Minutes of the PACE TMG Meeting no 6 Monday 22nd March 2004

Present:
Analasian
Apologies:
Welcome:
Previous minutes agreed
Matters arising not on the agenda
MRC award letter Staff salaries have been accepted The MRC want more details on consumables, etc. MRC are still waiting for further details from Queen Mary's
Advert for trial Co-ordinator in the Guardian this week
Advert for therapists Adverts will be separate and due to go out imminently
<i>Video conferencing</i> We decided to opt for this, if we can, once the trial is up and running
NHS service support costs and will liaise
Fine trial Cross referral of patients for trials:
Logo and notepaper This is still in process
Therapy manuals:
and will circulate their final copy of GET soon. Introductions will be the same in all therapy manuals. It has been agreed that the term CFS/ME will be used throughout the patient information.
Whenever we refer to any of the therapies, it should be as a supplementary therapy to SUSMC. Whenever we refer to therapies they should be referred to in alphabetical order APT, CBT, GET and SUSMC.

Language: "People with CFS/ME" before they become into the trial and "participants" once they are in the trial.

All therapy trainers to note comments and suggestions regarding the therapist and patient manuals, so that changes can be made at end of Pilot phase.

Therapy trainers to ensure that they write the words in full before using abbreviations.

All manuals should contain a glossary.

APT-manuals

has give Pilot versions to centre leaders

was thanked for information. feels that sessions 8-12 may need further work. Manual was accepted to be forwarded for TSC in April. will send the manual to accepted at

Need to ask the TSC whether or not they would need to see the final copies of the manuals, after piloting.

ACTION: to discuss this with the MRC

CBT manual:

Remove MRC etc from title pages.

Change the first page in the patient manual to include standard information.

Check language is understandable i.e mitochondria

Change "improve fatigue" to "reduce levels of fatigue"

Take out of therapists manual information about evidence about other treatment.

The manual was approved subject to minor alterations.

All trial documentation needs headers with trial numbers ISRCTN54285094, page numbering 1of 123, acronyms, version, date, as per trial protocol. Action:

All therapist and participant manuals to be completed and sent as a hard copy to by 14th April.

Action

Therapy quality assurance

A measure of quality assurance for all therapies will be drafted by and and

Action

Training programme

1 day introduction to CFS and the trial – combined Review training programme on 7th May, at next TMG meeting.

Public Relations

We agreed that **a second second** at the MRC would handle the media and general public relations in the future. All queries and approaches must be passed on to **a**

SUSMC

We discussed whether there should be one named doctor or different doctors at each centre

Centre Reports

There is a space problem at the Royal Free – this centre may have to use the Medical School

TMG documents

Any new documents to be circulated should be sent to **set of the set of the s**

Protocol

The protocol was revised in some detail and approved for submission to the TSC, subject to the following actions:

It was agreed that therapies should be listed in alphabetical order, where appropriate

Following discussion about whether we should be using 50% reduction in fatigue score and / or a score of 3 on the Chalder questionnaire, it was agreed that the power calculation for outcomes should be reviewed.

Action

It was agreed that it would be helpful to have a measure for sleep. It is using a 4- item Jenkins questionnaire for their trial. Item has a copy of the questionnaire and will send it to the and the second second

Action

Following discussion about screening and baseline procedures it was agreed that we should add a statement to the consent form stating "participants will be able to attend for the duration of the trial".

Action

For assessment purposes, it was agreed that a reading test would be useful in order to assess ability to read and understand English.

Action

Supplementary studies protocol

Comments regarding supplementary studies policy document, previously circulated, should be sent to

Date and time of next meeting: Friday 7th May at 2pm,