

"In the Expectation of Recovery"

MISLEADING MEDICAL RESEARCH AND WELFARE REFORM

by **George Faulkner**



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About the author:

George Faulkner is now an independent researcher who focuses on the political impact of problems within medical research. This is not what he intended to become, and nor did he intend to write this report. He was asked to briefly summarise concerns raised by others about the PACE trial, and explain why these concerns were relevant to people interested in welfare reform. What was expected to be two weeks of work led to three years of research and fact-checking, along with the grim realisation that the problems in this area were so serious and widespread that that no-one could hope to explore them comprehensively.

Acknowledgements:

While I take full responsibility for the fact checking and accuracy of this report, it is founded on the work of others. As David Tuller says in the introduction to his recently published pieces on the PACE trial, "much of what I report here will not be news to the patient and advocacy communities, which have produced a voluminous online archive of critical commentary on the PACE trial". I do not know who first raised many of the points highlighted in this report, so may not have given credit to those who deserve it, but I hope that I have fairly and accurately presented the evidence in a way that does justice to the work done by others.

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Foreword

by Simon Duffy, Director of the Centre for Welfare Reform

This is the world we've created for ourselves, a world where sick and disabled people are now expected to “recognise that the sick role is temporary, in the expectation of recovery.”

How things get twisted. In the past there was a rather patronising attitude that of course we should provide disabled people with an income, because they 'can't work'. Against this disabled people have had to assert their desire and their right to work. What is more, they have gone on to show the valuable role that disabled people can play as workers and, more importantly, as citizens.

But what happens when politicians are desperate to cut benefits? What happens when private insurance companies want to increase their market share? What happens when people start to value research for positive results rather than accuracy?

As George Faulkner explains, in this important report, it seems that standards for academic research can easily drop out of sight when the political and financial conditions are right. A treatment is hailed as a great success, but pain and fatigue have been reclassified as recovery, and now medical researchers fight to keep important information from the public. Furthermore misleading medical research is disguised behind layers of complex jargon and statistical manipulation. It takes careful work to expose the array of falsehoods that lie hidden behind the press releases, research papers and briefings.

Addressing the problems that George Faulkner outlines will take more than a renewed sense of intellectual rigour and honesty by researchers. More fundamentally we need to pay much more attention to our basic human instinct to turn groups with little political power into scapegoats for social problems that they clearly did not create.

I am honoured that independent researchers like George Faulkner continue to use the Centre for Welfare Reform to publish and share such important research. I hope that this research helps to further strengthen the confidence of all those fighting injustice and resisting the ongoing efforts to undermine the welfare state.

Summary

Recent government reforms to UK disability benefits have been presented as an attempt to improve the lives and increase the opportunities of disabled people, yet the available evidence indicates that they have not been successful in this regard.

The 'biopsychosocial' model of disability has played an important role in shaping these reforms, and is often portrayed as providing an evidence based approach to the management and understanding of disability.

This report will show how important claims about the value of biopsychosocial approaches have been founded upon evidence which was already potentially misleading, but has also been exaggerated and distorted in ways that further misrepresent the reality of living with ill health and disability.

The biopsychosocial model has been used to justify important changes in the state's relationship to those with health problems, with new obligations created for those suffering from common health problems, such as the responsibility to "recognize that the sick role is temporary, in the expectation of recovery." However it is not clear that these new obligations are reasonable. There is a danger that the belief that it is acceptable to encourage 'positive' views of ill health, disability and the efficacy of treatments have affected the design and reporting of medical research, encouraging unreasonable expectations of recovery.

A large and expensive assessment of biopsychosocial interventions, the only such trial to have received funding from the Department of Work and Pensions (DWP), provides a clear example of the problems which can affect academic research and distort our understanding of important issues. We will see how problems with the design of this trial, and the presentation of its results, led to seriously misleading claims about patients' recovery rates.

In a Lancet commentary, reviewed and approved by the trial's researchers, patients were classed as having fulfilled a "strict criterion for recovery" even though the criterion used was in fact so loose that patients could have reported a worsening of all their symptoms and yet still have been classed as recovered.

Despite the problems identified with the presentation of results the trial's team continue to fight against releasing important data from

this publicly funded research, with pre-specified primary outcomes remaining unreported. There have even been attempts to portray Freedom of Information requests about this trial as a form of harassment and stigmatise patients' concerns about the way in which the efficacy of potential treatments are being misrepresented to them.

While there is a growing popular awareness of the problems with non-blinded or poorly controlled trials being used to make unjustified claims about the value of alternative medicine, there is also a widespread failure to acknowledge that more mainstream rehabilitative approaches can be built upon a similarly poor evidence base. Greater honesty about this is needed, especially as attempts to cut welfare spending lead politicians to turn to rehabilitation as a key part of their policies on disability, and as something which may become compulsory for those claiming disability benefits.

Dubious claims of biopsychosocial expertise have been used to serve the interests of influential institutions and individuals in government, medical research and the insurance industry, where concerns about money and reputation will inevitably compete with concerns about public health and patients' rights.

This report will show the need for more critical engagement with biopsychosocial medical research. There is a danger that the lives of millions of people have been damaged by judgments based upon inaccurate and misleading claims, shifting power away from those suffering with ill health and disability by presenting policies which reduce their options and income as benevolent and empowering interventions.

The Biopsychosocial Model

When ill health and disability limits people's ability to compete in the labour market, opportunities are lost and costs created for the individual, the welfare system, private insurers, potential employers and society at large. It is in everyone's interest to see those with health problems recover, and efficacious treatments for common health problems would help us to avoid difficult decisions about our priorities as a society. There will always be a desire to curtail the cost of supporting those with ill health and disabilities, yet this is balanced against a wish to avoid further reducing the quality of life of those already facing hardship. While effective medical treatments and rehabilitation would help to minimise this dilemma, medical science does not always progress at the speed we would like. That is not to say that people will be unable to find research which tells them what they want to hear.

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Recent reforms to disability benefits have been founded on, and justified by, the biopsychosocial model of disability. This model emphasises the role an individual's cognitions, behaviour and social setting can play in perpetuating disability and a reliance on benefit payments, while assuming that these factors can be altered and managed in ways which help to restore functionality. Such an approach to disability and ill health raises fundamental questions about the extent to which benefit claimants bear personal responsibility for their own rehabilitation and return to work. It also leads to the concern that a welfare system which provides a livable income to those with disabling health problems may entrench worklessness and a culture of dependency. Instead of being viewed as a way of diversifying risk and supporting those who have suffered misfortune, social and private insurance systems can be understood as perverse incentives that pay people to remain ill and keep them from the paid work which could be the most effective treatment available to them.

To many people these concerns have an intuitive appeal, fitting with their own ideological perspectives, yet they should still be treated with caution when they have the potential to so profoundly impact the lives of those relying upon disability benefits. Collecting robust evidence on the psychological and social aspects of disability is difficult and problems with the systems surrounding medical research can lead to unfounded and exaggerated claims. In this report a particularly large and expensive medical trial, the first to have received funding from the Department of Work and Pensions (DWP), will be used as an example of the problems which can affect medical research and

distort our understanding of important issues. This trial led to misleading claims about biopsychosocial rehabilitation's recovery rates and attempts to discredit those seeking the release of information which would have helped correct these misunderstandings. These problems will be placed within the context of the use of the biopsychosocial model to change the British state's relationship with those who live with ill health and disability.

Recent attempts to cut the cost of disability benefits may have been sold with the rhetoric of empowerment and emancipation yet convincing evidence that they've led to real improvements in the lives of disabled people has yet to be produced. The government has refused to conduct a cumulative impact assessment on the effect of their changes on the lives of disabled people^[1], but recently released government figures report that the proportion of disabled people who do not believe that they frequently have "choice and control" over their lives has increased from 24% in 2008 to 35% in 2014^[2-4].

Atos, the firm first contracted by the DWP to carry out their new assessments of claimants for disability benefits, has stated that their examinations follow a biopsychosocial model^[5], yet generally disabled people do not see these assessments as having helped to improve their lives^[6-13]. Treating people as if they have more power to overcome the burden of their health problems than they actually do can be disempowering, even without the threat of a further loss of income. The good news that one's health is less of a restriction than one believes needs to be accurate before it can be welcomed, so it is important that the claims made about people's ability to find employment, and the value of rehabilitative approaches, are reasonable and supported by the evidence. Attempts to create a more positive outlook, and confident attitude, can destroy trust, promote prejudices, and leave those suffering with health problems even more isolated from society.

Within this report suggestions will be made for both the development of policy and medical research in an attempt to help reduce the likelihood of similar problems occurring in the future.

The responsibility to expect recovery

During a House of Lords debate on the abolition of Disability Living Allowance and its replacement with Personal Independent Payments, Lord Freud, Minister for Welfare Reforms at the Department of Work and Pensions (DWP), stated that:

"we have gone for the biopsychosocial model. That model has now garnered very significant academic support, as those noble Lords to whom I sent that very interesting piece of research will recognise."^[14]

The circulated document had been written by Mansel Aylward and Gordon Waddell^[15]. At the time of the debate Aylward, a former DWP chief medical officer, ran the Unum Provident Centre for Psychosocial and Disability Research^[16] while sitting on Atos Healthcare's Clinical Governance Board.^[17] He had helped develop LiMA, the software used in Atos's disability assessments.^[18] Their document laid out the biopsychosocial model and explained that this model promoted a new conception of the 'sick role' which served to dramatically increase the responsibilities of those living with health problems, stating that "there needs to be a fundamental shift in the culture that surrounds work and health, sickness and disability, and incapacity benefits."^[15]

The biopsychosocial model allowed the banal observation that psycho-social factors play an important role in how people feel and behave to be used as an excuse for dramatic changes in the way the state interacts with those who have disabilities and ill health, even though all human experience will include a psychological and social component. Those with 'common health problems' are told that they must now recognise that "rehabilitation depends on your own motivation and effort" and new obligations for these patients are listed, such as:

- "Recognize that the sick role is temporary, in the expectation of recovery
- Be motivated and cooperate with rehabilitation"

So what are 'common health problems' and how good is the evidence that the rehabilitative approaches patients supposedly have a responsibility to engage in truly lead to the recovery which we are now told they should expect? The document cites a DWP report, also co-authored by Gordon Waddell, *Concepts of rehabilitation for the management of common health problems*.^[19] Here it is claimed that 'common health problems' "cause most long-term disability and incapacity" and "often consist primarily of symptoms with limited evidence of objective disease or impairment" while "the obstacles to recovery are often predominantly psychosocial in nature rather than the severity of pathology or impairment."

On the matter of recovery it is stated that the biopsychosocial model changes how disability is approached:

"it is no longer what makes some people develop long-term incapacity, but why do some people with common health problems not recover as expected? The development of long-term incapacity is a process in which biopsychosocial factors, separately and in combination, aggravate and perpetuate disability. Crucially for the present argument, these factors can also act as obstacles to recovery and return to work. The logic of rehabilitation then shifts from attempts to overcome, adapt or compensate for impairment to addressing factors that delay or prevent expected recovery. Thus, management for common health problems must specifically address and overcome those factors acting as obstacles to recovery."

While this may sound like good news, the poor quality of the evidence supporting biopsychosocial theories and approaches needed to be repeatedly recognised within the report. The two areas where it was claimed there was stronger evidence were low back pain and Chronic Fatigue Syndrome (CFS). For CFS it was stated that "there is promising evidence on the effectiveness of graded exercise combined with cognitive behavioural therapy". When Mansel Aylward was Chief Medical Adviser at the DWP he helped secure DWP funding for a trial testing the efficacy of these interventions for CFS, and went on to sit as an observer on the Trial Steering Committee.^[20,21] Evidence to support the claims being made about the value of the biopsychosocial model was needed and the £5+ million PACE trial, the largest and most expensive of its kind, was expected to provide it.^[22,23]

The PACE trial

The PACE trial was a multicentre randomised trial that collected data for a number of outcome measures from the 641 participants placed into one of its four treatment arms. Randomly allocating participants to treatment groups helps avoid the danger that differences between groups' responses stem from prior differences between the participants. Otherwise it could be that those patients with attributes that predict greater improvements in health would tend to choose a particular treatment approach, creating an association between that treatment and improved health even if the treatment itself was ineffective.

It was decided that treatment efficacy would be assessed at fifty-two weeks post-randomisation, and the design of the trial allows for reasonable confidence that significant differences between the groups' responses would be a result of having been randomised to different interventions. Despite this strength, there were other problems with the PACE trial's design, and the reporting of its results, that have led to misleading claims about the efficacy of treatments and the likelihood of patients recovering.

1. What is 'Chronic Fatigue Syndrome'?

There are a wide range of contradictory views on CFS, with disagreement even on who should be considered to have the condition. The PACE trial required all patients to fulfil the Oxford criteria for CFS, a definition which has been widely criticised and requires only that a patient has severe and disabling fatigue as the principal symptom, that other fatiguing diseases have been excluded, and that the fatigue is not life-long but has lasted at least six months.^[24,25] A report for the National Institutes of Health recently recommended that the Oxford criteria be retired, stating that "continuing to use the Oxford definition may impair progress and cause harm".^[26] Nonetheless, patients were selected for the PACE trial using the Oxford criteria, and so this is how CFS will be defined within this report (see the Appendix for more details on the Oxford criteria).

Beyond concerns about the specific criteria for diagnosing CFS, there are even broader concerns about the value of Chronic Fatigue Syndrome as a label, with another recent report, this one from the Institute of Medicine, concluding that 'Chronic Fatigue Syndrome' was a misleading and unhelpful term which can lead to stigmatisation and trivialisation of patients' health problems while placing undue emphasis upon 'fatigue' (a concern shared by many patient organisations).^[27] Despite the controversies and uncertainty that surround CFS, it seems widely believed that patients with a range of different and poorly understood health problems are being given the diagnosis and that many of these people continue to be treated unfairly. The chair of the UK CFS/ME Research Collaborative summarised the current understanding of CFS by stating that:

"We are bathing in a bath of ignorance"^[28].

2. The problem with self-reported outcomes

One important difficulty with CFS is that we do not have a valid way of accurately measuring subjective symptoms like fatigue (which the Oxford criteria requires to be a patient's primary symptom).^[24] It can also be difficult to assess the impact of interventions like Cognitive Behavioural Therapy (CBT) and Graded Exercise Therapy (GET), where trials cannot be double-blind, in the way expected of drug trials.

Two questionnaires had been chosen as the PACE trial's primary outcome measures (one for fatigue and one for physical functioning, as detailed in the Appendix). These questionnaires were to be used to assess the impact the different interventions had on patients' health, yet we do not have evidence that these questionnaires are accurate and valid measures of the effect interventions like CBT and GET have on patients' health. Randomisation minimises the danger of allocation bias, but that does not mean that other potential sources of bias can be ignored.

In the PACE trial therapists and patients knew what treatment was being provided, introducing the risk of bias distorting results, particularly for self-report questionnaires.^[20,29,30] Patients who are encouraged to believe the interventions they are receiving are effective, that they have greater control over symptoms and hence a failure to improve may reflect poorly upon them, or who just spend more time with therapists they believe are trying to help treat their symptoms, can report improvements in questionnaires even when more objective measures of health do not improve. While this may indicate some genuine improvement, it could merely reflect their wish to be positive, or polite.^[30-34]

Patients in all four of the trial's groups received 3–6 sessions of a basic intervention, Specialist Medical Care (SMC), and this was all that was provided to patients in one of the four groups. Those in the other three groups received an additional 12–15 sessions of therapy: Cognitive Behavioural Therapy (CBT), Graded Exercise Therapy (GET) or Adaptive Pacing Therapy (APT).

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The PACE team stated that:

- "CBT was done on the basis of the fear avoidance theory of chronic fatigue syndrome. This theory regards chronic fatigue syndrome as being reversible."^[20]
- "GET was done on the basis of deconditioning and exercise intolerance theories of chronic fatigue syndrome. These theories assume that the syndrome is perpetuated by reversible physiological changes of deconditioning and avoidance of activity."^[20]
- "APT was based on the envelope theory of chronic fatigue syndrome. This theory regards chronic fatigue syndrome as an organic disease process that is not reversible by changes in behaviour and which results in a reduced and finite amount (envelope) of available energy."^[20]

The patients receiving CBT and GET were told during treatment that these therapies had already been shown to be effective and were provided with models of their illness that emphasised their own ability to alter their behaviour in a way that would actively improve their symptoms, while these claims were not made to those in the other two groups.^[35]

Self-report outcomes can be affected by peoples' desire to be viewed favourably by others. This is known as social desirability bias.^[36] The therapists providing both CBT and GET were trained to encourage gradual increases in activity (mostly walking for GET)

while in contrast those providing APT were told to encourage patients to follow the 70% rule: never going beyond 70% of your perceived energy limit.^[35] Approaches to illness which emphasise patients' ability to overcome the limitations of their health through their own efforts increase the danger of social desirability bias distorting self-report measures: there's an added incentive to reporting an improvement in symptoms if you feel that you can take some credit for it. The psychosocial components of CBT and GET included elements intended to affect how patients think about their symptoms, possibly improving self-report questionnaire scores merely by altering how patients view and talk about their symptoms or disability without there being any real change in symptoms or disability. These aspects of the PACE trial all added to the likelihood that self-report questionnaires would be unreliable measures of patients' actual symptoms and disability.

3. The presentation of results

Another potential problem with medical trials is that researchers can make important decisions about the presentation of results that dramatically alter how these results are interpreted. When researchers want to be associated with successful interventions there is a danger that they have an incentive to misrepresent their own data. To help avoid problems with results being spun in this way, before all data had been collected the PACE research team published a trial protocol which laid out how results were to be analysed and released.^[37] Whilst publishing the protocol after the trial had already started was not ideal, as non-blinded trials will allow researchers a sense of treatment efficacy even before results are collected, this protocol should still have reduced the danger of results being presented in a misleading manner.

The PACE trial's objective outcome measures

Once the PACE trial's protocol had been published and it was made clear that self-report questionnaires were being used as the trial's primary outcome measures, responses raised concerns about the marginal use of more objective outcome measures. In particular, the decision to use actometers (devices used to measure movement) to assess patients' activity levels only at the start of the trial, and not after treatment as an outcome measure, was queried.^[38]

One of the PACE trial's three principal investigators had previously stated that:

"The heart of CBT is a behavioural approach to the impairment of activity that is part of the definition of CFS,"^[39]

and that an increase in activity

"...must ultimately be the aim of any treatment".^[40]

Another principal investigator stated, when promoting results from the PACE trial, that CBT:

"aims to help people be able to gradually increase activity".^[41]

The decision to not measure the effect of these interventions on patients' activity levels was therefore a surprising one.

The explanation for this decision provided by the PACE team was that while they had intended to use actometers as an outcome measure, it was then 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".^[38] After the PACE trial's protocol was published actometer results from three earlier trials of CBT for CFS were released.^[42] If real improvements in patients' disabling fatigue were occurring as a result of CBT, then one would expect treatment to allow patients to increase their activity levels, yet this data showed that CBT led only to improvements in self-report measures and did not lead to increases in patients' actual activity levels.

In response to broader concerns about the lack of objective measures of outcome, the PACE team stated that:

"We have used several objective outcome measures; the six-minute walking test, a test of physical fitness, as well as occupational and health economic outcomes."^[38]

Results for these outcomes have now been released and they show that, despite adherence to treatment being rated highly for both CBT and GET, CBT did not lead to improvement in employment, physical fitness, or 6-min walking test outcomes.^[20,43,44] GET did not lead to improvement in employment or physical fitness, and the six-minute walking test showed an improvement that was statistically significant but fell short of the criteria used elsewhere in the trial to define a clinically useful difference.^[20,43,44]

The poor results from these more objective outcome measures have not been focused upon by the trial's researchers, who have chosen not to mention them in the abstracts of any of the nine papers they published on the PACE trial since results have been released.^[20,43-51] Nor, as we will see, have they led to a more tempered promotion of the results for the trial's more subjective self-report measures. Table 1 shows the result of the subjective self-report measures.

Data from the non-blinded PACE trial showed that randomisation to CBT and GET was associated with greater improvements in self-reported fatigue and physical-functioning questionnaire scores at 52 weeks post randomisation, but we cannot know if this reflects any genuine improvement in patients' health. Results for the trial's more objective outcome measures would seem to indicate that it does not. Results for the PACE trial's primary outcome measures were not released in the manner laid out in the trial's published protocol.

3158 patients screened

641 patients met the trial entry criteria
and were randomly allocated to treatment groups

	160 assigned to SMC alone	161 assigned to SMC+CBT	160 assigned to SMC+GET	160 assigned to SMC+APT
Baseline scores				
Likert Chalder Fatigue Questionnaire (CFQ): mean (SD)	28.3 (3.6)	27.7 (3.7)	28.2 (3.8)	28.5 (4.0)
SF36-Physical Functioning scale: mean (SD)	39.2 (15.4)	39.0 (15.3)	36.7 (15.4)	37.2 (16.9)

	8 lost to follow up 14 withdrew	13 lost to follow up 17 withdrew	6 lost to follow up 10 withdrew	6 lost to follow up 11 withdrew
	157 analysed	155 analysed	159 analysed	159 analysed

Reported results at 52 weeks post randomisation ^[20,45]	SMC	SMC + CBT	SMC + GET	SMC + APT
Likert CFQ: mean (SD)	23.8 (6.6)	20.3 (8.0)	20.6 (7.5)	23.1 (7.3)
Mean CFQ difference from SMC (95% CI)		-3.4 (-5.0 to -1.8)	-3.2 (-4.8 to -1.7)	-0.7 (-2.3 to 0.9)
SF36-PF - mean (SD)	50.8 (24.7)	58.2 (24.1)	57.7 (26.5)	45.9 (24.9)
Mean SF36-PF difference from SMC (95% CI)		7.1 (2.0 to 12.1)	9.4 (4.4 to 14.4)	-3.4 (-8.4 to 1.6)
'Back to normal'	15%	30%	28%	16%
Trial recovery	7%	22%	22%	8%
Clinical recovery	7%	21%	21%	8%

TABLE 1. The Pace Trial's Subjective Outcome Measures

Redefining 'recovery'

When results from the PACE trial were first released in *The Lancet* in 2011, they led to widespread claims of a recovery rate of just under a third for CBT and GET, with the *British Medical Journal* reporting that 30% and 28% of patients respectively had been "cured" by these treatments.^[52-59] These claims were not based upon results for the recovery criteria laid out in the trial's protocol, but upon a new outcome devised by the trial's researchers after they had seen the trial's results.^[20]

Accompanying the release of results was a Lancet commentary, reviewed and approved by the trial's researchers, which claimed that "about 30%" of patients who'd received CBT and GET satisfied a "strict criterion for recovery", even though the criterion used was in fact so loose that patients could have reported a worsening of all their symptoms during the trial and yet still been classed as recovered.^[54] The PACE team had created a post-hoc outcome for patients who had an SF36-Physical Function score of 60 or over and a Chalder Fatigue Scale score of 18 or under, describing these patients as "back to normal" to the media and in a leaflet for patients.^[59,60] This meant that, even ignoring potential problems with bias on self-report questionnaires, patients could start the trial being classed as suffering from fatigue which was severe and disabling, then report a worsening of both their fatigue and physical functioning following treatment, and yet still be classed as "back to normal", "recovered" and "cured".^[20,52-54,59,60]

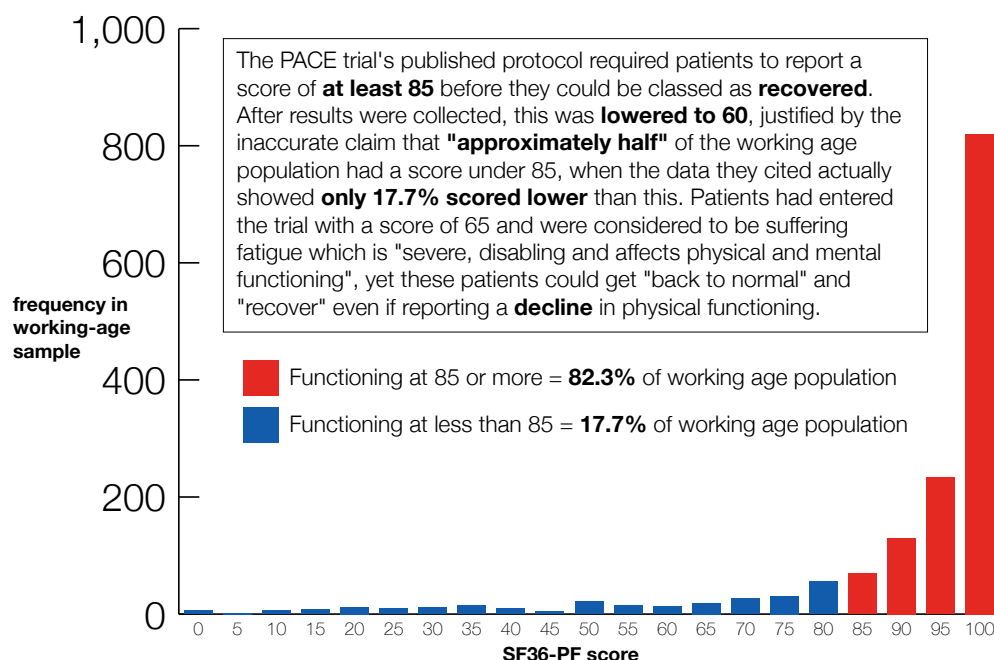
Within the Lancet paper these participants were described as "within normal ranges for both primary outcomes at 52 weeks", with these normal ranges having been newly created for this paper in response to a suggestion made during peer review.^[20] The new SF36-PF and Chalder Fatigue Questionnaire normal ranges were the foundation of the PACE team's "back to normal" outcome, and also for later released criteria for "trial recovery" and "clinical recovery". These new ranges differed from those described in the PACE trial protocol, and there were problems with the justifications for changing both.

For the Chalder Fatigue Questionnaire, patients could now be counted as recovered even if they had a Likert score of up to 18 (out of 33, with a higher score indicating greater fatigue), when that is worse than the score of 12 which patients could have reported at the start of the trial when being classed as suffering from fatigue which was "severe, disabling and affects physical and mental functioning".^[20,22,24] This change to the 'recovery' criteria was justified by reference to a paper recently published^[61] by one of the PACE trial's principal investigators (Trudie Chalder) which re-analysed data collected for a paper which she had co-authored in 1994^[62], long before the PACE trial's protocol was written and published.^[37] This 'new' data was used to claim that higher levels of fatigue within the general population justified a looser interpretation of fatigue scores both in the initial Lancet paper, and in their later publication dedicated to the PACE trial's recovery rates.^[45] Further information on the Chalder Fatigue Questionnaire and how it is scored is available in Appendix.

For the Physical Functioning Questionnaire (SF36-PF), the trial protocol had required patients to have a score of at least 85 (out of a maximum of 100, with a higher score indicating greater physical function) in order to be classed as recovered, while those scoring 75 or more, or whose score improved by 50% or more, could be counted as having a "positive outcome".^[37] A score of 65 or under was part of the trial's entry criteria, which required that patients be suffering from fatigue which was "severe, disabling and affects physical and mental functioning".^[20,22,24]

Once the trial was over the PACE team decided that those scoring as low as 60 could be counted as recovered. The claim that patients with a score of 60 had returned to a normal level of physical functioning was initially justified by stating that 60 was "the mean minus 1 SD scores of the UK working age population of 84(-24)"^[20,60], but it was later acknowledged that this mean and standard deviation was from a population which included the scores of all those aged over 65.^[63] As people tend to report lower levels of physical functioning when they get older this lowered the sample's mean physical function score as well as increasing the standard deviation. The mean minus 1 SD for those of working age was actually 71.^[64,65]

The PACE team had chosen new SF-36 PF population data to devise their new normal range, and it was reported that they now "believed this to be the most representative study for the trial sample".^[66] Fortunately, the new population data cited by the PACE team is available at the UK Data Archive, allowing us to look more closely at the validity of the justifications used for their redefinition of recovery.^[64,65] After acknowledging that they had included data from elderly members of the population to derive a score of 60, the PACE team then again used a cut-off of 60 in their later paper specifically on recovery rates from the PACE trial.^[45] They reported that the recovery criteria pre-specified in the trial's protocol was abandoned as a cut-off 85 was too demanding, supposedly meaning that "approximately half the general working age population would fall outside the normal range." The data they cite actually shows that only 17.7% of the general working age population, including all those with short and long-term health problems, scored under 85 (illustrated in Figure 1)^[65]. Furthermore, the trial's protocol indicates that the criteria for recovery (which included requiring that patients have a physical functioning score of 85 or over) was intended to be more demanding than the criteria for the mean -1SD normal range, stating that "A score of 70 is about one standard deviation below the mean... for the UK adult population".^[37]



Source: Frequency of SF-36 Physical Functioning scores within the working-age population, including all those suffering from ill health and disability. OPCS Omnibus Survey, November 1992

FIGURE 1. Distribution of SF36-Physical Functioning in Working Age Population

While one of the PACE trial's principal investigators has argued that the inclusion of some elderly patients among the PACE trial participants means that it is fair to compare results to scores from a population including all those aged over 65, only 3% of the PACE trial's participants were aged 60 and over^[67], compared 32% of the population actually used to define the recovery criteria, which would be reduced to 9% if those aged 65 and over are removed from the sample.^[65] The PACE trial's participants were actually a marginally younger group than the working age sample, with a mean age of 38 (SD 12) compared to 40(13), while the general population data actually used by the PACE team had a mean age of 48(19).^[65,67]

The data cited by the PACE trial, and illustrated in Figure 1, shows that the majority of the working age population reported the maximum SF36-PF score of 100, and that 91% of this population scored over 60, even though 15% reported having a long term health problem and an additional 13% reported needing to visit their doctor in the previous two weeks.^[65] Within the PACE trial's recovery paper it was claimed that another study assessing recovery after CBT for CFS had used a similar criteria to their own, "but the definition for normal range used was the more liberal population mean -2 SD rather than the more conservative 1 SD that we used".^[45] This was not true, and the study cited actually used a more stringent criteria of "the mean plus (or minus) 1 standard deviation (SD) of the healthy population", requiring patients to have an SF36-PF score of at least 80.^[68] Claiming that those patients scoring just 60 had been returned to a normal level of function, and could be considered recovered, served to mislead people about both the efficacy of the treatments developed by the PACE trial's principal investigators, and the extent to which managing patients' cognitions and behaviours could help them to overcome their health problems.^[52-60]

For the PACE trial's later, and less widely covered, recovery paper^[45] there were also additional components to the recovery criteria, which again deviated from those laid out in the trial's protocol.^[37] Patients were asked to self-rate their health improvement, giving a score from 1-7 with 1 representing "very much better" and 7 "very much worse". The protocol recovery criteria had required patients have a score of 1, but this was changed to include those with a score of 2, representing 'much better'. No research was cited to justify this change, just the researchers' claim that they now "considered that participants rating their overall health as 'much better' represented the process of recovery."

In order to satisfy the 'trial recovery' criteria^[45] it was stated that patients could not simultaneously fulfil the Oxford criteria for CFS, and this was not presented as a deviation from the protocol recovery criteria. However, by the time of the recovery paper it was decided that fulfilling the Oxford criteria now required that patients have a Chalder Fatigue Questionnaire score of 6 or more and a SF36-PF sub-scale score of 65 or less. In the 2011 Lancet paper those requirements for entry to the trial were described separately from the Oxford criteria, and listed as "other eligibility criteria". During the screening process for the PACE trial 235 patients were excluded because they reported a SF36-PF score of over 65 and 29 were excluded for have a Chalder Fatigue score of less than 6, separately from the 1011 excluded for not fulfilling the Oxford criteria.^[20] It appears that this was an undeclared deviation from the trial's protocol. The entry criteria for the FINE trial, described as PACE's sister trial, also required the Oxford criteria for CFS be fulfilled, but included patients who had a SF36-PF score of 70, and a bimodal Chalder Fatigue score of 4. Patients who fulfilled the most demanding recovery criteria for which results were released from the PACE trial could still have fulfilled the entry criteria for FINE, and been considered to suffer from severe and disabling fatigue.^[159]

The Politics of Distorted Research

Ongoing attempts to dismiss concerns and avoid releasing data

Troubled by the way results from the PACE trial were released, patient organisations made a joint Freedom of Information request for the results of those outcome measures laid out in the trial's protocol but not published in the trial's initial paper.^[20,37,69] The response to this stated that the results for the protocol's recovery criteria were exempt from the Freedom of Information Act as they would soon be published in an academic journal.^[66] This turned out not to be true. A later FOI request for these recovery results was refused by stating that the PACE team had not calculated these results and therefore:

"the requested data relating to the recovery rates and positive outcomes do not exist."^[70]

More recently it was argued that performing the analysis needed to generate these results would cost more than the appropriate limit laid out in the Freedom of Information Act (£450): supposedly Queen Mary University of London, who hold the data, would need to hire and train a new statistician in order to do the work.^[71] It is surprising that a university does not already employ someone able to perform this analysis.

Regardless of the justification given it is clear that the PACE team do not want to release this information, and there have even been attempts to stigmatise concerns about the PACE trial and the way in which CBT and GET have been promoted, presenting complaints as stemming from an unreasonable opposition to psychiatry, while Freedom of Information requests are portrayed as a form of harassment.^[56,72-79] These attempts may now be starting to crumble, with researchers from outside the interconnected community of British medical research beginning to intervene. Last year an article in the American Psychology Association's magazine, *Monitor*, reported that a number of experts have taken issue with the PACE trial's definition of recovery^[80] and an Australian researcher wrote a commentary which focused on problems with the way the PACE trial's team presented their results on recovery.^[81] This was followed by an Evidence Review conducted for the American government which singled out the PACE trial's new recovery criteria for criticism, describing it as "contradictory".^[82] Even the *British Medical Journal*, having played an important role in attempts to discredit concerns about the PACE trial^[52,73], recently published an editorial by two (non-British) long-term supporters of CBT and GET for CFS acknowledging problems with the "unduly liberal" way recovery was defined in the PACE trial.^[83] A summary of more recent developments is included in the Appendix.

Conflicts of Interest

The failure to release results for the pre-specified analyses laid out in the PACE trial's protocol is of particular note as concerns had already been expressed about the ideological biases of the trial's three principal investigators. All three have built their careers upon the development of biopsychosocial interventions for CFS, and the two who had been part of the Chief Medical Officer's CFS working group both resigned because the active biopsychosocial approaches of CBT and GET were not endorsed over 'pacing' in the way that they had wanted.^[84-86] The trial's protocol reported that "all staff involved in the PACE trial recorded their expectations as to which intervention would be most efficacious"^[37], and while this data has yet to be released it seems reasonable to assume that the trial's principal investigators favoured CBT and GET.

All three principal investigators also reported conflicts of interest involving the insurance industry.^[20] There has long been concern about private insurance companies influencing changes to the UK welfare state, a system of social insurance that they must compete against.^[8,87-90] These concerns seem likely to continue following reports of David Cameron's interest in encouraging individuals to fund their own unemployment or sickness benefits privately through financial products.^[91,92] When Michael O'Donnell was the Chief Medical Officer at Unum insurance (and before he moved on to Atos, and then Maximus^[90]), he wrote an internal document promoting the biopsychosocial model and claiming that Unum's thinking, along with that of their close associates, was driving government policy.^[93,94] More recently Unum funded a report from the think-tank Demos which encouraged the UK government to use private financial products to supplement social welfare.^[95]

Back in 1995 a Unum report on CFS stated that they could "lose millions if we do not move quickly to address this increasing problem".^[96] It was argued that CFS claims should be managed "more aggressively and in a proactive rather than a reactive fashion" while attempting to present CFS as "neurosis with a new banner". Emphasising the importance of psychosocial factors and classing CFS as a mental health problem could bring immediate financial benefits to insurance companies when policies limit payouts for mental health problems. One of the PACE trial's principal investigators gave a presentation on the results of the PACE trial to Swiss Re insurance. Swiss Re's report of his talk detailed the potential use of mental health exclusions to cut payments^[97], while a 2013 Swiss Re presentation on their approaches to mental health problems describes their use of specific exclusions for CFS and ME.^[98]

During the Swiss Re presentation on PACE no mention seems to have been made of the fact that PACE found neither CBT nor GET were associated with improved employment outcomes, and instead Swiss Re's claims managers continued to be encouraged to believe that promoting these active rehabilitative approaches would assist return to work.^[97] There has been concern about insurance companies pushing some patients with CFS to take part in CBT and GET against their wishes. A response to the paper which published the PACE trial's data on employment outcomes was titled *Coercive practices by insurance companies and others should stop following the publication of these results*^[99], but has yet to receive a response from the PACE team.

In 2006 a Parliamentary All Party Group inquiry into CFS/ME claimed that:

"There have been numerous cases where advisors to the DWP have also had consultancy roles in medical insurance companies. Particularly the company UNUM Provident. Given the vested interest private medical insurance companies have in ensuring CFS/ME remain classified as a psychosocial illness there is blatant conflict of interest here. The Group find this to be an area for serious concern and recommends a full investigation of this possibility by the appropriate standards body."^[100]

Perverse incentives

"It is difficult to get a man to understand something, when his salary depends upon his not understanding it!"^[101]

It is more difficult to assess the affect of biopsychosocial interventions on subjective symptoms than interventions for which double-blind trials can be conducted. The patient and therapist cannot help but be aware of the claims made during therapy and the approach being taken. An inability to overcome these problems seems to have led to a lowering of standards for biopsychosocial research. Had homeopaths or a pharmaceutical company conducted a trial and presented results in the manner of the PACE trial the British research community would have been unlikely to overlook its problems. A willingness to systematically lower standards for one area of research means that exaggerated claims about the value of work here are more likely to be accepted, distorting society's view of important issues.^[34,102]

One influential paper examining the widespread problems found within medical research reminded readers that entire fields of scientific endeavour are likely to be nothing more than wasted effort, measuring bias, without yielding true scientific information. It goes on to point out that:

"Of course, investigators working in any field are likely to resist accepting that the whole field in which they have spent their careers is a 'null field'."^[103]

It is not just those researchers directly involved in the biopsychosocial project who have incentives to avoid recognising the problems with research in this area, but also the network of journals, research funders and universities whose own reputation and prestige might be damaged by acknowledging error, exaggeration and incompetence. When the biopsychosocial model serves the interests of so many of those with authority and influence it increases the danger that legitimate criticism will be resisted and denounced rather than recognised and acted upon.

The first time a trial indicated that CBT was no more effective than placebo at allowing CFS patients to increase their activity levels^[104] those who had developed CBT for CFS argued that this result meant that the CBT could not have been conducted properly, as patients who were not able to increase their activity levels as a part of the therapy would have needed to drop out, leaving only those with raised activity levels to complete the programme:

"At the heart of CBT is a behavioral approach to the impairment of activity that is part of the definition of CFS" and

"if a patient completes the program, he or she must have increased their activity, even if everything else remains unchanged. We therefore suggest that patients... may have attended the sessions, but did not comply with the program by gaining targets and carrying out homework. If the patients were compliant with the program, then by definition the number of sedentary hours must have decreased."^[39]

As evidence from other trials continued to indicate that CBT failed to increase patients' activity levels, researchers in this area seemed to decide amongst themselves that actually CBT should not be expected to lead to increases in activity, and that performing like a placebo in changing only subjective self-report measures in non-blinded trials would be all that is needed to claim success.^[20,42,82,105] In response to concern that changes in self-report outcomes in non-blinded trials of CBT may reflect only biases and placebo response rather than real changes in health, particularly given the failure to improve objective outcome measures, the PACE team merely asserted that self-rated outcomes

"are the most appropriate measures to judge improvement in an illness that is currently defined by symptoms".^[106,107]

In response to a letter of my own on this topic the PACE team stated that they had already addressed these concerns in detail.^[108,109] I received no reply when I wrote to the corresponding author to ask where these points had been addressed in detail. If people are able to choose how to assess the value of their own work, they are unlikely to decide upon the method which indicates that their work is worth less.

Research Distorted by Politics

Cruel to be kind

"Behavioural approaches try to extinguish observed illness behaviour by withdrawal of negative reinforcements such as medication, sympathetic attention, rest, and release from duties, and to encourage healthy behaviour by positive reinforcement: 'operant-conditioning' using strong feedback on progress."

Waddell and Burton^[19]

Emphasising the role that reversible psychosocial factors play in benefit claimants' disability allows politicians to present plans to 'slash' welfare spending as a 'moral mission' to help people overcome a culture of dependency.^[110-122] Claiming that changes to disability benefits are needed to account for 'today's understanding of disability', supported by the work of medical researchers, helps politicians sidestep important moral and political debates, even if the research is poor and the results misrepresented.^[116-119]

Curing the sick would be a good way of cutting the social cost of disability, but if these cures involve nothing more than encouraging people to complete questionnaires more positively, and then changing how those questionnaires are interpreted, an emphasis on 'rehabilitation' is unlikely to be as useful as might be assumed.

Were a politician to argue that those whose health prevents them from working should be refused disability benefits if they do not try to adopt the cognitions, attitudes and behaviour desired by the state many voters would instinctively recoil. They may be less likely to do so in response to the argument that, instead of just 'writing-off' disabled people to a life on benefits, it would be better to make benefits conditional on co-operation with evidence-based rehabilitative approaches that will help people re-engage with, and feel valued by, society. The power to re-label and re-classify, changing official uses of language, helps academics and politicians further their own interests. The general public will find it easier to understand an announcement that from now on many of those who receive Incapacity Benefit will have payments reduced by nearly a third, than the news that the incomes of those joining the Work-Related Activity Group (WRAG) of Employment and Support Allowance (ESA) will now be aligned with that of those on Job Seekers Allowance. Such tongue-twister labels makes communicating clearly and concisely on these topics difficult.

The most recent disability cuts reduce ESA WRAG payments for new claimants from £102.15 a week to £73.10. A leaked Whitehall paper attempted to justify these cuts by arguing that ESA was a "passive" benefit which does not "incentivise" people to find a job.^[120,121]

Calling for Labour to support the legislation making these cuts, George Osborne argued that:

"We will protect the most vulnerable – disabled people, pensioners, who cannot change their circumstances, and those most in need."^[122]

Those being encouraged to adopt positive beliefs about recovery and their ability to change their circumstances may now be seeing these beliefs used as a justification for cutting their income. This well-meaning attempt to proactively provide the empowering poverty needed to help people overcome their adoption of the sick role reflects a view of those with health problems that may appeal to the British Establishment, but is poorly supported by the evidence.

The rise of the Biopsychosocial Model

"I think the biggest break I got was that Waddell and Burton had put out a document three months earlier that said that work is good for you. There I was looking at a system built up over a number of years that effectively protected people from work if they'd got a problem – single mothers, disabled people – and I thought to myself, this is bizarre. Here we have developed a system on entirely the wrong premise which basically makes people ill."

Lord Freud explaining what guided his approach to welfare reform.^[123]

The biopsychosocial model had been gaining influence within the British government for some time. In 1993 Mansel Aylward invited psychiatrist Simon Wessely to give a talk on his biopsychosocial approach to CFS before the then Minister for Social Security.

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It was recorded that Wessely claimed:

"As regards benefits:- it is important to avoid anything that suggests that disability is permanent, progressive or unchanging. Benefits can often make patients worse."^[124]

Even without good supporting evidence for his claims, this is the sort of expertise likely to appeal to a Minister for Social Security looking to cut costs, and with the rise of New Labour there came a strong cross-party belief that action needed to be taken to reduce the cost of disability benefits.^[89,125,126]

It was New Labour that truly embraced the biopsychosocial approach and its implications for how those with health problems and disabilities should be viewed and treated^[19,126,127]: prioritising the use of positive language over dealing honestly with difficult realities seemed to unite both movements.

The Blair government's first attempt at cutting disability benefits was greeted with revolt and protests, despite an early attempt to "shift the focus from one of cost-cutting to one of enabling".^[127-130] Since then attempts to shift the focus have been more successful. Both major parties and much of the media have been emphasising the role of attitudinal problems in preventing those with disabilities from finding work, and concerns that disability benefits were trapping people in a culture of dependency.^[125, 131-133] An analysis of public attitudes to welfare reported that the percentage of people who would like to

see more public spending on 'disabled people who cannot work' dropped from 74% in 1998 to 53% in 2011.^[134] It was suggested that this drop was a result of the Labour party's changing attitude to disabled people and also a growing belief that people are wrongly claiming to be unable to work.^[134]

In 2002 all three of the PACE trial's principal investigators, along with Aylward, Waddell and Wessely, contributed to a conference and book which promoted the use of the biopsychosocial model.^[127] The book was made up of conference papers and transcripts of discussions, and includes Waddell explaining how the biopsychosocial model was gaining political influence:

"It is all about money. The main thing was to persuade the treasury that there was an opportunity for keeping costs down, particularly over the longer term."

In response to another participant saying "if you go to Gordon Brown (UK Chancellor) and say, 'We can prove to you that if we address this issue, we can save £2 billion', then you will have his full attention", Mansel Aylward replied: "That is the approach that has been taken, but not in such a robust fashion."^[127]

Their discussions explained how, within government, the antipathy caused by the view that the biopsychosocial model lacked a hard evidence base had been overcome by the softer evidence of "authoritative and expert opinion". Unfortunately, those selected for their authoritative and expert opinions may not have risen to positions of influence because of their moral integrity and intellectual rigour. Systematic reviews were also described as being important for changing the views of key opinion makers, yet systematic reviews may merely combine results from a number of different non-blinded trials, putting aside problems with bias and making potentially misleading results appear more reliable than they truly are.^[135]

If politicians are not willing and able to engage critically with the scientific and medical evidence presented to them they could easily be manipulated.

Gordon Waddell pointed out that evidence may not even be what is needed to change people's minds:

"To take this a stage further, I am not sure that evidence is what convinces people. We do need an evidence base, but it is ideas that really influence people. People go to war for ideas, not for evidence. When you look at changing practice, it is really about ideas rather than evidence."

The biopsychosocial approach to disability was an appealing idea (to some) lacking a solid evidence base. It has now been used to present cuts to the incomes of sick and disabled people as a caring intervention in their lives.

The power of the 'evidence-based' label

"I used to be stupid. I'm not stupid anymore because my findings are based on evidence rather than supposition. And yes, I am arrogant, to some extent, because I don't see anything wrong with being arrogant if you think that what you're doing is right, and what you are doing is based on sound evidence."

Mansel Aylward^[136]

The 2015 Conservative Party manifesto stated:

"We will review how best to support those suffering from long-term yet treatable conditions, such as drug or alcohol addiction, or obesity, back into work. People who might benefit from treatment should get the medical help they need so they can return to work. If they refuse a recommended treatment, we will review whether their benefits should be reduced."^[137]

Waddell's DWP report on Common Health Problems^[19] had suggested the same thing:

"receipt of IB [incapacity benefit] being conditional upon participation in rehabilitation, though that would depend on the available interventions being of proven value."

While therapists' professional bodies have expressed concern about proposals for forced treatment, none have taken the time to acknowledge the extent to which their members' exaggerated claims about the value of treatments have promoted the unreasonable assumptions about those claiming disability benefits which in turn encouraged politicians' frustration with those who fail to recover.^[138,139]

When only limited funds are available this can lead to competition between those who think that money should be spent on therapists and those who believe that money should be provided directly to those with health problems. The recent drive to increase access to psychological therapies (IAPT) in the UK was funded partly because it was claimed that it would pay for itself by reducing the costs of welfare payments and increasing taxes paid by those returning to work.^[140] It is not clear how many of the psychological therapies for which access has been increased are truly more effective than a well designed placebo intervention, or that providing money to these therapists is the best way of improving the opportunities of those with health problems.

One of the PACE trial's principal investigators, Trudie Chalder, was President of the British Association for Behavioural and Cognitive Psychotherapies from 2012-14, and in their statement criticising the proposal for coercive therapy, the BABCP also make clear that they are not opposed to providing CBT in Jobcentres in order to increase fitness to work so long as such therapies were 'evidence-based'.^[139] Would they consider CBT to be an 'evidence-based' intervention for improving function in CFS? Would Chalder's claims in the media about patients getting "back to normal" be considered a breach of BABCP standards for accurate advertising?^[141] I fear that their standards for themselves and their members may not be as high as they should be, and that the low standards in this area reflect the prejudices and stigma which surround mental health. In response to the Government's *No Decision About Me Without Me* paper, the Royal College of General Practitioners expressed concerns about plans to allow patients more control over their healthcare, presenting CFS as a psychological problem which meant that patients' preferences may be dangerous:

"And what of patients with complex psychological problems, such as Chronic Fatigue Syndrome, where a choice of treatment might do more harm than good?"^[142]

The PACE trial's principal investigators had previously stated that "when asked to comment on benefits or insurance claims we support the patient as much as is possible,

but do not support claims for permanent disability or medical retirement until all reasonable efforts at rehabilitation have been tried"^[143], and that for sickness benefits "individual [CFS] cases should be treated on their merits, but it is reasonable to expect a patient to cooperate with treatment before being labelled as chronically disabled."^[144] One of the experts called upon to promote the PACE trials stated that the trial's results suggested "every patient who wishes to be helped should be willing to try one or both of the treatments."^[145] I do not believe that patients should be expected to engage in treatments that they do not want, especially when the evidence for their efficacy is as poor as that seen for CBT and GET for CFS.

Threatening to strip patients of financial support for not pursuing particular interventions may be seen as a step too far, but misrepresenting a treatment's recovery rates already serves to rob patients of the ability to make informed decisions about their healthcare and their lives. It is important that those with health problems are able to trust the information provided by their doctors, but too often the biopsychosocial model's emphasis on the benefits of 'reassuring' and 'empowering' cognitions has encouraged manipulation and dishonesty as a form of therapeutic wish-thinking that also plays in to the self-interest and prejudices of those working in government, the insurance industry and in medicine.^[144-147]

Exaggerating the extent to which patients can recover from their health problems through changing their cognitions and behaviour does not only distort patients' behaviour and how they think of themselves, but has political and social effects upon how others treat them too. There is a danger that attempts to promote positive and empowering cognitions amongst the sick has led to a dangerous spread of 'positive' delusions about ill health and disability, and that policy-makers will now resist a bumpy and expensive return to reality.

Prior to the publication of the 2015 Conservative Party manifesto, their intent to include a proposal for mandatory treatments for those claiming benefits was floated in The Daily Telegraph, and justified by a 'senior government source' with the claim that:

"Cognitive behavioural therapies work and they get people stable again but you can't mandate people to take that treatment" and

"there are loads of people who claim ESA who undergo no treatment whatsoever. It is bizarre. This is a real problem because we want people to get better."^[119]

The source was reported to suggest that:

"successful treatments could reduce the numbers of people with mental health issues claiming the benefits by up to 90 per cent."

It is difficult to see how this figure could be justified by the evidence, however we have seen how a desire to be 'positive' can lead to cumulative distortions as information is passed from one person to another and it is difficult to know how far from reality senior members of the government have now drifted.^[148,149] (As illustrated in the Appendix.)

In Waddell's DWP report on Common Health Problems^[19], aside from CFS, the other bright spot for evidence of the benefits of a biopsychosocial approach was low back pain. Unfortunately, results from medical trials have been disappointing here too. A recent Cochrane review of biopsychosocial rehabilitation for low back pain found that non-blinded trials showed some improvements in questionnaire scores prone to bias, but no improvement in the harder outcome of work status.^[150]

At one point Waddell's report stated that

"it is important to bear in mind that the lack of scientific evidence is not the same as evidence that something is ineffective".^[19]

This is true, but not a good foundation for cuts to spending on support for those with health problems, where it is fair to expect a degree of caution from those who could further their careers with bold speculations. The way in which the biopsychosocial model has been used and promoted, without good supporting evidence for many of the claims being made, is unethical.

Conclusion

Policy implications

Medical research can be used to justify assertions of political power and any attempt to reform the state's relationship with those with disabilities and ill health should be founded upon a rigorous examination of the available evidence. Researchers need to be honest and clear about the limitations of their research and their ability to accurately measure subjective symptoms.

Policy makers need to recognise that researchers can be influenced by their own self-interest, and that those who rise to prominence may do so through their own ability to play political games rather than because of the high quality of their work. The political power that comes with classing any rehabilitative approach as 'evidence-based' means that those involved in medical research need to do more to acknowledge the limitations of non-blinded trials using subjective self-report questionnaires as their outcomes, and results from these trials need to be placed in the context of what we know about the dangers of bias and the effect of placebos.

We also need to ensure that results are presented clearly and fairly so that patients and policy makers can make informed judgments about the value of available interventions. A small first step in this regard would be to ensure that results for all the outcome measures laid out in the PACE trial's protocol are now made available to the public who paid for it.

Dangerous assumptions

The biopsychosocial model has played a significant role in shaping the UK government's approach to disability and welfare over the last two decades, yet some important claims made about the value and benefits of biopsychosocial approaches have been based upon poor quality evidence and misleading claims. Even as awareness of these problems grows, many aspects of the biopsychosocial model are so advantageous to those wishing to justify cuts to state disability benefits that they are unlikely to be abandoned. While it may be that explicit references to the biopsychosocial model will now be avoided, the tactic of using the positive language of empowerment to promote policies which will cut the incomes of members of society living with ill health and disability looks likely to continue. So long as cuts to disability spending can go on being sold in this manner they will be a politically soft target for a government committed to finding £12 billion of welfare savings.^[137]

It is not just in the political sphere that the biopsychosocial model has caused problems. While there can be an assumption that medical researchers are more trustworthy than politicians, and that the interventions they promote as being 'evidence-based' will benefit patients, results from medical research can be exaggerated and misrepresented. When the biopsychosocial model encourages researchers and medical staff to see the management of patients' cognitions and expectations as a routine part of medical practice this can be seen as legitimatising the manipulation of the information provided about prognosis,

treatment efficacy and recovery rates. There seems to be a belief that informed consent is not required for this psychosocial treatment. It should not be surprising that presuming certain groups of patients deserve to be manipulated in this way will be stigmatising, and risks creating a culture of cynicism and distrust as knowledge of what has occurred spreads.

The PACE trial shows the danger of allowing researchers with an interest in reporting positive results to use subjective self-report outcome measures for a non-blinded trial. While the more objective outcome measures from the PACE trial indicated that the biopsychosocial interventions tested were not useful to patients, results were released in a way which led to a range of excited claims being made about them leading to recovery for patients.

In 2011 the chair of BACME, a professional organisation for those providing CBT and GET to CFS patients, was the corresponding author on a paper which cited the PACE trial to make the unjustifiable claim that:

"evidence from a recent evidence trial of cognitive behavioural therapy and graded exercise therapy indicated a recovery rate of 30-40% one year after treatment."^[58]

During an interview promoting this paper she stated that she hoped it would be read by the NHS commissioners who decide which services should be funded.^[151]

Those who have built their careers upon the development and provision of biopsychosocial interventions will have personal incentives to make exaggerated claims about the value of their work, even if doing so risks distorting the beliefs and actions of others and robbing patients of the ability to make informed decisions about the treatments to which they are being asked to consent. The bold claims made by medical researchers about the value of the biopsychosocial model of disability has allowed the British state to claim authority over the psychosocial aspects of disabled people's lives, and use their supposed expertise to justify cuts to disability welfare payments.

The biopsychosocial reforms, and the DWP's biopsychosocial disability assessments, have also led to inaccurate claims about claimants being fit for work, and now we have seen the culture of cynicism and distrust spread to others being affected by the biopsychosocial model. The satirical response of a campaigning group to the assessments carried out by Atos for the DWP, which routinely classed seriously sick and disabled people as 'fit for work', could be equally applied to the claims made about recovery in the PACE trial:

"Miracles are being wrought by the Sacred Tickbox at the Healing WCA Temples. We want to share the news of these miracles that are being performed upon us! Praise Be!"^[152]

Atos Miracles

For a welfare system to be genuinely enabling for disabled people it needs to be founded upon a reasonable understanding of disability, how it affects people, and the likelihood of recovery. An unduly positive view of peoples' health problems, and the benefits of psychosocial management and rehabilitation, can lead to policies which reduce disabled peoples' control over their own lives and how they manage their health. Until the serious

and ongoing problems distorting medical research in this area have been overcome, it is important to avoid assuming that civil servants and medical researchers have a better understanding of how people with disabilities should live their lives than disabled people themselves.

Appendix

1. Selected criteria from the PACE trial

For ease of reference and comparison, some of the criteria referred to within the PACE trial are provided here in full. The criteria laid out in the trial's 2007 protocol^[37] are consistently more demanding than those newly devised criteria for which results were later released. The operationalised Oxford criteria for Chronic Fatigue Syndrome used within the PACE trial is also included so that readers can better understand how participants were selected.

From the PACE trial's published protocol^[37]

ENTRY CRITERIA:

- ◆ The participant meets operationalised Oxford research diagnostic criteria for CFS [details of which are included beneath].
- ◆ The participant's Chalder Fatigue Questionnaire score is 6 or more.
- ◆ The participant's SF-36 Physical Function sub-scale score is 65 or less.
- ◆ The participant agrees to randomisation and the terms of the trial.

OUTCOME MEASURES:

Primary Outcome Measures:

The 11 item Chalder Fatigue Questionnaire measures the severity of symptomatic fatigue, and has been the most frequently used measure of fatigue in most previous trials of these interventions. We will use the 0,0,1,1 [bimodal] item scores to allow a possible score of between 0 and 11. A positive outcome will be a 50% reduction in fatigue score, or a score of 3 or less, this threshold having been previously shown to indicate normal fatigue.

The SF-36 Physical Function sub-scale measures physical function, and has often been used as a primary outcome measure in trials of CBT and GET. We will count a score of 75 (out of a maximum of 100) or more, or a 50% increase from baseline in SF-36 sub-scale score as a positive outcome. A score of 70 is about one standard deviation below the mean score (about 85, depending on the study) for the UK adult population.

Those participants who improve in both primary outcome measures will be regarded as overall improvers.

Recovery:

"Recovery" will be defined by meeting all four of the following criteria: (i) a Chalder Fatigue Questionnaire score of 3 or less, (ii) SF-36 Physical Function score of 85 or above, (iii) a CGI score of 1, and (iv) the participant no longer meets Oxford criteria for CFS, CDC criteria for CFS or the London criteria for ME.

Outcome measures for which results were released

Primary Outcome Measures^[20]:

Mean scores for Likert scoring of the Chalder Fatigue Questionnaire and the SF-36 Physical Functioning scale.

Participants who improved from baseline by two or more points for [Likert] fatigue and eight or more for physical function. These were classed as being clinically useful differences.

Within normal ranges for both primary outcomes/Back to normal/Recovered^[20]:

A Likert fatigue score of 18 or less and an SF36-PF score of 60 or more.

Trial Recovery Criteria^[45]:

Required i) a Likert fatigue score of 18 or less, ii) an SF36-PF score of 60 or more, iii) a CGI score of under 2 and iv) not fulfilling the Oxford criteria for CFS*.

Clinical Recovery Criteria^[45]:

Required i) a Likert fatigue score of 18 or less, ii) an SF36-PF score of 60 or more, iii) a CGI score of under 2 and iv) not fulfilling the Oxford criteria for CFS*, CDC criteria for CFS or the London criteria for ME .

* In the recovery paper, fulfilling the Oxford criteria required that patients have a Chalder Fatigue Questionnaire score of 6 or more and a SF-36 Physical Function sub-scale score of 65 or less. At baseline 235 patients were excluded from the trial because they reported a SF36-PF score of over 65, separately from the 1011 excluded for not fulfilling the Oxford criteria.^[20] The entry criteria for the FINE trial, PACE's sister trial, also required the Oxford criteria be fulfilled, but included patients who had an SF36-PF score of 70, and a bimodal Chalder Fatigue score of 4. Patients who fulfilled the most demanding recovery criteria used in the PACE trial could still have fulfilled the Oxford criteria for FINE.^[159]

	SMC	SMC+CBT	SMC+GET	SMC+APT
Likert CFQ: mean (SD)	23.8 (6.6)	20.3 (8.0)	20.6 (7.5)	23.1 (7.3)
Mean CFQ difference from SMC (95% CI)		-3.4 (-5.0 to -1.8)	-3.2 (-4.8 to -1.7)	-0.7 (-2.3 to 0.9)
SF36-PF: mean (SD)	50.8 (24.7)	58.2 (24.1)	57.7 (26.5)	45.9 (24.9)
Mean SF36-PF difference from SMC (95% CI)		7.1 (2.0 to 12.1)	9.4 (4.4 to 14.4)	-3.4 (-8.4 to 1.6)
'Back to normal'	15%	30%	28%	16%
Trial recovery	7%	22%	22%	8%
Clinical recovery	7%	21%	21%	8%

TABLE 2. Results for outcomes 12 months post randomisation^[20,45].

The Oxford criteria

This is a definition of chronic fatigue syndromes as laid out in *A report-chronic fatigue syndrome: guidelines for research*:^[24]

- ◆ A syndrome characterised by fatigue as the principal symptom
- ◆ A syndrome of definite onset that is not life long
- ◆ The fatigue is severe, disabling, and affects physical and mental functioning
- ◆ The symptom of fatigue should have been present for a minimum of 6 months during which it was present for more than 50% of the time
- ◆ Other symptoms may be present, particularly myalgia, mood and sleep disturbance
- ◆ Certain patients should be excluded from the definition. They include: (i) Patients with established medical conditions known to produce chronic fatigue (e.g. severe anaemia). Such patients should be excluded whether the medical condition is diagnosed at presentation or only subsequently. All patients should have a history and physical examination performed by a competent physician and (ii) Patients with a current diagnosis of schizophrenia, manic depressive illness, substance abuse, eating disorder or proven organic brain disease. Other psychiatric disorders (including depressive illness, anxiety disorders and hyperventilation syndrome) are not necessarily reasons for exclusion.

From the PACE trial's full protocol:^[22]

ASSESSMENT OF OXFORD CRITERIA FOR CFS:

Questions for which patients must answer 'yes':

- ◆ Is your fatigue (or a synonym), the principal (main, primary) symptom (e.g. tiredness, lack of energy, weariness, exhaustion)?
- ◆ For the Research Nurse to judge: Can the fatigue be distinguished from low mood, sleepiness and lack of motivation?
- ◆ Is your fatigue out of proportion to what you would expect as normal for this level of exertion?
- ◆ Is your fatigue a clear change from how you were previously?
- ◆ Did your fatigue start with a definite onset (which may be gradual)?
- ◆ Have you had your fatigue for the last 6 months, during which it was present for more than half of the time?
- ◆ Does your illness affect both your physical ability and mental functioning (thinking, concentrating, talking, reading or remembering)?

Questions for which patients must answer 'no':

- ◆ Have you had this fatigue all your life, as far as you can remember?

Medical exclusions:

Established medical conditions known to produce chronic fatigue (see medical screening SOP). RN to check that this has been done and documented by the clinic doctor.

Psychiatric Exclusions:

Schizophrenia, Manic depressive (bipolar) illness, Substance misuse, Eating disorder, Proven organic brain disease.

Other psychiatric disorders (including depressive illness, anxiety disorders, and hyperventilation syndrome) are not reasons for exclusion.

The changes from the outcome criteria laid out in the trial's 2007 protocol^[37] consistently served to make it easier to report positive results, and this will have served to inflate the claims that could be made about the benefits of treatments. While the PACE team continue to fight against the release of results for the criteria which they themselves had devised for their published protocol we cannot know exactly how great an impact these protocol changes will have had.

2. Patient expectations and the danger of bias

We cannot know that problems with bias explain why patients in the CBT and GET groups reported greater improvements for the trial's subjective outcomes compared to the more objective outcome measures used. It had been suggested that in fact, problems with bias could have adversely affected the results reported for CBT. Before they began treatment patients were asked about their views on the therapy that they were due to receive (Table 3), and as patients were less confident about CBT than APT, it could be argued that we need not be concerned about the danger of results for subjective self-report measures being biased in favour of CBT over APT.

	Adaptive pacing therapy (n=159)	Cognitive behaviour therapy (n=161)	Graded exercise therapy (n=160)	Specialist medical care alone (n=160)
Treatment is logical	134 (84%)	115 (71%)	135 (84%)	79 (49%)
Confident about treatment	114 (72%)	91 (57%)	112 (70%)	65 (41%)

TABLE 3. Participants' views before treatment.^[20]

However, as part of both CBT and GET patients were told that their treatments had already been shown to be effective (e.g. from the CBT participant's manual: "Cognitive behaviour therapy (CBT) is a powerful and safe treatment which has been shown to be effective in a variety of illnesses, including CFS/ME, headaches and back pain."^[35]) and no equivalent claims were made as a part of APT. Receiving these claims from clinicians in positions of authority during treatment may have affected patient beliefs and expectations in a way which biased results. Furthermore, the models of illness provided as a part CBT and GET were likely to encourage patients to believe that they had greater control over their symptoms, and that a failure to improve would reflect poorly upon their own efforts. There is a danger that simply promoting these models of illness to patients would encourage them to report their symptoms more positively.

APT was a therapy devised for the PACE trial and unlike the pacing most commonly used by patients, which is self-learned, is taught and supervised by a therapist.^[154] It was stated that this was done in order to reduce to danger of bias distorting results: "Given that having a sympathetic therapist usually influences the success of a therapy, having two parts of the trial supported by a therapist but one not, would have risked not giving pacing a fair chance."^[154]

This early awareness that the PACE trial was designed in such a way that the primary outcomes could be so easily distorted seemed to have faded away by the time results were being presented to the media.

The PACE team published the following graph, showing results for an objective measures of fitness^[44], but have refused to release the exact figures for this data, classing a request for this information as vexatious.^[76] Therapists providing APT were told that an important consideration in APT is the 70% rule: never going beyond 70% of a person's perceived energy limit^[35], while those providing CBT and GET encouraged patients to

gradually increases activity.^[35] This did not seem to lead to the differences in patients' fitness levels that one might expect.

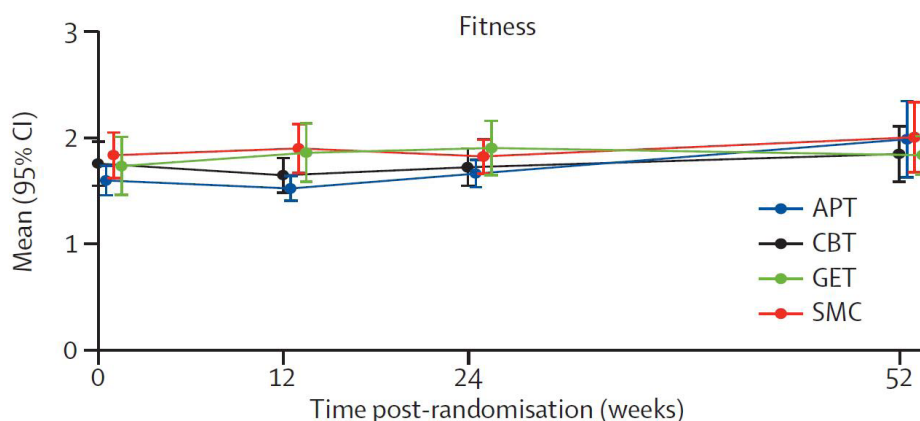


FIGURE 2. Results of the PACE trial's four groups' fitness results

We cannot be confident in any interpretation of the primary outcomes for the PACE trial. There are reasons that they could have been biased for or against any of the treatment groups. It is important that these problems with interpreting results are acknowledged when they are being presented, and that results for the trial's more objective outcome measures are provided in addition to those for the SF-36 Physical Functioning Scale and Chalder Fatigue Questionnaire.

3. Primary trial outcomes

The SF-36 Physical Functioning Scale and Chalder Fatigue Questionnaire served as the PACE trial's primary outcomes.^[22] Being aware of the specifics of these questionnaires and how they are scored encourages a better understanding of what those scores truly represent.

For the SF-36 Physical Functioning Scale people are asked, for ten activities, "does your health limit you in these activities? If so, how much?"

People are scored depending on which of three answers they choose:

- Yes, limited a lot (0)
- Yes, limited a little (5)
- No, not limited at all (10)

The 10 activities of SF36-PF are:

1. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.
2. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf.
3. Lifting or carrying groceries.
4. Climbing several flights of stairs.
5. Climbing one flight of stairs.
6. Bending, kneeling or stooping.
7. Walking more than a mile.
8. Walking several blocks.
9. Walking one block.
10. Bathing or dressing yourself.

For the Chalder Fatigue Questionnaire people are told:

"We would like to know more about any problems you have had with feeling tired, weak or lacking in energy in the last month.... If you have been feeling tired for a long while, then compare yourself to how you felt when you were last well."

People are scored depending upon which of the four answers that they choose and the scoring method used.

Less than usual	(Likert scoring: 0 Bimodal scoring: 0)
No more than usual	(Likert scoring: 1 Bimodal scoring: 0)
More than usual	(Likert scoring: 2 Bimodal scoring: 1)
Much more than usual	(Likert scoring: 3 Bimodal scoring: 1)

The eleven questions used are:

1. Do you have problems with tiredness?
2. Do you need to rest more?
3. Do you feel sleepy or drowsy?
4. Do you have problems starting things?
5. Do you lack energy?
6. Do you have less strength in your muscles?
7. Do you feel weak?
8. Do you have difficulty concentrating?
9. Do you make slips of the tongue when speaking?
10. Do you find it more difficult to find the correct word?
11. How is your memory?

The PACE team had classed the bimodal scoring of the Chalder Fatigue scale as the trial's primary outcome.^[37] Before the PACE trial's results were released its sister trial, FINE^[153], released results without deviating from its protocol and reported that biopsychosocial rehabilitation did not lead to an improvement in the trial's primary outcome compared to a 'treatment as usual' control. They also reported that had they used Likert rather than bimodal scoring for the Chalder fatigue scale then a small but statistically significant

improvement could have been reported. The PACE team have decided to only release results for Likert scoring of the Chalder Fatigue scale.

The trial's post-hoc recovery criteria uses Likert scoring, making it slightly more difficult to compare to the original criteria for recovery and entry to the trial, both of which used bimodal scoring. Within the main report's discussion of the changes to criteria, the original boundaries for the bimodal score were converted to Likert scoring, while the full original criteria are outlined above.

4. Exaggerated positive claims

"Information and advice should be evidence-based, accurate, and realistic; but it should also be positive - encouraging and supporting restoration of function and return to work."

Waddell and Burton^[19]

When there is a willingness to tolerate a systematic 'positivity' in the way information in presented distortions can grow and spread. Here is an example how exaggerated claims about the results from the PACE trial became more extreme within the peer-reviewed scientific literature as researchers misunderstood one another's claims in ways that served their own interests.

1. In the 2011 PACE paper researchers reported results for those who were *"within normal ranges for both primary outcomes at 52 weeks"*^[20]: 15% (SMC), 30% (SMC+CBT), 28% (SMC+GET) and 16% (SMC+APT). Patients could have entered the trial being classed as suffering from fatigue which was *"severe, disabling and affects physical and mental functioning"*, reported a worsening of their fatigue and physical functioning following treatment, and yet still have fallen within the PACE team's post-hoc normal ranges for fatigue and physical function.
2. To the press and to patients the PACE team described these patients as being *"back to normal"* and stated that *"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."*^[59,60]
3. In a commentary in The Lancet that accompanied the publication of the PACE paper, and was reviewed and approved by the PACE team, it was stated that: *"PACE used a strict criterion for recovery: a score on both fatigue and physical function within the range of the mean plus (or minus) one standard deviation of a healthy person's score. In accordance with this criterion, the recovery rate of cognitive behavioural and graded exercise therapy was about 30% — although not very high, the rate is significantly higher than that with both other interventions."*^[54] It was not true that PACE had used healthy people's score to derive their normal range and it is difficult to see how a 'strict criterion for recovery' could overlap with the trial's own entry criteria.
4. Those reporting on the PACE trial continued to promote the claim that about one third of patients had recovered with CBT and GET, with the BMJ reporting that *"Less than a third of patients were cured by either treatment (30% (44/148) after CBT and 28% (43/154) after graded exercise therapy)."*^[52,55-57]

5. In a column for The Telegraph, which has since received some alterations, Max Pemberton wrote that: *"The current gold standard for treatment is a combination of supervised exercise and talking therapies. A major British trial published in The Lancet found that at least one in three patients with ME recovered using this approach. The biggest hurdle faced by doctors is persuading people to actually attend and engage with treatment. They resist because they refuse to be seen as mentally unwell. It does seem bizarre that those with such a debilitating disease would refuse treatment because it was given by a psychiatrist."*^[56]
6. In a paper on the impact and costs of CFS/ME the PACE trial was cited to support the claim that: *"Evidence from a recent evidence trial of cognitive behavioural therapy and graded exercise therapy indicated a recovery rate of 30-40% one year after treatment."*^[58] The corresponding author for this paper was Esther Crawley, chair of BACME, a professional organisation for those providing CBT and GET to CFS patients, and she stated that she hoped that this paper would be read by the NHS commissioner who decide which services should be funded.^[151]

There is a danger that even more extreme misrepresentations of the evidence are made behind closed doors. If politicians and NHS commissioners assume that they can trust the claims being made in peer-reviewed medical papers then they are likely to be making many important decisions based upon a seriously distorted understanding of the evidence.

5. Informed consent

Even when randomised controlled trials are rigorously conducted and appropriately reported their results may still be misleading and differ from those seen outside of a research setting. Those patients selected for entry in to a trial may not be representative of the patient population, and volunteering for participation shows that these patients are happy to take part in the trial's treatments, so results cannot be used to claim that the forced treatment of others would be beneficial. Patients and therapists who know that they are being assessed as part of a trial may behave and respond differently to those outside of trials. Medical trials can also feature higher levels of supervision and oversight during treatment than those seen elsewhere, potentially leading to greater care and attention and therefore improved results. It is important that people are aware of the limitations which surround even relatively robust medical knowledge, that patients are made aware of these limitations before being asked to consent to treatment, and that systems are in place to ensure patient concerns about the treatments they receive outside of trials are listened to.

Information on treatment effects and patient satisfaction has been collected by those providing CBT and GET to CFS patients and by patient charities.^[155-157] Results from patient surveys are likely to be skewed by the self-selection of those who complete them, who are unlikely to be representative of the general patient population. There are other potential problems with such evidence too, such as a lack of independent confirmation of a patient's diagnosis, or the possibility that the treatment they received had not been provided properly. While results from surveys conducted by patient charities need to be treated with caution, they do provide an opportunity for patient voices to be heard without being filtered through researchers and medical staff. Perhaps unsurprisingly,

those providing CBT and GET to patients tend to report more positive findings for their interventions than patient groups, which routinely report that many patients found CBT and GET to be harmful.^[155-157]

A recently released report from one charity included patient statements which could help explain the discordancy of results: "They taught us positive mental attitude, so it was impossible to report back the truth without being accused of negativity."^[157] This sort of attitude can also be seen in the medical literature. For example, therapists from PACE's sister trial, FINE^[153], found that dealing with patients after they had been trained to provide biopsychosocial rehabilitation was frustrating.

This was illustrated by the quote:

"The bastards don't want to get better".^[158]

As a part of the FINE trial therapists had been trained to provide positive "rousing reassurance" such as:

"From the moment you walk out of this room your recovery is beginning.

There is no disease

Go for 100% recovery"^[159]

If people are encouraged to believe that patients' health problems are entirely reversible though rehabilitation, then their failure to recover is likely to lead to irritation.

Genuinely informed consent requires that the claims made to patients are not shaped by a desire to be positive or reassuring. A course intended to reduce unemployment which leaves the unemployed reporting greater confidence in their ability to find work, but does not lead to real improvements in employment rates could be a harmful waste of time and resources, and should not be sold as helping people to get back to work. A non-blinded trial of a medical intervention which enables patients to report less disabling fatigue on questionnaires but not increase their activity levels or show other more objective evidence of improvement should not be sold as an evidence-based treatment for disabling fatigue. It is important to be clear about the problems with relying upon self-report measures in non-blinded trials, and the danger that results for these outcomes may be misleading.

6. Recent developments

Since this report was first submitted for publication, there have been a number of interesting developments that I will attempt to briefly summarise here, as well as providing references to further reading.

First, David Tuller, a science journalist and academic coordinator of the concurrent masters degree program in public health and journalism at the University of California, Berkeley, began publishing a series of lengthy investigative pieces detailing problems with the PACE trial.^[160,161] Some of these problems have been covered within this report, but many were not. His pieces included criticism of PACE from a number of prominent researchers, who then went on to write an open letter expressing their

concerns to Richard Horton, editor of The Lancet, arguing that "such flaws have no place in published research".^[162] Following Horton's failure to respond, the letter was re-sent, with an additional thirty six signatories.^[163] Following publication of a piece by Tuller on problems with the PACE trial researchers' conflicts of interest involving the insurance industry, Swiss Re removed from its website one of the pages cited in this report.^[164,165] Fortunately this page had been backed up and made available elsewhere.^[97]

Soon after David Tuller had published his first piece a new PACE trial paper was published, providing mean Chalder Fatigue scale scores and SF-36 Physical Functioning scores for the trial's treatment groups at 2.5 year follow up.^[166] These results showed that patients randomised to receive CBT and GET in addition to Specialist Medical Care reported scores no better than those randomised to Specialist Medical Care alone.

In a press release promoting CBT and GET titled 'Treatments offer hope for Chronic Fatigue Syndrome (CFS/ME)' one of the PACE trial's researchers argued that:

"We found that participants who had originally been given SMC or APT appeared to be doing as well as those who had CBT or GET in the longer term. However as many had received CBT or GET after the trial, it does not tell us that these treatments have as good a long term outcome as CBT and GET."^[167]

This is true, yet within the paper's appendix is data which had been included at request of a reviewer which showed that the scores of those participants randomised to the SMC or SMC+APT groups who received no additional treatment improved by as much as the scores of those who received additional CBT or GET. The press release did not mention this evidence.

At 2.5 years follow-up the additional therapies provided had broken randomisation and made it difficult to claim anything with confidence. That did not prevent the researchers presenting results in a way which led to a front page article in *The Daily Telegraph* which began by claiming that:

"Chronic Fatigue Syndrome is not actually a chronic illness and suffers can overcome symptoms by increasing exercise and thinking positively, Oxford University has found."^[168]

The headline was *Exercise and positivity 'can overcome ME'*.

David Tuller's work, and problems with the way result for this new paper were presented, served to draw the attention of further academics, including James Coyne and Keith Laws, two researchers known for their attempts to raise standards within mental health research.^[169,170] In a co-authored response titled *Results of the PACE follow-up study are uninterpretable* they criticised the way in which previous concerns about the PACE trial had been responded to:

"the PACE investigators have previously complained in The Lancet Psychiatry of 'the apparent campaign to bring the robust findings of the trial into question'. We think the further scrutiny that the follow-up study has brought casts further doubt on whether there ever were 'robust findings'. The investigators should get more accustomed to rigorous post-publication peer review, which is not a campaign, but a reality of the 21st century."^[171]

Meanwhile, the Information Commissioner's Office released a decision notice that ordered the release of anonymised data from the PACE trial which would allow for the calculation of results for many of the outcomes laid out in the trial's protocol, including their original recovery criteria.^[75,172] The decision notice reveals the range of arguments Queen Mary University of London attempted to use to avoid the release of this data; including that the data release could contravene confidentiality agreements given to participants as, even though no plausible way third parties could re-identity participants was provided, they raised the concern that the participants themselves might be able to identify their own data, somehow potentially breaching their own confidentiality. Rather than releasing the requested data Queen Mary decided that they would prefer to appeal against the Information Commissioner's decision, and a three day tribunal hearing is now due to take place over 20-22 April 2016.^[173]

A separate refusal to release data from the PACE trial then attracted wider attention from the scientific community.^[174] An earlier PACE paper had been published in a scientific journal, PLOS ONE, that requires authors make data available to other researchers (the data used for this paper would not allow for the calculation of results for the recovery criteria laid out in the trial's protocol). James Coyne requested this data, and the PACE team's refusal to honour their commitment to data sharing drew the ire of a wide range of campaigners concerned about problems with the reliability of medical research, leading to yet further requests for access to this data.^[175, 176]

The refusal letter argues that:

"the active campaign to discredit the project has caused distress to the university's researchers who hold legitimate concerns that they will be subject to public criticism and reputational damage."

Such concerns should not be allowed to interfere with the critical assessment of scientific research. PLOS has now issued an editor's note stating that:

"several readers have raised concerns regarding the analyses reported in this article. We are also aware that there have been requests for the data from this study"

and concluding:

"As part of our follow up we are seeking further expert advice on the analyses reported in the article, and we will evaluate how the request for the data from this study relates to the policy that applies to the publication. These evaluations will inform our next steps as we look to address the concerns that have been noted."^[177]

Coyne has claimed that he and PLOS had:

"come under pressure from a number of sources, including Richard Horton, editor of the Lancet"

and suggested that:

"this is emerging as a major, maybe historic confrontation between the forces pushing for sharing of data and the British establishment".^[178]

A recently released report provided some information on a 2015 conference at the Royal Society where criticism of the PACE trial, and the Freedom of Information requests it attracted, were presented as an exogenous threat to science.^[179]

Since the release of the first PACE paper the Science Media Centre, an organization which has considerable influence over how the UK media report science stories, has played an important role in the promotion of the PACE trial and the exaggeration of its results, while critics were portrayed as misguided, unreasonable and perhaps even dangerous.^[72, 74, 145, 180-185] It has also played a role in attempting to aid efforts by Peter White, a principal investigator for the PACE trial, to secure further restrictions to the Freedom of Information Act in relation to research data. Correspondence from White forwarded on by Fiona Fox, director of the Science Media Centre, requested academics ask their own Universities, and other lobbyists, to get in touch with friendly Members of Parliament in order to argue for a weakening of the Freedom of Information Act.^[186] Peter White's personal submission to the recent Commission on Freedom of Information is also publicly available.^[187]

He argued that:

"we need science in the UK to be protected or it will continue to be damaged as this [PACE] trial has been (other examples include climate change science, and research into the health effects of tobacco). Exempting Universities from the FOIA would achieve that. Exempting scientific research data produced by Universities and other higher educational institutes might be a workable alternative."

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An earlier restriction to the Freedom of Information Act (exemption 22A) has already been presented by the PACE team as one the beneficial outcomes of the PACE trial.^[188] Considering the many problems with the way the PACE trial was designed, conducted and then presented, it is not surprising that Peter White was keen to avoid the scrutiny that the Freedom of Information Act can assist.

Following the attention attracted by the refusal to release data from the PACE trial a statement was released by the PACE team which reported that they are:

"currently seeking further ethical and scientific advice, as well as the advice of patients, on how best to provide independent decisions about appropriate access to relevant data".^[189]

In response to this a string of major ME/CFS patient organisations from around the world have written to Queen Mary arguing for the release of the requested data, including Action for ME, the patient charity which had been involved in assisting with the trial.^[190] ^[191] Over twelve thousand signatures have also been collected for a patient petition calling for the correction of misleading claims made within PACE trial papers and the release of results for the recovery criteria laid out in the trial's published protocol.^[192] So far, this advice from patients does not seem to have led to Queen Mary abandoning their appeal

to the Information Tribunal. While concerns have been expressed about protecting the personal data of trial participants, no explanation has been provided as to how the limited data request Queen Mary is appealing against could lead to the identification of participants. The closest we have seen is a vague reference to it being a 'very rich' data set by Simon Wessely, President of the Royal College of Psychiatrists.^[193] Sir Simon has also offered an attempted defence of the PACE trial in a blog post, however he failed to address the central concerns raised by the trial's critics, and he raised no points that required changes to be made to this report.^[194]

Since submitting this report awareness of the problems which surround the PACE trial, and criticism of it, has grown dramatically.^[161,169,170,195-198] Yet this change has largely occurred outside of the UK, while British reporting of the controversies around the PACE remains less well informed and seemingly more readily affected by the prejudices which can surround CFS.^[168,199-202] The PACE trial illustrates concerns about British medical research, politics and also science reporting and the role of the Science Media Centre in shaping public discourse. In parts of the British media it appears to have become fashionable to use CFS and the controversy surrounding the PACE trial as a justification for inane commentary on the problems of a dualistic understanding of body and mind, ignoring the real problems with biopsychosocial approaches to CFS and the prejudices that poorly researched work can promote.^[56, 72, 199,200 202-205]

While recent developments have brought more attention to the problems with the research at the centre of this report, we are still waiting for real progress to be made in correcting these problems. It should not be assumed that the PACE trial is a uniquely flawed piece of research, but it does serve as a useful case study for the political dangers of poor quality medical research, and the harm it can do. It also helps illustrate problems within the systems of science, that too often seem designed to serve the interests of researchers and those in positions of authority rather than society at large. While there are signs of some improvements to these systemic problems, progress is slow, and the PACE trial indicates how committed some are to protecting their own privileged positions. We must now wait to see if the Information Tribunal refuses Queen Mary's appeal, in which case we may soon have access to data that could help correct some of the misleading claims made about the PACE trial and the expectations patients can reasonably hold about recovery.

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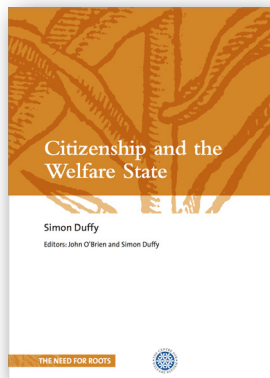
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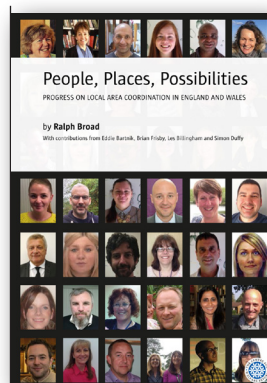
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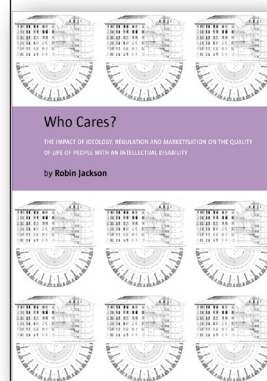
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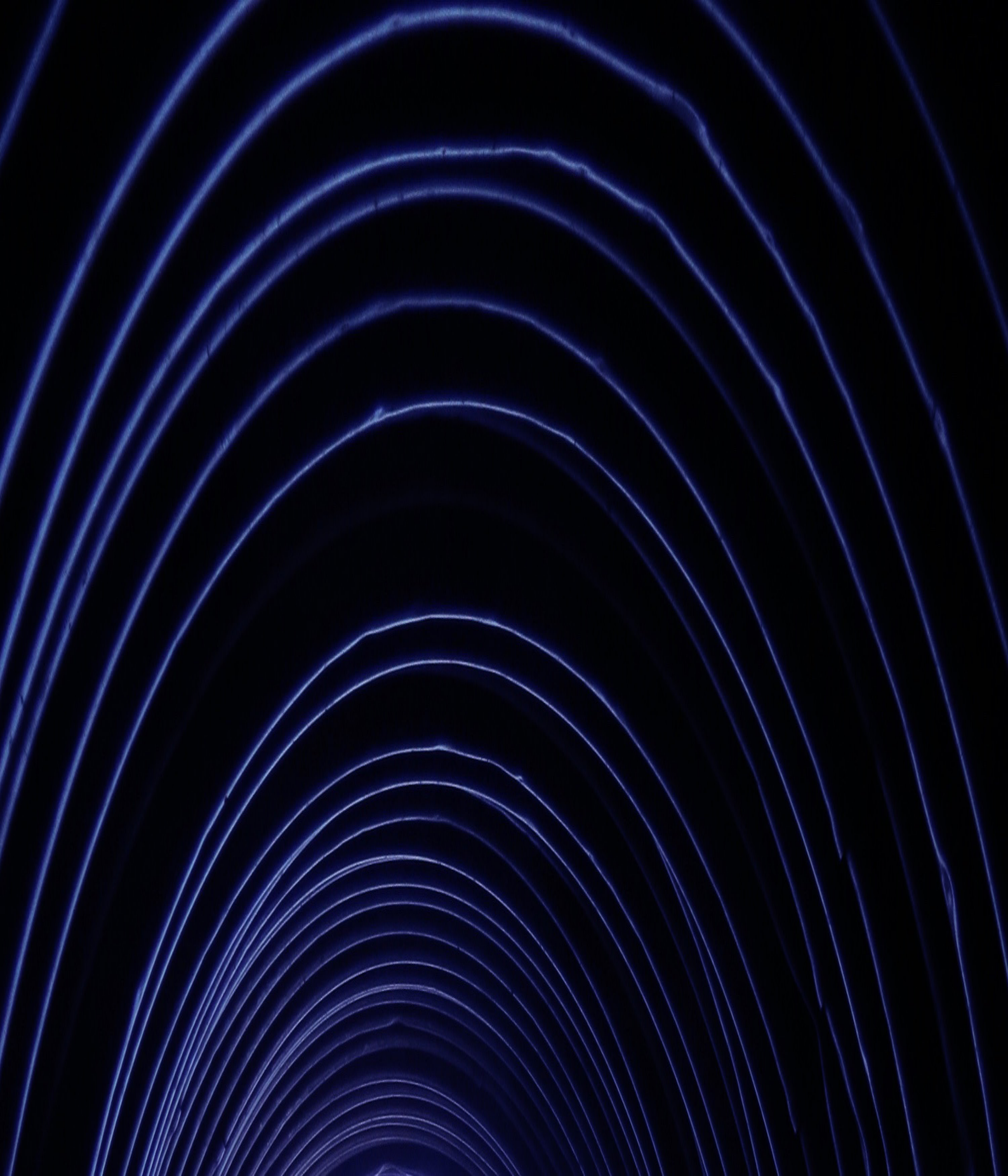
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