



Brazilian Journal of Physical Therapy

<https://www.journals.elsevier.com/brazilian-journal-of-physical-therapy>



EDITORIAL

The importance of determining the clinical significance of research results in physical therapy clinical research



Susan Armijo-Olivo^{a,b}

^a University of Alberta, Faculty of Rehabilitation Medicine, Faculty of Medicine and Dentistry, Edmonton, Canada

^b Institute of Health Economics, Edmonton, Canada

Available online 14 February 2018

Clinical research in physical therapy is fundamental to generate new knowledge and validate our therapies. The evaluation of research findings is crucial to help clinical decision making and to comply with the principles of evidence based-practice. Statistical significance testing has dominated the way researchers typically report their results and evaluate their significance.^{1,2} This approach has been commonly used to determine the importance and generalizability of research results and to demonstrate the effect of an intervention in health research. However, this approach has limited use for clinicians and decision makers trying to offer the best possible treatment to patients.

Statistical significance is based on hypothesis testing (i.e. null hypothesis vs. alternative hypothesis).³ The decision to accept or reject the null hypothesis is based on predetermined levels of probability (i.e. $p < 0.05$ or 0.01) used to test the strength of the evidence against the null hypothesis.⁴ The dichotomous choice that emerges from the hypothesis testing procedure (i.e. null hypothesis rejected or accepted) does not provide any insights whether the results of the study are important for different stakeholders such as patients, clinicians, and decision makers.^{5,6}

Statistical significance does not assure that the results are clinically relevant. Indeed, the use of null hypothesis sig-

nificance testing rarely determines the practical importance or clinical relevance of findings.^{1,7} In addition, statistical significance can also provide misleading results to the clinical community since a statistical difference between groups could be found if the sample size was large and/or if the inter-subject variability was low, even though the difference between groups was small to be considered clinically important by the patients or clinicians.⁵ This has been exemplified in one of our studies, where a difference between subjects with TMD and healthy controls on head and cervical posture was statistically significant but that difference was only 3.3° , [95%CI 0.15, 6.41], which according to any clinician working on the field, would not be clinically relevant since clinicians generally use clinical observation or in some cases, photographs to evaluate posture and it is unlikely that this assessment would allow to consistently detect such a small difference.

Given the limitations of statistical significance, it is relevant for physical therapy practice that results of clinical research are analyzed having in mind the clinical relevance of the results. The question whether a patient has improved in a meaningful way is fundamental to improve clinical decision making regarding treatment management. Since clinicians are interested in whether or not the intervention had an impact on clinical outcomes and also in the magnitude of such impact, relying solely on statistical significance

E-mail: susanarmijo@gmail.com

<https://doi.org/10.1016/j.bjpt.2018.02.001>

1413-3555/© 2018 Associação Brasileira de Pesquisa e Pós-Graduação em Fisioterapia. Published by Elsevier Editora Ltda. All rights reserved.

to conclude about relevance of results seems to be limited and insufficient.

Clinical relevance (also known as clinical significance) indicates whether the results of a study are meaningful or not for several stakeholders.⁷ A clinically relevant intervention is the one whose effects are large enough to make the associated costs, inconveniences, and harms worthwhile.⁸ Clinical relevance facilitates the understanding and interpretation of results for clinicians. In physical therapy, the assessment of this approach has become a popular method to assist the transfer of knowledge into clinical practice.^{1,7,9}

Diverse methodologies have been developed in the attempt to determine the clinical significance of an intervention. The most common methods are the "distribution-based methods" and the "anchor-based methods". The calculation of the effect size (ES), the minimum detectable change (MDC)/difference (MDD),¹⁰ and the standard error of measurement (SEM) are examples of the distribution-based methods.^{1,7} Anchor-based methods involve the client's perspective using an anchor, commonly the use of the Global Rating Scale of Change (GRSC)² to define the minimal important difference (MID). Researchers and clinicians interested in these methods are encouraged to see Jaeschke et al.,² Armijo-Olivo et al.,⁷ Musselman,¹ as well as De Vet et al.,¹⁰ for a complete description.

Researchers conducting clinical trials in the field of physical therapy have the obligation to report the clinical relevance of results to the clinical community to adhere to the principles of evidence based practice. This will help disseminate evidence in a useful and understandable way for end-users such as patients, health care clinicians, and policy/decision-makers. The information of "p" values is insufficient to achieve these requirements and because it provides insufficient and limited information, clinical

researchers needed to present the clinical relevance of their results to help busy clinicians with interpretation and easy uptake of research results in clinical practice.

References

1. Musselman KE. Clinical significance testing in rehabilitation research: what, why, and how? *Phys Ther Rev.* 2007;12(4):287–296.
2. Jaeschke R, Singer J, Guyatt GH. Measurement of health status: ascertaining the minimal clinically important difference. *Control Clin Trials.* 1989;10(4):407–415.
3. Kirk RE. Practical significance: a concept whose time has come. *Educ Psychol Meas.* 1996;56(5):746–759.
4. Sterne JAC, Smith GD. Sifting the evidence – what's wrong with significance tests? *Br Med J.* 2001;322(7280):226–231.
5. Millis SR. Emerging standards in statistical practice: implications for clinical trials in rehabilitation medicine. *Am J Phys Med Rehabil.* 2003;82(10 suppl).
6. Ogles BM, Lunnen KM, Bonesteel K. Clinical significance: history, application, and current practice. *Clin Psychol Rev.* 2001;21(3):421–446.
7. Armijo-Olivo S, Warren S, Fuentes J, Magee D. Clinical relevance vs. statistical significance: using neck outcomes in patients with TMD as an example. *Man Therapy.* 2011;16(6):563–572.
8. Ferreira ML, Herbert RD. What does clinically important really mean? *Aust J Physiother.* 2008;54(4):229–230.
9. Ferreira ML, Ferreira PH, Herbert RD, Latimer J. People with low back pain typically need to feel 'much better' to consider intervention worthwhile: an observational study. *Aust J Physiother.* 2009;55(2):123–127.
10. de Vet HC, Terwee CB, Ostelo RW, Beckerman H, Knol DL, Bouter LM. Minimal changes in health status questionnaires: distinction between minimally detectable change and minimally important change. *Health Qual Life Outcomes.* 2006;4.