PACE Trial
Minutes of Extraordinary Trial Management Group
Meeting # 8

10 – 5 pm, Monday 14th June 2004

[redacted]

N.B. This meeting was primarily for those designing and giving USC, and was open to non-members of the TMG who will be delivering USC.

1. **Welcome to new members of the TMG**
   This meeting took place on [redacted] first day in post as [redacted] This date therefore also signified the activation of the grant.

2. **Welcome to non-members/observers**
   [redacted] new locum academic secretary.
   [redacted] is a [redacted] in [redacted] and will be an [redacted] at one of the Bart's centres.

3. **Those present**
   [redacted]

4. **Apologies were received from**
   [redacted]

5. **Previous minutes**
   Attached for information; these were not discussed further since they will be on the agenda for TMG # 9.

6. **Care Pathway**
   Each centre leader or representative present explained their local referral process. Discussion ensued as to whether the diagnostic assessment could normally be condensed into one visit, but it was decided that it would be difficult to streamline the usual processes in each centre. Some centres have a one-stop assessment and triage visit, with all routine investigations already completed beforehand, whereas other clinics have more than one assessment visit. A potential PACE participant will always have at least two visits in that they will have a medical screening when seen

by the doctor and a research screening when reviewed by the Research Nurse for possible trial entry.

Summary of agreed points:
The clinic process must be tighter between all Centres. All investigations must have been done within six months of the potential PACE participant being screened for the trial, and the appropriate documentary evidence must be available for the RN. The patient should receive a standard letter explaining what will happen when they attend the clinic for the first time.

ACTION: [redacted] to produce a formalised flow diagram of the Process of Care.

ACTION: [redacted] to construct a standardised appointment leaflet for what happens in clinic. To be circulated before the 8th July TMG.

7. Medical Screening

The guidance from the Royal College should be used as the list for the minimum number of investigations to complete, along with the investigations recommended by Reeves et al, 2001.

ACTION: [redacted] to re-circulate Reeves et al (2003) to all TMG members, which contains the routine investigations that should always be carried out.
To the tabled list of investigations should be added the following:
Blood sugar, T4 and TSH, Urine test for blood, sugar and protein, Endomysial IgA autoantibody. ANA was deleted from the always necessary list.

ACTION: SOP to be created for clinicians that will be referring patients for PACE (to include guidelines for the full history and appropriate physical and mental state examination to be taken and investigations required). All Centres should follow this procedure and a physical examination should be a part of this. [redacted] to lead the writing of SOP guidance (in collaboration with [redacted] and [redacted].

ACTION: [redacted] to circulate the assessment proforma used at King's College Hospital. *(This completed 15/06/04).*

ACTION: All patients seen in clinic should be recorded and the reasons for their non-referral/refusal etc. should be recorded. A SOP is required for this. [redacted] to complete.

ACTION: [redacted] to type up [redacted] hand written notes and circulate these.

8. Usual specialist care information for the clinic patients

Discussion was held about the document entitled 'Information and advice about CFS/ME for patients taking part in the PACE trial'. The following action points relate to this document.

Summary of agreed points:
We agreed to have this document as the leaflet to be available to all clinic patients and PACE participants equally.

ACTION: [redacted] to revise document in the light of discussion and send it for further comment to [redacted] and finally [redacted], This final version should be circulated by [redacted] before the next TMG on 8th July.

ACTION: Simple lay summary statement to be written as a leader to each paragraph. [redacted] to investigate contacting an editor who has worked on similar documents in the past and get a quote for a review of the patient documentation.

9. Standardised Specialist Medical Care

Since usual medical care varies between clinics, we agreed that we should provide Standardised Specialist Medical Care (SSMC) which will offer three main items:

1. To give advice about avoiding extreme behaviours.
2. To educate about the controversy that surrounds treatment approaches for CFS/ME, summarising the two main approaches to activity/energy management. These are the Adaptive Pacing approach, of staying within the envelope, and the GET/CBT approaches of an incremental programme of activity.
3. To prescribe medication where appropriate or to advise the GP to do the same.

Summary of agreed points:

- USC becomes SSMC
- Patients to be asked what activity/energy management approach they had undertaken (see SSMC section)

ACTION: Usual Medical Care (UMC)/Usual Specialist Care (USC) should now be altered throughout all documentation to Standardised Specialist Medical Care (SSMC) to reflect the fact that each Centre's usual care is unique and dependent upon local resources and facilities. The PACE trial will now give SSMC.

10. SSMC Doctor's manual

The manual was discussed and revised during the meeting line by line.

ACTION: [redacted] to complete revision and send to [redacted] for circulation before the next TMG.

ACTION: The RN will record what medications the patients receive. [redacted] to incorporate in the CRF.

ACTION: RN to approach GPs and ask how often the patient has attended surgery through the duration of the trial. [redacted] to incorporate in the CRF.

ACTION: 'Are you happy that you will not be referred to another therapist through the duration of your involvement in the trial?' [redacted] to check that this is covered in the PIL and Consent Form.

11. SSMC Participant's manual

Made redundant by decision that all patients (PACE and non-PACE) should now get the same general information leaflet.

12. Interaction of SSMC with supplementary therapies

This topic was discussed earlier and highlights the importance of harmonising the SSMC arm across all participating clinicians.

ACTION: [redacted] to check that we are measuring beliefs regarding activity at baseline as well as at the other three assessment interviews, and [redacted] to incorporate in CRF.

13. SSMC monitoring

We agreed that it was important to measure the effect of SSMC on participant behaviour.

Summary of agreed points:

- Agreement that we should ask the patients their own interpretation of what will make them better and what supplementary trial therapy they believe they are receiving.
- Agreement to have regular meetings of the SSMC doctors to measure bias, give activity advice, conduct problem solving and harmonise advice being given to patients.

ACTION: Patients in each arm of the trial should be asked the following questions at four time points (Baseline, 10 weeks, 6 months and 12 months):
Qualitatively: 'What do you think you should do in order to get better?
What are you doing?'
Quantitatively: 'Are you a) pushing the envelope, b) working within it'
[redacted] to design this question proforma/CRF.

ACTION: Regular meetings of doctors delivering SSMC in order to:

- See what approaches are being used and attempt to harmonise these
- Monitor what advice is being given
- Discuss difficult questions arising and doctors methods for dealing with these
- Problem solving

ACTION: A lead SSMC needs to be identified, who will be responsible for SSMC training and leading supervisory meetings. [redacted] to approach a suitable TMG member.

ACTION: Follow-up on PACE website development and investigate the provision of a secure password protected and anonymous website forum for doctors to discuss difficulties and raise questions. Include a FAQ page. [redacted] to lead on this.

14. Other possible predictive factors not yet included in the protocol:

- Discussion held as to whether it would be useful to canvass the relative's beliefs as a potential predictor of response.
- Measurements of self-efficacy – how much control does the patient feel that they have over their life?

ACTION: At 8th July meeting the current version of the protocol will be considered. This meeting to include the agenda item: 'Are there any other predictors that are not currently included in the protocol?' [redacted] to check.

15. SSMC doctor's training programme (TBC)

We agreed on the importance of training for SSMC doctors. This would include training on recruitment (cf. [redacted] paper on recruitment), SSMC delivery and content and information about the supplementary therapies.

ACTION: SSMC leader to design a one day training programme for this purpose, as well as make a video tape of a simulated recruitment and FAQs.

16. Training of RNs and DMs

ACTION: To be added to the agenda of the next TMG: Training of research nurses and data managers. [redacted] to add. [redacted] and [redacted] to design.

ACTION: Attendances to appointments and hospital may be tracked by the research nurses through PAS. Move to section on asking GPs.

17. Date and time of next TMG #9 is 2 – 5 p.m. on Thursday 8th July 2004