



Department of Health

Freedom of Information Team
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Mr George Jenson
email address: mailto:request-376904-12c068a9@whatdotheyknow.com

19 June 2017

Dear Mr Jenson

Freedom of Information Request Reference FOI 1085858

Thank you for your request dated 19 May 2017 in which you asked the Department of Health (DH):

“CFS correspondence on the Department's view of the PACE trial

I refer to your claim that the PACE trial authors claimed that PACE style GET and PACE style CBT were moderately effective on the basis of subjective criteria. This claim was made by the PACE authors but is not substantiated by the analysis of their own data in accordance with their own published trial protocol. The claim relied on weakening the outcome criteria so much that 13% of the persons sick enough to enter the trial were subsequently classified as recovered on 2 of the outcome criteria.

A reanalysis of a small amount of the raw data (released by order of the first tribunal) found PACE style GET and CBT to be ineffective and even the PACE authors claims were never backed up by their objective evidence. After a year of PACE- style GET participants on average could walk a further 33 meters and remained as severely ill as patients with stage 3 congestive heart disease.

I request recorded/written information that the Department of Health has on how it views the PACE trial authors claims given the misleading claims made by the PACE authors.”

Your request has been handled under the Freedom of Information Act (FOIA).

DH does not hold this information, as DH has not outlined its own view of the PACE trial authors. To establish that this information is not held, I contacted the relevant policy officials.

However, outside of the scope of the FOI Act, and on a discretionary basis, you may be interested in the following information.

NICE (the National Institute for Health and Care Excellence) was established by Government in 1999 as the independent organisation responsible for developing evidence-

based approaches to the diagnosis and management of disease, as well as specific appraisals on the efficacy, safety and cost effectiveness of drugs and technologies. In the absence of NICE guidance, and/or national commissioning policy from NHS England, it is responsibility of individual clinicians to make treatment decisions on the basis of the available evidence, taking into account the individual circumstances of each patient and any commissioning guidance produced by the local NHS.

NICE considered the PACE trial in 2011 when reviewing its 2007 CFS/ME (Chronic fatigue syndrome/myalgic encephalomyelitis) guideline. The 2007 NICE guideline on CFS/ME recommended treatments, such as cognitive behavioural therapy (CBT) and graded exercise therapy (GET) approaches that had the clearest research evidence of benefit. In 2011 NICE looked very carefully at the relevance of the PACE results, which highlighted CBT and GET as safe and effective treatment options for people who have mild or moderate forms of the condition, and NICE concluded that the results supported its decision not to update the guidance at that time.

NICE has been made aware of three US reports that have indicated there are likely to be changes in diagnostic criteria that could have an impact on the CFS/ME guideline recommendations and decided to start a check of whether the guideline needs updating, and plan to publish its decision in summer 2017 (please follow this link for further information: <https://www.nice.org.uk/guidance/CG53/documents/surveillance-adhoc-report>). NICE has also been made aware of new information about the 2011 PACE trial, and it will also consider that in the check.

If you are not satisfied with the handling of your request, you have the right to appeal by asking for an internal review. This should be submitted within two months of the date of receipt of the response to your original letter and should be addressed to the address at the top of this letter, or the email address at the end of this letter.

Please remember to quote the reference number above in any future communications.

If you are not content with the outcome of your internal review, you may complain directly to the Information Commissioner (ICO) who may decide to investigate your concerns. Generally, the ICO cannot make a decision unless you have already appealed our original response, and received our internal review response. The ICO will not usually investigate concerns where there has been an undue delay in bringing it to their attention. You should raise your concerns with them within three months of your last meaningful contact with us.

The ICO can be contacted at:

The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire SK9 5AF

<https://ico.org.uk/concerns/>

Yours sincerely,
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