

P2P Comments from Tina Grimsmo, registered nurse

PUBLIC COMMENT ON THE ME/CFS “P2P” DRAFT REPORT

(My comments refer to the 403-line version.)

I welcome that the report reflects an understanding of the scope and burden of ME/CFS and is helpful in many places. I would especially like to thank you for the recommendation that the Oxford criteria for ME/CFS be retired (line 38).

I would like to focus my comments on one important area for improvement: that the report should communicate the harm done to thousands of patients by the treatment model CBT/GET (graded exercise therapy). These comments are applicable to lines 113-114 but also to the Conclusions of the report.

In the lines 113-114 the report claims that treatment with CBT and GET has demonstrated measurable improvement. I ask that this sentence be changed in two ways:

a) In fact, CBT and GET have not been shown to result in measurable improvement, since such improvements should be objectively measurable. No CBT or GET studies have shown improvements in objective outcomes. In the initial plans for the British PACE study, it was planned for actometers to be used to measure activity objectively, but this was eventually dropped as an outcome (activity was still measured at baseline). Instead, the PACE study used a 6 minute walking test which is a poor measurement of the ability to tolerate sustained activity, which comes with a large risk of “placebo effort” and in which the patients treated with CBT or GET still performed far below the result levels of a healthy person (indeed there was no improvement whatsoever in the CBT over the SMC (no therapy) group). No studies have demonstrated objectively measurable improvements in activity levels, return to work or school, or levels of incapacity benefits.

Therefore, the sentence in lines 113-114 should be changed to state that no objectively measurable improvements in activity levels, return to work or school, or levels of incapacity benefits have been shown by any CBT or GET studies.

b) The sentence (or section) should also be changed to state the vast amount of harm that has been caused to ME/CFS patients through GET treatment protocols. It is very possible that GET can be helpful for persons who do not have ME/CFS but instead Oxford defined general long-lasting fatigue (which can have a number of causes, including burn-out, deconditioning and psychiatric disorders). But for patients with narrowly defined ME/CFS, where Post-Exertional Malaise (PEM) is the key symptom, GET has been shown, again and again, to be extremely very detrimental.

Patient organizations around the world continually report on the harm caused to ME/CFS patients by GET or similar exercise programs. The patients are told to ignore their symptoms and push through the increase in symptoms, the theory being that this should, in the end, be beneficial for their health. Instead, the ME/CFS patients get much worse, and often they are then unable to return to the level of function they had before the GET program.

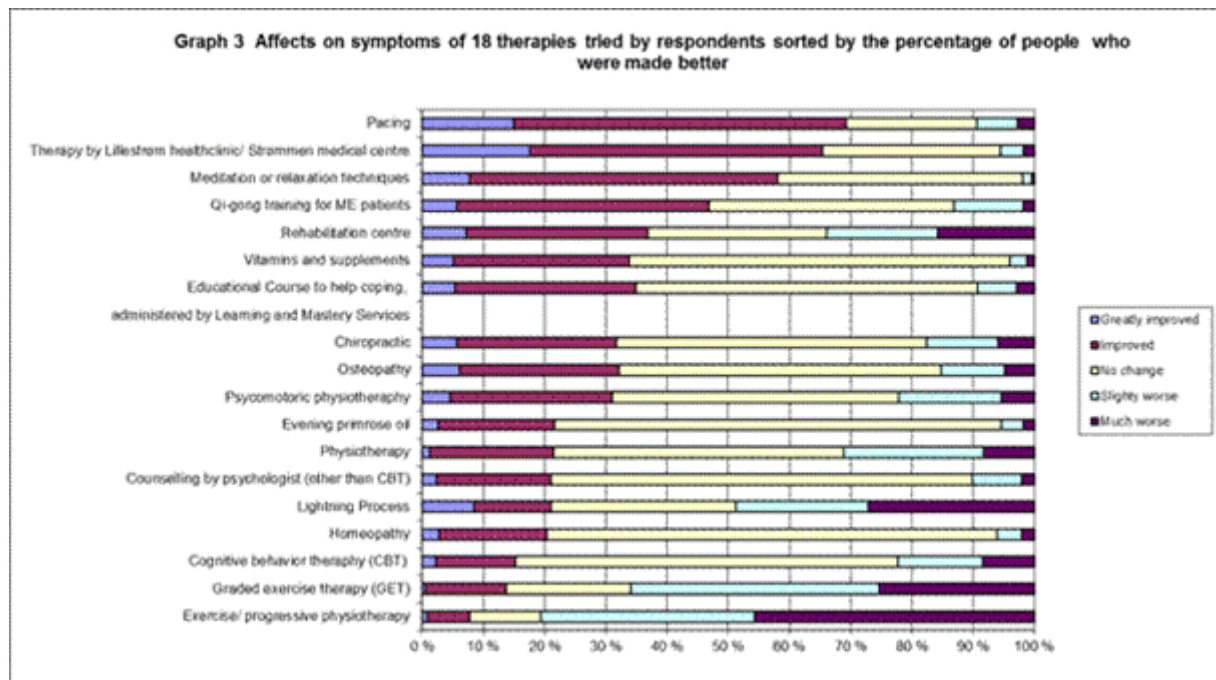
This clinical experience is unambiguous – patient surveys again and again show the same pattern. Clinical ME/CFS experts echo this: there have been hundreds of patients who have

experienced deterioration, sometimes irreversible, caused by GET programs before they came to the ME/CFS expert.

Here are a few examples of patient survey results regarding GET:

- Survey by the Norwegian ME Association, published May 2014 [1]:

Circa 65% of the patients report that GET made their condition worse, see the following graph:



- Survey by ME Association UK, published 2010 [2]:

Circa 56% of the patients report that GET made their condition worse.

- Survey by 25% M.E. Group, published 2004 [3]:
(The 25% M.E. Group represent the patients with severe M.E.)

Circa 82% of the patients report that GET made their condition worse.

This pattern is repeated in survey after survey, as well as in case after case in the ME/CFS physicians' offices.

A table with pooled data of harms from GET can be found on page 110 (Table 2) in the article "Reporting of Harms Associated with Graded Exercise Therapy and Cognitive Behavioural Therapy in Myalgic Encephalomyelitis/Chronic Fatigue Syndrome" [4]:

Table 2. Pooled Data of Harms from GET, CBT and Pacing reported in Surveys

Therapy	Sample Size	Harms ^a (N)	Mean rate of harms (%)	Range
Graded Exercise Therapy (GET) (or similar terms) ^b	4338	2223	51.24%	28.1 - 82%
Cognitive Behavioural Therapy (CBT) ^c	1808	360	19.91%	7.1 - 38%
Pacing (or similar terms) ^d	5894	152	2.58%	0.2 - 9.3%

^aThis includes any degree of harm e.g. both "somewhat worse" and "a lot worse" from the ME Association survey [85].

^bTaken from [75,78-80,82-85]; ^cTaken from [80,81,83-85]; ^dTaken from [79,80,83-85]

As you can see in this table, the mean rate of harms for GET is 51.24%.

By contrast, Pacing or "Envelope theory", meaning to determine the limits within which the ME/CFS patient can operate without causing PEM and then establishing a pattern of activity and rest where those limits are not exceeded, never pushing the symptoms, has practically no reports of harm, but a very good rate of reported improvements in health in all surveys.

I find this to be a very important fact: that GET is detrimental for patients with real ME/CFS and that Pacing, by contrast, is very useful, and I ask you to include this fact in the final version of the report.

Thank you for considering my comment and thank you for your work.

Regards,

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Sources/References:

1. <http://me-foreningen.com/meforeningen/innhold/div/2014/05/ME-Nat-Norwegian-Survey-Abr-Eng-Ver.pdf>
2. <http://www.meassociation.org.uk/wp-content/uploads/2010/09/2010-survey-report-lo-res10.pdf>
3. 25% ME Group. Severely Affected ME (Myalgic Encephalomyelitis) Analysis Report On Questionnaire Issued January 2004. Troon, Scotland. March 2004
4. <http://www.iacfsme.org/LinkClick.aspx?fileticket=Rd2tIJ0oHqk%3D>