

South West - Frenchay Research Ethics Committee

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31 March 2016

Dr Esther Crawley
 Consultant Paediatrician, Reader in Child Health
 University of Bristol
 School of Social and Community Medicine
 Oakfield House, Oakfield Grove
 Bristol
 BS8 2PS

Dear Dr Crawley

Study title: **The feasibility and acceptability of conducting a trial investigating the effectiveness and cost effectiveness of Graded Exercise Therapy compared to Activity Management for paediatric CFS/ME: A feasibility randomised controlled trial**

REC reference: **15/SW/0124**

Amendment number: **2**

Amendment date: **19 February 2016**

IRAS project ID: **176764**

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

This amendment sought approval for the updated protocol as it follows:

1. additional background information to provide further clarification on the current evidence based and better defines the treatments.
2. The aims and objectives have been re-worded to offer more specific details.
3. To enable any specifically trained member of the research team to carry out the intervention they have been trained for.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Notice of Substantial Amendment (non-CTIMP)	2	19 February 2016
Research protocol or project proposal	2.0	19 February 2016

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

15/SW/0124:	Please quote this number on all correspondence
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Yours sincerely



Dr Paul Allen
Alternate Vice-Chair

E-mail: nrescommittee.southwest-frenchay@nhs.net

Enclosures: List of names and professions of members who took part in the review

Copy to: Dr Jane Carter, Royal United Hospital Foundation Trust- RNHRD

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Attendance at Sub-Committee of the REC meeting on 30 March 2016

Committee Members:

Name	Profession	Present	Notes
Mr Paul Allen	Consultant Oral Surgeon	Yes	
Mr Jeremy Ruddock	Osteopath	Yes	