

CBT & GET – Parliamentary Q & Update

The Countess of Mar, Chair of the Forward-ME Group and Patron of ME Research UK has raised a number of points with the Department of Health and Social Care concerning how those affected by ME/CFS can report adverse effects experienced due to participation in Graded Exercise Therapy and/or Cognitive Behavioural Therapy (GET and CBT). These two ‘treatments’ are recommended by The National Institute for Health and Care Excellence (NICE) in their ‘Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy): diagnosis and management’ Guideline (CG53)



Q – To ask Her Majesty’s Government, further to the Written Answer by Lord O’Shaughnessy on 19 June (HL8366), what means are available for reporting and recording adverse health events resulting from non-pharmacological treatments such as graded exercise therapy or cognitive behavioural therapy on a similar basis to those for reporting adverse events to pharmacological treatments through the Medicines and Healthcare Products Regulatory Agency’s Yellow Card Scheme.

A – The Yellow Card Scheme includes a facility to report suspected adverse incidents associated with products used in psychological treatments. In addition, in guideline development, when reviewing the evidence relating to interventions, the National Institute for Health and Care Excellence’s guideline development committees will take into account any adverse outcomes that are reported, alongside the clinical and cost-effectiveness. Patients are able to raise concerns about such treatments directly with a healthcare professional, by raising a concern with the healthcare provider or by making a complaint.

The answer would suggest that the Yellow Card Scheme allows the Medicines & Healthcare products Regulatory Agency (MHRA) to monitor the safety of all healthcare products in the UK to ensure they are acceptably safe for patients and those that use them. According to its website, (11th July) reports can be made for all medicines including vaccines, blood factors and immunoglobulins, herbal medicines and homeopathic remedies, and all medical devices available on the UK market. The term ‘medical device’ was defined (11th July) so as to cover almost all products, except medicines, that are used in healthcare. They can be used for the diagnosis, prevention, monitoring or treatment of illness or disability. An adverse incident is an event that caused, or almost caused, an injury to a patient or other person or a wrong or delayed diagnosis and treatment of a patient.

However, on contacting MHRA they have indicated that the Yellow Card Scheme is not available to those reporting and recording adverse health events resulting from non-pharmacological treatments such as GET/CBT. GET/CBT are not deemed by the MHRA as products and they are to amend their definition of ‘devices’ on their website to make this clear.

Indeed, subsequently (August 2018) the MHRA website was updated to state that “ The term ‘medical device’ covers a broad range of products that are used in healthcare. They can be physical items or software which are used for the diagnosis, prevention, monitoring or treatment of illness or disability. Products reportable to the Yellow Card Scheme as a medical devices will have a CE mark.”

All that remains for those affected is to “raise concerns about such treatments directly with a healthcare professional, by raising a concern with the healthcare provider or by making a complaint.” as per the final sentence of the Ministerial Answer.

What is lost is a means by which adverse outcomes are recorded officially and the data capable of being drawn upon easily by NICE. ME Research UK has previously commented that there is a mismatch between the experiences of GET reported in patient surveys and the evidence from formal clinical trials. In surveys, between 39 and 57% of ME/CFS patients say that GET worsens their symptoms, while the scientific literature paints a picture of moderate benefit and rarely alludes to adverse effects.

It had initially been hoped that reports via the Yellow Card Scheme of adverse effects of GET/CBT would feed into the process of replacing the current NICE guideline and provide evidence of what many ME/CFS patients say is the reality of the efficacy of GET/CBT.

Attention has been drawn to an earlier written Answer (C132337) by Jackie Doyle-Price (Parliamentary Under-Secretary (Department of Health and Social Care)) to Jim Shannon MP's question

Q – To ask the Secretary of State for Health and Social Care, what the reasons are for the yellow card system for reporting medical harms not including psycho-social therapies including (a) graded exercise and (b) cognitive behaviour therapy.

A – The Medicines and Healthcare products Regulatory Agency (MHRA) regulates medicines, medical devices and blood components for transfusion within the United Kingdom. The MHRA runs the Yellow Card Scheme on behalf of the Commission on Human Medicines. The Yellow Card Scheme is the UK system for collecting and monitoring information on suspected Adverse Drug Reactions (ADRs). The Yellow Card scheme was introduced in 1964 with the aim of collecting suspected ADR reports from the whole of the United Kingdom in relation to all medicines and vaccines. In addition to the collection of suspected ADR reports for medicines and vaccines, the remit of the Yellow Card Scheme also covers the collection of suspected adverse incidents related to medical devices. As cognitive behaviour therapy and graded exercise therapy are both non-pharmaceutical or medical device treatments, they do not fall under the remit of the MHRA or the Yellow Card Scheme. Therefore, any harms associated with them would not be reported to the Yellow Card Scheme.

Amended 12th July and 9th August 2018

Reproduced from ME Research UK Website