



Invest in ME Research

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Charity number 1153730

Professor Mark Baker
Centre for Guidelines Director
National Institute for Health and Care Excellence

NICE Guidelines for Myalgic Encephalomyelitis (ME)

15 January 2018

Dear Professor Baker,

Invest in ME Research is a UK charity (charity nr 1153730) that seeks to educate and campaigns for biomedical research into myalgic encephalomyelitis (ME). The charity also facilitates and funds biomedical research into ME.

Although Invest in ME Research is a stakeholder in the NICE Guidelines review process, and will contribute to those discussions, we feel there is an urgent matter that needs to be addressed immediately, irrespective of progress with a NICE Guidelines review and separate from the full review process.

This concerns the continuing recommendation for use of Cognitive Behaviour Therapy (CBT) and Graded Exercise Treatment (GET) for ME which are still held in NICE Guidelines and still, apparently, being used by doctors treating people with ME.

It must surely be realised by all now that CBT and GET are inappropriate for treating ME and in many cases have proven to be deleterious to the health of patients.

The PACE Trial) [1], which was supposed to prove the efficacy of CBT and GET for ME, has been proven to be flawed [2], possibly fraudulent [3] and a complete waste of tax payers' money.

Reanalysis of PACE Trial results by Matthees et al (once the data was forced to be released from the authors following a legal challenge) stated -

"This re-analysis demonstrates that the previously reported recovery rates were inflated by an average of **four-fold**." [4]

The PACE Trial is now being used as an example of how not to perform research – and it is widely seen as flawed and is ridiculed. Several articles by David Tuller academic coordinator of the concurrent masters degree program in public health and journalism at the University of California, Berkeley, have exposed these flaws and demonstrated that the PACE Trial cannot be considered valid [5]

NICE cannot use PACE for anything other than to reject its previous guidelines comments. Continuing to use PACE Trial references to justify CBT and GET will invalidate any further review.



Invest in ME Research

The reason for sending you this letter now is that we believe a full review of the NICE guidelines that may take two years or more will leave patients exposed to these harmful treatments (CBT and GET) and it is not acceptable.

We stated this in our submission in July 2017 [6] -

"NICE will be accountable if it ignores the advice to withdraw this unsound recommendation. NICE would be negligent."

"NICE must be accountable for damages, and costs, relating to the burden brought on to patients by this erroneous and negligent recommendation."

"By ignoring the recent IOM, NIH, AHRQ [7] and CDC [8] decisions to remove CBT and GET from their recommendations and stipulate that the Oxford criteria and research using those criteria need to be abandoned then NICE are negligent."

You stated yourself [9] that " ... the ME/CFS Guideline specifically, did not meet our [patients'] needs and it did not meet theirs (NICE's) either."

By removing the recommendations for CBT and GET from the existing guidelines now, with an addendum or correction of some sort, it could go a long way to establishing some trust in NICE from patients that was forfeited when the previous guidelines were published and the views of patients were ignored.

It would publicise the fact that NICE are responsible and would avoid future possible litigation from those adversely affected by CBT and GET in the intervening period before a new set of guidelines have been published.

The full review of the guidelines for ME will take time. There would be no excuse not to remove what is already known to be faulty recommendations.

Thank you for taking the time to consider this request,

Yours Sincerely,

Kathleen McCall

Chairman Invest in ME Research
and the Trustees of Invest in ME Research

1. The PACE Trial Comparison of adaptive pacing therapy, cognitive behaviour therapy, graded exercise therapy, and specialist medical care for chronic fatigue syndrome (PACE): a randomised trial. Lancet 377: 823–836. doi: 10.1016/s0140-6736(11)60096-2
2. David Tuller Virology Blog: TRIAL BY ERROR: The Troubling Case of the PACE Chronic Fatigue Syndrome Study <http://www.virology.ws/2015/10/21/trial-by-error-i/>

3. Kelvin Hopkins Questions in parliament
<http://www.parliament.uk/business/publications/written-questions-answers-statements/written-question/Commons/2016-11-22/54266/>
4. A preliminary analysis of 'recovery' from chronic fatigue syndrome in the PACE trial using individual participant data
<http://www.virology.ws/wp-content/uploads/2016/09/preliminary-analysis.pdf>
5. David Tuller articles on PACE Trial

References for David Tuller

- Undark <http://undark.org/article/chronic-fatigue-graded-exercise-pace/>
- Undark Podcast <http://undark.org/2016/10/31/undark-podcast-chronic-fatigue/>
- TRIAL BY ERROR: The Troubling Case of the PACE Chronic Fatigue Syndrome Study (second instalment) <http://www.virology.ws/2015/10/22/trial-by-error-ii/>
- TRIAL BY ERROR: The Troubling Case of the PACE Chronic Fatigue Syndrome Study (final instalment) <http://www.virology.ws/2015/10/23/trial-by-error-iii/>
- PACE trial investigators respond to David Tuller
<http://www.virology.ws/2015/10/30/pace-trial-investigators-respond-to-david-tuller/>
- David Tuller responds to the PACE investigators
<http://www.virology.ws/2015/10/30/david-tuller-responds-to-the-pace-investigators/>
- Trial By Error, Continued: Did the PACE Study Really Adopt a 'Strict Criterion' for Recovery? <http://www.virology.ws/2015/11/04/trial-by-error-continued-did-the-pace-study-really-adopt-a-strict-criterion-for-recovery/>
- Trial By Error, Continued: Why has the PACE Study's "Sister Trial" been "Disappeared" and Forgotten? <http://www.virology.ws/2015/11/09/trial-by-error-continued-why-has-the-pace-studys-sister-trial-been-disappeared-and-forgotten/>
- [An open letter to Dr. Richard Horton and The Lancet](#)
- Trial by error, Continued: PACE Team's Work for Insurance Companies Is "Not Related" to PACE. Really? <http://www.virology.ws/2016/01/04/trial-by-error-continued-questions-for-dr-white-and-his-pace-colleagues/>
- [A request for data from the PACE trial](#)
- Revisiting the PLoS One economics analysis of PACE
<http://www.virology.ws/2015/12/22/revisiting-the-plos-one-economics-analysis-of-pace/>



- Trial By Error, Continued: Questions for Dr. White and his PACE Colleagues <http://www.virology.ws/2016/01/04/trial-by-error-continued-questions-for-dr-white-and-his-pace-colleagues/>
 - Trial By Error, Continued: Did the PACE Trial Really Prove that Graded Exercise Is Safe? (with Julie Rehmeyer) <http://www.virology.ws/2016/01/07/trial-by-error-continued-did-the-pace-trial-really-prove-that-graded-exercise-is-safe/>
 - Trial By Error, Continued: More Nonsense from The Lancet Psychiatry <http://www.virology.ws/2016/01/19/trial-by-error-continued-more-nonsense-from-the-lancet-psychiatry/>
 - Trial By Error, Continued: A Few Words About "Harassment" <http://www.virology.ws/2016/02/01/trial-by-error-continued-a-few-words-about-harassment/>
 - Trial By Error, Continued: My Questions for Lancet Editor Richard Horton <http://www.virology.ws/2016/09/01/trial-by-error-continued-my-questions-for-lancet-editor-richard-horton/>
 - Trial By Error, Continued: The Real Data <http://www.virology.ws/2016/09/22/trial-by-error-continued-the-real-data/>
6. <http://www.investinme.org/Documents/NICE/Invest%20in%20ME%20Research%20Comments-to-NICE-Consultation-Guidelines-Review-2017.pdf>
 7. USA Agency for Healthcare Research and Quality (AHRQ) has issued an Addendum to the 2014 ME/CFS evidence review and downgraded CBT and GET. <https://www.ncbi.nlm.nih.gov/books/NBK379582/>
 8. The CDC has updated their website about ME/CFS to use the 2015 Institute of Medicine report and has removed Graded Exercise Therapy (GET) and Cognitive Behavioural Therapy (CBT) from its recommendations <https://www.cdc.gov/me-cfs/about/index.html>
 9. <http://www.forward-me.org.uk/25th%20June%202014.htm>