

<http://www.angliameaction.org.uk/docs/Lancet-PACE-Letter.pdf>

Open Letter to *The Lancet* re discredited UK CBT/GET PACE Trial

**Signed by 127 Medical Professionals, Academics & Politicians
and signed by over 71 patient charities and organisations**

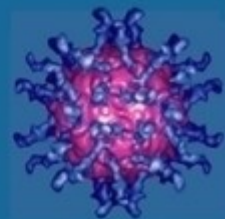
The PACE Trial is the UK government-funded flagship study, published in *The Lancet* in 2011, recommending CBT/GET treatments for "CFS/ME" patients. Doing so on the deeply flawed hypothesis that patients fear physical activity and become deconditioned as a result

THE LANCET

Comparison of adaptive pacing therapy, cognitive behaviour therapy, graded exercise therapy, and specialist medical care for chronic fatigue syndrome (PACE): a randomised trial

P D White, K A Goldsmith, A L Johnson, L Potts, R Walwyn, J C DeCesare, H L Baber, M Burgess, L V Clark, D L Cox, J Bavinton, B J Angus, G Murphy, M Murphy, H O'Dowd, D Wilks, P McCrone, T Chalder*, M Sharpe*, on behalf of the PACE trial management group†

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Trial By Error: Open Letter to The Lancet, version 3.0

INTRODUCTION

By David Tuller, DrPH

13 August 2018

Two months ago, Professor Racaniello sent *Lancet* editor Richard Horton [an open letter](#) about the **indisputable methodological and ethical failings of the PACE trial**. This was a follow-up to

[Virology Blog's 2016 open letter to Dr. Horton](#); the new one detailed what has happened since then. Last month, [I re-sent and reposted this new open letter](#), with organizations also signed on. Given Dr Horton's persistent defense of a study in which 13 % of the participants had already met a key outcome threshold at baseline, it is not surprising that he has failed to respond.

Yesterday I sent the letter to ***The Lancet*** for the third time, with more individual experts and organizations adding their voices to the demand for a reassessment of the reported PACE findings. For reasons only Dr Horton can explain, he appears determined to undermine his journal's reputation for scientific integrity with his robust support for a trial that objective observers clearly recognize as a piece of crap. PACE has caused great harm to the patient community. Dr Horton's refusal to take appropriate corrective action has amplified that harm many times over. He and his journal have a lot to answer for.

OPEN LETTER TO *THE LANCET*

**Signed by 127 Medical Professionals, Academics & Politicians
and signed by over 71 patient charities and organisations**

12 August 2018

Dear Dr. Horton:

In February, 2011, *The Lancet* published an article called "Comparison of adaptive pacing therapy, cognitive behaviour therapy, graded exercise therapy, and specialist medical care for chronic fatigue syndrome (PACE): a randomized trial." [1] The article reported that two rehabilitative approaches, cognitive behavioural therapy (CBT) and graded exercise therapy (GET), were effective and safe treatments for chronic fatigue syndrome, also often referred to as myalgic encephalomyelitis, ME/CFS and CFS/ME. The PACE study received international attention and has had widespread influence on research, treatments prescribed for patients, and attitudes toward the illness of both the medical community and the public at large.

At the press conference promoting the *Lancet* paper, one of the lead investigators stated that twice as many participants in the treatment groups got "back to normal," compared to those in the other study arms. [2] An accompanying *Lancet* commentary similarly claimed that these "back-to-normal" participants had met a "strict criterion for recovery." [3]

In fact, we now know that 13 % of the participants qualified at baseline as "recovered" or "within the normal range" for one of the study's two primary measures, self-reported physical function—even as they were simultaneously classified as disabled enough on the same measure to enter the study. [4] This anomaly, which occurred because the investigators weakened key outcome thresholds after data collection, invalidates any claims that patients "recovered" or got "back to normal." The overlap in entry and outcome criteria is only one of the trial's unacceptable methodological lapses.

The treatments investigated in the PACE trial were based on the hypothesis that ME/CFS patients harbor “unhelpful” convictions about having an ongoing organic disease and that the perpetuation of their devastating symptoms is the result of deconditioning. In contrast, a 2015 review from the U.S. Institute of Medicine (now the National Academy of Medicine), reported that ME/CFS is a complex, multi-system illness characterized by neurological, immunological, autonomic, and energy metabolism dysfunctions. [5] The cardinal symptom, noted the review, is a systemic intolerance to exertion; if patients exceed their available energy resources, they can suffer serious and prolonged relapses.

After *The Lancet* published the first PACE results, ME/CFS patients and advocates immediately pointed out major flaws. But few people outside the field took notice until the science site *Virology Blog* published a 15,000-word investigation by David Tuller, a public health researcher and journalist at the University of California, Berkeley, in October of 2015. [6] Subsequently, in February of 2016, many of us signed an open letter to *The Lancet* requesting an independent investigation of the study. [7]

Since then, much has happened:

- * In August of 2016, a U.K. tribunal, citing that open letter, ordered Queen Mary University of London to release raw trial data from the PACE study, sought by Australian patient Alem Matthees in a freedom of information request so that he and others could calculate the outcomes promised in the PACE trial protocol. [8]

- * Analyses of these data [9], including a study published in *BMC Psychology* in March [10], have confirmed what has long been argued: The PACE investigators engaged in such extensive outcome-switching that they were able to report dramatically better findings than the null or minimal results obtained under the original measures they promised in their protocol.

- * The U.S. Agency for Healthcare Research and Quality (AHRQ) downgraded its recommendations for CBT and GET. [11] This downgrading occurred after the agency removed from its analysis the PACE trial and other studies using overly broad selection criteria that generated cohorts of patients with a grab-bag of fatiguing conditions. And while the PACE trial claimed that GET is safe, AHRQ found that the therapy was associated with more adverse events.

- * Last summer, the U.S. Centers for Disease Control abandoned the recommendations that ME/CFS patients be treated with CBT and GET [12], having already removed references to the PACE trial. A couple of months later, the U.K. National Institute for Health and Care Excellence announced that it would pursue a full update of its 2007 guidance, citing concerns about the reliability and validity of the evidence base. [13]

- * Earlier this year, a report from the Dutch Health Council recommended that GET should not be used in the Netherlands as a treatment for the illness. [14]

- * In March, a group of leading American clinicians who specialize in ME/CFS unanimously agreed that the two PACE treatments are inappropriate and possibly harmful for patients with the illness and should therefore not be prescribed. [15]

Given the worldwide impact of PACE, we urge *The Lancet* to do what the open letter two years ago requested: commission an independent re-analysis of the individual-level trial data, with appropriate

sensitivity analyses, from highly respected reviewers with extensive expertise in statistics and study design. The reviewers should be from outside the domains of psychiatry and psychological medicine and predominantly from outside the U.K. They should also be completely independent of, and have no conflicts of interests involving, the PACE investigators and the funders of the trial.

Thank you for your quick attention to this matter.

Sincerely,

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25% ME GROUP
Support for severe ME sufferers
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Pandora Org
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Phoenix Rising
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REFERENCES

- [1] White PD et al. 2011. Comparison of adaptive pacing therapy, cognitive behaviour therapy, graded exercise therapy, and specialist medical care for chronic fatigue syndrome (PACE): a randomised trial. *The Lancet*, 377: 823–836
- [2] Boseley S. 2011. Study finds therapy and exercise best for ME. *The Guardian*, 18 Feb. Available at: <https://www.theguardian.com/society/2011/feb/18/study-exercise-therapy-me-treatment> (accessed on April 23, 2018)
- [3] Bleijenberg G, Knoop H. 2011. Chronic fatigue syndrome: where to PACE from here? *The Lancet*, 377: 786-788
- [4] Wilshire C et al. 2016. Can patients with chronic fatigue syndrome really recover after graded exercise or cognitive behavioural therapy? A critical commentary and preliminary re-analysis of the PACE trial. *Fatigue: Biomedicine, Health & Behavior*, 14 Dec. Available at: <http://www.tandfonline.com/doi/full/10.1080/21641846.2017.1259724> (accessed on April 23, 2018)
- [5] U.S. Institute of Medicine (now National Academy of Medicine). 2015. Beyond myalgic encephalomyelitis/chronic fatigue syndrome: redefining an illness. *The National Academies*: Washington, DC, USA.
- [6] Tuller D. 2015. Trial by error: the troubling case of the PACE chronic fatigue syndrome trial. *VirologyBlog*, 21-23 Oct. Available at: <http://www.virology.ws/2015/10/21/trial-by-error-i/> (accessed on April 23, 2018)
- [7] Racaniello V. 2016. An open letter to *The Lancet*, again. *VirologyBlog*, 10 Feb. Available at: <http://www.virology.ws/2016/02/10/open-letter-lancet-again/> (accessed on April 23, 2018)

- [8] Rehmeyer J. 2016. Bad science misled millions with chronic fatigue syndrome. Here's how we fought back. STAT, 21 Sept. Available at: <https://www.statnews.com/2016/09/21/chronic-fatigue-syndrome-pace-trial/> (accessed on April 23, 2018)
- [9] Geraghty K. 2017. 'PACE-Gate': when clinical trial evidence meets open data access. *Journal of Health Psychology*, 22: 1106-1112
- [10] Wilshire C et al. 2018. Rethinking the treatment of chronic fatigue syndrome—a reanalysis and evaluation of findings from a recent major trial of graded exercise and CBT. *BMC Psychology*; published online 22 March. Available at: <https://bmcp psychology.biomedcentral.com/articles/10.1186/s40359-018-0218-3> (accessed on April 23, 2018)
- [11] Smith M et al. 2016. Diagnosis and treatment of myalgic encephalomyelitis/chronic fatigue syndrome; addendum. U.S. Agency for Healthcare Research and Quality. July. Available at: <https://www.ncbi.nlm.nih.gov/books/NBK379582/> (accessed on April 23, 2018)
- [12] Rehmeyer J, Tuller D. 2017. Why did it take the CDC so long to reverse course on debunked treatments for chronic fatigue syndrome? STAT, 25 Sept. Available at: <https://www.statnews.com/2017/09/25/chronic-fatigue-syndrome-cdc/> (accessed on April 23, 2018)
- [13] Whipple T. 2017. Mutiny by ME sufferers forces a climbdown on exercise treatment. *The Times*, 25 Sept.
- [14] Health Council of the Netherlands. 2018. More scientific research on ME/CFS is needed to serve patients better. 19 March. Available at: <https://www.gezondheidsraad.nl/en/news/more-scientific-research-on-mecfs-is-needed-to-serve-patients-better> (accessed on April 23, 2018)
- [15] Tucker M. 2018. Much can be done to ease 'chronic fatigue syndrome' symptoms. *Medscape*, 12 March. Available at: <https://www.medscape.com/viewarticle/893766> (accessed on April 23, 2018)

ORIGINAL LETTER POSTED BY DR DAVID TULLER HERE:

<http://www.virology.ws/2018/08/13/trial-by-error-open-letter-to-the-lancet-version-3-0/>

<http://www.angliameaction.org.uk/docs/Lancet-PACE-Letter.pdf>