



<b>Title</b>	<b>Cognitive Behavioral Therapy in Chronic Fatigue Syndrome: A Randomized Controlled Trial of an Outpatient Group Program</b>
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<b>Reference</b>	Health Technol Assess 2006;10(37). October 2006. <a href="http://www.hta.ac.uk/execsumm/summ1037.htm">www.hta.ac.uk/execsumm/summ1037.htm</a>

## Aim

To assess the efficacy of treating chronic fatigue/myalgic encephalopathy syndrome through cognitive behavioral therapy (CBT) delivered in a group format.

## Conclusions and results

No evidence suggested that the physical state of the participants, as measured by the SF36 physical health summary scale, differed between the 3 treatment conditions (see Methods below), and no significant change over time was indicated. The mean scores for all 3 cohorts were slightly higher at 6 and 12 months compared to baseline, but well below the norm for the general population.

In contrast, some differences with respect to mental health were suggested, but the only statistically significant difference was between the CBT and SMC cohorts. Once again, no significant change over time was indicated. The mean scores in all 3 groups increased from baseline, but remained below the norm for the general population.

The Chalder fatigue scale also showed differences between the groups. The least squares mean score was significantly lower for the CBT cohort than for the other 2 cohorts. The HADS anxiety scale showed a trend toward lower scores (reduced anxiety) in the CBT treatment cohort and higher scores in the SMC treatment cohort. The difference across the 3 groups was not statistically significant. Treatment conditions did not impact on the HADS depression scores, or on the HUI3 overall utility score. For these outcomes, no differences between the scores at 6 and 12 months were found, and there were no significant differences between cohorts.

Similar trends were seen with the General Health Questionnaire and the number of shuttles walked, with lower GHQ scores and more shuttles walked in the CBT treatment cohort, higher GHQ scores and fewer shuttles walked in the SMC treatment cohort, and the EAS co-

hort showing results similar to the SMC group. Overall, across the 3 groups the differences were not statistically significant.

No significant differences in response to the cognitive tests were found across the 3 treatment conditions, with the possible exception of the repeated digits. The results of the economic evaluation were equivocal.

## Recommendations

The trial used a broad range of outcome measures. Three demonstrated a statistically significant change in the direction of the research hypothesis. All outcome measures showed a consistent trend in the same direction, and examination of clinical significance was also consistent. In the Whiting review, studies were classified as having an overall effect if they showed an effect for more than one clinical outcome. On this basis, the treatment was clearly effective.

## Methods

This was a double blind, randomized controlled trial with 3 research conditions: 1) Group therapy: CBT, 2) Control group: EAS (education and support), and 3) Standard medical care (SMC). Levels of fatigue, functional disability, emotional distress, and physical fitness were taken at baseline, 6, and 12 months. The data were analyzed on the basis of intention to treat.

## Further research/reviews required

The question of which patient subgroup this type of intervention is likely to be most effective should be addressed.