PACE trial

Trial Management Group
Meeting No.3

Thursday 13th November 2003 at [redacted]

Draft minutes of meeting

1. **Present:** [redacted]

2. **Apologies:** [redacted]

3. **Agenda agreed**

   (Noted that revision of the protocol is deferred to the next meeting which will be a whole day meeting).

   NB. A number of documents were tabled. [redacted] kindly offered to provide electronic versions of any documents to members of the trial team on request.

4. **Previous minutes of the meeting 5/9/03 agreed.**

5. **Matters arising not on the agenda.**

   a) [redacted] announced that [redacted] had been on the good clinical practice course and had relevant documentation. [redacted] received sympathy and applause.

   b) It was noted that we need to locally inform Data Protection officers and Caldicott Guardians but this required the new protocol.

   c) [redacted] announced [redacted] had agreed to be a member of our trial management group and that it was likely the PI's on the PACE trial would be management members of the FINE trial group. [redacted] also reminded the meeting that observers were welcome to attend as long as invited by a PI.

   d) [redacted] announced that the CSRI form for collection of health economic data would be ready by June 2004.

   e) LREC approval had been obtained for Bart's and King's and was pending for Edinburgh.

   f) NB. We are aiming for a start date to get the NHS staff in post to begin training in King's, Bart's, and Edinburgh of the 15th March 2004.

g) **Analysis strategy –** [redacted] said that this would be done sometime during the early stages of the trial.

6. **Accountancy and the payment arrangements for research salaries and expenses.**

[redacted] circulated a paper stating that the money would go from the MRC to Queen Mary College (administrator [redacted]) and that TMG members should seek reimbursement for their travel and personal expenses from their own institutions in the first instance, who would then bill Queen Mary College for the money. These expenses and salaries should be submitted by institutional finance departments (and 46% overheads on salaries where appropriate) quarterly in arrears.

It was pointed out that most institutions would therefore need to set up grant codes and would require an award letter before they were able to do this and consequently before we were able advertise University posts. [redacted] to chase up the MRC for the award letter. **Action:** [redacted]

There were some issues about the claiming of expenses for individuals who were not at one of the core institutions involved in the trial. It was agreed that these individuals will claim their expenses via GKT with the exception of [redacted] who would submit them via Bart's and [redacted] who would submit them via Edinburgh University.

7. **DOH excess treatment costs subvention**

The PI's were pleased to announce a verbal agreement that as a result of further discussion with the NHS clinical trials advisor support group and the MRC, that the NHS excess treatment costs had now been renegotiated upward to £1.9M. This would permit us to employ 0.6 whole time equivalent therapists for 4.5 years, and would allow <u>all patients</u> in all arms of the trial to be given additional therapy within the trial subvention costs if they needed it at their final follow-up.

(NB. There are also subvention costs for usual specialist medical care of approximately £96,000 this may help those doctors doing assessments to persuade their Trusts to let them have adequate time to do so.)

The rather elaborate system for the Trust to obtain reimbursement for their NHS costs was outlined. This involved the Trust being paid on a per patient basis of £3001 per randomised patient with the trial identification number (TIN) for each randomised patient being passed by centre leaders to their Trust R&D Department (a number will be obtained from the CTU), who will then pass this on to the Trust finance department, who will seek reimbursement from the central subvention fund, run by [redacted]. [redacted] will in turn check the TINs with the trial coordinator at Barts, before releasing the funds. Trusts should submit invoices three monthly in arrears. N.B. This means that Trusts will not receive any NHS monies until nine months into the trial.

NB. Given previous experience with NHS Trusts "mislaying" such money it was strongly recommended that you approach your Trust to set up a ring fenced fund managed by the R&D Department and that they are aware that this is a five year fund and is not one they can raid for end of year shortfalls.

8. **Job description specification of therapists**

[redacted] had circulated draft versions of these. A number of minor changes were made but they were generally approved. Revised versions will be circulated shortly. **Action** [redacted]

NB. If we are to make the deadline of having staff in place by mid March advertisements for the NHS therapy staff will need to be placed before Christmas.

It was noted that it was essential that the therapy supervisors felt comfortable with the individuals involved giving the therapy and should therefore be involved their selection.

9. **Job description and person specification of trial co-ordinator.**

There is some discussion about this and a draft job description has been given to [redacted] who will update and circulate it. It was agreed that this person needed to be of the highest possible quality and ability, and it was agreed that although we would seek someone with significant experience of trials, intelligence and personality were the key criteria. Although employed at Bart's the trial co-ordinator is answerable to all three PI's who should all be involved in their recruitment. [redacted] emphasised the trial co-ordinator should focus on organisation and problem solving and not to be accessibly weight down by data management (CTU and centre job).

12. **Job description and person specification of local research nurse and data clerk**

These were agreed and will be circulated. There was a discussion of the issues of blindness in ratings and the difficulty of keeping the local assessors blind to treatment allocation as they will be bound to discuss with other staff. As the principle outcomes are self rated it was decided not to worry excessively about this.

There was also a discussion about patient's ratings of expectation of improvement with therapy and it was decided to ask them to rate prior to randomisation their expectation of recovery of each of the four therapy conditions programme.

13. **GET manual and patient handouts**

This is still pending. **Action:** [redacted] **and** [redacted]

14. **CBT manual**

CBT manual is being written. An existing workbook of sheets for patients was discussed at the meeting. It was agreed that it was basically suitable although might require minor modification. **Action:** [redacted] **and** [redacted]

15. **Pacing manual**

[redacted] and [redacted] win the prize for the most progress made and a thick draft therapy manual was exhibited. This will be finalized. **Action** [redacted] **and** [redacted]

16. **SUSMC Manual**

There was a discussion about standardised usual specialist medical care, a draft manual had been circulated by [redacted]. It soon became clear that usual medical care was complicated because.

a) It varied between centres.

b) There was an issue of whether SUSMC involved referrals to other therapists.

c) SUSMC had to be compatible with any of the three additional therapies.

d) There was a risk that SUSMC could vary between treatment conditions (for example those administering SUSMC could refer only patients who had not been allocated one of the additional therapies to other therapists). It was agreed that this was a difficult issue and needed further discussion **Action:** [redacted]**, and** [redacted] **agreed to revise the guidance and bring it back to another meeting**

17. **General issues of therapy**

Other issues of therapy in general were discussed. There was a general discussion about the need to maintain therapy integrity and [redacted] emphasised the need to avoid therapy overlap. It was agreed that once the three manuals were written that there would need to be:

a) Standardisation so that the non-specific aspects of the therapy such as general descriptions of chronic fatigue and the number of handouts etc were similar.

b) That we made sure that the therapies are as differentiated as possible.

There was some discussion about whether there should be “what not to do” in therapy as well as “what to do” although this was left inconclusive and to be discussed at the future meeting on manuals and training.

a) That if patients were too ill to attend, telephone consultations were allowed (but the time spent on them should be recorded.

b) Telephone contact between sessions would be handled on a case by case basis and not banned but discouraged.

c) We agreed to match normal practice by providing a booster session at nine months for all three therapies.

d) It was agreed that for piloting the manuals and training at least six patients will be treated in each centre.

NB. It was now agreed that the therapy would be 14 sessions plus 1 (i.e. 15 in total). It was emphasised it was important to keep therapy separate from assessment.

18. **Therapy training**.

This is to be discussed at a future meeting.

The remaining items were deferred.

19. **Next meetings**

Friday the 23rd of January 2004 all day meeting 10am until 5pm to discuss revised protocol, which will be circulated in advance. **Action:** [redacted]

Friday the 20th Febraury 2004 2pm until 5pm half day meeting to discuss training and manuals.

March 22nd 2004 2pm half day meeting for general trial management issues

[redacted]