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A Qualitative Analysis of the Failure of CBT for Chronic Fatigue Conducted by General Practitioners

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Abstract. We assessed the efficacy of cognitive behaviour therapy (CBT) delivered by general practitioners (GPs) to fatigued employees on sick leave. CBT had no substantial effect on clinical outcomes. In the present study, we aim to describe the treatment protocol and present an analysis of the delivery of the intervention. To assess protocol execution, GPs used standardized registration forms in each treatment session. A quality check was performed to assess whether CBT was completed according to protocol. Of the 71 patients starting CBT, 51 patients completed the intervention. There were no striking differences in protocol execution between those who recovered after CBT and those who did not recover. Although there were differences in the performance and delivery of CBT, there was no association between protocol execution and treatment results of individual GPs. Despite the lack of efficacy, the intervention received a positive evaluation from both patients and GPs. CBT completers who recovered did not receive a clearly different treatment than those who did not recover. In addition, successful GPs did not deliver a clearly different treatment than less successful GPs. The lack of efficacy can at least partly be attributed to the inadequacy of the intervention, whether it is the intervention itself or its delivery by GPs.

Keywords: Cognitive behaviour therapy, quality check, general practitioners, fatigue, working population.

Introduction

In primary care, 5 to 10% of patients present with fatigue as their main complaint (Sharpe and Wilks, 2002). In most of these patients, fatigue lacks a clear somatic cause (Sharpe and

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Wilks, 2002) and appears to be a functional symptom (Wessely et al., 1999; Mayou and Farmer, 2002). Fatigue can best be understood as a continuum, ranging from mild complaints frequently seen in the community to severe, disabling fatigue like the chronic fatigue syndrome (CFS; Lewis and Wessely, 1992). When fatigue becomes severe and persistent, it may lead to long-term sick leave (Janssen et al., 2003) and work disability (Amelsvoort van et al., 2002).

Recently, we conducted a randomized controlled trial to assess the efficacy of cognitive behaviour therapy (CBT) delivered by nine general practitioners to severely fatigued employees who were on long-term sick leave (Huibers et al., 2004). Studies in secondary care have shown that CBT by skilled therapists is effective in the treatment of chronic fatigue syndrome (Prins et al., 2001; Whiting et al., 2001). Sharpe and Wilks have suggested that some GPs might also provide CBT in the treatment of (chronic) fatigue (Sharpe and Wilks, 2002), an approach that is particularly interesting from a stepped-care perspective. However, it was unknown whether CBT is effective in less advanced fatigue cases and whether GPs are able to deliver CBT.

CBT had no substantial effect on clinical outcomes or cognitive processes during 12 months of follow-up (Huibers et al., 2004). Our findings could not be explained by a difference in effect among GPs, withdrawal from the CBT intervention or lack of compliance with treatment. Unfortunately, our study design did not allow us to find out why exactly the intervention did not work. However, it is possible to investigate whether there is any association between the recovery of individuals in our trial and characteristics of the treatment received.

In this study, we present a descriptive analysis of the delivery of the intervention. We do this in four steps. First, a description of the intervention and the treatment protocol is given. Second, the execution of the treatment protocol is compared in four subgroups of patients. Third, treatment results and protocol execution of the participating GPs is compared. Finally, we describe how patients and GPs evaluated the intervention.

Description of the intervention

Structure of the intervention

The intervention consisted of five to seven 30-minute sessions of cognitive behaviour therapy (CBT) within the course of 4 months. The intervention was partly based on our CBT protocol for chronic fatigue syndrome (Prins et al., 2001). The intervention was written out in a treatment protocol. Participating GPs – none of whom had previous experience with CBT – were trained in delivering the intervention in two 5-hour workshops (theory, paper assignments, role playing with simulation patients) and supervised in monthly 2-hour sessions throughout the trial by an experienced behaviour therapist (EB). Supervision was conducted in small groups of two to three GPs where patients under treatment were discussed and future strategies were set out. An acquaintance meeting between GP and patient preceded the start of each intervention, because patients were not treated by their own GP. In most cases, spouses of patients were invited to attend one or more sessions. Patients were free to visit their regular GP for usual care.

Table 1. GP-delivered CBT programme for fatigue among employees

Goal of the intervention
– diminish fatigue and other complaints
– establishing work resumption and other personal goals
Steps in the intervention
– assessment of perpetuating factors on the level of:
○ cognitions (e.g. non-acceptance fatigue, lost sense of control over symptoms)
○ overt behaviour (e.g. disturbed sleeping pattern, unbalanced physical activities)
○ social factors (e.g. lack of social support, dysfunctional work environment)
– modification of identified perpetuating factors by:
○ explaining the perpetuating circle
○ setting goals for activities and other problem areas
○ providing helpful cognitions
○ planning systematic and gradual work resumption
○ planning achievement of other personal goals
○ involving the social environment

Steps in the intervention: treatment protocol

Goal and content of the intervention are briefly summarized in Table 1. Principal aim of the intervention was to diminish fatigue (and other health complaints) and to establish work resumption (and other personal goals). After explanation of the treatment process in the first session, the distinction between causal and perpetuating factors was discussed. Although complaints might have been initiated by somatic, psychological or a combination of factors, psychological factors probably perpetuate the complaints. The intervention was aimed at these perpetuating factors.

GPs were trained to use a diagnostic schedule to assess the perpetuating factors of each patient in a clinical interview. Perpetuating factors could be classified using the diagnostic schedule in three pre-specified categories. Cognitive factors were non-acceptance of fatigue, somatic attributions, lost sense of control over symptoms, having high personal standards, and fear that activity will aggravate symptoms. Behavioural factors were the amount of physical, mental and social activities and sleeping pattern. Social factors were the work environment and the amount of social support.

Once the perpetuating factors were fully assessed, interventions were tailored to fit the diagnostic schedule. Specific interventions included providing helpful cognitions by an "accepting-fatigue" exercise; explaining the role of perpetuating factors; helping to put things in perspective; instructions to restore a balance in the activity levels; an activity program to gradually increase activities; instructions for a normal sleep pattern. If the work environment was an impeding factor, restoring relations with the work environment was discussed.

GPs encouraged patients to start developing a work resumption plan from the second session on. Patients were asked to write down work activities, the problems to be expected when starting these activities and possible solutions for these problems. In following sessions, GPs encouraged patients to execute the work resumption plan in steps, by gradually building up activities, in time and in difficulty. Once patients had actually resumed work, each step was carefully evaluated and problems encountered were discussed.

An important aim during the intervention was enhancement of self-activity. Patients were encouraged to take responsibility for their own actions. GPs tried to assist in this process by asking questions such as 'What did you learn from what we discussed this session?', 'What can you do differently now to positively influence your complaints?', and 'What exactly are you going to do differently from now on?'.

GPs handed out standard forms to patients for the self-observation of perpetuating factors, and for the registration of cognitions and behaviours to be changed. For all steps in the intervention standard forms were handed out to GPs, to be used as homework assignments for patients.

Methods of the present report

Randomized trial

Details of the randomized trial we conducted are described elsewhere (Huibers et al., 2004). In short, we selected 151 employees with severe, medically unexplained fatigue for 4 months or more who were absent from work on sick leave for 6 to 26 weeks. Employees were recruited in collaboration with a local occupational health service. In total 76 patients were assigned to the experimental condition consisting of CBT delivered by a GP nearby their home address. The 75 patients in the control group received usual GP care.

For practical reasons, we chose to train and deploy a small number of "research" GPs (the prefix "research" is used to indicate that these GPs treated unfamiliar patients assigned to them for the purpose of the study only) instead of a large sample of GPs who would have to treat their own patients. GPs delivering the CBT were recruited from the GP population in the Southeast of the Netherlands based on their geographical position. To become a candidate for study participation, GPs had to attend both training sessions. A further requirement was willingness to treat up to 10 patients under supervision of an experienced therapist (EB). Fifteen of the 25 GPs whom we invited attended both training sessions. Based on their geographical position, we selected nine GPs who delivered all CBT interventions aside their regular practice. All active GPs attended at least 10 2-hour supervision sessions throughout the entire intervention period.

Study variables

Protocol execution. To assess the actual execution of the treatment protocol, GPs used standardized registration forms on which they registered the duration and the steps addressed in each session.

CBT completers and non-completers. Based on these registration forms and the information gathered in supervision, the CBT supervisor (EB) performed a quality check. For each patient it was assessed whether the CBT received was according to "protocol". If for the individual patient essential steps could not be addressed before the intervention was terminated, the intervention was considered not completed. It should be noted that these "essential steps" were not necessarily similar for all patients. Patients who completed CBT according to protocol will be referred to as "CBT completers".

Recovered and non-recovered cases. Immediately following the intervention (4 months after baseline), we assessed whether patients had recovered or not. Recovery was defined as

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having a CIS fatigue score below the cut-off of 35 (high CIS scores indicate high fatigue severity) (Vercoulen et al., 1999; Beurskens et al., 2000) in combination with self-reported work resumption. We chose this particular definition for the present analysis because a) it leads to a conservative estimate of recovery (see also Huibers et al., 2004) and b) it captures both goals of our intervention.

Evaluation of the intervention

At the post-treatment follow-up (4 months after baseline), we asked patients to evaluate the intervention using a short questionnaire. GPs were asked to evaluate the intervention after the entire intervention period was terminated.

Data analysis

We performed a descriptive analysis. Frequencies per group were examined and compared. No statistical parameters were applied.

Results

In total, 76 fatigued employees were randomly allocated to receive CBT. Five of these patients instantaneously refused the CBT offered to them. Of the remaining 71 patients who agreed to receive treatment, 51 patients (72%) completed the CBT according to protocol. Reasons for non-completion or drop out were: work resumption/too busy ($n = 6$); not satisfied with intervention ($n = 5$); psychiatric complications ($n = 2$); unknown reasons ($n = 7$).

Protocol execution

CBT completers versus non-completers. In Table 2, protocol execution in those who completed CBT according to protocol (CBT completers) and in those who did not complete CBT (non-completers) is compared. As can be expected, percentages of patients exposed to steps in the intervention were lowest in the non-completers group.

Recovered cases versus non-recovered cases. In Table 3, protocol execution in CBT completers who had recovered directly after treatment (recovered cases) and in CBT completers who had not recovered (non-recovered cases) is compared. Visual inspection of the data revealed no striking differences that might explain the different outcomes in both groups.

Results of individual GPs. In Table 4, the individual performance of the nine GPs and the characteristics of the interventions delivered by these GPs to CBT completers are presented. Despite differences in performance and delivery of the CBT intervention, visual inspection revealed no distinct associations between (patterns of) intervention characteristics and treatment results of individual GPs.

Evaluation by patients and GPs

Table 5 presents the overall evaluation of the intervention by patients who started the CBT and the nine GPs who delivered the intervention. In general, both patients and GPs evaluated the intervention positively. Most patients (98%) were positive about the GP assigned to them and satisfied (90%) and completely or almost completely compliant (78%) with the intervention.

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Table 2. Characteristics of the intervention received by CBT completers and non-completers

	Patients starting CBT ($n = 71$)			
	Non-completers ($n = 18^*$)		CBT completers ($n = 51$)	
Number and duration				
Mean (*SD*) no. of sessions	3.05 (1.23)		6.2 (1.2)	
Mean (*SD*) session duration	35.4 (7.2)		33.8 (6.4)	
Steps in the intervention:				
Percentage of patients exposed and mean number of sessions in which step was addressed	%	Mean (*SD*)	%	Mean (*SD*)
Explaining treatment goal	100	1.9 (0.7)	100	2.1 (0.8)
Explaining distinction causal and perpetuating factors	94	1.6 (0.8)	98	1.9 (1.0)
Discussing treatment goal	83	1.6 (1.1)	100	2.2 (0.9)
Assessment using diagnostic schedule	72	1.2 (1.0)	98	2.5 (1.0)
Intervening based on diagnostic schedule	50	0.8 (0.9)	90	2.0 (1.1)
Exercising to accept fatigue	61	0.8 (0.8)	74	1.4 (1.1)
Making a plan for work resumption	44	0.6 (0.8)	88	2.5 (1.4)
Discussing problems accompanying work resumption	38	0.6 (0.9)	96	3.2 (1.4)
Handing out self-observation assignments	61	0.8 (0.9)	91	1.5 (0.8)
Handing out homework assignments	16	0.2 (0.5)	86	2.3 (1.5)

CBT completers = those who completed CBT according to protocol.
Non-completers = those who did not complete CBT according to protocol.
* two patients missing.

GPs rated the intervention to be effective and feasible, training to be sufficient (78%) and supervision to be needed (100%).

Discussion

In the present report, we investigated the association between the effects of CBT in fatigued employees on sick leave and the execution of the treatment protocol. Overall, the protocol was reasonably well performed. Seventy-two percent of the patients starting CBT completed the intervention according to protocol, a compliance rate that is acceptable in psychotherapy research. However, we found no association between recovery after CBT and protocol execution. Furthermore, despite a broad range in individual performance (recovery rates from 0% to 38%), there was no association between the treatment results of individual GPs and characteristics of the CBT delivered by them. In general, the range of success among CBT completers was rather modest. Of the 51 patients who completed the CBT according to protocol, only 12 patients (23%) had recovered. Surprisingly, the intervention received a positive evaluation from both patients and GPs: the vast majority of patients were satisfied with the treatment received and GPs rated the intervention to be effective.

An important limitation of the present report is that we were able to assess the quantity of the steps in the intervention but not the quality of the intervention delivered. Additional information on how well the intervention was performed might have illuminated our trial results. Another limitation is the lack of a formal validity base in our analysis, especially in

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Table 3. Characteristics of the intervention received by recovered cases and non-recovered cases among CBT completers

	CBT completers ($n = 51$)			
	Recovered cases ($n = 12$)		Non-recovered cases ($n = 39$)	
Number and duration				
Mean (*SD*) no. of sessions	6.3 (1.3)		6.2 (1.2)	
Mean (*SD*) session duration	34.8 (6.2)		33.5 (6.5)	
Steps in the intervention				
Percentage of patients exposed and mean number of sessions in which step was addressed	%	Mean (*SD*)	%	Mean (*SD*)
Explaining treatment goal	100	1.9 (0.5)	100	2.2 (0.9)
Explaining distinction causal and perpetuating factors	100	1.6 (0.7)	97	2.0 (1.1)
Discussing treatment goal	100	2.0 (0.4)	100	2.2 (1.0)
Assessment using diagnostic schedule	100	2.4 (0.8)	97	2.5 (1.0)
Intervening based on diagnostic schedule	83	1.8 (1.1)	92	2.1 (1.1)
Exercising to accept fatigue	75	1.0 (0.7)	74	1.5 (1.2)
Making a plan for work resumption	92	2.7 (1.2)	87	2.5 (1.5)
Discussing problems accompanying work resumption	100	3.7 (1.1)	95	3.0 (1.5)
Handing out self-observation assignments	83	1.3 (0.8)	92	1.5 (0.8)
Handing out homework assignments	92	2.4 (1.6)	85	2.3 (1.6)

Recovered cases = CBT completers who scored < 35 on the CIS fatigue severity scale and resumed work at follow-up.
Non-recovered cases = CBT completers who scored = > 35 on the CIS fatigue severity score and/or did not resume work at follow-up.

the analysis of small groups of participants. However, while conducting the analysis we found that statistical parameters did not contribute to our findings.

How can our findings be explained? One explanation would be that our CBT approach was simply too difficult to be delivered by GPs. It should also be noted that GPs were only briefly trained in delivering the intervention (two training sessions), and they might have lacked the necessary experience to deliver the intervention effectively. After all, our GPs were not psychotherapists. Furthermore, GPs stated that they would need to treat three or four "training" patients before the intervention could be delivered optimally. However, a "training" effect could not be detected in the subsequent treatment results of individual GPs (results not shown). The fact that some GPs performed better than others might relate to differences in "attitude" or "treatment style", factors that are very difficult to assess. Perhaps the intervention itself required too much tailoring for it to be effective, a complex process that is not easily mastered. Another explanation would be that we have underestimated the impact of being assigned to an unfamiliar research GP, instead of the usual family doctor. Results from our evaluation, however, indicate that patients did not perceive this arrangement as unpleasant or disturbing.

As mentioned, we reported the lack of efficacy of CBT delivered by GPs compared to usual care in an earlier paper (Huibers et al., 2004). A per-protocol analysis yielded no significant

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Table 4. Performance of individual GPs among patients starting CBT ($n = 71$) and characteristics of the interventions delivered by individual GPs to CBT completers ($n = 51$)

General Practitioner †	1		2		3		4		5		6		7		8		9	
Performance																		
No patients treated (%)	8 (100)		6 (100)		9 (100)		7 (100)		7 (100)		7 (100)		10 (100)		7 (100)		10 (100)	
No CBT completers (%)	8 (100)		5 (83)		5 (56)		6 (86)		5 (71)		4 (57)		7 (70)		6 (86)		5 (50)	
No recovered CBT completers (%)	3 (38)		2 (33)		3 (33)		1 (14)		1 (14)		1 (14)		1 (10)		0 (0)		0 (0)	
Number and duration																		
Mean (*SD*) nr of sessions	5.9 (0.8)		7.4 (1.3)		6.8 (0.8)		6.2 (0.8)		5.8 (1.3)		5.3 (0.5)		5.9 (1.4)		5.5 (1.1)		7.4 (0.9)	
Mean (*SD*) session duration	30.8 (2.2)		36.4 (4.8)		40.6 (2.5)		33.1 (3.3)		30.9 (1.3)		43.9 (4.1)		33.7 (4.2)		22.8 (2.2)		38.1 (2.5)	
Steps in the intervention																		
Percentage of patients exposed and mean number of sessions in which step was addressed	%	*m* (*SD*)	%	*m* (*SD*)	%	*m* (*SD*)	%	*m* (*SD*)	%	*m* (*SD*)	%	*m* (*SD*)	%	*m* (*SD*)	%	*m* (*SD*)	%	*m* (*SD*)
Explaining treatment goal	100	*2.0* (*0.0*)	100	*1.8* (*0.4*)	100	*1.8* (*0.4*)	100	*2.2* (*0.8*)	100	*2.0* (*0.7*)	100	*1.3* (*0.5*)	100	*2.7* (*1.1*)	100	*2.0* (*0.6*)	100	*3.0* (*1.2*)
Explaining distinction causal and perpetuating factors	100	*1.4* (*0.5*)	100	*1.8* (*0.4*)	100	*1.4* (*0.5*)	100	*3.3* (*1.0*)	100	*1.0* (*0.0*)	75	*1.5* (*1.3*)	100	*2.6* (*0.8*)	100	*1.3* (*0.5*)	100	*2.4* (*1.1*)
Discussing treatment goal	100	*2.0* (*0.8*)	100	*2.0* (*0.0*)	100	*1.8* (*0.8*)	100	*2.0* (*0.6*)	100	*1.8* (*0.4*)	100	*1.5* (*0.6*)	100	*2.9* (*1.2*)	100	*2.3* (*1.0*)	100	*2.8* (*0.8*)
Assessment using diagnostic schedule	100	*2.9* (*0.6*)	100	*1.6* (*0.5*)	100	*3.0* (*0.0*)	100	*2.8* (*0.8*)	100	*2.8* (*1.6*)	100	*1.3* (*0.5*)	86	*1.9* (*1.2*)	100	*3.0* (*0.6*)	100	*3.0* (*0.0*)
Intervening based on diagnostic schedule	100	*2.1* (*0.8*)	100	*2.0* (*0.7*)	100	*2.0* (*0.0*)	100	*2.3* (*0.8*)	60	*1.0* (*1.0*)	50	*0.5* (*0.6*)	86	*1.6* (*1.1*)	100	*2.8* (*1.2*)	100	*3.0* (*0.7*)
Exercising to accept fatigue	63	*1.0* (*0.9*)	80	*1.2* (*0.8*)	60	*0.6* (*0.5*)	100	*2.0* (*0.9*)	40	*0.6* (*0.9*)	25	*0.5* (*1.0*)	100	*2.6* (*1.5*)	83	*1.2* (*0.8*)	100	*2.2* (*0.4*)
Making a plan for work resumption	100	*2.6* (*0.7*)	100	*2.2* (*1.1*)	100	*4.0* (*1.0*)	100	*2.2* (*0.8*)	80	*2.4* (*1.9*)	100	*3.8* (*1.0*)	71	*1.4* (*1.4*)	83	*2.5* (*1.4*)	60	*2.6* (*2.4*)
Discussing problems accompanying work resumption	88	*3.3* (*1.5*)	100	*3.4* (*1.8*)	100	*3.6* (*1.5*)	100	*3.2* (*1.7*)	100	*3.6* (*2.1*)	100	*2.8* (*1.0*)	86	*3.1* (*1.8*)	100	*2.5* (*0.8*)	100	*3.2* (*1.5*)
Handing out self-observation assignments	100	*1.8* (*0.7*)	100	*1.8* (*0.8*)	100	*1.6* (*0.5*)	83	*1.5* (*1.0*)	80	*1.0* (*0.7*)	50	*0.8* (*1.0*)	86	*1.3* (*0.8*)	100	*1.3* (*0.8*)	100	*2.0* (*0.7*)
Handing out homework assignments	88	*2.3* (*1.7*)	80	*3.6* (*1.1*)	100	*3.4* (*1.5*)	100	*1.8* (*0.8*)	80	*2.2* (*0.8*)	75	*1.0* (*0.8*)	43	*1.0* (*1.5*)	83	*2.0* (*1.1*)	100	*4.2* (*1.1*)

CBT completers = those who completed CBT according to protocol.

† ordering of GPs according to % recovered CBT completers (first order) and % CBT completers (second order).

Table 5. Evaluation of the CBT intervention by patients and GPs

Patients starting CBT ($n = 71$)		
Overall impression of GP delivering CBT	positive	98%
	neutral	2%
	negative	0%
Satisfaction with intervention	very satisfied	17%
	satisfied	73%
	dissatisfied	10%
	very dissatisfied	0%
Self-rated compliance with advice and instructions in intervention	completely compliant	32%
	almost completely compliant	46%
	partly compliant	15%
	hardly complaint	5%
	not compliant at all	2%
GPs delivering CBT ($n = 9$)		
Overall rating of the effectiveness of the intervention (0 = low, 10 = high)	mean (range)	7.1 (5–8)
Overall rating of the feasibility of the intervention (0 = low, 10 = high)	mean (range)	7.2 (6–8)
No. of "training" patients needed before intervention can be delivered optimally	mean (range)	3.7 (2–5)
CBT training was sufficient	yes	78%
Supervision meetings were necessary	yes	100%
No. of sessions was adequate	yes	89%
	no, less would be sufficient	11%
	no, more sessions needed	0%

differences between CBT completers and the control group. From a theoretical standpoint, we suggested that the lack of efficacy can be understood as reflection of a disturbance somewhere in the interaction between the patient, the doctor and/or the intervention. The question, however, is where, and in what way? In the present report, we focused on the intervention and found that CBT completers who recovered did not receive a clearly different treatment from those who did not recover. In addition, successful GPs did not deliver a clearly different treatment from less successful GPs. Consequently, we come to the conclusion that the lack of efficacy can at least partly be attributed to the inadequacy of the intervention, whether it is the intervention itself or the delivery by GPs. Also, it appears that satisfaction with the treatment delivered (GPs) or received (patients) is no guarantee or indication of the success of the treatment, a finding that once again stipulates the necessity of a control group in psychotherapy research.

In a review for the Cochrane Collaboration (Huibers et al., 2003), we found little evidence for the effectiveness of psychosocial interventions by GPs, except for a favourable effect of problem-solving treatment by a small number of experienced GPs on major depression

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(Mynors Wallis et al., 1995; Mynors-Wallis et al., 2000). The main finding in our efficacy study was that a small group of trained and highly motivated "research" GPs was not able to deliver CBT effectively. We concluded that it is unlikely that GPs in routine practice would be more successful in delivering a complex psychosocial treatment such as CBT. The findings in the present report seem to underline this conclusion.

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