

[Mobilising ME/CFS Charities To Smash Flawed PACE Trial Results](#)

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Lara, Health Advocate



Professor Simon Wessely, psychiatrist:
"What the patient doesn't know won't hurt."
UNUM Insurance, Chief Medical Officer's Report 2007

Summary

The following is a discussion of the outcome of the PACE trials which coincide with a shake-up of the UK state benefit systems. The latter involves a move towards a 'comply or be sanctioned' culture. Strategies for differentiating yourself from the PACE trial patients and for holding on to state benefits are discussed. Key to success is having the strong financial support from ME/CFS charities to fund individual biomedical testing for patients. The flaws and weaknesses of the biopsychosocial model and the increasingly nebulous definitions that identify CFS patients as having only 'subjective fatigue', psychological in origin, can be exposed with thorough biomedical testing. Start lobbying your charities to pay for it now or face being characterised as having a Functional Somatic Syndrome and your resources cut off indefinitely.

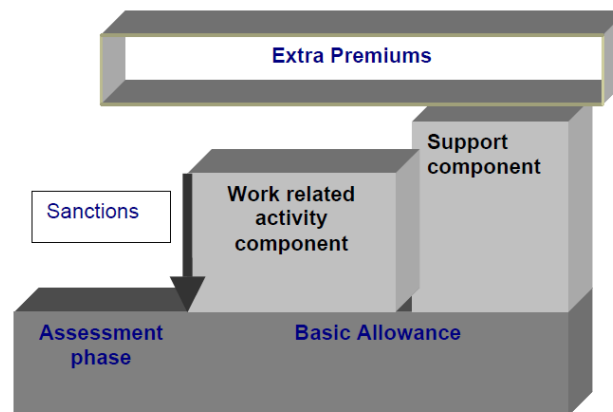
The Benefits System And ME/CFS Patients

As I write, the UK Department of Work and Pensions (DWP) assessors are reviewing the social security claims of thousands of claimants, in order to transfer them from Incapacity Benefit to Employment Support Allowance (ESA). The process started in April 2011, and will be completed by 2014, if all goes to plan.

As part of the ESA application process, the patient has to undergo a Work Capability Assessment (WCA). WCA's will be carried out by the French company ATOS who will be paid £100 million per year for its services. ATOS recently met with controversy when they told an undercover GP, Dr Margaret McCartney, that they treat people like 'claimants not patients'. ATOS have also met with controversy for denying disability benefit claims for terminally ill patients and have been accused of aggressively pursuing patients who are successful in appealing denial of their claims.

Based on the controversial WCA there are three possible outcomes. Firstly, the claim for ESA can be denied and the applicant is required to start looking for work in which he/she is placed on Job Seekers Allowance (JSA). Secondly, the claimant can be judged as being neither fit for work or Work Related Activity (WRA), and is placed in the Support Group where they are given full ESA benefit, (the basic and support components). Thirdly, the claimant can be judged as being unfit for work, but fit enough to undertake WRA - in which case they are placed into the Work Related Activity Group (WRAG).

Structure of Employment Support Allowance (ESA) Payments



Source: Medical Services Training & Development ESA Handbook, Final Version 2009
 (Available from Benefits & Work, ee <http://www.benefitsandwork.co.uk/>)

Those Claimants allocated to the WRAG, will be sent for a series of 'Work Focused Health Related Activity' interviews (WFHRA). The aim of these interviews is to assess and address barriers to the claimant's return to work. The interviews, (typically there are six), are structured to gather information on the patients' beliefs about their health and how these impact on their daily life, and to help them prepare to get back to work in incremental steps. At this stage the decision has been made that the patient can be returned to work. The WFHRA is work-focused and there is no more medical assessment of patients. The WHFRA is primarily aimed at discussing established functional work limitations and patient's subjective beliefs about them and how these can be overcome.

In order to receive the additional financial component obtained when in the WRAG, the claimant is required to take part in certain Work Related Activities (WRA) which are set out in law. In the WRAG, the claimant is required *'to demonstrate they are carrying out all reasonable steps to manage their condition and to help them move towards the workplace'*. They will be allotted a Personal Advisor (PA) who *'will support the claimant to realise their ambitions and/or overcome the perceived difficulties preventing them from entering a position of employment'*.

WRA may include Condition Management Programmes (CMP) and *'activities to stabilise health conditions (including mental health problems), for example use of CBT'*. The purpose is to facilitate the claimant to move back towards the work place. Refusal to take part in WRA may mean that the Decision Maker can conclude that there is not a reasonable cause for the condition not to be controlled. If the claimant fails to carry out WRA, the additional component provided to those in the

WRAG will be reduced by 50% for four weeks, then taken away altogether. It can only be given back if the patient takes part in the required WRA.

What seems clear from the above, is that If UK ME/CFS patients are to protect their health and ESA benefits it is key that they do not slip through into the WRAG. What this means is that the patients' GP must be prepared to provide evidenced recommendations that you be placed straight into the support group in order to avoid being placed in either the JSA group or the WRAG. If your GP has been informed of the PACE trial results and led to believe that these apply to any and all CFS-labelled patients, it seems likely that he/she will recommend that you can be 'rehabilitated' back into the work place. A similar story exists for most private insurance companies providing Permanent Health Insurance (PHI) and income replacement. Therefore, the PACE trial is likely to facilitate major savings for the benefits systems both government and private. This is at the expense of you, the patient, who may be forced to choose between carrying out an activity that is potentially harmful, or losing out on the money required to keep you fed and housed.

In summary, this potential loss of benefits is an immediate consequence of the PACE trial for ME/CFS Patients. Establishing new strategies to address this is imperative. Below is a discussion of how patients might correctly distance themselves from any association with PACE, a top priority for anyone relying on state benefits and healthcare.

The Deeply Flawed PACE Trial

Many other advocates have responded to the PACE trial, and they have rightfully pointed out its many flaws, and its complete irrelevancy to patients suffering with the neurological disease ME/CFS.

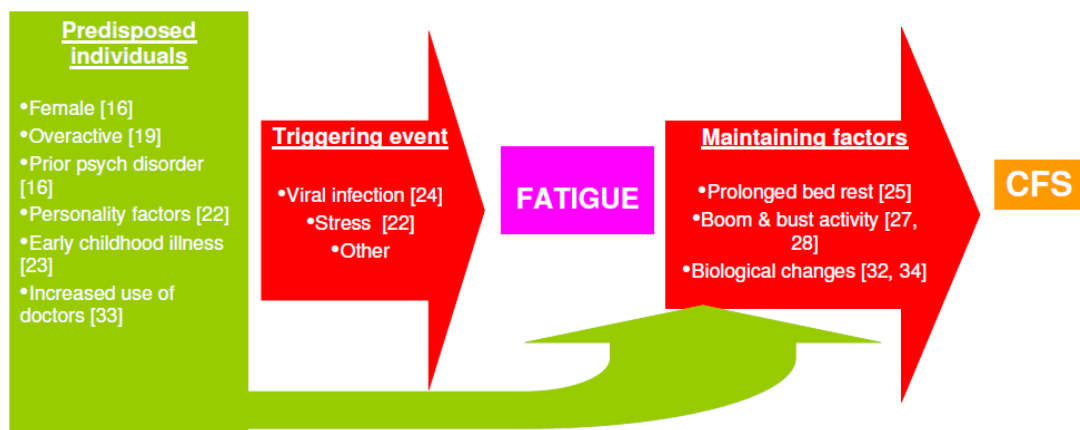
How PACE was allowed to come to fruition in this manner is a travesty. Patients have fought for over 50 years to get proper recognition for their illness, and several thousand research papers elucidating many of the biomedical factors behind their symptoms have been published. So why were they not taken seriously, and who failed to fight their corner? Could it be the ME/CFS charities who insisted that patients did not need any more than a set of standard blood tests (in line with Wessely School dogma); who seem content to broaden the definition of ME/CFS to include patients with no evidence of inflammation of the brain or spinal cord? The same charities who did not give their wholehearted support to the Canadian Criteria; which, while not perfect, at least recognised the neurological and other biomedical factors central to ME/CFS. And even now, what are the charities really doing about the mess that is the PACE trial publication? Very little seems to be the answer, and for that reason patients must now look to themselves, and each other to limit the damage.

So how do you ensure that you can persuade your doctors and benefits providers, not to mention family, friends and colleagues, that PACE has no bearing on your health or treatment options? The key is in seeing through the confusion and blur created by the endless number of definitions, revisions of definitions, arguments about definitions etc. This type of unproductive activity may best be left to academics in ivory towers who do not have to face the day-to-day consequences of the PACE trial. Instead, what may be needed is to take a fresh look at the actual Biopsychosocial model of CFS, put forward by the PACE trial researchers, and other Wessely school psychiatrists.

CFS according to the psychiatric lobby only occurs in predisposed individuals. According to Prof Simon Wessely, (quoting his own work as usual) all women or anyone with a prior psychological

disorder or 'personality factor' are inclined to develop CFS. In such unfortunate individuals, 'life altering events' (e.g. a major stressor or a flu) cause an initial 'feeling' of fatigue which is then followed by a period of rest. This rest apparently begins a process of physical deconditioning, leading to lower fitness levels. Then, having become so unfit by lying around, the patient now feels anxious at the prospect of exercise, and a vicious circle of inactivity and further deconditioning develops, finally resulting in a long-term reduction in physical abilities referred to as 'chronic fatigue'. Patients may become so inept at managing their activity in their 'fatigued' state that they 'boom and bust', making their symptoms even worse. The net effect of this deconditioning and poor coping strategies is the introduction of 'biological sequelae' that were not present at the start of the illness. This chronic fatigue is 'purely subjective' according to the psych lobby and cannot be measured in any physical way, relying entirely on self-reported statements by patients. This is a key issue and may well be the Achilles heel of the Biopsychosocial and other subjective models for CFS.

Wessely & Harvey's Proposed Model for 'Aetiology' of CFS



Source: *Chronic Fatigue Syndrome: Identifying Zebras Amongst The Horses.*
Simon Wessely and Sam B Harvey, *BMC Medicine* 2009, 7:58

The above model is taken from a paper which quoted 34 references. Of these 16 were authored by Simon Wessely, Michael Sharpe, Peter White, Trudie Chalder or Sam Harvey, and the majority of the others are from authors known to hold similar ideologies about CFS. Hundreds of other authors that would have disputed the above model were excluded.

The paper discusses the need to exclude any biomedical cause for fatigue using laboratory testing when making a diagnosis of CFS. The extent of testing is considered and for guidance, the authors point to a paper (Koch et al: *Br J Gen Pract.* 2009 April 1; 59(561): e93–e100) discussing the test results for the fatigue patients who took part in the Vague Medical Problems In REsearch (VAMPIRE) study from The Netherlands. The VAMPIRE study found that only 8% of patients with unexplained fatigue had positive results based on a total of 17 different routine blood tests (a standard set of 4 tests as well as 13 'extra tests'). Koch et al state that the 13 extra tests resulted in an increased number of 'false positives'. Results were apparently considered to be 'false positives' if they did not result in a full diagnosis of a somatic illness. But the possibility that *even further* testing may have uncovered a full diagnosis does not appear to have been considered. The construct employed seems to be that all possible causes of fatigue can be elucidated with a GP examination and 17 or fewer

blood tests (just 4 preferred). Rather than exercising caution based on such limited testing, Wessely & Harvey go further still by claiming that even when patients are suffering from a biomedical condition as severe as HIV, Rheumatoid Arthritis or cancer, that the fatigue is mainly subjective and psychological in nature, and not due either to the physical illnesses themselves or the drugs used to treat them. This fatigue in their view is potentially treatable with so-called 'evidence-based treatments' for CFS (GET/CBT).

The Wessely & Harvey paper received sharp criticism from other authors, in particular, Maes and Twisk (BMC Medicine 2010, 8:35) who put forward instead, an aetiological model based on Inflammatory, Oxidative and Nitrosative Stress (IO&NS) pathways. The IO&NS model takes into account much of the published data on biomedical factors which Harvey & Wessely ignored. Many inflammatory markers could be tested to show the presence of this pathway as outlined by Twisk & Maes, who also note that these pathways would need to be returned to normal through treatment, before any GET/CBT programme could be considered safe (or necessary) to administer.

The fact is that the PACE trial was designed with the intention of excluding patients with neurological symptoms, or any objectively measurable biomedical complaint. Patients put forward for the trial were screened, not once, but twice according to the Oxford Criteria, and anyone noted to have neurological or other biomedical complaints causing fatigue were excluded. Therefore the patients that were selected for the PACE trial were chosen to fit the Wessely School Biopsychosocial model for CFS, but not models which include physical causes for fatigue, which could be measured objectively. It rather seems as though the problem was defined in order to fit a preferred solution.

Having noted the aetiological model employed for the PACE trial, the key to avoiding assimilation with trial participants is to navigate the semantic traps that have been carefully laid along the way, and included in the PACE results publication. The latter repeatedly mentions the term 'Myalgic Encephalomyelitis' (ME) and so-called criteria which refer to that term as having been incorporated into the trial methodology. The PACE results also state that one of the therapies (Adaptive Pacing Therapy - APT) was administered according to a biomedical causation model, but using carefully screened patients with no biomedical complaints! Just the mere use of the term 'biomedical' however may lead the casual reader to conclude that the trial was designed to test the biomedical model, and therefore that the PACE trial results are applicable to all ME/CFS labelled patients. This is not the case - the trial participants had by definition only subjective (self-reported) symptoms.

The fact that the trial concludes that APT is not as effective as Graded Exercise Therapy (GET) and Cognitive Behaviour Therapy (CBT), will most likely be enough to convince many healthcare practitioners that the biomedical model is flawed, and that CBT/GET will suit all. Based on the experience of most ME/CFS labelled patients, the results of the PACE trial will just confirm what their medical practitioners have chosen (or been led) to believe all along. The art for patients is to shake this confirmation bias and inappropriate belief system just enough to make GPs, DWP staff and other relevant parties doubt that GET/CBT is safe or cost effective. Certainly not a quick or safe answer to returning patients to health.

How The ME/CFS Charities MUST Now Work For Patients

Anyone who does not have a purely subjective fatigue does not meet the Biopsychosocial model put forward by Wessely et al and nor do they meet the Oxford Criteria. Wessely school proponents

believe that all sources of physical fatigue can be excluded with as few as 4 blood tests and that any extra testing is unnecessary and more likely to result in false positives than helpful diagnostic information. They even go as far to suggest that fatigue in biomedical complaints is psychological in origin. This is a deeply flawed model because in reality, there are thousands of physical causes of fatigue; even a simple vitamin deficiency can cause devastating fatigue. Some tests (e.g. a vitamin profile) are not difficult and could be offered by the NHS, but are not. These are available on a private basis outside of the NHS. Others may only be available in specialised hospital departments or in research laboratories. Testing may include:

- functional blood tests for mitochondrial status, vitamin/mineral levels, antioxidant status
- testing for allergies and intolerances
- gut health, presence of pathogens etc.
- specialised testing for faulty IO&NS pathways
- genetic testing e.g. for mitochondrial disorders
- detailed immunological testing
- imaging studies e.g. X-Rays, MRI, SPECT and
- cardiac testing for orthostatic intolerance
- neurological examination and testing (e.g. nerve conduction/EMG).

Positive tests for the above can lend support to a physical cause for fatigue or other symptoms, thus creating a large-sized headache for healthcare practitioners attempting to shoe-horn patients into the Biopsychosocial model/Oxford Criteria. So how can patients access these tests? They are almost impossible to get from the NHS, because the 'gatekeeper' panel outlined in the NICE guidelines, which consist of a handful of relatively cheap blood tests, act as a barrier to more extensive testing. The NICE testing panel is more often than not negative, and once this is reported, then GPs are discouraged by the guidelines and by Wessely school proponents from performing any other testing or examinations.

At this stage, GPs seem content to live with the Biopsychosocial model and may not fight to get patients better treatment. This creates a serious impasse between the NHS doctor and ME/CFS patient. Rather than accept the limited medical help that these restrictions impose, patients may choose to pursue additional medical investigations and tests outside of the NHS at their own cost. This effectively leapfrogs the NICE testing panel. In some cases, it emerges that patients do not have ME/CFS at all, and have been placed under this banner due to a lack of appropriate testing and subsequently misdiagnosis. This should in itself demonstrate the inadequacies of the NICE ME/CFS testing panel. However, for some patients, their health may have deteriorated so badly since the initial ME/CFS diagnosis that they may no longer even be able to tolerate visits to specialists or to undergo further tests - so the need to get the correct testing done initially is absolutely imperative.

For the lucky patients who have both the health and resources to get their own tests, they may discover specific and treatable causes for their symptoms. These patients may present their results to their NHS doctors in the hope of obtaining appropriate medical attention. While the hell-bent healthcare practitioner, in an attempt to save face, may argue against or try to play down the relevance of positive tests, they can no longer prove that the patient fits into the PACE trial cohort (or other published studies for GET/CBT), because those patients were not given the same tests. If the DWP or a doctor then tries to coerce a patient with positive biomedical test results that could

account for their fatigue into a GET/CBT programme, the patient will most likely have a much stronger legal case against them.

Such testing however may not come cheap. Most patients are not going to be able to afford it on their own. What these patients need is serious financial, and maybe physical assistance, with obtaining the tests. So a key strategy would be to raise money so that every CFS patient who wants to be tested can be. £300 per patient would give access to mitochondrial testing such as the CFS panel offered by Acumen. This is a lot of money for one patient, but over the many years of collecting subscriptions it should not break the charity banks. So I think it is time the ME/CFS charities got together a testing fund for their members.

A mass testing programme for patients could have many positive outcomes, protecting the patients DWP and insurance benefits, providing vital information that might help to improve the patients health and could be used to put a case together showing that many thousands of patients have physical causes for their fatigue. If this information could be willingly gathered and logged into a central database, then it could be used to protest against the use of the PACE trial results as evidence for the suitability of the biopsychosocial model and the use of GET/CBT therapies for any CFS-labelled patients.

These may be considered ambitious endeavours, but what does the ME/CFS community want from its charities? More glossy brochures, the odd meeting and a few rounds of tea and biscuits? Or real decisive and powerful action? For charities to take the precious funds provided by patients and use them to shake the Wessely school's foundations to the core? The Wessely school's beliefs and research are weak and flawed and are only flourishing because of a lack of truly effective opposition. The gathering of objective evidence is an absolutely necessary step in combating the PACE trial results and Biopsychosocial model. If these results could be collated in a central database with patients' permission it could be used for a Class Action Law Suit against the DWP benefits changes and the lack of biomedical research funds from the UK government - a case for mass medical neglect of ME/CFS labelled patients.

For this to happen patients must lobby their charities, and threaten that if these requests are ignored, a new charity could be set up with the key mission to provide a testing fund for patients and the ambition to collate results and carry out a class action against the government for its terrible treatment to date of ME/CFS labelled patients. This action is long, long overdue, and now desperate in order to stop the Wessely school from implementing a 'final solution'...destruction of the neurological classification of ME/CFS in ICD-11 and GET/CBT for all patients regardless of the consequences. Act now to stop this before it is too late, and make sure your charities work hard to help; if they won't then vote with your feet towards a new charity which works tirelessly with 100% devotion to improving the ME/CFS patient community's livelihood and health.

Lara, Health Advocate
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Related Links:

* [The PACE Report - The MRC/PACE Trial Scandal](#)

Jane Bryant, The One Click Group
