Minutes of the PACE Trial Management Group
Meeting No. 5
Friday 20th February 2004
[redacted]

PRESENT

[redacted]

WELCOME TO:

[redacted] who represents the FINE trial in Manchester. The FINE trial is a two armed trial of a nurse based self-help with a rehabilitative emphasis versus client cantered counselling for patients with chronic fatigue syndrome referred from primary care. The treatment will take place in the patient's own home and will be delivered by three nurse therapists (G grade nurses with six months training). The trial will aim to recruit 120 patients per arm, and aims to begin recruiting in late 2004. The principle outcome measures of the trial are the physical function scale of the SF-36 (70 or 75% indicating good outcome) and the Chalder fatigue scale (less than 4 representing good outcome). These are now the same as those in the PACE Trial. They are also using a step test; the HADS scale the Jenkins sleep and the economic outcome.

APOLOGIES

[redacted]

PREVIOUS MINUTES

The minutes of the last TMG meeting were agreed.

MATTERS ARISING

The MRC award letter is still awaited but expected shortly. The point was made that we may able to get on recruiting with a brief indication (possibly an email) from the MRC even before the formal funding letter has been delivered. As the greatest urgency for research staff is for Edinburgh (where the research staff are needed to set up the service) [redacted] will pursue this. ***Action:*** [redacted]

[redacted] and [redacted] agree to co-ordinate joint advertising to employ therapists as soon as possible. ***Action:*** [redacted]

[redacted] asked if we could pursue video conferencing to reduce the travel time and cost particularly from [redacted], and [redacted] has undertaken to explore this at Bart's. ***Action:*** [redacted]

The NHS Service support costs (that go towards paying for SUSMC) still have to be pursued with the NHS Subvention Board and will be pursued by [redacted] and [redacted] ***Action:*** [redacted]

It was noted that there had been some adverse media coverage of the trial which was unhelpful giving the willingness of a small antagonistic group to make capital out of this. It was therefore agreed as a general media policy that we would put as little into the public domain as possible and would not have a public trial website. In the meantime could all media enquiries about the trial please be directed to [redacted]

The trial logo and notepaper was circulated and agreed. Printing will be undertaken ***Action:*** [redacted]

New MRC money (£9,650) had been agreed for the training of the therapist joining in the second year.

THERAPIES
The majority of the meeting was spent finalising the treatment and training manuals

General Points
We began with some general discussion about the content and format of the manuals for the three supplementary therapies. Each therapist/training manual will also have an associated patient manual. These should be of a similar size and form and look equally plausible. We must bear in mind throughout it is quite likely that all these materials will be leaked into the public domain.

There was discussion about the relationship between the three different therapies. On the one hand they could be defined as three entirely distinct approaches with different models (the three different cups) or as therapies of increasing complexity the more complex ones including the elements of the simpler ones (the Russian dolls). Whilst it was agreed that elements of both applied, the trial was based on the completely separate approaches (the different cups model). With this in mind we must go to great lengths to ensure that the therapies are both true to their model and as distinct from the other therapies as possible.

In order to ensure that they are distinct we agreed.

a). That the manuals be discussed by all therapy leads to minimise overlap and ensure distinctness. ***Action:*** [redacted] ***and*** [redacted]

b). Within the training manuals there should be clear statements of what things were <u>not</u> included in the therapy as well as <u>what was.</u> It was suggested that the original table showing a differentiation between the therapies is included in all the manuals. ***Action:*** [redacted]

c). That the therapists all receive an introduction to all three types of therapies so they can see how their therapy is distinct and so they can be clear what they must not do as well as what they should do. ***Action:*** [redacted]

It was also agreed that the front end of all the therapies had a similar component in explanation of the very basics of CFS (but not the actual model) and the practice of engagement and dealing with questions. It was therefore agreed that there could be a

common part to the manuals including a single side on what is chronic fatigue syndrome. [redacted] was asked to provide this. ***Action:*** [redacted]

It was agreed to develop and amend all the manuals along these lines. ***Action:*** [redacted].

It was agreed that there could be common training in these basic aspects (see below).

It was agreed that we should measure therapeutic alliance and [redacted] undertake to circulate this to all members of the TMG. ***Action:*** [redacted]

It was agreed that the length of therapy could vary. That is if the patient was completely well the therapy could be terminated prematurely or some sessions omitted. The length of the session and number of session must be recorded however so that the economic data would be accurate. Different lengths of therapy would assist in giving more variance to the economic outcome.

It was agreed that all therapy sessions (including telephone therapy where necessary) should be recorded and that a specific number of randomly selected sessions would be reviewed to ensure fidelity. Digital technology is now available for recording (using digital Dictaphones which can be downloaded on to a computer). [redacted] has a fully digital therapy recording setup (including telephone) running in his Cancer Research Group offices in [redacted] and is happy to advise and/or demonstrate on this technology. [redacted] should visit. ***Action:*** [redacted]

(a) APT

[redacted] was congratulated for producing a convincing and comprehensive manual of APT. We now have a fairly complete manual for APT, though it was agreed that this needs piloting. It was agreed that APT could include systematic relaxation although there was some discussion about how directive the therapy should be about sleep. It was generally thought that whilst achieving a structured and balanced day was part of pacing it was important that the therapist should not be too prescriptive about this and it was more encouraging the patient to find their own balance that would adapt them best to their illness. Specifically therefore if the patient found it helpful to sleep during the day it would not be for therapist to tell them they should not. ***Action:*** [redacted]

(b) GET

There was discussion about the use of the word 'avoidance' in the GET model and whether this had implications that it was a psychological as opposed to physiological therapy. After a vigorous discussion it was agreed that the word intolerance would be replaced for avoidance. ***Action:*** [redacted]

[redacted] was congratulated on the progress [redacted] had made with the GET manual despite being a "late starter". [redacted] will undertake to work it out together with [redacted] to be similar in style to the other manuals and within a companying patient manual. ***Action:*** [redacted]

(c) CBT

This is a large and sophisticated manual with a large and sophisticated patient handbook! Some comments were made about the front sheet and other minor points and about the need for a common text about the nature of chronic fatigue syndrome. [redacted] and [redacted] were congratulated. There is a certain amount of further development to be done on this. ***Action:*** [redacted]

TRAINING

It was agreed that some of the therapist training could be generic. It is anticipated that there would be five days general training for the therapists which was probably best be dispersed (a day per month) rather than occurring as a block. 10 days in all was scheduled for initial training. Subsequent training and supervision would be weekly one-to-one by telephone/and/or video link and monthly face-to-face in a group.

It was suggested that the initial training would comprise half a day on the nature of chronic fatigue syndrome, half a day on the different treatment models and half a day on questions about the therapy and general issues of engagement and explanation to patients. Subsequent therapy would then be in therapy specific groups.

NEXT MEETINGS

TMG-5 2pm to 5pm Monday 22nd March, [redacted].
Protocol to be finalized. Revised protocol to be circulated before hand

TSG-1 (probable) – 6th May

TMG-6 – 2pm 7th May

[redacted]