

AONM Exposing scientific fraud:
The Lancet PACE trial 2011 and the betrayal of people with ME (PWME)

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An update on the latest legal and scientific debates.

THE PACE STUDY Lancet 2011

[http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(11\)60096-2/abstract](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(11)60096-2/abstract)

The PACE study was one of the largest psychotherapy trials ever carried out on the chronic fatigue syndrome /myalgic encephalomyelitis (CFS/ME) patient community. Its aim was to assess the efficacy of cognitive behavioural therapy (CBT) and graded exercise therapy (GET) in the treatment of patients with CFS/ME.

The PACE study concluded that 59% of CFS patients receiving CBT and 61% receiving GET had improved, with an accompanying editorial suggesting that 30% of patients had “recovered” (2013 - revised to 22% recovery) . As a result of the PACE study, National and indeed International Guidelines for the treatment of CFS/ME have evolved based on psychological therapies. Moreover, because of the perceived ‘gold standard’ of PACE, CFS/ME has become generally regarded as a primarily psychological condition.

This has been highly damaging to PWME for 4 main reasons

1. The PACE trial has effectively determined CFS/ME as being a psychological condition. As a result, patients who suffer what is in fact a serious and debilitating physical condition have been subjected to therapies which at best are ineffective and at worst exacerbate the condition. Indeed, the concept of GET is an oxymoron because CFS/ME is a condition which by definition is worsened by exercise

[COMPLAINT – GMP Domain 2 Safety and Quality - CBT, GET worsen CFS/ME]] [COMPLAINT GPR ‘Protect from Harm’, paragraphs 15-20 - CBT, GET worsen CFS/ME]

2..... AND.....

Because PACE has reinforced the perception that CFS/ME is psychological, patients have been refused financial benefits for disability. Often this has been on the basis that they refuse to engage in CBT or GET. This is hardly surprising since other studies have clearly shown these therapies worsen their condition.

[COMPLAINT – Fraud Act 2006 – Fraud by false representation and Fraud by abuse of position – ie the results of PACE are falsely stated and this has caused loss to CFS/ME sufferers] [COMPLAINT – GMP Domain 2 Safety and Quality – CBT, GET worsen CFS/ME] [COMPLAINT GPR ‘Protect from Harm’, paragraphs 15-20 – CBT, GET worsen CFS/ME]

3..... AND

For the same reasons, patients have been denied proper compensation for CFS/ME caused by conditions in the work place (typically poisoning by toxic chemicals: Gulf War syndrome, Aerotoxic syndrome, Sheep Dip Flu, 9/11 Syndrome), and by chronic infections: Lyme, mycoplasma, EBV, chronic fungal infection with mycotoxins and so on!

[COMPLAINT – Fraud Act 2006 – Fraud by false representation and Fraud by abuse of position – ie the results of PACE are falsely stated and this has caused loss to CFS/ME sufferers]

4.....AND

Resources to explore biomedical physical therapies for CFS/ME have been diverted to what we know to be useless and often harmful psychological treatments.

[COMPLAINT – Fraud Act 2006 – Fraud by false representation and Fraud by abuse of position – ie the results of PACE are falsely stated and the PACE authors have gained from this] [COMPLAINT – GMP Domain 2 Safety and Quality- CBT, GET worsen CFS/ME] [COMPLAINT GPR ‘Protect from Harm’, paragraphs 15-20 - CBT, GET worsen CFS/ME] [COMPLAINT – GPR ‘Conflicts of Interest’, paragraphs 26-27 – PACE authors have gained fraudulently]

To protect doctors who do use biomedical therapies to treat PWME

I am the most investigated doctor in the history of the GMC

No patient has even complained against me

All complaints have come from other doctors, Health Authorities or the GMC

All complaints pertain to treatment recommendations which do not fall within NICE Guidelines

(The present score is Myhill 30, GMC 0. Within 1 working day of me informing the GMC that I would request a judicial review of its decision, it launched a further complaint against me that had been made by a GP 6 months previously)

PACE was funded by public money at a combined cost of nearly £5 million.

- Medical Research Council,
- The Department for Work and Pensions
- The Department of Health for England
- The Scottish Chief Scientific Office

[COMPLAINT – Fraud Act 2006 – Fraud by failing to disclose information and Fraud by abuse of position]

PWME, patient advocacy groups, academics and practitioners working with PWME knew that the PACE study could not be right!.

They demanded the release of the study design and raw data from the PACE team. The PACE team refused to release the data.

Mr Alem Matthees took this case to an Information Trial Appeal

The PACE team spent over £220,000 of public money from Queen Mary University of London to resist the Freedom of Information Act request for the raw data

Mr Matthees won his case, the raw data was released

Then the debate raged!

The raw data was reanalysed by Dr Keith Geraghty, doctor and statistician, and his findings were published in the Journal of Health Psychology Sept 2016

This paper was sent to the PACE authors for further comments

The PACE paper, the Geraghty response and the PACE author comments were sent to 40 academics (20 on each side of the debate), who were invited to submit a commentary.

All submissions were peer reviewed and judged on merit

Those which passed such scrutiny were published in the Journal of Health Psychology August 2017

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SPECIAL ISSUE: THE PACE TRIAL

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The Editor of The Journal of Health Psychology David F. Marks commented that *The PACE Trial investigators*

.....failed to engage with critics

.... demanded retraction of sections of the Geraghty paper because he had a conflict of interest.....that being because he suffered from ME

..... wanted their response not to be peer-reviewed

Marks also pointed out that the PACE Authors

...had strong allegiances to CBT and GET, treatments they had developed and promulgated

... also worked for the Government bodies that paid for the study AND were advisors to large insurance companies who had gone on record about the potential financial losses from ME being deemed a physical illness. These are clear Conflicts of Interest.

.....refused to engage in the spirit of scientific debate

..... refused to engage with PWME: *“We have no wish to enter into debates with patients”*

Craig Robinson, Mathematician, and myself went through the Journal with a toothcomb! It was clear from the multiple submissions that the PACE Authors were guilty of scientific and, by implication, financial fraud.

- On 14 January 2018 I reported the PACE Authors to the General Medical Council for multiple breaches of Good Medical Practice
- What follows are highlights of the findings of the Journal of Health Psychology together with my specific complaints to the GMC detailing breaches of Good Medical Practice and obvious examples of financial fraud.....

“Lead authors overstated the effectiveness of CBT and GET therapy by lowering thresholds they used to determine improvement. Patients discovered that the treatments tested had much lower efficacy after an information tribunal ordered the release of data from the PACE trial to a patient.....”

Once the statistical fraud had been uncovered, the PACE authors rewrote their paper. In doing so they self-diagnosed dishonesty.

[COMPLAINT - Fraud Act 2006 – Fraud by abuse of position]
[COMPLAINT - GPR ‘Research Design and Practice’, paragraphs 7-14]
[COMPLAINT GPR ‘Honesty and Integrity’, paragraphs 21-25]
[COMPLAINT GMP paragraph 67 – ‘act with honesty and integrity’]

.....the trial investigators had altered assessment thresholds after the start of the trial...

When it became clear that the trial was not getting the desired result, the PACE authors moved the goalposts in order to achieve their desired outcome!

[COMPLAINT - Fraud Act 2006 – Fraud by abuse of position] [COMPLAINT - GPR ‘Research Design and Practice’, paragraphs 7-14] [COMPLAINT GPR ‘Honesty and Integrity’, paragraphs 21-25] [COMPLAINT GMP paragraph 67 – ‘act with honesty and integrity’]

.....had applied a broad inclusion criteria, rather than strict sampling criteria.

Participants in PACE were drawn from milder cases, with more severe cases excluded.

[COMPLAINT - Fraud Act 2006 – Fraud by abuse of position]
[COMPLAINT - GPR ‘Research Design and Practice’, paragraphs 7-14]

.....and contaminated the trial by promoting the success of CBT and GET in newsletters to trial participants during the course of the trial.

Participants were told that the treatments (CBT and GET) they were receiving were very effective

[COMPLAINT - Fraud Act 2006 – Fraud by abuse of position]

[COMPLAINT - GPR ‘Research Design and Practice’, paragraphs 7-14]

[COMPLAINT – CR ‘Sharing information’, paragraphs 4-6] [COMPLAINT

– CR ‘Give information in a way people can understand’, paragraphs 7-

8]

.....some of the PACE team were in fact [also] the Cochrane reviewers [of the PACE paper].

The students marked their own papers!

[COMPLAINT - GPR 'Research Design and Practice', paragraphs 7-14] [COMPLAINT – GPR 'Conflicts of Interest', paragraphs 26-27 – some PACE authors were their own reviewers]
[COMPLAINT GPR 'Honesty and Integrity', paragraphs 21-25] [COMPLAINT GMP paragraph 67 – 'act with honesty and integrity'] [COMPLAINT – Fraud Act 2006 – Fraud by false representation and Fraud by abuse of position – ie the results of PACE are falsely stated]

Within days of the [PACE data] release.....It quickly became apparent that the improvements reported by White et al were much reduced when the original protocol thresholds were applied.the effectiveness of CBT and GET fell from the reported 59 and 61 percent to just 20 and 21 percent respectively.....the added benefit fell to 10 and 11 per cent respectively

An independent analysis clearly showed even the revamped PACE statistics were false.

CBT and GET were not effective

[COMPLAINT - GPR 'Research Design and Practice', paragraphs 7-14]
[COMPLAINT – GPR 'Conflicts of Interest', paragraphs 26-27 – some PACE authors were their own reviewers] **[COMPLAINT GPR 'Honesty and Integrity', paragraphs 21-25]** **[COMPLAINT GMP paragraph 67 – 'act with honesty and integrity']** **[COMPLAINT – Fraud Act 2006 – Fraud by false representation and Fraud by abuse of position – ie the results of PACE are falsely stated]**

.....initial gains reported at trial end (52 weeks) mostly disappeared between groups at follow up (2.5 years).....

Any benefits did not stand the test of time. Participants relapsed. Should we be surprised?

[COMPLAINT – Fraud Act 2006 – Fraud by false representation and Fraud by abuse of position – ie the results of PACE are falsely stated]

[COMPLAINT GPR ‘Honesty and Integrity’, paragraphs 21-25]

[COMPLAINT GMP paragraph 67 – ‘act with honesty and integrity’]

.....trial authors had favoured subjective self report measurement instruments over objective tests of physical function.

There were no objective measures of change

[COMPLAINT - GPR 'Research Design and Practice', paragraphs 7-14]
[COMPLAINT – Fraud Act 2006 – Fraud by false representation and Fraud by abuse of position – ie the results of PACE are falsely stated]

.....the PACE team lowered the threshold for improvement and recovery from a score of 85 on SF-36 to a score of 60 at the analysis stage.

This change meant some trial participants had reached the level required to be classified as improved or recovered at trial entry, before they had even taken any course of treatment.

[COMPLAINT - GPR 'Research Design and Practice', paragraphs 7-14]

[COMPLAINT – Fraud Act 2006 – Fraud by false representation and Fraud by abuse of position – ie the results of PACE are falsely stated]

....Much of the reported benefit in the PACE trial rested on patients' perceptions of mood and fatigue, rather than measurements of their physical improvement

[PACE] continuing to rely on subjective measures is potentially misleading and is rather like using different sets of elastic tape-measures at a Weight-Watchers meeting.

.....

[COMPLAINT - GPR 'Research Design and Practice', paragraphs 7-14]
[COMPLAINT – Fraud Act 2006 – Fraud by false representation and Fraud by abuse of position – ie the results of PACE are falsely stated]

There were many other comments from the 40 reviews which I included in the GMC complaint. These are summarised by

White and his colleagues took 5 million pounds in government funds and promised to bring back apples from the market. Instead they brought back pears, refusing to show anyone the apples they had rejected.

David Tuller, School of Public Health California

.....the PACE investigators' impartiality might reasonably be questioned. In fact they were testing their own theories of the illness

Steven Lubet Northwestern Pritzker School of Law Chicago

....there was no evidence from the [PACE] trial that patients can recover from CFS/ME as a result of either of these treatments

-one cannot conclude that these interventions [GET and CBT] are safe and risk free*
- We also know from the PACE trial itself that around 10% of patients find that CBT makes their condition “much worse” or “very much worse”*
- ...patient survey data provide compellingly consistent evidence....that for most patients GET results in worsening of symptoms, CBT is ineffective.....*

Dr Charles Shepherd:

.....the enormous amount of public money spent by the Medical Research Council and the Departments of Works and Pensions on funding the PACE trial, along with the legal costs met by Queen Mary University of London in appealing against the Freedom of Information request, merits a formal inquiry.....

What happened next?.....the rats started to jump out of the sinking ship

Dr Simon Wessely wrote “The National Elf Service”:

- *“I was not on the ship, neither as passenger or crew. I helped recruit some patients to the study from our clinic, as did many doctors, but that was as far as it went. I am not an author on the ship’s log, but I am not a neutral observer. I know a lot about how these ships sail (Everitt and Wessely, 2003).”*
- Ref - <https://www.nationalelfservice.net/other-health-conditions/chronic-fatigue-syndrome/the-pace-trial-for-chronic-fatigue-syndrome-choppy-seas-but-a-prosperous-voyage/>
- I wrote to the GMC *“It has come to my attention that Professor Sir Simon Wessely [SW] is attempting to distance himself from the discredited PACE trial. I believe this is a direct reaction to the evidence that this trial was in fact fraudulent and that the doctors involved breached so many GMC guidelines, as detailed in my complaint”.*

My evidence is as follows: Dr Wessely is

1. listed on the MRC PACE application as Core Collaborator with his CV – see exhibits 1 and 1a, extracts from a FOIA request.

2 listed in the PACE trial 2011 paper as an SMC doctor (under Acknowledgements): he treated patients, ie he was Clinical Lead of the Treatment Arm. Here is the relevant extract:

"specialist medical care doctors: Janet Andrews, Michael Broughton, Frauke Fehse, Eleanor Feldman, Janet Gray, Michael E Jones, Tara Lawn, Brian Marien, Tim Peto, Angharad Ruttley, Alastair Santhouse, Adrian Vos, and Simon Wessely." See [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(11\)60096-2/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(11)60096-2/fulltext)

3.listed in the PACE trial paper as a centre leader (under Contributors, towards the end) and as commenting on an early draft of the report (under Acknowledgements). See [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(11\)60096-2/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(11)60096-2/fulltext)

4.listed in the PACE Trial MRC Application as Core Collaborator and Director of Data Collection – see one such example – exhibit 2.

I can provide further evidence if required, but you will see that the 4 numbered points above adequately **refute SW's claim of being neither 'crew nor passenger' on the not so good ship PACE.**

Professor Peter White resigned his GMC membership days before the PACE data was forcibly released

I wrote to the GMC

Professor Peter D White [PDW] is one of the named doctors about whom this complaint is made and you have confirmed that, despite his resigning his GMC membership days before the PACE data was forcibly released following an Ombudsman ruling, he remains subject to GMC regulation.

Westminster Hall Debate 20 Feb 2018

MP Carol Monaghan stated

- ***“I think that when the full details of the trial become known, it will be considered one of the biggest medical scandals of the 21st century.”***
- ***“One wonders why the DWP would fund such a trial, unless it was seen as a way of removing people from long-term benefits and reducing the welfare bill.”***
- ***“The PACE trial was used to inform NICE guidelines, which has meant that symptoms have been disregarded, and sufferers are considered to be attention-seeking hypochondriacs or even, in the case of some female patients, hysterical.”***

.....and on the subject of conflicts of interest

- ***“The former chief medical adviser to the DWP sat on the trial’s steering committee, and ultimately the results of the trial have been used to penalise those with ME.***
- ***When we consider the relationship between key PACE investigators and major health insurance companies such as Unum, the trial takes on a far more sinister slant.***
- ***Sufferers have reported that their health insurance company would pay out only if they undertook a programme of GET— an impossible task, as the insurance giants knew”***

Further criticism of PACE ,. *“Rethinking the treatment of chronic fatigue syndrome—a reanalysis and evaluation of findings from a recent major trial of graded exercise and CBT”* was released on 21 March 2018 -Carolyn E. Wilshire Tom Kindlon, Robert Courtney, Alem Matthees, David Tuller, Keith Geraghty and Bruce Levin in *BMC Psychology*

“These findings raise serious concerns about the robustness of the claims made about the efficacy of CBT and GET. The modest treatment effects obtained on self-report measures in the PACE trial do not exceed what could be reasonably accounted for by participant reporting biases.”

Further evidence of patient harm

The GMC received 207 letters from my patients who had been harmed by GET and/or CBT

An online petition for those too ill to write achieved over 10,000 signatures

- <https://www.change.org/p/the-general-medical-council-i-am-showing-my-support-for-dr-myhill-s-complaint-to-the-gmc-about-the-pace-authors>

A series of Open Letters to the Lancet further criticising PACE

1-- AN OPEN LETTER TO DR RICHARD HORTON, EDITOR LANCET, FROM A PANEL OF EXPERTS, REGARDING PACE, THIS LETTER DATED 13 NOVEMBER 2015

This letter can also be found here - <http://www.virology.ws/2015/11/13/an-open-letter-to-dr-richard-horton-and-the-lancet/>

Please note that this letter is signed by a Panel of 6 international experts

2—AN OPEN LETTER TO DR RICHARD HORTON, EDITOR LANCET, FROM A PANEL OF EXPERTS, REGARDING PACE, THIS LETTER DATED 10 FEBRUARY 2016

This letter can also be found here - <http://www.virology.ws/2016/02/10/open-letter-lancet-again/>

Because Dr Horton failed to respond to the above letter, it was re-sent on 10 February 2016, with a further 36 signatories.

Please note that this letter is signed by a Panel of 42 international experts

3-- OPEN LETTER TO SIR ROBIN MURRAY AND DR KENNETH KENDLER OF PSYCHOLOGICAL MEDICINE, FROM A PANEL OF EXPERTS AND ORGANISATIONS, REGARDING PACE, THIS LETTER DATED 23 MARCH 2017

This letter can be found here - <http://www.virology.ws/2017/03/23/an-open-letter-to-psychological-medicine-again/>

Please note that this letter is signed by a Panel of 91 international experts and 52 international CFS/ME charities and patient groups.

Further debate in Westminster 21 June 2018

Briefing by ME Action, Action for ME, The ME Association, The ME Trust

White et al conclude that they stand firmly by the findings of the PACE trial, presumably because of their inability to understand its basic flaws.....the flaws are so egregious that it would serve well in an undergraduate textbook as an object lesson in how not to design a trial

Emeritus Professor of Medicine Jonathan Edwards

Carol Monaghan MP reported that

Professor Michael Sharpe [PACE author] had emailed her concerning her interest in ME and the PACE trial, stating that her behaviour was *'unbecoming of an MP'* [see page 7 of 54 of the Hansard transcript]

The Executive Chair of the Medical research Council Professor Fiona Watt wrote to The Times on 27 August 2018 making the assertions below. I requested of her the evidence base for such....

<https://mrc.ukri.org/news/browse/criticism-of-the-pace-trial/>

Excerpts from your letter.....require the following evidence base
<i>The Pace trial was funded following expert peer review.....</i>	Please give me the names and qualifications of ALL the expert peer reviewers together with a copy of their reviews
<i>...was overseen by an independent steering committee...</i>	Please give me the names and qualifications of ALL the members of that independent steering committee together with a copy of the deliberations of that committee
<i>....and its published findings have also been independently peer-reviewed</i>	Please give me the names and qualifications of ALL the members of those responsible for independent peer review together with a copy of their reviews
<i>Other research groups have drawn similar conclusions</i>	Please detail ALL other research groups that you have relied upon who have drawn such similar conclusions together with references to the relevant papers

An Fol response was promised me “no later than 18 Oct 2018”

On 5 November 2018 I wrote to Professor Watt “the UKRI has been unable to provide a proper evidence base for the first three of your statements and that for the fourth, the evidence base that they do provide has been heavily criticised. Effectively you have failed to substantiate the assertions made in your letter to the Times. This flags up the very real possibility that you have made these assertions with no proper evidence base. As the Executive Chair of the UKRI this is unacceptable”.

.....and I requested an Internal review of the above. This was taken forward by the MRC with the promise of a response

Despite 3 reminders and receipts of such, no proper evidence base has been forthcoming

So how did the GMC respond to these my 14 January concerns?

26 July 2018 The GMC refused to investigate my concerns.

19 Oct 2018 I pointed out several factual inaccuracies in the GMC letter.

And I requested the evidence base for its decision making

19 November 2018

The GMC reissued its 26 July 2018 letter with the necessary corrections.

It also sent me the results of my FOI search. It was a bundle of 719 pages. Contained within was no evidence base whatsoever! Some pages had been redacted

I informed the GMC that I would take that decision to the High Court for Judicial Review since it had supplied no evidence base for its decision.

3 Dec 2018

The GMC referred its decision for reconsideration back to the Rule 12 team.

The GMC informed me that the Rule 12 Team would be in contact with me “in the coming days” to allow me “to ask specific questions as part of that process”

The Rule 12 Team never got in contact with me

26 Feb 2019

AGAIN The GMC refused to investigate

Dr Gabrielle Murphy, Dr Brian Angus, Dr Maurice Murphy, Dr Michael Sharpe, Dr Timothy Peto, Dr Simon Wessley and Dr Peter Denton White

Because

“There are no grounds

8 April 2019

I applied to the High Court for Judicial Review of the GMC refusal to investigate on the grounds that:

The GMC has refused my request to release information on which it relied in its decision not to investigate the authors of the PACE study.

15 April 2019


- I reported the GMC to the Information Commissioner for failure to release its evidence base for its decision not to investigate the PACE authors

5 April: My most recent request to the MRC

- I await your response to my FoI request to supply the evidence base for assertions made by Professor Fiona Watt in the Times 21 August 2018. I have waited seven months and she has been unable to supply such. This is an untenable position for the Executive Chair of the MRC, hitherto assumed to be a scientist heading up a scientific organisation.
- On 10 May 2019 I am speaking at the Academy of Nutritional Medicine where I shall air this publicly. If you are unable to respond by then I shall have to assume that Professor Watt had no evidence base for the assertions made and this will be reported to the Press.

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Summary:



I object! The emperor is naked!

Our reanalysis shows that the emperor is naked!

My journalistic inquiry suggests the emperor has no clothes!

I and more than 100 top scientists conclude that this is obscene nudity!

And the emperor walked at a slow PACE stark naked through the city GATE.

The emperor's dress is a piece of beauty!

We prefer our definition of nudity!

The emperor's clothes are robust and colourful!

The rumours of imperial nudity are put forward by a small, vocal and very damaging group!

MAIMES Campaign (Medical Abuse in ME)

[https://www.drmyhill.co.uk/wiki/Medical_Abuse_In_ME_Sufferers_\(MAIMES\)](https://www.drmyhill.co.uk/wiki/Medical_Abuse_In_ME_Sufferers_(MAIMES))

This webpage has received 2,548,290 hits to date

AIM: A public Inquiry into the medical Abuse of PWME

WHAT YOU CAN DO: Sign up your local MP to support our aim

HOW to do this detailed on the webpage above

So far we have 157 MPs who have shown interest

38 have signed up **ANTONIAZZI Tonia CABLE Sir Vince CAMPBELL Ronnie COAKER Vernon DAVEY Edward DAVIES Chris DAY Martyn DONELAN Michelle DREW David GEORGE Ruth GOODWILL Robert HAIGH Louise HARRINGTON Richard HEPBURN Stephen HOLLINGBERY George HOYLE Sir indsay HUDDLESTON Nigel LAKE Ben LAING Eleanor LAMB Norman LAVERY Ian LEWELL-BUCK Emma LYNCH Holly McGUINN Conor NEULANDS Gavin O'MARA Jared OWEN Albert SHANNON Jim SHEERMAN Barry SIMPSON David SIMPSON Keith STEWART Bob STRINGER Graham WALKER Thelma WARBURTON David WEST Catherine WHATELY Helen WRAGG William**