

IACFS/ME Statement on the PACE Trial, reprinted with permission

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The much publicized UK-based PACE trial (Lancet, Feb. 18th; [see full text of article](#)) reported positive outcomes for patients with CFS/ME who were treated with cognitive-behavior therapy (CBT) or graded exercise therapy (GET) in comparison to a standard medical care condition or an adaptive pacing condition. The adaptive pacing condition was intended to help patients adjust their activity levels according to their available energy (based on envelope theory). The findings were similar to previous CBT and GET studies in CFS. This trial was unique in incorporating a pacing condition and recruiting a very large sample. That said, we have concerns about how the trial was reported.

We certainly support any effective treatment for CFS/ME, medical or behavioral. Behavioral interventions are helpful for a number of major medical conditions (cardiovascular disease, diabetes).

Illness “Reversal” and Behavioral Intervention

The most fundamental concern we have is focused on the type of causal model that was linked to the CBT and GET conditions in this study. The model, based on the application of cognitive-behavioral and physical conditioning principles, predicts that properly designed behavioral or exercise interventions will “reverse” the CFS illness. Not improve symptoms/functioning or provide better management, but “reverse” the illness. This term implies that the illness can be cured (or something close to it) with behavioral techniques.

If one assumes such a direct correspondence between behavioral treatment and curative outcomes, then the illness is by implication a psychiatric condition. Once this assumption is made, then research efforts to assemble a biomedical model of CFS are more likely to be

delegitimized. And the public's perception of the illness as simply being tired is again reinforced. Perhaps this is the most unfortunate aspect of the PACE trial: The omission of any reference to the medical complexity of this illness.

Furthermore, when one compares the study goal of illness "reversal" to the reported outcomes, the support for such reversal is modest at best: 30% of GET and CBT patients achieved normative physical functioning-- but the 30% figure was in comparison to 15% who achieved such normative function in the standard medical care control condition.

Thus a more accurate statement of this finding would be: An additional 15% of patients in the CBT and GET conditions achieved normal functioning in comparison to standard medical care. The critical standard of clinical significance is that a therapy results in restoration of normal function. But their own data do not support reversal outcomes above and beyond standard medical care for the vast majority of their subjects in the CBT and GET conditions.

Question of CFS/ME Diagnosis

In addition, the 15% advantage over standard care for patients in CBT and GET can be further questioned given that at least 1/3 of all patients did not meet the strict international criteria for CFS (Table 1 in study)—the diagnostic protocol most often used in published studies. Strict criteria for CFS are linked to poor prognosis and conversely, subjects who don't meet strict criteria for CFS have better outcomes. So the PACE trial folded in a significant number of subjects who do not have CFS according to standard criteria. Again this dilutes the significance of their findings as it makes it more difficult to generalize to the population of people who do have CFS.

To put behavioral approaches in context—they can be quite helpful, but they hardly meet the standard of clinical significance that would elevate them to curative interventions. If this had been made clear in the study, it would have provoked far less controversy and debate.

Media Mis-reports

Finally, the media message from this study has often been: "Exercise is good; Rest is bad." Although the PACE trial authors did not issue such a statement, I think there is some responsibility to explain to the media that this type of recommendation is simplistic and potentially harmful for patients with CFS/ME. Activity and exercise recommendations must be based on a thorough evaluation and a sensitive individualized approach, not the broad brush

that has become the take home message of this study.

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