Cognitive Behavior Therapy for Chronic Fatigue Syndrome: A Randomized Controlled Trial

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Objective: *Cognitive behavior therapy for chronic fatigue syndrome was compared with relaxation in a randomized controlled trial.* *Method:* *Sixty patients with chronic fatigue syndrome were randomly assigned to 13 sessions of either cognitive behavior therapy (graded activity and cognitive restructuring) or relaxation. Outcome was evaluated by using measures of functional impairment, fatigue, mood, and global improvement.* *Results:* *Treatment was completed by 53 patients. Functional impairment and fatigue improved more in the group that received cognitive behavior therapy. At final follow-up, 70% of the completers in the cognitive behavior therapy group achieved good outcomes (substantial improvement in physical functioning) compared with 19% of those in the relaxation group who completed treatment.* *Conclusions:* *Cognitive behavior therapy was more effective than a relaxation control in the management of patients with chronic fatigue syndrome. Improvements were sustained over 6 months of follow-up.*

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In chronic fatigue syndrome, continuous or recurring fatigue and marked disability often persist for many years. No definitive treatment or etiology has been established, and the available evidence suggests that chronic fatigue syndrome is heterogeneous and multicausal (1–3).

Uncertainty over cause need not prevent effective treatment. Cognitive behavior therapy is used for medically unexplained somatic problems (4) and for disorders analogous to chronic fatigue syndrome, such as fibromyalgia (5) and chronic pain (6, 7). Cognitive behavioral models suggest that a combination of physiological, behavioral, cognitive, affective, and social factors contribute to chronic fatigue syndrome (8–10). Cognitive behavior therapy is used to modify behaviors and beliefs that may maintain disability and symptoms.

Few randomized controlled trials of cognitive behavior therapy for chronic fatigue syndrome have been conducted. An uncontrolled pilot study produced encouraging results (11), which were largely maintained 4 years later (12). A nonrandomized study showed some improvement in depression but none in disability or fatigue (13). In a double-blind, randomized, controlled trial (14), a brief cognitive behavioral intervention was no more effective than routine clinic attendance. A slight improvement was attributed to nonspecific factors.

The purpose of this study was to test whether cognitive behavior therapy (comprising graded activity and cognitive restructuring) was significantly superior to relaxation, selected to control for nonspecific treatment factors, including support, therapist time and attention, expectations, and homework practice.

METHOD

Subjects and Design

Patients were recruited from consecutive referrals by primary care physicians and consultants to a hospital clinic specializing in chronic fatigue syndrome. Each referred patient received a standardized assessment interview with a consultant psychiatrist experienced in chronic fatigue syndrome (S.W.). A full history was taken. Diagnosis of chronic fatigue syndrome was made according to U.K. (15) and U.S. (16) case definitions. Psychiatric diagnoses were based on an abbreviated version of the Schedule for Affective Disorders and Schizophrenia (17) and were then made according to DSM-III-R criteria.

Patients eligible for trial entry received verbal and written descriptions of the study. Written informed consent was obtained. A randomization sequence was determined by using a table of random numbers, prepared in random permuted blocks stratified for source of referral (18) and kept in sealed envelopes that were opened after consent had been obtained, immediately before session 1. The patients were randomly assigned to cognitive behavior therapy or relaxation. Each patient received 13 treatment sessions over 4 to 6 months.

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Outcome measures were completed at pre-, mid-, and posttreatment and at 1-, 3-, and 6-month follow-up. An interview with a blind assessor took place at 3-month follow-up. The main determinant of outcome was the percentage of patients meeting preset outcome criteria.

The recruitment target of 30 patients per group was calculated on the basis of outcome in the pilot study (11) and a similar number of referred subjects in a longitudinal study (19). A trial with 60 patients would give a 90% chance of detecting a true difference between response rates of 20% and 60%, at a significance level of 5%.

The inclusion criteria specified that the patients meet the following diagnostic criteria for chronic fatigue syndrome (15): a main complaint of medically unexplained, disabling fatigue of at least 6 months' duration, with impairment of physical and mental activities. Patients taking antidepressant medication or anxiolytics (at a dose no greater than 10 mg/day of diazepam or equivalent) were eligible if the dose was stable for 3 months before entry and during the trial. The exclusion criteria were somatization disorder, severe depression (DSM-III-R melancholic subtype), ongoing physical investigations, concurrent new treatment, and inability to attend all treatment sessions.

Treatment Procedures

All patients were seen individually, at weekly or fortnightly intervals. Mean therapist time per patient was 15 hours. Information leaflets supplemented each phase of treatment. Each session began with a homework review and ended with agreement on homework tasks, which were recorded in daily diaries. The therapist followed detailed session-by-session treatment manuals devised for both cognitive behavior therapy and relaxation. The research team met fortnightly to review cases and ensure protocol adherence.

Cognitive behavior therapy. This treatment was collaborative, educative, and negotiated and had a behavioral emphasis. The aim was to show patients that activity could be increased steadily and safely without exacerbating symptoms. Sessions 1 to 3 involved engaging the patients in therapy and offering a detailed treatment rationale. Presenting problems were assessed, and patients kept diaries recording hourly details of activity, rest, and fatigue.

At session 4 a schedule of planned, consistent, graded activity and rest was agreed on. The initial targets were modest and small enough to be sustained despite fluctuations in symptoms. Rather than being symptom dependent, activity and rest were divided into small, manageable portions spread across the day (for example, three 5-minute walks daily rather than a 45-minute walk once a week). Patients were encouraged to persevere with their targets and not to reduce them on a bad day or exceed them on a good day.

Once a structured schedule was established, activity was gradually increased and rest was reduced, step by step as tolerance developed. Therapist and patient agreed on specific daily targets covering a range of activities (such as walking, reading, visiting friends, or gardening). A sleep routine was established—for example, stopping daytime sleep, rising at a specific time each morning, reducing time in bed, and using stimulus control techniques for insomnia (20).

Cognitive strategies were introduced at session 8 (while the graded activity program continued). Patients recorded any unhelpful or distressing thoughts and, in discussion and as homework, practiced generating alternatives (21). The unhelpful or distressing thoughts included fears about symptoms and treatment, perfectionism, self-criticism, guilt, and performance expectations.

In the final sessions, strategies for dealing with setbacks were rehearsed and patients drew up "action plans" to guide them through the coming months. The importance of maintaining the principles of therapy after discharge was reinforced.

Relaxation. The same session structure was followed in the relaxation group. The first three sessions involved engagement, rationale giving, information gathering, and diary keeping (recording daily events, feelings, fatigue, and muscle tension). No advice about scheduling activity, reducing rest, or altering sleep patterns was given. The relaxation techniques were adapted from applied relaxation training (22). Progressive muscle relaxation, visualization, and rapid relaxation skills were taught during the 10 treatment sessions and were practiced twice daily as homework.

Outcome Assessment

Ten outcome measures, involving functional impairment, fatigue, psychological distress and mood, and other variables, were used.

Functional impairment. Three outcome measures related to functional impairment:

1. Medical Outcomes Study Short-Form General Health Survey physical functioning scale (23). Limitations caused by ill health are measured on a scale of 0 (limited in all activities, including basic self-care) to 100 (no limitations, able to carry out vigorous activities, such as running or strenuous sports).
2. Work and Social Adjustment Scale (24). Impairment in work, home management, social activities, and private leisure is rated on 0–8 scales; 8 represents maximum impairment.
3. Long-term goals rating (24). Progress toward two individualized long-term goals (for example, "to go swimming for half an hour twice a week" or "return to part-time work") is rated on 0–8 scales.

Fatigue. Two measures were included in this category:

4. Fatigue problem rating (24). Severity of fatigue and accompanying symptoms and restrictions is rated on a 0–8 scale.
5. Fatigue Questionnaire (25). Eleven fatigue symptoms are each rated on a four-option continuum from "less than usual" to "much more than usual." Scoring is bimodal, giving a range of 0–11; scores of 4 or more indicate "caseness," or excessive fatigue.

Psychological distress and mood. These measures were as follows:

6. General Health Questionnaire, 12-item (26). The 12 depression- and anxiety-related items are each rated on the same four-option continuum used in the Fatigue Questionnaire. Bimodal scoring gives a range of 0–12; scores of 4 or more indicate "psychological caseness."
7. Beck Depression Inventory (27). On this measure, scores below 10 indicate no depression, 10 to 15 indicates dysphoria, 16–20 indicates mild depression, 20 to 30 represents moderate depression, and a score over 30 indicates severe depression.

Other variables. These measures include global self-ratings, assessor ratings, and the patients' judgments of what caused their illness.

8. Global self-ratings. Global improvement was rated on a 7-point scale from "very much better" through "unchanged" to "very much worse." Satisfaction with treatment outcome was rated on a 7-point scale from "very satisfied" to "very dissatisfied." Patients also rated how useful they found treatment, on a 5-point scale from "very useful" to "not at all useful." The ratings were then collapsed into two dichotomous categories: scores of 1 or 2 (representing "better," "satisfied," or "useful") versus scores of 3 or more ("unchanged/worse," "dissatisfied," or "not useful").
9. Assessor ratings. At 3-month follow-up, a blind assessor carried out a structured interview and rated degree of improvement in fatigue and in disability on 9-point visual analogue scales from "much better" through "unchanged" to "much worse." The ratings were collapsed into scores of 0–2 (representing "better") and scores of 3–8 ("unchanged/worse").
10. Illness attributions. The patients were asked to write down what they thought caused their illness. The responses were categorized as physical, psychological, or multifactorial.

All measures other than the assessor ratings were self-rated. Measures 1, 5, 6, and 7 have been extensively tested for reliability and validity. Measures 2, 3, and 4 have been widely used in clinical outcome trials with a range of populations (28) and, together with the other measures used, have been found sensitive to change in chronic fatigue syndrome (11). The Medical Outcomes Study health survey, Fatigue Questionnaire, General Health Questionnaire, and Beck Depression Inventory are recommended for use with chronic fatigue syndrome (16, 29), as are global well-being assessment instruments (measures 8 and 9) (16).

Statistical Analysis

Patient characteristics and pretreatment variables were compared by using nonparametric statistics (chi-square and Mann-Whitney U tests). We calculated 95% confidence intervals for mean scores.

Overall outcome was determined by degree of improvement shown on the physical functioning scale of the Medical Outcomes Study Short-Form General Health Survey from pretreatment to 6-month

TABLE 1. Characteristics of Patients With Chronic Fatigue Syndrome Treated With Cognitive Behavior Therapy or Relaxation

Characteristic	Cognitive Behavior Therapy (N=30)		Relaxation (N=30)	
	Mean	*SD*	*Mean*	*SD*
Age (years)[a]	31	9	38	11
Illness duration (years)	3.4	2.1	4.6	3.3
	N	*%*	*N*	*%*
Female	21	70	20	67
Marital status				
Single	13	43	10	33
Married	8	27	10	33
Social class I or II[b]	20	67	19	63
Unemployed	19	63	23	77
Disability benefit	16	53	20	67
Psychiatric diagnosis				
Current	11	37	12	40
Past	9	30	4	13
Antidepressants	4	13	8	27
Patient attribution of symptoms to physical illness	17	57	22	73

[a]Significant difference between groups (z=–2.60, p<0.01).
[b]According to Registrar General's classification (30).

follow-up. The criterion for improvement was an increase of 50 or more or an end score of 83 or more (which represents the ability to carry out moderate activities, such as lifting a table, carrying purchases, or bowling, without limitations). The difference between the proportions of improved patients was tested with the chi-square test.

The preceding outcome criterion was selected because percentage (rather than mean) change in a specified area is thought to be a more relevant and sensitive determinant of outcome in chronic fatigue syndrome (16). Also, as the aim of cognitive behavior therapy was to improve functional status, this was the main outcome of interest, and the physical functioning scale provides a reliable, well-validated, and recommended measure of functional status (16, 29).

The data from all of the outcome measures were skewed and not normally distributed, with varying distributions at each measurement point. We carried out a repeated measures analysis of covariance (ANCOVA), using pretreatment scores and age as covariates. The data were log transformed before the repeated measures analysis, which reduced the skewness of the data. The results of the repeated measures analysis are reported primarily as an illustration of change, with the proportion of patients improved being the main determinant of outcome.

RESULTS

Patient Characteristics

Of the 142 patients assessed for trial entry, 75 were ineligible: 50 did not meet the positive diagnostic criteria for chronic fatigue syndrome, eight had a primary diagnosis of somatization disorder, four had major depression, one had recently started taking antidepressant medication, and 12 were unable to attend sessions regularly (seven lived too far away or had work commitments, and five were bed bound or dependent on wheelchairs). Of the 67 patients eligible for trial entry, seven (10%) refused; two gave no reason for refusing, three did not wish to be randomized, and two did not wish to have cognitive behavior therapy.

The 60 patients who joined the trial (table 1) were similar to chronic fatigue syndrome populations seen in other specialist settings (11, 14, 19, 31): an excess of women, long illness durations, and marked disability and exhaustion. The patients fulfilled the U.K. diagnostic criteria (15) and the revised criteria of the Centers for Disease Control and Prevention (29). Five patients had additional diagnoses of dysthymia, nine had major depression, three had anxiety disorders, and six had both depression and an anxiety disorder. Twelve patients used antidepressants, and two used anxiolytics. The whole group had near-maximum scores on the measures of functional impairment and fatigue. Their scores on the General Health Questionnaire were moderate, but depression was not marked: the mean Beck Depression Inventory score was 14 (SD=7). The illness was attributed to a physical cause by 39 patients (65%); the remainder cited a multifactorial or unknown etiology. The only pretreatment difference between the groups was mean age: 31 for the cognitive behavior therapy group and 38 for the relaxation group.

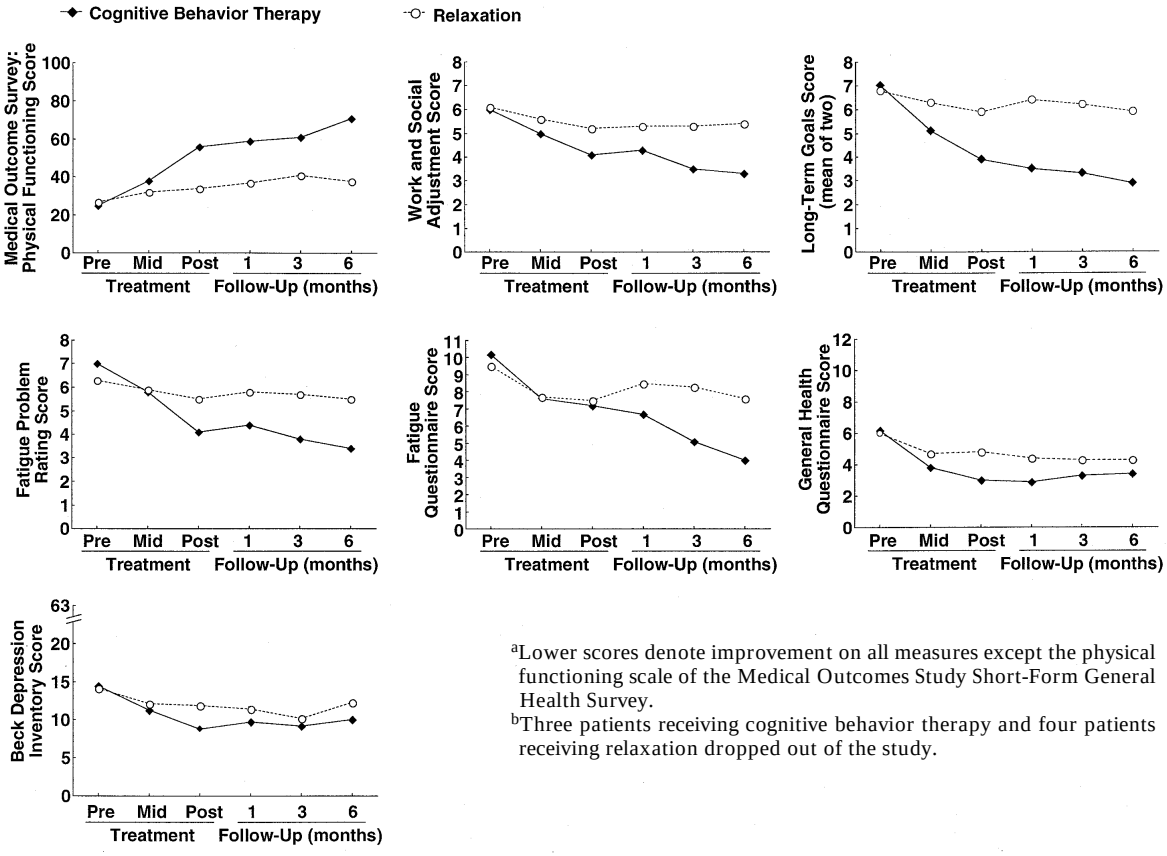
Seven patients (12%) dropped out of treatment and completed no more clinical measures. Three patients withdrew from cognitive behavior therapy: one found it ineffective, one felt too ill to attend as an outpatient (she subsequently improved with inpatient cognitive behavior therapy), and one improved and wanted no further treatment. Four patients withdrew from relaxation: one felt too ill to continue attending, one gave no

TABLE 2. Proportions of Patients With Chronic Fatigue Syndrome Treated With Cognitive Behavior Therapy or Relaxation Who Had Good Outcomes at 6-Month Follow-Up

Study Group	Good Outcome[a]			Difference Between Groups		Chi-Square Analysis (df=1)	
	N	%	95% Confidence Interval (%)	%	95% Confidence Interval (%)	χ^2	p
Treatment completers				51	28–74	11.9	<0.001
Cognitive behavior therapy (N=27)	19	70	53–87				
Relaxation (N=26)	5	19	4–34				
Completers plus dropouts[b]				46	24–68	11.7	<0.001
Cognitive behavior therapy (N=30)	19	63	46–80				
Relaxation (N=30)	5	17	4–30				

[a]An increase of 50 or more, from pretreatment to 6-month follow-up, or an end score of 83 or more on the physical functioning scale of the Medical Outcomes Study Short-Form General Health Survey.
[b]Dropouts were classified as unimproved.

FIGURE 1. Mean Scores on Outcome Measures[a] Over Time for Patients With Chronic Fatigue Syndrome Treated With Cognitive Behavior Therapy (N=30) or Relaxation (N=30)[b]



[a]Lower scores denote improvement on all measures except the physical functioning scale of the Medical Outcomes Study Short-Form General Health Survey.
[b]Three patients receiving cognitive behavior therapy and four patients receiving relaxation dropped out of the study.

reason, and two found the relaxation exercises overly tiring. Two of the patients receiving cognitive behavior therapy and three relaxation patients were unable to attend the assessor interview at 3-month follow-up but returned the self-rated questionnaires through the mail. There were no significant differences between the dropouts, refusers, and completers on any demographic characteristic or pretreatment measure.

Proportion of Patients Improved

At 6-month follow-up, 19 of the patients receiving cognitive behavior therapy and five of those receiving relaxation were improved (according to the outcome criterion described earlier) (table 2). The difference in proportions was significant for the treatment completers and remained so in an intention-to-treat analysis (treatment dropouts were included in the proportions and were classified as unimproved).

The patients receiving cognitive behavior therapy who were classified as improved showed greater change and higher end-point scores than the improved patients in the relaxation group. The mean pretreatment score on the physical functioning scale of the improved patients receiving cognitive behavior therapy was 24.6 (only able to carry out basic self-care; limited in all other activities, including walking more than 100 yards, bending, lifting, and climbing stairs). At 6-month follow-up, this had increased to 85.1 (able to carry out moderate activities without limitations, as described earlier). The five improved relaxation patients moved from a mean score of 33.3 to 69.9.

Many improved patients also showed substantial reductions in fatigue. At 6-month follow-up, 17 patients receiving cognitive behavior therapy were no longer fatigue "cases," compared with four relaxation patients (χ^2= 10.6, df=1, p<0.001). The combined improvement in physical functioning and fatigue was such that by final follow-up 15 cognitive behavior therapy patients and two relaxation patients no longer fulfilled the diagnostic criteria for chronic fatigue syndrome (χ^2=11.8, df=1, p< 0.001). Only three unimproved patients in the cognitive behavior therapy group had unchanged or worse scores on the physical functioning scale at 6-month follow-up, compared with 11 relaxation patients (χ^2=5.1, df=1, p<0.02).

Pattern of Change

The pattern of change is shown in figure 1, which presents the mean scores on the continuous variables for both groups at each measurement point.

Repeated measures ANCOVA of the log-transformed data (table 3) showed that over time the subjects receiving cognitive behavior therapy improved significantly

TABLE 3. Scores on Outcome Measures and Results of Repeated Measures ANCOVA for Patients With Chronic Fatigue Syndrome Treated With Cognitive Behavior Therapy or Relaxation[a]

	Score				Repeated Measures ANCOVA (df=4, 204)	
	Cognitive Behavior Therapy (N=30)		Relaxation (N=30)			
Measure and Time	Mean	SD	Mean	SD	F	p
Physical functioning scale of Medical Outcomes Study Short-Form General Health Survey[b]					0.83	>0.50
Pretreatment	25.5	18.9	27.8	27.1		
Posttreatment	56.2	26.2	34.6	28.3		
6-month follow-up	71.6	28.0	38.4	26.9		
Work and Social Adjustment Scale					5.59	<0.001
Pretreatment	6.0	1.2	6.1	1.3		
Posttreatment	4.1	1.9	5.2	1.8		
6-month follow-up	3.3	2.2	5.4	1.8		
Long-term goals rating (mean of two)					6.93	<0.001
Pretreatment	7.0	0.7	6.8	1.0		
Posttreatment	3.9	2.1	5.9	1.5		
6-month follow-up	2.9	1.9	5.9	1.8		
Fatigue problem rating					9.07	<0.001
Pretreatment	7.0	0.9	6.3	1.2		
Posttreatment	4.1	1.9	5.5	1.4		
6-month follow-up	3.4	2.2	5.5	1.9		
Fatigue Questionnaire					3.02	<0.01
Pretreatment	10.2	1.3	9.5	2.6		
Posttreatment	7.2	4.0	7.5	4.1		
6-month follow-up	4.1	4.0	7.2	4.0		
Beck Depression Inventory					1.21	>0.30
Pretreatment	14.5	7.2	14.2	6.1		
Posttreatment	8.9	5.6	11.9	7.4		
6-month follow-up	10.1	6.9	12.3	8.5		
General Health Questionnaire					0.45	>0.70
Pretreatment	6.2	3.6	6.0	4.2		
Posttreatment	3.0	3.1	4.8	3.8		
6-month follow-up	3.4	3.7	4.3	3.9		

[a]Data log transformed over all time points, with age and pretreatment scores as covariates.
[b]Significant group effect (F=4.62, df=1, 49, p<0.03).

more than did the relaxation subjects on the Work and Social Adjustment Scale, rating of long-term goals, rating of fatigue problems, and Fatigue Questionnaire.

No group-by-time interaction was found for the physical functioning scale. The two groups had similar scores at pretreatment, and then both made some linear improvement over time. However, from midtreatment onward there was a significant difference in overall level: the cognitive behavior therapy group had consistently higher scores. This difference remained stable at all subsequent time points.

There were no significant differences between groups on the General Health Questionnaire and Beck Depression Inventory. Both groups improved slightly, and the number of cases identified with the General Health Questionnaire dropped from 21 to eight at final follow-up in the cognitive behavior therapy group and from 20 to 13 in the relaxation group.

An intention-to-treat analysis (in which for all time points treatment dropouts were assigned the last value received) showed a pattern of results similar to that from the main analysis. This suggests that dropouts are unlikely to have biased the results.

Self- and Assessor-Rated Global Outcome

Self-rated global improvement at final follow-up (table 4) was consistent with outcome on the physical functioning scale of the Medical Outcomes Study health survey. At 6-month follow-up, five relaxation patients (but no cognitive behavior therapy patients) rated themselves as worse; none attributed this to treatment. More of the patients receiving cognitive behavior therapy rated themselves as satisfied with their level of improvement, but almost all patients rated the treatments as useful. The assessor ratings of improvement in disability and fatigue were consistent with the self-rated improvement.

Psychiatric Disorder and Antidepressants

The proportions of patients with psychiatric disorders at baseline were similar in the improved and unimproved groups. Outcome among the patients free of psychiatric disorder was consistent with the results for the entire group: 63% in the cognitive behavior therapy group and 6% of the relaxation group achieved good outcomes (χ^2= 11.0, df=1, p<0.001). Among the patients who were medication free, 65% of the cognitive behavior therapy group and 5% of the relaxation group improved (χ^2=16.3, df=1, p<0.001).

Factors Associated With Treatment Outcome

There were no significant differences between the improved and unimproved patients on any pretreatment characteristic, including psychiatric disorder and illness attributions. Poor outcome was associated with taking medical retirement or making a new claim for a disability-related benefit *during* (but not before) treatment (cognitive behavior therapy: χ^2=7.9, df=1, p<0.01; entire group: χ^2=5.3, df=1, p<0.02). The numbers involved were small and should be interpreted with caution.

Other Treatments

No patients embarked on any new treatments during sessions 1 to 13. Six patients sought further treatment for chronic fatigue syndrome during follow-up: in the improved group, two cognitive behavior therapy and two

relaxation patients had courses of antidepressants (one patient receiving cognitive behavior therapy stopped taking this medication after 3 weeks). In the unimproved group, one cognitive behavior therapy patient saw a homeopath, and one began but discontinued antidepressant treatment. Four patients sought treatment for problems other than chronic fatigue syndrome (gynecological problems and phobias).

TABLE 4. Self- and Assessor-Rated Global Improvement of Patients With Chronic Fatigue Syndrome Treated With Cognitive Behavior Therapy or Relaxation

	Cognitive Behavior Therapy		Relaxation		Chi-Square Analysis (df=1)	
Rating	N	%	N	%	χ^2	p
Self-ratings at 6-month follow-up	27	100	26	100		
Global improvement					8.3	<0.01
Better or much better	19	70	8	31		
Unchanged or worse	8	30	18	69		
Satisfaction with treatment outcome					4.4	<0.05
Satisfied or very satisfied	21	78	13	50		
Dissatisfied	6	22	13	50		
Usefulness of treatment					2.1	>0.10
Useful or very useful	26	96	22	85		
Not useful	1	4	4	15		
Assessor ratings at 3-month follow-up	25	100	23	100		
Physical functioning					14.0	<0.001
Better or much better	20	80	6	26		
Unchanged or worse	5	20	17	74		
Fatigue					14.4	<0.001
Better or much better	18	72	4	17		
Unchanged or worse	7	28	19	83		

DISCUSSION

Cognitive behavior therapy (comprising graded activity and cognitive restructuring) was more effective than a control treatment of relaxation in improving functional status and fatigue in patients with chronic fatigue syndrome. Substantial improvement occurred in 70% of the patients who completed cognitive behavior therapy, compared with 19% who completed the relaxation sessions. Mood improved slightly in both groups, possibly because of nonspecific treatment factors common to both interventions. The proportion of treatment dropouts was low.

The consistency between the measures of global improvement, functional impairment, and fatigue suggests that the degree of change and the magnitude of difference between the groups was robust and clinically meaningful. However, cognitive behavior therapy was not uniformly effective: a small proportion of patients improved substantially in functional ability but remained fatigued and symptomatic.

The improvements in the group who received cognitive behavior therapy continued for 6 months after treatment ended; this may in part be because the patients were taught to treat themselves and to practice relapse prevention. In clinical practice, treating patients until they reach optimum functioning may be unnecessary. Rather, outcome could be enhanced by treating patients until they can carry out self-directed treatment, followed by long, phased follow-up with "booster" sessions.

Although the results of this study are promising, the study has its limitations. These include the use of a single therapist; to offset this shortcoming, much effort was put into maximizing the face validity of the control treatment, which was delivered within a structured format, with detailed information leaflets and a careful rationale. The therapist was experienced in both interventions, having used both cognitive behavior therapy and relaxation techniques in behavioral medicine. Relaxation was evaluated positively by patients, compliance was high, and the dropout rate was similar to that for cognitive behavior therapy, suggesting that it was largely an acceptable and credible intervention.

Outcome assessment depended largely on self-rated outcome measures. However, no objective measures exist for subjectively experienced fatigue, disability, and mood disturbance, which are the areas of interest in chronic fatigue syndrome. It is acknowledged that investigators rely on patient self-report instruments (16); we therefore used recommended, reproducible measures that are sensitive to change in chronic fatigue syndrome (11, 16, 29). We had only one posttreatment independent assessment, giving a "snapshot" of status at 3-month follow-up. The results of this assessment were consistent with the global self-ratings and the proportions of patients improved, but given the fluctuating nature of chronic fatigue syndrome, more frequent independent assessments (for example, at baseline and posttreatment *and* each follow-up) and an interview with a relative or significant other may be useful in future studies.

The results of this trial are similar to those of the pilot study (11), but two controlled trials (13, 14) showed cognitive behavior therapy to be ineffective. This negative finding could be due to differences in the nature and delivery of the interventions studied. In a nonrandomized comparison of cognitive behavior therapy with a waiting list, graded activity (a key component in the present study) was excluded as it provoked relapse (13). This could reflect a difference in how graded activity was introduced. Often, the first step in our intervention was not to increase activity but to redistribute or even reduce it, interspersing it with sufficient rest. Activity levels were increased only after a consistent, manageable program was established.

A randomized comparison of cognitive behavior therapy and routine clinic attendance (14) produced an unsustained improvement in activity levels (32). This intervention may have been too brief (32): six sessions over 10 weeks, compared with 13 sessions over 4–6

months in the present study. A longer duration allows sequential skills acquisition, relapse prevention, and an opportunity for practicing self-directed treatment while still having therapist contact.

It has been suggested that improvement in chronic fatigue syndrome is due to placebo response and that many patients do well with supportive care from a concerned physician (3, 32, 33). However, the question of nonspecific treatment factors was only partially addressed in earlier controlled trials. To our knowledge, the present study is the first to compare cognitive behavior therapy with a psychological treatment that controls for factors such as therapist time and attention, support, and homework practice.

As chronic fatigue syndrome is heterogenous, effective clinical practice will probably require the pragmatic, flexible use of a *range* of behavioral and cognitive techniques, closely tailored to the individual patient, rather than adherence to a rigid protocol. However, further research is necessary in order to determine the efficacy of specific components in, and the optimal delivery of, cognitive behavior therapy for chronic fatigue syndrome. The issues of who benefits from such treatment and how the response rate can be maximized merit further attention.

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