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Reply to Hancock and Kent. Clinical important differences

Christiansen, David H.; Andersen, Nils Bo de Vos; Poulsen, Per H.; Ostelo, Raymond W.

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LETTERS TO THE EDITOR

Letter re: Christiansen DH, de Vos Andersen N-B, Poulsen PH, Ostelo RW, The smallest worthwhile effect of primary care physiotherapy did not differ across musculoskeletal pain sites, *Journal of clinical epidemiology* (2018), doi: 10.1016/j.jclinepi.2018.05.019



We read with great interest the recent paper titled “The smallest worthwhile effect of primary care physiotherapy did not differ across musculoskeletal pain sites.” We commend the authors for investigating this important topic and believe this paper makes very useful contributions. We agree that the widely used anchor or distribution-based methods for obtaining clinically important effect estimates are flawed. The approach of investigating smallest worthwhile effects (SWEs) using the benefit–harm trade-off is, in our opinion, a more valid approach. We do, however, have concerns that small sections of the manuscript are not consistent with the study findings and could easily lead to important misinterpretations.

A key finding of the present study was that the median SWE was 20% (IQR 10%–30%). To correctly interpret this, it is critical to distinguish between a 20% *relative difference* and a 20% *absolute difference*. Randomized controlled trials of musculoskeletal conditions commonly report baseline scores of approximately 5 on a 0 to 10 pain scale. If natural recovery was 30% (as in this study), pain would reduce to 3.5/10. A further 20% *relative reduction* (using the baseline 5/10 score) would be a 1-point reduction to 2.5/10. In contrast, an *absolute reduction* of 20% of the scale would be 2 points, which is twice as large. It is clear from the methods that participants were answering in terms of *relative reductions not absolute reductions*.

Most of the paper refers to 20% additional improvement, but it is unclear whether this is relative or absolute. However, in the discussion, the authors write “Our results suggest that patients need to see a reduction in pain and disability equivalent to 20 points on a 100-point scale to perceive that the effect of Physiotherapy is worthwhile.” In our opinion, this is an incorrect conclusion with important implications. This statement uses an absolute 20-point reduction, rather than a 20% relative reduction based on the person’s pain or disability. Many physiotherapy trials demonstrate effects of approximately 1 point on a 10-point scale. Incorrectly

interpreting the present study’s findings as absolute rather than relative differences would change the conclusion of many physiotherapy trials from producing clinically important effects to nonclinically important effects.

A second point is to emphasize that this study’s results are generalizable only to trials comparing physiotherapy interventions to natural recovery *with no treatment*. When comparing two active interventions with similar costs, risks and harms (e.g., two different exercise interventions), the SWE of 20% should not be used. A smaller effect would logically seem clinically important. Similarly, when comparing physiotherapy to a more expensive intervention with greater risks (e.g., surgery), the 20% SWE would be incorrect. This may seem obvious, but there are numerous examples in the literature where the same values for clinical importance are used despite very different comparisons. The same mistake should not be made using the SWE approach, and by definition, the benefit–harm trade-off approach should overcome this problem, if interpreted correctly.

We look forward to further work from the authors and others providing estimates of SWE for a range of different clinical comparisons.

Mark J. Hancock*

Faculty of Medicine and Health Sciences
Macquarie University
Sydney, Australia

Peter Kent

School of Physiotherapy and Exercise Science
Curtin University
Perth, Australia

*Corresponding author. Macquarie University, 75 Talavera Rd, Australia. Tel.: +61298506622; fax: +61298506630.
E-mail address: mark.hancock@mq.edu.au (M.J. Hancock)

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Reply to Hancock and Kent. Clinical important differences: a step toward a more intervention-specific approach



We thank Hancock and Kent for their letter [1]. We agree with them that the smallest worthwhile effect (SWE) estimates might be prone to erroneous

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interpretations, and we thank them for the opportunity to provide a more in-depth discussion of our study results. Indeed, the key finding of our study is that the median SWE was 20% (IQR 10%–30%) [2]. The interpretation of this figure should take into account our method of estimating the SWE. For this estimation we used the scripts as presented in Appendix A. There, we very specifically ask “how much additional improvement physiotherapy must have on your pain and the limitations they impose on you in your daily life.” This clearly illustrates that the participants were asked to depart from their situation, that is, to depart from their current level of pain and limitations. So, in the terminology used by Hancock and Kent, it is a relative reduction as it departs from the baseline score.

We appreciate the example presented where the percentage scores are transformed into scale points. However, we also think this might be potentially misleading. They use the baseline score of 5 (on a 0–10 numeric rating scale [NRS]), as an example, and then indeed a 20% reduction would mean a 1-point reduction (from baseline). But stressing the magnitude in terms of points on a scale may lead to the erroneous interpretation that our study suggests that a 1-point extra reduction on the NRS scale is the between-group difference which patients consider to be worthwhile. In our scripts we did not use any specific measurement instrument. This means that the 20% additional improvement patients consider being worthwhile results in different scale points for different patients (i.e., for a baseline NRS score of 8, it is 1.6; for a baseline NRS score of 5, it is 1). Therefore, we propose that the SWE is not transformed into scale points in this way, but rather that is used as intended. That is, for every patient, the percentage of reduction should be calculated and then, in a randomized controlled trial, the percentages of the treatment arms can be compared, using the SWE as a guideline for the interpretation of this between-group difference (i.e., percentage point difference).

Finally, we fully agree that the SWE we present has to be interpreted within the context of this study. The contextual factors are key issues in the SWE method; and therefore benefits, harms, costs, and inconveniences are included in the scripts that we used to elicit the SWE. Therefore the SWE should not be evaluated without a comparator condition (e.g., no treatment) and should include references to the costs, risks, and inconveniences of the specific intervention. The expectation is that, among patients who seek treatment for musculoskeletal pain, different estimates would be elicited for

different therapies, and we believe our study is an important step toward that direction. To what extent the between-group differences as estimated by the SWE are really different for various comparisons (e.g., exercise vs. surgery; exercise vs. medication) should be explored in more detail.

David H. Christiansen*

*Department of Occupational Medicine
Regional Hospital West Jutland University
Research Clinic
Gl. Landevej 61
Herning 7400, Denmark*

*Department of Clinical Medicine, Health, Aarhus University
Palle Juul-Jensens Boulevard 82
Aarhus 8200, Denmark*

Nils-Bo de Vos Andersen

*Primary Health Care and Quality Improvement
Central Denmark Region
Skottenborg 26
Viborg 8800, Denmark*

Per H. Poulsen

*Department of Occupational Medicine
Regional Hospital West Jutland University Research Clinic
Gl. Landevej 61
Herning 7400, Denmark*

Raymond W. Ostelo

*Department of Health Sciences
VU University
de Boelelaan 1081 HV
Amsterdam, The Netherlands
Department of Epidemiology and Biostatistics and
the Amsterdam Movement Sciences Research Institute
VU University Medical Centre
de Boelelaan 1081, HV
Amsterdam, The Netherlands*

*Corresponding author. Tel.: +45-21688431;
fax: +45-78433518.

E-mail address: david.christiansen@vest.rm.dk
(D.H. Christiansen)

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- [2] Christiansen DH, de Vos Andersen NB, Poulsen PH, Ostelo RW. The smallest worthwhile effect of primary care physiotherapy did not differ across musculoskeletal pain sites. *J Clin Epidemiol* 2018;101:44–52.

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