

THE BREAKDOWN OF ISSUES – PACE TRIAL

From Angela Kennedy

16 May 2004

ACT: ONECLICK Response to Peter White's statement on Co-Cure and recent letters in the Independent Newspaper.

There are a number of inaccuracies and inconsistencies in Peter White's recent posting on Co-cure and in the letters by White et al and Colin Blakemore in the Independent Newspaper. These need to be addressed.

BREAKDOWN OF ISSUES

1. Firstly, and this is a very important point, the letters published in the Independent are not letters of "correction", they are merely letters on the Letters Page. Indeed, the Independent also published, with the letters by White et al and Colin Blakemore, a letter by an ME sufferer thanking them for publishing Jerome Burne's article. White, Blakemore et al's letters may be rebuttals of the Jerome Burne article, they are not 'corrections', and the term 'misunderstandings' merely describes Dr White's opinion of the legitimate criticisms levelled at the PACE trial. The terms 'correction' and 'misunderstanding' are highly misleading.

2. The MRC has stated - as has The PACE Trial Identifier - that the Oxford criteria will be used for ***recruitment*** and ***entry*** to the PACE trial. The Oxford criteria exclusion definition prevents a patient with an organic brain disease from entering into this trial. ME/CFS ICD-10 G93.3 ***is*** an organic brain disease as listed by the WHO and this classification is agreed by the UK Government. What is more, most ME/CFS sufferers will exhibit signs and symptoms of organic brain disease, and especially those seriously affected. By the logic of the Oxford Criteria, they should be excluded. This anomaly is one of the major flaws of the Oxford Criteria. It therefore presents a major methodological problem, which we note has not been addressed by Dr White in his post, or indeed, elsewhere.

Using the Canadian Protocols (1) at the onset instead of Oxford would prevent this methodological problem. What would then happen is that people with Idiopathic Chronic Fatigue would be excluded, and ME/CFS sufferers included. This should be the aim of the research project, which has been awarded government funds on the basis that research should be about ME/CFS, a "serious research priority", according to the MRC, not Idiopathic Chronic Fatigue.

We note that this methodological flaw has NOT been addressed, and within the Pace Trial Identifier, the Canadian Definitions are conspicuous by their absence in the literature review. We also note that Dr White has chosen NOT to address this important and legitimate criticism, about the absence of the Canadian Definitions in the PACE Trial, in his post.

Those conducting the PACE Trials have constantly repeated that the Oxford Criteria will be used for Recruitment and Entry to the trial. If patients with ME/CFS have already been excluded by this process, using the Fukuda and London Criteria later in the trial will be a superfluous exercise.

The Oxford criteria are now superseded, are not in use by international consensus, have no predictive value and are out of date. Why are they being used as the primary criteria in this trial when more up-to-date criteria have been produced? We note that this question has not been addressed by Peter White.

3. It is also highly likely that those seriously affected will not be recruited as they cannot travel to the Centres. The FINE trial is a different project to PACE, and cannot be used to answer this criticism.

4. Contrary to the claims made by Peter White in his Co-cure post, there is substantive evidence demonstrating that Graded Exercise Therapy (GET) ***adversely*** affects sufferers. We note that this evidence has not formed part of the literature review in the PACE Trial Identifier. This therefore poses a profound ethical problem: The designers of the PACE trial Identifier intend to research a controversial 'treatment' on ME/CFS sufferers, even though they know that this treatment may damage the health of those who receive it.

Cognitive Behavioural Therapy has also been shown to harm ME/CFS sufferers (3) We note that the evidence demonstrating this was ***not*** explicitly addressed in the PACE Trial Identifier. This therefore poses the same ethical problems as those of Graded Exercise Therapy.

Neither CBT nor GET treatments have proved 'popular' - on the contrary they have been shown to be DAMAGING in many instances. APT is merely a term coined by the PACE Trial proponents, to describe the supervision by a 'therapist' of (and logically, an interference in) an unquantifiable, individual ***self-managed*** strategy for coping with the severe physical limitations caused by ME/CFS.

In fact, in the Pace Trial Identifier, the Acronym APT is used, but whether this indicates "Active Pacing Therapy" or "Adaptive Pacing Therapy" is not clarified, as no explanation as to the acronym is given. The fact that a 'therapist' will "input" into a self-managed strategy already suggests a major methodological problem to be addressed. The contents of the PACE Trial Identifier suggest this has not been considered.

We would also point out that true 'Pacing' does not include the use of targets and goals whereas APT appears to do so, therefore this cannot be a true trial of 'Pacing'.

5. What do the psychiatrists working on the PACE trial believe about ME? Do they subscribe to the WHO classification that ME/CFS is a neurological brain disease, or do they believe it is a 'somatization' disorder? A recent article by Winfried Rief and Michael Sharpe (2) describes "Chronic Fatigue Syndrome" as a 'medically unexplained' and 'functional syndrome, along with Fibromyalgia. They describe both as somatoform disorders.

This forms the crux of the problem: those psychiatrists, at least, conducting the PACE Trial, do NOT appear to subscribe to the WHO neurological classification of ME, but believe 'CFS' (merely another description for ME) is a 'somatization' disorder. For this reason, they also continue to (incorrectly) use the term Chronic Fatigue interchangeably with Chronic Fatigue Syndrome.

We note that this legitimate criticism was not addressed by Peter White in his post, and we have no assurances that those conducting the PACE Trial subscribe to the WHO classification either. This is particularly noteworthy as certain of these key psychiatrists are members of the Institute of Psychiatry at King's College, who were responsible for the dissemination of misinformation about the ICD-10 classification of ME/CFS. The frequently expressed belief in 'somatization' as has been applied to ME/CFS by the psychiatrists involved in the PACE Trial does

constitute a very clear assumption of an "original cause of illness", contrary to White et al's claims in their letter to the Independent.

We would also remind the ME/CFS community of the large amount of evidence documenting the much criticised views of the psychiatrists involved in the PACE Trial about ME/CFS sufferers and the disease, exemplified by the comment quoted in the Independent and made by one of these psychiatrists:

"I will argue that ME is simply a belief, the belief that one has an illness called ME".

6. The PACE Trial Identifier, written by the psychiatrists and submitted to the MRC clearly shows that the PACE Trial ***is*** being run by the psychiatrists. We refer to clauses 4.1, 4.2, 4.4 and 4.6. As will also be seen within the PACE Trial Identifier, The psychiatrists involved in the PACE Trial ***are*** employed to provide these therapies (CBT/GET). These facts make the denial by Peter White in his Co-Cure post all the more remarkable, and poses yet another ethical problem.

7. White et al claim in their letter that the protocols used in the trial are "approved by international and independent scientists". We ask: ***Who*** are these international and independent scientists? As such important methodological and ethical problems do appear to have arisen in this trial, there are important ramifications around their participation. We therefore call for their names to be made public to the ME community without delay.

8. We note that Colin Blakemore uses the involvement of the charity Action for ME (AfME) in the PACE Trial to support his argument. We therefore re-iterate that AfME has been frequently and severely criticised (by members of the ME/CFS community itself) for their support and active involvement in a trial that from the outset has presented such major problems for sufferers.

The above concerns, and those expressed in the PACE Report, and in the Independent Newspaper article, **MUST** be addressed. The fact that they are **NOT** being addressed by the leaders of the Pace Trial leads to the inescapable conclusion that these trials must be suspended and a public enquiry made into the trial immediately. ONECLICK has already called for this, and we ask all members of the ME community to do the same: There **MUST** be a Public Enquiry over the methodological and ethical problems caused by the PACE Trial.

Angela Kennedy MA
Social Sciences Associate Lecturer
Open University
16 May 2004

Angela Kennedy
Jane Bryant
THE ONE CLICK GROUP
<http://www.theoneclickgroup.co.uk/>

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