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Exercise therapy for chronic fatigue syndrome (individual patient data) (Protocol)

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[Intervention Protocol]

Exercise therapy for chronic fatigue syndrome (individual patient data)

Lillebeth Larun¹, Jan Odgaard-Jensen², Kjetil G Brurberg¹, Trudie Chalder³, Marianne Dybwad⁴, Rona E Moss-Morris⁵, Michael Sharpe⁶, Karen Wallman⁷, Alison Wearden⁸, Peter D White⁹, Paul P Glasziou¹⁰

¹Division for Health Services, Norwegian Institute of Public Health, Oslo, Norway. ²Medicinrådet, København Ø, Denmark. ³Department of Psychological Medicine, Institute of Psychiatry, Psychology & Neuroscience, King's College London, London, UK. ⁴Sunnaas Rehabilitation Hospital, Nesoddtangen, Norway. ⁵Section of Health Psychology, Institute of Psychiatry, King's College London, London, UK. ⁶Department of Psychiatry, University of Oxford, Oxford, UK. ⁷School of Sport Science, Exercise and Health, The University of Western Australia, Crawley, Australia. ⁸School of Health Sciences, University of Manchester, Manchester, UK. ⁹Centre for Psychiatry, Barts and The London School of Medicine and Dentistry, Queen Mary University of London, London, UK. ¹⁰Centre for Research in Evidence-Based Practice (CREBP), Bond University, Gold Coast, Australia

Contact address: Lillebeth Larun, Division for Health Services, Norwegian Institute of Public Health, Postboks 4404 Nydalen, Oslo, N-0403, Norway. lillebeth.larun@fhi.no.

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REASON FOR WITHDRAWAL FROM PUBLICATION

This protocol has been withdrawn and it is no longer being progressed to a Cochrane review.

This protocol was published in 2014 and a new protocol is required for any future individual participant data (IPD) meta-analysis on this topic.

The editorial group responsible for this previously published document have withdrawn it from publication.

FEEDBACK

Exercise therapy for chronic fatigue syndrome (individual patient data), 20 March 2018

Summary

In October 2016 a FOI request was submitted to Queen Mary University London QMUL for additional data from the PACE trial which was an included study in the previous Cochrane Review on Exercise for CFS. (http://www.cochrane.org/CD003200/DEPRESSN_exercise-treatment-patients-chronic-fatigue-syndrome). The PI of the PACE trial is now a co-author on this IPD review.

The freedom of information request was rejected in November 2016 citing an exemption in the law that covers data which is part of ongoing research or scheduled to be included in future publications. Does this refer to the future publication of this review and the previous review update?

An internal appeal to QMUL was rejected, and the complainant appealed to the Information Commissioners Office (ICO) in March 2017. In the interim, the PI of the PACE trial retired from QMUL.

During this time, QMUL changed its rationale for not providing the data saying that they were not available because the PI had gone and they are not required to hire staff to access data in response to FOI requests.

The PI of the PACE Trial is both an author of the Cochrane review and the PI of the PACE trial. So he should be able to provide all the data needed for the new review. However, QMUL told the ICO that they are the holder and owner of the raw data and have lost the means to locate and extract it because that requires specialist knowledge. I would argue that the patients that gave their time and bodies to participate in the trial, and the people who paid taxes to fund the research are the owners of the data, and to deny access to them is unethical.

Does this mean the Cochrane reviewers will also be unable to access all the raw data from the PACE trial despite the PI being on the author team?

Submitter name: Caroline Struthers

Role: Patient advocate

Reply

Your comment includes two specific questions in relation to availability of data from the PACE trial.

Your first question relates to the correspondence between QMUL and ICO, in which QMUL has cited an exemption in the law, which covers data in ongoing research or future publications. The authors of the Cochrane review have, however, not been involved in the correspondence between QMUL and ICO, and we have no knowledge of what QMUL has referred to in their response.

Your second question relates to the data availability for the Cochrane reviewers in relation to the data from the PACE trial. We can confirm that the Cochrane reviewers will have access to sufficient PACE trial data to perform the review in accordance with the Cochrane protocol (with it's appendices).

In addition, your comment contains certain statements relating to the FOI request submitted to QMUL, and their responses on the current availability of raw data from the PACE trial. The Cochrane reviewers have no knowledge of these matters, and can neither confirm nor reject the statements made in your comment. If someone submits a request for data related to this Cochrane review, it should however be noted, that the reviewers have a duty of confidentiality on terms equal to those outlined in Appendix 4 in the protocol.

Contributors

Response from Lillebeth Larun (first author)

WHAT'S NEW

Date	Event	Description
7 December 2018	Amended	Protocol for a Cochrane Review withdrawn from publication

HISTORY

Protocol first published: Issue 3, 2014

Date	Event	Description
10 May 2018	Feedback has been incorporated	Feedback comment and response added.
20 May 2014	Amended	Following questions around the involvement of trialists in the analysis, the protocol has been updated to clarify how independence will be ensured. Minor amendments were also made to the search strategy.

SOURCES OF SUPPORT

Internal sources

- Norwegian Knowledge Centre for the Health Services, Norway.

Wages for JO-J, KGB and LL

External sources

- No sources of support supplied