Study Overview

Objective. To determine whether a counseling intervention designed to educate patients and encourage exercise reduces symptoms of chronic fatigue syndrome.

Design. Randomized controlled trial. Analysis was by intention to treat.

Setting and participants. Patients aged 15 to 55 years were recruited from referrals to a chronic fatigue clinic and from an outpatient infectious diseases clinic, both single centers in Britain. Inclusion criteria required that participants meet Oxford criteria for chronic fatigue syndrome [1] and score less than 25 (range, 10 to 30) on the physical functioning subscale of the Short-Form Health Survey (SF-36) [2]. Patients were excluded if they were undergoing further evaluation for fatigue or receiving other treatments, such as antidepressants (unless symptoms were unchanged after a stable dose had been administered for at least 3 months); suffered from a psychotic illness, somatization disorder, eating disorder, or had a history of substance abuse; or if they were confined to bed or a wheelchair.

Intervention. Control patients received a medical assessment, advice, and an informational booklet that encouraged graded physical activity and positive thinking. Intervention patients received a similar evaluation plus an evidence-based explanation of symptoms designed to encourage graded physical activity and written materials reiterating verbal explanations. These patients were further randomized into 3 groups: a minimal intervention group, whose members received 2 face-to-face sessions (totaling 3 hours) during which the above explanation was delivered and the graded exercise program was designed; a telephone intervention group, whose members received the minimum intervention plus 7 planned telephone contacts (about 30 minutes each over 3 months) reiterating initial explanations and using motivational interviewing techniques to discuss problems associated with graded exercise; and a maximum intervention group, whose members received the minimum intervention plus an additional seven 1-hour face-to-face treatment sessions over 3 months, which had the same function as the telephone sessions. All intervention patients could receive additional telephone consultations by leaving a message on an answering machine.

Main outcome measures. Questionnaires were mailed to patients before randomization and at 3, 6, and 12 months. Primary outcomes were scores on the SF-36 physical functioning subscale and fatigue subscale (range, 0 to 11; a score of more than 3 indicates excessive fatigue). Changes at 1 year were considered clinically important if a patient’s physical subscale score was 25 or more or if it increased by 10 or more points from baseline.

Main results. Almost half of the 312 assessed patients were excluded, mostly for medical (69 patients) or psychiatric (23 patients) reasons or because their scores on the SF-36 physical functioning subscale were more than 24 (36 patients). Randomized patients had a mean age of 33 years (± 10.3), and most (78%) were women. Of the participants, 34% were working, 43% were receiving disability benefits, 18% were taking antidepressants, and 25% were participating in support groups. Of 148 randomized patients, 21 (14%) dropped out of the study, mostly from the intervention groups. Baseline mean SF-36 physical functioning score was about 16 for all groups. At 1 year, all intervention groups recorded an increase to about 25, while the control group did not show a significant change (P < 0.001 for all intervention groups compared with controls; no difference among intervention groups). Results from the fatigue scale were similar (baseline score, about 10; 1-year scores unchanged among controls but decreased to about 3 among all intervention groups [P < 0.001], with no differences seen among intervention groups).

Conclusion. Many patients with chronic fatigue syndrome may benefit from an educational intervention based on medical evidence and directed toward developing a graded exercise program.
OUTCOMES RESEARCH IN REVIEW

Commentary
This study was generally well done. Results were dramatic: 81% of intervention patients met criteria for clinically significant improvement, while control patients seemed to experience no placebo effect. In a small study, however, such results must be interpreted cautiously. The lack of placebo effect is particularly curious; nevertheless, Powell and colleagues note that the effect size is similar to other trials of graded exercise or cognitive behavior therapy. The principal weakness of this study lies in its generalizability. Almost half of all patients evaluated for the study were excluded. Further, although the authors claim that interventions did not require any special training, treatment success may have been partly related to the individuals who delivered it.

Applications for Clinical Practice
The interventions used by Powell and colleagues were benign, and the minimum intervention (which worked as well as the others) was not expensive or labor intensive. This study suggests a useful approach toward treatment of otherwise healthy patients with chronic fatigue syndrome. The question of whether the exact protocols used in this study should be copied or if the authors’ general approach is sufficient remains unclear; given that all 3 treatment groups responded positively, the latter seems more likely. Further studies may help elucidate critical elements of evidence-based teaching for graded exercise among chronic fatigue patients.

References