NHS
National Research Ethics Service

**South West Research Ethics Committee**
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19 July 2010

Dr Esther Crawley
Senior Lecturer
Centre for Child and Adolescent Health
Hampton House
Cotham Hill
Bristol
BS6 6JS

Dear Dr Crawley

| | |
|---|---|
| **Study Title:** | **Assessing the feasibility and acceptability of comparing the Lightning Process? with specialist medical care for Chronic Fatigue Syndrome or Myalgic Encephalopathy (CFS/ME) - pilot Randomized Controlled Trial.** |
| **REC reference number:** | **10/H0206/32** |
| **Protocol number:** | **Version 5** |

The Research Ethics Committee reviewed the above application at the meeting held on 08 July 2010. Thank you for attending to discuss the study.

You were invited to join the meeting and asked by the Chair to clarify the following issues:

**Q1. Where are the group interviews taking place?**

You replied there were no group interviews. The participant will be asked where they want the interview to take place.

**Q2. If the interviews are done in their home how will you manage this with other family members being around especially younger siblings?**

You replied we will try to arrange it when younger children are at school.

**Q3. If they choose to be interviewed at the hospital will you pay their travel expenses?**

You replied I have not really thought about it and no one has ever asked.

**Q4. Does the Lightning Process involve some kind of group intervention?**

You replied yes they meet with three groups.

**Q5. Where will this take place?**

You replied at the hospital or a hotel conference suite.

**Q6. Will all the sessions be recorded?**

You replied yes.

**Q7. Will all the researchers and the Lightning people all have CRB checks?**

You replied yes.

**This is not made clear in the PIS.**

**Q8. If at home and there are any issues or concerns how will these be dealt with?**

You replied we have a home worker policy which covers this.

**Q9. If there are concerns about child welfare how will this be dealt with?**

You replied it will be brought to the attention of the Child Protection Officer at the Trust.

**Q10. It should be made clear in the PIS that confidentiality will be broken if concerns are found with the child's welfare and t will be reported to the Child Protection Officer at the Trust.**

You replied yes we can do that.

**Q11. The questionnaires are quite long particularly for children with CFS/ME.**

You replied we have been using these for a long time and have only had positive feedback.

**Q12. The SF-36 questionnaire is validated for use with adults and asks some inappropriate questions for teenagers such as playing golf and bowls.**

You replied we are using an old version as we would need to pay for the copyright for version 2.

no I did not → American 'Rand' version X

**Q13. Will the children just not answer if they don't know?**

You replied there will be some variation of administration.

**Q14. Could there be some 16-17 year olds who are married or employed?**

You replied they don't tend to come to us so they must be in some kind of education.

**It states on the top of the Teenagers Consent 16 and 18 years old.**

**Q15. Can you take us through the consent process please?**

You replied yes if they don't get the treatment arm they may drop out so we do the interview before randomisation. We ask for initial consent for contact by the research nurse and to record.

**Q16. Teenagers over 12 years old if competent are able to give their own consent, but all the forms are entitled Consent when it should say Assent.**

You replied yes we could put this in the title.

**Q17. The PIS is very muddled, long and complicated some of which the children will struggle through. There is little difference in Adult and Children's PIS. There should be a specific teenagers PIS and a flow chart would help to make the process clearer.**

You agreed to do this.

**Q18. This is a two stage process, why tell them about the Lightning Process and then ask them what they know about it?**

You replied they already know about the Lightning Process.

**Q19. When the Research Nurse sees them at home does she take the first consent?**

You replied yes.

**Documents reviewed**

The documents reviewed at the meeting were:

| Document | Version | Date |
|---|---|---|
| Investigator CV | | 10 May 2010 |
| Protocol | 5 | 10 May 2010 |
| Interview topic guide | 2 | 10 May 2010 |
| Phil Parker - Training Assessment Form | | 20 May 2010 |
| Certificate of Professional Liability Insurance | | |
| GP Letter | 1 | 10 May 2010 |
| REC application | 2.5 | 24 May 2010 |
| Covering Letter | | 24 May 2010 |
| Participant Information Sheet: Information Leaflet for Parents | 4 | 10 May 2010 |
| Participant Consent Form: Parent Consent to study | 3 | 10 May 2010 |
| Participant Consent Form: Parental Consent to child interview | 3 | 10 May 2010 |
| Participant Consent Form: Teenagers Consent to study | 3 | 10 May 2010 |
| Participant Information Sheet: Information Leaflet for Teenagers | 4 | 10 May 2010 |
| Participant Consent Form: Teenager Consent to interview | 3 | 10 May 2010 |
| Participant Consent Form: Child Consent to study | 3 | 10 May 2010 |
| Participant Consent Form: Child Consent to contact | 3 | 10 May 2010 |
| Participant Consent Form: Parental Consent to contact | 3 | 10 May 2010 |
| Participant Consent Form: Parental Consent to inyerview | 3 | 10 May 2010 |
| Participant Consent Form: Consent to record intervention | 3 | 10 May 2010 |

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|---|---|---|
| Participant Consent Form: Teenager Consent to contact | 3 | 10 May 2010 |
| Questionnaire: Work Productivity and Activity Impairment | 2 | |
| Questionnaire: SF-36 | | |
| Questionnaire: Health Resource Use Questionnaire | 1 | 10 May 2010 |
| Flow Chart | | |
| Check List | | 24 May 2010 |
| Grant Letter | | 24 November 2009 |
| Confirmation of Grant | | 08 March 2010 |

**Provisional opinion**

The Committee would be content to give a favourable ethical opinion of the research, subject to receiving a complete response to the request for further information set out below.

The Committee delegated authority to confirm its final opinion on the application to the Chair.

**Further information or clarification required**

**Qs 3, 7, 10, 14, 16 and 17** above should be confirmed and addressed.

1. Further clarification is required on how the young people and parents are to be recruited; when and where will they receive the PIS and how will willingness to participate be obtained.
2. There seems to be some explanations missing form the PIS; young people are asked to consent for schools to be contacted but there is no explanation of how and why this is to be done.
3. It is still unclear how the consent forms are to be used and further clarification is required.

Patient Information Sheets, Leaflets and Consent Forms:

4. The title of the study is lost in all the print at the top of the page it needs to be differentiated from the rest.
5. The title of both parent and teenager PIS does not clearly say this is a trial or for which condition. It needs clarification in the heading.
6. The adult version needs shortening.
7. The invitation tells participants what is happening but gives no full description of CFS or ME at the first mention. In the introduction it presumes that they know what current treatment, the Lightning Process and the abbreviations are and although the Lightning Process is explained later it may be appropriate to give a brief outline at this point.
8. Need to explain exclusions under 'Why has my child been asked to take part?' (is included in the but one paragraph but is better placed under the above heading)
9. They should be told they are free to withdraw and withdraw their information at any point in the study.
10. It should include possible benefits for parents e.g. may find it helpful to talk to others about their experiences.
11. Needs to explain why they are informing their GP.
12. Explains privacy/confidentiality well but need to warn potential participants of the situations which may mean that they have to break confidentiality.

13. The teenage version needs significant modification for a young audience that starts at age 12 and the information needs to be much more concise. Words/phrases such as intervention, seminar, randomly allocated etc need to be explained or re phrased.
14. A flow chart for each group would make clear what is happening and when.
15. There is no information of who is conducting the Lightning Groups and where they will be held.
16. It is suggested that the PI be broken down into two elements to aid understanding:
    - First stage: the interview to obtain knowledge about what people know about Specialist Medical care and Lightning, and an opportunity to hand out information on the main study
    - Second stage: the work looking at the two groups
17. Consent for under16 years needs permission to inform their GP.
18. Consent to record intervention – the title is not clear for whom this is intended.
19. Teenager consent to interview – 1. Whilst it says that participant can stop the audio-tape or ask for the interview to stop without explanation, it does not tell them explicitly that they can withdraw at any time. 2. The title does not clarify specifically what age group is included in this. Meant for 16-18 years whereas the definition of teenager is anyone older that 12 years.
20. Teenager Consent to Study – 'I know that my school records will be checked' needs to be replaced with 'I agree for my school records to be checked'.
21. Child Consent Form for evaluation – 1. Needs to be entitled 'Assent'. 2. I know that my school records will be checked'/'I know that you will tell my GP...' needs to be replaced by 'I agree for my school records to be checked'. And 'I agree that you may inform my GP...' 3. Do 13, 14, and 15 year olds really want to be called children as title, would it not be better to entitle 'assent for under16 years'?
22. Child Consent to Contact – 1. Needs to be entitled 'Assent'. 2. Again do 13, 14, and 15 year olds really want to be called children as title, would it not be better to entitle 'assent for under 16 years'?
23. All Consents/Assents for under 16years and over 16 years need to include something which allows them to give their permission for their parents/guardian/carer to give their views about them. All consents are given overall headings of 'CFS/NHS/Paediatrics – specialist help for ME'. This is confusing (CFS versus ME) and may not be readily understood by all. (E.g. will everyone know what 'paediatrics' means?

Training Assessment Form for Participants:

24. Page 4 Q12 asks young people 'are you analytical?' This needs further explanation especially for the younger age range.
25. Page 5 states at the top 'if you are 18 years or under please ask your parent... and they also agree... to sign the form too'. This should state 'under 16 years'.
26. The pages should be numbered.

Health Survey:

27. Some of the activities do not relate to young people (especially for the younger participants) e.g. Q4 pushing a vacuum, bowling, playing golf, lifting or Q5 carrying groceries, Q13 time spent on work, Q22 normal work. This needs to make items more young person focused or add a column to say 'never done this'.

When submitting your response to the Committee, please send revised documentation where appropriate underlining or otherwise **highlighting** the changes you have made and ~~striking through~~ any deletions, giving revised version numbers and dates.

If the committee has asked for clarification or changes to any answers given in the application form, please do not submit a revised copy of the application form; these can be addressed in a covering letter to the REC.

The Committee will confirm the final ethical opinion within a maximum of 60 days from the date of initial receipt of the application, excluding the time taken by you to respond fully to the above points. A response should be submitted by no later than 16 November 2010.

**Membership of the Committee**

The members of the Committee who were present at the meeting are listed on the attached sheet.

**Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

| **10/H0206/32** | **Please quote this number on all correspondence** |
|---|---|

Yours sincerely

PP **Mr Richard Ashby**
**Chair**

Email: Southwest.REC@nhs.net

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments.

Copy to: Dr Jane Carter

## South West 2 REC

### Attendance at Committee meeting on 08 July 2010

**Committee Members:**

| Name | Profession | Present | Notes |
|---|---|---|---|
| Mr Richard Ashby | Chartered Manager Chair | Yes | |
| Mrs Isobel Brooks | Lay Member - Retired Social Care Manager | Yes | |
| Mrs Nicola Burch | Lay Member - Management Development Consultant | Yes | |
| Lee Burton | GP | No | Written comments submitted |
| Nicole Dorey | Consultant Clinical Oncologist | Yes | |
| Ms Judy Paice | Discharge Nurse | No | Written comments submitted |
| Dr Roy Powell | NIHR Research Design Service Consultant | Yes | |
| Joan Ramsay | Head of Nursing (Paediatrics) | Yes | |
| Dr Ken Read | Lay Member - Retired Statistician | Yes | |
| Phil Regan | | Yes | |
| Carol Richardson | | Yes | |
| Dr Lynda Rogers-Beel | Senior Lecturer/Registered Nurse/Tutor | Yes | |
| Dr Denise Sheehan | Consultant Oncologist | No | Written comments submitted |
| Dr Chris Vallance | Retired chemist (non-research) | Yes | |
| Dr Kim Wright | Lecturer in Clinical Psychology | No | |
| Dr Eleanor Zaremba | Associate Specialist in Anaesthetics | No | |

| Name | Position (or reason for attending) |
|---|---|
| Barbara Inger | Administrator |