Bulletin of the IACFS/ME
A Quarterly Publication of the International Association for CFS/ME

Reporting of Harms Associated with Graded Exercise Therapy and Cognitive Behavioural Therapy in Myalgic Encephalomyelitis/Chronic Fatigue Syndrome

Tom Kindlon
Information Officer (voluntary position)
Irish ME/CFS Association
PO Box 3075, Dublin 2, Rep. of Ireland
Tel: +353-1-2350965
E-mail: tkindlon@maths.tcd.ie or info@irishmecfs.org

ABSTRACT

Across different medical fields, authors have placed a greater emphasis on the reporting of efficacy measures than harms in randomised controlled trials (RCTs), particularly of nonpharmacologic interventions. To rectify this situation, the Consolidated Standards of Reporting Trials (CONSORT) group and other researchers have issued guidance to improve the reporting of harms. Graded Exercise Therapy (GET) and Cognitive Behavioural Therapy (CBT) based on increasing activity levels are often recommended for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS). However, exercise-related physiological abnormalities have been documented in recent studies and high rates of adverse reactions to exercise have been recorded in a number of patient surveys. Fifty-one percent of survey respondents (range 28-82%, n=4338, 8 surveys) reported that GET worsened their health while 20% of respondents (range 7-38%, n=1808, 5 surveys) reported similar results for CBT.

Using the CONSORT guidelines as a starting point, this paper identifies problems with the reporting of harms in previous RCTs and suggests potential strategies for improvement in the future. Issues involving the heterogeneity of subjects and interventions, tracking of adverse events, trial participants' compliance to therapies, and measurement of harms using patient-oriented and objective outcome measures are discussed. The recently published PACE (Pacing, graded activity, and cognitive behaviour therapy: a randomised evaluation) trial which explicitly aimed to assess "safety", as well as effectiveness, is also analysed in detail. Healthcare professionals, researchers and patients need high quality data on harms to appropriately assess the risks versus benefits of CBT and GET.