

Implementing Cognitive Behavioral Therapy for Chronic Fatigue Syndrome in a Mental Health Center: A Benchmarking Evaluation

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Objective: This study evaluated the success of implementing cognitive behavioral therapy (CBT) for chronic fatigue syndrome (CFS) in a representative clinical practice setting and compared the patient outcomes with those of previously published randomized controlled trials (RCTs) of CBT for CFS. *Method:* The implementation interventions were the following: spreading information about the new treatment setting to general practitioners and CFS patients; training mental health center (MHC) therapists in CBT for CFS; and organizing changes in the MHC patient workflow. Patient outcomes were documented with validated self-report measures of fatigue and physical functioning before and after treatment. The comparison of the treatment results with RCT results was done following the benchmark strategy. *Results:* One-hundred forty-three CFS patients were referred to the MHC, of whom 112 started treatment. The implementation was largely successful, but a weak point was the fact that 32% of all referred patients dropped out shortly after or even before starting treatment. Treatment effect sizes were in the range of those found in the benchmark studies. *Conclusions:* CBT for CFS can successfully be implemented in an MHC. Treatment results were acceptable, but the relatively large early dropout of patients needs attention.

Keywords: chronic fatigue syndrome, cognitive behavioral therapy, benchmark strategy, implementation, transportability of treatment manual

Chronic fatigue syndrome (CFS) is characterized by severe and unexplained fatigue that lasts for at least 6 months (Fukuda et al., 1994). It results in a strong reduction in physical and mental functioning (Bombardier & Buchwald, 1996; Jason et al., 2000). Systematic reviews have shown that cognitive behavioral therapy (CBT) and graded exercise therapy (GET) are currently the only evidence-based treatments for CFS (Afari & Buchwald, 2003; Chambers, Bagnall, Hempel, & Forbes, 2006; Whiting et al., 2001) with improvement rates of around 70% and 55%, respectively. CBT for CFS is only scarcely available in some specialist medical hospitals, hence many CFS patients have no access to it or can only start treatment after a waiting time of several years (Cairns & Hotopf, 2005). Therefore, as a step toward nationwide implementation, a pilot implementation and evaluation project was set up that took place in an outpatient mental health center (MHC). The present article focuses on the success of this implementation and on treatment outcomes in patients.

It has been demonstrated that, after training, CBT for CFS can effectively be performed by therapists who are inexperienced with CFS (Bazelmans, Prins, Hoogveld, & Bleijenberg, 2004; Prins et al., 2001). The transportability of randomized controlled trial

(RCT) results to clinical practice settings, however, has scarcely been studied as yet. So far only one study evaluated whether CBT for CFS can be delivered with the same effectiveness outside the RCT context (Quarmby, Rimes, Deale, Wessely, & Chalder, 2006), but this study was done in a CFS specialist clinic that had previously participated in a clinical trial of CBT for CFS.

Since rigorous evaluations such as RCTs always imply controlled conditions, it is unclear to what extent their positive effects can be generalized to clinical practice (Rothwell, 1995; Weersing, 2005; Whiting et al., 2001). Treatment effects may be more modest outside RCTs because of lower criteria for including patients and absence of direct access to CFS experts (Weersing, 2005; Wilson, 1995). This study therefore evaluated the treatment results of CBT for CFS in a clinical practice setting in comparison with previous RCT results.

When performing a benchmark study, it is important that the treatment location that is being compared with an RCT condition represents a real practice setting. Shadish, Navarro, Matt, and Phillips (2000) have formulated 10 clinical representativeness codes that can be checked to see to what degree a certain setting is clinically representative. These codes concern issues like the kind and heterogeneity of the patient problems, the referral route, or the connection with a research institute. In the present study, an MHC was chosen as clinical practice setting because it has the right facilities and sufficient CBT therapists to perform the 16-session CBT for CFS treatments, and at the same time it fulfils most of the Shadish criteria for clinical representativeness.

Secondly, the present study aimed to evaluate the success of the implementation itself and to assess the problems that arose during the implementation process. On the basis of explorations of possible barriers, the following implementation interventions were

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applied to create the basic conditions for successful implementation. Firstly, general practitioners (GPs) were informed of the study because none of the GPs in the regions concerned were familiar with the availability of CBT for CFS in the MHC. Secondly, CFS patients themselves were informed. Since not all CFS patients are still visiting their GP after several years of illness, informing them directly might increase the number of CFS patients entering the MHC. The third intervention implied selecting and training behavioral therapists in CBT for CFS and making arrangements with them about the treatment procedures. Fourth and finally, many employees of the MHC who might have been in contact with CFS patients were informed to pay attention to and cooperate with the CFS implementation project. The process evaluation aimed to assess the impact of these implementation interventions on the delivery of CBT to CFS patients and to analyze the problems that might occur during such an implementation process.

Method

Study Design

This study is a clinical evaluation of implementing CBT for CFS and a comparison of the clinical MHC treatment results with relevant RCTs, using the so-called benchmark strategy (Wade, Treat, & Stuart, 1998; Weersing, 2005).

Treatment Setting

The MHC was a regional mid-sized institution located in the east of the Netherlands, covering mostly rural and some urbanized areas. It had locations in four separate subregions; the CBT for CFS treatment was offered at two of them. This MHC was the main provider of mental health care in this area, offering services for the full range of problems and patients, both outpatient and inpatient.

Patients and Procedures

Inclusion criteria for referral to the MHC were as follows: All patients had to be referred by a GP or another physician, had to be diagnosed by this doctor as having CFS based on the Centers for Disease Control-94 (CDC-94) criteria (Fukuda et al., 1994), should be 18 years or older, and should not be engaged in a claim for disability-related benefits. This last criterion was an exclusion criterion since this is known to be a predictor for a negative treatment outcome (Prins, Bazelmans, van der Werf, van der Meer, & Bleijenberg, 2002). Patients were classified as CFS and included in this study if they scored at least 27 (which is the point of 1 *SD* above the mean score of healthy individuals) on the Fatigue Severity subscale of the Checklist Individual Strength (CIS-20; Vercoulen, Alberts, & Bleijenberg, 1999) and <70 on the Physical Functioning or Social Functioning subscales of the Rand-36 (Steward, Hays, & Ware, 1998). The patient inclusion period was 6 months shorter (namely 20 months) than was the implementation and evaluation period (26 months), so all included patients could finish their treatment in time.

Implementation Interventions

Informing GPs and CFS patients. Information letters and brochures were distributed repeatedly to all GPs in the surrounding

regions, namely four times with time intervals of about 4 months. Additionally, some small group education sessions about CFS were organized, and announcements about the new treatment setting were made in local newspapers. The focus was on informing GPs about the treatment possibility, educating them about the diagnostic criteria for CFS, and also encouraging them to refer CFS patients. To inform CFS patients, brochures were spread among libraries, pharmacies, and so on, and advertisements were placed in local newspapers.

Training therapists. Nine behavioral therapists, three men and six women, took part. They were selected on the basis of their prior education in CBT and on their willingness and availability to participate 1 day per week for at least 2 years in this project. None of the therapists had previous experience with CFS. Their number of years working as a behavioral therapist varied from 2 to 13 years. At the start of the project, two experts in CBT trained the therapists for CFS during two blocks of 2 days each. Additionally, the therapists were supervised every 2 weeks for 2 years.

Informing and instructing MHC employees. Employees directly involved in the project, like some secretaries and diagnostic assistants, were settled into the procedures and were asked to cooperate in the development of the patient flow design. Less involved employees were informed about the project and were instructed on whom to contact when dealing with a CFS patient.

Treatment Protocol

The CBT for CFS treatment protocol has been described in a manual for therapists (Bazelmans, Prins, & Bleijenberg, 2006; Bleijenberg, Prins, & Bazelmans, 2003). It prescribes 16 one-hour sessions over a period of 6 to 8 months. In the treatment, first the model of perpetuating factors is explained and the therapist attempts to motivate the patient for CBT. Next, fatigue-related cognitions are challenged to diminish somatic attributions, to improve sense of control over symptoms, and to facilitate behavioral change. At the same time, a structured physical activity program starts. After regulating and gradually increasing physical activity, a work rehabilitation plan is developed. Patients without gainful employment work on rehabilitation in other personal goals. From the start, patients define their own criteria for recovery and formulate personal therapy aims. The final sessions deal with relapse prevention and further improvement of self-control.

Measurement

Treatment outcomes. Treatment results were measured with validated measures for fatigue severity and physical functioning. Severe fatigue was measured with the Fatigue Severity subscale of the CIS-20 (Vercoulen et al., 1997, 1999), which has high reliability (Cronbach's $\alpha = .92$) and good discriminant validity and is also used in two of the four benchmark RCTs (Prins et al., 2001; Stulemeijer, de Jong, Fiselier, Hoogveld, & Bleijenberg, 2005). Physical functioning in daily life was measured with the Physical Functioning subscale of the Rand-36 (Steward et al., 1998).

Impact of the implementation interventions. To determine the impact of the implementation, positive impact was operationalized with five separate criteria that were formulated in cooperation with the MHC project group members. These criteria were the following: (a) Sufficient GPs ($\geq 50\%$) are informed about the new

treatment setting for CFS; (b) the majority of CFS patients ($\geq 50\%$) accept their GP's referral to the MHC; (c) sufficient CFS patients (≥ 150) are referred during the project; (d) a limited number of these referred patients ($\leq 15\%$) are falsely diagnosed as having CFS; (e) a limited number of referred patients ($\leq 30\%$) drop out of CBT. The number of 150 referred patients in the third criterion was based on the calculation of the number of CFS patients living in the implementation region, assuming a prevalence of 180 adult CFS patients per 100,000 and an incidence of 60 per 100,000 per year (Afari & Buchwald, 2003; Bazelmans et al., 1999).

The measurements related to these criteria were completed as follows: (a) One year after starting the project, a short questionnaire was distributed among all GPs in the regions concerned, which investigated how many GPs were informed about the new treatment setting and about how to diagnose CFS (Scheeres, Wensing, & Bleijenberg, 2007); (b) on this questionnaire, GPs were also asked to fill in the number of their CFS patients that did not accept their referral to the MHC; (c) the number of CFS patients referred to the MHC was registered each week; (d) after the intake session, the patient filled in a questionnaire on the main complaints and criteria for CFS; and (e) the number of patients that showed up at intake, did not show up at intake, started treatment, did not start treatment, and that dropped out during treatment were also registered each week, and dates of these events were included.

No show patients were patients who were referred to and registered at the MHC but who did not show up at intake. *Not starting patients* decided not to start treatment directly after the intake. *Dropout patients* were those who ended treatment after at least 1 and maximum 11 treatment sessions. *Completers* decided to stop treatment after 11 or more treatment sessions or finished the whole treatment. In cases of not starting and dropout, both patient and therapist were asked to fill in a form about the reason for it. Additionally, a structured telephone interview was held with 30 no show and not starting patients to further investigate these reasons.

Problems during the implementation process. These were measured and registered by a monthly diary that was kept by the researcher and discussed with the project group every month. This diary contained aspects like the weekly registration of the numbers of referred and treated patients, the mean waiting time between referral and intake, the experiences of therapists and other people concerned with the project, and unforeseen problems like trained therapists quitting the project or organizational changes influencing the implementation process.

Analysis

Treatment results. The recovery rate was analyzed by calculating the percentage of patients clinically significantly improved. Patients were defined as clinically significantly improved at post-treatment if they had a reliable change index > 1.96 on the CIS-20 Fatigue Severity subscale, a Fatigue Severity score ≤ 35 , and a Rand-36 Physical Functioning score ≥ 65 (Vercoulen et al., 1999). For missing data, the method of last observation carried forward was used, indicating that intake measurements were used at post-treatment.

Selection of the benchmark RCTs. In the most recent systematic reviews concerning treatment for CFS (Afari & Buchwald, 2003; Chambers et al., 2006; Whiting et al., 2001), seven RCTs

investigating the effect of CBT for CFS have been included (Deale, Chalder, Marks, & Wessely, 1997; Lloyd et al., 1993; Prins et al., 2001; Ridsdale et al., 2001; Sharpe et al., 1996; Stulemeijer et al., 2005; Whitehead & Champion, 2002). In this study, four of these RCTs (Deale et al., 1997; Prins et al., 2001; Sharpe et al., 1996; Stulemeijer et al., 2005) were included to create the benchmark. Our decisive criterion for including trials, in addition to methodological criteria that the reviews already adjusted, was homogeneity of the treatment manual (Streiner, 1991). In the RCTs of Ridsdale et al. (2001) and Lloyd et al. (1993), the therapy protocol counted only six to eight sessions in 6 to 12 weeks. This is about half as much as in the other trials, which may partly explain why little effect was found. In the RCT of Whitehead and Champion (2002), treatments were performed by GPs instead of behavioral therapists. Table 1 gives the characteristics of the trials included in this study.

Creation of the statistical benchmark and comparison of the treatment effects. Three of the four benchmark RCTs consisted of one intervention condition tested against a control condition; one also had a support group condition (Prins et al., 2001). For the purpose of this study, only the outcome data of the CBT conditions were used (since the implementation study also included only a treatment group) to compose a benchmark indexing the mean change of CBT under RCT conditions. The primary outcome measurements used in the benchmark RCTs are shown in Table 1. Since the different outcome measurements could not be compared directly, uncontrolled effect sizes of all studies were calculated to standardize the treatment effects (Streiner, 1991). Uncontrolled effect sizes obviously may inflate the effects of therapy as compared with conventional controlled effect sizes, since they do not control for spontaneous recovery. However, for the purpose of just comparing different study results, it provides a useful measure. The calculation of the composite benchmark thus involved two steps: First, uncontrolled pre-post effect sizes were calculated as $(M \text{ Start} - M \text{ End}) / SD \text{ Start}$ (Cohen, 1988; Westbrook & Kirk, 2004). Second, an average effect size was calculated, taking into account the size of the patient group in the different trials (Rosenthal & Rubin, 1982). When outcomes were reported at multiple time points (e.g., posttreatment and follow-up), we coded the effect size closest to the time interval of the other studies, which was about 6 months. The MHC's effect sizes for fatigue severity and physical functioning were calculated by using the same formula (Westbrook & Kirk, 2004) and on the basis of intention to treat, as was done in the RCTs.

Results

Treatment Results

Sample characteristics. Table 2 provides the sample characteristics of the implementation study and the four benchmark studies. Of the 143 patients being referred to the MHC, 18 did not show up at intake and 13 appeared not to fulfill the criteria for CFS (Table 5). In 4 cases, the fatigue and/or impairments were not severe enough, 3 patients yet had a possible somatic explanation for their fatigue (2 for obesity [BMI > 40] and 1 for recently detected diabetes), 3 suffered primarily from depression, 1 was primarily addicted to alcohol, 1 had primarily pain complaints, and in 2 cases the reason for rejecting the CFS diagnosis was not

Table 1
Comparison of Study Characteristics of an Implementation Study and Benchmark Randomized Controlled Trials

Characteristic	Implementation study	Sharpe et al. (1996)	Deale et al. (1997)	Prins et al. (2001)	Stulemeijer et al. (2005)
Treatment protocol					
No. of performed sessions	18	16	13	16	10
Duration	6 to 8 months	5 months	4 to 6 months	6 to 8 months	5 months
Therapists	9 nonexperienced therapists	3 experienced therapists	1 experienced therapist	13 nonexperienced therapist	2 experienced therapists
Sample size					
No. of patients	112	30	30	92	36
Not starting	28	0	0	10	4
Dropout	12	0	3	23	3
Inclusion criteria	CDC criteria for CFS	Oxford criteria for CFS	CDC criteria for CFS	CDC criteria for CFS	CDC criteria for CFS
Assessment scales					
Fatigue Severity	CIS-20 (8–56)	Likert scale (0–10)	Chalder et al. (1993) fatigue scale (0–11)	CIS-20 (8–56)	CIS-20 (8–56)
	Inclusion cutoff > 27	No inclusion cutoff	Inclusion cutoff \geq 40	Inclusion cutoff > 40	Inclusion cutoff > 40
Physical Functioning	SF-36 (0–100)	Karnofski (0–100; Grieco & Long, 1984)	SF-36 (0–100)	SIP (0–5799)	SF-36 (0–100)
	Inclusion cutoff < 70 on either physical or social functioning	Inclusion cutoff < 80	Inclusion cutoff < 83	Inclusion cutoff > 800	Inclusion cutoff < 65

Note. CDC = Centers for Disease Control; CFS = chronic fatigue syndrome; CIS-20 = Checklist Individual Strength; SF-36 = Short Form (Physical Functioning Scale) of the Rand-36; SIP = Sickness Impact Profile.

registered. The mean pretreatment score on CIS-20 Fatigue Severity was 48.7 ($SD = 7.1$), on Rand-36 Physical Functioning 53.5 ($SD = 23.2$), and on Rand-36 Social Functioning 39.1 ($SD = 22.9$). The mean total score on the Symptom Checklist–90 (Arrindel & Etteme, 1986) was 162.4 ($SD = 39.1$), and on the Beck Depression Inventory—Primary Care (Beck, Steer, & Garbon, 1988) 33 patients (30%) were indicated as having comorbid depressive disorder. Pain medication was used by 97 patients (87%) and antidepressants by 21 patients (19%). Overall, patients attributed their fatigue more to physical than to psychological causes.

A remarkable difference did exist in CFS illness duration, which was longer in the MHC sample. Age, gender, and marital status were not statistically different, except for the study of CBT for CFS in adolescents (Stulemeijer et al., 2005), of course. No significant differences were found on any demographic characteris-

tics or pretreatment illness scores between patients who did not start or did not finish CBT or who finished the treatment.

MHC treatment results. The mean number of treatment sessions of all 84 patients starting treatment was 14.5 ($SD = 5.6$), varying from 3 to 31 treatment sessions. Table 3 shows the mean scores of Fatigue Severity and Physical Functioning at intake and follow-up. Table 3 also shows the percentage of patients clinically significantly improved after treatment at the MHC.

Comparison of treatment effects. The noncontrolled effect sizes of the implementation study and the benchmark studies are given in Table 4 and in Figures 1 and 2. The mean pre–post treatment effect size of the four benchmark studies for fatigue was $\{1.02$ (Sharpe et al., 1996) $+ 2.05$ (Deale et al., 1997) $+ [3 \times 1.25$ (Prins et al., 2001)] $+ 1.83$ (Stulemeijer et al., 2005)} $/ 6 = 1.44$ (95% confidence interval [CI] = 0.97, 1.89). This is somewhat

Table 2
Comparison of the Implementation Sample With the Benchmark Randomized Controlled Trials Samples

Characteristic	Implementation study (N = 112)	Sharpe et al. (1996) (N = 30)	Deale et al. (1997) (N = 30)	Prins et al. (2001) (N = 92)	Stulemeijer et al. (2005) (N = 36)
Years of illness duration, <i>M</i> (<i>SD</i>)	5.5 (4.9)	2.8 (0.8)	3.4 (2.1)	4.9 (4.8)	1.4
Age in years, <i>M</i> (<i>SD</i>)	39 (10.2)	34 (9.1)	31 (9.0)	36 (9.4)	16 (1.3)
Gender (men/women)	34%/66%	40%/60%	30%/70%	24%/76%	11%/89%
Marital status (married or cohabiting)	72%	63%	57% ^a	70%	—
Unemployed or not attending school	53%	87%	63%	46%	89% ^b

Note. Marital status was not recorded for Stulemeijer et al. (2005) because participants were adolescents.

^a This percentage was not presented directly in the article, but was derived from data indicating that 43% of participants were single.

^b Including partial nonattendance.

Table 3
Percentages of Recovered Patients and Mean Fatigue Severity and Physical Functioning Scores Before and After Treatment

Patient group	Patients clinically significantly improved		Fatigue Severity score at intake		Fatigue Severity score at follow-up		SF-36 score at intake		SF-36 score at follow-up	
	<i>n</i>	%	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
Finished treatments, including dropout (<i>N</i> = 84)	46	54.8	48.5	7.1	29.3	14.0	52.8	21.2	73.6	22.9
Intention to treat (<i>N</i> = 112)	46	41.1	48.7	7.1	35.4	15.3	53.5	23.2	69.1	25.6

Note. SF-36 = Short Form (Physical Functioning Scale) of the Rand-36.

higher than the effect size of fatigue in the MHC, which was 1.12 (95% CI = 0.85, 1.38). For physical functioning, the mean pre-post treatment effect size of the benchmark studies was {1.93 (Deale et al., 1997) + [3 × 0.71 (Prins et al., 2001)] + 1.19 (Stulemeijer et al., 2005)} / 5 = 1.04 (95% CI = 0.63, 1.44). This is again somewhat higher than the effect size at the MHC for physical functioning, which was 0.64 (95% CI = 0.38, 0.89).

Impact of the Implementation

Table 5 provides the results on the research questions that defined the overall impact of the implementation. It reveals that three of the five subquestions (1, 2, and 5) got positive results and two (3 and 4) got results that did not meet the criteria for positive impact, the high percentage of patients not starting and not finishing treatment being the most problematic. As can be seen in Table 6, of the 112 patients eligible for CBT, only 72 finished treatment. In an additional analysis, we checked what characteristics not starting patients and dropout patients had that were different from completers. The results showed no differences between these groups.

Reasons for no show, not starting, and dropout. The main reason for no show and not starting treatment, reported by 8 patients, was having found another doctor or (alternative) therapist. Seven patients thought they had a medical reason for their fatigue and hence thought they would not profit from psychological treatment. Another 7 patients were of the opinion that the treatment did not suit them, mainly because it would be too heavy. The other 8 patients had practical reasons. The main reasons for dropout were the opinion that CBT was not the right treatment for CFS (4 patients), experiencing too much pain or other complaints during treatment (4 patients), and feeling sufficiently recovered after some sessions already (3 patients).

Problems During the Implementation Process

Loss of trained therapists. Within 1 year, four therapists dropped out of the project for several reasons. Twice, an extra training had to be organized, and new therapists had to be found. Since this took several months, this loss of expertise led to delays in the patient flow.

Table 4
Mean Scores at Intake and Follow-Up and Effect Sizes of the Four Benchmark Studies and the Implementation Study

Subscale	Sharpe et al. (1996)	Deale et al. (1997)	Prins et al. (2001)	Stulemeijer et al. (2005)	Statistical benchmark	Implementation study
Fatigue Severity						
Intake score, <i>M</i> (<i>SD</i>)	7.8 (1.5)	10.2 (1.3)	52.2 (3.9)	52.5 (3.8)		48.7 (7.1)
Follow-up score, <i>M</i> (<i>SD</i>)	4.7 (4.1) ^a	4.1 (4.0)	42.0 (10.9)	30.2 (16.8)		35.4 (15.3)
Pooled <i>SD</i>	3.1	3.0	8.2	12.2		11.9
Effect size	1.02	2.05	1.25	1.83	1.44	1.12
Confidence interval	0.47, 1.54	1.40, 2.65	0.93, 1.56	1.21, 2.41	0.97, 1.89	0.85, 1.38
Physical Functioning						
Intake score, <i>M</i> (<i>SD</i>)	71 (3.3)	25.5 (18.9)	1,752 (611)	42.1 (16.5)		53.5 (23.2)
Follow-up score, <i>M</i> (<i>SD</i>)	—	71.6 (28.0)	1,285 (703)	69.4 (28.0)		69.1 (25.6)
Pooled <i>SD</i>	—	23.9	659	23.0		24.2
Effect size	—	1.93	0.71	1.19	1.04	0.64
Confidence interval	—	1.29, 2.51	0.41, 1.00	0.62, 1.71	0.63, 1.44	0.38, 0.89

Note. Sharpe et al.'s (1996) article did not give follow-up data for the Karnofski scale, hence this study was not included in the analysis of the benchmark effect size of physical functioning.

^aThe follow-up *SD* was not given in Sharpe et al.'s article; it was estimated based on the assumption that an *SD* at follow-up is in general about 2.8 times higher an *SD* at intake.

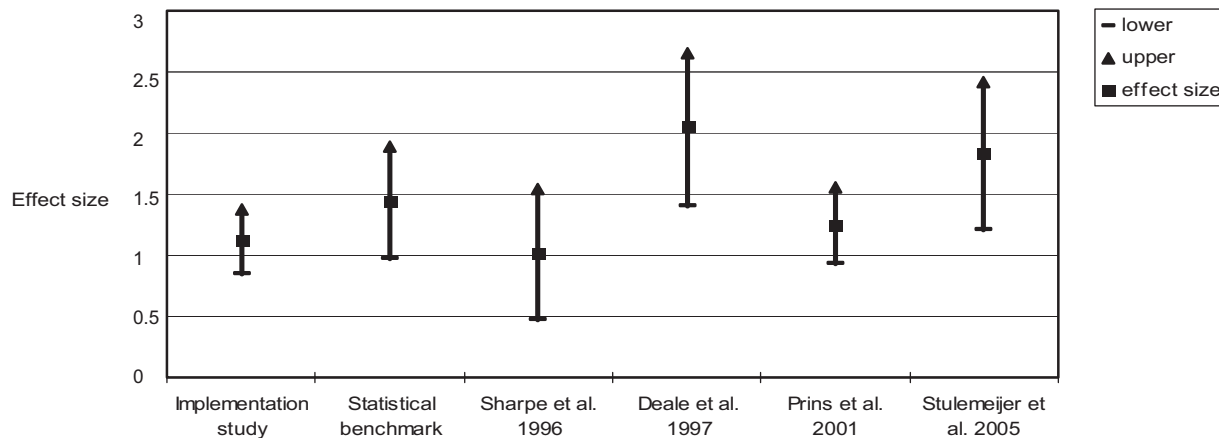


Figure 1. Mean noncontrolled pre-post treatment effect sizes and confidence intervals of fatigue severity at the mental health center and the benchmark randomized controlled trials.

Long waiting list. During the 1st year, the waiting times before intake were increasing, and during the 2nd year, they stayed on this level. The mean waiting time before intake was 7.3 weeks. Waiting time was significantly higher for not starting patients than for starting patients ($M = 9.5$ weeks, $SD = 5.6$; and $M = 6.8$ weeks, $SD = 5.1$, respectively; t test $p = .02$).

Limited use of the time reserved for CFS patients. Therapists appeared not to use all the time reserved for CFS treatments. The problem was that beforehand it was said 1 day per therapist was reserved for CFS, in which they should be able to see 6 to 7 patients, but in practice they saw only 3 to 6 patients per week. What we did not find out is whether this was because of inefficient use of time or just because of seeing more of the “usual” non-CFS patients at the expense of CFS.

Long treatment duration. Therapists appeared to have difficulties with ending a CFS treatment within the prescribed 16 sessions, which also hindered the patient flow. We had not expected that deviations in number of sessions would turn out to be

so large. Generally in RCTs, and also in the present benchmark RCTs, this issue does not become a problem.

Extra analyses were performed to gain more insight into this problem. It turned out that especially among beginning therapists some treatments were long, up to a maximum of 31 sessions. None of the therapists with experience in CBT for CFS, having finished 5 or more treatments, used more than 19 sessions for a treatment. Analyses on predictors of treatment success did not reveal any relations except for pretreatment fatigue severity. Neither treatment duration nor number of sessions correlated with treatment effect.

Discussion

The treatment results of CBT for CFS in an MHC compared quite favorably with those of the benchmark RCTs. The effect on fatigue severity at the MHC was comparable with that of previous RCT results, while the effect on physical functioning was some-

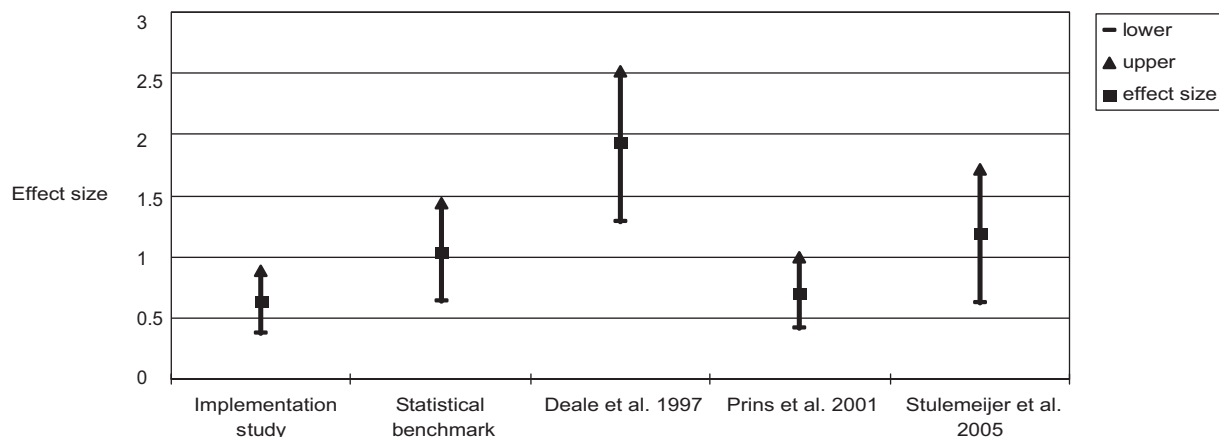


Figure 2. Mean noncontrolled pre-post treatment effect sizes and confidence intervals of physical functioning at the mental health center and the benchmark randomized controlled trials. An effect size for physical functioning for Sharpe et al. (1996) could not be calculated.

Table 5

Operationalization of Positive Impact of the Implementation and Formulation of the Related Subquestions and Their Results

Subquestions related to criteria for successful implementation	Results of the subquestions
1. How many GPs were after 1.5 years familiar with the new treatment setting for CFS?	1. Of the 452 questionnaires that were sent to all GPs, 301 were completed and returned, implying a response rate of 67%. Of these 301, 212 GPs (70%) remembered to have been informed by us about CFS and knew about the new treatment possibility.
2. How many CFS patients did not accept a referral to the MHC?	2. Thirty of all 212 informed GPs (14%) reported to have met 1 or more patients that did not want a referral to the MHC. In total, this concerned 41 patients, which is 22% of the 184 (143 + 41) patients that were proposed a referral to the MHC by their GP.
3. How many CFS patients were referred for CBT?	3. During the 20-month inclusion period, 143 patients were referred for CBT. The number of patients referred per month varied from 3 to 13.
4. How many patients were diagnosed incorrectly or unjustly as having CFS?	4. From the 143 referred patients, 125 actually appeared at intake; the other 18 did not show up at intake. Of these 125 patients, 13 (10.4%) turned out to be referred unjustly because they did not meet the CDC-94 criteria for CFS.
5. How many patients finished treatment and what were reasons for not finishing treatment?	5. From the 112 patients that showed up at intake and appeared to have CFS, 72 finished treatment, implying a total dropout rate of 36%. Reasons for not finishing treatment are described in the text of this article.

Note. GP = general practitioner; CFS = chronic fatigue syndrome; MHC = mental health center; CBT = cognitive behavioral therapy; CDC = Centers for Disease Control.

what smaller at the MHC. Overall, apart from the high levels of not starting and dropout patients, the impact of the implementation of CBT for CFS could be called successful.

Because of the flexible prerequisites for client inclusion, the treatment results are in fact quite remarkable. No strict minimum fatigue or physical impairment scores were required for participation, hence these complaints, especially on physical functioning, were initially somewhat mild compared with those in RCTs, providing a conservative test of pre–post comparisons. Also, if the MHC will manage to reduce the numbers of not starting patients in future, the treatment effects might even increase.

The most worrying aspect of the implementation was the relatively high number of patients not showing up at intake and deciding not to start treatment after the intake (together more than 32% of all referrals). In the benchmark RCTs, the number of patients refusing to start CBT was generally much lower. Namely, 2 of 62 (3%) refused RCT participation and 0 of 30 refused CBT after randomization in Sharpe et al. (1996), and 7 of 67 (10%) refused RCT participation and 0 of 30 refused CBT after randomization in Deale et al. (1997). The study of Stulemeijer et al. (2005)

did not report any refusals. Only Prins et al. (2001) had relatively higher refusal rates, namely 99 of 476 (21%) refusals to participate in the RCT and 10 of 92 (11%) refusals for CBT after randomization. Probably, Sharpe et al.'s and Deale et al.'s studies had lower refusal rates because they offered therapy from experienced "expert" therapists, which was not the case in the trial of Prins et al. (2001) or in the present implementation study. One explanation might be that apparent experience of the therapist stimulates patients to start with CBT. However, the higher refusal rate after intake in the present study (25%) in comparison with the rate after randomization (11%) in the study of Prins et al. (2001) cannot be explained by a difference in therapist expertise. In the MHC, patients could have been motivated better during the intake session. The most reported reasons for not starting treatment were "I think this treatment does not fit me" and "I think there is a medical reason for my fatigue." With the right and well-timed information about the treatment, at least part of those patients could presumably have been convinced to at least try the treatment with CBT. Looking back, we conclude that motivating CFS patients during the first contacts got too little attention in training and supervision. MHC therapists are not accustomed to motivating patients for psychological treatment. We recommend paying attention to this point, in training as well as in supervision, in future implementation projects.

In the present MHC benchmark study, a clear connection could be seen between waiting time and the high rate of "lost" patients. The loss of trained therapists and the shortcoming of the MHC to quickly find new ones, the limited use by therapists of their time reserved for CFS patients, and the long duration of treatments were all partly responsible for the increasingly long waiting times. These long waiting times for their turn appeared to facilitate patients to quit; they gave the patients reason and opportunity to look further for other treatments. Future implementation projects of CBT for CFS should therefore take care to minimize the waiting times.

Regarding the selection of benchmark studies, the question may arise whether including the Stulemeijer study (2005) was sensible, since it is a study of adolescents. Our reason to include it was that

Table 6

Sample and Subsample Sizes of Chronic Fatigue Syndrome (CFS) Patients Referred to the Mental Health Center (MHC)

Sample or subsample	N or n	%	Remaining patients
Patients referred to the MHC	143		
No show patients not showing up at intake (% of the 143 referrals)	18	12.6%	125
Non-CFS patients, referred unjustly (% of the 125 intakes)	13	10.4%	112
Patients that after intake decided to not start treatment (% of the 112 CFS patients after intake)	28	25.0%	84
Patients dropping out during treatment (% of the 84 started treatments)	12	14.3%	72
Patients finishing treatment	72		

Stulemeijer et al.'s study used the same and most recent version of the Dutch protocol (Bazelmans et al., 2006), also used in this implementation study. Yet, an adolescent study population of course has a lower age and shorter illness duration than adult populations do, which probably makes it incorrect to compare these studies. However, it has been demonstrated before that neither age nor illness duration influences effects of CBT for CFS (Deale et al., 1997).

Concerning the MHC population characteristics, only illness duration was different, namely longer, compared with illness duration in the three benchmark RCTs of adults. This is quite remarkable; one might just expect that specialized hospital settings attract patients with a severe, complex, and longer duration of fatigue. Possibly there was a "reservoir" of CFS patients with long illness duration in the MHC region that could have developed during the many years that no effective treatment was available. Since this reservoir might now have dwindled, CFS patients being referred today and in the coming years probably will have shorter illness duration.

The present study fulfills most of the Shadish et al. (2000) criteria for clinical representativeness. Two criteria were not met, namely the monitoring and the therapist pretherapy training criteria. However, training therapists inexperienced with CFS is quite common and also endorsed by us because treating a somatic complaint with CBT is new for most therapists working in an MHC. The monitoring mainly included supervising therapists, which is like pretherapy training, is quite useful, and always accompanies a training of CBT for CFS. Only the monitoring aspects like measuring treatment results, registering the reasons for dropout, and reporting problems during the implementation process contradicted full clinical representativeness. Overall, though, from our point of view the MHC setting is clearly clinically representative. This means that this study demonstrated that CBT for CFS is also effective after implementing it in the clinical practice of an MHC.

The results of the present study contradict the results of Quarmby et al.'s (2006), who found a discrepancy in treatment effect between their RCT and clinical results. However, those effect differences might be explained by the fact that their RCT was extremely effective, which was the result of including only one specialized therapist who was very experienced with CFS.

The question arises whether the treatment results will also remain sufficient in the long term. Given the rather high turnover of therapists and other related persons, the treatment program might lose some of its strengths and effectiveness. Secondly, during this project the MHC knew an external researcher would evaluate it. In fact, this makes the study less representative for clinical practice, although this is not a criterion that Shadish et al. (2000) defined. It might be interesting to perform a longer lasting but much less confrontational and less visible study to investigate the "lifetime" and development of a CBT for CFS implementation project after the 1st years of the research period have passed.

To conclude, the results of this study suggest that implementing CBT for CFS in an MHC can be successful and that treatment results were comparable with RCT results. The positive outcome should facilitate the decision for healthcare providers to adopt CBT for CFS in their institution so that more CFS patients can recover after years of illness.

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