I am concerned by the change in assessment method between the published results of the PACE trial and the trial protocol. Seven secondary outcomes were not reported and there were changes in several of the measures that were reported. In particular, the protocol stated that those with short-form 36 physical function subscale scores of 65 or less would be deemed ill enough to participate, and that those with scores of 85 or more would be regarded as “recovered.” However, the authors have questioned the original definition of “fatigue” as a score of 60 or more, based on general population scores which did not exclude those reporting chronic illnesses. In the cited study of working-age adults, the mean physical function score for respondents without long-term health problems was 92.7 (SD 31.4). The mean physical function scores for those aged 75–84 years, including those with long-term health problems, was 57.9.

The lack of objective data, such as hours employed or actometer results, is problematic, since Wiborg and colleagues showed that improvements on questionnaires are not reflected in an increase in activity, as would be expected if the patients had more energy.

The only significant difference between treatments for the 6-min walking test was for graded exercise therapy. But the increase in walking distance is small when compared to the distance walked by healthy elderly people (mean age 65 years), which was shown to be 631 m (SD 58).

Unfortunately, the overall results of the PACE treatments were unimpressive, and with only 41% of patients reporting “positive” change after cognitive behavioural therapy or graded exercise therapy, further biomedical research is imperative.

I declare that I have no conflicts of interest.

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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 2001; 377: 911–20.


3 The findings of the PACE trial seem impressive, but the discrepancy between the definitions of improvement in the protocol 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