Trial Management Group Meeting #17

17th November 2005 [redacted]

1. Present

[redacted]

2. Apologies

[redacted]

3. Welcome

[redacted] welcomed all members and introduced new staff who were observing. It was acknowledged that all staff have worked hard and that the trial is progressing well. There are now 75 people involved in the trial.

4. Previous minutes and matters arising

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TMG #16 – ACTION 19: Outstanding. [redacted] to revise the SCID.

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ACTION 4: [redacted] to send a copy of the financial agreement for Oxford to [redacted] for [redacted] to take to his finance office.

Advantages to CDs are that they can be reviewed at 1.4 or even 2 x normal speed; we can access any point in files immediately (indexing); digital recordings last longer than alternatives in storage.
Still further training required so that TLs get recordings on a regular basis.

TMG#16 – ACTION 32: Outstanding. [redacted] to contact the DMEC [redacted] with the TMGs suggested measures for an operational definition of serious deterioration and to suggest the threshold for review of an arm.

ACTION 5: [redacted] to copy the correspondence to the DMEC regarding an operational definition of serious deterioration to [redacted].

ACTION 6: [redacted] to send instructions around to explain how to set up multiple signatures on MS Outlook.

5. Recruitment

Bart's I: This centre has recruited to target. As Bart's Psychiatry and ID clinics have now merged to a joint service. Bart's II will now exist in financial terms only; all referrals will now be to Bart's joint clinic. For the purposes of the trial and analysis, there will now be only one Bart's centre. There will still be double the therapists at this centre and the recruitment rate will need to double to meet target.

ACTION 7: [redacted] to write a statement to explain the merging of the two Bart's CFS clinics for the files.

Edinburgh: Feedback was given as to changes being made by [redacted] and [redacted] at Edinburgh to improve the recruitment rate. A third doctor has been appointed and is being trained and the two existing doctors are going to see more new patients.

King's: Recruitment is almost on target.

ACTION 8: [redacted] & [redacted] to create a script for doctors to aid in selling SSMC alone.

ACTION 9: [redacted] to re-circulate the self-help reading list to King's.

6. Second wave centres

a) Recruitment of staff

Bart's II: CBT person recruited, APT interviews on 19/11, GET post still vacant and going for a third round of advertising.

Oxford: All therapists recruited. Research staff are not yet in post.

Royal Free: All therapists recruited. Research staff are not yet in post.

b) Therapist training

APT training has begun for the two therapists in post. The Royal Free therapist has been fast tracked as they have already worked in a CFS clinic.

CBT training has begun for all three second wave centres.

GET training as begun for the Royal Free staff member and is ongoing for the replacement therapist at Edinburgh. These staff are close to achieving competence. There is one therapist yet to be recruited, however.

ACTION 10: [redacted] to negotiate more time with the Trust for [redacted] to offer more days PACE training to allow for centres recruiting staff later.

c) Doctor training

Bart's II doctors are already trained.

Oxford doctors are soon to be visited by [redacted]

Royal Free doctor is [redacted] and is the SSMC lead so no training will be required. Another doctor will need to listen to [redacted]'s tapes.

d) Research staff training

ACTION 11: [redacted] and [redacted] to arrange two days of RN training for the second wave centres nurses and [redacted] and [redacted] to arrange training for data managers. SCID training days to be organised additionally by [redacted] and/or [redacted], with the help of established RNs.

ACTION 12: Second wave centre leaders to ensure that the RN/RAs sit in on as many assessments as possible and liaise with local therapists to listen to sessions and learn about the therapies.

e) Target dates and process for starting participant recruiting

To be determined by therapist recruitment, rate of training and achieving competence. At present, recruitment start is anticipated for mid-February/early March 2006.

If required, the TMG will consider buying sessions with trained therapists to cover. Alternatively Oxford and Royal Free may be able to start recruitment once two therapists are competent, with therapy cover being provided by Bart's.

ACTION 13: [redacted] to discuss with relevant therapist (probably [redacted]) at Bart's to see whether [redacted] might be willing and this is attainable on a temporary basis to cover other centres whilst staff recruitment and training is ongoing.

King's is at capacity at present. [redacted] agreed to review the hold ups to recruitment at the centre and decide whether more money is required to increase the RA hours. One possibility is that the TMG asks King's to be a double centre for the next two years, in the same way as Bart's is about to be.

ACTION 14: [redacted] to consider whether the King's team could double their recruitment rate with the rest of the King's team.

7. Database and data entry

Data entry has begun. Bug reports have been sent to the CTU and will be reviewed by [redacted] and [redacted] in December and a new version of the database released in the New Year. Data already coded will be transferred across to the new database.

ACTION 15: [redacted] to highlight those key issues in the SOPs that are most important and send to [redacted]

8. TSC and DMEC meetings

As above on operational definition to be sent to DMEC and TSC (copied to [redacted].

9. Newsletter

First issue of the newsletter was released. The aim is to make these quarterly but that will depend upon contributions!

ACTION 16: [redacted] to write a letter to COREC to find out what we do if we receive a FoI request that is for information that is not MREC approved to be viewed by patients and their relatives.

ACTION 17: [redacted] to ensure that new staff receive back copies of the newsletters.

10. Centre leader agreements and financial agreements

As above, [redacted] is distributing these.

11. Budgets

Feedback to a meeting with QMUL finance who have promised more detailed transaction lists and break downs to enable us to monitor spending more effectively.

12. Feedback from treatment leaders and PIs meeting

Request from some PIs/TLs to make these meetings less formal over lunch or coffee. Abandonment of minutes and action points from these meetings. From hereon the TL/PI meeting will be an informal lunch before the TMG.

13. CGI for SSMC doctors

Issue discussed as to whether an additional CGI for SSMC alone participants should be rated by the doctors at 24 weeks to be comparable with that for the therapists CGI.

The TMG decided that this was a minor point and that as per protocol doctors would only rate at 52 weeks.

14. Scoring of SF-36 and CFQ

Clarification by [redacted] that the previous TMG#16 minute should not have been agreed, in that no comment should be made by the RN/RA once the scales have been scored. However, according to the protocol, the RN/RA clarifies verbally the instructions on all self-rated questionnaires. This discussion must be held before the participant completes any trial questionnaires so that there is no question of leading the participant.

ACTION 18: Centre leaders to ensure that RN/As read out only the printed instructions for questionnaires at their own centres.

ACTION 19: [redacted] to alter the SOP for doctors so that only participants with a CFQ of 6 are sent to the RN/A for screening.

15. Ancillary studies

a) Qualitative study of clinician – participant interaction

This has not been funded by the CSO and different funding sources are being sought.

b) Genomics study

A decision from the MRC is expected in March 2006. 400K is already promised from the CDC, which would pay for all the SNP analyses.

c) Two year follow up study

No further progress on this at this time.

ACTION 20: [redacted] to put the two year follow up ancillary study in to the MRC (not for the next round but for the one after) when drop-out rates are truly known.

d) Experience of participating in a research study
[redacted] has put forward this proposal and initial draft comments are sought from other PIs to TLs.

ACTION 21: Any comments from TLs and PIs about [redacted] proposed ancillary study to go to [redacted] before 08/12/2005.

16. Monitoring visits
Issue discussed as to whether PI involvement should be part of the monitoring process and who should be responsible for this. The TMG agreed it is essential that this is done.

ACTION 22: [redacted] to amend the Monitoring report to include 'Do you have regular local PACE meetings where the CL is present?' and 'Are these minutes circulated to the trial PIs?'

TMG also think that this should include a team lunch with the monitoring visit.

Importantly, there was reinforcement of the message that *monitoring is a supportive process and not an audit process*.

17. SOPs
SOPs are being rolled out for re-drafting and feedback at present.

18. PANTS feedback and next date for the PACE team day
Briefly discussed along with the question about whether the second wave centres need any support and a reinforcement of the system of mentoring.

Friday 16th June for the next PACE annual day.

19. Date and venue of next TMG
8th February, 2006 at [redacted]

Summary of Action Points

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