



**WAKE UP CALL
BEWEGING**
WAAKZAAM VOOR DE CVS VALKUIL

ME-gids 
Informatienetwerk voor ME

Belgium, 7th March 2016

To: Mr. Paul Smallcombe, Records & Information Compliance Manager (p.smallcombe@qmul.ac.uk)
To: Professor Simon Gaskell, Principal (principal@qmul.ac.uk)
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Copy to:

Dr. Richard Horton (richard.horton@lancet.com)
The Lancet
125 London Wall
London, EC2Y 5AS, UK

Dear Sirs,

Myalgic Encephalomyelitis (ME) (WHO-ICD-10 G93.3) – which is unjustly called Chronic Fatigue Syndrome (“chronisch vermoeidheidssyndroom” or in short “CVS”) in Belgium – is a chronic, complex, multi-systemic disease that devastates the lives of millions around the world, and for which there is currently no cure ¹. Based on available epidemiological data, it is estimated that in Belgium between 20,000-30,000 patients are affected by this disease.

There is a growing international concern expressed both from scientists inside and outside the ME field/community ² with respect to the methodological flaws of the PACE trial ³, which have now been clearly established.

Quotes by scientists about PACE and its methodological flaws:

Dr. Bruce Levin, Columbia University: “the height of clinical trial amateurism.”

Dr. Ronald Davis, Stanford University: “I’m shocked that the Lancet published it [...] don’t understand how it got through any kind of peer review.”

Dr. Jonathan Edwards, University College London: “It’s a mass of un-interpretability to me...All the issues with the trial are extremely worrying, making interpretation of the clinical significance of the findings more or less impossible.”

Dr. Leonard Jason, DePaul University: “The PACE authors should have reduced the kind of blatant methodological lapses that can impugn the credibility of the research, such as having overlapping recovery and entry/disability criteria.”

Dr. Arthur Reingold, University of California, Berkeley: “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.”

(from: <http://www.virology.ws/2015/10/21/trial-by-error-i/>)

In an open letter to The Lancet⁴ more than 40 scientists explained the seriousness and scale of the unforgivable methodological flaws of the PACE trial. Their conclusion: “Such flaws have no place in

published research". They therefore urged "The Lancet to seek an independent re-analysis of the individual-level PACE 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 U.K. and outside the domains of psychiatry and psychological medicine. They should also be completely independent of, and have no conflicts of interests involving, the PACE investigators and the funders of the trial."

Concerns about the PACE trial are not new, patients have been pointing these out for years (but were ignored). Recently, the international ME patient community from the UK ^{5,6,7,8,9,10,11,12}, US ^{13,14}, Canada^{15,16}, Ireland ^{17,18} and The Netherlands ^{19,20} have written to Queen Mary University of London (QMUL) and/or The Lancet to address these problems which have resulted in false and exaggerated conclusions by the PACE authors and an unfair generalization of these conclusions to the ME patient community as a whole.

QMUL in a statement (December 18th 2015)²¹, said that they were seeking further ethical and scientific advice, as well as the advice of patients on the issue of providing appropriate access to relevant research.

Indeed, when (flawed) science directly influences patient care, and thus the health of patients, the voice of the patient should be taken seriously and their health made a priority. We as a Belgian patient organisation for ME patients, the "Wake Up Call Beweging (WUCB) vzw" (*Wake Up Call Movement*) supported by ME-gids.net, a large patient information website on ME, hereby add our voice to the existing calls made for QMUL to release appropriately anonymised data from the PACE trial. We support all previous requests QMUL and The Lancet have received for the raw anonymised PACE data to be released, so that an independent re-evaluation and analyses can show whether or not the data collected can indeed support the published conclusions and whether conclusions can be generalized to ME patients.

PACE has directly influenced health care policies and (limited) treatment options for this patient group on an international scale. Patient experiences in Belgium and worldwide over the years have contradicted the PACE study findings (patient organisations from different countries, have repeatedly reported worsening of symptoms with ME patients after CBT and GET). The so called "CVS-referentie-centra" in Belgium (centers in Belgium to which patients are referred to get "treatment" (CBT/GET)), have proven ineffective, as an evaluation report by the governmental RIZIV (National Institute for Health and Disability Insurance) clearly showed in 2006 ²². This was again confirmed by two other governmental reports from "het Kenniscentrum voor de gezondheidszorg (KCE)" ²³ (Belgian Health Care Knowledge Center) and "de Hoge Gezondheidsraad (HGR)" ²⁴ (Superior Health Council) in 2008. One of the conclusions was that employment status had even *decreased* after CBT/GET therapy.

The ME patient community has a right to demand high quality research, transparency and integrity from researchers. Scientific journals can not sit back and do nothing when flaws are this obvious and patients' health is directly affected by the research they publish, their integrity and reputation as a journal will be questioned and damaged as a result.

So, to be clear, there can only be two options at this point: the release and re-analysis of the anonymised PACE data; or a retraction of the 2011 PACE Lancet paper, as the PACE author's refusal to show their data means that they can no longer substantiate any claims made by them with respect to effectiveness of or need for CBT/GET for patients with this disease.

It is time for QMUL and the Lancet to realize that they can no longer defend the indefensible. We therefore expect both QMUL and The Lancet to take appropriate action.

Awaiting your response,

Yours Sincerely,

Gunther De Bock

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ME-gids (*ME-guide*)

Belgian/Dutch Information network about ME

Contact: <http://www.me-gids.net/module-Info-view-pid-2.html>

<http://www.me-gids.net>

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2. <http://www.virology.ws/2015/12/17/a-request-for-data-from-the-pace-trial/>
<http://www.virology.ws/2016/02/10/another-request-for-data-from-the-pace-trial/>
<http://www.virology.ws/2015/11/13/an-open-letter-to-dr-richard-horton-and-the-lancet/>
3. White P.D., Goldsmith K.A., Johnson A.L., et al. Comparison of adaptive pacing therapy, cognitive behaviour therapy, graded exercise therapy, and specialist medical care for chronic fatigue syndrome (PACE): a randomised trial. *Lancet* 2011, 377, 823-836. PMID: 21334061. doi: 10.1016/S0140-6736(11)60096-2.
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5. <http://www.meassociation.org.uk/2016/02/me-association-writes-in-support-of-foi-request-relating-to-release-of-pace-trial-data-9-february-2016/>
6. <http://www.investinme.org/Documents/Lancet/Letter%20to%20Editor%20of%20the%20Lancet%20February%202016.pdf>
<http://www.investinme.org/newslett-Feb16-02-a.htm>
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7. <https://www.actionforme.org.uk/news/our-letter-in-support-of-pace-trial-data-release/>
8. <http://www.meassociation.org.uk/2016/02/the-young-me-sufferers-trust-tymes-trust-joins-call-for-independent-analysis-of-pace-trial-data-15-february-2016/>

9. <http://www.25megroup.org/Campaigning/Awareness%202016/Letter%20to%20QUMUL.dot#quml>
10. <http://www.mererearch.org.uk/news/accessibility-of-data/>
11. <http://wames.org.uk/cms-english/2016/02/wames-writes-in-support-of-releasing-pace-trial-data/>
12. <http://solvecfs.org/Solve+ME/CFS+Initiative+Calls+for+Review+of+PACE+Trial>
13. <https://dl.dropboxusercontent.com/u/89158245/AHRQ%20Request%20Feb%203%202016.pdf> Follow-up letter group of us organizations
14. <https://www.facebook.com/MEFMAActionNetwork/posts/1118452658174676?fref=nf>
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17. <https://www.dropbox.com/s/1dvs763svrrmjhh/IMET%20QMUL%20Letter%20Feb%202016.pdf> Irish ME Trust to QMUL
18. [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(11\)60096-2/abstract](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(11)60096-2/abstract)
19. Letter Dutch Citizens' Initiative for ME patients and recognition of ME
<https://www.facebook.com/GroepMEDenHaag/posts/67881697555397>
20. Letter ME/ CVS Stichting, ME/cvs Vereniging, Steungroep ME <http://www.me-cvsvereniging.nl/sites/default/files/Brief%20aan%20The%20Lancet%20over%20heranalyse%20PACE%20trial.pdf>
21. <http://www.qmul.ac.uk/media/news/items/smd/168729.html>
22. RIZIV report <https://drive.google.com/file/d/0BxnVj9ZqRgk0QTVsU2NNLWJSbIU/edit>
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