The Pedro scale (partitioned): Guidelines and explanations

The PEDro scale was developed to rate the methodological quality trials on PEDro, the Physiotherapy Evidence Database and includes 10 criteria. Ratings of trials in OTseeker, however, are presented separately with respect to items relevant to a trial's internal validity (8 items) and items relevant to a trial's statistical reporting (2 items). This is called the PEDro scale (partitioned). A copy of the PEDro scale (partitioned) and this information sheet may be reproduced with acknowledgement of both the OTseeker (www.otseeker.com) and PEDro website (www.pedro.org.au). This document provides explanations about each criteria.

Please note: The best interpretation of this information is to consider the potential impact that the presence or absence of each of these criteria might have on the trial, rather than the number of criteria met.

Internal Validity (8 Criteria)

Criterion Number	Guidelines and Explanations
Criterion 1 Random allocation	Random allocation ensures that (within the constraints provided by chance) treatment and control groups are comparable. In OTseeker, a trial is considered to have used random allocation if the trial report states that allocation was random. The precise method of randomisation need not be specified. Procedures such as coin tossing and dice-rolling should be considered random. Quasi-randomisation allocation procedures such as allocation by hospital record number or birth date, or alternation, do not satisfy this criterion. For more information about random allocation, read: Altman, D.G. & Bland, M. (1999). Treatment allocation in controlled trials: Why randomise? *BMJ, 318*, 1209. http://bmj.bmjjournals.com/cgi/content/full/318/7192/1209
Criterion 2 Concealed allocation	Concealed allocation means that the person who determined if a participant was eligible for inclusion in the trial was unaware, when this decision was made, to which group the participant would be allocated. If allocation is not concealed, it may be possible (consciously or unconsciously) to influence the group to which a participant is allocated. This may occur either by changing the order in which participants are enrolled, or the order in which treatments are provided. This could produce systematic biases in an otherwise random allocation. In OTseeker, this criterion is met, if the trial report states that allocation was by sealed opaque envelopes or by contacting someone "off-site" for instruction. The report does not need to explicitly state that allocation was concealed. For more information about concealed allocation, read: Altman, D. & Schulz, K. (2001). Statistics notes: Concealing treatment allocation in randomised trials. BMJ, 323, 446-447. http://bmj.bmjjournals.com/cgi/content/full/323/7310/446
Criterion 3 Baseline similarity	While random assignment prevents selection bias, it does not mean that groups are always equivalent at baseline. Imbalances between groups in key prognostic variables at baseline (variables that have the potential to influence outcomes), may subsequently bias treatment outcomes (for example, a group with greater disability at baseline may have worse outcomes post-treatment, masking true treatment effects). In OTseeker, the rater must be satisfied that group outcomes would not be expected to differ, on the basis of differences in key prognostic variables at baseline by a clinically significant amount. This criterion is satisfied even if only baseline data of study completers are presented. The trial report must therefore provide baseline data for comparison of important demographic variables, and at least one measure of the severity of the condition AND one (different) key outcome measure. Simple reporting of p-values indicating that groups were statistically similar is not sufficient. To understand more about baseline comparability read: Roberts, C. R. & Torgerson, D.J. (1999). Understanding controlled trials: Baseline imbalance in randomised controlled trials. BMJ, 319,185. http://bmj.bmjjournals.com/cgi/content/full/319/7203/185

	Key outcomes are those used as the primary measure of effectiveness (or lack of effectiveness) of the intervention. In most studies, there are multiple outcome measures.
Criteria 4, 5, 6 Blinding of subjects, therapists and assessors	*Blinding* means the person in question (participant, therapist or assessor) did not know to which group the participant had been allocated. In addition, participants and therapists are only considered to be "blind" if it could be expected that they would have been unable to distinguish between the treatments applied to different groups. In trials in which key outcomes are self-reported (for example, visual analogue scale, pain diary), the assessor is considered to be blind if the participant was blind. When participants have been blinded, the reader can be satisfied that the apparent effect (or lack of effect) of treatment was not due to placebo or Hawthorne effect. When therapists have been blinded, the effects found are not due to therapists' enthusiasm or lack of enthusiasm for the treatment or control conditions. Assessor blinding ensures effects were not due to assessor biases. For more detail see: Day, S.J. & Altman, D.G. (2000). Statistics notes: Blinding in clinical trials and other studies. *BMJ, 321,*504. http://bmj.bmjjournals.com/cgi/content/full/321/7259/504
Criterion 7 Measures of key outcomes from more than 85% of subjects	It is important that follow up measurement of outcomes is obtained from as many participants that are randomised to groups as possible. Participants who are lost to follow-up may differ systematically from those who remain in the study, potentially introducing bias. The level of bias increases correspondingly with the proportion of participants lost to follow up. In OTseeker , this criterion is only satisfied if the trial report explicitly states both the number of participants initially allocated to groups and the number from whom key outcome measures were obtained. Where outcomes are measured several times, a key outcome must have been measured for more than 85% of participants on at least one post-treatment occasion for this criterion to be met. Key outcomes are those used as the primary measure of effectiveness (or lack of effectiveness) of the intervention. In most studies, there are multiple outcome measures.
Criterion 8 Intention to treat analysis	Almost inevitably there are protocol violations in clinical trials. Protocol violations may involve participants not receiving treatment as planned or receiving treatment when they should not have. Analysis of data according to how participants were treated (instead of according to how participants *should* have been treated) may produce biases. It is important that data are analysed as if each participant had received the treatment or control condition as planned. This is usually referred to as analysis by intention to treat. This criterion is satisfied if the trial report states “intention to treat analysis” was used or explicitly states that all participants received treatment or control conditions as allocated, but does not mention intention to treat analysis specifically. Further reading on intention to treat analysis can be found: Hollis, S. & Campbell, F. (1999). What is meant by intention to treat analysis? Survey of published randomised controlled trials. *BMJ, 319,* 670-674. http://bmj.bmjjournals.com/cgi/content/full/319/7211/670?

Statistical Reporting (2 Criteria)

Criterion 9 Between-group statistical comparisons	In clinical trials, statistical tests are performed to determine if the difference *between groups* is greater than can plausibly be attributed to chance. A *between-group* comparison involves statistical comparison of the outcomes of one group with another (*not* changes *within* a group). Depending on the design of a study, there may be a comparison of two or more treatments, or comparison of one treatment with a control condition. The analysis may involve a simple comparison of the group's outcomes post-treatment, or a comparison of the group's change scores. (When a factorial analysis of variance has been used to analyse data, the latter is often reported as a group by time interaction). Statistical comparisons may be in the form of hypothesis testing, which provides a "p" value describing the probability that the groups differed only be chance. Comparison may also be in the form of an estimate of the size of the treatment effect (eg. differences in mean or proportions between groups) and its confidence interval (CI).
Criterion 10 Point measures and measures of variability	Clinical trials potentially provide relatively unbiased estimates of the size of treatment effects. The best estimate of the size of a treatment effect is sometimes referred to as a "point estimate" or "point measure" (for example, mean or proportion) that tells us about the difference between, (or ratio of), treatment and control group outcomes. The treatment effect may be described as a difference between group outcomes post-treatment; as the difference between group change scores post–treatment, or simply by presenting the outcomes for multiple groups post-treatment. Where outcomes are categorical (for example, yes/no; dependent/ independent), this criterion is met if the number of participants (or proportion) achieving the different categories is reported for each group. Measures of variability presented with these point estimates include standard deviations, standard errors, confidence intervals, interquartile ranges (or other quantile ranges), and minimum/maximum ranges. Point measures and/or measures of variability may be provided graphically (for example, standard deviations may be presented visually using error bars in a figure) as long as it is clear what is being graphed (for example, whether error bars represent standard deviations or standard errors). For more information related to criteria 9 and 10, two useful papers are: Herbert, R.D. (2000a). How to estimate treatment effects from reports in clinical trials. I: Continuous outcomes. Australian Journal of Physiotherapy, 46, 229-235. Herbert, R.D. (2000b). How to estimate treatment effects from reports in clinical trials. II: Dichotomous outcomes. Australian Journal of Physiotherapy, 46, 309-313. Key outcomes are those used as the primary measure of effectiveness (or lack of effectiveness) of the intervention. In most studies, there are multiple outcome measures.

(Reported separately) Eligibility criteria	This criterion influences external validity, but not the internal or statistical validity of the trial. This item is reported on separately on the database. It has been included here so readers know if eligibility criteria are reported in the trial. This criterion is satisfied if the trial report describes the source of participants and a list of criteria used to determine who was eligible to participate in the study.

More information about the PEDro scale can be found on the OTseeker Frequently Asked Questions page or in the following article: Maher, C.G., Sherrington, C., Herbert, R., Moseley, A., & Elkins, M. (2003). Reliability of the PEDro scale for rating quality of randomized controlled trials. *Physical Therapy,* 83 (8) 713-721.
http://www.ptjournal.org/cgi/content/abstract/83/8/713