PACE Trial Results: an Update

Margaret Williams 9th June 2011

In the interests of transparency and openness, Professor Hooper thinks it important to put in the public domain the fact that The Lancet has agreed to correct the Comment by Bleijenberg and Knoop in which they asserted that 30% of PACE Trial participants "recovered" with CBT and GET (<u>Chronic Fatigue Syndrome: where to PACE from here?</u> G Bleijenberg and H Knoop: DOI:10.1016/S0140-6736(11)60172-4).

On 6th June 2011 an email was sent on behalf of Professor Hooper to Zoe Mullan, Senior Editor at The Lancet, and relevant points of the text are reproduced here:

"There is a major problem with the Comment by Bleijenberg and Knoop which The Lancet editorial team has so far failed to address, namely their claim of a 30% recovery rate with CBT and GET for PACE participants.

"It cannot be argued that this is merely a matter of semantics (Bleijenberg & Knoop state: "The answer depends on one's definition of recovery"): those authors have unequivocally misrepresented the findings of the published paper.

"The PIs do not report the number of participants who recovered, only those who fell within their own much criticised definition of "normal range" for fatigue and physical function.

"It cannot be acceptable for The Lancet to allow Bleijenberg and Knoop to claim that 30% of participants recovered after CBT or GET when the definition of "recovered" on which they rely has been set artificially low by White et al - so low in fact that a participant described by them as recovered could still be sufficiently disabled to meet the trial's entry criteria.

"This surely represents a significant failure of both the peer review process and editorial oversight."

"Anyone reading Bleijenberg and Knoop's Comment will be left with a grossly incorrect understanding of the results of the PACE Trial.

"As mentioned in his response to Peter White, Professor Hooper quoted medical statistician Professor Martin Bland: "Potentially incorrect conclusions, based on faulty analysis, should not be allowed to remain in the literature to be cited uncritically by others" (BMJ: 19th February 2000:320:515-516).

"In view of this, Professor Hooper once again formally requests that The Lancet either retracts or corrects the Bleijenberg & Knoop Comment and he would appreciate being informed of your editorial decision about this important issue".

On 8th June 2011 Zoe Mullan replied in the following terms:

"Thank you for your message and the attachments, which I will read. In the meantime, yes I do think we should correct the Bleijenberg and Knoop Comment, since White et al explicitly state that recovery will be reported in a separate report. I will let you know when we have done this".

Professor Hooper is most grateful to The Lancet for this clarification.