

**Minutes of the PACE team meeting
Held on 9.5.03 at [REDACTED]**

Present

[REDACTED]
[REDACTED]

Welcome

[REDACTED] and [REDACTED] were welcomed to their first meeting of the PACE team. [REDACTED] has been appointed as the PACE [REDACTED], based at the [REDACTED]
[REDACTED]

MRC press release

The MRC will be making its announcement on both the PACE and FINE trials on 15.5.03. [REDACTED] *agreed to send around the draft release once received.* (Note: in the end there was no time to do this.) *We agreed to swap protocols between the FINE and PACE teams.* (Note: done)

Protocol

[REDACTED] *agreed to revise the protocol,* in the light of the changes we agreed with the MRC, in order to get final agreement within the PACE team, so that it can be submitted to the Trial Steering committee. [REDACTED] *agreed to send [REDACTED] a protocol from an old trial to act as a template.*

Trial Steering committee (TSC) and Data Monitoring and Ethics committee (DMEC)

[REDACTED] reported that [REDACTED] would be discussing membership with the MRC the week after the announcement was made. There were some initial concerns that [REDACTED] was in the same institute as [REDACTED], but this would be discussed further.

Contracts/Agreements for members of the PACE team

We agreed with [REDACTED]'s suggestion that it would be a good idea if we all signed agreements of what we expected to do and be responsible for in the trial, including a clear understanding of what would happen if recruitment fell behind target. [REDACTED] *agreed to lead on drafting contracts/agreements.*

Extra questionnaires that had not yet received ethical approval

We discussed the measure of self-help group membership, which will be tested as a predictor. On one side, it was felt important to clarify the differences between local and national groups, as well as the different groups. On the other side, there was concern about sufficient power to find differences. After discussion we agreed to differentiate local and national groups, as well as current membership only, while allowing some free text to expand on answers, which we could revisit should current group membership prove significant as a predictor. [REDACTED] *agreed to lead on this.*

Trial Management committee (TMC)

We agreed to [REDACTED]'s suggestion to invite the MRC to be represented on the TMC. They will be automatically represented on the TSC and DMEC. We agreed other members would include the three co-applicants, all centre leaders, the trial statistician, and [REDACTED]. We agreed to meet every 2 months on average (although these meetings would be more frequent at certain times) and explore the possibilities of teleconferencing.

Study start times

The MRC have not yet given us a start time so we do not know when the grant would be primed. We agreed to aim for February 2004 as the pilot three centres start time with a view to starting randomisation in September 2004.

CBT training

There was uncertainty over [REDACTED] being the CBT trainer and supervisor due to his moving to [REDACTED]. *We agreed to delegate this to [REDACTED] and [REDACTED] to resolve. [REDACTED] at KCH would be a good alternate.*

Subject Data booklet

[REDACTED] *agreed to lead with designing this, with a view to getting it printed properly.*

Ethics approval and Patient information sheet

Some members of the team reported that they had not received these. [REDACTED] *agreed to send these documents out again to all team members.*

R & D directors

We agreed that all centre leaders would now write to their Trust CEOs, copied to their R & D directors to inform them about PACE, and to arrange a meeting to resolve issues of space, therapists, costs and service support. *Action: All centre leaders*

Therapy needs

Some had replied to [REDACTED]'s emails on this. We agreed that it was important that there were sufficient therapists to deliver the treatments, and that this would probably mean all six centres requiring the three therapists (0.5 WTEs). *Action: all centre leaders please write to [REDACTED] confirming your needs.*

Recruitment strategy and communication

[REDACTED] has written a helpful guide to this. [REDACTED] *agreed to circulate this for comments and revisions.*

Analysis Strategy

[REDACTED] *agreed to write this, but there was no immediate hurry.*

Trial inquiries

We agreed that the Trial co-ordinator would lead on this, supported by [REDACTED]. We agreed that we would set up a web-site for the trial.

Other trials

We agreed that we would pass on information about other trials to the DMEC.

Next meeting

We agreed to suspend arrangements for the next meeting depending on various decisions being made over the next few weeks.

The meeting being declared over, we all trooped over to Smiths of Smithfield for the commiseration meal.

██████

21.5.03