



## A. Why is 'blinding' important in a trial?

The '#PEDroTacklesBarriers to evidence-based physiotherapy' campaign will help you to tackle the four biggest barriers to evidence-based physiotherapy – lack of time, language, lack of access, and lack of statistical skills.

If you are new to the campaign, we suggest that you start at the beginning by looking at earlier posts on strategies to tackle the barriers of lack of time and language. These are available on the [campaign webpage](#), [blog](#), Twitter ([@PEDro\\_database](#)) or Facebook ([@PhysiotherapyEvidenceDatabase.PEDro](#)).

A lack of statistical skills is a common barrier to interpreting evidence and implementing evidence-based physiotherapy. Last month, the #PEDroTacklesBarriers campaign focused on interpreting [comparative effects in trials](#). This month, we focus on understanding the importance of blinding in trials with three clinician-researchers.





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Exercise Physiologist and researcher, University of New South Wales, Australia

**Area of practice:** Comparative effectiveness of interventions for people with chronic pain



**Kate Scrivener**

Physiotherapist, educator and researcher, Macquarie University, Australia

**Area of practice:** Post-stroke physiotherapy intervention and research.



**Mark Elkins**

Scientific Editor of Journal of Physiotherapy

**Area of practice:** Physical and pharmacological therapies in respiratory disease and improving the understanding and application of published research by clinicians.

**Understanding the importance of blinding in trials**

There are numerous stakeholders involved in any clinical trial. These include patients and participants, therapists, researchers, outcome assessors and statisticians. Stakeholders are a source of bias in trials. This is because they can consciously or subconsciously influence procedures or results based on knowing whether a patient has been allocated to the intervention or control group. To minimise biases, a trial can 'blind' the stakeholders to which group participants are allocated. Blinding is considered successful if the stakeholder is unable to distinguish between the treatments applied to the groups.

Three important people or groups to be blinded in clinical trials include the:

1. **Patient or participant:** where the patient is unaware if they are receiving the intervention or control
2. **Therapist:** where the therapist is unaware if they are delivering the intervention or control

3. **Assessor:** where outcome assessor(s) are unaware if the participant being assessed had received the intervention or control

In most physiotherapy trials, it is very difficult to blind participants and therapists. For example, if interventions are physical or active (e.g. exercise), participants will know they are receiving the intervention and therapists will know if they are delivering it. In regard to blinding the assessor, blinding is successful if the assessor does not know which group the patient has been allocated to and outcome measures are objective (e.g. passive range of motion). However, when outcome measures are patient-reported or self-reported (e.g. pain), the assessor is considered blind if the patient was blinded.

Studies frequently report the occurrence of blinding in the title or abstract using terms such as 'single blinded' or 'double blinded'. However, there is inconsistent use of these terms. For example, one 'double blinded' trial may have blinded the therapists and outcome assessors, while another may have blinded the patients and statisticians. Readers should investigate which elements of a clinical trial have been blinded and authors should avoid this ambiguous terminology and explicitly state who was blinded.

Some clinical trials attempt to blind patients to their allocated group by providing control interventions that are similar to active interventions. To assess the perceived similarity of the control and active intervention, some studies report the 'treatment credibility', where patients are asked 'How convinced are you that you have received an active therapy?'. Similar treatment credibility between the active and control interventions usually indicates successful blinding.

Many people in a clinical trial can be blinded. Although blinding helps minimise biases, it is often difficult to blind every person. Readers need to assess how a lack of blinding could influence the conduct and reporting of a trial.

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## **B. Benefits of being a volunteer PEDro rater**

A unique feature of PEDro is that articles reporting the results of randomised controlled trials are pre-appraised. Trained raters use the PEDro scale to assess the methodological quality and completeness of statistical reporting to give each trial a score of 10. Each trial is independently evaluated by two raters and, if they disagree on any PEDro scale items, a third rater arbitrates. As at [October 2022](#), over 42,000 trials have been evaluated using the PEDro scale. The scores are used to rank the search results so that PEDro users can quickly identify the trials that are likely to be valid and provide sufficient data to guide clinical decision-making.

Volunteer PEDro raters make an invaluable contribution to appraising trials indexed in

PEDro. There has been a four-fold increase in the number of volunteers between 2013 (n=25) and 2022 (n=99). In a recent editorial published in the [Journal of Physiotherapy](#), four volunteer PEDro raters outline the benefits of volunteering along with how to become a volunteer rater.

Being a volunteer rater allows physiotherapists to contribute to the PEDro global evidence resource and multinational educational initiative from any location and at any time. The editorial outlines 28 benefits of being a PEDro rater that apply to all clinicians, researchers, students, and bilingual volunteers. Importantly, rating enhances reading and appraisal skills, allows you to keep up to date with new and clinically relevant research, and improve patient care through practice change guided by high-quality clinical research. One of the great motivations to be a volunteer PEDro rater is to contribute to the strengthening of evidence-based physiotherapy around the world.

To become a volunteer PEDro rater, you must demonstrate proficiency with the PEDro scale. PEDro offers an online self-paced training program. The program provides step-by-step training with instructional videos, real-world examples, and practice articles to obtain feedback about your rating skills. Subscribers who pass the final accuracy test receive a certificate and can become a volunteer rater. More details can be accessed at the [PEDro training website](#).

[Vitorino Fandim J, Crowe-Owen L, Romanyshyn M, Chan SWW. Reasons to become a volunteer rater for the Physiotherapy Evidence Database \(PEDro\). J Physiother 2022 Oct 13:Epub ahead of print](#)

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### **C. PEDro update (7 November 2022 2022)**

[PEDro](#) contains 56,803 records. In the 7 November 2022 update you will find:

- 43,361 Reports of randomised controlled trials (42,538 of these trials have confirmed ratings of methodological quality using the PEDro scale)
- 12,713 reports of systematic reviews, and
- 729 reports of evidence-based clinical practice guidelines.

For latest guidelines, reviews and trials in physiotherapy visit [Evidence in your inbox](#).

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### **D. DiTA update (7 November 2022 2022)**

[DiTA](#) contains 2,390 records. In the 7 November 2022 update you will find:

- 2,136 reports of primary studies, and
- 254 reports of systematic reviews.

For the latest primary studies and systematic reviews evaluating diagnostic tests in physiotherapy visit [Evidence in your inbox](#).

## E. Infographic for systematic review found that standalone gamified smartphone apps have a small-to-moderate effect on increasing physical activity levels in people of all health statuses and ages

Last month we [summarised the systematic review by Yang et al.](#) The review concluded that standalone gamified smartphone apps have small-to-moderate positive effects on physical activity levels in people of all health statuses and ages, compared to usual care/waitlist control, diet, physical activity trackers, non-gamified apps or lifestyle counselling. The certainty of evidence was rated as moderate.

Some findings are included in this infographic.

Yang Y, Hu H, Koenigstorfer J. Effects of Gamified Smartphone Applications on Physical Activity: A Systematic Review and Meta-Analysis. *Am J Prev Med.* 2022 Apr;62(4):602-613

<p><b>INCLUSION CRITERIA</b></p> <p><b>Study design:</b> Systematic review of randomised controlled trials and pre-post single-group trials</p> <p><b>Population:</b> People of all ages and health statuses</p> <p><b>Intervention:</b> Gamified smartphone apps without additional interventions or support</p> <p><b>Comparator:</b> Usual care/waitlist control, diet, physical activity trackers, non-gamified apps or lifestyle counselling</p> <p><b>Outcome:</b> Indicators of physical activity: step count and moderate-to-vigorous physical activity</p>	<p><b>FINDINGS</b></p> <p><b>Between-group comparisons</b></p> <ul style="list-style-type: none"> <li>• moderate level evidence demonstrated small-to-moderate size effect of apps in increasing physical activity (SMD 0.34, 95% CI 0.06 to 0.62).</li> </ul>  <p><b>Within-group comparisons</b></p> <ul style="list-style-type: none"> <li>• very low level evidence demonstrated small-to-moderate size effect of apps in increasing physical activity (SMD 0.38, 95% CI 0.17 to 0.59).</li> </ul>
<p><b>INCLUDED TRIALS</b></p> <p>Common gamification features:</p> <ul style="list-style-type: none"> <li>• in-game rewards</li> <li>• virtual teams</li> <li>• points</li> <li>• leader rankings</li> </ul>  <p>Social support, behaviour comparison, and imaginary rewards were the most frequently implemented behaviour change techniques.</p> <p>Duration of intervention ranged from 1-24 weeks.</p>	<p><b>TAKE AWAY</b></p> <p>Standalone gamified smartphone apps have small-to-moderate positive effects on physical activity levels in people of all health statuses and ages.</p> 
<p><b>NOTE</b></p> <p>Trial quality was evaluated using the Cochrane Risk of Bias tool and Risk of Bias in Non-randomised Studies of Interventions. Certainty of evidence was evaluated using the GRADE approach.</p>	

Yang Y, Hu H, Koenigstorfer J. Effects of Gamified Smartphone Applications on Physical Activity: A Systematic Review and Meta-Analysis. *Am J Prev Med.* 2022 Apr;62(4):602-613. doi: 10.1016/j.amepre.2021.10.005. Epub 2021 Dec 7. PMID: 34893387

[Read more on PEDro.](#)

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## **F. Cochrane systematic review found moderate certainty evidence that physical activity interventions for 6 months or more probably improve exercise capacity in people with cystic fibrosis, when compared to no training**

This Cochrane systematic review aimed to estimate the effects of physical activity on exercise capacity, lung function and health-related quality of life in people with cystic fibrosis. This review was an update of a previously published review.

This was a Cochrane systematic review of randomised controlled trials (RCTs) or quasi-randomised controlled trials. Relevant trials were identified from three trial registries. Trials were included if they included people with cystic fibrosis (of any age) who underwent any type of physical activity intervention compared to usual care (no physical activity intervention). Interventions needed to be two weeks or more in duration. The primary outcomes were exercise capacity (VO<sub>2</sub> peak), lung function (FEV<sub>1</sub>), and health-related quality of life (using generic or disease-specific instruments).

Two review authors independently assessed studies for inclusion, extracted data, and undertook the assessment of risk of bias of included studies. Risk of bias was evaluated using the Cochrane risk of bias tool. Certainty of evidence was evaluated using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework.

There were 24 parallel RCTs included in the review (875 participants). Trial size varied from 9 participants to 117 participants and included a mix of adults, children, and adolescents. 12 studies used a supervised training approach, 11 used a partially supervised approach and one study used an unsupervised approach. Physical intervention durations varied from less than a month to up to 3 years.

Compared to no physical activity intervention (usual care), there was moderate certainty evidence that physical activity interventions of longer than 6 months probably have a small positive effect on aerobic exercise capacity in people with cystic fibrosis (MD 1.60 mL/min per kg bodyweight, 95% CI 0.16 to 3.05; I<sup>2</sup>=59%; n=348). There was low certainty evidence that physical activity interventions probably have no effect on lung function and health-related quality of life. No difference between groups was found for the number of adverse

events over six months (odds ratio 6.22, 95% CI 0.72 to 53.40; 2 RCTs, 156 participants; low-certainty evidence).

Physical activity interventions of 6 months or more probably improves exercise capacity in people with cystic fibrosis. Adverse events are rare and there is no reason to discourage physical activity in people with cystic fibrosis.

Radtke T, Smith S, Nevitt SJ, Hebestreit H, Kriemler S. Physical activity and exercise training in cystic fibrosis. *Cochrane Database of Systematic Reviews* 2022, Issue 8. Art. No.: CD002768. DOI: 10.1002/14651858.CD002768.pub5.

[Read more on PEDro.](#)

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## **G. Almost one in five clinical trials evaluating physiotherapy interventions for low back pain excluded people due to lack of language proficiency**

People need to communicate fluently to adequately participate in some physiotherapy interventions, for example, interventions for health promotion or behaviour modification. Language proficiency is also a requirement for participating in most clinical trials. This prerequisite may cause a hindrance to people from culturally and linguistic diverse backgrounds who have language barriers to access clinical treatments. Lack of language proficiency prevents them from fully engaging in physiotherapy interventions and being represented in clinical trials.

A meta-epidemiological study was recently published that identified physiotherapy trials which specified language proficiency as an eligibility criterion. Randomised controlled trials evaluating at least one type of physiotherapy intervention for low back pain were retrieved from the Physiotherapy Evidence Database (PEDro), LILACS and SciELO from inception to May 2021. The study compared the characteristics of the trials (e.g., country of recruitment, category of intervention, year of publication), and estimated the proportion of people who were excluded from these trials due to lack of language proficiency.

The study included 2,555 trials, of which 2,538 were indexed in PEDro. A language-grounded eligibility criterion was specified in 463 (18.1%) trials. The proportion was higher in trials that were conducted in North America and Europe, published after 2000, investigated cognitive and behavioural interventions, and had large sample sizes. Of these 463 trials, 75 trials (16.2%) reported that a total of 2,152 people were excluded due to lack of language proficiency, equivalent to 12.5% of randomised participants.

The reason for a language-grounded eligibility criterion was justified in 41 trials; language proficiency was required to obtain informed consent, complete questionnaires, read the

information or materials, participate in interviews or group discussion, follow treatment instructions, and communicate with therapists. The language requirement removed the opportunity for linguistically diverse populations to participate and be represented in clinical trials.

Future physiotherapy trials could minimise the exclusion of people lacking in language proficiency by implementing strategies to address potential language barriers. Good examples include recruiting interpreters or multilingual staff or providing validated questionnaires in other languages. Understanding these issues and developing targeted strategies are of great significance when planning for the delivery of physiotherapy services to culturally and linguistically diverse communities.

[Chen Q, Sánchez Medina CM, Maher CG, et al. Almost one in five physiotherapy trials excluded people due to lack of language proficiency: A meta-epidemiological study. \*J Clin Epidemiol.\* 2022;152:13-22. doi:10.1016/j.jclinepi.2022.09.007](#)

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## **H. PEDro's World-Wide Journal Club on understanding comparisons in trials is now available**

Welcome to the PEDro World-Wide Journal Club. The purpose of the PEDro World-Wide Journal Club is to encourage the global physiotherapy community to read trials, reviews and guidelines that have important implications for clinical practice. We hope that facilitating discussion of this research will help physiotherapists to implement the results into their clinical practice.

Journal clubs are a great way to translate research into practice. In March 2020 PEDro published a blog that outlined some key features of running a successful journal club. Since then, PEDro has run six journal clubs which have been well received. The idea is for physiotherapists to use resources provided by PEDro as the basis for running a local journal club with their peers.

This PEDro World-Wide Journal Club is the first to focus on a research topic. It discusses issues raised in two short papers that explain why it is important to focus on the between-group difference as the estimate of the effect on an intervention in randomised controlled trials. If you are interested in being involved, please follow these five steps.

1. Invite your colleagues to be involved
2. Read the article

[Kamper SJ. Interpreting Outcomes 1 – Change and Difference: Linking Evidence to Practice. \*J Orthop Sports Phys Ther\* 2019;49\(5\):357-358](#)

3. Read the article  
[Bland JM, Altman DG. Comparisons within randomised groups can be very misleading. \*BMJ\* 2011;342:d561](#)
4. [Watch \(or listen to\) the video](#) of the panel discussing the topic
5. Meet with your colleagues to have your own discussion about interpreting comparative effects in trials

If you are interested in being involved, please visit the [PEDro web-site for more information](#).

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## **I. PEDro's World-Wide Journal Club on understanding blinding in trials is now available**

Welcome to the PEDro World-Wide Journal Club. The purpose of the PEDro World-Wide Journal Club is to encourage the global physiotherapy community to read trials, reviews and guidelines that have important implications for clinical practice. We hope that facilitating discussion of this research will help physiotherapists to implement the results into their clinical practice.

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[Kamper SJ. Blinding: Linking Evidence to Practice. \*J Orthop Sports Phys Ther\* 2018;48\(10\):825-826](#)
3. Read the article  
[Devereux PJ, et al. Physician interpretations and textbook definitions of blinding terminology in randomized controlled trials. \*JAMA\* 2001;285\(15\):2000-2003](#)
4. [Watch \(or listen to\)](#) the video of the panel discussing the topic
5. Meet with your colleagues to have your own discussion about interpreting comparative effects in trials

This discussion should focus on the implications of the papers' demonstration of the importance of blinding in reducing bias from affecting the results of randomised trials. You should consider the areas of clinical practice of the members of the group, and consider how blinding or lack of blinding might affect a trial's outcomes. In particular, consider which common interventions in your subdiscipline that it might be possible to blind. Where such blinding is not possible, consider which typical outcome measures might be particularly exposed to bias due to lack of blinding.

If you are interested in being involved, please visit the [PEDro web-site for more information](#).

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## J. Next PEDro and DiTA updates (December2022)

The next [PEDro](#) and [DiTA](#) updates are on 5 December 2022.

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