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Records and Information Compliance Manager
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Re The PACE TRIAL

Dear Sir,

The European ME Alliance (EMEA) is an organisation of national patient organisations and charities in thirteen European countries campaigning for better research and more funding for research into Myalgic Encephalomyelitis (ME or ME/CFS), as defined by WHO-ICD-10-G93.3.

As you are aware 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*) has come under further scrutiny recently – this time by an increasing number of scientists and journalists who have looked at this trial from an unbiased viewpoint [1].

As the PACE Trial was carried out in the UK then our UK group member – UK Charity Invest in ME – has responded forcefully requesting that the PACE Trial data be released for independent review and analysis or that the PACE Trial paper be retracted by the Lancet.

As funders of the trial the MRC have been contacted by Invest in ME to request that they support patient and charity requests for you to have this data released [2].

EMEA fully endorse the position of Invest in ME and now also request you to ensure that this data is released.

The evidence from the PACE Trial not only affects decisions made by healthcare providers in the UK but also those in many European countries. This directly affects patients across Europe and therefore the data must be freely available for independent scrutiny.

On 27th October 2015 the Information Commissioner's Office (ICO) ruled in favour of a complainant that had requested information from the PACE trial to be made available by the QMUL [3].

Yet QMUL continue to avoid acceding to the mounting number of reasonable requests to release this data – from professional academics as well as patients.

The MRC's own policy requires that data is allowed to be open and is unequivocal on this.

The UK Medical Research Council (MRC) 2011 policy on data sharing and preservation has endorsed principles laid out by the Research Councils UK including



"Publicly funded research data are a public good, produced in the public interest, which should be made openly available with as few restrictions as possible in a timely and responsible manner.

To enable research data to be discoverable and effectively re-used by others, sufficient metadata should be recorded and made openly available to enable other researchers to understand the research and re-use potential of the data. Published results should always include information on how to access the supporting data."

You may believe that you have fulfilled this requirement by submitting information to the April 2014 Cochrane review (Larun et al.) [4]. However, this is not an independent review as three of the original PACE authors, Professors White, Sharpe and Chalder were involved in this review.

It is totally unacceptable for QMUL to ignore the many reasonable requests for data to be released for truly independent review.

QMUL now have an opportunity to save, or even restore their reputation before it is too late.

We therefore request that you take action yourself and release the data from the publicly funded PACE Trial and allow it to be reviewed by independent researchers, in any country – having been, of course, suitably anonymised beforehand to avoid identification of participants.

Yours Sincerely,

The Chairman and Board of European ME Alliance

References

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<http://www.virology.ws/2015/10/22/trial-by-error->
<http://www.virology.ws/2015/10/23/trial-by-error->
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<http://www.virology.ws/2015/11/09/trial-by-error-continued-why-has-the-pace-studys-sister-trial-been-disappeared-and-forgotten/>
- 2 <http://www.investinme.org/newslett-Feb16-02-a.htm>
- 3 https://ico.org.uk/media/action-weve-taken/decision-notices/2015/1560081/fs_50565190.pdf

- 4 Larun L, Odgaard-Jensen J, Brurberg KG, Chalder T, Dybwad M, Moss-Morris RE, Sharpe M, Wallman K, Wearden A, White PD, Glasziou PP. Exercise therapy for chronic fatigue syndrome (individual patient data). Cochrane Database of Systematic Reviews 2014, Issue 4. Art. No.: CD011040. DOI: 10.1002/14651858.CD011040