

**Background to the attached “Statistics and ME” by Professor Malcolm Hooper
about the PACE Trial**

Professor Malcolm Hooper and Margaret Williams

29th November 2011

“Significance” is a quarterly magazine published by the Royal Statistical Society (RSS); it is an official magazine for both the RSS and the American Statistical Association (ASA) and is edited by Julian Champkin. It is the executive of “Straight Statistics” (see below). The stated aim of “Significance” is to show how statistics benefit society and the magazine is said to be of interest to people working in central and local government, medicine and healthcare, administration, economics, business and commerce, industry, social studies, survey research, science and the environment.

The RSS is one of the most influential and prestigious statistical societies in the world and has an international membership. Its key aim is to nurture the discipline of statistics and maintain statistical standards.

The ASA is the world’s largest community of statisticians; its members serve in industry, government and academia in more than 90 countries and it claims to promote sound statistical practice to inform public policy and improve human welfare.

“Straight Statistics” is a pressure group whose publicly stated aim is to detect and expose the distortion and misuse of statistical information/data, and to identify those responsible.

It specifically states that its aim is to examine the statistical basis of claims made in scientific and medical journals.

It is run by a Board of Directors, comprising *inter alia* of Lord (David) Lipsey (Chairman), Nigel Hawkes (Director) and Dr Ben Goldacre, a psychiatrist and former research fellow at the Institute of Psychiatry (see below).

A member of the editorial board of “Significance” is Simon Briscoe, formerly Statistics Editor at the Financial Times who in the 1980s worked in the UK Civil Service at the Treasury and at the Central Statistical Office; on 22nd September 2010 he was appointed Vice President of Product at Timetric, which indexes the world’s economic data.

On 28th June 2011 a copy of Professor Malcolm Hooper’s further concerns about the PACE Trial article published in The Lancet (<http://www.meactionuk.org.uk/Normal-fatigue.htm>) was sent to Simon Briscoe by an ME/CFS patients’ advocate who thought it would be of rightful concern to him. This document set out in detail

Professor Hooper's analysis of the apparent misuse of statistics presented by Professor Peter White et al in their report of the PACE Trial that was published in March 2011 (Comparison of adaptive pacing therapy, cognitive behaviour therapy, graded exercise therapy, and specialist medical care for chronic fatigue syndrome (PACE): a randomised trial. *Lancet* 2011; 377: 611-690). In his analysis, Professor Hooper was assisted by others, including a well-qualified medical statistician, other (non-medical) statisticians, mathematicians and research analysts, as well as by experienced professionals from other relevant disciplines.

Also on 28th June 2011, a copy was sent directly Lord Lipsey, as well as to Nigel Hawkes. Lord Lipsey's reply was perhaps prescient: *"I am forwarding to Straight Statistics director Nigel Hawkes, formerly health editor of The Times and an authority, for comment – I know he has been following this issue"*, so Nigel Hawkes received it twice.

On 30th June 2011, instead of dealing with Professor Hooper's article at Straight Statistics as had been anticipated, Simon Bristow sent it directly to Julian Champkin at the RSS, saying: *"Dear Julian, Please see the attached which is self-explanatory. I will leave you to get back to prof (sic) Hooper. Best wishes, Simon"*.

To Professor Hooper's surprise, on 30th June 2011 he received a request from Julian Champkin, saying that Simon Briscoe had forwarded his article about the PACE trial to him; Champkin's email continued: *"I edit Significance, a magazine published by the Royal Statistical Society and the American Statistical Association (Simon is a member of our Editorial Board)...**We do publish, among other things, articles exposing unjustified statistical claims. A piece on ME would be specially welcome to us, as ME is a topic of great interest to the public and treatment for it, if unjustified, should be exposed as such.** We could not publish your piece as written...our articles are less formal than a scientific journal would require; also shorter (2,800 words would be about the maximum). It would also need to explain the background to the episode....Would you be willing to write such a piece?...For the December issue, we would need it by September. Is that in principle something that would appeal to you? With best regards, Julian"*.

On 2nd July 2011 Margaret Williams sent an email to Julian Champkin: *"Malcolm Hooper has asked me to reply to your email on his behalf (his wife is very sick at present)...He thanks you for your invitation to write a piece on the PACE Trial for your magazine and he'd be delighted to do so. He'll hope to let you have a first draft in the next few weeks and in any event well before your deadline of September. You are right: ME is indeed a topic of great interest....We will be in touch shortly"*.

That same day, Julian Champkin replied to Margaret Williams: *"Thank you very much for your e-mail of 2nd July. Please convey my sympathies to Professor Hooper on the illness of his wife.....(The article) would go first to my editorial board for their consideration, and I would be guided by their comments....**The focus of the article should be on the curious situation that could result in participants being deemed to have attained levels of physical function and fatigue 'within the normal range'**"*

when they had actually deteriorated on these parameters over the course of the trial...What you describe as the 'tragedy for patients' is our main concern....It may be that, having seen the piece, I would ask Prof White to respond to it, his response to appear in the same issue. I hope that all this is acceptable to you. I very much look forward to seeing the draft article. Thank you again, and best regards, Julian".

Mindful of the prestige in which the RSS is held, Professor Hooper was encouraged to receive this invitation from such an august institution and was hopeful that, at last, the unjustified acclaim afforded to the over-exaggerated success of the PACE Trial would be exposed.

On 12th September 2011 Margaret Williams sent the requested article directly to Julian Champkin: *"Here at last is Malcolm Hooper's piece about the PACE trial that you asked him to write for possible use in your December issue....You mentioned that you were minded to send it to Peter White for his comment with a view to publishing them side by side. We have real concerns that if he sees this, he may seek an injunction to stop it being published (it wouldn't be the first time that Wessely School psychiatrists have threatened that); he has already tried to suppress legitimate criticisms of the PACE trial. It is hugely important that this analysis should not be suppressed: PACE and its media spin are causing untold distress and destitution among people with ME, and it's shocking to read that one of the PIs is now proclaiming that these patients demonstrate 'embarrassment avoidance cognitions' when in reality they're physiologically half dead. Do, please, contact me in the first instance rather than Malcolm, as he's got so much on his plate. Best regards, Margaret".*

Just afterwards, further and similar concerns as were set out in Professor Hooper's RSS article were noted: at the September 2011 International CFS/ME Conference in Ottawa, Professor Christopher Snell from the University of the Pacific described the 6 minute walk test used in the PACE Trial as essentially useless at determining real functionality; he translated the PACE result figures to physiological measures and reported that the PACE data indicated that at the end of the trial the participants would be described as *"a severely physically disabled person according to the New York Heart Association figures"*.

Anticipating a short acknowledgement (not a decision as to whether or not the article would be published), Margaret Williams was somewhat surprised to receive no acknowledgment of Professor Hooper's article from Julian Champkin so, concerned in case it had not been received, on 16th September 2011 she sent the following email to Champkin: *"We wondered if you had safely received Malcolm Hooper's article for possible use in your December issue that I sent to you and Simon Briscoe last Monday? Also, we thought you'd be interested to see that the PACE misinformation is being cited and extended:*

<http://www.biomedcentral.com/content/pdf/1472-6963-11-217.pdf>: *'Evidence from a recent evidence trial of cognitive behavioural therapy and graded exercise therapy indicated a **recovery rate of 30-40%** one year after treatment'. The reference is no:*

24, which is the PACE Trial. Such claims are statistically insupportable but seemingly unstoppable. Regards, Margaret”.

(For the record, one of the authors of that study for the UK CFS/ME National Outcomes Database was Esther Crawley, a member of the NICE Guideline Development Group which produced the NICE Guideline CG53 that recommended only cognitive behavioural therapy and graded exercise, and notorious for her study of the Lightning Process in young people with ME/CFS).

Still having heard nothing from Julian Champkin, on 29th September 2011 Margaret Williams telephoned the RSS, who confirmed that he was not on holiday or away sick; the receptionist offered to send him an email herself saying that there had been an enquiry wondering if he had received Professor Hooper’s article and asking him to let Margaret Williams know, but once again there was no response.

In one final attempt to find out what was happening, on 26th November 2011 Margaret Williams sent another email to Significance, asking that she be urgently informed about the situation.

Two days later, on 28th November 2011 she received an email from Abdel Khairoun, Editorial and Membership Assistant, saying: *“The Editor was considering the article for an issue but I regret to inform you that after consideration and consultation has now decided against using it. I apologise for my error in not communicating this to you sooner”.*

From Julian Champkin’s unsolicited invitation for an article from Professor Hooper to his friendly emails, through his initial eagerness to expose concerns about the PACE Trial (especially unjustified statistical claims) and his very real unease about the PACE Trial being a tragedy for patients with ME, to his total refusal to engage in civil communication (which some might see as plain bad manners) – what went wrong?

The following facts may, of course, be entirely coincidental:

1. Ben Goldacre is a psychiatrist at the Institute of Psychiatry, where Professor Simon Wessely is Vice-Dean of Academic Psychiatry; he is a regular Guardian columnist in which he *“skewers the enemies of reason. If you’re a journalist who misrepresents science for the sake of a headline....then beware: your days are numbered”*. He seeks to promote his opposition to what he regards as “bad science”; he is the author of a book “Bad Science”, as well as the host of The Bad Science Forum. According to Wikipedia, Goldacre claims to be *“devoted to criticism of scientific inaccuracy”* and (somewhat ironically) on 24th July 2010 he wrote: *“Even those carrying out academic research are guilty of twisting scientific facts to suit their purposes”* (this being the very subject of Professor Hooper’s article for the RSS) yet, as a member of the Board of Directors of Straight Statistics, Goldacre has remained strangely silent about the obfuscatory and clearly contrived statistical analysis of the PACE Trial data.

2. The views of Nigel Hawkes (Director of the Board of Straight Statistics, Significance being the executive of Straight Statistics) cannot be in doubt, as he makes no secret of the contempt in which he holds Professor Hooper and seems to have been involved in what appears to have been a concerted campaign to discredit him.

In his article “Dangers of research into chronic fatigue syndrome – Nigel Hawkes reports how threats to researchers from activists in the CFS/ME community are stifling research” published in the British Medical Journal on 22nd June 2011, Hawkes allied Professor Hooper with a vicious campaign of intimidation by people who have allegedly sent death threats to Professor Simon Wessely and who, it is claimed, are responsible for the lack of good scientists working in the field, thereby drawing Professor Hooper’s reasoned concerns about the PACE Trial into something with which he is in no way involved.

It seems inescapable that Hawkes was on a mission. He began by mentioning Professor Hooper’s complaints about the PACE Trial to the Medical Research Council (MRC) and quoted a less-than-complimentary but less-than-accurate comment about him made by Dr Frances Rawle, Head of Corporate Governance and Policy at the MRC before emphasising -- inaccurately -- that Professor Hooper’s complaint to both the MRC and The Lancet were rejected (the MRC was eventually forced to concede some of Professor Hooper’s concerns and The Lancet confirmed in writing that what had been published was incorrect).

Hawkes then went on to quote Professor William Hamilton (who, with Esther Crawley, was a member of the NICE Guideline Development Group that produced Clinical Guideline 53 on CFS/ME); referring to the fact that Hamilton was reported to the General Medical Council (by Professor Hooper, for allegedly knowingly misleading the High Court in the Judicial Review of the NICE Clinical Guideline, for which Professor Hooper has irrefutable evidence written by Hamilton himself and which it is alleged perverted the course of justice), Hawkes wrote: *“The personalised nature of the campaign has much in common with that of animal rights activists, who subjected many scientists to abuse and intimidation in the 1990s...While the campaigners have stopped short of the violent activities of the animal rights groups, they have another weapon in their armoury – reporting doctors to the GMC”*.

Hawkes also quoted Professor Peter White as saying: *“The paradox is that the campaigners want more research into CFS. But if they don’t like the science they campaign to stop it. They want more research but only research they agree with”*.

Hawkes also stated: *“Professor Wessely says that scientists have been appalled at their treatment and that some have sworn never to work in the field again”*.

Overall, Hawkes left the reader in no doubt that Professor Hooper was supporting those immoderate activists who were responsible for intimidating and threatening good scientists.

Given what he had published in the BMJ that same month, Hawkes' response of 29th June 2011 to Professor Hooper's in-depth analysis of the PACE Trial was very much in keeping: *"I will read it when I have time. My article for BMJ has nothing to do with Straight Statistics. I haven't written about this subject for Straight Statistics and don't propose to"*.

As Julian Champkin had made it clear that he would be guided by his editorial board, he could not have published Professor Hooper's invited article without the Director of Straight Statistics seriously losing face, so once again pride and profit have taken precedence over patients.

Sadly, what started as a real hope that the statistical manipulation of the PACE Trial data would be exposed has become just another chapter to be chronicled in the on-going tragedy that is ME/CFS.