

Results

You were one of the 640 patients who kindly took part in the PACE trial between March 2003 and January 2010. The trial was conducted in six hospitals in England and Scotland and compared the safety and effectiveness of four treatments: Specialist medical care (SMC) alone, and SMC plus one of the following therapies: adaptive pacing therapy (APT), cognitive behaviour therapy (CBT), and graded exercise therapy (GET). The results are now available and summarised below. We would like to take this opportunity to thank you very much for taking part.

What were the treatments?

Cognitive behavioural therapy (CBT) – A clinical psychologist or specialist nurse helped the patient to understand how their symptoms were affected by the way that they think about and cope with them, and encouraged them to try out increasing their activity.

Graded exercise therapy (GET) – A physiotherapist or exercise physiologist helped the patient to try a gradually increasing tailored exercise programme which took into account the individual patient's symptoms, fitness, and current level of activity.

Adaptive pacing therapy (APT) – An occupational therapist helped the patient to match their activity level to the amount of energy they had, and aimed to help the patient adapt to the illness rather than assuming they could gradually do more.

Specialist medical care (SMC) – A hospital doctor with experience in CFS gave general advice about managing the illness and prescribed medicines for symptoms such as insomnia and pain. When given alone, self-help management of the patients' choice was encouraged.

What did the trial show?

We found that patients with CFS were more likely to improve their fatigue and physical function if they were given CBT or GET as well as seeing a hospital specialist, than if they just saw the specialist. APT was not found to reduce fatigue or improve physical function any more than SMC alone.

How many patients improved and how many were back to normal?

Around six out of ten patients made an improvement in both fatigue and physical ability after CBT or GET, compared to four out of ten patients who improved with APT or SMC. The number of patients returning to normal levels of fatigue and physical function was about three out of ten after CBT or GET; about twice as many as those who received APT or SMC.

Did the results apply to patients with ME?

The PACE trial classified participants using different ways of diagnosing both CFS and ME to test whether the results applied to both groups. The results were similar however the illness was diagnosed, as long as the primary symptom was fatigue (something all patients required to enter the trial).

Were the treatments found to be safe?

In any trial, some participants may not respond or have adverse reactions to treatment. In the PACE trial adverse reactions to treatment were monitored closely by independent experts. We found that serious adverse reactions to treatment were rare (less than 2% for all treatments) and the number of reactions did not differ between treatments. Patients can therefore have confidence in the safety of APT, CBT, GET and SMC.

Why did you find that APT was less effective when patients report it to be helpful?

We know the treatment was delivered as planned and that patients were satisfied with it, but it didn't help as much as CBT and GET. Although we do not know for sure, it may be because adapting to CFS is less effective than being helped to return towards normal health and abilities.

Do these findings bring us any closer to a cure for CFS?

When added to the knowledge from previous studies, we now have very strong evidence that CBT and GET can help. But like you we hope that even more effective treatments will become available.

Where can full details of the PACE trial results be found?

The results have been published in the Lancet and further details are available on the PACE trial website www.pacetrial.org. This website will be kept up to date with any further news and results coming from the PACE trial.

What will happen now?

As you know we are continuing to collect long-term follow up data for the trial to give us more information about whether the benefits of receiving GET and CBT are long lasting. We are also interested to look at what characteristics determine how patients respond to treatment and how treatments work, as well as the cost effectiveness of treatments.

I have a question about the trial or results, whom should I speak to?

Please refer to the PACE trial website for further information and if this does not answer your question please email the PACE trial team at pace@qmul.ac.uk or contact your local specialist doctor who treated you.

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