NHS
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03 July 2015

Dr Esther Crawley
Consultant Paediatrician, Reader in Child Health
University of Bristol
School of Social and Community Medicine
Oakfield House, Oakfield Grove
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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**
IRAS project ID:	**176764**

Thank you for responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager, Mrs Naazneen Nathoo, nrescommittee.southwest-frenchay@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from NRES. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
GP/consultant information sheets or letters [Letter to participants GP]	d0.1	09 April 2015
Interview schedules or topic guides for participants [MAGENTA discussion topic guide]	d0.2	17 April 2015
IRAS Checklist XML [Checklist_23042015]		23 April 2015
IRAS Checklist XML [Checklist_02072015]		02 July 2015
Letter from funder [Confirmation of NIHR Award]		19 September 2013
Other [CFSActivityRestSleepdiary.]		
Participant consent form [8-15 assent to contact]		
Participant consent form [8-15 assent to record]	d0.6	16 April 2015
Participant consent form [8-15 assent to study]		
Participant consent form [8-15 assent to record treatment session]		
Participant consent form [16-17 consent to contact]	d0.5	09 March 2015
Participant consent form [16-17 consent to record]	d0.6	16 April 2015
Participant consent form [16-17 consent to study]	d.04	09 March 2015
Participant consent form [16-17 consent to record treatment session]	d0.5	09 March 2015
Participant consent form [Parent/Carer consent to contact]	d0.5	09 March 2015
Participant consent form [Parent/Carer consent to record]	d0.6	16 April 2015
Participant consent form [Parent/carer consent to study]	d0.4	09 March 2015
Participant consent form [MAGENTA 16-17 consent to study 17052015 d0.5]	d0.5	17 May 2015
Participant consent form [MAGENTA parent carer consent to study 17052015 d0.5]	d0.5	17 May 2015
Participant information sheet (PIS) [8-11]	v0.6	30 March 2015
Participant information sheet (PIS) [12-17]	v0.7	31 March 2015
Participant information sheet (PIS) [Parent/Carer]	v0.6	30 March 2015
Participant information sheet (PIS) [MAGENTA PIS 8-11 30032015 v0.6]	v0.6	30 March 2015
Participant information sheet (PIS) [MAGENTA PIS 12-17 17052015 v0.8]	v0.8	17 May 2015

Participant information sheet (PIS) [MAGENTA PIS Parent OR Carer 17052015 v0.7]	v0.7	17 May 2015
REC Application Form [REC_Form_17042015]		17 April 2015
Referee's report or other scientific critique report [ECrawley Fellowship Review]		
Research protocol or project proposal	v.09	09 April 2015
Summary CV for Chief Investigator (CI)		
Summary, synopsis or diagram (flowchart) of protocol in non technical language [MAGENTA Summary flowchart]		15 April 2015
Validated questionnaire [Sleep diary]	April 2015	
Validated questionnaire [Paediatrics follow-up postal assessment (under 12's)]		
Validated questionnaire [Paediatrics follow-up postal assessment (over 12's)]		
Validated questionnaire [MAGENTA Postal questionnaire pack over 12's v0.1 20042015]	v0.1	20 April 2015
Validated questionnaire [MAGENTA Postal questionnaire pack under 12's v0.1 20042015]	v0.1	20 April 2015

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.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

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

15/SW/0124	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

pp. Mr Peter Jones
Chair

Email:nrescommittee.southwest-frenchay@nhs.net

Enclosures: "After ethical review – guidance for researchers" *[SL-AR2]*

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