



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

03 September 2016

Re The PACE TRIAL

Dear Sir John,

UK Charity Invest in ME wrote to you in February 2016 regarding 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*).

We reminded you of the MRC's own policy requiring data and in this new era of openness and in this new era of supposedly open and transparent science the public, who fund the MRC, expect that the MRC would act in that way -

"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." [1]

In your reply of 18th February 2016 you stated -

"I wasn't aware of the issue you raise, but I have asked my colleagues to look into this. We have very limited administrative capacity but will do our best to complete enquiries within a reasonable period."

We have received no reply or any update regarding our request.

We are uncertain of the MRC's definition of a "reasonable period" - but we would suggest that seven months might have been sufficient time to ascertain the details of this issue - after all, the MRC awarded nearly £2.8million toward a trial that has been responsible for influencing healthcare decisions across the world - much to the detriment of ME patients.



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Since the time of our letter to you Queen Mary's University London has continued to obfuscate and delay and avoid acceding to the overwhelming voice of patients and their carers, which is now supported by growing numbers of professional academics.

On 22nd April 2016 A First-Tier Tribunal rejected QMUL's spurious and absurd reasons why they refused to comply with the FOI act to release PACE Trial data [2].

At this point in time QMUL have still not complied and continue to withhold the data. One can only assume that they, and the others involved in this debacle, have something to hide.

We would also like to draw your attention to the recent news that the USA Agency for Healthcare Research and Quality, in response to requests from patient organizations and advocates, has issued an Addendum to its 2014 ME/CFS evidence review. This Addendum downgrades the conclusions on the effectiveness of cognitive behavioural therapy (CBT) and graded exercise therapy (GET). [3]
This further undermines any basis for continuing to support these failed pseudo-treatments.

As the MRC is responsible to the public then it is inherent on you to demand immediate release of the data in compliance with MRC policy and the demands of the public - or join us in supporting a complete retraction of this flawed and rejected research.

The Tribunal rejected the MRC's Head of Corporate Governance and Policy statement in defence of QMUL with this statement -

"(N.B. This Tribunal is of the view that QMUL cannot rely on the strict wording of the consent forms regarding confidentiality if they are happy to share the anonymised data with independent scientists as research collaboration rather than an auditing situation. In our view, they are tacitly acknowledging that anonymization is effective, or else they would be in breach of the consent agreement and the DPA principles.)"

We now repeat our original request to you - 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.
Our proposal for action was made in our newsletter from 2015 [4] which we would ask to be reviewed.

Should the data continue to be refused to be made available for independent review, or if it turns out that any falsification of data or incorrect practices have occurred then we also request that the MRC demand the funding for the trial to be returned and a full, independent inquiry be held into this trial and the conduct of its PIs.
As an interim measure we feel that the Principal Investigators of this Trial should be prohibited from applying for, or being granted any further research funding from the MRC until all of the above issues have been satisfactorily dealt with.



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Doing this would go some way to restoring any faith or hope that the MRC might treat ME in the same way as other diseases.

The time really has come for the MRC to come down on the side of patients and not be influenced by vested interests who continue to see patients as mere pawns in their bizarre world of psychiatric theories.

We would appreciate a reply to our request. The lack of attention to this issue surely confirms what the majority of ME patients believe to be the case – that those in the MRC responsible for ME are unaccountable, unelected and totally apathetic to the needs of patients and the requirements to resolve this disease.

We would suggest that it would be sad if the MRC's overall reputation would suffer by this scandal and the great work that the MRC does elsewhere would continue to be undermined by mediocre management of ME research.

As we wrote in our earlier letter, 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 – and doing far more than any other UK charity to advance research into ME.

As an offer also to help you understand more about ME and the work of our charity then we would like to offer you a place at our 2017 international ME Conference in London on 2nd June 2017 as our guest – where you will see the exciting work of researchers we are funding and the international collaboration in research which this charity has formulated in our ten years of existence,

Yours Sincerely,

Chairman and Trustees Invest in ME
Charity Nr 1114035

References:

- 1 Professor James Coyne - Why the scientific community needs the PACE trial data to be released
<http://blogs.plos.org/mindthebrain/2015/11/11/why-the-scientific-community-needs-the-pace-trial-data-to-be-released/>
- 2 Freedom of Information Act 2000 (FOIA) Decision notice
<https://dl.dropboxusercontent.com/u/23608059/OCR-Queen%20Mary%20University%20of%20London%20EA-2015-0269%20%2812-8-16%29.pdf>
- 3 Evidence Report/Technology Assessment - Diagnosis and Treatment of Myalgic Encephalomyelitis/ Chronic Fatigue Syndrome
<https://effectivehealthcare.ahrq.gov/ehc/products/586/2004/chronic-fatigue-report-160728.pdf>
- 4 THE PACE TRIAL - A Time for Reflection - A Time for Retraction (November 2015)
<http://www.investinme.org/IIME-Newslet-1511-01.htm>