

## **Absence of Evidence**

Margaret Williams    18<sup>th</sup> February 2017

### **Introduction**

As is widely known, Professor Sir Simon Wessely is President of the Royal College of Psychiatrists and is President-elect of The Royal Society of Medicine; his GP wife Dr Clare Gerada, now Lady Wessely, was Chair of the Council of the Royal College of General Practitioners.

A "Joint Commissioning Panel for Mental Health" from these two Royal Colleges has just produced a 24 page document entitled **"Guidance for Commissioners of services for people with medically unexplained symptoms – practical mental health commissioning"** in which they include myalgic encephalomyelitis/chronic fatigue syndrome as a functional somatic syndrome ie. as a mental disorder (<http://www.jcpmh.info/wp-content/uploads/jcpmh-mus-guide.pdf>).

The document is intended for, amongst others, Commissioners of NHS services, Directors of Adult Social Services, the Royal College of Nursing and the Clinical Commissioning Groups that are run mostly by GPs who commission local health care.

This could sound the death knell for people with ME/CFS who currently receive care packages funded by their Local Authority because there is abundant evidence that cash-strapped Local Authorities spend next to nothing on mental health.

For decades, the proponents of the now-infamous PACE Trial -- particularly Professors Simon Wessely and Peter White -- have maintained that without hard evidence of organic pathology, they will not accept the WHO classification of ME/CS as an organic disorder and they insist that it is a functional somatic syndrome (FSS).

In other words, ignoring the existing evidence-base of pathoetiology, since there is not as yet a definitive test for ME/CFS, they believe that absence of evidence really is evidence of absence, so they continue to categorise ME/CFS as a behavioural disorder that can be "cured" by cognitive behavioural therapy (CBT) and graded exercise therapy (GET) and they advise Departments of State that these interventions are both effective and cost-effective.

In their own insular world of psychiatry, however, they appear to have convinced themselves that absence of evidence is not evidence of absence when it comes to the clinical and cost-effective benefit of CBT/GET for people with ME/CFS.

The PACE Trial was funded because it was acknowledged that previous trials of CBT and GET were insufficiently robust. As is now undeniable, the PACE Trial failed, so not only is there no evidence that ME/CFS is a functional somatic syndrome but there is no credible evidence that CBT/GET are effective interventions for its management.

### **Lack of evidence of both clinical benefit and cost effectiveness**

1. In 2001 the York Centre for Reviews and Dissemination reviewed the available evidence for the clinical effectiveness of CBT/GET in ME/CFS; the review team's negative comments referred to methodological inadequacy; study withdrawal; drop-out rates for CBT; drop-put rates for GET; the unacceptability of treatments; reported improvements may be illusory (*"the modest gains may be transient and even illusory"*); there was no objective evidence of improvement and there was little lasting benefit from CBT (Interventions for the treatment and management of chronic fatigue syndrome: a systematic review. Whiting P, Bagnall AM et al: JAMA 2001: Sept 19:286(11):1360-1368).
2. In 2005, Bagnall AM et al from the same Centres for Review and Dissemination produced the 488-page "York Review" of the "evidence" of the effectiveness of CBT/GET from the same studies they had reviewed in 2001 (The diagnosis, treatment and management of chronic fatigue syndrome (CFS) / myalgic encephalomyelitis (ME) in adults and children – Work to support the NICE Guidelines).

Notably, given that the same RCTs were scrutinised, all previous negative comment from 2001 had disappeared from the 2005 version, but in both the 2001 and 2005 versions, two important issues were not mentioned: (i) corrupted data and (ii) follow-up data revealed relapse, but the 2005 version was the "evidence" upon which the NICE Guideline was predicated.

3. In August 2007 NICE duly produced its Guideline on "CFS/ME" in which it acknowledged the lack of adequate research evidence whilst simultaneously asserting: *"The guideline provides recommendations for good practice that are based on the best available evidence of clinical and cost effectiveness"*.

In his CV, Professor Sir Simon Wessely states about the NICE Guideline: *"My work has significantly influenced the management of chronic fatigue syndrome, reflected in the 2007 NICE Guidelines"*.

Not only did NICE rely on “illusory” clinical benefit, it manufactured its own evidence on the cost-effectiveness of CBT and found no convincing evidence of the cost-effectiveness of GET.

There were numerous basic arithmetical errors in the Guideline (conceded by Professor Peter Littlejohns, Clinical and Public Health Director of NICE, in his Witness Statement for the High Court Judicial Review) but, importantly, NICE’s own cost-effectiveness search found that out of 60 papers reviewed, only three were considered suitable.

One was a study by Wessely et al which showed no benefit from CBT (BJGP 2001:51:15-18).

Another was the Severens et al paper (Severens JL et al, Q J Med 2004:97:153-161), which in turn relied on the flawed Prins et al study (Lancet 2001:357:841-847), a study about which in his evidence for the Judicial Review, Martin Bland, Professor of Health Statistics, University of York, presented convincing evidence showing why *“the entire Prins trial”* was *“invalidated”*.

NICE, however, decided that the Severens et al paper upon which its entire costing analysis had to rely had under-reported the benefit because the timescale used was insufficient to show long-term benefit (its timescale being only 14 months in total and not the desired five years).

NICE therefore decided to “extend” the Severens timescale to fit its own requirements to show long-term cost benefit of CBT.

Since there was no evidence of long-term cost-effectiveness in the Severens et al paper, NICE decided to use the 2001 study by Deale et al which was a five-year follow-up of their 1997 paper (Long-term Outcome of Cognitive Behavioural Therapy Versus Relaxation Therapy for Chronic Fatigue Syndrome: A 5-Year Follow-Up Study. Alicia Deale, Trudie Chalder, Simon Wessely et al. Am J Psychiat 2001:158:2038-2042).

To obtain the “evidence” it needed, ignoring the fact that the two trials used different cohorts and different criteria, NICE extrapolated Deale et al’s 2001 results published in the American Journal of Psychiatry and projected those results into the Severens et al’s 2004 paper to produce what NICE thought might have been Severens’ results in five years’ time.

Of importance is the fact that this sole 5-year follow-up study by Deale et al suffered from corrupt data: the authors themselves acknowledged that: *“56% of the patients undergoing CBT reported receiving further treatments for their chronic fatigue symptoms; other treatments used were antidepressants, counselling, physiotherapy and complementary medicine”*, and over the

course of the five year follow-up, treatment of many patients had deviated from the trial protocol, rendering the outcome measures meaningless.

This did not deter NICE from using the corrupted data from the Deale et al study to create its own cost effective “best evidence” in relation to CBT for ME/CFS.

It is difficult to understand how NICE could get away with creating “evidence” which did not exist and relying on the “evidence” it had created to underpin a national Guideline that claimed to set out best practice.

In the key (Severens) paper upon which NICE relied as “evidence” of the cost-effectiveness of CBT, the Guideline Development Group did not have access to the source data (conceded on page 209 of the Full Guideline). When it subsequently became available, the objective actometer data showed no statistically significant difference between cohort and controls.

This means that NICE produced a Guideline with a potential catchment of 240,000 sick people based on a flawed analysis that failed to consider objective data which showed no benefit from CBT.

With regard to GET, the single study which attempted to examine the relative cost-effectiveness of CBT and GET found that the cost-effectiveness of CBT and GET were similar but the study was limited by its small size and by “*the use of a non-randomized comparison*” (McCrone P et al: Psychological Medicine 2004:34:991-999).

Given that both clinical benefit and cost-effectiveness were based on very limited and poor quality evidence, the development of the Guideline was hardly a scientific approach, let alone one that was “excellent” by the-then titled National Institute for Health and Clinical Excellence.

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4. In 2008 the Cochrane Systematic Review of CBT/GET found that costing was under-researched and that there was a pronounced lack of research into the likely costs to the NHS of CBT/GET for patients with ME/CFS. Importantly, Cochrane regarded CBT and GET as integral: “*For the treatment of CFS, CBT combines a rehabilitative approach of a graded increase in activity with a psychological approach addressing thoughts and beliefs about CFS that may impair recovery*”, hence the Cochrane comments on costing applied to both CBT and to GET.
5. On 6<sup>th</sup> January 2011 Frances Rawle PhD, Head of Corporate Governance and Policy at the Medical Research Council, wrote to Professor Malcolm Hooper

confirming about CBT/GET that, prior to the PACE Trial: *“there was insufficiently strong evidence from randomised controlled trials to support their effectiveness”*. This was a surprising admission, because the NICE Guideline that advocated CBT/GET was published four years before the initial results of the PACE Trial appeared.

6. In 2012 McCrone et al published their cost-effectiveness results of CBT/GET based on the PACE Trial data (Adaptive Pacing, Cognitive Behaviour Therapy, Graded Exercise, and Specialist Medical Care for Chronic Fatigue Syndrome: A Cost-Effectiveness Analysis. Paul McCrone, Michael Sharpe, Trudie Chalder, Martin Knapp, Anthony L. Johnson, Kimberley A. Goldsmith, Peter D. White Published: August 1, 2012 <http://dx.doi.org/10.1371/journal.pone.0040808>).

Over three years later, despite legitimate efforts by Professor James Coyne to gain access to the data so that he could independently verify McCrone et al's economic analysis, since 11th December 2015 his request has been refused as a “Vexatious Request” by King's College, London: *“The university considers that there is a lack of value or serious purpose to your request. The university also considers that there is improper motive behind the request. The university considers that this request has caused and could further cause harassment and distress to staff”*, hence there has been no independent scrutiny of McCrone et al's claim of cost-effectiveness for CBT/GET in ME/CFS.

The PACE Investigators refuse to accept that their favoured interventions of CBT and GET are neither clinically beneficial nor cost-effective so, as Professor Jonathan Edwards notes on Phoenix Rising about their latest attempt to save face (<http://dx.doi.org/10.1080/21641846.2017.1288629>): *“We seem to live in a world full of people digging holes for themselves”*.

Perhaps the best summary of what has become a farcical situation is provided by “Sean” who wrote on Phoenix Rising: *“So let me get this straight: PACE was justified on the grounds that the existing literature was insufficiently robust and needed proper ‘definitive’ testing.*

*“But when the results from PACE did not support the results from previous studies, nor hence the underlying theoretical model, the numbers were simply fiddled until they did, and this was justified by saying the new numbers now agree with those previous studies, the same ones that were insufficiently robust enough that they provided the justification and necessity for the “definitive” PACE in the first place.*

*“So the previous results being tested by PACE, because they were not robust enough, became the standard by which the results from PACE were determined to be robust or not.*

*“Circularity City, or what”.*

Whilst the clinical benefit and the cost-effectiveness of CBT/GET may both be illusory, the Report for Commissioners from the two Wessely family-influenced Royal Colleges is anything but an illusion.

By categorising ME/CFS as a mental disorder, it intentionally disregards the mandatory use of the ICD-10 classification codes throughout England as required by NICE.

This is a serious and dangerous situation: patients with the profoundly disabling neuro-immune disease ME/CFS are now likely to be subject to even more iatrogenic harm.

Documented iatrogenic harm includes not only lack of medical care, where patients' symptoms are ignored, dismissed and denied, but also abuse and ridicule.

Sufferers may yet again be bullied into undertaking harmful management interventions and if they do not comply, their State and insurance benefits are likely to be reduced or withdrawn, putting their very survival at risk.