

## Self-help treatment of chronic fatigue in the community: A randomized controlled trial

T. Chalder\*

*Department of Psychological Medicine, King's College School of Medicine & Dentistry and the Institute of Psychiatry, 103 Denmark Hill, London SE5 8AZ, UK*

P. Wallace

*Department of General Practice, Royal Free Hospital School of Medicine, London NW3, UK*

S. Wessely

*Department of Psychological Medicine, King's College School of Medicine & Dentistry and the Institute of Psychiatry, London SE5 8AZ, UK*

**Objectives.** To evaluate the efficacy of a self-help booklet and specific advice in reducing chronic fatigue in a primary care population aged 18–34 years.

**Design.** A randomized controlled trial.

**Methods.** A self-help intervention ( $N = 70$ ) was compared with no treatment ( $N = 80$ ). The main outcome measures were a fatigue questionnaire and the 12-item General Health Questionnaire. Follow-up was completed on 127 patients.

**Results.** The self-help group showed significantly greater improvements in fatigue ( $p = .01$ ) and psychological distress ( $p < .01$ ) than controls. At follow-up, 63 per cent of the self-help completers achieved a good outcome (scored less than 4 on the fatigue questionnaire) compared with 39 per cent of the control group.

**Conclusions.** The provision of a self-help booklet and specific advice during a consultation with a research nurse was more effective than no treatment at improving fatigue and psychological distress. General practitioners should be encouraged to use self-help literature in the management of patients with chronic fatigue.

Fatigue is a subjective somatic symptom which is common in the community and primary care. Up to 40 per cent of the general population complain of substantial fatigue lasting for more than one month (Pawlikowska, Chalder, Hirsch, Wallace, Wright & Wessely, 1994). As with many other symptoms, fatigue is best viewed on a continuum, with those most severely affected fulfilling the criteria for chronic fatigue syndrome (CFS) (Sharpe, Archard & Banatvala, 1991). There is a close association between fatigue and

\*Requests for reprints.

psychological distress (Buchwald, Sullivan & Komaroff, 1987; Cathebras, Robbins, Kirmayer & Hayton, 1992; Chen, 1986; McDonald, David, Pelosi & Mann, 1993; Morrison, 1980; Pawlikowska *et al.*, 1994; Wessely, Chalder, Hirsch, Pawlikowska, Wallace & Wright, 1995) with the majority of patients attributing their tiredness to psychosocial factors (Pawlikowska *et al.*, 1994). Higher rates are consistently found in women (Cox, Blaxter & Buckle, 1987; Hammond, 1964; Ingham & Miller, 1979; Kroenke, Wood, Mangelsdorff, Meier & Powell, 1988).

In recent years the problem of fatigue has attracted attention, largely because of the emergence of CFS. It is characterized not so much by the symptom of fatigue but the degree of disability associated with it. When left untreated, the prognosis for patients with CFS is poor (Wilson *et al.*, 1994). However, cognitive-behavioural treatment approaches have been developed which focus on the role of fatigue-related behaviours and beliefs (Butler, Chalder, Ron & Wessely, 1991; Sharpe & Chalder, 1994). Evidence supporting the effectiveness of this approach in hospital settings is growing (Deale, Chalder, Marks & Wessely, *in press*; Sharpe *et al.*, 1996).

Despite the ubiquity of chronic fatigue, little has been offered to these patients in the way of treatment. This study was designed to determine whether patients with chronic fatigue (not CFS) in the primary care setting might benefit from specific advice about management.

## Method

### *Design*

Six general practices in London and the south-east of England took part in the study and are described in detail elsewhere (Pawlikowska *et al.*, 1994). A research nurse was employed in each practice. The aim of the first phase of the study was to examine the population prevalence of fatigue and psychological morbidity, and to determine pre-exposure vulnerability factors for the subsequent development of post-infectious fatigue (Stage 1) (Pawlikowska *et al.*, 1994). During the following year all patients between the ages of 18 and 45 years attending the general practices with a possible viral infection were invited to join the study (Stage 2) (Wessely *et al.*, 1995). The next person who presented to the general practitioner with a complaint not related to an infection was invited to participate as a control. Measures of fatigue and psychological distress were given. Written consent was obtained from all participants.

Six months later all of those recruited were sent the fatigue questionnaire (Chalder *et al.*, 1993) and the General Health Questionnaire (GHQ; Goldberg & Williams, 1988) (Stage 3), and participants in the current study were identified at this stage. Those who scored 4 or more on the fatigue questionnaire for more than six months were classified as being chronically fatigued and were asked to return to the general practitioner's surgery for further investigation and assessment. This included an assessment by the research nurse (Wessely *et al.*, 1995).

The purpose of this study was to evaluate the efficacy of a self-help booklet and specific advice as compared to a no-treatment control in reducing chronic fatigue in a primary care population aged 18–45.

The recruitment target of 75 patients per group was calculated assuming a reduction in fatigue in approximately 20 per cent of untreated patients and approximately 50 per cent of those given a self-help book.

The first 150 chronically fatigued infection cases ( $N = 74$ ) and controls ( $N = 76$ ) were randomized by the study coordinator to receive a self-help booklet and specific advice or no treatment. A simple unrestricted randomization procedure was used based on a computer-generated sequence of random numbers (Pocock, 1994). There were no exclusion criteria. This decision was made on the basis that there is a range of psychological, physical and social causes of fatigue and the intention was to test the efficacy of the intervention within a heterogeneous group.

### *Measures*

Psychiatric morbidity was ascertained by the Revised Clinical Interview Schedule (CIS-R; Lewis, Pelosi, Araya & Dunn, 1992) (Stage 3 only), which was designed to record psychiatric morbidity in primary care. It is intended for use by non-psychiatrists, and has low observer bias. The research nurses received specialist training in its use prior to the study.

Self-rating questionnaires were completed by participants at Stage 3 and at follow-up (Stage 4) three months later. Since the main aim of the self-help booklet was to improve levels of fatigue, the fatigue questionnaire (Chalder *et al.*, 1993) was designated as the primary outcome measure. This is an 11-item, self-rating scale which addresses physical and mental fatigue. Respondents were also asked to give a perceived reason for their tiredness.

Subsidiary measures included the 12-item GHQ (GHQ 12; Goldberg & Williams, 1988) and the Medical Outcome Study (MOS) short-form general health survey, physical functioning subscale (Stewart, Hays & Ware, 1988). The latter measures the extent to which ill-health interferes with a variety of activities, e.g. sports, carrying groceries, climbing stairs and walking. It is rated on a 0–100 scale with 0 representing limitations in all activities including dressing, bathing and using the toilet, while 100 indicates the ability to carry out vigorous activities or strenuous sports like running.

### *Procedure*

The CIS-R and completion of the self-rating questionnaires took about 45 minutes. The experimental group was given a self-help booklet (Chalder, 1995). The nurse then spent between 10 and 15 minutes discussing its contents, focusing on information that as a result of the assessment seemed pertinent to the individual. All participants were asked to return to the practice for a follow-up three months after recruitment (Stage 4).

The booklet was divided into three sections. Part 1 provided general information about fatigue and outlined different factors which contribute to both onset and maintenance of fatigue. Part 2 described the importance of self-monitoring and how diary-keeping helps to build a clear picture of fatigue in relation to activities. Part 3, the largest section, described a variety of cognitive and behavioural techniques for overcoming fatigue. The booklet indicated that fatigue may be associated both with doing too much and with doing too little, and the emphasis was on achieving a balance between the two. As sleep problems are common in people who complain of fatigue a section on how to improve sleep was included (Morin, Culbert & Schwartz, 1994). Basic cognitive techniques such as identifying and challenging unhelpful thoughts were introduced (Beck, 1989; Burns, 1981).

### *Analysis*

Statistical analysis was performed with SPSS-PC. Continuous measures of outcome, fatigue questionnaire, GHQ and MOS were examined with ANOVA using baseline scores as covariates and the treatment condition as the main predictor variable. The proportion of patients who improved in the two groups was compared using chi-square. An intention to treat analysis was conducted on all patients who entered the trial using the baseline scores as end of treatment scores in drop-outs.

## **Results**

### *Characteristics of study population*

Of the 150 participants who were recruited into the study, 70 (47 per cent) were in the intervention group. Their characteristics are shown in Table 1. The groups did not differ with regard to age, sex, marital status or social class.

All participants scored 4 or more on the fatigue questionnaire at Stage 3; 63 per cent were GHQ cases using a cut-off of 3/4 and 66 per cent were CIS cases (fatigue item

Table 1. Demographic characteristics of the sample (percentages in parentheses)

Patient characteristics	Self-help (N = 70)	Control (N = 80)
Mean (SD) age in years	36 (10.1)	35 (7.5)
Male : Female	21/49	17/63
Marital status		
Married	40 (57)	46 (57)
Cohabiting	6 (9)	6 (7)
Single	23 (33)	26 (33)
Missing	1 (1)	2 (3)
Occupation		
Professional	4 (6)	3 (4)
Intermediate	24 (34)	20 (25)
Skilled	19 (27)	27 (34)
Part-skilled	6 (9)	10 (12)
Unskilled	1 (1)	7 (9)
Unclassified	16 (23)	13 (16)
Attributions		
Psychosocial	27 (39)	35 (44)
Physical	15 (21)	12 (15)
Psychological	9 (13)	12 (15)
Pregnancy	2 (3)	0 (0)
Normalizing	6 (9)	11 (14)
Missing	11 (15)	10 (12)

excluded). Eighteen (12 per cent) fulfilled the Oxford criteria for CFS; 79 (52 per cent) had been given a psychiatric diagnosis by their general practitioner; 30 (20 per cent) had been prescribed psychotropic medication but only 2 had been admitted to a psychiatric hospital. Physical functioning scores are shown in Table 2.

Biochemical screening was carried out on all patients. One had hypothyroidism and one had possible hypopituitarism.

#### *Response to questionnaires*

*Drop-outs.* There were 25 (16.6 per cent) drop-outs in total, 11 in the intervention group and 14 in the control group. There were no differences between drop-outs and completers on any demographic characteristics or pre-treatment measures. ANOVA revealed the same pattern of results whether baseline fatigue scores for drop-outs were included or not.

*Outcome.* Fifty (71 per cent) participants in the intervention group said they had read the booklet and of these, 42 (84 per cent) felt it was helpful. Mean scores (with 95 per cent confidence intervals) in the main and subsidiary outcome measures for both groups are shown in Table 2.

Fatigue scores were available at three time points prior to the intervention, at baseline

Table 2. Outcome measures: mean fatigue, GHQ, CIS and physical functioning scores (with 95 per cent confidence intervals, CI) for the intervention and control group participants at baseline and follow up

	Baseline		3-month follow-up	
	Self-help	Control group	Self-help	Control group
Fatigue score (0-11)	7.04 (CI 6.35-7.73)	6.89 (CI 6.346-7.43)	3.20 (CI 2.25-4.15)	4.89 (CI 3.88-5.90)
Number of fatigue cases	100%	100%	22 (37%)	40 (61%)
GHQ-12 bimodal scoring	6.27 (CI 5.27-7.27)	5.92 (CI 5.04-6.80)	3.06 (CI 2.06-4.07)	4.31 (CI 3.33-5.29)
Number of GHQ cases	43 (61%)	52 (65%)	21 (35%)	34 (51%)
MOS physical functioning	74.0 (CI 66-88)	70.0 (CI 62-77)	76.1 (CI 68-84)	66.6 (CI 58-75)

(Stage 3), six months previously (stage 2) and between 1 and 12 months prior to this (Stage 1). These scores were stable over time and so a mean baseline fatigue score was calculated using these three time points. An intention-to-treat analysis was conducted. Fatigue scores fell in both the intervention and control group but, after controlling for pre-treatment fatigue levels, the intervention group was less fatigued than the control group ( $F(1) = 6.72, p = 0.1$ ). This held true for physical and mental fatigue when analysed separately.

Of the completers, 22 (37 per cent) in the experimental group and 40 (61 per cent) in the control group were fatigue cases (scoring at least 4) at follow-up ( $\chi^2(1) = 6.78, p < .01$ ). A similar pattern emerged with the GHQ. After controlling for baseline scores the intervention group was less distressed than the control group at follow-up ( $F(1) = 7.07, p < .01$ ). The pattern of change in fatigue and GHQ scores is shown in Fig. 1.

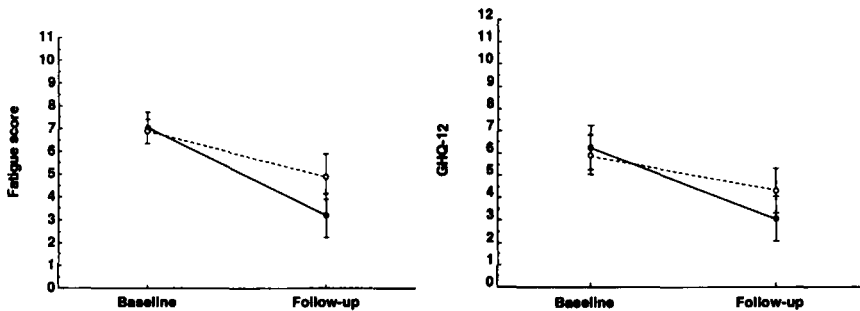


Figure 1. Pattern of change in fatigue and GHQ scores. —●—, self-help, —○—, control.

There was a significant difference between the two groups on the MOS physical functioning subscale ( $F(1) = 3.94, p < .05$ ). While the self-help group had only slightly improved, the control group had deteriorated.

## Discussion

This is the first randomized clinical trial to find that fatigued patients in primary care who received a self-help booklet and specific advice from a nurse were less fatigued and less psychologically distressed at follow-up than controls. There was a 24 per cent difference in the number of fatigue cases at follow-up between the two groups. The similarity in change with regard to fatigue and GHQ score was not surprising given the close correlation between the two constructs (David, *et al.*, 1990; Pawlikowska *et al.*, 1994). These results were achieved in a primary care population which, whilst not complaining primarily of fatigue, had been chronically fatigued for at least six months. The proportion of drop-outs was low and did not differ between the two groups.

Improvement in fatigue and GHQ scores was noted in both the intervention and control groups. One explanation for this is regression to the mean. However, this possibility was tested by examining the pre-treatment scores at three different time

points. As these scores were stable, it seems unlikely that this is the full explanation. Rather, the detailed assessment with the research nurse might have led to a non-specific improvement. Above and beyond these non-specific effects the superior outcome in the self-help and advice group can be attributed to the booklet.

We noted a reduction in physical functioning in the control group, while the intervention group slightly improved. It is possible that this may have reflected the nature of the information in the self-help booklet, as a section was devoted to the role of maintaining a balanced approach to rest and activity.

The limitations of this study require attention. Firstly, the selected nature of the patients needs consideration. They came from a previous cohort study examining the role of infections in the development of fatigue and as such were not complaining primarily of fatigue or attending the GP with a complaint of fatigue, even though it was a substantial problem. Secondly, outcome was judged solely on subjective self-rated questionnaires. An independent assessment carried out at follow-up, or an interview with an informant, might have improved the reliability of the assessment. Thirdly, the intervention was carried out by a research nurse, not by a member of the patient's own primary care team. The study now needs replicating on a group of patients complaining primarily of fatigue, with the intervention being delivered by either the GP or a nurse. Finally, there was only one follow-up, at three months, and it is possible that any gains made during this period were subsequently lost.

The weaknesses have to be set against the strengths. Firstly, there were no exclusion criteria. All patients who scored 4 or more on the fatigue questionnaire for at least six months were eligible for the trial regardless of the cause of their fatigue. This means that the findings can be interpreted as clinically meaningful and can be generalized to other fatigued populations. Secondly, the randomization method was robust in that the procedure was carried out by a researcher who was not delivering treatment, thereby avoiding any inadvertent deviations from the protocol. The minor disadvantage of using a computer-generated list was the uneven number in each group.

In conclusion, the results of this study show that a self-help booklet and advice given to patients with chronic fatigue, during a research interview, can be effective in reducing fatigue. There is a growing body of evidence demonstrating the usefulness of self-help literature (Gould & Clum, 1993). Given that self-help books are cheaper than a prescription, it seems reasonable to suggest that GPs should use written information as an integral part of their management of patients with fatigue. To enhance compliance, patients should be followed up soon after the intervention has been prescribed. It is possible that the book operated as a health promotion strategy and that by intervening at this stage (primary care), the extreme disability seen in some patients was prevented. It does not follow, however, that the self-help intervention described in this paper would be sufficient to bring about clinically meaningful changes in patients who fulfil the criteria for CFS, who by definition are considerably more disabled than their chronically fatigued counterparts. A follow-up study could show whether gains were maintained in the long term with a resultant decline in GP attendance rates.

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