

fatigue syndrome (PACE): a randomised trial. *Lancet* **377**, 823–836.

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Letter to the Editor

'Recovery from chronic fatigue syndrome after treatments given in the PACE trial': data on the recovery groups as a whole would be useful

White *et al.* (2013) report various recovery rates from chronic fatigue syndrome (CFS) following the PACE Trial. However, additional information would have been useful.

White *et al.* use a selection of broad criteria to define recovery, none of which allow one to be confident recovery has been achieved. Firstly, Chalder Fatigue Questionnaire (CFQ) and SF-36 Physical functioning (PF) scores within the normal range are in fact possible at baseline. This means it is possible to have fatigue that is classed as 'severe, disabling and affected physical and mental function' and yet satisfy this particular recovery criterion.

Secondly, not satisfying the Oxford criteria only requires a change on just one measure, and the change may be minimal, across a threshold, e.g. going from an SF-36 PF score of 65 to 70 or a CFQ (bimodal) score of 6 to 5. A sign that this criterion is not that stringent can be seen with the fact that 41% of the specialist medical care (SMC) group, which received no active treatment, no longer met the Oxford criteria at 12 months, much higher than recovery rates seen in previous studies (Cairns & Hotopf, 2005).

Finally, a CGI score of 2, which means a participant rated as 'much better' but not 'very much better' also gives no assurance that somebody had recovered. It seems quite possible that many with CGI scores of 2 have simply improved but not recovered.

Declaration of Interest

None.

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Letter to the Editor

Comments on 'Recovery from chronic fatigue syndrome after treatments given in the PACE trial'

It is debated whether cognitive behaviour therapy (CBT) or graded exercise therapy (GET) reliably facilitate recovery in chronic fatigue syndrome (CFS). As such, any data on this issue, such as those presented by White *et al.* (2013), are always of interest.

The trial was not blinded, however, with participants, therapists and research assessors aware of the treatment group for each individual (White *et al.* 2007). Consequently, there is the possibility of significant response bias. Indeed, while the CBT group performed better than the adaptive pacing therapy (APT) and the specialist medical care only (SMC) groups on the self-rated SF-36 physical functioning (SF-36 PF) scale, there were no significant differences and minimal numerical differences on the more objective six-minute walk distance test (6MWD) (White *et al.* 2011).

This discrepancy between subjective and objective outcome measures is not a novel finding in the CFS literature. Wiborg *et al.* (2010) analysed three randomized control trials (RCTs) of three CBT interventions, finding that while fatigue was improved in the CBT groups compared to waiting-list controls, there was no difference in actometer readings between the two groups. Moreover, a mediation analysis showed changes in physical activity were not related to changes in fatigue. Similarly, in a GET RCT, Moss-Morris *et al.* (2005) found that an increase in physical fitness did not mediate the treatment effect of reduced fatigue. In an uncontrolled trial of a graded activity programme, Friedberg & Sohl (2009) reported improvements in SF-36 PF and fatigue while actometers showed overall reduction in total activity levels.

The 6MWD is one objective outcome measure White *et al.* (2013) could have incorporated into their recovery criteria (White *et al.* 2007). Reference ranges for 6MWDs, which adjust for gender and age *inter alia*, exist for healthy adults (e.g. Chetta *et al.* 2006;

Casanova *et al.* 2011). Then, after calculating the new recovery percentages with the 6MWDs, analyses could be preformed to compare the means with predicted values.

Declaration of Interest

None.

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Letter to the Editor

Comments on 'Recovery from chronic fatigue syndrome after treatments given in the PACE trial'

Important outcome data from the PACE trial (White *et al.* 2011) appears to be missing from the paper describing recovery in ME/CFS (White *et al.* 2013) and the participants do not appear to have been asked whether they had recovered as a result of receiving cognitive behaviour therapy (CBT), graded exercise therapy (GET) or Pacing.

The paper would have been improved had three specific markers of recovery been reported. First is the receipt of a state sickness or disability benefit. Claiming such a benefit indicates that the person is still ill and has not recovered. This data was included in the cost analysis study (McCrone *et al.* 2012) that reported: 'Receipt of benefits due to illness or disability increased slightly from baseline to follow-up.'

Second is employment or education status. The recovery paper argues that 'Return to work is not, however, an appropriate measure of recovery if the participant was not working before their illness and is influenced by other factors such as the job market.' However, a sustained return to meaningful paid employment, or education, or the ability to do so, is an objective marker of recovery.

Third is ability to mobilize. Recovery in a condition whose cardinal clinical features relate to mobility—exercise-induced muscle fatigue and weakness—must be matched with an ability to mobilize in a normal and timely manner. The overall results for all the treatments in the PACE trial relating to changes in the six-minute walking test from baseline to 52 weeks do not represent a return to normal levels of activity. It can be seen that the figures for all the treatment groups at 52 weeks are below the 402 m reported to be present in patients with class 3 heart failure (Lipkin *et al.* 1986). So the results for those who had recovered—who should now be achieving a much higher distance—ought to have been included. In addition, the question could be raised as to how it is possible to meet the entry criteria for the PACE trial with a Short Form-36 physical function subscale score of 65 yet leave the trial as recovered with a lower score of 60.

The term 'recovery' implies a sustained return to symptom-free health with the ability to repeatedly and reliably participate in all aspects of normal life—employment, education, social activities, etc. Without this information it is difficult to conclude that these patients have in fact recovered.