

**ME/CFS Australia (SA) has signed an open letter to the journal *Psychological Medicine* asking for the 2013 PACE paper to be retracted.**

No doubt you will remember the PACE trial, a research study conducted in the UK looking at the effectiveness of GET (graded exercise therapy) and CBT (cognitive behaviour therapy) in the treatment of ME/CFS.

In 2013 the research team published a paper in the journal *Psychological Medicine*, in which they stated that each of these treatments led to recovery in 22% of patients, compared with only 7% in a comparison group. The two treatments, they concluded, offered patients “the best chance of recovery.”

There has been much criticism of the research methods used in this study from other researchers and from the ME/CFS community. ME/CFS Australia (SA), also, has serious concerns about methodological design flaws in the PACE trial.

One (long but clear) paper outlining research design and statistical issues in the PACE study was published in March 2016 by statistics professor Rebecca Goldin. It can be found at <http://www.senseaboutscienceusa.org/pace-research-sparked-patient-rebellion-challenged-medicine/>

Poor research design means that the findings of the study may well be incorrect, and cannot be trusted as a sound basis for deciding clinical treatment. In particular, there is the risk that treatments could actually be harmful to patients. Many patients with ME/CFS have reported that GET, and the graded increase in activity often advocated in CBT, have resulted in increases in their symptoms, often to a significant degree and of long duration.

In a 2011 review of studies to that time, Tom Kindlon found that “exercise-related physiological abnormalities have been documented in recent studies and high rates of adverse reactions to exercise have been recorded in a number of patient surveys. Fifty-one percent of survey respondents ... reported that GET worsened their health while 20% of respondents ... reported similar results for CBT.” His paper can be found at <http://www.ncf-net.org/library/Reporting%20of%20Harms.pdf>

It is not surprising that increases in exercise levels according to an external schedule might result in increases in symptoms, given that in 2015 the expert group of the Institute of Medicine listed post-exertional malaise as one of the core diagnostic characteristics of ME/CFS.

After reviewing sixty years of research into the illness, the committee released a report *Beyond Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Redefining an Illness* (available at <http://nap.edu/19012> - click on “Read online”). In it they said that post-exertional malaise (PEM) “is an exacerbation of some or all of an individual’s ME/CFS symptoms that occurs after physical or cognitive exertion and leads to a reduction in functional ability ... PEM is unpredictable in duration, potentially lasting hours, days, weeks, and even months”.

As a result of these various concerns, many people had called on the PACE trial investigators to release their (anonymised) data so that other experts could review their analyses. The investigators refused. Then in September 2016, after fighting for over two years, an Australian patient, Alem Matthees, was able to have the anonymised trial data released under the UK Freedom of Information Act.

This data has been reanalysed according to the original research protocol, and it was found that the CBT and GET treatment groups had results that were not statistically different from the comparison groups (general medical treatment, and a version of pacing put together by the researchers). And the improvement found in all groups was very low, only a very few percent of the people studied.

The authors of the reanalysis (Wilshire, Kindlon, Matthees and McGrath, 2016) concluded that “[t]he claim that patients can recover as a result of CBT and GET is not justified by the data, and is highly misleading to clinicians and patients considering these treatments.”

This year the UK’s ME Association paid the publishers of this article to allow the complete text to be available on the MEA website, so we can now read it for ourselves. (Previously only the abstract had been publicly available.) Many thanks to them for this action in the public good. The paper can be found at

<http://www.tandfonline.com/doi/full/10.1080/21641846.2017.1259724>

or a PDF can be downloaded from

[www.tandfonline.com/doi/pdf/10.1080/21641846.2017.1259724?needAccess=true](http://www.tandfonline.com/doi/pdf/10.1080/21641846.2017.1259724?needAccess=true)

Therefore, on the basis of the evidence to date, ME/CFS Australia (SA), does not support the CBT and GET treatments described and implemented in the UK PACE trial as suitable treatments for ME/CFS, and has concerns about the possibility that they could cause harm.

*However*, the original paper claiming that GET and CBT are useful treatments for ME/CFS still stands in the journal *Psychological Medicine*, and has not been retracted by the editors. This gives the impression to new readers of the article that it is scientifically sound and its conclusions are still valid.

There is now **an international open letter** to the editors of *Psychological Medicine* asking for the 2013 PACE paper to be retracted from the journal. It currently has 141 signatories from individual scientists and other experts, and from ME/CFS organisations, including us. We have added the signature of our association to the list as we believe it to be important that such a paper, which does not meet the generally accepted standards of research methodology, and thus draws unsupported conclusions about the treatment of ME/CFS, should not be part of the medical literature on ME/CFS. This is particularly important given that these treatments may well cause harm.

The full text of the open letter, and the signatories to date, can be seen at

<http://www.virology.ws/2017/03/23/an-open-letter-to-psychological-medicine-again/>