

Chronic fatigue in general practice: is counselling as good as cognitive behaviour therapy? A UK randomised trial

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SUMMARY

Background: Fatigue is a common symptom for which patients consult their doctors in primary care. With usual medical management the majority of patients report that their symptoms persist and become chronic. There is little evidence for the effectiveness of any fatigue management in primary care.

Aim: To compare the effectiveness of cognitive behaviour therapy (CBT) with counselling for patients with chronic fatigue and to describe satisfaction with care.

Design of study: Randomised trial with parallel group design.

Setting: Ten general practices located in London and the South Thames region of the United Kingdom recruited patients to the trial between 1996 and 1998. Patients came from a wide range of socio-economic backgrounds and lived in urban, suburban, and rural areas.

Method: Data were collected before randomisation, after treatment, and six months later. Patients were offered six sessions of up to one hour each of either CBT or counselling. Outcomes include: self-report of fatigue symptoms six months later, anxiety and depression, symptom attributions, social adjustment and patients' satisfaction with care.

Results: One hundred and sixty patients with chronic fatigue entered the trial; 45 (28%) met research criteria for chronic fatigue syndrome; 129 completed follow-up. All patients met Chalder et al's standard criteria for fatigue. Mean fatigue scores were 23 on entry (at baseline) and 15 at six months' follow-up. Sixty-one (47%) patients no longer met standard criteria for fatigue after six months. There was no significant difference in effect between the two therapies on fatigue (1.04 [95% CI = -1.7 to 3.7]), anxiety and depression or social adjustment outcomes for all patients and for the subgroup with chronic fatigue syndrome. Use of antidepressants and consultations with the doctor decreased after therapy but there were no differences between groups.

Conclusion: Counselling and CBT were equivalent in effect for patients with chronic fatigue in primary care. The choice between therapies can therefore depend on other considerations, such as cost and accessibility.

Keywords: chronic fatigue; cognitive behaviour therapy; counselling; randomised controlled trial.

Introduction

FATIGUE is a common symptom for which patients consult their doctors in primary care.¹ With usual medical management 70–75% of patients report that their symptoms persist and become chronic.² The risk of chronicity is increased when there is previous and/or concurrent psychological distress and fatigue of more than three months' duration at presentation.² Patients with fatigue symptoms consult their general practitioners (GPs) more frequently than age–sex matched counterparts³ and attendance is more closely associated with the level of concurrent psychological symptoms than it is with fatigue symptoms *per se*.⁴

Hospital-based trials in the United Kingdom (UK) have consisted of treatment packages for patients who conform to criteria for the more narrowly defined chronic fatigue syndrome which requires six months of fatigue, with activity reduced more than 50% of the time.⁵ Evidence from two trials supported the hypothesis that cognitive behaviour therapy (CBT) is more effective than usual medical care or relaxation^{6,7} in reducing symptoms or increasing physical functioning.

There is little evidence for the effectiveness of any management when patients present to their doctor with fatigue in primary care. A study in primary care suggested that the provision of a self-help booklet and advice given by a research nurse could reduce fatigue and psychological distress.⁸ This group of patients did not consult with fatigue but were recruited in a cohort study of patients consulting with infections, and also from a control group. Our study aimed to assess the efficacy of CBT for a group of patients consulting their GP because of fatigue symptoms. Therapist time and attention has an important effect in psychological interventions; it was therefore decided to compare CBT with an active intervention provided by therapists with appropriate and equivalent training. Counselling is commonly available in UK primary care but there was little evidence for its efficacy.⁹ We therefore decided to test the hypothesis that CBT was more effective than counselling, as a comparison group.

Method

Design

Between 1996 and 1998 ten general practices collaborated in recruiting patients to the trial. The practices were located in London and the South Thames region of the UK. Patients came from a wide range of socioeconomic backgrounds and lived in urban, suburban, and rural areas. The practice population size varied, with a combined population of 77 500 eligible patients aged 16 to 75 years. Doctors were asked to recruit all patients who were suitable for the study (Box 1). If a patient refused to take part then the doctor was asked to complete a refusal form, detailing the age and sex

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Submitted: 6 March 2000; Editor's response: 30 May 2000; final acceptance: 29 September 2000

©British Journal of General Practice, 2001, 51, 19–24.

Inclusion criteria

- Aged 16 to 75 years old;
- complains of fatigue as a main or important problem;
- three months' duration or more of fatigue symptoms;
- doctor performed a complete blood count, erythrocyte sedimentation rate, and thyroid function tests on entry or in the previous six months, and the results were normal;
- may have concurrent physical problems but, in the doctor's judgement, they have not caused the fatigue symptoms;
- no recent change in drug regimen.

Exclusion criteria

- score of less than 4 on fatigue questionnaire (bi-modal scoring);
- psychotic illness;
- patient unable to read English;
- learning difficulty precludes completion of questionnaires;
- current treatment from a psychiatrist, psychologist, community psychiatric nurse, or counsellor;
- patient unable to attend the doctors' premises for therapy sessions.

Box 1. Inclusion and exclusion criteria for the study.

of the person and the reason for refusal.

Assessment and randomisation

Patients were assessed on three occasions: before treatment (baseline), after therapy completion (approximately three months after baseline), and at six months after baseline (outcome). Baseline assessment of the patients was undertaken at their doctor's practice by one of the authors (EG) after she had explained the trial and obtained written, informed consent. The unit of randomisation was the individual patient. Patients were randomised in blocks of 10 using computer generated random number combinations. Opaque sealed envelopes bearing sequential ID numbers were prepared, containing the randomly allocated treatment codes. EG took an envelope in sequence to each baseline assessment. She opened the envelope in front of the patient and explained the assignment to one of the two treatment modalities. After therapy was completed the therapist gave the patient the second questionnaire with an envelope, asking them to complete it at home and send it to EG. Six months after baseline, EG sent each patient the final questionnaire to be returned by post.

Intervention and comparison intervention

Three qualified CBT therapists and three qualified counsellors, all of whom had experience in primary care, were supervised respectively by one of the authors (TC) and Dr Sue Davison. Therapists offered six sessions of up to one hour to each patient. All therapists used the first session for assessment and engagement. To assist with supervision, all therapy sessions were recorded. Therapists were blinded to which session would be assessed by four independent raters who were specialists in counselling or CBT. This independent rating (of the third session) confirmed that there were clear differences in the management approach of the two groups; all counsellors used a psychodynamic approach and all cognitive behaviour therapists used CBT.

Cognitive behaviour therapy included providing a treatment rationale, activity planning, homework, establishing a sleep routine and other cognitive interventions.¹⁰ It was based on a model of understanding fatigue that makes a distinction between precipitating and perpetuating factors. Perpetuating factors were the focus of the intervention. The

four main areas focused on were: the fatigue was managed by insuring that levels of activity and rest were both consistent and realistic given the patient's responsibilities; sleep disturbance was addressed using conventional methods; negative beliefs regarding the symptom of fatigue, self-expectations or self-esteem were identified and patients were encouraged to challenge them in the conventional way; specific lifestyle changes were encouraged if deemed appropriate. A clear rationale for treatment was provided after a thorough assessment and relapse prevention was addressed in the last two sessions.

Counselling has been defined and applied in a variety of ways in primary care. The manual that was used in this trial was originally devised for a trial of counselling for patients with depression and mixed anxiety and depression in primary care.¹¹ This model of counselling is non-directive and client-centred; it offers the patient an opportunity to talk through their concerns and difficulties in a non-judgmental and supportive environment. The aim of such counselling is to help patients to understand themselves better, to suggest alternative understandings, to uncover the links between current distress and past experience, and to provide the conditions for growth and healing.

Instruments

Self-report measures were used as main outcome measures to avoid interviewer bias. At baseline all patients were assessed to see if they conformed to CDC (1994) criteria for chronic fatigue syndrome,¹² which include: a definite onset, a minimum duration of six months, substantial functional impairment, and four or more other symptoms. Patients were asked if they had consulted a doctor in the past for psychological problems and data about psychological problems were extracted from doctors' notes. The Fatigue Questionnaire,¹³ the Hospital Anxiety and Depression Rating Scale,¹⁴ an attribution scale¹⁵, a social adjustment scale¹⁶, and the Medical Outcomes Study Short Form General Health Survey (MOSSFGHS)¹⁶ were all used. Patients were asked about their satisfaction with therapy using a 10-item questionnaire with each item scored from 1 ('not at all useful') to 5 ('very useful'). We extracted information about consultation frequency, prescribing, and referrals made to specialists.

Sample size and analysis

Our main outcome measure was the 11-item Fatigue Questionnaire¹³ scored using a Likert scale of 0 to 4, with a maximum score of 33. Our pre-study power calculation demonstrated that if the mean falls in fatigue scores for CBT and counselling were 11 and 5 with a standard deviation (SD) of 12, approximately 130 patients (65 per group) would give 80% power to demonstrate this effect at the 5% significance level. As no data on the standard deviation of change in fatigue score were available we chose a conservative estimate of 12. The estimated reductions of 11 and 5 were based on a trial of CBT for patients with the chronic fatigue syndrome⁷ and a cohort study,² the assumption being that counselling would be equivalent to usual care. Secondary outcomes were anxiety and depression mean scores on the HAD and mean scores on the social adjustment scale. An intention-to-treat analysis was carried out and treatment effects were adjusted for baseline scores.

Hollis and Campbell¹⁷ advocated primary analysis on all recruited patients and emphasised the importance of including all subjects as randomised. We decided to base our

analysis on data from all recruited patients, imputing the last value in place of missing data. As a sensitivity analysis a number of alternative approaches were considered: complete data only, and single and multiple imputation.¹⁸⁻²¹ The effect on the estimates performed in this way was in each case too small to alter the study's conclusions.

Results

Participant flow

Doctors asked 193 patients, all of whom met the eligibility criteria to participate (Figure 1). Thirty-three (17%) refused to participate, mainly owing to lack of time or lack of willing-

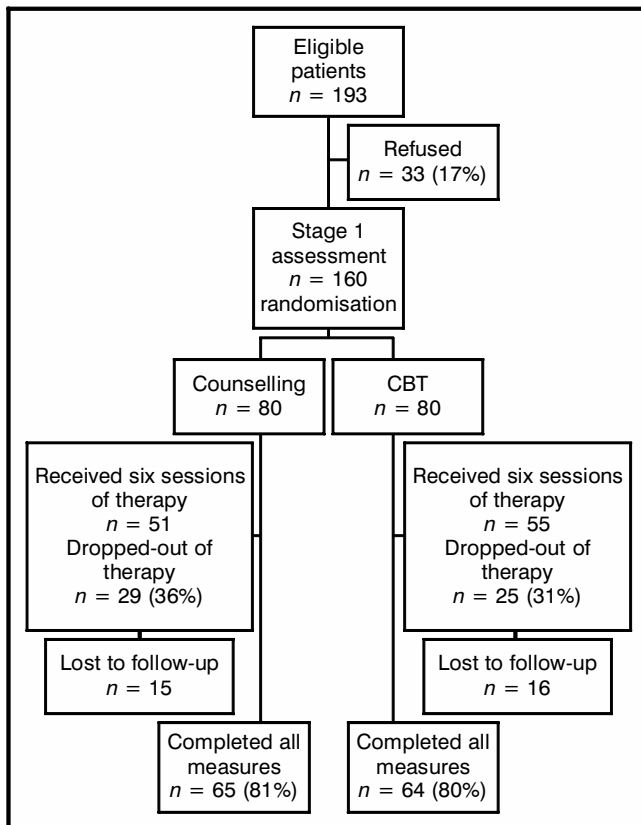


Figure 1. Trial profile.

ness or ability to attend the practice for a randomised treatment. The mean age of refusers was 42 years (SD = 12.7) and 6/33 were men. Thus 160 (87%) patients entered the study with 80 being allocated to counselling and 80 to CBT. Fifty-one (64%) patients randomised to counselling completed all six therapy sessions, as did 55 (69%) of those randomised to CBT. The 29 counselling and 25 CBT patients who completed fewer than six sessions cited various reasons for stopping: not tired any more, too busy to come, did not find therapy useful. Twenty-six of these patients had no therapy. The mean number of therapy sessions provided for all 160 patients was 4.2 (SD = 2.5), and for those patients receiving some therapy it was 5.1 (SD = 1.8). At six months' follow-up 129 (81%) patients returned completed questionnaires. The characteristics of completers and non-completers are shown in Table 1.

The two groups were similar at baseline (Table 2). The mean duration of fatigue symptoms for all patients was 38 months (SD = 41) and their mean fatigue score was 23.2 (SD = 5). All patients assessed met operational criteria fatigue¹³. Forty-five (28%) met operational criteria for the chronic fatigue syndrome. Six patients belonged to the Myalgic Encephalitis (ME) Association, all of whom met the criteria for CFS.

Follow-up

At three months the mean fatigue scores had fallen to 15.6

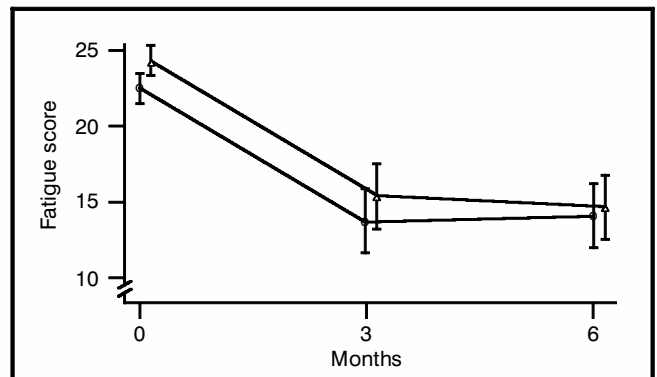


Figure 2. Mean fatigue scores (with 95% CI) at baseline, three months and six months for patients randomised to CBT and counselling. \blacktriangle - counselling; \circ - CBT.

Table 1. Patients who completed measures at 6 months compared with those who did not complete measures.

Variable	Completers (n = 129)	Non-completers (n = 31)	Difference (95% CI)
Male patients	34 (26%)	9 (29%)	-2.7 (-20.4-15.0)
Mean age (years)	40.0 (SD = 13.6)	37.2 (SD = 13.5)	2.8 (-2.6-8.2)
Fatigue at baseline (mean)	23.2 (SD = 5.0)	23.8 (SD = 5.0)	-0.64 (-2.7-1.4)
Duration of fatigue (mean number of months)	39.8 (SD = 43.0)	31.2 (SD = 29.0)	6.5 (-4.4-21.6)
History of anxiety and depression (from doctors' notes)			7.3 (-12.2-26.8)
Yes	76 (59%)	16 (52%)	
No	53 (41%)	15 (48%)	
Anxiety score (mean)	9.9 (SD = 4.4)	8.8 (SD = 4.4)	1.1 (-0.7-2.9)
Depression score (mean)	7.6 (SD = 3.8)	7.5 (SD = 3.8)	0.8 (-1.4-1.6)
On antidepressant treatment at baseline	27 (21%)	6 (19%)	1.6 (-0.1-0.2)
Social adjustment score (mean)	19.3 (SD = 7.0)	20.5 (SD = 7.4)	-1.2 (-4.2-1.9)
Patient's beliefs of cause			-18.6 (-37.5-0.34)
Physical or mainly so	62 (48%)	20 (67%)	
Psychological or mixed	67 (52%)	10 (33%)	
Met CFS criteria	37 (29%)	8 (26%)	2.9 (-14.4-20.1)

Table 2. Baseline profile characteristics for all patients.

Variable	All patients (n = 160)	Counselling (n = 80)	CBT (n = 80)
Male patients	43 (27%)	23 (29%)	20 (25%)
Mean age (years)	39.4 (SD = 13.6)	37.7 (SD = 13.0)	41.2 (SD = 13.9)
Fatigue score at baseline (mean)	23.3 (SD = 5.0)	24.2 (SD = 4.8)	22.4 (SD = 5.1)
Duration of fatigue (mean number of months)	38.2 (SD = 40.8)	42.1 (SD = 38.4)	34.2 (SD = 43.1)
History of anxiety and depression (from doctors' notes)			
Yes	92 (58%)	48 (60%)	44 (55%)
No	68 (42%)	32 (40%)	36 (45%)
Anxiety score	9.7 (SD = 4.4)	10.6 (SD = 4.2)	8.8 (SD = 4.5)
Depression score	7.6 (SD = 3.8)	7.8 (SD = 3.5)	7.3 (SD = 4.1)
On antidepressant treatment at baseline	33 (21%)	17 (21%)	16 (20%)
Social adjustment score	4.9 (SD = 1.8)	4.9 (SD = 1.7)	4.9 (SD = 1.8)
Patient's beliefs of cause			
Physical or mainly so	82 (52%)	40 (50%)	42 (53%)
Psychological or mixed	77 (48%)	40 (50%)	37 (47%)
Met CFS criteria	45 (28%)	25 (31%)	20 (25%)

Table 3a. Outcome of trial for patients who completed all measures: descriptive.

Variable	Counselling (n = 65)	CBT (n = 64)	Difference (95% CI)
Fatigue score	15.6 (SD = 8.0)	15.0 (SD = 8.5)	0.55 (-2.3-3.4)
Change in fatigue score	8.2 (SD = 7.3)	7.3 (SD = 8.1)	0.90 (-1.8-3.6)
Case of fatigue	34 (52%)	34 (53%)	0.06 (-0.9-1.1)
Anxiety score	8.9 (SD = 4.2)	7.9 (SD = 4.0)	0.95 (-0.5-2.4)
Depression score	6.2 (SD = 4.1)	6.3 (SD = 4.3)	-0.13 (-1.6-1.4)
On antidepressant treatment	9 (14%)	8 (13%)	-1.3 (-0.1-0.1)
Social adjustment	3.5 (SD = 2.2)	3.7 (SD = 2.2)	-0.22 (-1.1-0.6)

Table 3b. Outcome of trial analysed by multiple imputation and adjusted for baseline scores.

Outcome at six months (n = 160)	Estimated treatment effect ^a	95% CI
Fatigue	1.04	-1.7-3.7
Anxiety	-0.22	-1.4-1.0
Depression	0.22	-1.0-1.4
Social adjustment	-0.05	-2.5-2.4

^aCBT subtracted from counselling.

Table 4a. Main outcome of trial for the CFS patients who completed all measures: descriptive.

Variable	Whole CFS group (n = 37)	Counselling (n = 20)	CBT (n = 17)
Fatigue score	19.6 (SD = 8.9)	18.6 (SD = 8.4)	20.8 (SD = 9.7)
Change in fatigue score	7.9 (SD = 8.1)	9.1 (SD = 7.4)	6.4 (SD = 8.8)
Case of fatigue	27 (73%)	13 (65%)	14 (82%)
Anxiety score	10.4 (SD = 4.5)	9.6 (SD = 5.0)	11.4 (SD = 3.8)
Depression score	8.8 (SD = 4.3)	7.6 (SD = 4.2)	10.1 (SD = 4.2)
Social adjustment score	5.1 (SD = 2.1)	4.7 (SD = 2.2)	5.5 (SD = 2.0)

Table 4b. Outcome of trial for the CFS group of patients analysed by multiple imputation and adjusted for baseline scores.

Analysis	Estimated treatment effect ^a	95% CI
Complete data (n = 37)	2.7	-2.8-8.2
Last value carried forward (n = 45)	1.8	-3.0-6.7
Multiple imputation (n = 45)	1.9	-3.8-7.6

^aCBT subtracted from counselling.

(counselling) and 14.0 (CBT), and 15.6 (counselling) and 15.0 (CBT) at six months (Figure 2 and Table 3a). Analysis was undertaken on data for all 160 patients using multiple imputation for patients who had not completed all questionnaires. At six months' follow-up, mean fatigue scores of the two groups were adjusted for baseline level of fatigue. Scores in the counselling group were used for comparison and the scores of the CBT group were subtracted, the difference being 1.04 (95% confidence interval (CI) = -1.7 to 3.7, Table 3b), a non-significant trend in favour of counselling. Sensitivity analyses, using complete data only, did not alter the results substantially.

At follow-up there were no significant differences between groups in anxiety, depression, and social adjustment scores (Table 3b). However, the group allocated to CBT was significantly more satisfied than the counselling group with the process of therapy (39 versus 32 respectively; 95% CI of difference = 1.9 to 12.6). Mean GP consultations fell from 4.2 (SD = 2.5) in the six months before therapy to 3.1 (SD = 2.6) in the six months afterwards, and there was no difference between groups. Use of antidepressants fell from 27/129 (21%) at baseline to 17/129 (13%) at follow-up, and there was no significant difference between groups.

Patients with chronic fatigue syndrome

In our study 45 (28%) patients conformed to CDC criteria for CFS.¹² The mean duration of fatigue symptoms at baseline was 55.8 months, and their mean fatigue score 27.5. At six months follow-up the mean fatigue score was 18.6 (SD = 8.4) in the counselling group and 20.8 (SD = 9.7) in the CBT group (Table 4a). Scores in the counselling group were used for comparison and the scores of the CBT group were subtracted; the difference being 1.9 (95% CI = -3.8 to 7.6), a non-significant trend in favour of counselling (Table 4b).

We compared our results in primary care for the subgroup conforming to criteria for chronic fatigue syndrome with Deale *et al*'s trial of hospital outpatients with CFS.⁷ At baseline there were no differences in mean fatigue scores between our data and Deale *et al*'s, which were 27.5 and 27.0 respectively, or in functional impairment scores, which were 6.4 and 6.1 respectively. Patients in primary care reported a slightly higher level of activity on the six-item MOSSFGHS, with scores of 35 versus 26 in Deale's study. A smaller proportion of those in primary care 25/45 (56%) versus 39/65 (65%) in secondary care attributed their fatigue to a physical cause. A lower proportion of people in primary care were members of the ME Association (13% versus 30%). After CBT the mean score of patients in our trial was 20.8 (14% reduced), whereas it was 15.0 (46% reduced) after treatment by Deale.

Discussion

The evidence from this study does not support our original hypothesis; counselling and CBT were equivalent in their effect for patients with fatigue in primary care. There was equivalence in outcome between the two therapies for patients with fatigue of three months' duration or more, and there was equivalence for the subgroup whose symptoms conformed to criteria for chronic fatigue syndrome. However, the latter was a post hoc analysis that lacked power.

In this context the question arises: are these therapies more effective than usual care? Some evidence is available from two studies, both of which were undertaken in primary care, that had the same entry criteria and six months' follow-

up using the same outcome measures. One of these was the control arm of a randomised control trial²² and the other was the cohort study used in planning this study.² At baseline, patients in all three studies met case criteria for fatigue (four or more positive responses at any level). In this trial, in which CBT and counselling were equivalent, 68/129 (53%) of patients were cases of fatigue six months later. At six months' follow-up 60/79 (76%) of patients in the control arm of a trial²² and 60/87 (69%) in a cohort study² met case criteria for fatigue. When the outcome from these usual medical care studies are combined and compared with the effect of CBT or counselling, therapy was associated with a 19.6% relative risk reduction (95% CI = 8.6% to 30.6%). This corresponds to a number of patients needed to treat of 5.1 (95% CI = 3.3 to 11.6) to prevent one case of continued fatigue. We recognise the limitations of historical controls but this is the best available evidence in primary care. We cannot be sure of the reason for the difference between outcomes between active treatment and no treatment. Most of our patients were distressed and the effect of time spent with them by a therapist could be attributed to a placebo effect.

There is evidence that cognitive behaviour therapy is more effective than usual medical management⁶ or relaxation⁷ for patients with CFS in secondary care. In our study of chronic fatigue, CBT was compared with counselling rather than usual care or relaxation provided by a CBT therapist. The choice and effect of comparison with a control group is likely to be important in explaining results in primary and secondary care; where therapists believe in an intervention there are likely to be placebo effects. Another possible cause of the different effect is that patients with CFS referred from primary to secondary care are, in some respects, different. Most of our patients had chronic fatigue with an average duration of three years. General practitioners refer only 2% of patients with fatigue²³ and it is likely that this subgroup is different. Two-thirds of our group did not conform to criteria for the chronic fatigue syndrome. The differences we found between our patients' illness attributions and self-help group membership and those reported in secondary care supports the hypothesis that they are in some respects different groups.

Balint emphasised the role of 'the drug doctor', with the implication that GPs themselves could have a therapeutic or medicinal effect.²⁴ Howie and others have shown that more of this medicine measured in time has important measurable effects.²⁵ It is reasonable to infer that this will be equally or more important in evaluating the role of therapists working with general practice attendees with high psychological distress levels. A possible reason for the difference in efficacy of CBT in primary care might be a dose-response effect; patients were offered six sessions by our therapists and received a mean of 4.2 hours of therapy. Deale offered 13 sessions and, on average, patients received 15 hours of therapy: nearly four times more time. The hypothesis that there may be a dose-response effect is supported by evidence from a trial by Lloyd *et al*²⁶ in secondary care. They offered six sessions of CBT in a controlled trial to patients who met Australian criteria for the chronic fatigue syndrome. No additional benefit was found over standard medical management.

Another possible cause of lack of efficacy is therapist effect. All our therapists were trained and were already working in primary care. The training, qualifications, and experience of therapists working in secondary care research may be quite different. A paper on therapist effect is in preparation.

Between the design and publication of our study, some evidence has been adduced that counselling is more effective than usual medical care for patients who present to doctors with moderate to severe depressive symptoms.^{27,28} Evidence that counselling has a beneficial effect equivalent to CBT for patients with fatigue will be useful to doctors in general practice in the UK, as counsellors frequently form part of the primary health care team. Evidence about the economic costs of treatment is a second determinant in planning care and this is reported in a companion paper in this issue.²⁹

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Acknowledgements

This trial was funded by the Wellcome Trust. We acknowledge the contribution of the Fatigue Trialists' Group which included all the GPs who referred patients into the study, and particularly the practice lead GPs, Drs A Barnes, B Booth, E Brenner, P Cantillon, C Gerrada, C Hughes, H Juchniewicz, S Loveless, M Palmer, and G Roberts. We also acknowledge S Wilkinson who worked as study co-ordinator for six months, Dr S Davison who supervised the counsellors, Professor P Campion who allowed us to use his unpublished data, the therapists A Attwood, S Darnley, C Fernando, V Gordon-Graham, A Perera, G Pidd, those therapists who rated tape recordings of therapy sessions, B Ash, J Mills, P Petkova and I Soylu-Bray, also L Darbyshire and Professor R Jones, who provided feedback on the report in draft form, and all the patients who took part in the study.

HOW THIS FITS IN

What do we know?

Fatigue is a common symptom, and most patients report concurrent physical distress. With usual medical care symptoms tend to persist, and this increases when there is previous or current psychological distress.

A long course of cognitive behaviour therapy (CBT) provided in specialist settings is more effective than usual care for patients with chronic fatigue syndrome.

Counselling is widely available in primary care, but there is no evidence for the effectiveness of counselling or CBT for fatigue in this setting.

What does this paper add?

A short course of counselling and CBT were equivalent in their effect for patients with chronic fatigue syndrome in primary care.

Employing practice-based counsellors or CBT therapists may enable more patients with fatigue to recover, and prevent chronic fatigue syndrome. The choice of therapy should depend on the availability of therapists and cost.

