

M.E. Analysis – Evaluating the results of the PACE study

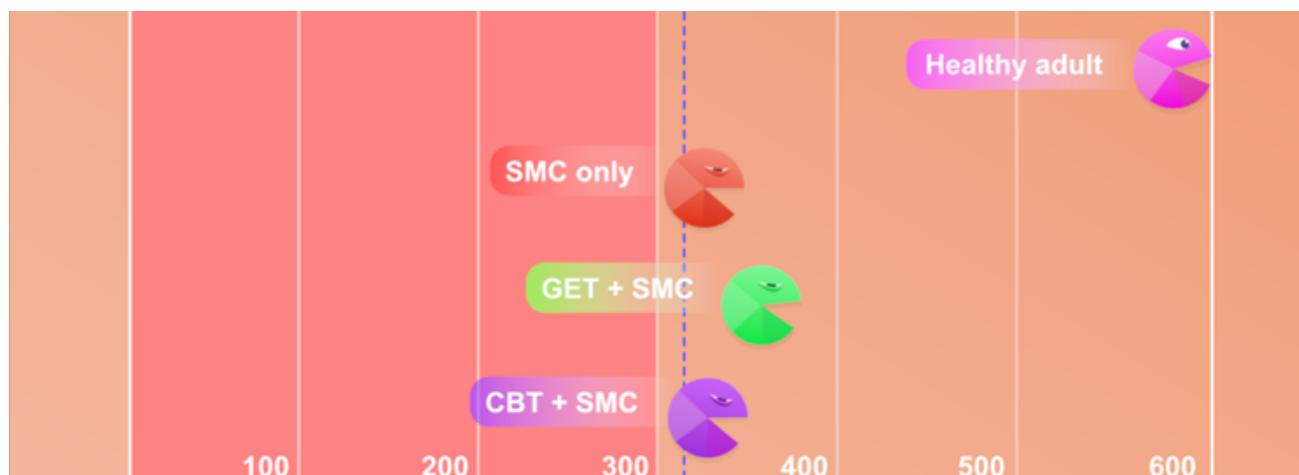
a project supported by Phoenix Rising

In March 2011, a study in the UK into possible treatments of patients with ME/CFS (Chronic Fatigue Syndrome) was published in *The Lancet*. Called the PACE trial, it was based on the hypothesis that therapies with a psychological basis would be highly effective in treating the condition and significantly improve the prospects of most patients to return to normal health and functioning.

Patients were split into four groups: one had approximately 5 sessions of Specialist Medical Care (SMC) and nothing more: the other three groups had 3 or 4 sessions of Specialist Medical Care and approximately 12 to 15 sessions of Cognitive Behaviour Therapy (CBT), Graded Exercise Therapy (GET) or Adaptive Pacing Therapy (APT). CBT was “*based on the illness model of fear avoidance*” (of activity); whilst GET was “*based on the illness model of deconditioning and exercise avoidance*”. Under NICE guidelines, CBT and GET are all that are available for ME/CFS under the NHS.

All but one of the assessments used in the trial were subjective, and were carried out by means of questionnaires. Only one objective assessment was carried out and reported upon in the study: the six-minute walking test, which measured how far the patients could walk in 6 minutes. Patients were assessed both at the start and at the end of the trial.

Altogether 462 out of the 640 patients actually completed the assessment. The average distance walked at the start of the trial in six minutes was 321 metres (shown on the diagram as a blue dotted line). At the end of the year, the group that only had approximately 5 sessions of Specialist Medical Care increased their distance by 22 metres. Those that had CBT in addition to SMC did not manage any better. Those that had GET managed an extra 45 metres more than the SMC. group – a total of 67 metres improvement from their results at the start of the year.



A Slow PACE: Those increases may sound good, but we have to remember three important facts. The first is that the GET group used walking as its main form of exercise, so these patients had been concentrating on walking for a year. The second is that a distance of less than 300 metres is medically quite grim, especially as these patients had an average age of 38. Even after a year of practising walking, the GET group average was still below 400 metres. The third is that a low estimate of the distance that an average healthy adult should manage, allowing for the increased proportion of women patients in the trial, is at least 600 metres.

That objective result clearly indicates that even GET, with its focus on walking, did not bring patients anywhere close to a normal, healthy score.

CBT added nothing to the improvement obtained simply from a few sessions of Specialist Medical Care.

As part of the original application (protocol) for a grant, the authors of the trial proposed that they would use actometers (pedometers) strapped to patients' ankles, and use the data as a baseline measure. This would have produced a better objective assessment of patients' true activity levels. After the trial had got under way, they decided that "a test that required participants to wear an actometer around their ankle for a week was too great a burden at the end of the trial." We do not understand that reasoning, especially as they decided to retain the six-minute walk assessment.

The PACE report itself concentrated on two of the subjective assessments: fatigue and physical function. With such a poor objective result on the 6-minute walk, and a failure to report on how many patients were able to "return to work", their weak overall results lack conviction. Near the end of the report the authors stated: "*our finding that studied treatments were only moderately effective also suggests research into more effective treatments is needed. The effectiveness of behavioural treatments does not imply that the condition is psychological in nature*". We would go further: in our view the extremely poor results of this trial showed rather than the ineffectiveness of these therapies demonstrates that the condition is **not** psychological in nature.

The Daily Mail, prompted by the briefing from the Science Media Centre, stated "*scientists have found encouraging people with ME to push themselves to their limits gives the best hope of recovery*". Did they even look at the results? Statements like this create widespread misunderstanding and difficulties for patients.

There can be only one conclusion drawn from the PACE study: there is no support for the proposition that a major factor holding back the recovery of patients with ME/CFS is psychological in nature. Therefore continuation of the automatic use of these therapies for all such patients should be halted. It must be remembered that CBT and GET are closely tied to assumptions about false illness beliefs and deconditioning, and as these are the only treatments on offer in the NHS, they colour people's perception of the illness. In reality, it would be entirely reasonable to suggest that these small improvements in test results could be caused simply through better illness management (including pain relief and improved sleep patterns).

The NICE guidelines state clearly that they do "*not regard CBT or other behavioural therapies as curative or directed at the underlying disease process, which remains unknown. Rather, such interventions can help some patients cope with the condition and experience improved functioning, and consequently an improved quality of life*".

Yet only very recently has the UK government started to fund biomedical research into ME/CFS. The experience of patients both with the benefit system and with their medical care shows that the pervasive belief that the illness is primarily psychological in nature continues to be a major negative influence.

The PACE trial has cost in excess of £5 million. It has amassed a large amount of data, the likes of which we have not seen before for ME/CFS, nor are we likely to see such a similar size of study in the near future. So what lessons can we learn from it? How should we proceed? What should we do with the information that this trial contains?

These are the questions we asked ourselves as we looked deeper into one of the biggest treatment trials ever carried out for ME/CFS.