



Charity Nr: 1114035

INVEST in ME

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Sir John Savill
Chief Executive
Medical Research Council
13th Floor
One Kemble Street
London WC2B 4A

19 February 2016

Re The PACE TRIAL

Dear Sir John,

Invest in ME is a UK charity facilitating, initiating and funding biomedical research into Myalgic Encephalomyelitis (ME or ME/CFS), as defined by WHO-ICD-10-G93.3.

As you may be 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].

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 [2].

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 – as pointed out by Professor James Coyne PhD [3].

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."

So it is even more incongruous that in, all of the recent discussions on the PACE Trial data, the MRC has remained so silent regarding this clear breach of guidance.

In this day and age it is unacceptable that research performed with public funding can be allowed to be performed in this way and patients' valid requests are ignored or cast away under the pretence of being "vexatious".

Invest in ME have written to the editor of the Lancet requesting that they retract the PACE Trial paper or request that the data be made available for independent review and analysis.

The charity did not receive any response form the editor of the Lancet.

That is his prerogative – he only has to answer to the board who elect him.

However, the Medical Research Council is a publicly funded body and cannot decline to answer a request from a charity that is leading the way in research into this disease.

The MRC does a great deal of good work that benefits patients and in many other fields are a source of pride for many.

Sadly, those responsible for policies on ME research over the last decade or more have let patients down. This has to change and a new team assembled that will really deal with this disease in a responsible and accountable manner.

We do not believe that is really happening and has not been the priority for the MRC.

Years of failure to do anything by those responsible for ME in the MRC, by funding the wrong research and by ignoring patients' needs, have all produced a perception of the MRC (with regard to ME research) as being either apathetic, incompetent or just biased.

This would now be a good time for the MRC to clear the decks and start again.

Invest in ME have shown it is possible to construct a sensible strategy of biomedical research into ME building on strengths and European and international collaboration.

It would be a great shame to see the MRC follow the Lancet and QMUL where their reputation and standing becomes damaged due to failure to take honourable action against one piece of profoundly flawed research.



INVEST in ME

We therefore request that you take action yourself and demand that QMUL 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,

Chairman and Trustees Invest in ME
Charity Nr 1114035

References:

1	<p>http://www.virology.ws/2015/10/21/trial-by-error-</p> <p>http://www.virology.ws/2015/10/22/trial-by-error-</p> <p>http://www.virology.ws/2015/10/23/trial-by-error-</p> <p>http://www.virology.ws/2015/10/30/pace-trial-investigators-respond-to-david-tuller/</p> <p>http://www.virology.ws/2015/10/30/david-tuller-responds-to-the-pace-investigators/</p> <p>http://www.virology.ws/2015/11/09/trial-by-error-continued-why-has-the-pace-studys-sister-trial-been-disappeared-and-forgotten/</p>
2	<p>https://ico.org.uk/media/action-weve-taken/decision-notices/2015/1560081/fs_50565190.pdf</p>
3	<p>Professor James Coyne - Why the scientific community needs the PACE trial data to be released</p> <p>http://blogs.plos.org/mindthebrain/2015/11/11/why-the-scientific-community-needs-the-pace-trial-data-to-be-released/</p>