

Deliberate Deceit or Inexcusable Ignorance?

Margaret Williams 4th March 2008

The UK Government's response of 27th February 2008 to a petition containing 8,481 signatures asking that myalgic encephalomyelitis / chronic fatigue syndrome (ME/CFS) be accepted in the UK in the same category as in the World Health Organisation's International Classification of Diseases was predictable.

That petition asked: *"We the undersigned petition the Prime Minister to get the Health Service and medical profession to accept the WHO classification of ME/CFS as an organic neurological disorder and not as a psychosocial syndrome"* and it noted that official Guidelines are still directing the Health Service to treat ME sufferers by means of cognitive behavioural therapy (CBT) and graded exercise therapy (GET), these being tools used to treat mental illnesses. The petition asked for money to be invested in research into the physiological aetiology of ME/CFS and noted that: *"Patients should not be forced into becoming psychiatric cases or lose their benefits"* (see <http://petitions.pm.gov.uk/ME-is-real/>).

The Government's response was tortuous: *"The World Health Organisation classifies CFS/ME as a neurological illness, but we recognise that many others working in the field of CFS/ME believe that until further research identifies its aetiology and pathogenesis, there is a risk of restricting research into the causes, mechanisms and future treatments for CFS/ME. There is currently very little information about the relative benefits of CBT and graded exercise treatment and a scientific trial is the only way to find out which is the most effective approach. The aim behind CBT is to support a sustainable improvement in functioning and adaptation to illness (and) CBT can help the patient to feel more in control of their illness. In common with other illnesses such as cancer where it has been successfully used, its use does not imply that the cause of (CFS/ME) is psychological"* (see <http://www.pm.gov.uk:80/output/Page14656.asp>).

On 4th March 2008, Amanda O'Donovan, Lead Clinical Psychologist at St Bartholomew's Hospital, London (whose CFS Unit is heavily involved with the psychosocial model of "CFS/ME") posted a message of support for the Government's response on a UK ME/CFS internet group (<http://health.groups.yahoo.com/group/IMEGA-e/message/24450>), stating: *"The use of CBT in cancer is not used to justify its application in CFS/ME, nor does (the Government's response) imply that. CBT is recommended for management of CFS/ME as the evidence base shows it (and GET bien sur) to be the most effective interventions. The list of physical conditions where CBT is recommended is much longer than CFS/ME and cancer and includes cardiac rehabilitation and chronic pain as well as diabetes, stroke, cystic fibrosis (and) HIV. I hope this clarifies"*.

This would seem to be a most disingenuous response as it implies (i) that CBT has been shown to be efficacious in “CFS/ME” and (ii) that CBT is used as a primary intervention in other organic disorders to help sufferers deal with serious illness (so “CFS/ME” sufferers should not reject it), when neither of these implications is true.

In relation to the first point, the reality is that the so-called “evidence-base” for the efficacy of CBT that NICE (National Institute for Health and Clinical Excellence) relied upon in its Guideline of 22nd August 2007 for the management of “CFS/ME” simply does not exist.

This is because NICE chose to rely on the “evidence” produced by psychiatrists of the Wessely School, whose data was flawed because they deliberately included patients in their studies who, by the psychiatrists’ own case definition, could not be suffering from ME, yet they claim their studies refer to “CFS/ME”.

Furthermore, it has been clearly demonstrated that in the Systematic Review of the literature on CBT/GET which formed a major part of the “evidence-base” used in the NICE Guideline on “CFS/ME”, information was skewed and even deleted in order to cast CBT/GET in a more favourable light than the evidence permitted, a matter which may constitute research misconduct (for a detailed exposition of the evidence, see http://www.meactionuk.org.uk/FINAL_on_NICE_for_Gibson.html).

It will be recalled that even the team from the Centre for Reviews and Dissemination at York who carried out the Systematic Review specifically to support the NICE Guideline found that after a course of CBT, there is no objective evidence of improvement and that any transient gains may be illusory (Whiting P, Bagnall A-M et al; JAMA 2001;286:1360-1368).

In relation to the second point, the NICE Guideline on “CFS/ME” itself does not interpret CBT or GET as adjunctive support in dealing with a devastating disorder, and neither does the Chief Medical Officer’s Working Group Report of January 2002.

The CMO’s Working Group Report defines CBT as: “*a tool for constructively modifying attitude and behaviour*” (Annex 6: 11:8).

The NICE Guideline recommends the use of CBT to correct “*unhelpful beliefs*”; it states that CBT should be used to address “*the relationship between thoughts, feelings, behaviours and symptoms*” and it refers to “*the distinction between causal and perpetuating factors*”. It specifically states that the CBT plan will include “*identifying perpetuating factors that may maintain CFS/ME symptoms*” and that the CBT plan will address “*any over-vigilance to symptoms*”. This is wholly unacceptable: it demeans people with ME/CFS and it ignores the substantial body of evidence that ME/CFS is not a psychosocial disorder.

Referring to GET, the NICE Guideline specifically states that the intensity of GET should be incrementally increased, leading to aerobic exercise. This is in direct contradiction to international experts such as Professor Paul Cheney from the US, who advise that aerobic

exercise should not be used in patients with ME/CFS who may be in a form of heart failure.

It would thus seem to be improper for anyone to suggest that in “CFS/ME”, CBT/GET is merely providing adjunctive support for people who have to deal with serious organic disease.

As shown in the Spring 2008 edition of “Breakthrough” produced by the research charity ME Research UK (MERUK), it is only in the case of “CFS/ME” that a NICE Guideline recommends CBT as the primary management approach, and contrary to the implications of Ms O’Donovan’s statement, CBT is not promoted by NICE or anyone else as the main intervention in cancer, chronic heart failure, Parkinson’s Disease, multiple sclerosis, chronic pulmonary disease, diabetes, hypertension or indeed in any other physical disorder.

Since NICE was founded in 1999, well over one third of its appraisals (42) have been challenged and gone to appeal, and nearly half of these appeals have been upheld. On 10th January 2008 the UK House of Commons Health Select Committee called for a major review in the way that the Government-appointed NICE makes its recommendations. The Committee’s decision is not surprising, given the current levels of public, patient and industry dissatisfaction with the Institute’s performance (see: The Patient as Activist: HSCNews International, issue 11, February 2008; <http://www.patient-view.com>).

A significant amount of evidence showing that CBT is not effective (either in ME/CFS or in other organic disorders) was submitted to NICE during the consultation period. NICE, however, chose to disregard this evidence, just as it disregarded all the evidence that was unsupportive of its seemingly pre-determined policy (i.e. ensuring that the only regime to be recommended for the management of “CFS/ME” would be CBT/GET).

In particular, evidence from world-renowned psychiatrists such as Per Dalen, a Professor of Psychiatry from Sweden, and from Australian psychiatrist Neil McLaren was disregarded (for their evidence, see “Myalgic Encephalomyelitis: a review with emphasis on key findings in biomedical research”. M Hooper. J Clin Pathol 2007;60:466-471).

To date, there has been no explanation from NICE as to why, for example, it disregarded the evidence contained in “Clinical Psychology Forum 162”, June 2006 (i.e. over a year before the publication of its Guideline), in which internationally renowned psychologists exposed the reality that psychological therapies do not actually work and may in fact harm patients who submit to them.

For the avoidance of doubt, the following are quotations from that issue (all are fully referenced in the document itself):

“Reflections on the practice of clinical psychology” by Bob Diamond (pp 3- 8)

*“Clinical psychology is part of mental health services that, on occasions, contribute more to people’s distress than provide possible benefits. There are plenty of testaments to suggest that the iatrogenic effect of mental health services contribute to the ongoing damage to people’s lives. **There’s plenty of evidence showing positive outcomes to psychotherapy to be much more modest than our profession has so far acknowledged.** We should ensure that our work is based in reality and not premised on prevailing popular, even fashionable, concepts. Whilst specific psychological approaches may continue to offer some help to some people, some of the time, such claims should be more modestly made”.*

“Fundamental questions for psychology” by John Cromby (pp 9 – 11)

“This paper argues that the mainstream of psychology is misconceived in ways which make it largely unsuitable as a basis for clinical interventions”.

“Implications for practice” by David Smail (pp 17 – 20)

“Evidence for the effectiveness of psychological therapies is far weaker than can be considered acceptable. Largely to avoid these difficulties, clinical psychology has tended to opt for dogma rather than truth. Perhaps the greatest danger facing us is that we become reduced to production-line workers who deliver packages of treatment in accordance with centrally authorised notions of what constitutes an ‘evidence-base’. This certainly is the direction advocated by Richard Layard and endorsed by prominent members of the profession”.

“Lost for Words” by Paul Kelly and Paul Maloney (pp 21 – 24)

“Narrative therapy emerged from its parent discipline of family therapy (and) its theoretical base draws upon social constructionism. It has become clear that social constructionist philosophy may have serious practical implications”.

“That was then, this is now” by Penny Priest (pp 25 – 28)

*“The gulf between fiction and reality – perhaps we cling to the illusion of control because it’s unbearable to think about the possibility that sometimes we are not much more powerful than the people we are trying to help. **It’s easy to get caught up in playing this game of changing people.** We might feel disingenuous pretending that our work is a scientific exercise, calling an intervention ‘CBT’, as if this is some quantifiable thing and then calling the outcome successful or not successful on the basis of scores on a questionnaire”.*

“The trouble with psychotherapy” by Paul Maloney (pp 29 – 33)

“The supposedly sound evidence base for the effectiveness of the psychological therapies may be far more questionable than is widely supposed. The term ‘psychotherapy’ refers to a broad family of talking treatments which are of proven effectiveness. The assumptions contained within this sentence constitute the taken-for-granted world of the profession (and) are endorsed in central government recommendations for the use of psychological therapies in the NHS, and most recently in calls by Richard Layard (for CBT to be the) main answer to the personal and social malaise which seems to be afflicting us at record levels. In contrast, the enduring reality is that the psychotherapy outcome literature offers precious little support for any of the above notions. This is an observation that seems to have been consistently ignored. A large number of investigations (assessing the effectiveness of psychological therapies) have been conducted, and although the results of these studies have been extremely variable, so-called meta-analyses suggest that most forms of psychological therapy are at least mildly helpful (and) undergoing psychological therapy is claimed to reliably lead to significant improvement in the mental health of up to a quarter or above of all recipients. Not surprisingly, these claims seem to be authored by the core psychotherapy professions. Yet there are a number of serious methodological problems associated with attempts to assess the effectiveness of psychotherapy in this way, so much so that some academics and practitioners admit that it is hard to decide whether studies do or do not support the notion that psychotherapy is generally helpful.

“To begin with, the field has long suffered from a bias towards selective reporting and publication of those studies that show only the desired positive results. Many trials have included inadequate control groups (and) a large proportion of studies have also suffered from systematic participant attrition or selection effects that make the result hard to interpret. Statistically significant differences in outcome have often concealed large numbers of people for whom psychotherapy has been ineffective. Aside from these far from minor difficulties, this literature may suffer from an even more pervasive problem. This is the tendency to rely almost exclusively upon the reports of participants in the absence of any fully independent check upon the treated person’s progress in the world outside the consulting room.

“Rather than getting to grips with these findings, the clear possibility remains that most of the claimed benefits of psychotherapy might reside in the placebo effects. This last prospect is strongly underscored by four further lines of evidence (these are set out in the article). A reliable trend within the psychotherapy outcome literature is that the closer the study comes to real life settings, the less significant the outcomes tend to be. The recent American multi-centre research trial involved the analysis of 42,000 clients over a span of five years. The results were disappointing in that there was no evidence that psychological therapy led to improvement in the lives of these recipients. As Tana Dineen (1999) observes: ‘ These results should raise serious doubts about some current clinical beliefs about the effectiveness of psychological services....there is scant evidence of its effectiveness in real life settings’. None of (this evidence) seems to be very encouraging for the official view of psychological therapy as a well-validated body of

*effective clinical treatments, (yet) the tendency inside the therapeutic professions seems to have been to ignore or downplay these considerations. Personal conviction is doubtless one of the reasons. **Another element may be the reliance upon meta-analytic studies, a trend that is reinforced by the accumulating NICE guidelines on psychotherapeutic practice in the NHS. Although officially presented as both definitive and authoritative, such methods are notoriously prone to generating misleading or inconclusive data***".

Given that this is actual confirmation that CBT is ineffective and that this evidence was in the public domain for over a year before the production of its Guideline on "CFS/ME", why would NICE have ignored this relevant evidence that was available to its Guideline Development Group?

Although it post-dates the publication of the NICE Guideline on "CFS/ME", there is further criticism of the NICE policy of recommending CBT. On 10th January 2008 Malcolm Learmonth, a senior art psychotherapist with Devon Partnership NHS Trust, wrote an article called "The wrong advice" (see <http://www.psychminded.co.uk/news/news2008/jan08/wrongadvice001.htm>). It was also published in Openmind magazine. He said the following:

"Both (the Layard report) and the NICE guideline on depression are shaping policy and having a major impact on what help is available to people. And both claim that CBT is the 'evidence-based' psychological treatment. The full NICE guideline runs to 358 pages, but it is also available in three shortened versions. Unsurprisingly, few people – including those who implement the guideline – read the full version. Yet it is only in the full version that the flaws show themselves. The shortened versions simply remove all the doubts. What is presented to the world as 'Now we know all the facts we can tell you what's good for you' turns out to be highly questionable. Let's start with user participation. The guideline claims that 'For any guideline to be credible it has to be informed at every stage of its development by the perspective of patients' (p31). Yet the service user perspective takes up less than one page out of 358. This is mere lip service: there is no evidence of service user participation having taken place beyond this statement. The apparent logic and coherence of the guideline's approach breaks down under scrutiny.

"Then there is the question of what constitutes 'evidence'. Grade A evidence is obtained from random controlled trials (RCTs). Grade B evidence is (from) well-designed controlled studies without randomisation. Grade C evidence is expert opinion. It is extraordinary to claim that the guideline is based on the clinical experience of healthcare professionals, when only the professional group define who they regard as expert authorities and what constitutes evidence. As we have seen, evidence that is service user based doesn't count, making a nonsense of claims that these perspectives are central.

"And then there are the vested interests of those who manufacture the evidence (and who), as the guideline acknowledges, may produce unreliable evidence. The writers of the guideline know that this evidence is distorted, and say so. And yet it is still presented

as Grade A evidence. Even this evidence for CBT is a lot weaker than the abbreviated guideline would have us believe. Read the shortened guideline and you could believe that antidepressants and CBT are 'facts' of what 'works'. Read the full version or try talking with a few people and you get a different picture.

"I conclude that the guideline is a logically flawed mouthpiece for the professional and commercial vested interests that have created it. We must challenge NICE's approach to mental health, root and branch".

On 29th February 2008 Learmonth followed this up with a letter published in The Guardian, which was unequivocal: *"Only in the small print of the National Institute for Health and Clinical Excellence guidelines that are pushing CBT as the psychological therapy do we find statements like 'the clinical evidence review showed no overall superiority for CBT alone on treatment outcomes over antidepressants' "*.

There is also the recent Dutch report of February 2008 by Drs MP Koolhaas, H de Boorder and Professor Elke van Hoof (see <http://www.immunesupport.com/library/showarticle.cfm/ID/8724>) which comes to unambiguous conclusions about CBT:

"In recent years, Chronic Fatigue Syndrome, also known as Myalgic Encephalomyelitis (ME/CFS), has been getting a lot of attention in scientific literature. There is as yet no consensus about the treatment of ME/CFS. The different treatments can be subdivided into two groups, the pharmacological and the psychosocial therapies.

*"Most of the scientific articles on treatment emphasize the psychosocial approach. **The most intensively studied psychological therapeutic intervention for ME/CFS is cognitive behaviour therapy (CBT).** In recent years several publications on this subject have been published. **These studies report that this intervention can lead to significant improvements in 30% to 70% of patients, though rarely include details of adverse effects.***

*"**This pilot study was undertaken to find out whether patients' experiences with this therapy confirm the stated percentages.** Furthermore, we examined whether this therapy does influence the employment rates, and could possibly increase the number of patients receiving educational training, engaged in sports, maintaining social contacts and doing household tasks.*

***"Method:** By means of a questionnaire posted at various newsgroups on the Internet, the reported subjective experiences of 100 respondents who underwent this therapy were collected. These experiences were subsequently analysed.*

"Results:

- *Only 2% of respondents reported that they considered themselves to be completely cured upon finishing the therapy*

- 30% reported ‘an improvement’ as a result of the therapy
- The same percentage [30%] reported no change
- 38% said the therapy had affected them adversely, the majority of them even reporting substantial deterioration
- Participating in CBT proved to have little impact on the number of hours people were capable of maintaining social contacts or doing household tasks
- A striking outcome is that the number of those respondents who were in paid employment or who were studying while taking part in CBT was adversely affected. The negative outcome in paid employment was statistically significant.

“A subgroup analysis showed that:

- Those patients who were involved in legal proceedings in order to obtain disability benefit while participating in CBT did not score worse than those who were not.
- Cases where a stated objective of the therapy was a complete cure did not have a better outcome.
- Moreover, the length of the therapy did not affect the results.

“Conclusions: This pilot study, based on subjective experiences of ME/CFS sufferers, does not confirm the high success rates regularly claimed by research into the effectiveness of CBT for ME/CFS.

“Overall, CBT for ME/CFS does not improve patients’ well-being: More patients report deterioration of their condition rather than improvement.

“Our conclusion is that the claims in scientific publications about the effectiveness of this therapy, based on trials in strictly controlled settings within universities, has been overstated and are therefore misleading”.

(Source: Medisch Contact, February 2008, ISBN: 978-90-812658-1-2, by Koolhaas MP, de Boorder H, van Hoof E. The Netherlands. Information from m.p.koolhaas@consunet.nl).

The evidence of the lack of efficacy of CBT continues to mount up, but who – apart from the ME/CFS community – is paying attention or cares about this travesty?

Could it be that both NICE and Amanda O’Donovan (not forgetting the UK Government and the Wessely School psychiatrists who act as its advisers on “CFS/ME”, the NHS, the Department of Health, the Department for Work and Pensions and the Medical Research Council) prefer their personal conviction to actual evidence?