

# Cognitive behavioural therapy in chronic fatigue syndrome: a randomised controlled trial of an outpatient group programme

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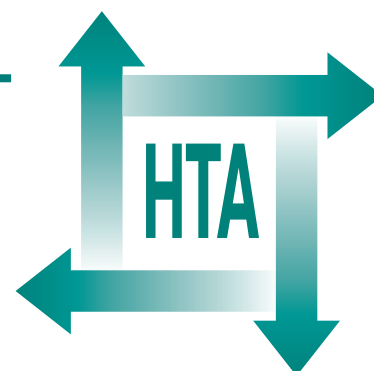
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## Executive summary

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## Executive summary

### Background and objectives

This report describes the conduct and results of a double-blind randomised controlled trial to compare group cognitive behavioural therapy (CBT) with education and support (EAS) and with standard medical care (SMC) for the treatment of patients with chronic fatigue syndrome/myalgic encephalopathy (CFS/ME). The research hypothesis was that group CBT would provide an effective and cost-effective management strategy for patients in primary care with CFS/ME and that treatment gains in these areas would be found even when controlling for the non-specific effects of therapist exposure.

### Methods

#### Design

A double-blind, randomised controlled trial was adopted with three arms. Outcomes were assessed at baseline and 6 and 12 months after first assessment and results were analysed on an intention-to-treat basis.

#### Setting

The study was set in a health psychology department for the management of chronic illness in a general hospital in Bristol, UK.

#### Participants

Adults with a diagnosis of CFS/ME were referred by their GP. Over a 2-year period (August 2000–July 2002), 153 eligible patients were recruited and consented to participate; 52 were randomised to receive CBT, 50 to EAS and 51 to SMC. The target sample size for the trial, set at 43 per condition, was met. Seven patients did not receive the treatment assigned for clinical or ethical reasons and fear of contamination but all analyses were carried out on an intention-to-treat basis. Twelve patients failed to attend for the 12-month follow-up and 19 patients attended one follow-up, but not both. The sample was found to be representative of the patient group and the characteristics of the three groups were similar at baseline.

#### Interventions

The primary analyses compared the outcome scores between the three treatment interventions.

Differences between the treatment cohorts are reported with 95% confidence intervals (CIs). For the primary outcome measures, the SF-36 physical and mental summary scales, the numbers of patients reporting a 15% increase over the baseline score (defined as a successful outcome) and the numbers returning to the normal range are also reported.

### Outcome measures

A range of generic outcome measures were used as validated disease-specific outcome measures were not available for this condition. The primary outcome measure was the Short Form with 36 Items (SF-36) physical and mental health summary scales. Other outcome measures included the Chalder fatigue scale, Hospital Anxiety and Depression Scale (HADS), General Health Questionnaire, measures of physical function (shuttles walked, walking speed and perceived fatigue), health utilities index, cognitive function (mood, recall and reaction times) and resource use. Outcomes were measured as baseline (before randomisation) and at 6 and 12 months after the initial assessment.

### Results

Three outcome measures, SF-36 mental health score, Chalder fatigue scale and walking speed, showed statistically significant differences between the groups. The CBT group had significantly higher SF-36 mental health scores (difference +4.35, 95% CI +0.72 to +7.97,  $p = 0.019$ ), less fatigue (difference -2.61, 95% CI -4.92 to -0.30,  $p = 0.027$ ) and was able to walk faster (difference +2.83 shuttles, 95% CI +1.12 to +5.53,  $p = 0.0013$ ) than patients in the SMC group. CBT patients also walked faster and were less fatigued than those randomised to EAS (walking speed, difference +1.77, 95% CI +0.025 to +3.51,  $p = 0.047$ ; fatigues, difference -3.16, 95% CI -5.59 to -0.74,  $p = 0.011$ ). Overall, no other statistically significant difference across the groups was found, although for many measures a trend towards an improved outcome with CBT was seen. Excepting for walking speed, which, on average, increased by +0.87 shuttles (95% CI +0.09 to +1.65,  $p = 0.029$ ) between the 6- and 12-month follow-ups, the scores were similar at 6 and 12 months.

At baseline, 30% of patients had an SF-36 physical score within the normal range and 52% had an SF-36 mental health score in the normal range. At 12 months, the physical score was in the normal range for 46% of the CBT group, 26% of the EAS group and 44% of SMC patients. For mental health score, the percentages were CBT 74%, EAS 67% and SMC 70%. Of the CBT group, 32% showed at least a 15% increase in physical function and 64% achieved a similar improvement in their mental health. For the EAS and SMC groups, this improvement in physical and mental health was achieved for 40 and 60% (EAS) and 49 and 53% (SMC), respectively, but these changes were not statistically significant.

There were multiple difficulties in completing the economic evaluation. A cost–utility (or cost-effectiveness) analysis was planned, but the quality of the data prevented this objective being realised. The intention was to use data from participating primary and secondary care centres and patient questionnaires. However, owing to the unexpected departure of the health economist early in the trial, the study was almost complete before it was realised that patient records would need to be scrutinised for resource use data. This meant that limited resources were available for this exercise, and minimal data were obtained. Also, the patient questionnaire was inadequate. It asked patients about treatments and medication use but failed to ascertain the cost involved. Data on direct patient costs and indirect societal costs was sought but the response was too poor for the data to be of much value, with a great deal of missing data. As a result, the quality of the health economic data was poor; the evaluation was limited to the perspective of the healthcare provider (NHS) and the reporting of results was descriptive only. The descriptive data tentatively suggest that most of the cost of CFS/ME is borne by family and friends. The economic impact appears substantial, with over 60% of patients citing the onset of CFS/ME as the main reason why they cannot work.

### Limitations

The trial had a number of limitations: patients were referred from the GP, without a specialist diagnosis, and the individuals' suitability for group treatment was not assessed prior to randomisation. One patient was withdrawn because an alternative diagnosis was made and several patients would not, in clinical practice, have been considered psychologically appropriate for group treatment. Also, some subjects were already using good management techniques and could not, therefore, be expected to show a significant improvement.

On average, the patients in the study population were more fatigued, had been ill for longer and were more distressed than samples used in previous research, although they were able to attend an outpatient programme, which implies a certain level of ability. It is not possible to assess from this trial whether the interventions investigated would be effective, ineffective or even hazardous for more severely disabled individuals.

### Conclusions

Group CBT did not significantly improve cognitive function, quality of life, employment status or healthcare utility measures, although such changes have been demonstrated in the literature for individual CBT. The increased measures of mood and fitness and decreased symptoms of fatigue seen with CBT are comparable to the changes seen in the individual research literature. The similarity of the Borg perceived fatigue scores across each condition, both initially and at follow-up, indicates that each cohort reported exercising to a similar level of fatigue. This indicates that the significant increase in shuttle walking found in the CBT group was not an artificial gain achieved by 'pushing through' fatigue. It appears to be more substantial. These subjects reported increases in their normal walking pace. It seems that the gain is for both speed and endurance. This is of great functional significance for CFS/ME sufferers. This study is unable to shed any light on the mechanism underlying this change, and it may be possible that patients are feeling more confident and able to manage the condition.

### Recommendations for future research

Further research is needed to develop better outcome measures, assessments of the broader costs of the illness and a clearer picture of the characteristics best fitted to this type of intervention.

### Publication

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# NHS R&D HTA Programme

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The HTA Programme commissions research only on topics where it has identified key gaps in the evidence needed by the NHS. Suggestions for topics are actively sought from people working in the NHS, the public, service-users groups and professional bodies such as Royal Colleges and NHS Trusts. Research suggestions are carefully considered by panels of independent experts (including service users) whose advice results in a ranked list of recommended research priorities. The HTA Programme then commissions the research team best suited to undertake the work, in the manner most appropriate to find the relevant answers. Some projects may take only months, others need several years to answer the research questions adequately. They may involve synthesising existing evidence or conducting a trial to produce new evidence where none currently exists.

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