



PRESS RELEASE

TRIBUNAL ORDERS RELEASE OF WITHHELD DATA FROM CONTROVERSIAL £5 MILLION CHRONIC FATIGUE SYNDROME STUDY

University claims of activist behaviour also found to be “grossly exaggerated”.

Thursday, 18th August 2016, London, UK - A tribunal has ruled that data from a treatment trial into Chronic Fatigue Syndrome (CFS) must be released, rejecting an appeal from Queen Mary University of London (QMUL).

PACE was a £5 million, publicly-funded clinical trial of exercise and cognitive behavioural therapy for CFS. It has been highly influential in determining treatment in the UK and abroad, but has been controversial. Academics and patients have both voiced concerns over “misleading” claims. Dr Richard Smith, former editor of the British Medical Journal, said in December 2015 of QMUL’s failure to release the data, “...the inevitable conclusion is that they have something to hide”.

QMUL spent over £200,000 on legal fees in this case, to appeal the Information Commissioner’s decision that they should release anonymised data from the trial. The request for data was made under the Freedom of Information Act by Mr Alem Matthees, to allow analysis of the data according to the study’s original published protocol.

QMUL made several arguments why the data should not be released, their main claims being that the data was personally identifiable information, and was not sufficiently anonymised. However, the tribunal rejected these arguments, noting that QMUL had already shared the data with a small selection of other scientists, stating, “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.”

The tribunal was satisfied that the data “...has been anonymised to the extent that the risk of identification is remote.” The tribunal also noted the “strong public interest in releasing the data given the continued academic interest” and “the seeming reluctance for Queen Mary University to engage with other academics they thought were seeking to challenge their findings.”

In his correspondence with the court, Mr Matthees expressed “concerns that QMUL are restricting the registered researchers to whom they disclose the data upon request.” The tribunal said, “The evidence before us is not clear but if QMUL are cherry-picking who analyses their data from within the recognised scientific research sphere to only sympathetic researchers, there could be legitimate concerns that they wish to suppress criticism and proper scrutiny of their trial.”

In its submissions QMUL made a number of accusations of harassment from patients, while QMUL’s expert witness characterized PACE trial critics as “young men, borderline sociopathic or psychopathic”, remarks the Information Commissioner dismissed as “wild speculations”.

When pushed to provide evidence of these threats and harassment under cross examination, witnesses speaking for QMUL were unable to do so, and ultimately conceded that "no threats have been made either to researchers or participants."

The tribunal found QMUL's assessment of activist behaviour to be, "grossly exaggerated" stating that "the only actual evidence was that an individual at a seminar had heckled Professor Chalder." [Professor Chalder is a leading researcher in the PACE trial and a key witness for QMUL.]

Expert reaction to the decision

Jonathan C.W. Edwards, MD
Emeritus Professor of Medicine
University College London

"I think this is the right decision and I congratulate Mr Matthees on persevering with a very reasonable request. The report indicates that the Tribunal considered arguments from both sides very thoroughly. It has become clear that the reasons given for not providing the information requested are essentially groundless. It is also clearly appreciated that critics of the PACE trial are not young sociopaths - they include senior medical scientists like myself, concerned about poor science!"

Bruce Levin, PhD
Professor and Past Chair
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"I am heartened by the Tribunal's finding that the Commissioner had reached a correct decision in ordering release of anonymized data for the PACE trial. The Tribunal's assessment that the perceived risks of data release were neither substantiated nor demonstrated in the evidence before them and that such minimum risk as had been expressed to them would not in their view outweigh the public interest in disclosure of the disputed information is quite important, not only for patients in this trial and around the world, but also because it underscores how essential transparency and open, critical review of clinical trials are to the scientific method."

Keith Geraghty, PhD
Honorary Research Fellow
University of Manchester

"I read the tribunal decision with great interest. I was surprised that the PACE authors declared in evidence that they had shared their trial data with other researchers. I contacted lead author Prof. Peter White to request access to PACE data to run an independent analysis, but my request was first ignored, then later refused. I now understand that the authors shared the data with a select few academics who they picked to co-write papers, but they have failed to share the data with the broader scientific community. Selectively sharing this publicly-funded data with collaborators but

refusing to share data with anyone else, is not in the best interests of patients or science, and it creates a perception that the PACE team do not want independent critical analysis of this trial. I find it regrettable that the Medical Research Council, who partly funded this very expensive study, did not specify that the trial data be made available to other researchers.”

Dr Charles Shepherd
Hon Medical Advisor, ME Association

“The tribunal decision to firmly reject the QMUL case for not releasing anonymised PACE trial data will be widely welcomed by the ME/CFS patient community.

This means that there can now be an independent analysis of data from the PACE trial that has been used to support a number of conclusions and recommendations regarding the benefits of CBT and GET in ME/CFS that are just not consistent with patient evidence for these interventions

Having attended the hearing, where a number of unsubstantiated and serious accusations were made against the patient community, I am pleased to see that this 'red herring' was also rejected by the tribunal

I hope that QMUL will now accept this judgement to release the data and do so without further delay and that they will not spend any more public money on an appeal”

David Tuller, DrPH,
Investigative journalist and public health expert
University of California, Berkeley

"This decision is a thorough repudiation of the efforts by the PACE investigators to protect their claims and findings from being exposed as utter nonsense. You don't actually need the data to determine that the trial is a piece of garbage, but having the data at last will make it clear to everyone. They will likely appeal, but they will ultimately lose."

Alem Matthees
Patient and Second Respondent
Australia

I am very pleased with this outcome. Both the Tribunal’s decision and commentary are a long overdue victory for the patient community, as well as for advocates of clinical trial transparency and open data sharing. I want to thank everyone who gave support, advice or assistance, as well as anyone who engaged in debate over the PACE trial and the sharing of clinical trial data. This case ended up costing me greatly in time, energy, and health (currently bedridden).

I utilised the FOIA to loosen the vice grip control over the data and allow truly independent and open analyses that do not rely on the approval of QMUL or the PACE trial investigators. All this came about largely because of their refusal to publish or release the protocol-specified outcomes, and their generally questionable and poorly or erroneously justified changes to the published trial protocol, i.e. outcome switching, after the trial was over and/or after seeing trial data. Claims of clinically significant improvement may be open to interpretation, but false or misleading claims of recovery or remission from debilitating illness simply have no place in the scientific literature.

Tom Kindlon
Information Officer
Irish ME/CFS Association

I hope Queen Mary University of London won't appeal again and cause more public money and resources to be spent on the case. Now that a court has ruled that the data is non-identifiable and that releasing it will not contravene agreements with trial participants, there is no good reason to continue to withhold it. If QMUL appeal, people may suspect this case was at least partly about trying to hide inconvenient results. Indeed, the tribunal decision notice itself raised the question of whether QMUL may wish to avoid proper scrutiny of their trial.

Patients want nothing more than to recover from this condition, so misleading claims about recovery rates are a particularly serious matter. Many are very sceptical of suggestions they can recover with talk therapy or by steadily increasing their levels of exercise. This is not their experience. Extraordinary claims require extraordinary evidence but the researchers have not yet released such evidence: they revised all four aspects of the recovery criteria to make it much, much easier to be classed as recovered and have so far failed to provide valid justifications for these changes. Some of the PACE Trial investigators have conflicts of interest, such as doing work for insurance companies, which can make people concerned about bias.

This is a huge victory for patients, who have a right to examine the evidence for the treatments that affect their lives. I expect that the recovery rate will only be a small fraction of what the PACE researchers claimed, due to the dramatic changes they made to the criteria.

Jane Colby
Tymes Trust Executive Director

"Tymes Trust is pleased at the judge's ruling. We believe that, pending independent analysis of PACE data, the MAGENTA (PACEstyle) study in children should be suspended immediately."

Leonard A. Jason, PhD
Professor of Psychology and Director
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"I believe that an independent analysis of the controversial trial would be in the best interest of scientists, clinicians and patients."

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References

[Tribunal decision \(pdf\)](#)

[QMUL legal costs](#)

Resources

[What is ME \(Action for ME\)](#)

[Tribunal orders release of PACE data \(ME Action\)](#)

[QMUL Studying PACE data release ruling \(ME Action\)](#)

[PACE research sparked patient rebellion challenged medicine \(Stats.org\)](#)

[Editorial on PACE \(Stats.org\)](#)

[ME/CFS articles \(Virology blog\)](#)

[BMJ Rapid Response from Alem Matthees on changes to PACE trial protocol](#)

About #MEAction

#MEAction is an international network of patients empowering each other to fight for health equality for Myalgic Encephalomyelitis. #MEAction is not structured like a traditional advocacy organization. We are a platform designed to empower patients advocates and organizations, wherever they might be, with the technological tools and training to do what they are already doing – better. We aim to become a mass, grassroots organization by 2017. For more information, visit <http://www.meaction.net/>.