

The BMJ

Richard Smith: QMUL and King's college should release data from the PACE trial

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Several times when I was the editor of *The BMJ* the journal was declared the worst medical journal in the world by an ME association. Sometimes we shared the award with *The Lancet*. At another time my wife was telephoned and told that if I didn't take a different line on ME (which is better known as chronic fatigue syndrome) then "something horrible" would happen to me. So I know something about the emotion that surrounds chronic fatigue syndrome, but I still think that Queen Mary College London (QMUL) and King's College London are making a serious mistake in refusing to release the data behind a controversial trial of treatments for chronic fatigue syndrome.

The emotion stems from sufferers from the condition resenting greatly the idea that it may have psychological causes with the stigma that implies. The resentment seems to be that psychological problems are not seen "real" in the way that physical ones are and that they may result from "moral weakness" rather than a morally neutral virus. I've always disliked the stigma that goes with mental illness and any idea that it is not as real or serious as physical illness. But at the same time neither I nor *The BMJ* had a line on the causes or treatments of chronic fatigue syndrome. We simply published what we thought was the best research on the subject that we were sent and commissioned material from the people we thought best informed on the subject. It's true that several of those people were psychiatrists, but that didn't mean that we thought chronic fatigue syndrome to be a psychological condition. We had open minds.

The trial that has evoked huge controversy—a Wikipedia page filled with criticisms and even questions in parliament—is called the PACE trial and was published in *The Lancet* in 2011. The trial compared adaptive pacing therapy, cognitive behaviour therapy, graded exercise therapy, and specialist medical care for chronic fatigue syndrome in 641 patients. Its conclusion was that cognitive behaviour therapy and graded exercise therapy moderately improved outcomes if added to specialist medical care but adaptive pacing therapy did not. These findings conflict with what many sufferers believe—that adaptive pacing therapy helps, but cognitive behaviour therapy and graded exercise therapy may lead to deterioration.

Many questions were raised about the validity of the trial, but the Medical Research Council, which funded the trial, and *The Lancet* stood by the trial. The authors have been not only criticised but abused.

In 2012 the cost effectiveness study from the PACE trial was published in PLOS One and found that cognitive behavioural therapy was the most cost effective treatment followed by graded exercise therapy and that adaptive pacing therapy was probably less cost effective than specialist medical care alone. Long term results were published in *Lancet Psychiatry* this year and showed continuing benefit from cognitive behavioural therapy and graded exercise therapy.

Kings College London and Queen Mary University of London (QMUL) own the raw data of the trials as they are the employers of the researchers. QMUL has already been asked to release the data under the Freedom of Information Act but declined, arguing that among other things that it would be possible to identify individual patients. The complainant appealed to the Information Commissioner's Office, which dismissed the university's arguments and ordered that the data be released. QMUL had 28 days to appeal the ruling and has presumably appealed.

In the meantime, James Coyne, a professor of psychology and a blogger for PLOS, has asked King's College to release the data from the PLOS One study "consistent with the PLOS journals' data sharing policies." He wrote that he was "interested in in

reproducing your empirical results, as well as conducting some additional exploratory sensitivity analyses.” These are wholly legitimate scientific practices.

King’s College on 11 December wrote to Coyne saying that it would not release the data because they considered his request “vexatious”; The Freedom of Information Act has a clause that allows a public body to decline to release data for this reason. The King’s letter is long and legalistic and comes from the Information Compliance Officer.

QMUL and King’s are making a mistake. As somebody who has been abused by people who care passionately about chronic fatigue syndrome, I can sympathise with their decision, but I still think it wrong.

Firstly, the inevitable conclusion is that they have something to hide. This is the age of transparency, and, whether people like it or not, what is not transparent is assumed to be wrong, corrupt, or biased until proved otherwise. I think of a scene from Not the 9 O’Clock News where we see pictures of a house with its roof blown off by a hurricane. “We rang the Gas Board, and they answered “no comment.” We are led to think that the Gas Board is responsible for the hurricane.

Secondly, QMUL and King’s are going against basic scientific principles. In Popperian science we pose falsifiable hypotheses and then do all we can to tear them down. Hypothesis are never true, they are simply not falsified. This process should include other scientists being able to manipulate the data. Now it is true that “if you torture the data enough they will confess,” and those who disbelieve the results of the PACE trials will probably be able to come up with analyses that contradict the results of the trial authors.

But critics finding results that contradict those of the authors doesn’t mean they are right. Supporters of the original authors and neutral scientists can also work with the data. It’s at this point that I always wheel out my favourite quote from John Milton: “Truth was never put to the worse in a free and open encounter.... It is not impossible that she [truth] may have more shapes than one.... If it come to prohibiting, there is not ought more likely to be prohibited than truth itself, whose first appearance to our eyes bleared and dimmed with prejudice and custom is more unsightly and implausible than many errors....Where there is much desire to learn there of necessity will be much arguing, much writing, many opinions; for opinion in good men is but knowledge in the making.”

The refusal of two universities to release data relates to the current debate within universities over freedom of speech. In several universities students have stopped the appearance of speakers who have views—on, for example Islam or transgender people—that the students don’t like. This is a dangerous development. Democracies depend on free speech, and universities should be bastions of free speech—and the whole point and value of free speech is that you hear views that may disgust, distress, and anger you.

Finally, the universities may have failed to notice that customs around sharing data in science are changing rapidly. We have recognised that huge value is lost by scientists taking their datasets to the grave with them. More and more funders of research require the release of data they have funded, and journals like F1000Research require authors not just to make their data available on request but actually to submit their data with their study so that anybody can use the data either to confirm or refute the study or do other studies.

I fear that QMUL and King’s are defending the indefensible and like King Canute failing to stop a tide that is coming in fast.

Competing interest: *RS was on the board of the Public Library of Science for eight years and is consulting for a fee for F1000Research.*

Richard Smith was the editor of *The BMJ* until 2004.

Correction: *The text of this blog was changed on 4 February 2016. Previously it said that “Several times when I was the editor of The BMJ the journal was declared the worst medical journal in the world by the ME (Myalgic Encephalomyelitis) Association.” The MEA pointed out that I was mistaken in saying this and that they never used this description. My apologies to the MEA.*

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Jonathan Edwards • 10 months ago

I entirely agree with the proposal. We need more scientific and medical colleagues adding their voices to this. I think it is actually a pity even to mention the expression of emotion by patients. It simply reflects exasperation when faced with what is very bad science that purports to provide a solution to the problem. I think enough people have agreed for it to be pretty much a consensus, with the exception of the authors, that the PACE trial, as an unblinded trial with subjective endpoints, fails the most basic test of reliability. The fact that the MRC and Lancet have stood by it tells us nothing other than reminding us of the motto 'nullis in verba'. I assume that Richard Smith has read the paper and has seen for himself that it is uninterpretable.

This is a Canute case, indeed. We just need the tide of colleagues to start flowing in - and with respect, stop the discussion about patients' emotive response.

Yours sincerely,

Jonathan Edwards

Professor Emeritus

Department of Medicine

University College London

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Sasha • 10 months ago

Thank you for your thoughtful and timely post on this topic. I am sorry that you have been on the receiving end of abuse in relation to CFS. As one of the 250,000 ME/CFS patients in this country who have not subjected anyone to abuse and would never dream of doing so, I find it appalling that this should happen: but as you will appreciate, in such a large population of patients, we will have our fair share of those with personality disorders, just as the population of patients with cancer, arthritis or multiple sclerosis will.

You write that “The emotion stems from sufferers from the condition resenting greatly the idea that it may have psychological causes with the stigma that implies” but I think you misunderstand why ME/CFS patients resist a psychological diagnosis. It’s simply because it’s the wrong diagnosis, and if you have an organic disease and only receive treatment directed at a psychological cause, you won’t get better: and research into your condition will be misdirected down a useless avenue.

The prestigious US Institute of Medicine spent a year reviewing the research evidence and in its report emphasised that ME/CFS is “is a medical — not a psychiatric or psychological — illness”.

<http://www.ncbi.nlm.nih.gov/pu...>

I’d like to see the UK establishment catch up.

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Carolyn Wilshire • 10 months ago

Richard, I completely agree with your overall message, but it includes some things a scientist would never say:

"Now it is true that "if you torture the data enough they will confess," and those who disbelieve the results of the PACE trials will probably be able to come up with analyses that contradict the results of the trial authors. But critics finding results that contradict those of the authors doesn't mean they are right. Supporters of the original authors and neutral scientists can also work with the data"

Surely "disbelieving the results" should not come into it! The conclusions of the study are either supported by the data, or they are not.

I'm also troubled by your concept of "critics" and "neutral scientists". First of all, both are required for good science. Second, we need to be careful who we describe as "neutral". Anyone with a strong belief or an investment in the conceptual framework underlying this study is clearly not neutral.

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John Peters • 10 months ago

Thank you for an interesting blog. As an ME patient, I recognize your attempted balance. I very much welcome your support for the release of data, though, as your reasons make clear, the release is more about good scientific practice than it is about ME.

"At another time my wife was telephoned and told that if I didn't take a different line on ME (which is better known as chronic fatigue syndrome) then "something horrible" would happen to me."

That's disgraceful. I'm sure the vast majority of patients would agree with me that such behaviour is appalling.

"...sufferers from the condition resenting greatly the idea that it may have psychological causes with the stigma that implies. The resentment seems to be that psychological problems are not seen "real" in the way that physical ones are and that they may result from "moral weakness" rather than a morally neutral virus."

That is a misrepresentation. We all know that the illness has been recognized as real for 25 years. Nor are we concerned about the stigma of mental illness. Many ME patients have co-morbid mental health problems. I, and I know many others, support the attempts to reduce the

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Simone → John Peters • 10 months ago

Well said, John. Thank you 😊



uab9876 · 10 months ago

I write this not as a ME patient but as a carer for someone suffering and practically housebound from ME. It feels like the most stigmatized illness so many people seem to just think lazy and these views are backed up by the tone of much of the press coverage of this most devastating disease. These views extend to doctors to quote one 'I don't know why she can't just pull herself together'. Whilst other coverage such as this article paint those who suffer with ME as aggressive and irrational. My experience is neither I watch my child try so hard to do even small things, sometimes she succeeds but often cannot manage what most people would consider simple routine activities. There is no aggression or irrationality even though she is a teenager!

As a carer with a research and technical background I have, of course, taken an interest in the medical literature and there are some fascinating studies. In taking an interest I have become involved on an internet forum where the latest papers are discussed and critiqued. That is not just the psychological literature that gets critiqued and carefully analyzed but also the literature looking at physical causes. Whilst as with any group there is a mix of different personalities the vast majority of people are kind, caring and take a very analytic view towards the science. Points made on the forum are intelligent and stimulating with patients aiming to understand the research and the disease and perhaps that is why researchers are starting to get involved. For an online community it is remarkably friendly; I found facebook very off putting and I've seen

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Sasha · 10 months ago

You mentioned, "Many questions were raised about the validity of the trial, but the Medical Research Council, which funded the trial, and The Lancet stood by the trial. The authors have been not only criticised but abused."

I think it's very important to separate criticism from abuse; and very important not to assume that because the MRC or Lancet fail to act in response to criticism, that the criticism must be invalid.

A case in point: in PACE, the protocol-specified analyses for the main outcome measures and for defining "recovery" were abandoned partway through the trial and replaced, even though the trial was open-label and such an action couldn't be properly blind.

The new "recovery" threshold for physical function (SF-36) was so low that it was below the level of trial entry: that is, patients could get worse during the trial and be classed as having recovered their physical function. This new threshold (60/100) is close to the mean for Class II congestive heart failure (57/100).

This is just one of the many problems in PACE. You might like to read the background pages of this petition. now 11.000-strong. which calls on the Lancet to retract claims that CBT and

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Mary Schweitzer • 10 months ago

Thank you for writing this.

As both a scholar and a patient, I was appalled by the discrepancies in what should have been a pretty simple study, if CBT/GET was as effective as White, Wessely, and Sharpe have claimed for two decades.

I am very sorry that there was anyone in the patient community who would have phoned your wife with a message like that. Most of us are not abusive. The problem is that these authors have conflated questions about their research (and requests for data) with what I would call abuse. What happened to your wife WAS abusive. When someone questions research, as I just did, that is not abuse.

You may be unaware of a series of studies that have been conducted using CPET (cardio-pulmonary exercise testing), a method long used by cardiologists. The patient wears a mask so a machine can measure the use of oxygen and amount of carbon dioxide expelled while the patient exercises to maximum effort, either on a bicycle or a treadmill.

Researchers in California found that when compared to a cohort of deconditioned, but healthy, normal controls, patients with ME/CFS (Canadian definition 2003) scored the same on the first

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Zach • 10 months ago

The blog suggests: "The emotion stems from sufferers from the condition resenting greatly the idea that it may have psychological causes with the stigma that implies. The resentment seems to be that psychological problems are not seen "real" in the way that physical ones are and that they may result from "moral weakness" rather than a morally neutral virus."

This is an interesting discussion, but it unfortunately fails to reflect the realities of an exceptionally nuanced and complex issue. I suspect that no patients were consulted when writing these claims as they do not reflect the central concerns of patients.

The PACE trial interventions were not designed to treat a psychological illness. Instead the trial interventions were based on a hypothesis that ME/CFS is not actually an illness, but is simply a set of illness beliefs. These illness beliefs, it is claimed, lead to maladaptive behaviour and deconditioning which perpetuate a set of symptoms.

There are many reasons why such hypotheses are widely considered to be inappropriate. Too many to discuss here. But, in a way, these are not controversial ideas because very few patients and no patient organisations (that I am aware of) give them any credence whatsoever

and no patient organisations (that I am aware of) give them any credence whatsoever.

Indeed, a recent highly influential and respected Institutes of Medicine report on ME/CFS,

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Helle Rasmussen • 10 months ago

Retraction Watch about the PACE trial, with interesting comments: PLOS ONE issues editor's note over controversial chronic fatigue syndrome research <http://retractionwatch.com/201...>

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Stephen Wright • 10 months ago

Hi Richard

I'm heartened to hear your comments regarding the release of the PACE trial data. I agree with some of your points regarding transparency. Im sorry to hear that whilst at the BMJ your wife received an unpleasant and threatening phone call. As an ME/CFS patient for the last 10 years and Biology graduate, it is very disappointing to hear of researchers and scientists receiving threats.

Unfortunately many patients myself included are very angry at the way ME/CFS has been dealt with over the last two-three decades, having seen years or decades go by in debilitating pain and exhaustion every day with no effective help in infact - stigmatization. Sadly amongst the thousands and thousands of people suffering severe loss of life, there will I guess be a few bad apples who cross the line from protest or criticism to more nasty behavior.

The claim that patients with ME/CFS are anti mental illness or somehow against the attribution of it is false. This is a game that has been played to deflect criticism from the ineffective treatments of GET and CBT, and reaction against it. Yes patients with a severe (WHO defined neurological) illness do not like to have as their only treatment, one which tells you the symptoms are not as bad as you think they are. Its not much use when you are so ill you are

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Helle Rasmussen • 10 months ago

The PACE trial is being criticized for its obviously flawed science.

See David Tuller's articles "Trial by error":

<http://www.virology.ws/2015/11...>

<http://www.virology.ws/2015/10...>

<http://www.virology.ws/2015/10...>

The American IOM report from 2015, based on more than 9000 scientific articles, stated that "ME/CFS is a serious, chronic, complex, multisystem disease that frequently and dramatically

limits the activities of affected patients. In its most severe form, this disease can consume the lives of those whom it afflicts."

<http://www.iom.edu/Reports/201...>

<https://www.iom.edu/~media/Fi...>

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Giles • 10 months ago

Mr Smith, firstly thank you for publicly standing up for integrity and openness in medical science and saying that the PACE trial data should be released.

However, your assertion that "the emotion surrounding CFS" is caused by patients rejecting the stigma of a mental illness is laughably fallacious!! Having spoken to many hundreds of ME/CFS sufferers in the UK and worldwide, I would suggest that most would far rather have the stigma of a mental illness, rather than the much worse stigma usually associated with their disease.

Patients are actually angry partly because M.E has been classified by the WHO as neurological since 1969, and pretty much all the credible evidence demonstrates that the predisposing factors are predominantly physiological, the triggers are predominantly physiological, the pathologies are predominantly physiological, the symptoms are predominantly physiological, and (arguably pending a review of the PACE trial) the most effective treatments are predominantly physiological.

However, they are most angry that the treatment they are given has severely disabled countless thousands of patients, making them bed-bound even for decades, and on top of that, that the abuse they receive all too often from medics, the media, and society, is appalling, and far, far beyond any abuse of which you or your colleagues could justifiably claim to be victims

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marmite234 • 10 months ago

"The emotion stems from sufferers from the condition resenting greatly the idea that it may have psychological causes with the stigma that implies. The resentment seems to be that psychological problems are not seen "real" in the way that physical ones are and that they may result from "moral weakness" rather than a morally neutral virus."

Why would you pretend to know this? What other patient group would you stigmatise in this way?

Maybe patients just dislike being manipulated with misleading claims about the efficacy of treatments? Homeopaths complain about being harassed by 'militant sceptics' too. If a trial to assess the efficacy of homeopathy had been carried out in the way the PACE trial was, do you think that anyone would respect the researcher's results? That such poor quality work is widely seen as acceptable for psychosocial interventions reflects the real problem with stigma and mental health: too often claims being made to patients are assessed to a lower evidentiary

mental health. too often claims being made to patients are assessed to a lower evidentiary standard and within a culture that can view 'positive' claims about treatments and prognosis as a part of patient's 'care', but honesty as a form of 'therapeutic nihilism'.

This blog post provides an excellent illustration of why open data is needed. Many of those in positions of authority are so comfortable with their own prejudices and biases that they feel no

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Jenni • 10 months ago

I have ME and object to the PACE trial. But not on the grounds that I don't wish to be thought of as having a mental health condition because I'm worried about the stigma. I don't want to be labelled and treated as though I have a condition which I don't in fact have. So I also wouldn't want to be labelled and treated as though I have a heart condition (my ME causes orthostatic intolerance, which includes palpitations and raised heart rate on standing) - because I don't.

The PACE trial used a seriously flawed criteria for selection of participants, methodology and changed its success criteria part way through, so it was possible to be deemed 'ill' at the beginning and 'recovered' at the end while remaining the same on a test for functional disability. (1)

In other countries (US and Norway) bio-medical research has identified physical differences in the brains(2) of people with ME and in the way their immune systems operate(3) and their muscles process oxygen(4).

In Norway, two clinical trials (5) have found that a cancer drug which suppresses the immune system can move over 60% of ME patients into remission. Compare this rate of success with that of CBT /GET, even if you believe everything in the PACE trial. The Norway government apologised for their mistreatment of ME patients in light of this research(6)

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clark ellis • 10 months ago

I agree with your calls for transparency. As a patient I just want access to the data so that the most can be wrought from the research and conclusions can be fairly tested. It doesn't seem at all unreasonable to me as this was paid for with a lot of public money and I am sure the authors have nothing to hide so I honestly don't understand that resistance. I don't think it can be explained by one or a handful of people abusing the authors over the years though, I am sure that the authors appreciate that there are many tens of thousands of patients in this country with ME/CFS who are normal, decent people like everyone else and I doubt they would withhold the data from the majority just because of isolated incidents of abuse.

It is inaccurate to say ME/CFS patients believe mental health is inferior to, or less real than, physical health, or worried that other people may hold this stigma about mental health were

they to be labelled as having a psychological illness. I his claim misrepresents me as a patient, so I want to explain what it is really about from my point of view. The issue is rather that ME/CFS, like other diseases with non-psychological aetiology and symptoms, such as cancer, ought to be researched and treated accordingly. And that core psychological treatments would be inappropriate for such a disease, in the same was as chemotherapy would not be an appropriate treatment for mental health illnesses such as depression. Rather than an emotional response, it is a logical one.

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Dr Charles Shepherd · 10 months ago

Five quick points:

1 Richard Smith is mistaken when he states that The ME Association (MEA) has 'several times' described the BMJ as the 'worst medical journal in the world'

Yes, The MEA has been very critical for a considerable period of time on the way in which the BMJ has covered the subject of ME/CFS, and the choice of people it has commissioned to provide material and editorial comment on the illness. But we have never used this description.

In fact, I was very happy to ask Fiona Godlee, currently editor in chief at the BMJ, to chair the meeting at the Royal Society of Medicine on controversies surrounding ME/CFS that I helpeed to organise earlier this year:

<http://www.meassociation.org.u...>

I think an apology would therefore be appropriate

2 Having worked in hospital psychiatry, I know that mental illness is just as real and horrible as physical illness.

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Milo Paradiso · 10 months ago

Mr Smith. i am sorry you and your wife have received threats from patients. We all know that violence or threats is never acceptable. As a patient with ME, the stigma, horrible science and influence of the psych lobby is horrendous. Patients fight because they know this illness is not psychiatric, and not a figment of their imagination. most have an infectious onset.

I appreciate very much you take the side of open access to data and that you take the side of good science, because it's the way to go.

I would like to invite you to read that David Tuller serie on the methodology woes of the PACE trial <http://www.virology.ws/2015/10....> Dr Tuller can explain it much better than me.

I would also like to point out that the lomaterm follow-up of the PACE trial vielded no difference

in between groups, but the results are invalidated in the fact that patients jumped treatments, and yet the media portrayed a very different interpretation of this paper.

As a patient and former health care professional, I know that science has much better to offer us the patients. Biomedical research has not been funded because of the pace trial and because of the Psych lobby who have maintained CBT and GET is the way to go. Patients know that these approaches are not only useless, they are harmful.

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stq • 10 months ago

"The emotion stems from sufferers from the condition resenting greatly the idea that it may have psychological causes with the stigma that implies."

No, this is not correct. The issue is nothing to do with the "stigma" of mental illness, despite this claim constantly being pushed upon sufferers, it is really not where the problem lies at all.

The issue is poor science and a lack of decent research. Couple that with the drive to force CBT/GET onto people for whom these "treatments" in most cases actually worsen the condition and yes, you will have resentment when we see the fraud that is PACE continually trumpeted as a cure, and ME sufferers slandered as "harrasers" and bigots who just can't get over mental health stigma.

The establishment is very, very wrong on this, the science will out in the end, but people continue to suffer serious ill health and disability meanwhile.

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Oldfarticus • 10 months ago

"The emotion stems from sufferers from the condition resenting greatly the idea that it may have psychological causes with the stigma that implies. The resentment seems to be that psychological problems are not seen "real" in the way that physical ones are and that they may result from "moral weakness" rather than a morally neutral virus."

That is quite an alarming generalisation. As an ME/CFS patient, I have never seen psychological problems as 'not real'. Initially when I was diagnosed, I tried psychological treatments on three occasions, each time suffering worsened symptoms afterwards (as so many ME/CFS patients do). It was ONLY at this point that I began to question the efficacy of these treatments and the nature of my diagnosis.

I'm pleased that you support the data being released, but perhaps you would like to address the many passionate ME/CFS patients who have neither harassed or abused you and perhaps refrain from misrepresenting and generalising our beliefs.

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Victor • 10 months ago

Thank you for writing this article, Richard. Let's hope that reason prevails and QMUL and King's release the data without further ado.

I feel I need to correct a popular misconception that you have disappointingly thought fit to repeat, viz. that people with ME/CFS "resent greatly the idea that it may have psychological causes with the stigma that implies" and that their resentment seems to be founded on a belief that "psychological problems are not seen as 'real' in the way that physical ones are".

I've met many people with a diagnosis of ME/CFS, but not one of them has ever intimated to me that they resent the attribution of their condition to psychological causes on the grounds that "psychological problems are not seen as 'real' in the way that physical ones are". What they have said, practically unanimously, is that they resent the attribution of their condition to psychological causes on the grounds that their condition, according to their privileged experience of it, does not have a psychological cause.

The distinction is crucial, as I hope you can see.

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Sasha • 10 months ago

Some more, very heavy-duty scientists have today requested PACE data from QMUL under the Freedom of Information Act. They include Professor Ronald Davis of Stanford University, who is world-famous for his work in genetics that made possible the Human Genome Project:

<http://www.virology.ws/2015/12...>

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Paradigm Change • 10 months ago

With few exceptions, the ME patients I know are reasonable people and want desperately to improve and to be able to exercise again without negative consequence.

If the therapies indicated by the PACE trials and related studies were effective, then those patients would have no problem pursuing those therapies, from what I have seen.

The problem is that the results of the studies - all of which have severe methodological problems - are not consistent either with research from other scientists, with the observations of physicians specializing in the disease, or with patients' own personal experiences.

Here is a summary of more than two dozen studies suggesting different conclusions about exercise for these patients:

<http://paradigmchange.me/exerc...>

Here is a summary of comments about exercise from more than thirty clinicians and researchers

specializing in the disease.

<http://paradigmchange.me/exerc...>

Thank you very much for writing about this topic.

Lisa Petrisson, Ph.D.

Executive Director

Paradigm Change

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Sasha • 10 months ago

You mentioned, “Finally, the universities may have failed to notice that customs around sharing data in science are changing rapidly... More and more funders of research require the release of data they have funded, and journals like F1000Research require authors not just to make their data available on request but actually to submit their data with their study so that anybody can use the data either to confirm or refute the study or do other studies.”

These are very welcome developments. PACE cost £5 million of taxpayer’s money and it is extraordinary that (appropriately anonymised) data from such a trial is not regarded as a public good. As you say, “QMUL and King’s are making a mistake... the inevitable conclusion is that they have something to hide.” QMUL and King’s are not doing PACE, taxpayers, clinicians, researchers or patients any favours by keeping the data locked away.

You said, “I fear that QMUL and King’s are defending the indefensible and like King Canute failing to stop a tide that is coming in fast.”

I agree. Thank you for supporting patients who just want (and deserve) good scientific practice applied to PACE.

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Madeline • 10 months ago

I don't believe that any abuse the author has encountered can be anywhere near as harmful as the years of neglect that people with ME have experienced from the medical profession. There has been an accepted institutional bigotry towards this condition for far too long. No-one with ME is offended by psychological treatments because they fear a stigma of a mental health diagnosis. They are offended because it is wrong, and therefore it does not work. Every day that it does not work is another day of my life which is being wasted for me, by people who will not listen to what I have to tell them about my own body. In 1996 I had a viral infection to which my body reacted vigorously, confirmed by very high white blood cell counts in blood tests for years after. I never recovered. I remain ill, and will remain ill, until science looks into the biological cause, effect and cure for ME. In the USA, this is a physical disease with a commitment to biological research from now on. In the UK, I am told that I have a mental illness, and that I fear a stigma if I object. It does not work because it is not correct.

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Trish Davis · 10 months ago

Dear Richard Smith,

Thank you for standing up for good science, which must always be willing to be tested by the full disclosure of data so that others can check the analysis.

I have a dream...

I have a dream that influential people like you will go the next step in good science, and approach the topic of ME research with a completely open mind. Are you prepared to look at the possibility that some of your assumptions may be wrong and to take a fresh look at all aspects of ME research, physical as well as psychological?

Remember the drama of the discovery that stomach ulcers were not due to stress after all, but to an infection. The scientist who discovered this was prepared to think the unthinkable, to have a completely open mind and to look at the evidence. That is how great science happens.

Are you bold and open minded enough to take that step? If so, I suggest a good place to start is with David Tuller's series of blog posts as signposted by others. Then do a thorough search for published papers on the cardiac, neurological, metabolic, muscular, endocrine, immunological research that has been going on all over the world into ME.

I have a dream...

Be bold.

Think it possible you are have been misled.

[see more](#)

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Peter Trehitt · 10 months ago

Thank you Richard Smith for entering this debate in a public forum. Firstly, along with other commentators, I find it heartening that these issues are now being debated by more than just the ME community.

Firstly I want to express my abhorrence of any personal attacks, abuse or threats. It is not acceptable that you and your family were subject to this. I hope you raised this with the Police and they took appropriate action. It is good you cited this concrete example of the unacceptable telephone threat to your wife, as the PACE researchers so often raise the issue of threats and abuse in response to any criticism without out any confirming evidence, making it hard to evaluate how reasonable they are being or if it has become a tactic for avoiding rational criticism.

However, I can not agree with your assumption that ME/CFS suffers respond emotionally because we resent the 'stigma of mental illness'. Where is the evidence for this? There are many other possible explanations for an emotional response:

- the disease can take people's careers, their homes, their pastimes, their independence and can severely compromise personal relationships;
- suffers are still regularly disbelieved and even abused by health professionals and benefits

[see more](#)

3 ^ | v • Reply • Share ›



Peter Trehwitt → Peter Trehwitt • 10 months ago

Have several times tried to correct an error in my comment above but the 'edit' just seems to get lost.

The sentence "Emotional does inevitably mean irrational" should read "Emotional does not inevitably mean irrational". Apologies for the slip.

^ | v • Reply • Share ›



Zach • 10 months ago

Thank you for this interesting blog. The issue of transparency and access to trial data is widely understood. Usually such discussions relate to big-pharma, but in this case we are discussing publicly funded data held by a public institution.

It does not seem controversial that patients are asking for access to the data. ME/CFS patients simply wish to have access to this publicly funded data that has a direct impact on their health care.

Patients and their clinicians need to be able to assess the interventions for themselves.

The PACE trial is high-profile, and has a major impact on health care policy and on the attitudes of health care workers and the wider public. It will continue to have an impact on patients' lives directly and indirectly, so it is no surprise that it has attracted attention. For £5m of public money, it seems like rather an oversight not to have planned for public scrutiny.

The PACE literature has so far failed to publish the primary analyses, as set out in the trial protocol. Instead, the published primary and recovery analyses are post-hoc. The recovery analysis is obviously problematic, even to a casual observer, as participants could deteriorate on physical function and be declared recovered. Making the data available will answer many

[see more](#)

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Susan Hall • 10 months ago

I am a person who has the diagnosis of CFS who values psychology. I have put time into helping myself through the help of professional psychologists and have gained from this immensely. I still suffer from the symptoms of CFS which have changed over the years but have not been relieved by the psychological work I have done. What is difficult for me now is the fact that science is not giving me clarity on whether exercise is beneficial or harmful. I welcome more investigation being carried out on the data from the PACE Trial so that the science behind it can be either validated or discounted.

2 ^ | v • Reply • Share ›



disquietingly → Susan Hall • 10 months ago

A new PLOS ONE paper shows

"ME/CFS patients had large changes in their symptoms of pain, fatigue, and confusion at various times post-exercise compared to controls".

This correlated with

"...significant changes in the abundance of major bacterial phyla in the gut in ME/CFS patients not observed in healthy controls. In addition, compared to controls clearance of bacteria from the blood was delayed in ME/CFS patients following exercise. These findings suggest a role for an altered gut microbiome and increased bacterial translocation following exercise in ME/CFS patients that may account for the profound post-exertional malaise experienced by ME/CFS patients."

<http://journals.plos.org/ploso...>

1 ^ | v • Reply • Share ›



disquietingly → Susan Hall • 10 months ago

The uncertainty about exercise will remain whatever happens to the PACE data. PACE reported low levels of harm from GET. Patient surveys report high levels of harm. Both analyses may be biased, for different reasons. Meanwhile, the NICE guidelines recommending GET are not due for review any time soon. Patients, carers and clinicians need a neutral forum where they can meet on equal terms to formulate the most important unanswered questions about treatments. The Priority Setting Partnerships organised by the James Lind Alliance might be suitable.

1 ^ | v • Reply • Share ›



esthersiebert • 10 months ago

I am very sorry to learn that your wife received such a terrible threat and that several ME/CFS caregivers and/or patients have struck out at you and others in the UK regarding their support of the PACE studies. As mentioned below, it is important to distinguish between unconscionable threats and substantive criticism. And as an ME/CFS patient for thirty years in the US, I have not heard of such threats being issued here though there are no doubt many instances of angry verbal confrontations.

Personally I and probably many of the up to 1 million patients in the US would have welcomed a psychological diagnosis if it had come with valid treatments and methods to show us how to recover. Alas, though we questioned our own sanity at times after being told so often that it was "all in our head," we had to face the reality that we had a medical biological illness for which the only treatment was rest and pacing as best we could. And that this devastating debilitating illness would rob us of the rest of our lives.

The damage the PACE studies have done and why they need to be independently reviewed is that they essentially stopped biomedical research in the UK. What I don't understand, however,

is how and why the medical establishment in England ignored the studies reviewed in the IOM report linked in a comment below for so long? I've always supported a single payer health system but now I wonder if one becomes bogged down in dogma which can't be refuted in any way?

2 ^ | v • Reply • Share ›



I dont hate you • 10 months ago

This idea that M.E patients resent the stigma of mental illness is idiotic at best and disingenuous at worst.

It completely ignored that some of us already have experienced mental illness or had experience of it. I have no problem being considered to have a mental illness if that was the cause. M.E patients are more likely to be sympathetic because of the stigma of M.E.

The tide has turned, hanging onto that view now is just embarrassing quite frankly. I can't believe so called educated people still hold it. It is amusing to me though.

Over thirty years a small group of psychologists have had the M.E football to kick around. They have no results to show for it other than a floored Pace trial and a lot of very suspicious behavior, that is very damaging to the reputation of mental health services. It is quite a concern really.

2 ^ | v • Reply • Share ›



Dr Charles Shepherd • 9 months ago

Dear Dr Smith

It is now over a month since I sent a reply to this blog item - see below

I pointed out that your opening sentence

'Several times when I was the editor of The BMJ the journal was declared the worst medical journal in the world by the ME (Myalgic Encephalomyelitis) Association.'

was inaccurate and therefore requested an apology and retraction for what is a derogatory statement about the MEA.

I assume that you read your own blog and the comments it produces

I am therefore surprised and disappointed that you have not responded

A prompt response would now be appreciated

If not, I will pursue an apology and retraction through other routes

Dr Charles Shepherd

[see more](#)

1 ^ | v • Reply • Share ›



Peter Trehitt • 10 months ago

Over the last couple of weeks I have pondered whether it is always reasonable to have an 'open mind'. The above post states:

"But at the same time neither I nor The BMJ had a line on the causes or treatments of chronic fatigue syndrome. We simply published what we thought was the best research on the subject that we were sent and commissioned material from the people we thought best informed on the subject. It's true that several of those people were psychiatrists, but that didn't mean that we thought chronic fatigue syndrome to be a psychological condition. We had open minds."

On the surface it seems reasonable to advocate an open mind, but is this always rational. The PACE study is based on an hypothesis, untested by the researchers, that ME/CFS is a persistence of inappropriate illness behaviour based on false cognitions. Given the number of peer reviewed studies world wide indicating ongoing physiological and/or neurological abnormalities in ME/CFS are well into the thousands, is it still rational to give equal weight to theories based on a psychological genesis? I would argue this is about as reasonable as a biologist giving equal weight to creationist as well as Darwinian theories of evolution. The world wide research findings certainly suggests it is now hardly rational to maintain an open mind on this question.

[see more](#)

1 ^ | v • [Reply](#) • [Share](#) ›



Robert Morley • 10 months ago

Thank you for this post, Richard, but you seem to have a misguided impression of why ME/CFS patients disagree with the results of this study. We don't disagree with it because we "[resent] greatly the idea that it may have psychological causes with the stigma that implies", we resent it because we KNOW that that's simply not the case. It's as ridiculous to me to say that my condition is psychological as it is to tell me that I'm imagining I have a broken arm, and that that's actually a psychological condition as well.

Let me be clear here: I suffer no stigma from the idea that I might have a psychological condition. I have Asperger's and ADD. While perhaps not as stigmatized as other "more psychological" conditions, they are psychological conditions nevertheless and I'm quite comfortable telling the world that I have them. I am equally comfortable telling the world that I have ME/CFS...and that it is in no way psychological.

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timothy sorensen • 10 months ago

Hear! Hear!

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DerekH • a month ago



By the authors' own (very belated) admission, the protocol change halfway through the study increased its apparent effectiveness by at least a factor of three (from 20% "recovery" to 60%). Third-party analysis has found that under the original protocol, the study would have had no statistically significant results at all. It's disappointing that the PACE authors have spent so much time and money (more than a million pounds, according to Lancet) fighting the release of this information and attacking the CFS patient community, instead of forthrightly addressing the glaring methodological problems in their study.

<https://www.statnews.com/2016/...>

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