From Ellen Goudsmit

A few months ago, I wrote an article for Healthwatch explaining the BPS press release on the NICE guidelines for CFS. NICE were given, and duly provided Healthwatch with a right of reply and my article was accepted for publication in October. Healthwatch, however, forgot they had received the right-of-reply, then thought they might be sued for libel, and rejected the article.

The BPS had the courage to stand up for good science and 'out' NICE. And as I am insured for libel cases, I can submit the article here.

It's disappointing that Healthwatch is against quackery, but not when it comes to CFS and not, apparently, when faced with an article challenging a large organisation.....

Healthwatch is OK with fiddling of data
Ellen M. Goudsmit PhD CPsychol AFBPsS Text:

Shortly after the publication of the NICE guidelines for chronic fatigue syndrome (CFS), the British Psychological Society (BPS) submitted a formal complaint to the organisation for the way in which it had responded, or rather, not responded, to its suggestions. I know about this as I was a member of the team which assessed the draft on behalf of the BPS. What angered the psychologists was not only the dismissal of evidence-based arguments and the lack of alternatives to the three approaches recommended - cognitive-behaviour therapy (CBT), graded exercise and gentle graded exercise (GET). More importantly, the complaint challenged the failure to correct factual errors.

In the draft, we had identified a number of inaccuracies and omissions and although anyone can make a mistake, it was a strange coincidence that virtually all the errors and missing information supported the use of CBT. The BPS response noted the relevant studies which had not been considered and corrected the most important inaccuracies. For example, the draft guidelines had included a controlled trial of a physician-led, multi-dimensional programme in an NHS setting which had found significant group differences on five outcome measures and therefore showed, according to the NICE criteria, a positive treatment effect. Independent analysis of the data using a different strategy to deal with missing data confirmed significant group differences on three of the measures and a trend towards significance on a fourth. The fact that a quarter of the patients had recovered to such a degree that they were discharged after six month supported the view that this was a promising alternative to CBT, and a useful addition to the rather limited range of therapeutic options currently available on the NHS. It wasn't a controversial intervention, indeed, it resembled many programmes used for other medical disorders during the past decade. Moreover, there were several published articles on similar programmes, some of which also met the NICE criteria for inclusion in their review. All the studies were controlled and indeed, one was a randomized controlled trial (RCT). In the study in question, the Center for Reviews and Dissemination (CRD) who compiled the literature review for NICE turned three significant group differences into non-significant ones. This left two significant differences and therefore should still have been listed as showing a

positive effect. For some unknown reason, it wasn't. This particular example drew my attention more than some of the others as I knew the statistics well. It was my study they had 'amended'.

In addition to correcting errors, the BPS offered information on additional interventions, including a simple and effective strategy used to stabilise the condition: pacing. This too was a subject I was familiar with. I had devised it in the late eighties and within months, it had been taken up by both national charities in the UK and several others around the world. During the past 15 years, patients have consistently rated it as one of the three most helpful interventions for CFS, and it is increasingly used as a 'phase 1' in several graded activity regimes. However, the draft devoted only one sentence to the strategy and classified the relevant RCT under graded exercise, even though the paper clearly stated that the exercise was consistent with the principle of pacing. In other words, patients were allowed to stop an activity to avoid over-exertion and an exacerbation in symptoms.) Knowing that there was no academic article on the subject in the public domain, we offered them a comprehensive position paper, complete with indications, limitations and research.

To our surprise, NICE showed no interest. As the guidelines later revealed, they preferred a concept of pacing written by an anonymous author whose version was based on a psychiatric model and aimed at patients with localised, static conditions such as back pain. It's a version which as yet, has not been formally tested in a fluctuating, multi-system disorder like CFS. When asked, they claimed that as far as pacing was concerned, they had seen 'no evidence'. Yes, they had. They had reviewed the RCT. The paper on pacing written for NICE has been published and a longer version is available online1.

From a clinical perspective, the guidelines provide practitioners with little choice. Not only is graded exercise not appropriate for the subset with evidence of ongoing disease (summarised in Goudsmit, and Howes1), but none of the trials cited in support of this intervention have shown significant increases in activity levels where these were assessed using objective measures. NICE ignored the latter and summarily dismissed the patients' reports of adverse effects as a reflection of extreme regimes and poor practice. Which makes one wonder how they interpreted the high attrition rates in some of the trials which they used to justify CBT and GET.

The discussion of alternatives was very limited. Cohen's delta, a measure of effect size, shows us that all psychological interventions have only modest effects, but an advantage of the more flexible, multi-dimensional programmes is that the drop out rates tends to be lower, ergo, one can help more patients. Still, NICE absolutely refused to give these therapeutic options the attention they deserved.

In all, there were four controlled studies which backed the views in the BPS submission. One trial was classified under CBT and therefore not recognised for what it was. Two were not included. Mine was 'amended' and dismissed. Since then, Malouff et al2 have confirmed, using the appropriate statistics, that the effects of CBT and graded exercise are generally modest. In addition, when Jason et al3 compared CBT with an alternative programme promoting coping skills and pacing, (as in my study), it was the latter which came out best.

I used to assume that NICE would take all sound evidence into account. In relation to CFS, it appears that I was wrong.

1. Goudsmit, EM. Pacing to manage chronic fatigue syndrome. Health Psychology Update, 2008, 17, 1, 46-52.

2. Malouff, JM., Thorsteinsson, EB., Rooke, SE., Bhullar, N and Schutte, NS. Efficacy of cognitive behavioral therapy for chronic fatigue syndrome: A meta-analysis. Clin Psychol Rev, 2008, 28, 5, 736-745.

3. Jason, LA., Torres-Harding, S., Friedberg, F., Corradi, K., Njoku, MG., Donalek, J., Reynolds, N., Brown, M. Weitner, BB., Rademaker, A & Morris Papernik. Non-pharmacologic interventions for CFS: A randomized trial. J Clin Psychol Mel Settings, 2007 14, 4, 275-296.