

Template for new NHS ME Services in Northern Ireland:

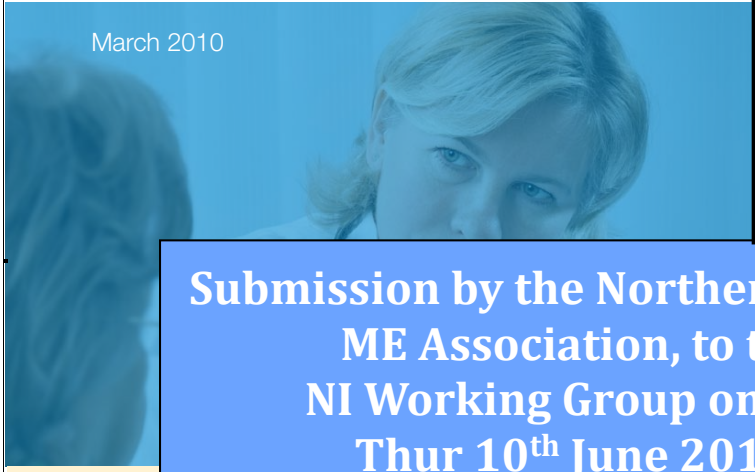
The Evidence Base

All-Party Parliamentary Group on ME



Inquiry into NHS Service
Provision for ME/CFS

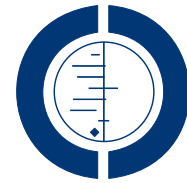
March 2010



Submission by the Northern Ireland
ME Association, to the
NI Working Group on ME.
Thur 10th June 2010.

Cognitive behaviour therapy for chronic fatigue syndrome in
adults (Review)

Price JR, Mitchell E, Tidy E, Hunot V



THE COCHRANE
COLLABORATION®



Chronic fatigue syndrome/myalgic
encephalomyelitis (or encephalopathy):
diagnosis and management of chronic
fatigue syndrome/myalgic encephalomyelitis
(or encephalopathy) in adults and children

Managing my M.E.

What people with ME/CFS
and their carers want
from the UK's health and
social services



National Institute for
Health and Clinical Excellence

NCCPC The National
Collaborating Centre
for Primary Care



Royal College of
General Practitioners

Template for new NHS ME Services in Northern Ireland: The Evidence Base.

Submission by the Northern Ireland ME Association, to
The NI Working Group on ME.

Thur 10th June 2010.

Main Points:

- Most ME patient charities regard the NICE Guideline on CFS/ME as deeply flawed, and NIMEA will not give them any blanket endorsement.
- Some proposals in the NICE guidelines are welcome, but will be expensive to implement, especially given the large number of ME patients currently neglected by the NHS.
- The principal NICE treatment recommendations, on Cognitive Behavioural Therapy (CBT) and Graded Exercise Treatment (GET), are unpopular with patients, and encounter widespread opposition and non-compliance.
- There is only a small research evidence base for CBT & GET; NIMEA therefore suggests that these treatments have not been properly tested, and that the NICE recommendations were premature.
- There are consistent complaints from very large percentages of patients, that GET is dangerous, with high rates of adverse effects.
- In 2009 the Cochrane Collaboration established that the safety and acceptability of the CBT/GET combination has never been scientifically assessed. Assurances by NICE on the safety of these treatments are therefore ill-founded.
- The lack of NHS practitioners experienced in the management of ME, will be a major obstacle to improvement for patients in Northern Ireland. There is an urgent need to establish strong clinical leadership at tertiary level, and to educate and train all grades of NHS staff, particularly GPs.

Evidence Base:

NICE Guideline CG53: Turnbull N, Shaw EJ, Baker R, Dunsdon S, Costin N, Britton G, Kuntze S and Norman R (2007). *Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy): diagnosis and management of chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy) in adults and children*. London: Royal College of General Practitioners. NICE August 2007.

Price JR, Mitchell E, Tidy E, Hunot V. *Cognitive behaviour therapy for chronic fatigue syndrome in adults*. Cochrane Database of Systematic Reviews 2008, Issue 3. Art. No.: CD001027.

Review: *CBT reduces fatigue in adults with chronic fatigue syndrome but effects at follow-up unclear*, Alastair M Santhouse, Evid Based Ment Health 2009; 12: 16.

All-Party Parliamentary Group on ME : *Inquiry into NHS Service Provision for ME/CFS*, March 2010.

Managing my M.E.: *What people with ME/CFS and their carers want from the UK's health and social services*. The ME Association, May 2010.

Making the diagnosis of Chronic Fatigue Syndrome/Myalgic Encephalitis in primary care: a qualitative study, BMC Family Practice 2010, 11:16, Carolyn Chew-Graham, Christopher Dowrick, Alison Wearden, Victoria Richardson.

NICE Guideline CG53 on CFS/ME.

There are erroneous reports that a consensus emerged at the NI Working Group's first meeting in October 2009, to the effect that implementation of the NICE Guidelines were the best way forward. In fact NICE was not formally discussed at that meeting, and NIMEA would not have supported such a blanket endorsement.

Most patient charities in the UK were unimpressed with the procedures followed by NICE when formulating the CFS/ME guideline. The evidence base was very small and obviously inadequate, and in practice the patient voice was studiously excluded. One result was that when two ME patients challenged NICE at Judicial Review in Feb 2009, they received widespread support from UK charities and the patient community.

NIMEA therefore take an *À la carte* approach to the NICE recommendations. In common with most other ME charities in the UK, we welcome some of the proposals, but are strongly opposed to others.

Welcome proposals by NICE are that:

- ME should be developed as a distinct specialty within the NHS. (*passim*)
- All GPs should become proficient in the diagnosis and management of ME.
- All ME patients should receive a diagnosis within 3 months.
- Children with ME, and the severely affected, should be referred to specialist care immediately.
- There should be separate ME specialist provision for children and adolescents.

- Severely affected ME patients who are bedbound and housebound should be provided with comprehensive medical, nursing, and Social Services support in their own homes.
- NHS staff should provide documentation in support of ME patients' applications for Social Security benefits.
- NHS staff must respect ME patients' right to choice and consent.
- If ME patients decline treatments such as CBT & GET, they must be offered alternative forms of management.

**CBT and GET treatments offered by the NHS
are ineffective and unpopular.**

A recent survey by a leading UK charity, the ME Association, confirmed that in the patients' view, rest and pacing were the most effective management strategies. Of the treatments recommended by NICE, only ..% of patients found CBT helpful, while --% found GET damaging. This was the largest-ever survey of patient opinion in the UK, confirming similar findings in previous surveys.

CBT & GET are not real "treatments".

NICE's own description of these treatments is not calculated to inspire patients with any enthusiasm. In fact the NICE GDG did not truly view these approaches as treatments at all, but merely a means to teach coping strategies.

Psychiatric Stigma.

Additionally, CBT for CFS/ME was developed in the UK by a small group of liaison psychiatrists. For most ME patients in England, CBT is predominantly administered in psychiatric units. Since the cause of this syndrome is as yet unknown, these psychiatric overtones make most ME patients regard the NICE recommendation on CBT as premature and repellent. Psychiatric stigma still flourishes within the NHS and in wider society, and ME patients have valid and compelling reasons for not wanting to be contaminated with it. A recent BMJ editorial contained a belated admission that CBT is unacceptable to ME patients on these and other grounds.

**Graded Exercise Therapy
has high rates of adverse effects.**

Over the past decade there have been regular large, well-conducted surveys of the patient experience, published by the two main UK charities, AfME and the MEA. The consistent finding is that find that GET, one of the principal treatments recommended by NICE, actually makes the condition worse for a large percentage of patients.

The view in a recent report by group of UK Parliamentarians seemed to be that, if any pharmaceutical product had resulted in equivalent rates of harmful side effects, it would never have been licensed in the first place.

However NICE disregarded many warning voices, insisting the evidence showed that benefits of GET outweighed adverse effects. The NICE GDG branded patient surveys reporting poor experiences with GET, as “unscientific” and “self-selecting”.

Cochrane Collaboration: Safety of CBT/GET has never been assessed.

It soon emerged that this dismissive attitude was a case of the NICE pot calling the Patient kettle “black”. A year after the NICE recommendation was published, the Cochrane Collaboration concluded that, in fact, the safety of GET had never been scientifically tested. Cochrane publications are at the summit of the medical research hierarchy, and their conclusions are generally considered to be unchallengeable.

Even the warmest advocates of CBT/GET (the psychiatrists) were then obliged to accept Cochrane findings on the limitations and hazards of these treatments.

NICE assurances on safety of CBT/GET are ill-founded.

NIMEA have therefore no hesitation in saying that NICE assurances on the safety of GET were ill-founded and erroneous, and that NHS clinicians who accept this reassurance are being dangerously misled.

In 2006 when the GET/CBT recommendations were first mooted, all UK ME patient charities unanimously protested, on grounds that the research evidence base was too undeveloped to permit the drawing of firm conclusions. (The NICE recommendations were based on only – RCTs for GET, and only – for CBT).

In the USA, the Centers for Diseases Control takes the view that

NHS money spent on CBT/GET for ME, is money wasted.

NIMEA still take the view that these NICE recommendations on CBT/GET were premature, and that they should not be implemented in Northern Ireland. Finance allocated to CBT and GET treatments for ME patients would be better spent on other sectors of the ME care spectrum, such as domiciliary-based support for the severely affected.

GP based services.