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Bart Stouten[a], Ellen M Goudsmit[b],Neil Riley[c]

The findings of the PACE trial[1] seem impressive, but the discrepancy between the definitions of improvement in the protocol[2] and paper requires an explanation. In the paper "clinically useful differences" were defined as 0·5 SD changes in fatigue or physical functioning compared with baseline. However, the criteria for improvement published in the trial protocol were much more demanding (see table[2]). Use of a cut-off score of 75 on the short-form 36 physical functioning subscale, as originally proposed, would halve the number of "recovered" patients. Moreover, consulting the normative data for the scale reveals that the mean score of 59 after both cognitive behaviour therapy and graded exercise improved a chronic fatigue syndrome patient's physical functioning to the level of someone 40 years older than himself.[3] Is this a case of "outcome reporting bias"?[4]

Table

Definition of positive outcome/improvement in the trial protocol and the final publication

	Trial protocol	Final publication
Fatigue (bimodal Chalder scale)	50% reduction or score ≤3	7% reduction* or score ≤4†
Physical functioning (SF-36 subscale)	50% increase or score ≥75	21% increase‡ or score ≥60

* Clinically useful difference of 2 points (0·5 SD) and mean baseline Likert score of 28·2.
† Likert score of ≤18 used by the authors implies bimodal score of ≤4.
‡ Clinically useful difference of 8 points (0·5 SD) and mean baseline short-form 36 (SF-36) physical function subscale score of 38·0.

1 White PD, Goldsmith KA, Johnson AL, et al, on behalf of the PACE trial management group. Comparison of adaptive pacing therapy, cognitive behaviour therapy, graded exercise therapy, and specialist medical care for chronic fatigue syndrome (PACE): a randomised trial. Lancet 2011; 377: 611–90.

2 White PD, Sharpe MC, Chalder T, et al, on behalf of the PACE trial group. Protocol for the PACE trial: a randomised controlled trial of adaptive pacing, cognitive behaviour therapy, and graded exercise, as supplements to standardised specialist medical care versus standardised specialist medical care alone for patients with the chronic fatigue syndrome/ myalgic encephalomyelitis or encephalopathy. BMC Neurol 2007; 7: 6.

3 Bowling A, Bond M, Jenkinson C, Lamping DL. Short form 36 (SF-36) health survey questionnaire: which normative data should be used? Comparisons between the norms provided by the Omnibus Survey in Britain, the Health Survey for England and the Oxford Healthy Life Survey. J Public Health Med 1999; 21: 255–70.

4 Smyth RMD, Kirkham JJ, Jacoby A, Altman DG, Gamble C, Williamson PR. Frequency and reasons for outcome reporting bias in clinical trials: interviews with trialists. BMJ 2011; 342: c7153.

a Einsteindreef 67A, 3562 XT Utrecht, Netherlands
b School of Psychology, University of East London, London, UK
c Byways, Chichester Road, Dorking, UK