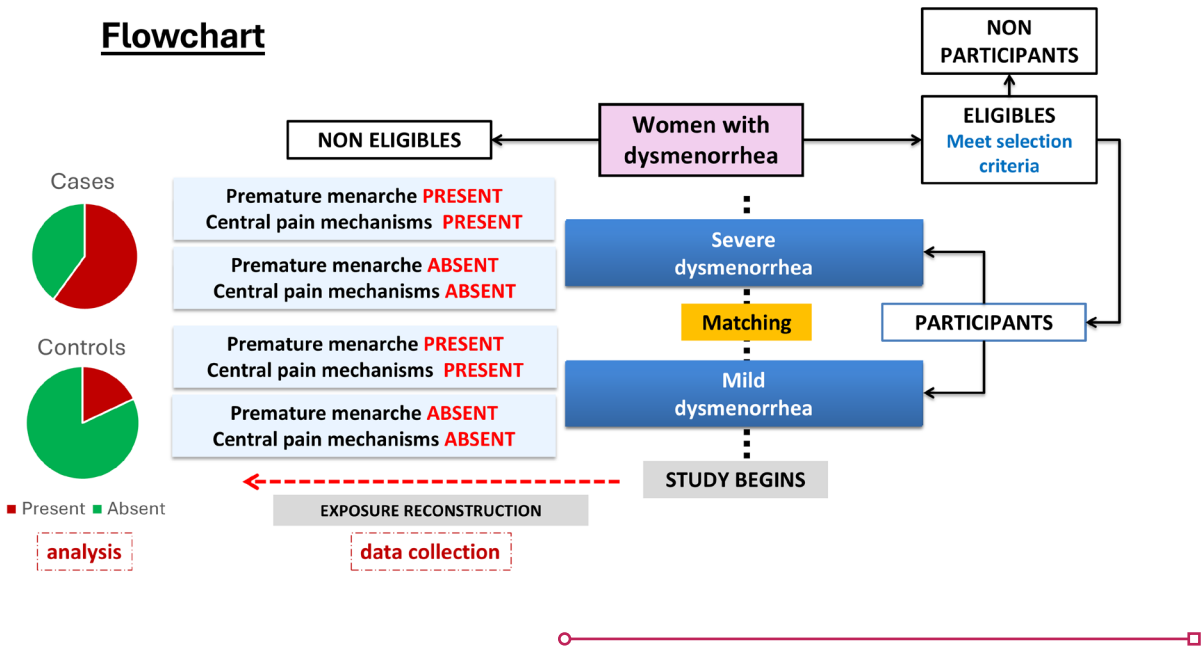

Figure 4. Example number one of a flowchart for a case-control study

Practical examples in physiotherapy

Now, let's look at a practical example in geriatric physiotherapy:

Example: Risk factors for falls in older adults

— **Research question:** Is reduced lower limb strength associated with a history of falls in the last 6 months in older adults?

— **Components:**

- **Population:** Older adults aged 65 and above.
- **Cases:** Older adults who have experienced a fall within the past six months.
- **Controls:** Older adults who have not experienced a fall in the same period, matched for age and gender.
- **Exposure:** Lower limb strength (measured through a standardized test such as a sit-to-stand assessment).

What would the flowchart look like and what could its results tell us?

Their results could identify reduced lower limb strength as a risk factor for falls, guiding fall prevention programs in physiotherapy.

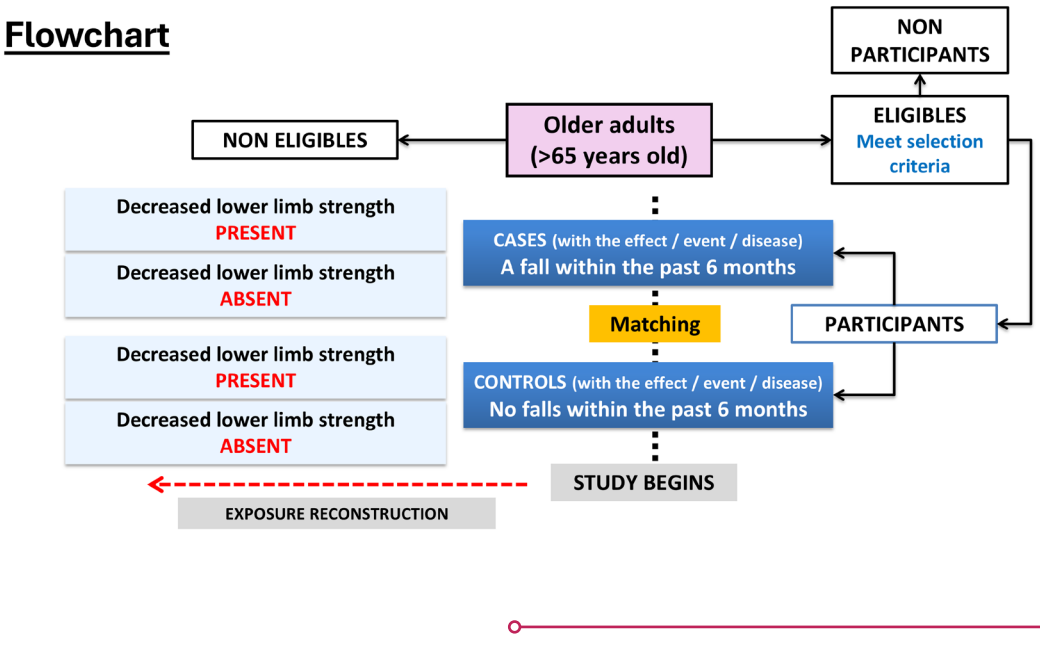

Figure 5. Example number two of a flowchart for a case-control study

Conclusion

To summarize:

— Case-control studies are analytical, retrospective, and observational.

— They are well-suited for exploring associations in rare conditions or those with long latency periods.

— Participants in the case and control groups are recruited according to the presence or the absence of the effect.

— Matching is a key characteristic, which helps to reduce bias and improve the validity of findings.

Reflection

To conclude, think of a clinical question in physiotherapy that a case-control study design could help answer.

What population, effect and exposure would you focus on?

Prepare your own flowchart and be ready to discuss it in class.

Next steps

That's all for now.

In the next video, we'll explore cohort studies and how they apply to physiotherapy research.

See you in class!

Link to video version

https://vimeo.com/1092106087

Follow-up multiple choice questions

3.1. What is the key characteristic of matching in case-control studies?

a) Random assignment of cases and controls ☐

b) Ensuring cases and controls are similar in key variables ☐

c) Manipulating exposure variables ☐

d) Measuring treatment effectiveness ☐

3.2. Case-control studies are best suited for studying:

a) Common conditions ☐

b) Rare expositions ☐

c) Rare conditions and effects ☐

d) Experimental interventions ☐

Video 4: Cohort studies

Welcome to the fourth video in our series on research study designs. Today, we'll explore cohort studies.

By the end of this video you'll understand what a cohort study is, its key characteristics, how it's conducted, and how it applies to physiotherapy research.

Let's begin!

Contextualization

Why are cohort studies important in healthcare research?

Cohort studies are vital for examining how certain exposures affect the development of specific effects over time. They allow researchers to track participants prospectively, offering a powerful method for studying relationships between exposures and effects.

In physiotherapy, findings from cohort studies help clinicians understand risk factors, predict outcomes, and design preventive strategies for various conditions.

Definition and key characteristics

A cohort study follows a group of individuals, or a 'cohort,' over a period of time to observe how certain exposures influence the occurrence of outcomes.

Let's break this down with its key characteristics:

— **Descriptive or analytical:** They can test hypotheses about associations.

— **Retrospective or prospective:** They can track participants forward in time from the present.

— **Observational or experimental:** They are observational because the research team observes without manipulating exposures.

A particular characteristic of cohort studies is that we can differentiate between two cohort types:

— **Type 1 cohort:** Defined by the exposures, where exposed and non-exposed groups are followed.

— **Type 2 cohort:** Defined by population, where the entire group is followed, and exposures are documented along the way.

Methodology with a flowchart

Let's break down the methodology of a cohort study type 1 using a flowchart:

1. **Define the target population:** Start by identifying a population relevant to your research question, such as women who have undergone mastectomy surgery.
2. **Select participants taking into account the exposure:**
   - **Exposed group:** Patients who received early manual lymphatic drainage.
   - **Non-exposed group:** Patients who did not receive early manual lymphatic drainage.
3. **Follow-up period to collect data:** Track the development of the effect, such as the presence or absence of lymphedema over one year.
4. **Statistical analysis:** Compare the incidence of lymphedema between the exposed and non-exposed groups to determine the preventing effect of early lymphatic drainage in the appearance of lymphedema.

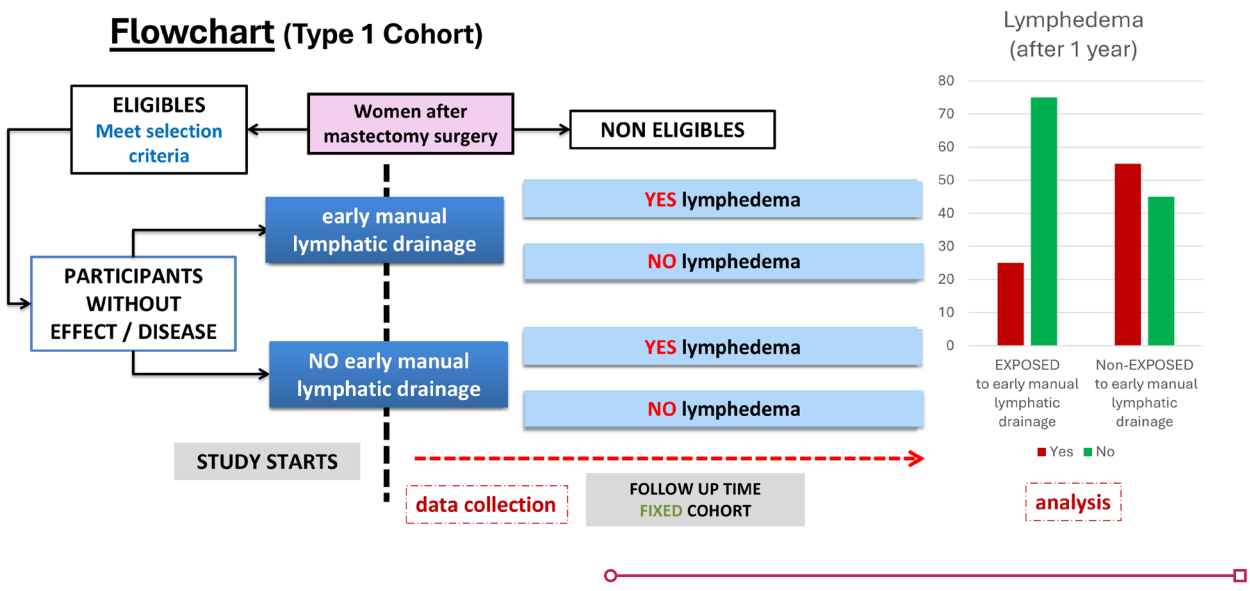

Figure 6. Example of a flowchart for a cohort study type 1

Practical examples in physiotherapy

Now, let's look at another practical example in orthopaedic physiotherapy of a cohort type 2:

Example: Orthopaedic Physiotherapy – Wrist Fracture Rehabilitation

— **Research Question:** What patient characteristics affect functional recovery after a distal radius fracture treated conservatively?

— **Components:**

- **Population:** Adults treated conservatively for a distal radius fracture.
- **Exposures:** Duration of immobilization (e.g., 4 weeks vs. 6 weeks), age, gender, type of fracture, pain intensity, etcetera.
- **Effects:** Functional recovery measured by grip strength and wrist mobility at six months.

What would the flowchart look like and what could its results tell us?

This study could help refine rehabilitation protocols for wrist fractures.

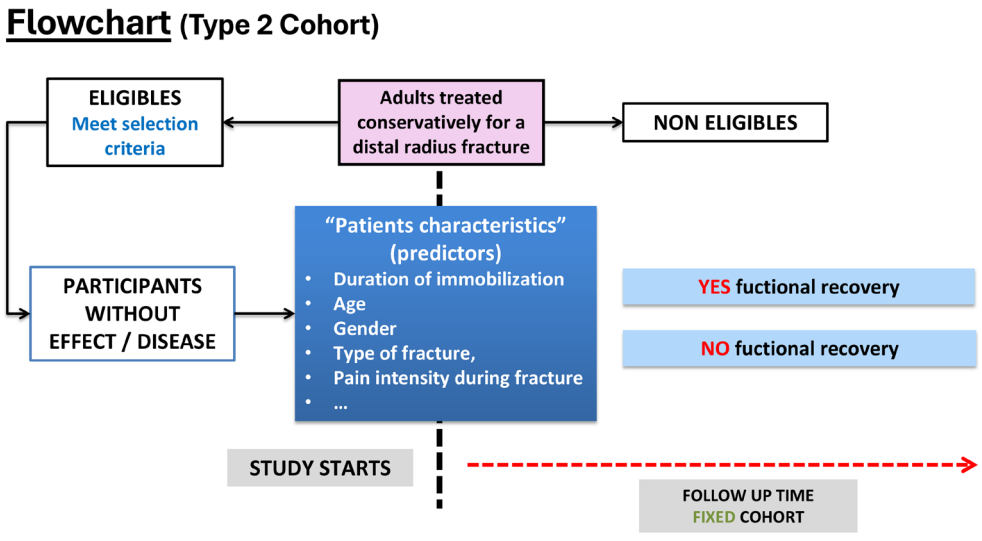

Figure 7. Example of a flowchart for a cohort study type 2

Conclusion

To summarize:

— Cohort studies are powerful tools for understanding relationships between exposures and outcomes over time.

— They are analytical, prospective, and observational.

— Type 1 cohorts follow-up individuals based on a specific exposure, while Type 2 cohorts follow the entire group without distinctions.

Reflection

To conclude, think of a clinical question in physiotherapy that a cohort study design (Type 1 and/or Type 2) could help answer.

What kind of cohort study could help answer those questions? Consider the population, exposure, and outcome.

Prepare your own flowchart and be ready to discuss it in class.

Next steps

That's all for now.

In the next video, we'll explore randomized controlled trials, the gold standard of research designs to evaluate treatment effectiveness.

And… remember to share your doubts and examples in the forum in the PDU.

See you in class!

Link to video version

https://vimeo.com/1092107344

Follow-up multiple choice questions

4.1. Which of the following is NOT a characteristic of cohort studies?

a) Observational ☐

b) Analytical ☐

c) They require follow-up ☐

d) Always retrospective ☐

4.2. A Type 1 cohort study is defined by:

a) Following groups according to their exposure status ☐

b) Following the entire population without distinction of the exposure status ☐

c) Matching ☐

d) Single-time data collection ☐

Video 5:
PROMs – Patient Reported Outcome Measures

Welcome to a complementary video of our series on research study designs. Today, we're shifting our focus to a critical but often overlooked aspect of clinical research–validation studies for Patient-Reported Outcome Measures, or PROMs.

By the end of this video, you'll understand the process behind validating PROMs, why it's crucial for healthcare research, and its impact on clinical practice in physiotherapy.

Let's get started!

Contextualization

Why are validation studies for PROMs important?

PROMs are essential tools in healthcare research, capturing patients' perspectives on their health status, symptoms, and quality of life. These measures are particularly relevant in physiotherapy, where patient-centred outcomes often drive treatment decisions.

A validated PROM ensures that the data we collect is accurate, reliable, and meaningful. This process ensures clinicians and researchers can trust the results to guide care and decision-making. Without proper validation, PROMs may lead to incorrect interpretations and less effective interventions.

Definition and key characteristics

A validation study assesses whether a PROM is measuring what it's intended to measure, and whether it does so consistently across different populations or contexts. In other words, if the PROM is both scientifically robust and practical for clinical use.

Methodology with a flowchart

Now, let's break down the validation process using a flowchart:

Phase 1. Creation of a preliminary version the research question:

a. Start with a thorough literature review to identify existing related questionnaires.

b. Conduct a Delphi study with experts and patients to refine the items.

c. Define scoring methods and the overall structure of the PROM.

Phase 2. Testing the preliminary version:

d. Administer the PROM to a representative sample of patients, ensuring the group reflects those you aim to study.

e. Conduct interviews with participants to ensure they understand the questions as intended (this is called ´face validity´).

f. Ask participants to complete other health-related questionnaires to see if their answers align with similar tools (helping to establish construct validity).

Phase 3. Items reduction

In this step, we refine the questionnaire by removing or revising questions that don't work well. Here's how we decide:

g. **Floor and ceiling effects:** If most participants choose the lowest or highest possible answers, those items might not be capturing meaningful differences.

h. **High percentages of missing values:** If many people skip a question, it could mean the item is confusing, irrelevant, or hard to answer.

i. **Intercorrelated items:** Sometimes, questions are so similar they provide the same information. In these cases, we might keep only the stronger or clearer item.

j. **Low internal consistency:** This means the question doesn't fit well with others in the PROM, suggesting it might not belong in the final version.

By addressing these issues, we ensure the final questionnaire is concise, clear, and relevant.

Phase 4. Psychometric properties of the final version:

Once the final version is ready, we test its scientific reliability and usefulness. Let's define these properties in simple terms:

k. **Discriminant validity:** This checks whether the PROM can tell the difference between distinct groups, like patients with mild versus severe symptoms.

l. **Construct validity:** This asks whether the PROM truly measures what it's supposed to. For example, if it's designed to measure pain, do the results align with other known measures of pain?

m. **Reliability:** This ensures the PROM gives consistent results. If someone takes the test today and again next week (and their condition hasn't changed), their scores should be very similar.

n. **Responsiveness:** This measures whether the PROM can detect changes over time. For instance, if a patient improves after treatment, the PROM should reflect that improvement clearly.

Phase 5. Translation to other languages

Translate and adapt the PROM while ensuring cultural relevance and maintaining validity across different languages."

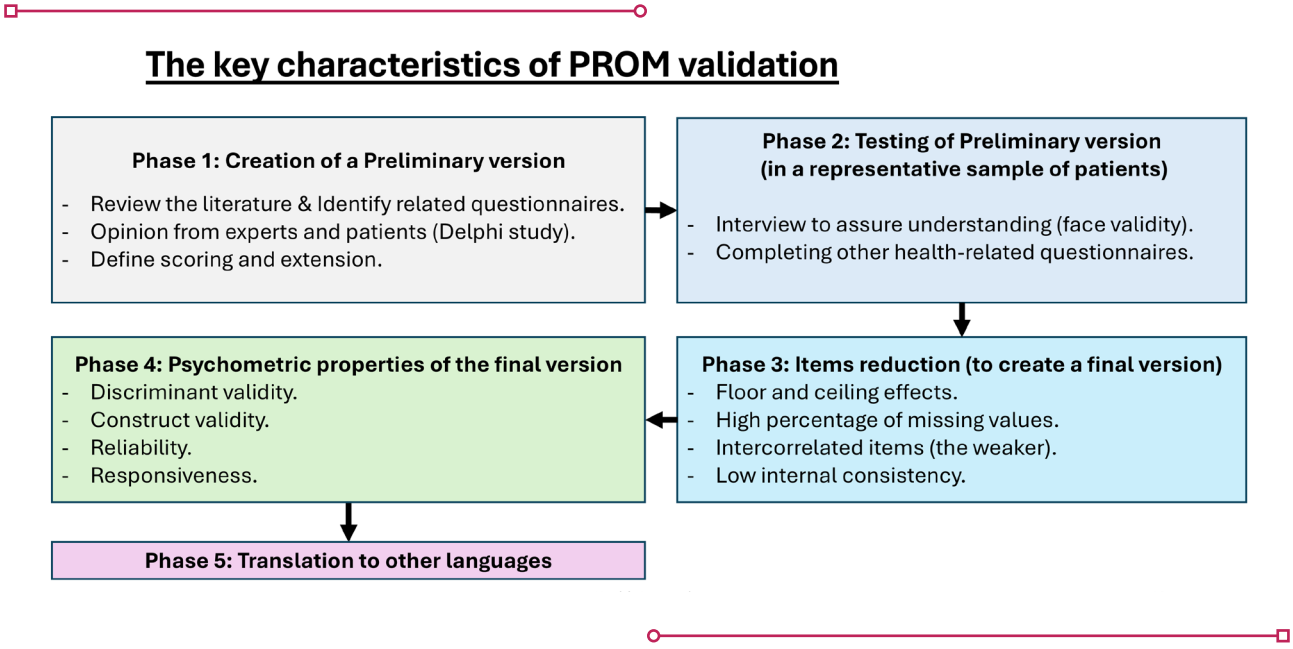

Figure 8. Synthesis diagram of the phases for the validation of Patient-Reported Outcome Measures

Conclusion

To summarize:

— Validation studies for PROMs are essential for ensuring the reliability and accuracy of patient-centered data.

— The process involves multiple stages, from preliminary design and item reduction to psychometric evaluation and translation.

— Validated PROMs enhance clinical decision-making and ensure better outcomes in physiotherapy and healthcare.

Reflection

To conclude, here's a question to reflect on:

How might a validated PROM improve the way you evaluate a specific intervention in your clinical practice or research?

Think about the steps you'd take to ensure its validity.

Next steps

That's all for now.

Thank you for watching the video and as always, let's continue advancing evidence-based practice together!

See you in class!

Link to video version

https://vimeo.com/1095000211

Follow-up multiple choice questions

8.1. What psychometric properties are evaluated in the final version of the PROM?

a) Construct validity ☐

b) Reliability ☐

c) Responsiveness ☐

d) All options are correct ☐

8.2. What is the main goal of item reduction?

a) Interview a representative sample of participants ☐

b) Shorten the PROM while ensuring quality ☐

c) Make the PROM easier to translate ☐

d) Improve the scoring method ☐

Video 6: RCTs – Randomized controlled trials

Welcome to the fifth video in our series on research study designs. Today, we'll explore randomized controlled trials, also called RCTs.

By the end of this video, you'll understand what an RCT is, its unique features, how it's structured, and its applications in physiotherapy research.

Let's begin!

Contextualization

Why are RCTs essential in healthcare research?

RCTs are considered the gold standard for evaluating the effectiveness of treatments. Their design ensures high levels of validity by minimizing bias and establishing causal relationships between interventions and effects.

In physiotherapy, RCTs provide evidence that directly informs clinical practice. For example, they guide decisions about the best rehabilitation protocols or therapeutic modalities, helping clinicians deliver evidence-based care.

Definition and key characteristics

An RCT is a prospective, experimental study where participants are randomly allocated to one or more intervention groups or a control group. The outcomes are then compared to evaluate the effectiveness of interventions.

Let's break this down with its key characteristics:

— **Descriptive or analytical:** RCTs are designed to test hypotheses.

— **Retrospective or prospective:** Data is collected forward in time from the point of participant allocation, so they are prospective.

— **Observational or experimental:** Researchers actively control the exposure (in other words, the treatment) and observe its effects, so it's experimental.

RCTs have two particular characteristics that we can highlight:

— **Randomization:** It ensures participants are assigned to groups by chance, reducing selection bias.
— **Blinding:** Participants, researchers, or both may be blinded to group assignments to prevent bias during data collection and analysis.

Methodology with a flowchart

Let's break down the methodology of an RCT using a flowchart:

1. **Define the target population:** Identify a group relevant to your clinical question. For instance, stroke survivors requiring balance rehabilitation.

2. **Performance of the baseline assessment and group allocation after randomization:** Participants are randomly assigned to different groups. Considering our example:

   — **Intervention group:** It receives specific balance training integrated into conventional physiotherapy.

   — **Control group:** It receives only conventional physiotherapy.

3. **Intervention period and data collection:** Both groups undergo treatment over a set period, with effects (the outcome measures) assessed after the end of the intervention.

4. **Statistical analysis:** Compare changes in balance metrics, such as stability or fall risk, between groups. Use statistical analysis to determine the treatment's effectiveness.

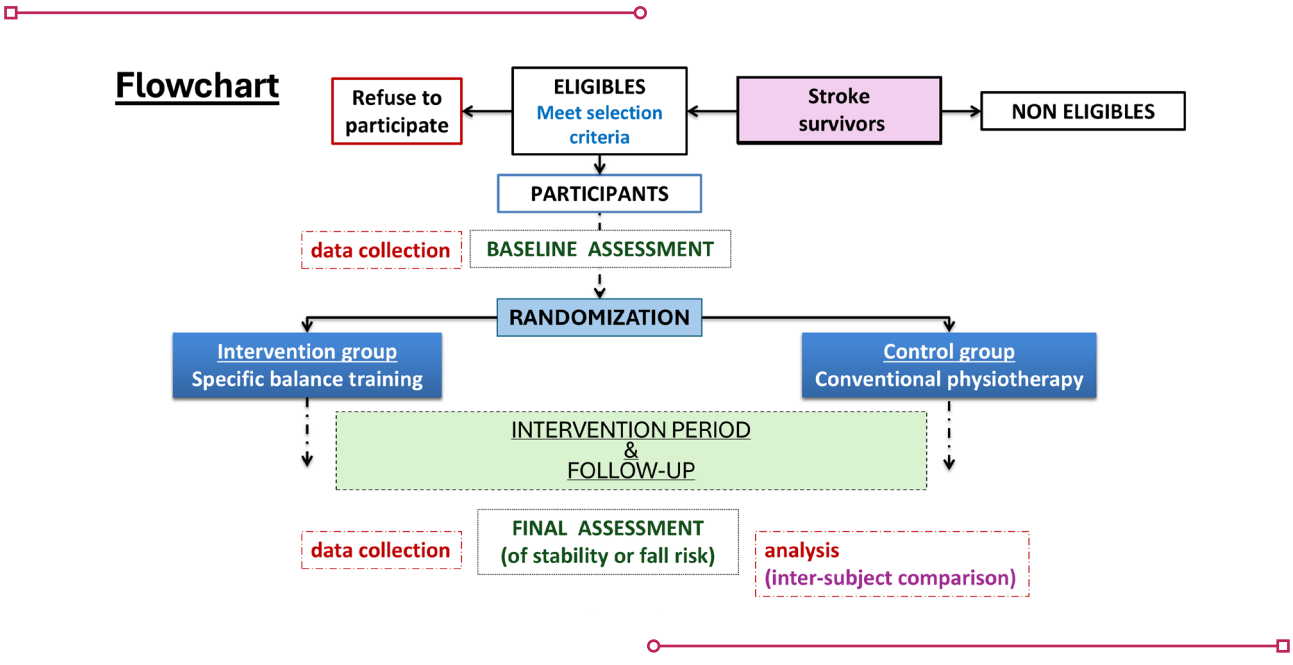

Figure 9. Example number one of a flowchart for a randomized controlled trial

Now, let's look at another practical example in musculoskeletal physiotherapy:

Example: Musculoskeletal physiotherapy – chronic plantar pain

— **Research question:** Is dry needling more effective than exercise therapy in reducing chronic plantar pain?

— **Components:**

- **Population:** Adults with chronic plantar pain.
- **Exposures:** Group A receives dry needling, and Group B receives exercise therapy over six weeks.
- **Effects:** Pain reduction and quality of life measured by patient-reported scales.

What would the flowchart look like and what could its results tell us?

Both examples demonstrate how RCTs can address clinically relevant questions in physiotherapy.

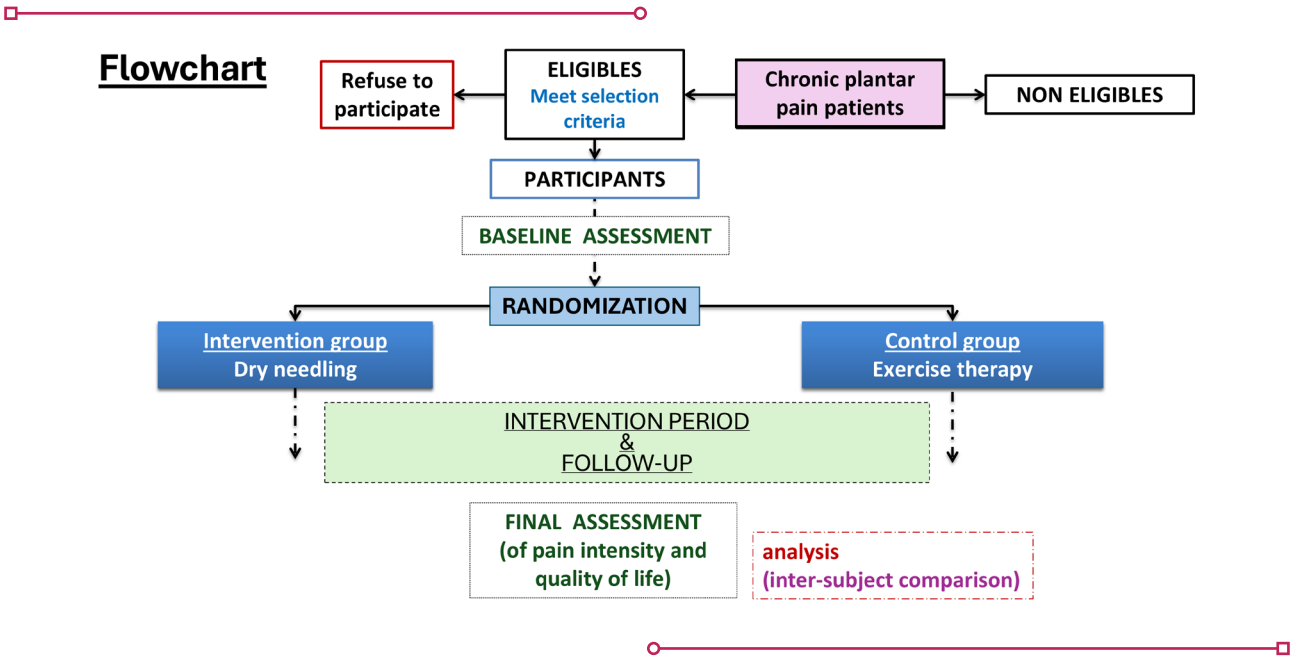

Figure 10. Example number two of a flowchart for a randomized controlled trial

Conclusion

To summarize:

— RCTs are the gold standard for testing treatment efficacy of controlled exposures, with characteristics like randomization and blinding.

— They are experimental, analytical, and prospective.

Reflection

To conclude, think about a physiotherapy intervention you're curious about.

Could an RCT help answer a question about its effectiveness? How would you structure it — what population, intervention, and outcomes would you choose?

Prepare your own flowchart and be ready to discuss it in class.

Next steps

That's all for now.

In our next video, we'll discuss randomized crossover trials, a design where participants serve as their own controls to test multiple interventions.

See you in class!

Link to video version

https://vimeo.com/1092107887

Follow-up multiple choice questions

5.1. Which of the following best describes an RCT?

a) Observational and retrospective ☐

b) Analytical and prospective ☐

c) Retrospective and experimental ☐

d) Prospective and observational ☐

5.2. What makes an RCT experimental?

a) Observing participants over time ☐

b) Actively assigning treatments to participants ☐

c) Comparing historical data ☐

d) Performing hypothesis testing ☐

Video 7: Randomized crossover trials

Welcome to the sixth video in our series on research study designs. Today, we'll focus on crossover randomized trials, a unique and powerful design that builds upon the foundation of traditional RCTs.

By the end of this video, you'll understand what a crossover trial is, its defining characteristics, how it's structured, and its specific applications in physiotherapy research.

Let's get started!

Contextualization

Why are randomized crossover trials important in healthcare research?

Crossover trials allow us to evaluate the effects of treatments while minimizing variability between participants. Since each participant serves as their own control, this design offers increased statistical power with fewer participants compared to RCTs.

In physiotherapy, this is especially valuable when studying chronic conditions in a stable phase. The findings from crossover trials help clinicians refine their approaches to maximize patient outcomes.

Definition and key characteristics

A randomized crossover trial is a prospective, experimental study where participants receive multiple interventions in a sequential order. The key difference from a traditional RCT is that each participant experiences both the treatment and control conditions at different times.

Let's break this down with its key characteristics:

— **Descriptive or analytical:** Crossover trials are analytical and test hypotheses.

— **Retrospective or prospective:** Data is collected prospectively, moving forward in time.

— **Observational or experimental:** Researchers control and manipulate the exposures, making the study experimental.

Randomized crossover trials also present particular characteristics that we can highlight:

Like RCTs, participants are randomly assigned to sequences of interventions, instead of groups, ensuring unbiased comparisons. Moreover, blinding can be applied to minimize measurement bias, just as in RCTs.

However, crossover trials present a unique characteristic called "Washout Period", which is a period between interventions where participants do not receive any treatment to eliminate 'carryover effects'.

Methodology with a flowchart

Let's break down the methodology of a randomized crossover trial using a flowchart:

1. **Define the target population:** Identify a group relevant to your clinical question, such as stable COPD patients.
2. **Performance of the baseline assessment and sequence allocation after randomization:** Participants are randomly assigned to different sequences:
   - **Sequence A:** Treatment 1 → Washout → Treatment 2.
   - **Sequence B:** Treatment 2 → Washout → Treatment 1.

This way each participant receives both interventions (e.g., a new physiotherapy technique and the standard approach) in alternating periods.

3. **Statistical analysis:** Before and after each intervention period, the effects and outcomes measures are assessed and compared. Statistical analyzes are then conducted to assess the relative effectiveness of the treatments within each participant.

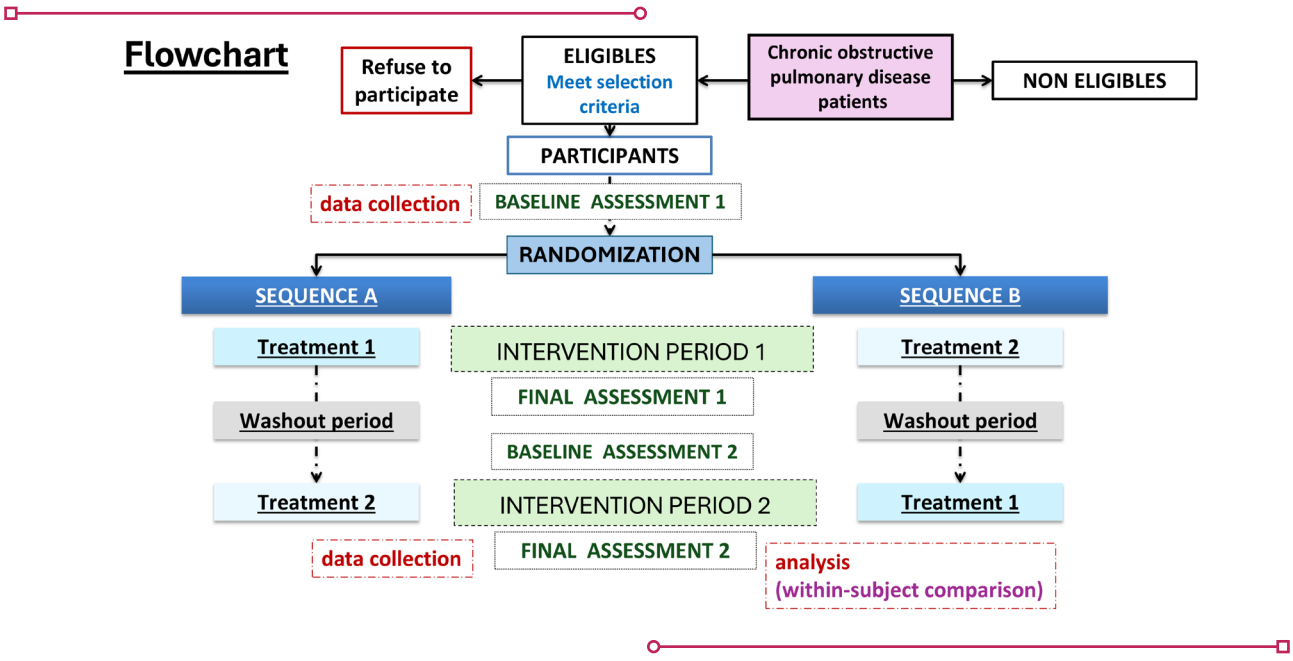

Figure 11. Example number one of a flowchart for a randomized crossover trial

Now, let's look at another practical example in neurological physiotherapy:

Example: Neurological physiotherapy – spasticity management

— **Research question:** Does an intervention aimed at reducing spasticity have better effects than conventional stretching in chronic stroke survivors??

— **Components:**

- **Population:** Adults with chronic post-stroke spasticity.
- **Exposures:** Treatment A consists of three sessions of task-specific techniques, and Treatment B consists of three sessions of conventional stretching.
- **Washout:** One week to avoid lingering effects of the interventions.
- **Effects:** Muscle tone reduction measured with a myotonometer.

What would the flowchart look like and what could its results tell us?

Both examples demonstrate how crossover trials can address clinically relevant questions in physiotherapy.

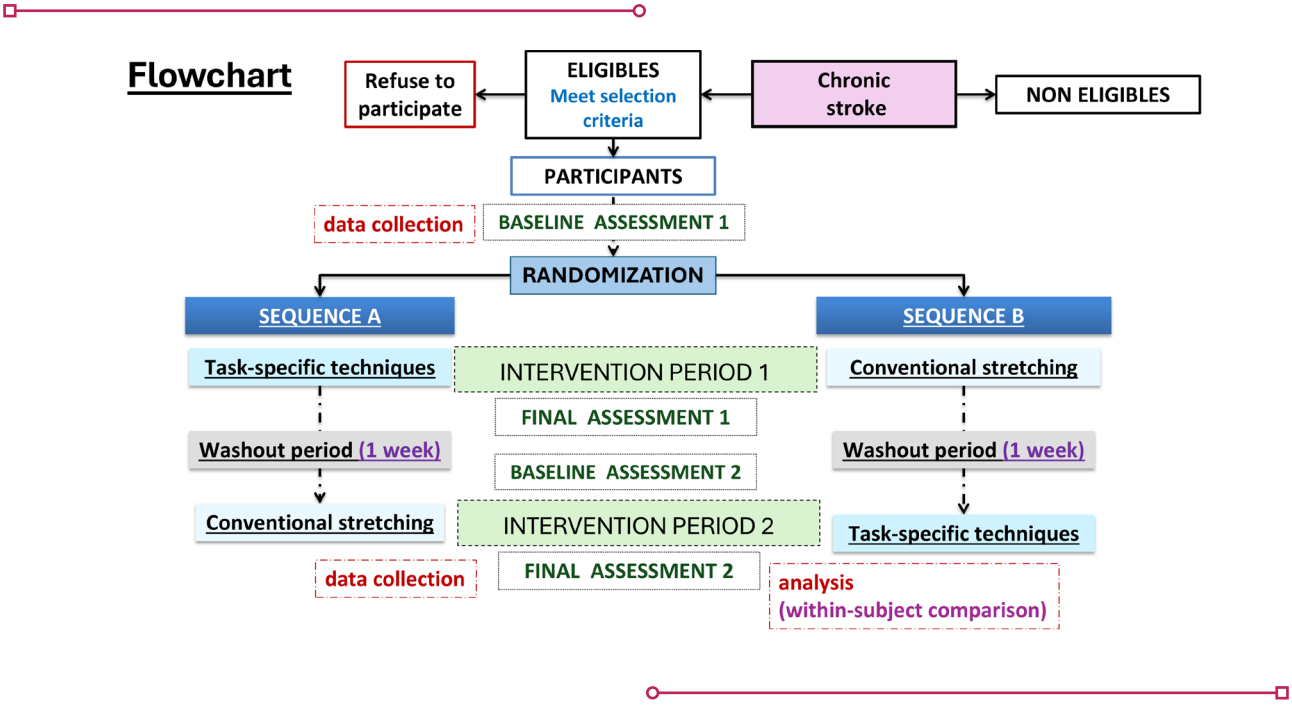

Figure 12. Example number two of a flowchart for a randomized crossover trial

Conclusion

To summarize:

— Crossover randomized trials are a powerful design that builds on traditional RCTs, allowing each participant to act as their own control.

— Key features include randomization, sequential treatments, and a washout period to minimize carryover effects.

— These trials are particularly useful for chronic conditions and interventions with measurable short-term effects.

Reflection

To conclude, think about a physiotherapy intervention you've encountered in your practice.

Could a crossover trial help compare its effectiveness against an alternative? How would you structure the study, and what effects would you measure?

Prepare your own flowchart and be ready to discuss it in class.

Next steps

That's all for now.

In our next video, we'll focus on systematic reviews, with and without meta-analyzes. These study designs synthesize evidence from multiple studies, offering clinicians and researchers a broader perspective on specific clinical questions.

See you in class!

Link to video version

https://vimeo.com/1094999485

Follow-up multiple choice questions

6.1. What distinguishes a crossover trial from a traditional RCT?

a) Participants receive only one treatment ☐

b) Participants are exposed to multiple treatments ☐

c) Randomization is not used ☐

d) Blinding of evaluators is not performed ☐

6.2. What is the purpose of a washout period?

a) To test the long-term effects of a treatmentq ☐

b) To enhance the positive effects of the treatments ☐

c) To avoid carryover effects ☐

d) To ensure blinding ☐

Video 8: Systematic reviews and Meta-Analyses

Welcome to the final video in our series on research study designs. Today, we'll explore systematic reviews, with and without meta-analyses—an essential approach for synthesizing evidence in healthcare research.

By the end of this video, you'll understand the purpose of systematic reviews, how they're conducted, and their impact on physiotherapy practice.

Let's get started!

Contextualization

Why are systematic reviews crucial in healthcare and physiotherapy?

Systematic reviews represent the maximum of evidence-based research, offering comprehensive evaluations of all available studies on a specific topic. By consolidating findings, they provide a clear and reliable summary of evidence.

In physiotherapy, systematic reviews are indispensable for guiding clinical decision-making, helping practitioners identify the most effective treatments and avoid those that are less beneficial.

Definition and key characteristics

A systematic review is a structured and transparent process to identify, select, and critically appraise all relevant studies on a specific research question.

When combined with a meta-analysis, it quantitatively synthesizes data from multiple studies to produce a pooled estimate of the effect.

Let's break this down with its key characteristics:

— **Comprehensive search strategy:** A clearly defined protocol ensures all relevant studies are considered.

— **Study selection:** Predefined inclusion and exclusion criteria are used to select studies.

— **Critical appraisal:** The quality and risk of bias in the included studies are systematically assessed.

— **Data extraction:** Key information is extracted from studies for analysis.

When a meta-analysis is added, statistical methods combine results from individual studies, increasing precision and power to detect true effects. However, not all systematic reviews include meta-analyzes, as the decision depends on the homogeneity of the included studies.

Methodology

Let's visualize the methodology of a systematic review with a flowchart:

1. **Define the research question:** For example, if you want to synthesize evidence from RCTs, you can use the PICO framework (Population, Intervention, Comparison, Outcome) to guide the question.
2. **Develop a protocol:** Outline the search strategy, databases, and inclusion criteria.
3. **Search for studies:** Conduct a comprehensive search across databases like PubMed, PEDro, and Web of Science.
4. **Screen studies:** Use inclusion/exclusion criteria to identify eligible studies.
5. **Appraise study quality:** Evaluate the risk of bias in included studies using standardized tools like the Cochrane Risk of Bias Tool.
6. **Extract data:** Collect relevant data from studies for synthesis.
7. **Synthesize findings:**
   — First, provide a narrative summary, a feature of systematic reviews.
   — Second, if possible, perform a meta-analysis to combine data.
8. **Report results:** Follow guidelines like PRISMA to ensure transparency and clarity.

Conclusion

To summarize:

— Systematic reviews and meta-analyzes are powerful tools for synthesizing evidence and guiding clinical practice.

— Systematic reviews involve a transparent and rigorous process of study selection, appraisal, and synthesis.

— Meta-analyses combine data to provide precise estimates of treatment effects.

Reflection

To conclude, how could a systematic review enhance your understanding of a specific intervention in physiotherapy?

Consider the steps involved and think about how you'd ensure the review is comprehensive and unbiased.

Next steps

That's all for now! This marks the end of our series on research study designs. We've covered everything from cross-sectional studies to systematic reviews, equipping you with the knowledge to critically appraise and contribute to evidence-based practice.

Thank you for joining this journey and see you in class!

Link to video version

https://vimeo.com/1094999882

Follow-up multiple choice questions

7.1. What is the primary purpose of a systematic review?

a) To conduct experiments on a large population ☐

b) To analyze data from a single study ☐

c) To replicate clinical trials ☐

d) To summarize all relevant studies on a research question ☐

7.2. What is a key feature of meta-analyzes?

a) Narrative summaries ☐

b) Statistical combination of study results ☐

c) Observational data collection ☐

d) Single-study appraisal ☐

Video 9: Precision (I): sample size estimation

Hello everyone! How are you doing? Are you ready to learn a bit more about sample size error? This video will help you!

What is a sample size error and why is it important to avoid it?

When the number of participants you recruit for your study is either insufficient or too large, you face a methodological issue known as a sample size error. This error negatively impacts the precision of your study and it is considered a random error. If you have this error, it becomes impossible to extrapolate your results to real-life situations. Sample size errors can significantly compromise the validity and applicability of your research findings, making it crucial to understand and avoid them in your study design.

What strategies should I implement in my studies to avoid the presence of a sample size error?

To avoid sample size errors, you should implement two key strategies: first, calculate the theoretical number of participants needed to ensure you have an appropriate target sample size before starting the recruitment of the study; second, at the conclusion of the study (when you have finished the recruitment), verify the actual number of participants who completed it, specifically checking that you have the correct number of participants with data for the primary outcome. By following these strategies, you can significantly reduce the risk of sample size errors and enhance the validity of your research results.

Tips to implement the first strategy

To estimate the sample size for your study, you need to determine specific values for several parameters, including alpha and beta, as well as those related to your primary outcome and potential losses during follow-up.

One of the most crucial steps is setting appropriate values for alpha and beta to minimize the risk of Type I and Type II errors. In biomedical research, the conventional values are 0.05 for alpha and 0.2 for beta. A Type I error (false positive) is often associated with multiple hypothesis testing, where you explore relationships between multiple exposures and effects in a single study (for example in a cross-sectional studies). A Type II error (false negative) typically relates to small sample sizes, where too few participants complete the study. However, you can further reduce the probability of these errors by

adjusting these values. For instance, setting alpha to 0.01 would decrease the likelihood of a Type I error (false positive), while setting beta to 0.1 would reduce the chance of a Type II error (false negative). By carefully selecting these parameters, you can significantly improve the accuracy of your study results.

Additionally, you need to consider your primary outcome and select an appropriate tool for its assessment. From the chosen tool, you need to gather data on variability or dispersion from existing literature. For experimental studies, you must also identify the minimal clinically important difference – the smallest change in the outcome measure that patients perceive as beneficial. Both parameters are essential in the equation estimation of a sample size. Finally, it's essential to include an additional percentage of participants in your recruitment to account for potential dropouts, especially in long-term studies. This extra percentage acts as a safeguard, helping to prevent sample size errors if participants withdraw during the follow-up period. By incorporating these elements into your sample size calculation, you can ensure that your study maintains statistical power.

Tips to implement the second strategy

At the conclusion of your study, after recruitment has ended, it's crucial to incorporate a final step to ensure that a sample size error is not present. You need to verify that the actual number of participants who completed the study, specifically those who completed the assessment of the primary outcome, is at least equal to the theoretical number of participants calculated in the initial step. This comparison should be made without considering the additional percentage added for potential losses. By confirming that your final sample size meets or exceeds the originally calculated theoretical number, you can be confident that your study maintains its statistical power and that the results are generalizable, as long as the internal validity is sufficient.

You will find that watching the videos greatly helps you understand the concepts that will be covered in class and successfully complete the activities! See you in class!

Link to video version

https://vimeo.com/1095000772

Follow-up questions

9.1. Could you identify the following parameters in this sample size estimation?

Sample size

Sample size was estimated using the G*Power software, version 3.1.9.7 (Heinrich-Heine University, Düsseldorf, Germany). For an alpha level of 0.05 with 80% power, calculation was based on the observed effect of PEMF treatment, compared to placebo, on fatigue symptoms in this population.[22] We considered 2 groups, 3 measurements and a mean between group difference after intervention of 8 points (SD = 12) on the Modified Fatigue Impact Scale. This generated a sample of 44 patients (including a 10% dropout rate) to complete the trial.

PEMF = Peripheral low-frequency pulsed electromagnetic field

Granja-Domínguez A, Hochsprung A, Luque-Moreno C, Magni E, Escudero-Uribe S, Heredia-Camacho Bet al. Effects of pulsed electromagnetic field therapy on fatigue, walking performance, depression, and quality of life in adults with multiple sclerosis: a randomized placebo-controlled trial. Braz J Phys Ther. 2022;26(5):100449

Parameters	Values
Type I error	
Type II error	
Power of study	
Primary outcome	
Tool used for primary outcome	
Variability	
Minimal change	
Losses	
Total sample required (with losses)	
Total sample required (without losses)	

Figure 13. Follow-up question for Precision (I)

Video 10: Precision (II): remaining errors affecting the precision of a study

Hi again! Are you ready for another educational pill about the errors that may affect the precision of studies? Don't miss this video!!

What are the other random errors that may negatively affect the precision of studies?

Apart from random sample size errors, there are three additional random errors that negatively impact the accuracy of results. It's important to learn more about these errors with the main goal of reducing their potential influence on our results as much as possible. These random errors are: instrumental error, intra- or inter-subject error, and data entry error. Would you like to know more about each one? Keep watching the video to find out!

Instrumental error: what is it about and how can I minimize its occurrence?

This is a random error related to the tools used for assessing outcomes or selection criteria. While the chosen tool can be appropriate for evaluating your variables, it may not be sufficiently accurate. This could be due to the tool being electronic and requiring calibration, or because your study uses different models of the same tool, which may produce varying levels of accuracy in results. For example, if you're using an algometer to evaluate pain as an outcome, you need to ensure two things: first, that the measuring device has been calibrated appropriately and periodically; and second, if you're using multiple algometers for the assessment, they should all be the same model. These precautions help to minimize the risk of this random error.

Intra / inter-subject error: what is it about and how can I minimize its occurrence?

This is a random error related to the investigator's involvement in assessing outcomes or selection criteria. We refer to intra-subject error when the methodological issue arises from the same researcher, and to inter-subject error when the issue involves different researchers conducting the same assessments. This random error occurs when, despite being trained and having prior experience in assessing outcomes or selection criteria, an investigator's performance is not consistent across all assessments. This inconsistency may result from not following a standardized protocol for outcome assessment or

from not adhering to the same steps during evaluations. For example, if you are evaluating patients' physical function using maximal tests, it is important to encourage them to achieve their best performance. To minimize this random error, it would be ideal to establish a specific protocol for encouragement that all researchers follow during assessments. Another option, particularly in multicenter studies if resources allow, is to implement a quality control system. These precautions help reduce the risk of this random error.

Data entry error: what is it about and how can I minimize its occurrence?

This random error is related to the investigator's involvement in entering data into the general database of the study. It occurs when the investigator makes a mistake while inputting a specific value, which can negatively impact the accuracy of the findings and alter the statistical results. To minimize this random error, it would be ideal to implement technology that allows for direct data transfer to the database, thereby reducing the potential for errors. Additionally, a double-check system should be established, involving a second investigator or a quality control process to detect potential outlier values or significant discrepancies between assessments of individual participants. These precautions can help reduce the risk of this random error.

Thank you for your attention! In class, we will delve deeper into the topic of precision through examples and engaging activities, so don't miss it!

Link to video version

https://vimeo.com/1095001689

Follow-up questions

10.1. What random error is most probable to have if we use the outcome measure described below?

Gait performance was assessed with the GAITRite® system (CIR Systems Inc., Franklin, NJ, USA), which is an 8-meter mat with motion sensors arranged in a grid-like pattern. This system is valid and highly reliable to monitor spatiotemporal gait parameters, e.g., speed, cadence, and functional ambulation performance, in patients with MS;[25] and with

MS = Multiple sclerosis

Granja-Domínguez A, Hochsprung A, Luque-Moreno C, Magni E, Escudero-Uribe S, Heredia-Camacho Bet al. Effects of pulsed electromagnetic field therapy on fatigue, walking performance, depression, and quality of life in adults with multiple sclerosis: a randomized placebo-controlled trial. Braz J Phys Ther. 2022;26(5):100449

You can choose more than one option.

a. Sample size error
b. Instrumental error
c. Inter-subject error
d. Intra-subject error
e. Intra and inter-subject error
f. Data entry error

Figure 14. Follow-up question number one for Precision (II)

10.2. What random error is most probable to have if we use the outcome measure described below in a multi-center study?

Health-related QOL was self-reported with the Multiple Sclerosis International Quality of Life Questionnaire, which covers nine dimensions: daily life activities, psychological well-being, symptoms, relationships with friends, family and the healthcare system, sentimental and sexual life, coping, and rejection.[28]

Granja-Domínguez A, Hochsprung A, Luque-Moreno C, Magni E, Escudero-Uribe S, Heredia-Camacho Bet al. Effects of pulsed electromagnetic field therapy on fatigue, walking performance, depression, and quality of life in adults with multiple sclerosis: a randomized placebo-controlled trial. Braz J Phys Ther. 2022;26(5):100449

You can choose more than one option.

a. Sample size error
b. Instrumental error
c. Inter-subject error
d. Intra-subject error
e. Intra and inter-subject error
f. Data entry error

Figure 15. Follow-up question number two for Precision (II)

Video 11: Validity (I): selection bias

Hello students! It's time to delve into one of the most crucial topics of the course: understanding systematic errors that negatively impact the internal validity of a study and affect the credibility of its findings. Are you ready to explore what these errors entail? Let's dive in and discover more about the first one, selection bias.

What is a selection bias and why is it important to avoid it?

A selection bias is a methodological mistake that occurs when the recruitment process fails to obtain a representative sample. This can happen either because the characteristics are significantly different from the target population, or because the groups in the study are not comparable in their main characteristics, or because the low completion rate and high number of dropouts prevent obtaining representative findings despite an initially appropriate number of participants recruited. The key point is to be aware of these methodological mistakes with the intention of avoiding them from the beginning. This means implementing effective methodological strategies during the recruitment and during the follow up to prevent the occurrence of these errors. By doing so, researchers can enhance the validity of their studies, ensuring more robust and credible findings.

What types of selection bias are there?

The six most important types of selection bias are: sampling bias, comparability bias, survivorship bias, self-selection bias, attrition bias, and non-response bias.

In summary, sampling bias occurs when the selection criteria or the context in which recruitment is performed are not suitable for obtaining a representative sample of the target population of the study.

Comparability bias occurs in studies that involve established groups for comparison. The methodological issue in this bias is that the groups are not comparable at the beginning of the study. Consequently, any potential differences observed at the end of the study could be attributed to these initial differences rather than to the exposure being investigated.

Survivorship bias occurs when investigators focus their recruitment solely on successful individuals while excluding those who did not survive the effect or did not show a successful response to the exposure. Thus, findings may be underestimated or overestimated.

In prospective studies, participants tend to drop out over time. If the rate of attrition is high, it can negatively impact the findings of the study, potentially leading to underestimation or overestimation of effects and creating an attrition bias if the characteristics of those who drop out differ systematically from those who remain in the study.

Nonresponse bias occurs in surveys or questionnaires when the completion rate is too low, compromising representativeness of the sample. This bias arises because there's a high risk that responders and non-responders may have different characteristics.

What strategies should I implement in my studies to avoid the presence of selection bias?

In class, we will delve deeper into the methodological strategies that can be implemented to avoid selection bias and enhance the internal validity of our studies. However, we can highlight a few key approaches: Implementing randomized recruitment is the primary strategy to obtain participants with characteristics similar to the target population and obtain initial characteristics between groups. Additionally, blinding the investigators involved in recruitment, randomization, and assessments helps guarantee allocation concealment. Finally, we will learn how to implement strategies to encourage participants to remain in studies, thereby reducing high dropout rates, which ultimately contributes to minimizing selection bias and strengthening the internal validity.

Don't miss the class, where we will explore selection bias in greater depth using examples!

Link to video version

https://vimeo.com/1095002247

Follow-up questions

11.1. What selection bias are the authors avoiding with the methodological procedure described below?

Participants

Patients with a confirmed diagnosis of RRMS, according to the 2017 revisions of the McDonald criteria,[18] were recruited from the MS unit at a large public hospital in southern Spain. Participants between 18 and 65 years were included if they reported a moderate to high level of fatigue (score $\geq$ 4 in the Fatigue Severity Scale) and were able to walk without aid for at least 100m (score $\leq$ 5.5 in the Expanded Disability Status Scale, EDSS).[19] The exclusion criteria were: a severe neuropsychologist-confirmed cognitive and/or psychiatric impairment; a relapse episode in the previous month or during the study protocol;[20] a history of epilepsy or traumatic brain injury; prior lower limb fracture or severe trauma; changes in MS disease-modifying therapy within the previous month;[20] having internal metallic devices;[21] and pregnancy or breastfeeding.[21] Participants were asked not to engage in any new treatment for their MS during the study period but were allowed to continue with their regular medication intake.

Granja-Domínguez A, Hochsprung A, Luque-Moreno C, Magni E, Escudero-Uribe S, Heredia-Camacho Bet al. Effects of pulsed electromagnetic field therapy on fatigue, walking performance, depression, and quality of life in adults with multiple sclerosis: a randomized placebo-controlled trial. Braz J Phys Ther. 2022;26(5):100449

You can choose more than one option….

a. Sampling bias
b. Comparability bias
c. Survivorship bias
d. Self-selection bias
e. Attrition bias
f. Non-response bias

Figure 16. Follow-up question number one for Validity (I)

11.2. What selection bias are the authors describing below?

RESULTS

Mailed survey responses

Of the 28 284 mailed health surveys, 2706 (10%) were returned to sender. The five most common reasons for these returns were vacant address (n=777), unable to forward (n=660), no mail receptacle (n=373), insufficient address (n=325) and addressee unknown (n=234). Of the remaining 25 578 surveys, we received 5230 responses (20%), which was similar to our expectation, based on our prior experience performing a one-time mailed health survey in this rural region, which previously outperformed telephone-based approaches.[18] 28 of the returned surveys were partially completed and could not be used for the analysis as they were missing key demographic data. In addition, we excluded an additional 468 survey

Lee DC, Ross L, Quintero Arias C, Rony M, Patel R, Jensen E, et al. Demographic and geographic distribution of diabetes and pre-diabetes risk in rural settings: results from a cross-sectional, countywide rural health survey in Sullivan County, New York. BMJ Open. 2024; 6;14(8):e080831

You can choose more than one option.

a. Sampling bias
b. Comparability bias
c. Survivorship bias
d. Self-selection bias
e. Attrition bias
f. Non-response bias

Figure 17. Follow-up question number two for Validity (I)

Video 12: Validity (II): information bias

Hello students! At this point, you've learned about all the methodological issues related to sample selection in your study. Now, we're shifting our focus to potential mistakes associated with the procedures for assessing exposures, effects, and interventions (in the case of experimental studies). Are you ready to delve deeper into understanding these concepts? Let's explore them together!

What types of information bias are there?

An information bias primarily comprises three types: detection bias, recall bias, and performance bias (in experimental studies). These methodological mistakes negatively impact the accuracy of data obtained from the sample during the study, affecting both exposures and, more critically, effects or outcomes.

This can occur due to inappropriate tools with inadequate measurement properties, untrained or inexperienced investigators, or inconsistent tool usage across participants. The risk of bias increases if investigators involved in assessments are aware of group allocation (i.e., whether a participant is in the exposure group or in the non-exposure group).

Recall bias becomes significant when information is based on participants' past experiences, potentially leading to inaccurate data.

Performance bias, applicable only to experimental studies, relates to providing different levels of attention to groups or when participants and investigators involved in interventions are aware of group allocation (i.e., whether a participant is receiving active or comparative treatment). The key to mitigating these biases is awareness and proactive prevention throughout all planned study assessments.

What strategies should I implement in my studies to avoid the presence of information bias?

Implementing effective strategies is essential for enhancing the internal validity of study findings, including selecting and using appropriate measurement tools, providing proper investigator training, establishing standardized assessment procedures, and employing blinding techniques. When choosing outcomes, it is crucial to select the best available tool; while the gold standard may not always be feasible, gathering information about the measurement properties of alternative tools—such as validity,

reliability, and responsiveness to clinical changes—is advisable. Investigators involved in assessments and interventions should have prior experience or receive specific training on proper tool usage, particularly for sophisticated instruments, or proper intervention technique to ensure consistency and accuracy in data collection or implementation of the treatment. Additionally, blinding participants, assessors, and those implementing interventions is the most effective strategy to try to avoid any potential human influence on findings or intervention delivery. By adopting these strategies, researchers can significantly improve the quality of their study results, thereby enhancing the overall credibility of their research.

Thank you for watching the video to the end —great job! We look forward to seeing you all in class, where we can enhance our understanding of information bias through examples.

Link to video version

https://vimeo.com/1095002684

Follow-up questions

12.1. How can detection bias be avoided when using a portable dynamometer to assess quadriceps strength in people with rheumatoid arthritis?

Video 13: Validity (III): analysis bias

Welcome to this new education pill! In this video, you'll learn about the final category of systematic error: analysis bias, which can negatively impact the internal validity of studies. This methodological issue arises when there's a discrepancy between how you initially planned to analyze your findings or data and how you ultimately conduct the analysis or present your results in the manuscript. By being aware of this potential bias, you can take steps to ensure the accuracy of the conclusion of your study.

What types of analysis bias are there and what strategies should I implement to avoid the presence of bias?

Primarily, this systematic error relates to the procedure of analysis. Analysis bias can manifest when researchers fail to account for potential confounding factors that may influence both the exposure and the outcome. In experimental studies, low adherence rates to planned treatments further complicate result interpretation, making it difficult to determine whether negative results are due to treatment ineffectiveness or poor patient adherence. Additionally, it can arise when investigators deviate from their pre-specified analytical plan, selectively report results, or manipulate data to achieve desired outcomes.

The presence of potential confounding factors, defined as variables that may influence both the exposure and the effect, is a crucial consideration for investigators before initiating a study and planning data analysis. To address this issue, researchers can implement stratified randomization when the study involves at least two groups, which helps balance baseline characteristics among groups and can lower variance. Alternatively, investigators can account for potential confounding factors in their analysis plan by including these variables in statistical tests, using techniques such as multivariate analysis methods to control for multiple confounders simultaneously. By employing these strategies, researchers can minimize the influence of confounding factors on both the exposure and the effect, thereby increasing the accuracy of their findings.

In experimental studies, low treatment adherence can significantly lead to underestimated results. If participants fail to follow the prescribed treatment plan (for instance, home-based balance exercises), negative outcomes may reflect non-adherence rather than treatment inefficacy. To address this issue, it's crucial to establish a priori strategies for monitoring and promoting adherence. Additionally, investigators should conduct both intention-to-treat analyzes (including all participants) and per-protocol analyzes (considering only adherent participants, typically those completing >80% of planned sessions). This dual approach allows for a comprehensive evaluation

of treatment effectiveness, accounting for the impact of adherence on study outcomes.

To mitigate the risk of reporting bias, it's essential to address the potential for researchers to manipulate their analysis plan to achieve desired outcomes. Such practices may include selectively reporting only positive outcomes or altering the presentation of data. A robust strategy to prevent such practices is the pre-registration of the analysis plan before the study begins. This proactive step promotes transparency and holds researchers accountable to their original intentions. Additionally, when feasible, blinding the investigator responsible for data analysis can further reduce the potential for bias. By keeping the data analyst unaware of the hypotheses or group assignments, the risk of unconscious or deliberate data manipulation decreases. These measures collectively make the research more trustworthy. They help make sure that the results we share are the real findings of the study, not just what the researchers hoped to see or wanted to prove.

Thank you for watching the video! We look forward to seeing you in class, where we can clarify any doubts and deepen our understanding of analysis bias.

Link to video version

https://vimeo.com/1095003168

Follow-up questions

13.1. Do you identify any confounding factor?

Randomisation and masking

After completing the baseline questionnaire, participants were randomly assigned to the individualised, progressive walking and education intervention or a no treatment control group in a 1:1 allocation ratio. The randomisation sequence was created by a senior research team member (C-WCL) who was not involved in screening, randomisation, or data collection. The randomisation schedule comprised randomly permuted blocks of 4, 6, and 8, stratified by history of more than two previous lifetime episodes of low back pain, which is the only consistently reported prognostic factor for low back pain recurrence,[2] and recruitment from community advertising versus clinician referral. The randomisation sequence was embedded within Research Electronic Data Capture (REDCap), and a member of the research team (NCP) randomly assigned participants to their groups and notified them of their allocation.

Pocovi NC, Lin CC, French SD, Graham PL, van Dongen JM, Latimer Jet al. Effectiveness and cost-effectiveness of an individualised, progressive walking and education intervention for the prevention of low back pain recurrence in Australia (WalkBack): a randomised controlled trial Lancet. 2024; 13;404(10448):134-144

Figure 18. Follow-up question for Validity (III)

Video 14: How to interpret the results

Hello students! Welcome to a new block in our course. This educational pill focuses on a crucial skill: interpreting results described in research manuscripts. Mastering this ability is vital as it will enable you to quickly analyze future works in your field of expertise and make informed decisions in your clinical practice based on the most recent evidence. This video is divided into two components: the first part offers tips for interpreting data expressions, while the second part focuses specifically on how to interpret tables and figures. Don't worry – you don't need to be a statistician to understand how to interpret results. With our tips, you'll gain confidence in reading tables and figures. Let's dive in and start building your skills in interpreting scientific results!

How to interpret the data expression in a manuscript?

In research manuscripts, findings are typically analyzed using hypothesis testing, where statistical tests are employed to evaluate the investigator's hypotheses. Results are often expressed using p-values, with a value below 0.05 generally considered statistically significant in biomedical research. However, relying solely on p-values provides limited information. To fully understand the results, it's crucial to examine the magnitude and direction of any significant differences. This requires looking at the specific values obtained from the hypothesis testing. For continuous variables (such as level of pain, falls frequency, range of motion, PROs score, muscle strength), you'll likely encounter mean or median differences with their respective 95% confidence intervals. In contrast, for dichotomous outcomes (such as presence of pain or fall or improvement in the range of motion, you'll typically find ratios (such as odds ratios or risk ratios) along with their 95% confidence intervals. By considering these additional metrics, you can gain a more comprehensive understanding of the findings of the study beyond mere statistical significance.

The range of the confidence interval expresses the estimated range of values within which the true population parameter is likely to fall, with 95% probability. This means that if the study were repeated many times, 95% of the calculated intervals would be expected to contain the true population value.

The interpretation of confidence intervals varies depending on the nature of the outcome. For continuous variables, you should check if the value 0 is included within the confidence interval. If 0 is included, it indicates no significant difference in the analyzed outcome. However, if 0 is not within the interval, it suggests a significant difference in your comparison. For dichotomous variables, the interpretation follows a similar principle, but

instead of 0, you need to check if the value 1 is included in the confidence interval. Again, if 1 is included, there is no significant difference in the compared outcome. Conversely, if 1 is not included, it indicates a significant difference.

An alternative to hypothesis testing is estimating the effect size, which provides a measure of the magnitude of the difference between groups. Unlike hypothesis testing, effect size is not dependent on sample size, making it a more robust tool for understanding the practical significance of findings. Additionally, effect size is commonly used to combine data from multiple studies, such as in meta-analyzes, allowing for a more comprehensive evaluation of evidence across research. Effect sizes are typically interpreted as small, moderate, or large following standardized scales (usually included in the manuscript).

How to interpret tables and figures in a manuscript?

Tables in research manuscripts typically follow a standard structure to present data clearly. The first column lists the outcomes, including their names and units of measurement, while subsequent columns show the values obtained for different comparison groups or assessment time points. The final column presents the statistical approaches, hypothesis testing results, or effect sizes. To enhance readability and interpretation, it is essential to include a footnote that explains all abbreviations used, specifies the statistical tests employed, and provides interpretation scales when necessary (i.e., for effect sizes).

Interpreting figures in research manuscripts follows a similar approach to tables, but with visual elements. Typically, figures include a legend to guide readers in understanding results based on group allocation or assessment time points. The y-axis generally represents the magnitude of the outcome, including units of measurement, while the x-axis often depicts different groups or time points of assessment. To highlight significant differences, authors frequently use symbols or asterisks. A footnote is usually provided to explain all abbreviations, specify the statistical tests used, and clarify the meaning of any symbols included. This comprehensive approach ensures that readers can accurately interpret the visual data presentation, making complex information more accessible and understandable.

It was a pleasure to share these tips with all of you to help interpret the results obtained from manuscripts.

Link to video version

https://vimeo.com/1095078471

Follow-up questions

14.1. How do you interpret the findings of this table?

Table 2 Changes in fatigue measures.

Outcomes	Within group differences		Between group differences
	PEMF group	Placebo group	
Fatigue Severity Scale, 1 to 7			
Baseline (T1)	5.7 ± 1.1	5.8 ± 0.9	
Post-intervention (T2)	4.8 ± 1.5	5.5 ± 1.3	
Change T1 to T2	**-0.9 (-1.4, -0.4)**	-0.3 (-0.8, 0.2)	-0.6 (-1.3, 0.1)
3-months post-intervention (T3)	4.8 ± 1.6	5.5 ± 1.6	
Change T1 to T3	**-0.9 (-1.4, -0.3)**	-0.3 (-0.9, 0.3)	-0.6 (-1.4, 0.2)

Data are mean(standard deviation) or mean difference (95% confidence interval).
PEMF= Peripheral low-frequency pulsed electromagnetic field.
Fatigue Severity Scale= higher scores, higher fatigue

Granja-Domínguez A, Hochsprung A, Luque-Moreno C, Magni E, Escudero-Uribe S, Heredia-Camacho Bet al. Effects of pulsed electromagnetic field therapy on fatigue, walking performance, depression, and quality of life in adults with multiple sclerosis: a randomized placebo-controlled trial. Braz J Phys Ther. 2022;26(5):100449

Figure 19. Follow-up question for interpreting results

Video 15: How to write a manuscript

Welcome to the final video of this subject. In this session, you will receive valuable tips on writing a scientific manuscript. The information required for a manuscript is quite similar to that of a research project. Therefore, we are confident that this guidance will also be useful in developing your Final Degree Project (TFG).

Scientific manuscripts typically include the following sections, which help organize the research and make it accessible to readers: introduction, methods, results and discussion.

What should be included in the introduction?

The introduction section of a research manuscript should begin by highlighting the clinical problem, offering an updated description of the condition and providing context, including epidemiological data to capture the reader's attention due to its impact on health outcomes, resource utilization, or social implications. This approach effectively sets the stage for the significance of the study.

Following this, the introduction should include a brief literature review that highlights gaps in current knowledge. This review should lead to a clear rationale for the research question being addressed, potentially introducing findings from previous studies that have attempted to address the topic.

Finally, the introduction should conclude with a concise statement explaining the specific research objectives, outlining what the study aims to achieve. In some cases, it may be appropriate to include the alternative hypothesis at this point.

This structure ensures a logical flow from the broader context to the specific focus of the study, providing readers with a clear understanding of the purpose of the research. Additionally, in this section, it is common to use the present tense to address general information and the past tense / passive voice to describe evidence from previous studies.

What should be included in the methods?

In the methods section, it is essential to provide sufficient information to evaluate the precision and internal validity of the study. This includes detailed descriptions of the population, particularly regarding inclusion and exclusion criteria, as well as dropout criteria. Additionally, information about the study design is crucial for understanding the methods employed,

especially details about the randomization procedure. It is also important to include data collection methods, covering not only the outcomes measured but also the measurement properties of the tools used. In experimental studies, authors should provide comprehensive details about the treatments administered to all groups, including the type of exercise, frequency, intensity, implementation methods, and any changes over time, along with how these changes are protocolized. Finally, authors need to outline the data analysis process, specifying the statistical tests used and how the data will be presented. Overall, it is important to highlight each investigator's role at every stage of the study and to provide information about their previous experience and training, as well as details regarding the blinding procedures employed.

The past tense is typically used in this section because it describes the methods applied during the study–actions that have already been completed.

What should be included in the results?

The results section is often the most engaging part of a manuscript, as it presents new knowledge derived from the study. It typically begins with a description of the baseline characteristics of the sample, along with the number of participants and the reasons for any losses during the follow-up period. This is followed by a detailed account of the findings related to both the primary and secondary outcomes, often supported by graphs and tables to enhance clarity and understanding. Finally, authors usually report on any adverse events observed in experimental studies, as well as the adherence rates of participants throughout the research.

What should be included in the discussion?

The discussion section is often considered the most challenging part of a research manuscript, as it is the only section where authors can express their perspectives, allowing for greater flexibility than in other sections. The depth of knowledge and creativity of the authors can significantly influence the overall quality of this section and therefore, the manuscript. However, it is important that the discussion includes at least a brief summary (without data) of the main findings. This should be followed by an in-depth analysis of each outcome, referencing previous studies that support the findings while also contrasting them with studies that present differing results. Authors should also suggest potential future directions for research on the topic and discuss the main strengths and limitations of their study. Finally, it is common to conclude with a statement emphasizing the potential applications of the findings in clinical practice.

By following a clear structure and addressing key components in each section, authors can enhance the clarity and impact of their research, ultimately facilitating better communication of their findings.

Thank you for joining us in watching the videos for this course. We hope they have been helpful, and we look forward to seeing you in class!

Link to video version

https://vimeo.com/1095079659

Follow-up question

15.1. In which section do I have to include this information?

Information	Section
Inclusion criteria	
Weak points of my study	
Measurement properties of the outcomes	
Objective	
Rate of adherence	
Rate of dropouts	
Statistical test used	
Future lines of reseach	
Previous findings	
Blinding procedure	

Figure 20. Follow-up question for how to write a manuscript

Key to follow-up questions

0.1. A
1.2. C

2.1. A
2.2. B

3.1. B
3.2. C

4.1. D
4.2. A

5.1. B
5.2. B

6.1. B
6.2. C

7.1. D
7.2. B

8.1. D
8.2. B

9.1.

Could you identify the following parameters in this sample size estimation?

Sample size

Sample size was estimated using the G*Power software, version 3.1.9.7 (Heinrich-Heine University, Düsseldorf, Germany). For an alpha level of 0.05 with 80% power, calculation was based on the observed effect of PEMF treatment, compared to placebo, on fatigue symptoms in this population.[22] We considered 2 groups, 3 measurements and a mean between group difference after intervention of 8 points (SD = 12) on the Modified Fatigue Impact Scale. This generated a sample of 44 patients (including a 10% dropout rate) to complete the trial.

PEMF = Peripheral low-frequency pulsed electromagnetic field

Granja-Domínguez A, Hochsprung A, Luque-Moreno C, Magni E, Escudero-Uribe S, Heredia-Camacho Bet al. Effects of pulsed electromagnetic field therapy on fatigue, walking performance, depression, and quality of life in adults with multiple sclerosis: a randomized placebo-controlled trial. Braz J Phys Ther. 2022;26(5):100449

Parameters	Values
Type I error	0.05
Type II error	0.2
Power of study	0.8
Primary outcome	Fatigue
Tool used for primary outcome	Unknown
Variability	12
Minimal change	8
Losses	10%
Total sample required (with losses)	44 (22 each group)
Total sample required (without losses)	40 (20 each group)

Figure 21. Key to follow-up question for Precision (I)

10.1. B
10.2. B and F

11.1. A
11.2. F

12.1.

1. Blind the assessors.
2. Experience / previous training using the device.
3. Check if the measurement properties are sufficient for this specific population.
4. Check how it has to be measured → 3 times taking the greatest value, for example.
5. Use a portable dynamometer for all participants involved in the study.

13.1.

Do you identify any confounding factor?

Randomisation and masking

After completing the baseline questionnaire, participants were randomly assigned to the individualised, progressive walking and education intervention or a no treatment control group in a 1:1 allocation ratio. The randomisation sequence was created by a senior research team member (C-WCL) who was not involved in screening, randomisation, or data collection. The randomisation schedule comprised randomly permuted blocks of 4, 6, and 8, stratified by history of more than two previous lifetime episodes of low back pain, which is the only consistently reported prognostic factor for low back pain recurrence,[2] and recruitment from community advertising versus clinician referral. The randomisation sequence was embedded within Research Electronic Data Capture (REDCap), and a member of the research team (NCP) randomly assigned participants to their groups and notified them of their allocation.

Table 1. Baseline characteristics

	Intervention (n=351)	Control (n=350)
Total number of previous episodes		
Two or fewer	13 (4%)	13 (4%)
More than two	338 (96%)	337 (96%)

The randomization was stratified to ensure this potential confounding factor was equal across the groups.

Pocovi NC, Lin CC, French SD, Graham PL, van Dongen JM, Latimer Jet al. Effectiveness and cost-effectiveness of an individualised, progressive walking and education intervention for the prevention of low back pain recurrence in Australia (WalkBack): a randomised controlled trial Lancet. 2024; 13;404(10448):134-144

Figure 22. Key to follow-up question for Validity (III)

14.1.

1. Baseline data of the two groups → they seem to be similar → no comparability bias
2. Within group differences → statistically significant only for the experimental group at two time points: post-intervention and after the follow-up period of 3 months. As the values decrease, it means that the fatigue was improved. → CI without 0
3. Despite these significant changes in the experimental group, there are no differences between groups at any time point. (CI with 0)

15.1.

In which section, do I have to include this information?

Information	Section
Inclusion criteria	Methods
Weak points of my study	Discussion
Measurement properties of the outcomes	Methods / discusión
Objective	Introduction
Rate of adherence	Results
Rate of dropouts	Results
Statistical test used	Methods / Tables /figures
Future lines of reseach	Discussion
Previous findings	Introduction / Discussion
Blinding procedure	Methods

Figure 23. Key to follow-up question for how to write a manuscript

Acknowledgements

This handbook is the result of the Teaching Innovation Project titled "Flipped Health Research: Educational Modules in English," supported and funded by San Jorge University through its 8th Call for Applications for Grants for Teaching Innovation Projects for the 2024–2025 academic year.

This handbook is a tailored self-study resource for fourth-year Physiotherapy students at San Jorge University, enrolled in the Health Research course. Designed to support a flipped classroom methodology, it empowers students to engage actively and reflectively with course content before each session.

Featuring full transcripts of instructional videos, complemented by explanatory diagrams and end-of-unit questions, the handbook fosters deep understanding of key research concepts and clinical applications. It equips future physiotherapists with essential tools to interpret and apply evidence-based knowledge.

Entirely taught in English, the course promotes internationalization and prepares students for global professional environments, while addressing the challenges of learning in a non-native language through innovative, student-centered strategies.

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