



Petition Calling for HHS to Investigate PACE

November 3, 2015

TO: Dr. Thomas Frieden, Director of the CDC, and Dr. Richard Kronick, Director of AHRQ

In the U.S., various clinical guidelines, including some from the Centers for Disease Control (CDC), recommend that ME/CFS patients be treated with cognitive behavioral therapy (CBT) and graded exercise therapy (GET), based in part on the U.K.'s £5 million PACE trial for chronic fatigue syndrome. In 2014, the Agency for Healthcare Research and Quality (AHRQ) issued an evidence review that also recommended CBT and GET, also based in part on PACE.

David Tuller, DrPH, published a series of articles[1] describing fundamental flaws in the conduct, analysis, and results of the PACE trial. These flaws call into question the validity of the recommendations for CBT and GET made in the AHRQ ME/CFS Evidence Review[2] and in the CDC's clinical guidelines for ME/CFS.[3]

We, the undersigned, call on the CDC and the AHRQ to investigate the validity of the PACE trial reports and take appropriate steps to protect patients, including:

- the CDC to remove all treatment recommendations and risk and prognosis statements based on PACE and other Oxford studies from its current and planned medical education material;
- the AHRQ to issue a revision of its 2014 Evidence Review in light of the concerns with PACE outlined by Dr. Tuller and the recommendation made by NIH's Pathways to Prevention report to retire the overly-broad Oxford definition used in the PACE trial;
- HHS to use its leadership position to communicate these concerns to other U.S. mainstream clinical guidelines providers; and,
- HHS to call upon The Lancet to ensure that an independent re-analysis is conducted.

Many patients and ME/CFS researchers have already voiced their strong concern about the PACE trial's quality, content, and methodology. Numerous patient surveys have reported physical harm from these therapies.[4] Dr. Arthur Reingold, University of California, Berkeley told Mr. Tuller, "Under the circumstances, an independent review of the trial conducted by experts not involved in the design or conduct of the study would seem to be very much in order." Six prominent researchers have since called on The Lancet to seek an independent re-analysis of the PACE trial data.

For the sake of patients, we call on CDC and AHRQ to also act.



WHY IS THIS IMPORTANT?

The multiple and fundamental flaws of the PACE trial would be problematic in any field. However, the UK's £5 million PACE trial has been hugely influential in bolstering the incorrect view that the debility of ME/CFS is the result of false cognitions, a "fear of activity," and subsequent deconditioning. This view informs how patients around the world are treated in the media, by society, and especially in medical practice.

Numerous U.S. clinical guidelines and medical education material, including CDC's, reference PACE in support of their recommendations for CBT and GET. Basing treatment recommendations on such a questionable study creates a significant risk of harm for patients, particularly when the study could include patients with other conditions.

This potentially affects patients globally because the AHRQ Evidence Review could be referenced in future journal articles and used to justify recommendations for CBT and GET in the clinical guidelines of any country.

REFERENCES:

- [1] David Tuller. "TRIAL BY ERROR: The Troubling Case of the PACE Chronic Fatigue Syndrome Study." Virology Blog. October 21-23, 2015.
Part 1 & 2: <http://www.virology.ws/2015/10/21/trial-by-error-i/>
Part 3: <http://www.virology.ws/2015/10/22/trial-by-error-ii/>
Part 4: <http://www.virology.ws/2015/10/23/trial-by-error-iii/>
- [2] Smith MB, Haney E, McDonagh M, Pappas M, Daeges M, Wasson N, et al. "Treatment of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: A Systematic Review for a National Institutes of Health Pathways to Prevention Workshop." *Ann Intern Med.* 2015; 162: 841-850. <http://dx.doi.org/10.7326/M15-0114>
- [3] U.S. Centers for Disease Control and Prevention. "Diagnosis and Management of Chronic Fatigue Syndrome" CDC Chronic Fatigue Syndrome. June 27, 2012. <http://www.cdc.gov/cfs/education/diagnosis/index.html>
- [4] The ME Association. "ME/CFS Illness Management Survey Results 'No decisions about me without me'." May 2015. Last accessed October 26, 2015. <http://www.meassociation.org.uk/2015/05/23959/>

NOTE:

On 11/16/15, twelve ME/CFS organizations sent a letter to the CDC and ARQ directors asking for the same actions listed in this petition.