

# A. #PEDroTacklesBarriers to evidence-based physiotherapy: Intention to treat analysis

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 <a href="webpage">webpage</a>, <a href="blog">blog</a>, <a href="Twitter">Twitter</a> (@PEDro\_database) or <a href="Facebook">Facebook</a> (@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 intention to treat analysis in trials with three clinician-researchers.





**Aidan Cashin**, 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.

#### Intention to treat analysis: what is it?

Intention-to-treat is an approach to analysing results in randomised controlled trials. Intention to treat means that all participants who are randomized are included in the

statistical analysis and analysed according to the group they were originally assigned, regardless of what treatment (if any) they received. Intention-to-treat is the recommended approach to analysing randomised controlled trial data.

#### **Example**

In a hypothetical randomised trial, 100 participants with acute back pain were randomised to receive advice to stay active or bed rest. The primary outcome was back pain, assessed at baseline and at 4 weeks. Participants' demographic and clinical characteristics (e.g. age, sex, pain scores, duration of pain, etc.) were similar in both groups at baseline.

At 4 weeks, 10 participants could not be contacted (7 in the bed rest group) and therefore they had no data at follow-up. An additional 10 participants did not adhere to the intervention they were initially allocated to – 3 patients randomised to advice to stay active group rested in bed and 7 participants in the bed rest group remained active.

There is a misconception that the best way to analyse data from this hypothetical trial would involve excluding participants who did not contribute to data at follow-up and those who did not adhere to the intervention. That approach is wrong as it introduces bias in results of the trial and does not represent what happens in everyday clinical practice.

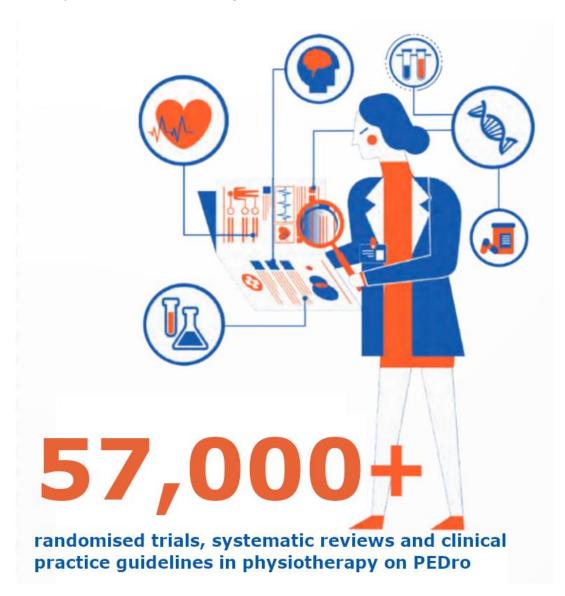
#### Why is intention to treat important in a trial?

Both groups in the hypothetical trial were similar in relation to key demographic and clinical characteristics. Excluding participants who were lost to follow-up may create imbalance in these important characteristics, which in turn will bias the results of the trial. For example, perhaps the participants who were lost to follow-up had more severe pain and did not see any benefit with the recommended treatments and decided to ignore the researchers' requests for data. Excluding them from the analysis would unbalance in a key clinical characteristic (pain intensity), as there were more participants with more severe pain who were lost to follow-up in the bed rest group. This is likely to generate biased treatment effects. Intention-to-treat analysis avoids this problem by preserving the original groups.

In clinical practice, it is common for patients not to do what clinicians recommend them to i.e. adherence is rarely perfect. Excluding trial participants who did not adhere to the assigned interventions (also known as 'per protocol analysis') creates an artificial scenario of perfect adherence that does not represent clinical practice and introduces bias to the results, which are typically overestimated. If adherence to treatments is poor, analyses by intention to treat may underestimate the magnitude of the treatment effect that will occur in patients who adhered to the treatment.

### B. PEDro now contains 57,000+ reports of trials, reviews and guidelines

We are pleased to announce that PEDro has just achieved a new milestone. There are now 57,000+ reports of trials, reviews and guidelines indexed on PEDro.



## C. The PEDro partnership

The PEDro partnership has expanded to collaborate with international centres that contribute to the development and operations of PEDro and DiTA databases.

We acknowledge and express gratitude for the valuable contribution of <u>PEDro international</u> <u>centres</u>.

# D. Support for PEDro comes from the American Physical Therapy Association

We thank <u>APTA</u> who have renewed their association partnership with PEDro for another year.

# E. Infographic for systematic review found that physical activity interventions of 6 months or more probably improve exercise capacity in people with cystic fibrosis compared to no training

Last month we summarised the <u>systematic review by Radtke et al 2022</u>. The review concluded that physical activity interventions of 6 months or more probably improves exercise capacity in people with cystic fibrosis compared to no training. The certainty of evidence was rated as moderate. Adverse events are rare and there is no reason to discourage physical activity in people with cystic fibrosis. The certainty of evidence was rated as low.

Some findings are included in this infographic.

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.

#### **INCLUSION CRITERIA**

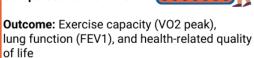
Study design: Cochrane systematic review of randomised controlled trials or quasi-randomised control trials

Population: People with cystic fibrosis of any

age

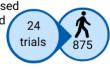
Intervention: Physical activity intervention for ≥ 2 weeks

Comparator: Usual care



#### **INCLUDED TRIALS**

Most studies used a supervised (n=12) or partially supervised (n=11) training approach, one used an unsupervised approach.



Physical activity intervention durations varied from < 1 month to up to 3 years.



#### **FINDINGS**

Moderate certainty evidence:

 Compared to control, 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; I2=59%; n=348).

Low certainty evidence:

- Physical activity interventions probably have no effect on lung function and health-related quality of life.
- No difference was found for the number of adverse events (odds ratio 6.22, 95% CI 0.72 to 53.40; 2 RCTs, 156 participants).

#### TAKE AWAY

- 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.

#### **NOTE**

This review was an update of a previously published review.

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.

# F. Systematic review found mobility strategies led to an increase in mobility in adults after surgery for hip fracture compared to usual care.

Improving mobility outcomes after hip fracture is key to recovery. Mobility is the ability to move about, including standing up and walking and mobility strategies are treatments that aim to help people move better. This Cochrane systematic review aimed to evaluate the benefits and harms of interventions for improving mobility and physical functioning after hip fracture surgery in adults.

This Cochrane systematic review included randomised controlled trials or quasirandomised controlled trials that assessed mobility strategies after hip fracture surgery.
Eligible trials were identified from 8 electronic databases. Trials were included if they
investigated the effect of strategies aimed to improve mobility. These could include care
programmes, exercise (gait, balance, functional training,
strength/resistance/endurance/flexibility training, three-dimensional exercise and general
physical activity) or muscle stimulation. Interventions could be compared to usual care
(both in-hospital), no intervention, sham exercise or social visits (post-hospital). Critical
outcomes were mobility, walking speed, functioning, health-related quality of life, mortality,
adverse effects, and return to living at pre-fracture residence.

Two reviewers identified and selected studies, extracted data, and assessed risk of bias using the Cochrane Risk of Bias 2.0 tool. Certainty of evidence was evaluated using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework.

The review included 40 randomised controlled trials (n = 4059 participants) from 17 countries. Patients were mostly elderly (average age 80 years) and female (80%). All trials had unclear or high risk of bias for one or more domains.

In the hospital setting, there is low certainty evidence that mobility strategies may lead to a moderate, clinically meaningful increase in mobility compared to usual care (standardised mean difference [SMD]: 0.53, 95% confidence interval [CI] 0.10 to 0.96; n = 360). Posthospital, there is high certainty evidence that mobility strategies compared to usual care, no intervention, sham exercise or social visit led to a small, clinically meaningful increase in mobility (SMD: 0.32, 95% CI 0.11 to 0.54; n = 761). Adverse events were rarely measured

by included trials so the safety of these programs in the hospital and out of hospital settings remains unknown.

Compared with conventional care, interventions that target improvement in mobility after hip fracture may improve mobility and walking speed, both in hospital and post-hospital settings. However, long term and economic outcomes have not yet been determined.

Fairhall NJ, Dyer SM, Mak JC, Diong J, Kwok WS, Sherrington C. Interventions for improving mobility after hip fracture surgery in adults. *Cochrane Database Syst Rev.* 2022 Sep 7;9(9):CD001704.

#### Read more on PEDro.

# G. Did you know all randomised controlled trials indexed on PEDro are rated by at least two PEDro raters?

We acknowledge and thank all <u>2022 volunteer PEDro raters</u> for their valuable contribution.

#### PEDro training program

PEDro offers an online, self-paced training program for using the PEDro scale to rate randomised controlled trials. Access training at: <a href="https://training.pedro.org.au/">https://training.pedro.org.au/</a>

## H. PEDro update (5 December 2022)

PEDro contains 57,071 records. In the 5 December 2022 update you will find:

- 43,561 Reports of randomised controlled trials (42,715 of these trials have confirmed ratings of methodological quality using the PEDro scale)
- 12,781 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**.

## I. DiTA update (5 December 2022)

DITA contains 2,395 records. In the 5 December 2022 update you will find:

- 2,140 reports of primary studies, and
- 255 reports of systematic reviews.

For the latest primary studies and systematic reviews evaluating diagnostic tests in physiotherapy visit *Evidence in your inbox*.

## J. Next PEDro and DiTA updates (February 2023)

The next PEDro and DITA updates are on 6 February 2023.



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