

## **FAQ 1: written during the progress of the trial**

### **Why are these four particular treatments included in the trial?**

Standardised specialist medical care (SSMC) is a standardised version of the usual treatment to which CFS/ME patients are referred by their GPs in the UK. Typically, patients attend a hospital clinic where specialist doctors can offer advice and medicines to relieve some of the symptoms. Patients are often then referred on for supplementary therapies and the three most likely to be available are: cognitive behaviour therapy (CBT), administered by a cognitive behaviour therapist, often a psychologist; graded exercise therapy (GET), usually administered by a physiotherapist; and pacing therapy, usually administered by an occupational therapist.

### **What are the four treatments?**

Adaptive pacing therapy (APT) is a version of pacing, a therapy that has been found to be helpful in chronic pain disorders. It is based on the theory that people with CFS/ME have a fixed amount of available energy to which they must adapt. The approach is popular with CFS/ME patient organisations but, to date, little research has been done to judge its effectiveness.

CBT is a form of psychotherapy in which patients are encouraged to examine how their thoughts, beliefs and behaviour interact. They do this by first establishing a baseline of both physical and mental activities, and then gradually increasing it, noting problems or symptoms as they arise for discussion with their therapist. For patients with CFS/ME, CBT can offer help in finding new ways of coping with the illness.

GET is about gradually increasing physical activity, first through establishing a basic routine, centred on a preferred activity such as walking, and then gradually increasing the amount of exercise and activity, allowing patients to do more and feel better.

CBT and GET have both been found to be beneficial to patients in small trials, but subsequent surveys of members of patient organisation have suggested that CBT and especially GET may make some patients worse. The PACE trial will compare the relative effectiveness of the three supplementary therapies when added to SSMC against SSMC alone and will also seek evidence of deterioration or other adverse events for patients. It will also compare the cost-effectiveness of the different therapies.

### **Who is eligible to join the PACE trial and how can I become a participant?**

Recruitment for the PACE trial started in 2005 and will continue until 2007. Patients interested in joining the trial should speak to their GP or consultant in the first instance. Only patients who are over 18 and have been referred from specific specialised hospital clinics in Scotland and England and who meet certain diagnostic criteria can be included in the PACE trial.

PACE will recruit people using the Oxford research criteria. This will include people with CFS/ME who may also meet one or more other international definitions of CFS/ME, such as the International (Centers for Disease Control) criteria for CFS and the London criteria for ME.

The Oxford criteria will allow researchers to generalise their findings to the largest possible number of people with CFS/ME and ensure the trial can recruit enough people to give meaningful results. Assessing participants using International and London criteria once they've been enrolled into the trial may shed light on whether different groups of people respond differently to different treatments. The ultimate aim is to rigorously evaluate all the treatments on offer so that patients and doctors can make informed choices about which treatment might best improve an individual's quality of life.

### **Who designed the PACE trial?**

The trial was designed by the principal researchers, all specialists who have years of experience treating people with CFS/ME.

### **Who oversees the trial?**

The trial is led by three Principal Investigators (Professors PD White, MC Sharpe and T Chalder), aided by a trial management group, composed of all the centre and treatment leaders and statisticians. The study was and is also subject to a series of independent checks. There was an independent peer review process when the researchers first applied for funding. Approval for the trial and for any changes to it are sought from an

independent research ethics committee. There is also a Trial Steering Committee, which has an independent chair, to ensure that the scientific approach is sound and can deliver the objectives of the study.

**Who is funding the PACE trial?**

The trial is funded by the Medical Research Council (MRC), the Department of Health, the Department of Work and Pensions and the Scottish Chief Scientist Office.

**Is PACE the only major trial for CFS/ME being carried out in the UK?**

The MRC announced funding in May 2003 for two trials looking at the effectiveness of various treatments for CFS/ME. The other trial is FINE, (Fatigue Intervention by Nurses Evaluation) which will test two different treatments that are particularly suited to those who are too ill to attend a specialist clinic. The FINE research is being carried out in NW England.

The MRC has designated CFS/ME a priority research area and other scientists are being encouraged to submit research proposals.