

# Fatal flaws in PACE chronic fatigue syndrome follow-up study

November 2 2015, by James Coyne Phd

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At the outset, let me say that I'm skeptical whether we can hold the PACE investigators responsible for the outrageous headlines that have been slapped on their follow-up study and on the comments they have made in interviews.

The Telegraph screamed

*Chronic Fatigue Syndrome sufferers 'can overcome symptoms of ME with positive thinking and exercise'*

*Oxford University has found ME is not actually a chronic illness*

My own experience critiquing media interpretation of scientific studies suggests that neither researchers nor even journalists necessarily control shockingly inaccurate headlines placed on otherwise unexceptional media coverage. On the other hand, much distorted and exaggerated media coverage starts with statements made by researchers and by press releases from their institutions.

The one specific quote attributed to a PACE investigator is unfortunate because of its potential to be misinterpreted by professionals, persons who suffer from chronic fatigue syndrome, and the people around them affected by their functioning.

"It's wrong to say people don't want to get better, but they get locked into a pattern and their life constricts around what they can do. If you live

within your limits that becomes a self-fulfilling prophecy."

It suggests that willfulness causes CFS sufferers' impaired functioning. This is ridiculous as application of the discredited concept of fighting spirit to cancer patients' failure to triumph against their life altering and life-threatening condition. Let's practice the principle of charity and assume this is not the intention of the PACE investigator, particularly when there is so much more for which we should give them responsibility.

Go [here](#) for a fuller evaluation that I endorse of the Telegraph coverage of PACE follow-up study.

Having read the PACE follow-up study carefully, my assessment is that the data presented are uninterpretable. We can temporarily suspend critical thinking and some basic rules for conducting randomized trials (RCTs), follow-up studies, and analyzing the subsequent data. Even if we do, we should reject some of the interpretations offered by the PACE investigators as unfairly spun to fit what has already a distorted positive interpretation of the results.

It is important to note that the PACE follow-up study can only be as good as the original data it's based on. And in the case of the PACE study itself, a recent longread critique by UC Berkeley journalism and public health lecturer David Tuller has arguably exposed such indefensible flaws that any follow-up is essentially meaningless.

This week's report of the [PACE long-term follow-up study](#) and a [commentary](#) are available free at the *Lancet* Psychiatry website after a free registration. I encourage everyone to download a copy before reading further. Unfortunately, some crucial details of the article are highly technical and some details crucial to interpreting the results are not presented.

I will provide practical interpretations of the most crucial technical details so that they are more understandable to the nonspecialist. Let me know where I fail.

To encourage proceeding with this longread, but to satisfy those who are unwilling or unable to proceed, I'll reveal my main points are

The PACE investigators sacrificed any possibility of meaningful long-term follow-up by breaking protocol and issuing patient testimonials about CBT before accrual was even completed.

This already fatal flaw was compounded with a loose recommendation for treatment after the intervention phase of the trial ended. The investigators provide poor documentation of which treatment was taken up by which patients and whether there was crossover in the treatment being received during follow up.

Investigators' attempts to correct methodological issues with statistical strategies lapses into voodoo statistics.

The primary outcome self-report variables are susceptible to manipulation, investigator preferences for particular treatments, peer pressure, and confounding with mental health variables.

The Pace investigators exploited ambiguities in the design and execution of their trial with self-congratulatory, confirmatory bias.

### **The *Lancet Psychiatry* summary/abstract of the article**

Background. The PACE trial found that, when added to specialist medical care (SMC), cognitive behavioural therapy (CBT), or graded exercise therapy (GET) were superior to adaptive pacing therapy (APT) or SMC alone in improving fatigue and physical functioning in people

with chronic fatigue syndrome 1 year after randomisation. In this pre-specified follow-up study, we aimed to assess additional treatments received after the trial and investigate long-term outcomes (at least 2 years after randomisation) within and between original treatment groups in those originally included in the PACE trial.

Findings Between May 8, 2008, and April 26, 2011, 481 (75%) participants from the PACE trial returned questionnaires. Median time from randomisation to return of long-term follow-up assessment was 31 months (IQR 30–32; range 24–53). 210 (44%) participants received additional treatment (mostly CBT or GET) after the trial; with participants originally assigned to SMC alone (73 [63%] of 115) or APT (60 [50%] of 119) more likely to seek treatment than those originally assigned to GET (41 [32%] of 127) or CBT (36 [31%] of 118; p

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