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LETTERS

MEASURING CLINICAL DIFFERENCE

Guidance on minimally important clinical difference and trial size is needed

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The authors of a randomised controlled trial that compared surgical intervention with rehabilitation in patients with chronic low back pain reported a statistically significant difference of less than 10 points in the Oswestry disability index between groups.¹ They concluded that it “did not clearly exceed the pre-specified minimally important clinical difference,” the value used in the sample size calculation. It is important to note that the use of a value in the sample size calculation does not make it the minimally important clinical difference, as acknowledged by the authors. The 10 points difference was not justified other than to reference another trial,² which itself provided no justification. We support the view that the reporting of how sample size is determined requires greater clarity and transparency and acknowledgment of the discussion that takes place during trial design.³

Clear guidance is needed on robust methods to determine what an important difference is and what trial size is needed. The different requirements of commissioners of trials, reviewers of grant applications and reports of trial results, and consumers of research need to be recognised.

The Difference ELicitation in TriAls (DELTA) project is investigating methods for determining the target difference.⁴ The project includes a systematic review of methods, a survey of current trial practice, and development of a guidance document. We hope this project will facilitate discussion in the trial community and improve this vital, yet neglected, aspect of trial design.

Competing interests: None declared.

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- 2 Brox JI, Reikeras O, Nygaard O, Sorensen R, Indahl A, Holm I, et al. Lumbar instrumented fusion compared with cognitive intervention and exercises in patients with chronic back pain after previous surgery for disc herniation: a prospective randomized controlled study. *Pain* 2006;122:145-55.
- 3 Charles P, Giraudeau B, Dechartres A, Baron G, Ravaud P. Reporting of sample size calculation in randomised controlled trials: review. *BMJ* 2009;338:b1732.
- 4 Health Services Research Unit. University of Aberdeen Difference ELicitation in TriAls (DELTA) project. www.abdn.ac.uk/hsru/research/assessment/methodological/delta/.

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