# PACE trial

# Trial Management Group

# Meeting No. 2

**held on Friday 5th September 2003 at** [redacted]

**Draft minutes of meeting**

1. **Present:** [redacted]

2. **Apologies:** [redacted]

3. **Agenda agreed**

4. **Secretary appointed** for this meeting – [redacted]

**5. Caldicott Guardian and Data Protection Officer**

These two individuals need to be informed of the trial for reasons of patient confidentiality. The Trust R&D Officer should be able to help with this.

a) *Action: It was agreed that all centre leaders should contact their Caldicott Guardian and Data Protection Officer regarding patient confidentiality in relationship to the trial..*
*b) Action: A copy of the trial protocol (when agreed) should be given to each of these individuals.*
*c) Action: It was agreed that PI's would standardise information for the various centres.*

6. **Trial Management Group (TMG)**

It was agreed that it should consist of the:
3 PIs
All centre leaders
3 therapy supervisors
1 health economist
Trail statistician
Representative from AfME
Representative from the MRC
[redacted] (for facilitation and information between PACE and FINE trials)

*d) Action:* [redacted] *to contact* [redacted]

**7. Trial Steering Committee (TSC)**

It was agreed that there should be 3 independent members plus the PIs and the trial statistician.

[redacted] & [redacted] had been approached but are now part of the same Medical School as one of the PIs. [redacted] in [redacted] and [redacted] at Imperial College were suggested as alternatives. Both had already agreed to serve.

[redacted] and MRC representative were suggested as potential observers. All had agreed to serve as observers.

Suggestions for the Chair person include 1) [redacted] 2) [redacted] 3) [redacted] 4) [redacted] 5) [redacted]

*e) Action:* [redacted] *to contact the above as required*

**8. Data Monitoring Committee**

Suggestions included [redacted]
The first two had already agreed to serve.

*f) Action:* [redacted] *to contact the above*

9. **Trial Protocol**

**10. Assessment**

The protocol requires that all potential patients require an appropriate clinical assessment, which includes a physical examination and psychosocial assessment. It was agreed that anyone (psychiatrist, infectious diseases specialist, nurse therapist, psychologist, physician) could carry out the initial assessment of patients as this is what already happens in different clinics. Whenever the initial assessment has been carried out by a non-doctor, a further assessment would be required by a doctor. This will need further discussion following agreement of the full protocol.

Any patient who agrees to take part in the trial would then be seen by the research nurse who would conduct a SCID on each patient, as part of the eligibility criteria.

[redacted] has already written instructions for recruitment for assessors, which will be used as a basis for discussion.

*g) Action: Any comments on the recruitment paper should be fed back to* [redacted].
*h) Action:* [redacted] *to complete protocol for discussion and agreement at next meeting.*

**11. Primary outcome measures**

Our current positive symptom outcome is less than 4 on the 11 item Chalder fatigue questionnaire. This is equivalent to normal healthy population levels of fatigue, so this would represent recovery rather than clinically significant improvement. It was agreed that we should propose changing the positive symptom outcome to a 50 per cent reduction in baseline score as a better representation of improvement, with a score of 3 or less being a secondary outcome measure.

We noted that a score of 75 or more on the SF-36 physical function sub-scale represents a score of one standard deviation below the working adult UK population score, which was considered reasonable.

*i) Action: [redacted] to mark the change in the protocol for approval by the TSC and MRC.*

**12. Patient information leaflets**

It was agreed that the 3 additional intervention groups should be given written information as per normal good clinical practice.

*j) Actions: [redacted] agreed to write the CBT handout*
*k) [redacted] agreed to write the APT handout*
*l) [redacted] and [redacted] will write the GET handout*

**13. Usual medial care**

It was agreed that the UMC group needed to be standardised.

(Added note: Later discussions with DoH R & D staff suggested it would be more accurate to call UMC "Standardised Usual Specialist Medical Care" or SUSMC. We can discuss this at our next TMG meeting.)

*m) Action: [redacted] and colleagues will draft a Usual Care Guide*

**14. Health Economics**

Outcomes will include cost effectiveness and cost utility. The CRSI and Euroquol can generate cost utility scores.It was agreed that we could use the SF-36 social sub-scale scores to generate cost utility scores.

It was noted that the physical functioning and social functioning sub-scales of the SF-36 *only* will be used.

*n) Action: [redacted] agreed to finalise the CRSI*

15. **LREC approval discussed**

*o) Action: All Centre leaders to send copy of LREC approval letter and application to* [redacted]

16. **Therapy Training was discussed**.

It was agreed that there would be 10 days initial training: CBT at King's, APT in Edinburgh and GET at Bart's. The training will commence on 15th March 2004 for the first three centres.

**17. Therapy supervision**

Supervision of specific therapy will take place at 3 centres. Therapy supervision will take place fortnightly, either face to face, via video conferencing, or telephone. Monthly therapy supervision will also take place face to face. Supervisors to liaise with each other regularly to ensure treatment integrity.

*p) Action:* [redacted] *will (as therapy supervisors) will keep a log of supervision.*

*q) Action:* [redacted] *and* [redacted] *will liaise closely to ensure treatment manuals do not overlap and that treatment integrity is ensured.*

**18. Clinical responsibility**

Clinical responsibility was discussed and should remain on site with the responsible centre leader or other team clinician; for example, if a patient is depressed and needs an emergency assessment by a psychiatrist. Weekly clinical supervision will take place on site.

**19. Professional line management**

Professional line management should be supplied by the relevant employing Health Authority or Trust.

**20. Training patients**

Six training patients were agreed as the necessary minimum for each therapist over the six month training period. 18 patients in each centre will be needed in the first six months of the trial (March to September 2004).

21. **Trial start dates**

15th March 2004 – 3 therapists per initial centres and Trial Co-ordinator need to start by then.

15th June 2004 – Research nurses and data entry clerk will start then, some 3 months later.

15th September 2004 – 1st 3 Centres will start recruiting patients for the trial.

15th March 2005 – Next 3 Centres will start training therapists.

15th September 2005 – 2nd 3 Centres will start recruiting for the trial.

We discussed the possibility of the 2 Bart's Centres starting together.

r) *Action:* [redacted] *will discuss 2 Barts centres starting together with the MRC*

**22. Subvention of excess treatment costs by the NHS:**

Congratulations to [redacted] for completing this document with the help of [redacted]. The final application will be submitted by 24th September 2003, to be considered by the Clinical Trials Advisor Support Group (CTASG) on 3rd October 2003.

**23. Therapy employment**

It was agreed that 0.5 or 0.6 WTE therapy posts would be easier to recruit to than whole time or 0.4 WTE. [redacted] suggested that a job share between the trial and an academic post was possible and would make the job more attractive.

What should we do if a therapist falls ill, pregnant or leaves? [redacted] made the point that it is possible and important to continue to randomise if a centre loses a therapist for a while. It is possible to take a treatment arm out of one centre of the trial temporarily.

Given that patients will be able to choose an alternative therapy after 12 months follow up is complete, it will be necessary to employ therapists until six months after the 12 months follow up is complete in all groups. This will ensure clinical equipoise within the PACE team, so that recruitment will be enhanced. It will also ensure we are complying with the Helsinki convention on Good Clinical Practice for trials on humans, by ensuring best clinical care of our trial patients.

s) *Action:* [redacted] *agreed to oversee staff recruitment.*
t) *Action:* [redacted] *will bid for the excess treatment cost of additional (post-trial) therapy for all PACE patients from the DoH.*

**24. Statistics and Clinical Trials Unit**

u) *Action:* [redacted] *agreed to liaise with* [redacted] *and* [redacted] *about how to spend the £30,000 allocated to the Clinical Trials Unit.*

**25. Measures**

v) *Action:* [redacted] *agreed to circulate measures.*

**26. Travel expenses:**

To be reimbursed in March 2004. Please keep all receipts until then.

27. **Next meeting of the TMG**:

Thursday 13th November at 2pm until 5pm in [redacted]

**28. Next meeting agenda items**

Urgent agenda items for then: training programme, measures, job descriptions, protocol.

[redacted]