

Statements of Concern about Cognitive Behavioural Therapy and Graded Exercise Therapy provided for the High Court Judicial Review of February 2009

Margaret Williams 22nd July 2009

Over twenty renowned ME/CFS experts provided Statements in support of the Judicial Review of the NICE Guideline on "CFS/ME" heard in February 2009 in the High Court in London. They were specifically written in support of the challenge to the NICE Clinical Guideline on "CFS/ME" and they express concern about the recommendation by NICE that the only management of ME/CFS should be CBT and GET (the same interventions that are the subjects of the Medical Research Council's PACE Trial).

None of the Statements was accorded the recognition that they merit.

Extracts from those Statements (some of which were of considerable length) are now being placed in the public domain in the interests of ME/CFS sufferers and those who support and care for them.

- "In my view, the Guideline is biased and over rigid in its recommendations and will put a large number of ME sufferers at risk of harm through its strong recommendations for the use of CBT and GET. CBT is based on the idea that somatoform disorders are maintained by abnormal or unhelpful illness beliefs which lead to abnormal or unhelpful behaviour. The first requirement for a somatoform diagnosis is that there be no physical cause for the symptoms. This is not the case in ME/CFS" (Malcolm Hooper, Professor Emeritus of Medicinal Chemistry, University of Sunderland, November 2007)
- "Two forms of treatment...are CBT and GET. CBT is a psychological treatment. Its application in what is certainly an organic disorder is basically irrational. Its putative mode of action is based on the proposition that patients with ME/CFS feel unwell because they have an 'abnormal illness belief', and that this can be changed with CBT. It has never been proven to be helpful in the majority of patients with ME/CFS. GET comprises a regime of graded exercise, increasing incrementally over time. It has been almost universally condemned by most patient groups. A number of patient surveys have shown it to be, at best, unhelpful, and at worst, very damaging. Its application is counter-intuitive, particularly when one of the most debilitating and well recognised symptoms of ME/CFS is post-exertional malaise which can put some patients in bed for days after relatively trivial exertion" (Dr William Weir, Consultant Physician, November 2007)
- "The GDG has placed undue reliance upon a small number of RCTs that were methodologically flawed because they did not adequately define the patient population" (Dr Terry Mitchell, formerly Consultant Clinical Lead (CNCC) of the Norfolk, Suffolk & Cambridgeshire NHS ME/CFS Service, 23rd June 2008)
- "The predominance of psychologists / psychiatrists on the GDG is entirely inappropriate and has led to a biased analysis in my opinion. The GDG has placed undue emphasis on a few UK clinical trials which support the use of psychological treatments, however, these studies did not properly or adequately define their patient population" (Dr Jonathan Kerr, Hon. Consultant in Microbiology; Consultant Senior Lecturer in Inflammation; Principal Investigator of the CFS Group, St George's University of London, 11th August 2008)
- "You will see from my attached treatise that I consider that the recommendation of CBT and GET as blanket treatments of 'clinically excellent' first choice is extremely dangerous to patients. I am

- concerned that NICE claims that an adequate evidence base supports CBT/GET, when in fact the Guideline Development Group (GDG) relied almost exclusively on a handful of extremely controversial RCTs (random controlled trials). I have no doubt that patients in the research quoted by the GDG did not have ME/CFS" (Dr Irving Spurr, Newcastle ME Research Group; 12th August 2008)
- "My overall impression reading the Guidelines for the first time was one of alarm. I will limit my comments to the deficiency which has the greatest potential for harm to patients. The NICE Guidelines do not make any reference to the biomedical literature on ME/CFS. A physician who is new to the field and who has not had time to read the thousands of paper reporting measurable abnormalities in ME/CFS may get the impression that: (1) Biomedical issues are irrelevant in ME/CFS and that (2) CBT and GET actually make the core symptoms of people with ME/CFS better. A close read of the literature reveals that none of the core symptoms of ME/CFS improve with CBT or GET. The recommendation for GET stems from the often quoted but unproven assumption that deconditioning causes or exacerbates ME/CFS. In fact this assumption has been disproven (Bazelmans et al 2001; Harvey et al 2008) and cannot therefore be used as a basis for treatment. Informed consent is an ethical requisite in the practice of medicine. Informed consent requires that patients embarking on any therapy be told the potential benefits and risks of the therapy being recommended. Meeting this legal standard in ME/CFS requires that patients be told about the potential benefits and risks of CBT/GET. If patients are being coerced to believe what is not true, psychological trauma can result. If patients are pushed to increase activity beyond their capabilities, exacerbation of symptoms can be expected. The NICE Guidelines are biased towards a particular model of CBT/GET that is widely viewed as ineffective and potentially unethical" (Dr Eleanor Stein, Consultant Psychiatrist, Calgary, Alberta, Canada, 12th August 2008)
 - "(Graded exercise therapy) is not therapy – it is simply the enforcement of an opinion rather than a treatment based upon any scientific examination of a patient's pathology and treatment of that pathology. I believe that those who developed (the) graded exercise programme as a valid treatment of ME have already been soundly criticised to the Courts. I also believe scientific evidence that such a programme is against the best interests of ME patients has already been presented. The benefit of such a programme is to the interests of the insurance industry and not the patient. Graded exercise programmes may be significantly dangerous to many of these ME patients" (Dr Byron Hyde, Clinician specialising in ME, having examined over 3,000 patients between 1984 – 2008; Ottawa, Canada; 15th August 2008)
 - "(The GDG) produced a Guideline that recommends CBT and GET as the prime treatment yet there is in fact published evidence of contraindication / potential harm with GET. This has been published by independent researchers (e.g. Peckerman et al). The NICE GDG claims that CBT/GET are supported by significant research. In fact the GDG relied almost exclusively on specious reports which are unproven" (Dr Derek Enlander, Virologist specialising in ME/CFS; formerly Assistant Professor at Columbia University and Associate Director of Nuclear Medicine at New York University; Physician-in-Waiting to the UK Royal Family and to members of HM Government when they visit New York; 18th August 2008)
 - "I regard the continuing aura of disbelief surrounding the illness and mainly emanating from the psychiatrists as detrimental to both medical progress and the interests of sufferers" (Dr Nigel Speight, Consultant Paediatrician specialising in ME/CFS; 20th August 2008)
 - "It is with regret that I note that the NICE Guidelines do not take into account recent developments in the management of ME. They lean towards a psychological and psychiatric basis, when it is now recognised that there are a large number of medical problems associated with ME. Recent studies on genetics, the central nervous system, muscle function and persistent infections have shown that there is a great deal of medical information available with regard to the management of ME" (Dr

Terry Daymond, Consultant Rheumatologist and recently Clinical Champion for ME for the North-East; 22nd August 2008)

- “Research from the ‘organic school’ identified many pathophysiological abnormalities in patients with ME/CFS resulting from dysfunction in a number of vital control systems of the body such as the central nervous system, the autonomic nervous system, the endocrinological system and the immune system. The attitude of the ‘psycho-social’ school continues to be to largely ignore this research. It seems they can only maintain their hypothesis by discouraging the search for an organic basis and by denying the published evidence, which they are certainly doing. This unseemly battle of ideas has been settled politically by proclamation and manipulation, not by science, and not by fair and open means. CBT and GET appear to be based on the rationale that patients with CFS/ME have ‘faulty’ belief systems concerning the ‘dangers’ of activity, and that these aberrant beliefs are significant perpetuating factors. If CBT to ‘correct’ these ‘false’ beliefs can be combined with a graded exercise programme to re-condition these patients, it is virtually promised that a significant proportion of them will improve both their attitude and their physical functioning, and thus cure their illness. Using CBT, patients are therefore to be challenged regarding their ‘aberrant’ thoughts and expectations of relapse that the ‘psycho-social school’ psychiatrists believe affect symptom improvement and outcomes. Cognitions concerning fatigue-related conditions are to be addressed; these include any alleged ‘over-vigilance to symptoms’ and reassurance-seeking behaviours, and are to be dealt with using re-focusing and distraction techniques. It is when a therapy such as CBT begins to interfere with the natural warning systems, of which both pain and fatigue are a part, that the increased risks arise. In particular, musculo-skeletal pain and fatigue have essential function in modulating activity when the body is in a state of disease as in ME/CFS. NICE, however, recommends over-riding this essential safety-net, thus the risk of serious harm is increased in this situation of simultaneous activity and symptoms denial. This will become a more serious risk in patients with more severe ME/CFS. The Guideline does not indicate how the clinician can tell whether patients’ beliefs concerning their symptoms are aberrant and/or when the symptoms accurately point to the underlying state of the disease process” (Dr Bruce Carruthers, Consultant Physician, Vancouver, Canada, 29th August 2008)
- “There have been only five trials of CBT with a validity score greater than 10, one of which was negative for the intervention; and only three RCTs of GET with a validity score greater than 10. The total number of available trials is small; patient numbers are relatively low; no trial contains a ‘control’ intervention adequate to determine specific efficacy, and their results are relatively modest. In addition, some of the studies (particularly those on GET) have used the Oxford criteria for diagnosis, a rubric which allows selection of patients with chronic fatigue states and which do not necessarily exclude certain psychiatric disorders, raising the question of the applicability of the results of these studies to the many patients with specific biomedical symptoms and signs consistent with myalgic encephalomyelitis. Again, the heterogeneity of the trials, the potential effect of publication or funding bias for which there is some evidence, and professional doubts about the evidence base for some behavioural therapies themselves give grounds for caution as regards the usefulness of (CBT/GET). A commentary in the BMJ (Bolsover 2002) is particularly relevant: **‘Until the limitations of the evidence base for CBT are recognised, there is a risk that psychological treatments in the NHS will be guided by research that is not relevant to actual clinical practice and is less robust than is claimed’**. Indeed, a large body of both professional and lay opinion considers that these essentially adjunctive techniques have little more to offer than good medical care alone” (Dr Neil Abbot, Director of Operations, ME Research UK; Hon Research Fellow, Department of Medicine, University of Dundee, 29th August 2008)
- “The overall flavour of the Guideline is to lump together all patients with ‘medically unexplained fatigue’, from relatively mild to profoundly disabling illness and to treat all patients with a standard approach of gradual reconditioning and cognitive behavioural modification. By lumping such a heterogeneous mix of patients...patients with CFS or ME are left with very limited options,

and little hope. In addition, this document proscribes immunological and other biologic testing on patients with (ME)CFS in the UK, despite the evidence in the world's medical literature that such testing produces most of the biomedical evidence of serious pathology in these patients. Equally unfortunate is the GDG's recommendation for behavioural modification as the single management approach for all 'medically unexplained fatigue'. This month we participated in the International Conference on Fatigue Science in Okinawa, Japan. Dr Peter White of the UK presented his work using behavioural modification and graded exercise. He reported a recovery rate of about 25%, a figure much higher than seen in US studies in (ME)CFS and, even if possible, simply not hopeful enough to the 75% who fail to recover" (Professors Nancy Klimas and Mary Ann Fletcher, University of Miami; 13th September 2008)

- Attached as an appendix to their Statement was a separate Summary of Current State of Understanding of (ME)CFS), from which the following quotations are taken: "Many of the symptoms of (ME)CFS are inflammatory in nature. There is a considerable literature describing immune activation in (ME)CFS. Overall the evidence has led workers in the field to appreciate that immunologic abnormalities are a characteristic of at least a subset of (ME)CFS and that the pathogenesis is likely to include an immunologic component. Fulcher and White (2000) suggest a role for deconditioning in the development of autonomic dysfunction and overall level of disability in (ME)CFS patients. On the other hand, Friedberg et al (2000) suggest the long duration (ME)CFS subjects are more likely to have symptoms suggestive of chronic immune activation and inflammation. We are currently working with investigators at the Centres for Disease Control and the University of Alberta looking at the mediators of relapse after exercise challenge using gene expression studies, neuroendocrine, immune and autonomic measures"
- "My main concern about the NICE document is that what must be great uncertainty in both costs and particularly in quality of life difference is not allowed for" (Martin Bland, Professor of Health Statistics, University of York, 17th September 2008)
- "The guideline is dominated by positive and largely uncritical recommendations for CBT and GET. However, the guideline plays down the fact that patient experience has consistently reported that significant numbers of people with ME/CFS find these approaches to be either unhelpful or, in the case of GET, makes their condition worse. Some of the hospital-based services are not being physician-led but 'therapist-led'. In some cases people are now being given little more than a 'therapist-led' management assessment followed by an offer of CBT and/or GET. I received some very unhappy patient feedback on this type of service on Saturday 11th October (2008) in Colchester, Essex, where great dissatisfaction was expressed by many members of the audience who attended the ME Association's 'Question Time' meeting" (Dr Charles Shepherd, Medical Adviser, ME Association, 24th October 2008)
- "I am a consultant immunopathologist and before retirement worked at St James' University Hospital, Leeds. A key area of my professional interest was and remains myalgic encephalomyelitis and I have carried out research into the disorder. For a number of years I ran clinics specifically for patients with ME. In my opinion NICE guidelines overemphasise the usefulness of CBT and GET to the detriment of patients. I have no hesitation in stating that in my opinion, the situation for ME/CFS patients is worse, not better, since the publication of the NICE Guideline" (Dr Layinka Swinburne, Leeds, 22nd October 2008)
- "As my clinical freedoms were progressively eroded, it meant that I was becoming ineffective and indeed possibly dangerous as a practitioner. All that patients could be offered was CBT coupled with GET, which I consider not to be appropriate for many of my patients and in the case of GET potentially damaging for some" (Dr Sarah Myhill, General Practitioner specialising in ME/CFS, Powys; Secretary of the British Society for Ecological Medicine, 10th November 2008).